## T-Data Exclusivity

#### Interpretation: The aff may not transition towards data exclusivity, that’s extra-T

**Wilkinson 21** (Margaret Ann, Professor of Law at Western University, Canada, Director of the Area of Concentration in Intellectual Property, Information and Technology Law)

\*\* TPM = Technological Property Management

\*\* RMI = Rights Management Information

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In each of the international settings discussed above and shown in Table 9.1, data exclusivity, TPM and RMI are treated as IP in the sense of being placed in texts in an IP context. But can such placement define the nature of the contents? If the various protections so classified as IP within international instruments are found to differ in nature, is it appropriate or useful to try to sort them into subclasses of IP as either 'primary' IP or 'secondary' IP? Historically, the classic devices of patent and copyright have been brought together under the term 'intellectual property' through their similarity in being private monopo-lies created to encourage public dissemination of ideas:um might they thereforebe considered 'primary' and all those created afterwards, but which seem to be related to them, secondary?10` The definitions of 'secondary' posit some greater relationship than simply being 'earlier.' The Merriam Webster defi-nition of 'secondary' includes 'immediately derived from something original, primary or basie'iGs Similarly, the Oxford English Dictionarym definitions include one, tracing back to 1398, that begins with, 'Belonging to the second order in a series related by successive derivation, causation, or dependence; derived from, based on, or dependent on something else which is primary; not original, derivative.

As the analyses above have shown, **data exclusivity is not** dependent upon the presence of patent **nor does it take the form of** an **IP** device, for, although it has a limited term, **it does not create a monopoly market** rather it censors the flow of information for the period of its existence. TPM and RM1, on the other hand, formally show more dependence on the existence of copyright (than data exclusivity does on patent) because their enactment invariably refers to 'works' and other vocabulary familiar in copyright — but, also invariably, TPM and RMI capture far more information than the subject matter of copyright. Like data exclusivity, neither 'PM nor RMI have limited terms. And, again like data exclusivity, TPM and RMI do not create monopoly markets — rather, between them, they shore up existing channels of distribution and make them effective beyond the copyright terms of whatever materials arc flowing (along with un-copyrighted materials and data) within them. All three appear inde-pendent of patent and copyright, rather than secondary to them.

#### Violation:

#### Their solvency advocate talks about data exclusivity in a separate article about the one and done approach- I read yellow

Feldman 19 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

I believe that one period of protection **should be enough**. We should make the legal changes necessary to prevent companies **from building patent walls** and piling up mountains of rights. This could be accomplished **by a “one-and-done” approach** for patent protection. Under it, a drug would receive just one period of exclusivity, and no more. The choice of which “one” could be left entirely in the hands of the pharmaceutical company, with the election made when the FDA approves the drug. Perhaps development of the drug went swiftly and smoothly, so the remaining life of one of the drug’s patents is of greatest value. Perhaps development languished, so designation as an orphan drug or some other benefit would bring greater reward. The choice would be up to the company itself, based on its own calculation of the maximum benefit. The result, however, is that a pharmaceutical company chooses whether its period of exclusivity would be a patent, an orphan drug designation, a period of [or] data exclusivity (in which no generic is allowed to use the original drug’s safety and effectiveness data), or something else — but **not all of the above** and more. Consider Suboxone, a combination of buprenorphine and naloxone for treating opioid addiction. The drug’s maker has extended its protection cliff eight times, including obtaining an orphan drug designation, which is intended for drugs that serve only a small number of patients. The drug’s first period of exclusivity ended in 2005, but with the additions its protection now lasts until 2024. That makes almost two additional decades in which the public has borne the burden of monopoly pricing, and access to the medicine may have been constrained. Implementing a one-and-done approach in conjunction with FDA approval underscores the fact that these problems and solutions are designed for pharmaceuticals, not for all types of technologies. That way, one-and-done could be implemented through **legislative changes to the FDA’s drug approval system**, and would apply to patents granted going forward. One-and-done would apply to both patents and exclusivities. A more limited approach, a baby step if you will, would be to invigorate the existing patent obviousness doctrine as a way to cut back on patent tinkering. Obviousness, one of the five standards for patent eligibility, says that inventions that are obvious to an expert or the general public can’t be patented. Either by congressional clarification or judicial interpretation, many pile-on patents could be eliminated with a ruling that the core concept of the additional patent is nothing more than the original formulation. Anything else is merely an obvious adaptation of the core invention, modified with existing technology. As such, the patent would fail for being perfectly obvious. Even without congressional action, a more vigorous and robust application of the existing obviousness doctrine could significantly improve the problem of piled-up patents and patent walls. Pharmaceutical companies have become adept at maneuvering through the system of patent and non-patent rights to create mountains of rights that can be applied, one after another. This behavior lets drug companies keep competitors out of the market and beat them back when they get there. We shouldn’t be surprised at this. Pharmaceutical companies are profit-making entities, after all, that face pressure from their shareholders to produce ever-better results. If we want to change the system, we must change the incentives driving the system. And right now, the incentives for creating patent walls are just too great.

#### Standards:

#### Limits – data exclusivity is straight up just not IP. Their interp allows anything tangentially related to patents like replacing IP with employee noncompetes and medical software DRM which explodes the topic.

#### Ground- Neg ground is primarily based on unified generics like innovation, allowing the aff to add extra parts to their plan to get out of the innovation disad means negs have no stable stasis point. Further, this justifies extra-T planks that solve for any disad the neg can think of.

#### Topicality should be a voting issue evaluated through competing interpretations—you can’t be reasonably topical because anything beyond the resolution justifies everything beyond the res and topicality debates are very substantively educational and relate directly to the topic. Pre-round prep has already been skewed which means the only remedy is to drop the debater.

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#### Fairness and education are voters – debate’s a game that needs rules to evaluate it and education gives us portable skills for life like research and thinking.

#### 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.

#### No RVIs – a) illogical – you shouldn’t win for being fair

## 2

#### CP Text: Member Nations of the WTO should implement section 3(d) law from India

#### Solvency advocate

Kapczynski 09-- Kapczynski, Amy. "Harmonization and its discontents: a case study of TRIPS implementation in India's pharmaceutical sector." Calif. L. Rev. 97 (2009): 1571. (AG DebateDrills)

The most important exclusion is section 3(d), which forbids patents on both new uses of known substances and on new forms of known substances that do not enhance “efficacy.”102 An important explanatory note clarifies the restriction on patents on new forms:103 “For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.”104 Other countries have limited patents in some of the ways included in section 3(d), for example, restricting patents on new uses of known substances.105 But the scope of section 3(d), and in particular its expansive exclusion of patents on new forms of known substances, is new to patent law.106 It can be explained as a classic act of legal borrowing:107 the definition was taken virtually word-for-word from an EU drug regulatory directive.108 The motivation was to enhance access to medicines and prevent so-called “evergreening” (where companies secure successive patents to extend the effective period of their exclusive control over a drug).109 The significance of the provision can only be appreciated when situated in the context of contemporary pharmaceutical patent practice. In the United States and European Union, for example, pharmaceutical compounds are rarely protected only with a patent on the active ingredient itself. Companies frequently seek other forms of patents, in order to generate or extend their exclusive rights over a medicine.110 Patents on the new use of a known substance (for example, claiming the use of a given compound to treat HIV) are common in the United States and Europe today, and do not cover a compound but rather a compound’s use in a particular way.111 New forms of known substances that have pharmaceutical applications are also commonly patented. Such patents may claim new structural forms of a compound with different properties, such as polymorphs (new crystalline forms)112 or enantiomers (mirror-image isomers).113 They may also claim particular salts, esters, or ethers of a base compound. Salts, for example, are formed in a reaction between acids and bases; adding different acids to a base will produce different salts with potentially distinct properties. Pharmaceuticals are typically administered in salt form because salts dissolve more easily into the bloodstream and are thus more “bioavailable” than base compounds.114 Different salts of the same base compound may also differ substantially in properties that are important to manufacturing and storage, such as yield, hygroscopicity (attraction to water), stability, and stickiness.115 Salt selection is a straightforward, trial-and-error process, one that has been well described in the field of pharmaceuticals for more than thirty years. 116 Nonetheless, patents on pharmaceutical salts have been granted for decades in the United States, upon a showing that the salt differed from the previously disclosed compound in an unexpectedly beneficial way.117 Patents on enantiomers were rejected by U.S. courts in the 1940s, because enantiomers are necessarily present in the disclosed “racemic” mixtures from which they are derived.118 Such patents nonetheless have been accepted in recent years, also on a showing that they possessed surprisingly superior properties over the prior art.119

#### Solves the entire aff- salts is how companies evergreen- Indian system proves this works

Moir and Gleesen 14—Hazel Moir and Deborah Gleeson; professor in IP and public health respectively; Explainer: evergreening and how big pharma keeps drug prices high; November 5 2014; https://theconversation.com/explainer-evergreening-and-how-big-pharma-keeps-drug-prices-high-33623

Evergreening is achieved by seeking extra patents on variations of the original drug – new forms of release, new dosages, new combinations or variations, or new forms. Big pharma refers to this as [“lifecycle management”](http://mmj.sagepub.com/content/8/4/293.abstract). Even if the patent is dubious, the company can earn more from the higher prices than it pays in legal fees to keep the dubious patent alive. Evergreening is possible because in Australia the standard required to get a patent is very low. Different methods of delivering drugs (such as extended release, for example) have been known for decades. But when one of these known delivery methods is combined with a known drug, the patent office considers this sufficiently inventive to grant a new 20-year patent. Another favourite evergreening strategy is to patent a slight variation of the drug. Brand pharmaceutical companies argue that these “lifecycle management” patents provide improved health outcomes to the community. They meet the (very low) patentability thresholds of novelty and inventiveness. Critics argue that the claimed improved health outcomes are small or non-existent.

No perms:

1. Mutually exclusive: you can’t give data exclusivity and not give data exclusivity
2. Data exclusivity means less solvency because companies still have an incentive to hide the best salt compound and use that to force insurance companies to buy those drugs
3. CPs that are different methods of the aff and could be plan texts for the aff should not be permable: creates more real-world discussion about utilization of resources and best methods to solve a problem

## 3

#### Scholz wins the election now but its close—a clear win is necessary to have a quick transition.

Steitz 9-19[Christoph Steitz, SPD's Scholz wins third TV debate as German election draws close, 9-19-2021,Reuters,https://www.reuters.com/world/europe/merkel-aide-warns-against-protracted-coalition-talks-tv-debate-nears-2021-09-19/, 9-20-2021 amrita]

FRANKFURT/BERLIN, Sept 19 (Reuters) - **Social Democrat Olaf Scholz brushed off a last-gasp attack from his conservative rival in a televised election debate on Sunday, cementing his position as front runner to succeed Chancellor Angela Merkel after Germans go to the polls in a week.** The debate, the last of three ahead of Germany's national election slated for Sept. 26, comes as pressure on the conservative Christian Democratic Union party candidate Armin Laschet intensified to close a gap in polls which have consistently put him behind SPD's Scholz. **Scholz, who serves as finance minister, used the issue of social inequality to lash out at his main opponent, reiterating that as chancellor he would push through a minimum wage of 12 euros ($14.08) per hour, something the CDU opposes. "Mr Laschet, that may be the difference between you and me. I'm not doing that because there is an election campaign right now. I have made this demand for years," Scholz said. "To me it's about the dignity of citizens. That is, however, what perhaps distinguishes us on this issue."** A snap poll shortly after the event, which also included Annalena Baerbock of the Greens **and featured issues ranging from climate change to digitalisation and security, declared Scholz as winner, giving him a clean sweep in the series of debates.** Earlier, an INSA poll for Bild am Sonntag had put the SPD at 26% support, stable from a week ago, while the conservative bloc of Merkel's centre-right Christian Democratic Union and its Bavarian sister party, the Christian Social Union, added half a percentage point to come in at 21%. The gap has been even wider in polls measuring the popularity of the individual chancellor candidates, **indicating the uphill struggle Laschet is facing against Scholz ahead of the election. Laschet has been under fire since he was caught on camera laughing during a visit in the summer to a flood-stricken town. FRAGMENTED** PICTURE Current polls, which show a highly fragmented picture as voters increasingly flock to smaller parties, leave room for several coalition scenarios, giving the liberal Free Democrats a potential king-maker role in upcoming coalition talks. read more FDP party chief Christian Lindner on Sunday rebuffed demands by the CDU to rule out a so-called traffic light coalition with the SPD and the Greens. "We will not take orders from this (CDU)," he said at a party event. Meantime, Scholz on Sunday expressed his preference for a coalition with the Greens, which current polls put at 15%. Merkel's chief of staff had earlier called on all parties to agree quickly on who should succeed her after the election and avoid the kind of protracted coalition talks that followed the last vote four years ago. The likelihood of long coalition talks after the vote means Merkel will not be leaving office any time soon. She remains chancellor until a majority of Bundestag lawmakers elect a successor, who is then sworn in. read **more "My wish is for a swift government formation," Helge Braun told Reuters, adding that even though the current government would continue to govern during looming coalition talks there were certain limitations over the scope of leadership. "So I warn against losing time due to a very long government formation. One can certainly ask for the parties to swiftly express their preferences after the election over what their** favoured coalitions are - so that one does not endlessly lose time in discussions." **There are no formal restrictions on Merkel's powers until a successor is chosen, but she is a consensus seeker and previous chancellors have not taken radical decisions during this time.** Following Germany's last general election in 2017, it took a record six months before the new government was sworn in.

#### Plan is seen as Germany budging  and causes CDU unity—IP rights are a core issue. The 3d counterplan avoids, it’s a lot less obviously about IP.

Sangameshwaran 8-13 [Rithika Sangameshwaran, Understanding Germany’s Trenchant Opposition To the TRIPS Waiver,08-13-2021, Geneva Health Files ,https://genevahealthfiles.substack.com/p/understanding-germanys-trenchant, 9-20-2021 amrita]

In January 2021, Achim Kessler, **member of the Left Party of Germany** (known as Die Linke) co-submitted a motion in the Bundestag (Parliament). It **called on the German Federal Government to support the TRIPS waiver**. After months of deliberation, the motion was rejected in May 2021, with majority members voting against it. **While they unanimously agreed that more needed to be done to increase global vaccine production, just like at the WTO, they differed on ways to achieve it. “There is a difference even within the government, between members of the Social Democratic Party (SPD) and members of the conservative party. Some members of the Social Democrats have been more open. They also rhetorically supported the TRIPS waiver. But when it came to voting, and to the final votes, they opposed it,”** Achim Kessler told Geneva Health Files. First proposed by South Africa and India in October 2020, the TRIPS waiver proposal seeks to expand access to COVID-19 vaccines, diagnostics and related medical products by temporarily relaxing certain intellectual property rules. Almost a year later, **the EU, led by Germany, remains a prominent opponent to the waiver.** Notwithstanding the farrago of arguments against the waiver, it is useful to examine Germany’s reasons for doing so. This story maps German policy positions and politics on intellectual property and its implications for the TRIPS Waiver discussions. **The politics of scientific knowledge: who owns it and who gets to use it? The belief that relaxing patents would impede innovation was one of the main reasons for rejection of the Left’s motion. Responding to a question thereon, the federal government stated that it was skeptical about the need for a waiver.** It added (translated from German; can be accessed here): “The European Commission, which leads the negotiations in the TRIPS Council for the member states of the EU, has not yet been convinced by the arguments put forward, according to which intellectual property rights represent a barrier to increasing global production capacities for vaccines against Covid-19**. It sees the protection of intellectual property rights as an essential stimulus for research and development of new vaccines and drug**s. This position of the European Commission is shared by the German government**. The current international and national legal framework for the protection of intellectual property rights already provides the basis for patent holders to grant other companies (voluntarily) licenses for the use of their pharmaceutical invention**. Private companies are already making extensive use of this possibility of cooperation to expand the necessary resources and should do so even more in the current pandemic. If voluntary solutions to increase production are not sufficient, the TRIPS Agreement already enables the granting of patent compulsory licenses at national level**.” Germany, and in particular, Chancellor Angela Merkel’s party, the Christian Democratic Union of Germany (CDU), places great importance on intellectual property (IP) as a driver for innovation and considers it inviolable. “I think to understand Germany’s opposition to the waiver, we have to look back on German beliefs on IP rights. And I think in particular, in the German conservative party there is a strong belief that IP is key and an important incentive for creation of medical tools.”** Lara Dovifat, International Campaign Manager at Médecins Sans Frontières (MSF) told Geneva Health Files in an interview.

#### CDU doesn’t act on climate change—their role in the EU means that other European countries follow.

Thurau 9/23—DW; Jenn Thurau; german news reporter; Sep 23 2021; https://www.dw.com/en/german-election-and-climate-change-what-are-the-parties-pledges/a-59285491

The center-right Christian Democrats (CDU), who have led governments under Chancellor Angela Merkel for the last 16 years, along with their Bavarian sister party, the Christian Social Union (CSU), are committed to the target of climate neutrality by 2045 and want to greatly expand renewable energies. This includes simpler programs for photovoltaics on roofs. In the economy, the CDU and CSU are focusing on climate-neutral hydrogen to replace coal in industry. Exactly how this can be achieved, however, is disputed by many economic experts. For the time being, the CDU/CSU is also sticking to its decision to phase out coal-fired power generation by 2038, which many environmental experts consider far too late. Chancellor candidate Armin Laschet has stuck firmly to this date, while Friedrich Merz, the former head of the CDU parliamentary group, recently stated that he could imagine an earlier date. The CDU/CSU's plans fall short of achieving the international climate target.The center-left Social Democrats (SPD), who have been the junior coalition partner in government for the last eight years, want Germany's electricity to come entirely from renewable energies as early as 2040. This would be achieved, among other things, by installing solar panels on all suitable roofs. The SPD is also backing hydrogen; by 2030, Germany is to become the "lead market" in this area. But if hydrogen is to be climate-neutral, it must be produced using renewable energies. The SPD wants rail travel to become more attractive than flying, as well as to promote electric cars and the infrastructure for them — but the party does not have plans to ban flights. The party is in favor of a speed limit of 130 kph (80 mph) on German highways. And for the time being, it is sticking to the coal phaseout by 2038, even if its candidate for chancellor, Olaf Scholz, has suggested an earlier date, such as 2034, in TV discussions. But that is not yet confirmed.

#### European inaction on climate change means extinction.

Sears 21-- Sears, Nathan Alexander. "Great Powers, Polarity, and Existential Threats to Humanity: An Analysis of the Dis-tribution of the Forces of Total Destruction in International Security." (2021).

Humanity faces existential risks from the large-scale destruction of Earth’s natural environment making the planet less hospitable for humankind (Wallace-Wells 2019). The decline of some of Earth’s natural systems may already exceed the “planetary boundaries” that represent a “safe operating space for humanity” (Rockstrom et al. 2009). Humanity has become one of the driving forces behind Earth’s climate system (Crutzen 2002). The major anthropogenic drivers of climate change are the burning of fossil fuels (e.g., coal, oil, and gas), combined with the degradation of Earth’s natural systems for absorbing carbon dioxide, such as deforestation for agriculture (e.g., livestock and monocultures) and resource extraction (e.g., mining and oil), and the warming of the oceans (Kump et al. 2003). While humanity has influenced Earth’s climate since at least the Industrial Revolution, the dramatic increase in greenhouse gas emissions since the mid-twentieth century—the “Great Acceleration” (Steffen et al. 2007; 2015; McNeill & Engelke 2016)— is responsible for contemporary climate change, which has reached approximately 1°C above preindustrial levels (IPCC 2018). Climate change could become an existential threat to humanity if the planet’s climate reaches a “Hothouse Earth” state (Ripple et al. 2020). What are the dangers? There are two mechanisms of climate change that threaten humankind. The direct threat is extreme heat. While human societies possesses some capacity for adaptation and resilience to climate change, the physiological response of humans to heat stress imposes physical limits—with a hard limit at roughly 35°C wet-bulb temperature (Sherwood et al. 2010). A rise in global average temperatures by 3–4°C would increase the risk of heat stress, while 7°C could render some regions uninhabitable, and 11–12°C would leave much of the planet too hot for human habitation (Sherwood et al. 2010). The indirect effects of climate change could include, inter alia, rising sea levels affecting coastal regions (e.g., Miami and Shanghai), or even swallowing entire countries (e.g., Bangladesh and the Maldives); extreme and unpredictable weather and natural disasters (e.g., hurricanes and forest fires); environmental pressures on water and food scarcity (e.g., droughts from less-dispersed rainfall, and lower wheat-yields at higher temperatures); the possible inception of new bacteria and viruses; and, of course, large-scale human migration (World Bank 2012; Wallace-Well 2019; Richards, Lupton & Allywood 2001). While it is difficult to determine the existential implications of extreme environmental conditions, there are historic precedents for the collapse of human societies under environmental pressures (Diamond 2005). Earth’s “big five” mass extinction events have been linked to dramatic shifts in Earth’s climate (Ward 2008; Payne & Clapham 2012; Kolbert 2014; Brannen 2017), and a Hothouse Earth climate would represent terra incognita for humanity. Thus, the assumption here is that a Hothouse Earth climate could pose an existential threat to the habitability of the planet for humanity (Steffen et al. 2018., 5). At what point could climate change cross the threshold of an existential threat to humankind? The complexity of Earth’s natural systems makes it extremely difficult to give a precise figure (Rockstrom et al. 2009; ). However, much of the concern about climate change is over the danger of crossing “tipping points,” whereby positive feedback loops in Earth’s climate system could lead to potentially irreversible and self-reinforcing “runaway” climate change. For example, the melting of Arctic “permafrost” could produce additional warming, as glacial retreat reduces the refractory effect of the ice and releases huge quantities of methane currently trapped beneath it. A recent study suggests that a “planetary threshold” could exist at global average temperature of 2°C above preindustrial levels (Steffen et al. 2018; also IPCC 2018). Therefore, the analysis here takes the 2°C rise in global average temperatures as representing the lower-boundary of an existential threat to humanity, with higher temperatures increasing the risk of runaway climate change leading to a Hothouse Earth. The Paris Agreement on Climate Change set the goal of limiting the increase in global average temperatures to “well below” 2°C and to pursue efforts to limit the increase to 1.5°C. If the Paris Agreement goals are met, then nations would likely keep climate change below the threshold of an existential threat to humanity. According to Climate Action Tracker (2020), however, current policies of states are expected to produce global average temperatures of 2.9°C above preindustrial levels by 2100 (range between +2.1 and +3.9°C), while if states succeed in meeting their pledges and targets, global average temperatures are still projected to increase by 2.6°C (range between +2.1 and +3.3°C). Thus, while the Paris Agreements sets a goal that would reduce the exis 6 - tential risk of climate change, the actual policies of states could easily cross the threshold that would constitute an existential threat to humanity (CAT 2020). How do the CO2 emissions of the leading states affect the existential risk of climate change? One way to measure this would be to compare the leading states’ CO2 emissions against the global “carbon budget”—or the amount of CO2 emissions over a period of time that would keep global average temperature below the existential threshold of +2.0°C above preindustrial levels (IPCC 2018). If any of the leading state’s CO2 emissions—existing or projected—are equal to the global carbon budget, then this would constitute an absolute existential threat capability. None of the leading states appear to possess such an absolute existential threat capability. For example, the benchmark of total global annual CO2 equivalent emissions for a +2.0°C “compatible pathway” are 46 billion tonnes (bt) in 2025 and 38bt in 2030 (CAT 2020). China’s CO2 emissions are by far the largest amongst the leading states, which amounted to 10.17bt in 2019 and are expected to climb to somewhere below 15bt in the period between 2025 and 2030. China’s emissions are therefore far below the global carbon budget. Similarly, one 2019 study by the International Energy Agency estimated a remaining global carbon budget of 880 billion tonnes for having a 66% change of remaining well below 2.0°C (or 1.8°C) (Dalman 2020). Assuming China’s CO2 emissions were to remain on average at their current levels of approximately 10bt per year over the next 40 years until reaching China’s goal of “carbon neutrality” by 2060, China’s total emissions would still account for less than half of the global carbon budget. It is therefore highly unlikely that any 7 one of the leading states meets the threshold of CO2 emissions that would constitute an absolute existential threat capability, since no single state realistically accounts for the entire global carbon budget.

## 4

#### Counterplan text– The member nations of the World Trade Organization except for Germany ought to reduce intellectual property protections for medicines by implementing a one-and-done approach for patent protection.

Solves the aff, the entire aff is about the US

## Case

#### They can’t solve,- own card shows alt causes for evergreening like orphan drug exclusivities and slightly revised compounds- we read yellow

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."

### Reasonability---1NC

#### Use reasonability on theory with the briteline that it was clearly delineated and answerable—

#### 1. Competing interps over-incentivizes reading theory which detracts from substantive clash

#### 2. Over-punishing—otherwise you vote on a tiny amount of abuse—kills proportionality which is the definition of fairness

#### Arbitrariness inevitable—there’s no objective way to judge rights vs. death, reps vs. consequences, etc. so it’s best to intervene in a way that reduces the asinine nature of LD theory