## 1

### 1NC – FW

#### Permissibility and presumption negate – [a] the resolution indicates the aff has to prove an obligation, and permissibility would deny the existence of an obligation [b] Statements are more often false than true because any part can be false. This means you negate if there is no offense because the resolution is probably false.

#### Morality must be grounded in a priori truth to guide action, otherwise everyone would have different ethical codes and follow different rules. And, truth exists independent of human experience since certain things can be self-proving, i.e. a triangle has three sides. This is the difference between a priori and a posteriori. Things that are true by observation are just true by a matter of chance. For example, the cat may be on the mat, but we can also conceive of a world in which the cat is not on the mat. In contrast, we can’t conceive of a world in which a triangle does not have three sides since it is tautologically true. Reject a posteriori truth since they are just arbitrary states of being, not constitutive of ethics.

#### And, a priori truth has to apply to everyone: [a] absent universal ethics, morality becomes arbitrary and fails to guide action, which means that ethics is rendered useless. [b] it’s a tautological contradiction: any non-universal norm justifies someone’s ability to impede on your ends, which also means universalizability acts as a side constraint on all other frameworks.

#### Thus, the standard is consistency with willing universal maxims.

#### Performativity—freedom is the key to the process of justification of arguments. Willing that we should abide by their ethical theory presupposes that we own ourselves in the first place. Thus, it is logically incoherent to justify the aff standard without first willing that we can pursue ends free from others

### 1NC – Offense

#### 1] Intellectual property is an inalienable personal right of economic use

**Pozzo 6** Pozzo, Riccardo. “Immanuel Kant on Intellectual Property.” Trans/Form/Ação, vol. 29, no. 2, 2006, pp. 11–18., doi:10.1590/s0101-31732006000200002. SJ//DA recut Cookie JX

Corpus mysticum, opus mysticum, propriété incorporelle, proprietà letteraria, geistiges Eigentum. All these terms mean **intellectual property, the existence of which is intuitively clear because of the unbreakable bond that ties the work to its creator.** The book belongs to whomever has written it, the picture to whomever has painted it, the sculpture to whomever has sculpted it; and this independently from the number of exemplars of the book or of the work of art in their passages from owner to owner. The initial bond cannot change and it ensures the author authority on the work. Kant writes in section 31/II of the Metaphysics of Morals: “Why does unauthorized publishing, which strikes one even at first glance as unjust, still have an appearance of being rightful? Because on the one hand a book is a corporeal artifact (opus mechanicum) that can be reproduced (by someone in legitimate possession of a copy of it), so that there is a right to a thing with regard to it. On the other hand a book is also a mere discourse of the publisher to the public, which the publisher may not repeat publicly without having a mandate from the author to do so (praestatio operae), and this is a right against a person. The error consists in mistaking one of these rights for the other” (Kant, 1902, t.6, p.290). The corpus mysticum, **the work considered as an immaterial good, remains property of the author on behalf of the original right of its creation. The corpus mechanicum consists of the exemplars of the book or of the work of art. It becomes the property of whoever has bought the material object in which the work has been reproduced or expressed.** Seneca points out in De beneficiis (VII, 6) the difference between owning a thing and owning its use. He tells us that the bookseller Dorus had the habit of calling Cicero’s books his own, while there are people who claim books their own because they have written them and other people that do the same because they have bought them. Seneca concludes that the books can be correctly said to belong to both, for it is true they belong to both, but in a different way **The peculiarity of intellectual property consists thus first in being indeed a property, but property of an action; and second in being indeed inalienable, but also transferable in commission and license to a publisher. The bond the author has on his work confers him a moral right that is indeed a personal right. It is also a right to exploit economically his work in all possible ways, a right of economic use, which is a patrimonial right. Kant and Fichte argued that moral right and the right of economic use are strictly connected, and that the offense to one implies inevitably offense to the other.** In eighteenth-century Germany, the free use came into discussion among the presuppositions of a democratic renewal of state and society. In his Supplement to the Consideration of Publishing and Its Rights, Reimarus asked writers “instead of writing for the aristocracy, to write for the tiers état of the reader’s world.” (Reimarus, 1791b, p.595). **He saluted with enthusiasm the claim of disenfranchising from the monopoly of English publishers expressed in the American Act for the Encouragement of Learning of May 31, 1790. Kant, however, was firm in embracing intellectual property. Referring himself to Roman Law, he asked for its legislative formulation not only as patrimonial right, but also as a personal right.** In Of the Illegitimity of Pirate Publishing, he considered the moral faculties related to **intellectual property as an “inalienable right (ius personalissimum) always himself to speak through anyone else, the right, that is, that no one may deliver the same speech to the public other than in his (the author’s) name”** (Kant, 1902, t.8, p.85). Fichte went farther in the Demonstration of the Illegitimity of Pirate Publishing. **He saw intellectual property as a part of his metaphysical construction of intellectual activity, which was based on the principle that thoughts “are not transmitted hand to hand, they are not paid with shining cash, neither are they transmitted to us if we take home the book that contains them and put it into our library.** In order to make those thoughts our own an action is still missing: we must read the book, meditate – provided it is not completely trivial – on its content, consider it under different aspects and eventually accept it within our connections of ideas” (Fichte, 1964, t.I/1, p.411). At the center of the discussion was the practice of reprinting books in a pirate edition after having them reset word after words after an exemplar of the original edition. Given Germany’s division in a myriad of small states, the imperial privilege was ineffective against pirate publishing. Kant and Fichte spoke for the acceptance of the right to defend the work of an author by the usurpations of others so that he may receive a patrimonial advantage from those who utilize the work acquiring new knowledge and/or an aesthetic experience. In particular, Fichte declared the absolute primacy of the moral faculties within the corpus mysticum. He divided the latter into a formal and a material part. “This intellectual element must be divided anew into what is material, the content of the book, the thoughts it presents; and the form of these thoughts, the manner in which, the connection in which, the formulations and the words by means of which the book presents them” (Fichte, 1964, t.I/1, p.411). Fichte’s underlining the author’s exclusive right to the intellectual content of his book – “the appropriation of which through another is physically impossible” (ibid.) – brought him to the extreme of prohibiting any form of copy that is not meant for personal use. In Publishing Considered anew, Reimarus considered on the contrary copyright in its patrimonial aspects as a limitation to free trade: “What would not happen were a universal protection against pirate publishing guaranteed? Monopoly and safer sales certainly do not procure convenient price; on the contrary, they are at the origin of great abuses. The only condition for convenient price is free-trade, and one cannot help noticing that upon the appearance of a private edition, publishers are forced to substantially lower the price of a book” (Reimarus, 1791a, pp.402-3). Reimarus admitted of being unable to argue in terms of justice. Justice was of no bearing, he said, for whom, like himself, considered undemonstrated the author’s permanent property of his work (herein supported by the legislative vacuum of those years). What mattered, he said, was equity. In sum, Reimarus anticipated today’s stance on free use by referring to the principle that public interest on knowledge ought to prevail on the author’s interest and to balance the copyright. Moreover, Reimarus extended his argument beyond the realm of literary production to embrace, among others, the today vital issue of pharmaceutical production on patented receipts. “Let us suppose that at some place a detailed description for the preparation of a good medicine or of any other useful thing be published, why may not somebody who lives in places that are far away from that one copy it to use it for his own profit and but must instead ask the original publisher for the issue of each exemplar?” (Reimarus, 1791b, t.2, pp.584). To sum up, Reimarus’s stance does not seem respondent to rule of law. For in all dubious case the general rule ought to prevail, fighting intellectual property with anti-monopolistic arguments in favor of free trade brings with itself consequences that are not tranquilizing also for the ones that are expected to apply the law. **By resetting literary texts, one could obviously expurgate some errors. More frequently, however, some were added, given the exclusively commercial objectives of the reprints. The valid principle was, thus, that reprints were less precise than original editions, but they were much cheaper for the simple reason that the pirate publisher had a merely moral obligation against the author and the original publisher. In fact, he was not held to pay any honorarium to the author upon handling over the manuscript, nor to paying him royalties, nor to pay anything to the original publisher. The** only expense in charge of the pirate publisher was buying the exemplar of the original edition out of which he was to make, as we say today, a free use.

#### 2]The aff encourages free riding- that treats people as ­means to an end and takes advantage of their efforts which violates the principle of humanity

**Van Dyke 2** Raymond Van Dyke, 7-17-2018, "The Categorical Imperative for Innovation and Patenting," IPWatchdog, <https://www.ipwatchdog.com/2018/07/17/categorical-imperative-innovation-patenting/id=99178/> SJ//DA recut SJKS

Also, **allowing the free taking of ideas, content and valuable data, i.e., the fruits of individual intellectual endeavor**, would disrupt capitalism in a radical way. **The resulting more secretive approach in support of the above free-riding Statement** would be akin to a Communist environment **where the State owned everything and the citizen owned nothing, i.e., the people “consented” to this. It is, accordingly, manifestly clear that no reasonable and supportable Categorical Imperative can be made for the unwarranted theft of property, whether tangible or intangible,** apart from legitimate exigencies.

## 2

#### Interpretation: Reduce means unconditional and permanent – the aff is a suspension.

Reynolds 59 – Judge (In the Matter of Doris A. Montesani, Petitioner, v. Arthur Levitt, as Comptroller of the State of New York, et al., Respondents [NO NUMBER IN ORIGINAL] Supreme Court of New York, Appellate Division, Third Department 9 A.D.2d 51; 189 N.Y.S.2d 695; 1959 N.Y. App. Div. LEXIS 7391 August 13, 1959, lexis)

Section 83's counterpart with regard to nondisability pensioners, section 84, prescribes a reduction only if the pensioner should again take a public job. The disability pensioner is penalized if he takes any type of employment. The reason for the difference, of course, is that in one case the only reason pension benefits are available is because the pensioner is considered incapable of gainful employment, while in the other he has fully completed his "tour" and is considered as having earned his reward with almost no strings attached. It would be manifestly unfair to the ordinary retiree to accord the disability retiree the benefits of the System to which they both belong when the latter is otherwise capable of earning a living and had not fulfilled his service obligation. If it were to be held that withholdings under section 83 were payable whenever the pensioner died or stopped his other employment the whole purpose of the provision would be defeated, i.e., the System might just as well have continued payments during the other employment since it must later pay it anyway.  [\*\*\*13]  The section says "reduced", does not say that monthly payments shall be temporarily suspended; it says that the pension itself shall be reduced. The plain dictionary meaning of the word is to diminish, lower or degrade. The word "reduce" seems adequately to indicate permanency.

#### Violation:

#### Vote neg:

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

#### 2] 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.

#### 3] TVA – defend the advantage to a whole rez timeframe. We don’t prevent new FWs, mechanisms, or advantages. PICs don’t solve – our model allows you to specify countries and medicines.

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

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

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

#### No RVIs – a] illogical, you don’t win for proving that you meet the burden of being fair, logic outweighs since it’s a prerequisite for evaluating any other argument, b] RVIs incentivize baiting theory and prepping it out which leads to maximally abusive practices

## 3

#### Bipartisan antitrust bills passing now but continued PC needed to pacify republicans.

Perlman 9/3 [Matthew; 9/3/21; “*Interest Groups Back Big Tech Antitrust Bills In House,*” LAW360, <https://www.law360.com/competition/articles/1418789/interest-groups-back-big-tech-antitrust-bills-in-house>] Justin

Law360 (September 3, 2021, 7:25 PM EDT) -- A contingent of public interest groups are urging leaders of the U.S. House of Representatives to advance a package of legislation aimed at reining in Big Tech companies through updates and changes to antitrust law, though free market advocates have been jeering many of the bills. A total of 58 public interest and consumer advocacy groups signed on to a letter Thursday asking House leaders to swiftly pass the package of six antitrust bills that the Judiciary Committee approved in late June after a marathon markup session. The proposals include legislation prohibiting large platform companies from acquiring competitive threats, preferencing their own services and using their control of multiple business lines to disadvantage competitors in other ways. The proposals would also impose interoperability and data portability requirements on large tech platforms, increase merger filing fees and boost enforcement by state attorneys general. Charlotte Slaiman, competition policy director for Public Knowledge, which signed on to the letter, said in a statement Thursday that the package charts a path toward putting "people back in control of the digital economy." "The broad range of groups supporting this package shows just how widespread the problem of Big Tech dominance is, and that these bills deserve a full vote in the House imminently," Slaiman said. The letter contends that America has a monopoly problem that is resulting in lower wages, reduced innovation and increased inequality, while also undermining the free press and perpetuating "racial, gender and class dominance." "Big Tech monopolies are at the center of many of these problems," the letter said. "Reining in these companies is an essential first step to reverse the damage of concentrated corporate power throughout our economy." The proposals followed a 16-month investigation by the House antitrust subcommittee into Amazon, Apple, Facebook and Google that resulted in a sprawling report from Democratic members calling for a range of reform measures to rein in the dominance of the companies. While consumer advocacy groups have largely supported the measures, the tech companies themselves and other interest groups have been highly critical, including a coalition of more than 25 right-leaning groups that sent a letter to Congress ahead of the markup hearing. The letter called the bills a "Trojan horse package" aimed at cynically using conservative anger over Big Tech, particularly at perceived censorship by social media platforms, to seek bipartisan support for "European-style over-regulation." For its part, Facebook has called the proposals a "poison pill for America's tech industry at a time our economy can least afford it" and said the bills underestimate the fierce competition the U.S. companies face from abroad. Apple and Google also raised concerns about the impact the bills would have on innovation, as well as on privacy and security. And Amazon has warned about the potential consequences of the proposals for both small businesses that sell on its platform and the consumers who use it to shop. Ending Platform Monopolies Act Thursday's letter said that the Ending Platform Monopolies Act would address "the most problematic aspects of the Big Tech companies" by allowing enforcers to break-up or separate pieces of the businesses when they create conflicts of interest that give the platforms an advantage over potential competitors and business users. A fact sheet from Public Knowledge accompanying the letter said that the bill is an important tool to help the antitrust agencies "protect consumers from mammoth platforms and to ensure compliance with other parts of the package." But during the markup hearing, ranking Republican committee member Rep. Jim Jordan of Ohio blasted the bill as a regulatory overreach, calling it "quite literally central planning" and arguing that it has significant ambiguities, which is bad for business. The Competitive Enterprise Institute argued in a June statement that the bill "kills the goose that lays the golden egg," and would actually result in small businesses being unable to access the large platforms, which in turn would focus on their own offerings instead. The Chamber of Progress has warned that the proposal could bar Amazon from offering its Prime services and its Amazon Basics private label products, since they would compete against other sellers on the platform. Other groups have also warned it could also force tech companies to divest popular apps, including Google's Maps and YouTube, Facebook's WhatsApp and Instagram and Apple's iMessage and FaceTime. American Innovation and Choice Online Act The American Innovation and Choice Online Act is aimed at barring the platform companies from preferencing their own products and services over those of rival businesses and from excluding or discriminating against rivals. Thursday's letter said this proposal would "promote innovation and competition" by preventing the platforms from protecting their monopolies. The right-leaning think tank American Enterprise Institute and others have argued that the bill could prevent Apple from pre-installing certain apps on its mobile phones, since that would advantage it over competing app developers. It could also prevent Google from integrating maps or customer reviews into search results, among other things. "At a minimum, the act would significantly disrupt these platforms' business models in ways that undermine consumer value," Daniel Lyons, a senior fellow for the group wrote in a blog post in June. Platform Competition and Opportunity Act The Platform Competition and Opportunity Act is aimed at preventing platform companies from acquiring potential or nascent competitors and its supporters argued in Thursday's letter that it would prevent the tech giants from enhancing or maintaining their market power. The bill would presumably have blocked Facebook's purchases of WhatsApp, Instagram and other services it has acquired, as well as a slew of deals by Google over the past two decades. Detractors have contended that this bill would limit investments in startups because it restricts their ability to be acquired by the larger technology firms, which they say is a key way for founders to benefit from their success. An American Enterprise Institute blog post from June argues that "opportunities for acquisition have been important drivers of innovation in tech" and also said the bill would prevent the tech companies from entering new areas of business to compete with each other. ACCESS Act The Augmenting Compatibility and Competition by Enabling Service Switching, or ACCESS Act, imposes requirements for the tech companies to make user data portable and able to be used by competing services. The bill's supporters argued in Thursday's letter that this prevents the tech giants from locking users into their services, since users can take their data with them and use it on other networks. Privacy and security implications have been flagged as potential problems for the proposal, with the Competitive Enterprise Institute saying in a statement in June that it's an "anti-privacy bill" that forces companies to turn over private user information to others. The group also said the bill would try to micromanage "complex, dynamic, and highly competitive markets" that are beyond understanding for most politicians and regulators. The American Enterprise Institute has also contended that the requirements would actually make rivals even more dependent on the incumbent platforms. Filing fees and state enforcement Of the antitrust bills approved by the House Judiciary Committee, the ones with the most bipartisan support appear to be the Merger Filing Fee Modernization Act and the State Antitrust Enforcement Venue Act, though it took a day of debate before the committee passed them. A Senate version of the filing fee bill passed that chamber in June as part of the U.S. Innovation and Competition Act. It would raise the fees merging parties pay when reporting large transactions, while lowering fees for smaller deals, in order to raise more resources for the antitrust agencies. Information Technology & Innovation Foundation argued in an August blog post that the legislation does not give Congress enough oversight over how the agencies will use the funds that it raises and called for the bill to include provisions requiring the money be used to hire more staff dedicated to antitrust enforcement. The Competitive Enterprise Institute also raised concerns about congressional oversight and contended that the bill would increase the cost of doing business at a time when the economy is sputtering. "U.S. consumers need innovative services and affordable products, not higher prices passed onto them by businesses avoiding new, unnecessary regulatory compliance costs," the group said in a June blog post. The state enforcement bill would prevent antitrust cases brought by state attorneys general from being transferred to a different venue by the Judicial Panel on Multidistrict Litigation, similar to protections afforded to federal enforcers. The bill is intended to prevent companies targeted by state-led enforcement actions from trying to move the cases to more favorable venues, and it also has an analog in the Senate. Information Technology & Innovation Foundation acknowledged in their August post that having cases included in multidistrict litigation can handicap state enforcers, but contended the changes should only apply to criminal matters and that the current version is wrong to block transfers of civil cases too. Thursday's letter from supporters of the bills said the proposals were carefully crafted to address the abusive practices of Big Tech, informed by the House antitrust subcommitee's sprawling investigation and "historic" 450-page report. "We believe that these bills will bring urgently needed change and accountability to these companies and an industry that most Americans agree is already doing great harm to our democracy," the letter said.

#### Aff doesn’t solve but requires negotiations that saps PC.

Pooley 21 [James; Former deputy director general of the United Nations’ World Intellectual Property Organization and a member of the Center for Intellectual Property Understanding; “Drawn-Out Negotiations Over Covid IP Will Blow Back on Biden,” Barron’s; 5/26/21; <https://www.barrons.com/articles/drawn-out-negotiations-over-covid-ip-will-blow-back-on-biden-51621973675>] Justin

The Biden administration recently announced its support for a proposal before the World Trade Organization that would suspend the intellectual property protections on Covid-19 vaccines as guaranteed by the landmark TRIPS Agreement, a global trade pact that took effect in 1995.

The decision has sparked furious debate, with supporters arguing that the decision will speed the vaccine rollout in developing countries. The reality, however, is that even if enacted, the IP waiver will have zero short-term impact—but could inflict serious, long-term harm on global economic growth. The myopic nature of the Biden administration’s announcement cannot be overstated.

Even if WTO officials decide to waive IP protections at their June meeting, it’ll simply kickstart months of legal negotiations over precisely which drug formulas and technical know-how are undeserving of IP protections. And it’s unthinkable that the Biden administration, or Congress for that matter, would actually force American companies to hand over their most cutting-edge—and closely guarded—secrets.

As a result, the inevitable foot-dragging will cause enormous resentment in developing countries. And that’s the real threat of the waiver—precisely because it won’t accomplish either of its short-term goals of improving vaccine access and facilitating tech transfers from rich countries to developing ones. It’ll strengthen calls for more extreme, anti-IP measures down the road.

Experts overwhelmingly agree that waiving IP protections alone won’t increase vaccine production. That’s because making a shot is far more complicated than just following a recipe, and two of the most effective vaccines are based on cutting-edge discoveries using messenger RNA.

As Moderna Chief Executive Stephane Bancel said on a recent earnings call, “This is a new technology. You cannot go hire people who know how to make the mRNA. Those people don’t exist. And then even if all those things were available, whoever wants to do mRNA vaccines will have to, you know, buy the machine, invent the manufacturing process, invent creation processes and ethical processes, and then they will have to go run a clinical trial, get the data, get the product approved and scale manufacturing. This doesn’t happen in six or 12 or 18 months.”

Anthony Fauci, the president’s chief medical adviser, has echoed that sentiment and emphasized the need for immediate solutions. “Going back and forth, consuming time and lawyers in a legal argument about waivers—that is not the endgame,” he said. “People are dying around the world and we have to get vaccines into their arms in the fastest and most efficient way possible.”

Those claiming the waiver poses an immediate, rather than long-term, threat to IP rights also misunderstand what the waiver will—and won’t—do.

The waiver petition itself is more akin to a statement of principle than an actual legal document. In fact, it’s only a few pages long.

As the Office of the United States Trade Representative has said, “Text-based negotiations at the WTO will take time given the consensus-based nature of the institution and the complexity of the issues involved.” The WTO director-general predicts negotiations will last until early December.

That’s a lot of wasted time and effort. The U.S. Trade Representative would be far better off spending the next six months breaking down real trade barriers and helping export our surplus vaccine doses and vaccine ingredients to countries in need.

#### Antitrust is key to the DIB – brink is now.

Sitaraman 20 [Ganesh; Vanderbilt University Law School; “The National Security Case for Breaking Up Big Tech,” Knight First Amendment Institute at Columbia; 3/12/20; <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3537870>] brett // Re-Cut Justin

Concentration in the tech sector also threatens the defense industrial base due to higher costs, lower quality, less innovation, and even corruption and fraud.71 Each of these dynamics has already been a problem for America’s over-consolidated defense industrial base. As technology becomes more and more central to defense and national security, it is likely that these same dynamics will replicate themselves with big tech companies. This will become a national security threat, both directly, in terms of the quality and speed of procurement, and indirectly, by reducing innovation and functionally redirecting defense budgets from research spending to higher monopoly profits.72 Conventional economic theory suggests that monopolists have the ability to increase prices and reduce quality because consumers are captive.73 When it comes to defense spending, the Government Accountability Office commented in 2019 that “competition is the cornerstone of a sound acquisition process and a critical tool for achieving the best return on investment for taxpayers.”74 At the same time, the GAO observed that “portfolio-wide cost growth has occurred in an environment where awards are often made without full and open competition.”75 Indeed, it found that 67 percent of 183 major weapons systems contracts had no competition and almost half of contracts went to a handful of firms. Of course, consolidation also means that the Defense Department is in a symbiotic relationship with these big contractors. Some startup executives wanting to sell to the government thus see the Pentagon as “a bad customer, one that is heavily skewed in favor of larger, traditional players,” and they don’t feel like they can break into the sector.76 Standard stories about political economy and capture also suggest that these firms will have outsized power over government.77 As Frank Kendall, the former head of acquisitions at the Pentagon, has said, “With size comes power, and the department’s experience with large defense contractors is that they are not hesitant to use this power for corporate advantage.”78 In the defense context, that means monopolists retain power (and profits), even if they overcharge taxpayers and risk the safety of military personnel in the field. In an important article in The American Conservative on concentration in the defense sector, researchers Matt Stoller and Lucas Kunce argue that contractors with de facto monopoly at the heart of their business models threaten national security. They write that one such contractor, TransDigm, buys up companies that supply the government with rare but essential airline parts and then hike up the prices, effectively holding the government “hostage.”79 They also point to L3, a defense contractor that had ambitions to be a “Home Depot” for the Pentagon, as its former CEO put it. L3’s de facto monopoly over certain products, according to Stoller and Kunce, means that it continues to receive lucrative government contracts, even after admitting in 2015 that it knowingly supplied defective weapons sights to U.S. forces.80 Consolidation also threatens U.S. defense capacity. The decline of competition, according to a 2019 Pentagon report, leaves the military vulnerable to “sole source suppliers, capacity shortfalls, a lack of competition, a lack of workforce skills, and unstable demand.”81 With a limited number of producers, there is less talent and knowhow available in the country if there is a need to build capacity rapidly.82 In 2018, the Defense Department released a report on vulnerable items in the military supply chain, including numerous items in which only one or two domestic companies (and, in some cases, zero domestic companies) produced the essential goods.83 How did the United States lose so much of its industrial base? The combination of consolidation and global integration is part of the story. As Stoller and Kunce argue, companies consolidated in the 1980s and 1990s while shifting emphasis from production and R&D to Wall Street-demanded profits. Globalization then allowed them to shift production overseas at a lower cost. The result was to gut America’s domestic industrial base—and, in many cases, to shift it to China, which engaged in a decades-long strategic plan to develop its own industrial base. The result, in the words of the 2018 Defense Department report, is that “China is the single or sole supplier for a number of specialty chemicals used in munitions and missiles.” In other areas too, the risks of losing access to critical resources are real. Describing the problem of limited carbon fiber sources, the same Pentagon report notes, “[a] sudden and catastrophic loss of supply would disrupt DoD missile, satellite, space launch, and other defense manufacturing programs. In many cases, there are no substitutes readily available.”84 As technology becomes more integral to the future of national security, it is hard to see how big tech will not simply go the way of the big defense contractors. Corporate mottos not to “be evil” are long gone,85 and big tech companies spend millions on conventional Washington, D.C., lobbying efforts.86 Over time, as contracts move to tech behemoths, there will no longer be competitive alternatives, and the Pentagon will likely be locked into relationships with big tech companies—just as they currently are with big defense contractors.87 Some commentators suggest that robust antitrust policies are a problem because only a small number of tech companies can contract for defense projects.88 But there is another way to look at it: The goal should be to encourage competition in the tech sector so that there are multiple contractors available. As former secretary of homeland security Michael Chertoff has said, defending the antitrust case against Qualcomm, “a single-source national champion creates an unacceptable risk to American security—artificially concentrating vulnerability in a single point. ... We need competition and multiple providers, not a potentially vulnerable technological monoculture.”89 The consequence of consolidation in tech is that taxpayers will likely see higher bills even as innovation slows due to reduced competition. Worse still, every taxpayer dollar that goes to monopoly profits—whether in the form of higher prices or fraud and corruption—is a dollar that is not going toward innovation for the future. A concentrated defense sector means not only less innovation due to the lack of competition in the sector; it means that funding that could have been available for innovation instead gets redirected via monopoly profits to the pockets of big tech executives and shareholders.

#### That solves extinction through great power war.

Marks 19 [Michael; Former Senior Policy Advisor to the Under Secretary for Security Assistance, Science and Technology at the U.S. Department of State; "Strengthen US Industry To Counter National Security Challenges," American Military News; 10/10/19; <https://americanmilitarynews.com/2019/10/strengthen-us-industry-to-counter-national-security-challenges/>] Justin

While U.S. defense budgets have recently been on the rise, it is likely that we will see a spending decline in the coming years as competition for non-defense federal budget dollars increases and deficits grow. The United States, therefore, must take action to ensure that we maintain our technological edge against our adversaries by empowering the private sector to provide cost-effective innovation for America’s defense. Since the end of the Second World War the U.S. has relied on qualitative superiority over its potential adversaries, especially those like the Soviet Union/Russia and China, who enjoyed comparative quantitative advantages. These qualitative advantages were vital to maintaining global stability and helped enable our nation to become the preeminent global economy, but they have been eroded over the last few decades. In 1960, the U.S. share of global research and development (R&D) spending stood at 69%. U.S. defense-related R&D alone accounted for 36% of total global expenditures. Soon thereafter other nations recognized the need to increase their R&D expenditures and build their own defense industrial bases to compete with the United States. From 2000-2016, China’s share of global R&D rose from 4.9% to 25.1% while the U.S. share of global R&D dropped to 28%. U.S. defense-related R&D meanwhile now makes up a mere 4% of global R&D spending. There can be no doubt that Russia and China are determined to challenge America’s qualitative advantage. From the rebirth of Russian military power under Vladimir Putin to the ever-growing Chinese military prowess across the board, their efforts show no sign of slowing down. Russia has been and continues to undergo a major modernization of its armed forces. For example, they are in the midst of a ten-year program to build hundreds of new nuclear missiles and have set a goal of modernizing 70% of the Russian Ground Force’s equipment by 2020. One of the most frightening examples of Russia’s resurgence is its development of a hypersonic missile that could be ready for combat as early as 2020. Worryingly, the US is currently unable to defend against this type of missile. To accompany these developments came the emergence in 2017 of Russia as the world’s second-largest arms producer, ready and able to support nations hostile to US interests. China, on the other hand, used to be a country that only manufactured cheap products and knockoffs, but that is no longer true. Technology development and innovation figure prominently in all of China’s national planning goals, with plans to make the country the global leader in science and innovation and the preeminent technological and manufacturing power by 2049, the 100th anniversary of the Chinese communist revolution. This, of course, has huge implications for China’s military capability. The country now has the second-largest national defense budget behind the U.S. and wants to be Asia’s preeminent military power. Beijing is developing next-generation fighter jets, ICBMs and shorter-range ballistic missiles, as well as advanced naval vessels. The People’s Liberation Army has reached a critical point of confidence and now feel they can match competitors like the United States in combat. This has implications for the security of Taiwan, Japan, other US allies in the region as well as to America itself. To make matters worse, there are a growing number of experts that see China developing asymmetric technologies, combined with conventional and nuclear systems that could create an existential threat to the U.S. pacific based assets. It is in the wake of these growing threats to our national security American industry will likely be expected to shoulder an even larger responsibility concerning investment in defense-related R&D. One of the ways we can empower companies to make these additional investments and lead next-generation defense innovation is to allow commonsense mergers between important defense and aerospace companies. Horizontal consolidation eliminates the redundancy of enormous fixed costs, leading to savings passed down to customers. Mergers can also create economies of scale and existing synergies that help the combined company realize access to larger numbers of engineers and innovators, while keeping costs low and improving the timeline for taking a product from concept to development. FA recent example of how this can work is the proposed Raytheon and United Technologies merger. The two parties project that the new combined company will employ more than 60,000 engineers, hold over 38,000 patents and invest approximately $8 billion per year in research and development. This will allow the development of new, critical technologies more quickly and efficiently than either company could on its own. Such private sector investments in innovation will be critical in the face of the growing challenges to American military dominance. America’s R&D advantage, crucial to maintaining military superiority, is increasingly at risk. As China and Russia continue to challenge America’s military dominance and pressures on the defense budget continue to mount, the federal government will likely turn more and more to contractors and commercial companies to develop next-generation defense capabilities. Strengthening U.S. industry, therefore, will be critical to countering our national security challenges.

## Case

#### New 2nr responses – 1. their arguments are incomplete and I can’t know the implications until the 1ar 2. Clash – their model allows debaters to just extend one argument and ignore the rests of the flow

#### Reject 1AR Theory They have two speeches on theory and I have one which is def irreciporcal Its not inf abuse because I only have 7 mins If you don’t buy that,

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

#### DTA on 1AR shells - They can blow up a blippy 20 second shell to 3 min of the 2AR while I have to split my time and can’t preempt 2AR spin which necessitates judge intervention and means 1AR theory is irresolvable so you shouldn’t stake the round on it.

#### Aff gets circumvented- powerful countries use bilateral agreements to force other countries to accept their IPR protections- its empirically proven

DC = developing country

NIT = Net Importers of Technology (this references developing countries)

NET = Net Exporters of Technology (countries with advanced economies)

Marcellin 16 Marcellin, Sherry (Professor, London School of Economics). The political economy of pharmaceutical patents: US sectional interests and the African Group at the WTO. Routledge, 2016./SJKS

In July 1988, prior to the Montreal Mid-Term Review, DCs had sensed that the approach being proposed by industrialised countries was desirable on the grounds that the alternative would be a proliferation of unilateral or bilateral actions (MTN.GNG/NG11/8: 31). These NITs maintained that acceptance of such an approach would be tantamount to creating a licence to force, in the name of trade, modifications in standards for the protection of IP in a way that had not been found acceptable or possible so far in WIPO (ibid). Brazil subsequently informed the Group that on October 20, 1988, unilateral restrictions had been applied by the US to Brazilian exports as a retaliatory measure in connection with an IP issue; that this type of action seriously inhibited Brazil’s participation in the work of the Group, since ‘no country could be expected to participate in negotiations while experiencing pressures on the substance of its position’ (MTN.GNG/NG11/10: 27). The Brazilian delegate maintained that such action by the US constituted a blatant infringement of GATT rules and was contrary to the Standstill commitment of the Punta del Este Declaration. ‘The United States action was an attempt to coerce Brazil to change its intellectual property legislation, and furthermore represented an attempt by the United States to improve its negotiating position in the Uruguay Round’ (ibid). A US delegate countered that the measures had been taken with regret and as a last resort after all alternative ways of defending legitimate US interests had been exhausted, and that the US further believed that the adoption of effective patent protection was in Brazil’s own interest (ibid: 28). The US had therefore applied its strategy of coercive unilateralism against one of the two most important players championing the cause of the South in the TRIPS negotiations, the other being India. Apprehensive about the resistance of this dominant Southern duo, the United States sought to utilise its market size as a bargaining tool to secure changes to national IP regimes. It therefore decided to impact the more powerful of the two at the time, thereby indirectly admonishing India and the entire coalition against strengthened IP rules, as well as their domestic export constituencies who would be affected by US decisions to restrict imports. Moreover, because Brazil and India appeared to be collaborating extensively in maintaining a united front, a resulting strain on Brazil’s economy would likely affect their co-operation. However, since market opening and closure have been treated as the currency of trade negotiations in the post-war period (Steinberg 2002: 347), the move to place restrictions on Brazilian exports by the largest consumer market in the GPE should not have been entirely unanticipated. Brazil was also the regional leader in South America and disciplining it would send an unequivocal warning to other South American countries (Drahos and Braithwaite 2002: 136), including Argentina, Chile and Peru who were also active participants in the negotiations. This would mark the start of a series of coercive strategies aimed at compliance with the US private-sector envisioned GATT IPP.

#### Evergreening is a myth – this card ends the debate.

Lietzan 20 [Erika; Professor of Law, University of Missouri School of Law, Research interests in Pharmaceutical Regulation, Device Regulation, Intellectual Property; “The Evergreening Myth Claims that drug innovators extend their patents obscure a radical policy‐​making goal.,” Cato Institute; Fall 2020; <https://www.cato.org/regulation/fall-2020/evergreening-myth>/] Justin

In recent years, U.S. policymakers have considered proposals intended to prevent — or at least reduce — “evergreening” by pharmaceutical companies. Some proposals would change the antitrust enforcement landscape, others the intellectual property landscape, and still others the regulatory framework that governs new medicines. Some proposals — such as those creating new causes of action under the antitrust laws or limiting the availability of patents for discoveries — are profound and their proponents cite a body of academic and policy literature that decries supposed “evergreening” by companies to justify their ideas.

The term “evergreening” is a metaphor, meant to remind audiences of evergreen trees, which have green foliage year‐​round. It implies that something has been extended, and users of the metaphor view this extension as improper or undesirable. When offering descriptions and examples of evergreening, they focus on drug companies continuing to innovate after first introducing a new molecule, and on the broader marketplace for medicines after subsequent innovations have been introduced to the market. But proponents are frustratingly inconsistent and unclear about what, exactly, has been “extended” in these situations. A close look at the regulatory landscape in which continuing pharmaceutical innovation occurs shows that arguments for reform are grounded in myths, such as the myth that pharmaceutical companies continuing to innovate somehow “extend” their patents.

Once the myths of “evergreening” are laid bare, it becomes apparent that proponents of these proposals really want for the government to limit medical innovators to one medical product in the marketplace for each useful new molecule discovered. They are arguing that an innovator should not enjoy an exclusive market — and the resulting advantageous pricing — for innovations that, though discrete and independently satisfying the standard for a patent under U.S. law, stem in some fashion from an earlier innovation for which that innovator separately enjoyed exclusivity and the resulting pricing advantages. Or, at least, that drug innovators should not. This is a radical proposal that merits careful reflection and discussion, and it is not ripe for action. Understanding that this is the true policymaking objective requires unpacking the regulatory landscape and market more carefully, and paying closer attention to word choice, than proponents of reform often do. The Evergreening Allegation In the United States, every new medicinal product requires premarket approval from the Food and Drug Administration. The drug statute refers to approval of a “new drug,” and ambiguity in the term “drug” provides fertile ground for confusion and rhetorical mischief, as discussed later in this article. A firm that wants to market a new drug must prove to the FDA that the drug is safe and effective. Generating this information takes years, beginning with work in the laboratory and on animals, and progressing through several rounds of “clinical” testing in humans. For new molecules, the clinical portion of this research and development program averages six years. The process is also expensive: the Tufts Center for the Study of Drug Development now estimates the average cost of developing a new molecular entity at $2.6 billion. That figure includes average out‐​of‐​pocket costs of $1.4 billion and reflects the cost of unsuccessful projects. Most research and development programs fail. When new drugs are first launched by innovators, they tend to be sold under brand names and protected by patents as well as statutory rights in the data that supported FDA approval (known as “data exclusivity”). Although the pricing of these products may reflect competitive pressure from other branded products, it also reflects the fact that patent rights and statutory data exclusivity delay the launch of cheaper copies. But no more than five years later, and often earlier, the innovator’s competitors may file applications seeking approval of their own products based on the innovator’s research, rather than performing their own. They file what are known as “abbreviated applications” — abbreviated because they omit some, or all, of the research needed to prove safety and effectiveness. Abbreviated applications are much less expensive and time‐​consuming to assemble, and the competitors’ drugs correspondingly much less expensive than the original drugs they copy. When a competitor seeks to market an exact copy through an abbreviated application, we call its drug a “generic” drug. Pharmacists usually dispense generic copies even when doctors prescribe the corresponding branded products by name. Some people use the “evergreening” label when an innovator holds more than one patent protecting its product, especially if some patents expire later than others. More often, though, these people use the label when an innovator introduces a newer version of its own product that is already on the market. These newer products tend to be sold under brand names and protected by their own patents and statutory data exclusivity. Sometimes the innovator also stops selling its older product. If purchasers shift to the innovator’s newer product rather than purchasing cheap copies of the innovator’s older product, some say the innovator has engaged in evergreening. Although the term “evergreening” is a metaphor and signifies an extension of something, proponents of reform proposals do not agree on the particulars of the term’s use. Some say the company has evergreened its invention, its drug, or its product. Others say the company has evergreened the drug’s patent or patent life, or its exclusivity. Some say it has extended the drug’s patents, or the drug’s patent coverage or patent life, or the drug’s exclusivity period. Some say the company has evergreened the drug’s price, or its own profits or monopoly, or the company has extended its market power. Many argue that through evergreening — whatever the term means — the innovator has improperly blocked other firms from competing with it. On this basis, they seek government intervention. For instance, one recent proposal would allow the Federal Trade Commission to bring antitrust actions against innovators who introduced newer products to replace their older products. Three Myths of Evergreening The circumstances that trigger the “evergreening” label occur at the intersection of several complex bodies of law: the federal framework requiring premarket approval of new medicines and their copies, federal intellectual property laws, federal and state laws governing promotion of medicines, and federal laws and practices and state laws relating to prescribing and dispensing medicines. Many who propose aggressive government intervention because of evergreening give short shrift to this landscape, which allows the perpetuation of three myths that distort policymaking discussions. Before reviewing the myths, it will help to understand two points about the framework in which innovators compete with the companies that submit abbreviated applications. First, the FDA approves products, not active ingredients. And second, patents protect inventions, not products. Federal law states that every “new drug” requires an approved application. But at the FDA the term “drug” has more than one meaning. It includes a medicine’s active ingredient, to be sure. But it also includes drug products. A drug product is a medicine in its finished form, meaning the form that will be sold in the market and administered to patients. And the FDA approves a particular product described in a particular application — the specific combination of active and inactive ingredients (often called a drug’s “formulation”), in a particular dosage form (such as capsule or tablet), for a particular route of administration (such as oral or topical), at a particular strength, for particular medical uses (also known as the product’s “indications”), manufactured as described in the application, and accompanied by labeling written for prescribers based on the data in the application. Federal law allows a patent to issue for any new, useful, non‐​obvious invention, including a process, a composition of matter, and an improvement to an existing process or composition of matter. The patent usually expires 20 years after its application date. For any particular drug product approved by the FDA, the innovator might own patents on various types of inventions. The innovator usually owns a patent claiming the product’s active ingredient, and because the innovator generally files this patent before starting clinical trials, it is usually the first to expire. Other inventions protected by patent might include the product’s formulation or a dosage form and dosage of the active ingredient (or formulation). These inventions may emerge later in the premarket development process. If the resulting patent applications refer to the active ingredient patent, the patents will expire when the active ingredient patent expires, but otherwise they will expire later. The innovator may also own other patents claiming inventions embodied in the product, such as a patent claiming methods of using or administering the product, a patent claiming the manufacturing process, or a patent claiming a metabolite of the active ingredient. These, too, could expire later than the first patent — sometimes much later. These two points work together. A single active ingredient associated with a single brand name might be the subject of a half dozen, dozen, or more discrete products. Suppose an active ingredient was formulated into tablets and the innovator sold six strengths. Suppose the innovator also formulated an injectable version, which it sold in two strengths. Suppose it also developed a disintegrating tablet for oral administration, which it sold in four strengths. This innovator would sell 12 discrete products with the same active ingredient and probably (though not necessarily) the same brand name. And because a single product might incorporate many discrete inventions, the patents relevant to one product might differ from the patents relevant to another. Failure to realize this — and its regulatory significance — leads to three myths, as follows.

Myth of evergreening patents / The first myth is that innovators extend their patents. This is legally impossible. In the United States, a patent expires 20 years after its application date.

There are only two ways a patent’s expiration date can shift later in time: (1) When it issues a patent, the U.S. Patent and Trademark Office (PTO) adjusts the expiry date later to compensate for routine delays at the PTO. And (2), if the marketing application proposed a new active ingredient, then if the company asks the PTO for a patent term extension within 60 days of FDA approval, the PTO will use a statutory formula to extend one patent claiming the product to compensate partially for the lapse of patent life during premarket testing and regulatory review. There is no other mechanism by which a patent might be extended. In particular, a patent on one invention — no matter when it expires — does not extend the patent on another invention.

Myth of blocked competitors / The second myth is that when an innovator holds patents that expire after its active ingredient patent, or when it introduces newer products to market, it can prevent its competitors from bringing their copies to market. Instead, once the initial patent and (if applicable) statutory exclusivity on the innovator’s active ingredient have expired, its competitors have substantial freedom to operate. This freedom reflects two facts that are often overlooked.

First, the innovator’s competitor does not have to propose an exact copy. Federal law permits the competitor to rely on the innovator’s research but propose competing products that are not identical. To be sure, a competitor may submit an ANDA for a product that essentially duplicates the innovator’s product — that is, a generic. Ordinarily, the company shows in the ANDA that its product has the same active ingredient, route of administration, dosage form, strength, and labeling as the innovator’s product. The generic must also be “bioequivalent” to the original drug that it references, meaning that its active ingredient must reach the site of action in the body to the same extent and at the same rate as the active ingredient of the referenced product. But even a generic can be a little different. For example, it usually does not need the same inactive ingredients in the same quantities. And the generic competitor need not use the same manufacturing process.

If a competitor wants to offer a different route of administration, dosage form, or strength — for instance, to avoid infringing a patent — it may still be able to use the generic drug approval pathway. It simply files a “suitability petition” asking the FDA’s permission. The agency will approve the petition unless more data are needed to establish the proposed product’s safety and effectiveness. And at this point, the competitor may file an ANDA. More significantly, though, a competitor can always use a different abbreviated application pathway: a “505(b)(2)” application for a product that differs more substantially from the innovator’s product. Although the changes proposed in this hybrid application must be supported by new data, the competitor otherwise relies on the innovator’s data, avoiding the expensive and time‐​consuming research and development process the innovator went through. In addition to using this mechanism to propose modifications that avoid a patent, a competitor might use the mechanism to propose innovations that will offer an advantage in the market — such as changes to the active ingredient and new medical uses.

Second, an abbreviated application cites a specific innovative product, not the active ingredient or brand writ large. The competitor selects one innovative product as the reference product on which it relies — for instance, one of the 12 products in the hypothetical above. Its regulatory burden is tied to that specific product alone. The requirement to show sameness and bioequivalence (for an ANDA) and, critically, the obligation to contend with patents and wait for statutory exclusivity to expire are linked to the one specific product, alone. (In rare circumstances, when filing a hybrid application, a competitor might cite two innovative products, but the same point applies.)

To be sure, the patents associated with the cited innovative product affect when the FDA may approve the abbreviated application. Whether it files an ANDA or a hybrid application, a competitor must address the unexpired patents listed in the FDA’s “Orange Book” for the specific innovative product it has chosen to cite. For each listed patent, it has two choices, and its selection dictates the timing of FDA approval as far as that patent is concerned. The competitor may state the date on which the patent will expire, signaling that it does not plan to market its product until expiry. This precludes final approval of its product until patent expiry. Or it may assert that the patent is invalid or will not be infringed by its product, notifying the innovator of this position. If the innovator sues within 45 days, the drug statute stays final approval of its abbreviated application for 30 months. Under changes to the law made in 2003, though, unless the competitor changes its position on a patent after filing its abbreviated application, approval of its application is stayed only once. At the end of the 30 months, the FDA must approve the abbreviated application if the approval standard is met, even if there is ongoing patent litigation.

Although a competitor using the abbreviated application pathway must contend with the innovator’s patents and approval of its product may be delayed because of those patents, this is true of only the patents associated with the specific product that it references. The competitor does not have to contend with patents associated with other products that happen to contain the same active ingredient or bear the same brand name. Similarly, the competing applicant grapples with only the statutory exclusivity associated with the product it references. The drug statute provides five years of exclusivity in the data supporting new chemical entities and three years of exclusivity for most new products that are not new chemical entities. Separately, if an innovator introduces what the FDA calls a new “condition of approval” — such as a new strength or dosage form — the drug statute may provide three years of exclusivity. This delays approval of abbreviated applications proposing products with the same active ingredient for the same condition of approval. But a competitor that proposed a different strength or dosage form — or that cited a product with a different strength or dosage form (such as the innovator’s original product) — would not need to grapple with that exclusivity.

This debunks the myth that an innovator with later‐​expiring patents and an innovator that introduces newer products can prevent its competitors from bringing copies to market. Instead, competitors have several options. For instance, empirical studies show that competitors file abbreviated applications as early as the law permits them to do so, arguing that the innovator’s patents are invalid or, if applicable, not infringed by the new drug. They tend to lose these arguments when the active ingredient patent is at issue, but they tend to win if a formulation patent is at issue. If a competitor believed it would infringe a patent or feared it would lose the patent infringement suit brought by the innovator, it could seek a license. Settlements of patent litigation between innovators and competitors seeking to market generic copies usually include a license allowing the competitor to bring its product to market earlier than the date of patent expiry. There are also other options.

Once the patent on the active ingredient expires, a competitor can use the ingredient in its own product and file an abbreviated application, relying on the research performed and submitted by the innovator. Even in an ANDA, a true generic application, only the active ingredient must be the same. A competitor may be able to design around patents claiming other aspects of the innovator’s product (such as its strength and route of administration) and still file a true generic application. The competitor would simply file a suitability petition and, upon approval of that petition, a generic application proposing the difference that allowed it to avoid patent infringement. Then it would assert non‐​infringement in its application. If it could not file a generic application (for instance, because the FDA requested data to support the changes made), it could always file a hybrid application. It would still rely on the innovator’s research and it would similarly assert non‐​infringement in its application. In either case, the innovator might not sue if the competitor clearly avoided its patents.

It is thus misleading for advocates of intervention to complain about the number of “patents” associated with a “drug.” A competitor filing an abbreviated application does not copy a “drug” in the broad sense of the term. Accurately describing a company’s freedom to operate in the market would require focusing on discrete products that can serve as references for abbreviated applications and on the number, scope, and breadth of the patent claims held by the innovator for those products. This would tell policymakers more about the market effects of a firm’s innovation and patenting practices than the number of patents associated with a particular brand name or the number of patents associated with the many finished products containing a particular active ingredient.

Myth that automatic substitution is critical / The final myth of evergreening is that continuing innovation — especially when an innovator introduces a newer version of its product and stops selling its old version — precludes uptake of less expensive medicines by interfering with automatic pharmacy substitution under state pharmacy law. This myth reflects an assumption that competitors who file abbreviated applications depend on automatic pharmacy substitution — rather than the ordinary rough and tumble of a competitive marketplace — to obtain market share. The truth may be more complicated.

Automatic pharmacy substitution arises through a combination of longstanding FDA practices and state pharmacy law. Once the agency has approved two products with the same active ingredient, it assesses whether they are “therapeutically equivalent.” Designating two as therapeutically equivalent means that they have the same clinical profile and that they can be “substituted”: either can be dispensed instead of the other. A true generic drug, an exact copy of the innovator’s product approved based on an ANDA, will be deemed therapeutically equivalent. Every state either permits or requires pharmacists to dispense a therapeutically equivalent generic drug when a doctor prescribes an innovator’s drug by its brand name, unless the doctor has said not to. The notion advanced by critics of alleged “evergreening” is that once an innovator introduces a newer version of its branded product, doctors will prescribe the newer version. And because the generic company instead copied the older version, pharmacists will not — cannot under state law — substitute the generic product when the patient presents a prescription for the newer innovator product.

The problem with this argument is that actual dispensing decisions probably reflect a more complex interaction of prescriber decisions, payer preferences, and state law. To begin with, a doctor may specify either branded drugs or generic drugs. A doctor could write the brand name, to be sure, but the doctor could also simply identify the active ingredient, which will usually lead the pharmacist to dispense one of the available generic drugs. In theory, the doctor could even identify a particular generic company’s drug containing a particular active ingredient. And while drugmakers rarely promote generic drugs to doctors and patients, nothing prevents them from doing so. They do promote their therapeutically equivalent generic drugs to pharmacies and payers, focusing on the lower prices they offer. And a company that filed a hybrid application for a product that differed from the innovator’s product might brand its product and promote the distinguishing features, or (depending on the reason it filed the hybrid application) position the product as a near‐​duplicate of the more expensive branded alternatives and promote it as such.

In short, an innovator’s newer product creates a new choice for doctors and payers. To be sure, if doctors select this product, pharmacists will dispense it rather than generic copies of the innovator’s older product. Doctors might shift their prescribing to the newer product for many reasons, including persuasive advertising and promotion — meaning they come to believe (based on advertising that, per FDA rules, must be truthful and not misleading) that there are benefits to the newer product. They might shift for other reasons, including experience treating patients with the two options. But companies may advertise and promote generic products to doctors and patients as well, and based on this advertising (or for other reasons, such as experience with the older innovative product that the competitor copied) doctors might not select the innovator’s newer product. They might specify the innovator’s older product (which would lead to automatic substitution, even if the innovator no longer markets the product) or, again, a generic product itself.

Generic companies will be able to introduce copies of the innovator’s first product and they may or may not enjoy sales depending on the choices they make and the choices made by others in the market.

The assumption that competing companies depend on automatic substitution for market share may be simplistic. Only a minority of states require substitution; most instead have permissive laws. In these states, if a generic product is therapeutically equivalent to the prescribed product and the payer requires its use, the permissive state pharmacy law makes it possible for a pharmacist to substitute, in accordance with the patient’s insurance, without consulting the physician. In these cases, the patient’s insurance drives the product selection. State law just makes it possible to comply with the insurance without contacting the doctor. If a payer perceives the innovator’s new product as less cost effective than available generic drugs containing the same active ingredient, it may decline to cover the product. A rational payer will adopt strategies that steer doctors and patients to less expensive products that are equally or adequately effective — not only those that are therapeutically equivalent, but also those that are not. In these cases, even if a doctor specifies a branded product, the patient’s insurance might prompt a conversation among the doctor, pharmacist, and patient, ultimately leading to modification of the prescription and dispensing of the cheaper copy of the innovator’s first‐​version product.

In short, when an innovator introduces a new product into the market, generic companies will be able to introduce copies of the innovator’s first product and they may or may not enjoy sales depending on the choices they make and the choices made by others in the market. In this scenario, products compete for the business of rational payers based on their comparative benefits and cost. Substitution may play almost no true role, and whether the innovator still markets its older branded product may be irrelevant.

#### Prefer legal studies.

Parker and Mooney 7 [Scott and Kevin; “Is ‘evergreening’ a cause for concern? A legal perspective,” Journal of Commercial Biotechnology; 2007; <https://link.springer.com/article/10.1057/palgrave.jcb.3050066>] Justin

THE LEGAL BACKGROUND The patent system provides an incentive for companies to incur the cost and risk of research by providing the time-limited exclusive right to commercialise a patented product. At the heart of the patent system in the UK (and all other fully TRIPs compliant countries) is the requirement that to qualify for the monopoly right that the patent confers (20 years from the date of filing the patent application) the invention covered by the patent must be novel, non-obvious (ie it involves an inventive step) and capable of industrial application (‘utility’ or ‘usefulness’ in the US). The novelty and inventiveness of the patent is evaluated against the ‘state of the art’, which consists in general of every item of information which has ever been made available to the public by any kind of publication, or by use, anywhere in the world, at any point in time before the first filing date of the patent. It is a basic principle of patent law that once details of a product have entered the public domain (by being published anywhere without patent protection, or when any patents for the product or proposal expire or lapse), then everyone has freedom to use that information and any obvious developments of it. So before assuming that any new development relating to a known compound can be patented, we have to ask: 1 Is this new? Any previous publication or use, no matter how obscure, of the same invention destroys novelty and prevents a patent being issued or, if issued in ignorance of such a publication, this will subsequently cause the patent to be declared invalid if sought to be enforced. 2 Is there an inventive step? A patent cannot be granted for anything which is simply an obvious development or variant on any individual piece of information which is part of the state of the art. It is no answer that the piece of information in question may never have come to the attention of the fictitious ‘person skilled in the art’ who is central to any determination of ‘obviousness’. 3 Is there a proposed industrial application for the invention (in the broad sense of having some useful purpose)? The invention does not have to demonstrate an improvement on what is already known, but it cannot be speculative. It must have a use. For example, a DNA sequence for a recombinant gene fragment with a well-defined function is a patentable invention whereas a DNA sequence alone without any indication of function or of its useful attributes is not. 4 Does the patent describe how to put the invention into effect? The patent must be ‘enabling’; it must add to public knowledge, and contribute in its own right to the state of the art. In this way each new patent moves the frontier of the state of the art forward and makes it more difficult to find improvements which are neither old nor obvious. This disclosure enables third parties to implement the invention once the patent has expired and, is the consideration (in the legal sense) for the monopoly right granted by a patent. HOW THE PATENT SYSTEM DEALS WITH ‘EVERGREENING’ The criteria of patentability set out above apply equally to all inventions from the most basic mechanical patent to the most complex microelectronic or biotechnological invention. Similarly patent law does not distinguish between the invention of a wholly new product and inventions relating to improvements upon an existing product. The same criteria for patentability apply. ‘Double patenting’ is prohibited. That is to say the same invention cannot be covered by more than one patent. Thus for an improvement upon an existing pharmaceutical product to be patentable in its own right it will need to satisfy the criteria of novelty and non-obviousness taking into account the earlier product and all that is known about it in the public domain at the time that the second patent is applied for. If a patent is granted in respect of this improvement it will only cover the improvement to which it relates and will not extend to the originator product. That is to say a patent for a new product in a class will always be broader than any subsequent patent covering an improvement, modification or derivative of that product and so the exclusivity granted is in broad terms commensurate with the scope of the scientific advance that it reflects. An important corollary to the prohibition on ‘double patenting’ is that a patent covering an improved version of a pharmaceutical (or any other) product does not preclude a generic company from copying all forms of the originator product once the patents protecting these forms have expired. For example, if a company selling a patented pharmaceutical reformulates that product as a syrup for paediatric administration and then patents the new formulation, generic competition to the original adult formulation will be possible once the patents covering it expire or are invalidated. The existence of the patent on the paediatric formulation will not delay or prevent generic competition on the original formulation. The innovator company will, however, continue to have the exclusive right to sell the paediatric formulation for the remainder of the life of the patent covering this specific improvement. If in the above example the improvement made is not a paediatric formulation but a slow release formulation that allows once daily dosing and so improves patient compliance as a result of increased convenience, doctors and patients will have a choice between generic versions of the original formulation or the new once-daily product once any patent on the original formulation expires. The patents on the slow release formulation will not delay or prevent marketing of the original formulation. The market will then decide whether the benefits offered by the improved formulation make it worth paying for in the face of cheaper versions of the original product. The answer to this question will inevitably vary from market to market and between different patient populations. Either way the patient would appear to benefit from the increased choice available. A simple and further example of this is ibuprofen. The supermarket shelf carries premium-priced ibuprofen formulations which typically are quicker acting or easier to take than the traditional tablet. These formulations may be patent protected. Customers can, however, decide for themselves whether the added benefit is worth the extra cost. The patents do not prevent anybody from buying the ordinary, cheapest kind of tablet. Reference to patents covering the colour and scoring of tablets has been made in several articles criticising the pharmaceutical industry (without the specific patents that are complained of being identified).4 It is informative to consider how the patent system would apply to such ‘developments’. To the best of the authors’ knowledge no patents have ever been granted for the colour of pharmaceutical products. In fact, since UK patent law (and most others) expressly excludes the patenting of ‘aesthetic creations’ the colour of a pharmaceutical product could only ever be patentable if either: (a) it could be established that the colour itself produces a technical effect, such as a therapeutic benefit caused by increased compliance, that is novel and not obvious; or (b) that the means of obtaining that colour, the manufacturing process of colouring the tablet, is itself novel and not obvious. It goes without saying that for a ‘pink pill’ patent application the technical effect, novelty and inventiveness would be scrutinised carefully. Nevertheless, the application would be looked at on its own facts and applying the patentability criteria described above. Similarly, as regards the scoring of tablets, the same standard of patentability and scrutiny must be satisfied. It would need to be established that tablets had never been scored in this way before and that to do so was not an obvious departure from what has gone before. Without further investigation it should not be assumed that such an invention would be of no value to patients (eg it could be that compliance among children would be improved if the tablet is more cleanly cut as a result of the means of scoring employed). There are plenty of examples of developments (reformulations, new salts, combinations and the like) that have real therapeutic benefit but which at first blush may seem trivial. Again, the more minor that a variation is (eg a pink tablet or means of scoring the tablet) the more narrow the relevant patent protection will be and the easier it should be for a competitor to design around the patent without needing to seek to invalidate it. For example, if a patent is (or has been) granted that covers a particular colour of tablet or a particular means of scoring such tablet then such a patent would not stop a competitor from marketing (respectively) a different colour tablet or a tablet that is not scored or that is scored in a different way. In summary, therefore, the patent system is inherently adapted to reflect how much innovation in fact takes place (by way of improvements to existing technology) and to prevent ‘evergreening’. It allows the use of ‘old’ technology while protecting (and thus providing incentives for) improvements to that technology. Another factor to be taken into account in any debate on the patenting of ‘minor variations’ is that it is not only the company that owns the patents covering the originator product that can patent improvements thereto. Other companies (including generics) can (and do) do this, with the consequence that there may be a number of companies having similar products (some of which may for a variety of reasons be better suited to particular patients) and healthy competition in the marketplace. ‘STRATEGIC PATENTING’ A related charge that is sometimes made against innovator companies is that they file numerous patents on multiple attributes of a single product so as to create a ‘patent thicket’ that so complicates third-party research that it strangles innovation, or that they are guilty of what is sometimes referred to as ‘strategic patenting’.5 Implicit in these charges is that the only reason for filing these patents is maintenance of market share for as long as possible after the expiry of the patents covering the originator product itself. This is a serious charge that deserves to be looked at in more detail. Of course, pharmaceutical and biotechnology companies (like companies in all other R&D-based industries) have patenting strategies. In no other industry is there any suggestion that companies should restrict themselves to patenting inventions that meet some higher standard over and above the basic criteria for patentability or that companies should not seek protection for certain types of technological advance or that exceeding a certain number of patents in a technical area is per se reprehensible. When one considers that intellectual property rights are the life-blood that propels pharmaceutical advances in the private sector (and to an increasing extent in the public sector as well) and takes into account the sums that are typically spent on a new product during the 10–15-year-period from discovery through pre-clinical and clinical trials to regulatory approval and market launch, any company that did not do all that it could to protect its inventions would be acting negligently towards its shareholders. On the subject of patenting strategies in the pharmaceutical industry the UK Patents Court judge Mr Justice Jacob (now Lord Justice Jacob) said in the case of Synthon v SmithKline Beecham ‘I ask myself whether SB have done anything blameworthy…and I cannot see that they have. On the contrary, so far as I can see, they have employed competent and careful patent agents to obtain for them the best patent position which they think they can get. It may be good, it may be bad, but they are doing their job and I see no criticism whatever in the conduct of SB’.6 If one accepts that the nature of pharmaceutical and biotechnological innovation (as with other R&D based industries) is most often incremental and cumulative then it follows that the patent system should reflect this reality. This is indeed the case. As we have seen above, the patent system does not distinguish between ‘breakthroughs’ and ‘incremental improvements’ in terms of the patentability requirements that apply. At the same time a greater reward (a broader patent) is granted in respect of the ground breaking research than for inventions directed at solving further technical hurdles and optimisation of the initial invention. In the experience of the authors most of the patents that have been challenged by generic companies wishing to enter the market were applied for during the development of the originator product rather than once it has been established as a commercial success. This reflects the organic process of drug discovery and development and the time lag between drug discovery development, clinical testing and regulatory approval (ie that inventions are made in overcoming the various technical challenges faced during drug development). Nevertheless, some innovations are made at a later stage. For example, it may be that it is only after the product has been prescribed to a population of patients post-launch that it will become evident that further improvements need to be made to improve efficacy, deal with a compliance (or other) problem or expand the target patient population or disease indications. Such improvements may stem from greater experience of the product, problems unexpectedly encountered in particular patient populations or other advances made in the field. Given that the purpose of the patent system is to encourage innovation and (in the pharmaceutical sector) to lead to better medicines, it would be strange indeed if this incentive was removed or diminished once the first product of a particular type has been launched.

#### Evergreening is good---your authors misunderstand it.

Banana 19 [BananaIP; “DEMYSTIFYING THE EVERGREEN MYTH,” Executive Office of the President of the United States; 7/19/19—originally appeared 5/19/14; [https://www.bananaip.com/ip-news-center/chapter-iii-demystifying-evergreen-myth-comprehending-apprehension-apprehending-comprehension/]](https://www.bananaip.com/ip-news-center/chapter-iii-demystifying-evergreen-myth-comprehending-apprehension-apprehending-comprehension/%5d) Justin

Evergreening is like any other business strategy that market players would adopt to seek a competitive edge in the market. It doesn’t stop anyone from making the product claimed in the expired patent, but only makes sure that they can differentiate themselves from the other generic products through incremental inventions. More often than not, the R&D efforts and investments that go into the making of these incremental inventions can be very high and their results invaluable for treatment.

One of the rationales of the patent system is to incentivize innovation which is believed to lead to the progress in technology. A patent application is published 18 months after it is filed so as to ensure that the knowledge in the patent is made public for aspiring inventors to design around and build on it. Anyone, including the owner of an existing patent and their competitors, is free to invest in research in this direction as early as 18 months from the filing of such a patent. If a competitor files for an incremental patent, it is branded as innovation, but when a patent holder files for an incremental patent, it is looked upon as innovation leading to life cycle management or Evergreening.

In most parts of the world, life cycle management is considered as positive development. However, to the frustration of many pharmaceutical companies, symbolically represented by Bayer, life cycle management is quite a tricky business in India, thanks to the infamous Section 3(d) of the Indian Patent Act, often alluded to as the anti-evergreening law, which bears the burden of keeping a check on incremental pharmaceutical inventions that add no therapeutic value. Section 3(d) states that “the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus, unless such known process results in a new product or employs at least one new reactant” is not patentable.