## 1

#### Bipartisan infrastructure bill passing now but PC is needed – there is no margin for error.

Kapur et al 9/8 [Sahil, Frank Thorp, and Leigh Ann Caldwell; 9/8/21; Sahil Kapur is a national political reporter for NBC News, Frank Thorp V is a producer and off-air reporter covering Congress for NBC News, managing coverage of the Senate, Leigh Ann Caldwell is an NBC News correspondent; “*Democrats plow 'full speed ahead' on sweeping Biden budget, despite tensions*,” <https://www.nbcnews.com/politics/congress/democrats-plow-full-speed-ahead-sweeping-biden-budget-despite-tensions-n1278722>] Justin

WASHINGTON — The top two Democrats said they’re pushing forward with President Joe Biden’s sweeping safety net expansion, as House committees circulate legislative text with hearings scheduled Thursday to start advancing major sections of the bill. “We're moving full speed ahead,” Senate Majority Leader Chuck Schumer told reporters on a call Wednesday. The New York Democrat effectively cast aside calls by Sen. Joe Manchin, D-W.Va., for a “strategic pause” in the process of crafting the bill, as he voiced concerns about inflation and debt in a recent op-ed for the Wall Street Journal. Schumer is navigating demands by Manchin, as well as Sen. Kyrsten Sinema, D-Ariz., to reduce the price tag that Democrats set at a maximum of $3.5 trillion in the budget resolution. “There are some in my caucus who believe $3.5 trillion is too much; there are some in my caucus who believe it's too little,” Schumer said. “We're going to work very hard to have unity, because without unity, we're not going to get anything.” Speaker Nancy Pelosi said Wednesday the House is moving forward at the $3.5 trillion level. But she left open the possibility of a lower final price tag before the bill becomes law, while promising that “we will get the job done” with “a great bill” that honors Biden’s vision. “We will have our negotiations,” Pelosi, D-Calif., said, when asked by NBC News if the House could pass a bill at a lower amount. “I don’t know what the number will be. We are marking at 3.5 [trillion]. ... We will pay for more than half, maybe all of the legislation.” The remarks by Schumer and Pelosi point to a complicated balancing act, facing a broad range of opinions from centrist lawmakers skeptical of the price tag to progressives who believe $3.5 trillion should be the minimum. Democratic leaders are also juggling an aggressive timeline by seeking to ready the bill by Sept. 27 — the self-imposed House deadline to vote on the separate infrastructure bill — to ensure progressives will support the latter. They are betting Manchin can ultimately be won over on the substance of the package. Lawmakers and committees are keeping options open in case the price tag needs to be cut: For instance, they’ve privately discussed setting some provisions to expire sooner. Manchin has been somewhat vague in his demands. He has not specified what price tag he would support or what provisions of the emerging bill he wants to cut. His office did not have a comment when asked those questions Wednesday. In June, he said on ABC's "This Week" that he wants to “make sure we pay for” the bill. A source close to Manchin said he is a big proponent of targeting benefits on the basis of income and capping them so the money reaches people who need it the most — principles he believes are critical for Democrats' proposals on community college subsidies and on home-based care provisions for the disabled and elderly. Manchin also has issues with the climate change proposals in the legislation, the source said. As chairman of the Senate Energy and Natural Resources Committee, Manchin has major influence over the climate provisions. His committee was instructed to write legislation costing $198 billion for a clean electricity payment program, consumer rebates to weatherize and electrify homes, the creation of financing for domestic manufacturing of clean energy and auto supply chain technologies and climate research. “He’s not opposed to the overall bill,” the source said. “He’s going to shape the bill to what he feels is closer to the needs. People shouldn’t read into it more than that.” Senate Budget Chair Bernie Sanders, I-Vt., has said if the safety net package does not pass, the $550 billion bipartisan infrastructure package — which Manchin co-wrote — will fail as well. He told reporters the $3.5 trillion level was too low. “To my mind, this bill, that $3.5 trillion, is already the result of a major, major compromise,” Sanders said. “And at the very least, this bill should contain $3.5 trillion.” Pelosi said slashing the cost would require making difficult policy choices. “We have to talk about: What does it take? Where would you cut?” she asked. “Child care? Family medical leave paid for? Universal pre-K? Home health care?” On Thursday, the House committees on ways and means and education and labor will hold hearings on major portions of the bill they released this week. That includes 12 weeks' paid family and medical leave for all workers; expanding Medicare to cover dental, vision and hearing benefits; universal pre-K for 3- and 4-year-olds; and two years' tuition-free community college. Republicans are unified against the effort, leaving Democrats to pass the bill alone under narrow majorities. The package can bypass a Senate filibuster. Senate Minority Leader Mitch McConnell, R-Ky., said Wednesday that he hopes Manchin and Sinema “will dig in their heels” against some of the tax increases Democrats are eyeing to finance the package. “It comes down to — in the Senate — to two people,” he said. “Either one of them could kill the whole bill. I don't expect that to happen,” he said. “Either one of them could make dramatic changes in it — that could happen. Or either one of them could basically make a few cosmetic changes and throw in the towel.”

#### 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.

#### Infrastructure secures the grid against worsening and increasing cyberattacks.

Carney 21 [Chris; 8/6/21; Senior policy advisor at Nossaman LLC, former US Representative, former professor of political science at Penn State University; "*The US Senate Infrastructure Bill: Securing Our Electrical Grid Through P3s and Grants*," JDSupra, <https://www.jdsupra.com/legalnews/the-us-senate-infrastructure-bill-4989100/>] Justin

As we begin to better understand the main components of the Infrastructure Investment and Jobs Act that the US Senate is working to pass this week, it is clear that public-private partnerships ("P3s") are a favored funding mechanism of lawmakers to help offset high costs associated with major infrastructure projects in communities. And while past infrastructure bills have used P3s for more conventional projects, the current bill also calls for P3s to help pay for protecting the US electric grid from cyberattacks. Responding to the increasing number of cyberattacks on our nation’s infrastructure, and given the fragile physical condition of our electrical grid, the Senate included provisions to help state, local and tribal entities harden electrical grids for which they are responsible. Section 40121, Enhancing Grid Security Through Public-Private Partnerships, calls for not only physical protections of electrical grids, but also for enhancing cyber-resilience. This section seeks to encourage the various federal, state and local regulatory authorities, as well as industry participants to engage in a program that audits and assesses the physical security and cybersecurity of utilities, conducts threat assessments to identify and mitigate vulnerabilities, and provides cybersecurity training to utilities. Further, the section calls for strengthening supply chain security, protecting “defense critical” electrical infrastructure and buttressing against a constant barrage of cyberattacks on the grid. In determining the nature of the partnership arrangement, the size of the utility and the area served will be considered, with priority going to utilities with fewer available resources. Section 40122 compliments the previous section as it seeks to incentivize testing of cybersecurity products meant to be used in the energy sector, including SCADA systems, and to find ways to mitigate any vulnerabilities identified by the testing. Intended as a voluntary program, utilities would be offered technical assistance and databases of vulnerabilities and best practices would be created. Section 40123 incentivizes investment in advanced cybersecurity technology to strengthen the security and resiliency of grid systems through rate adjustments that would be studied and approved by the Secretary of Energy and other relevant Commissions, Councils and Associations. Lastly, Section 40124, a long sought-after package of cybersecurity grants for state, local and tribal entities is included in the bill. This section adds language that would enable state, local and tribal bodies to apply for funds to upgrade aging computer equipment and software, particularly related to utilities, as they face growing threats of ransomware, denial of service and other cyberattacks. However, under Section 40126, cybersecurity grants may be tied to meeting various security standards established by the Secretary of Homeland Security, and/or submission of a cybersecurity plan by a grant applicant that shows “maturity” in understanding the cyber threat they face and a sophisticated approach to utilizing the grant. While the final outcome of the Infrastructure Investment and Jobs Act may still be weeks or months away, inclusion of these provisions not only demonstrates a positive step forward for the application of federal P3s and grants generally, they also show that Congress recognizes the seriousness of the cyber threats our electrical grids face. Hopefully, through judicious application of both public-private partnerships and grants, the nation can quickly secure its infrastructure from cyberattacks.

#### Cyberattacks on the grid spiral to all-out nuclear conflict.

Klare 19 [Michael; November 2019; Professor emeritus of peace and world security studies at Hampshire College; “*Cyber Battles, Nuclear Outcomes? Dangerous New Pathways to Escalation*,” Arms Control Association, <https://www.armscontrol.org/act/2019-11/features/cyber-battles-nuclear-outcomes-dangerous-new-pathways-escalation>] Justin

Yet another pathway to escalation could arise from a cascading series of cyberstrikes and counterstrikes against vital national infrastructure rather than on military targets. All major powers, along with Iran and North Korea, have developed and deployed cyberweapons designed to disrupt and destroy major elements of an adversary’s key economic systems, such as power grids, financial systems, and transportation networks. As noted, Russia has infiltrated the U.S. electrical grid, and it is widely believed that the United States has done the same in Russia.12 The Pentagon has also devised a plan known as “Nitro Zeus,” intended to immobilize the entire Iranian economy and so force it to capitulate to U.S. demands or, if that approach failed, to pave the way for a crippling air and missile attack.13 The danger here is that economic attacks of this sort, if undertaken during a period of tension and crisis, could lead to an escalating series of tit-for-tat attacks against ever more vital elements of an adversary’s critical infrastructure, producing widespread chaos and harm and eventually leading one side to initiate kinetic attacks on critical military targets, risking the slippery slope to nuclear conflict. For example, a Russian cyberattack on the U.S. power grid could trigger U.S. attacks on Russian energy and financial systems, causing widespread disorder in both countries and generating an impulse for even more devastating attacks. At some point, such attacks “could lead to major conflict and possibly nuclear war.”14

## 2

#### Permissibility and presumption negate – a. if the resolution indicates the affirmative has to prove an obligation, 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. C. we don’t presume everything true, that’s why we don’t believe in conspiracy theories

#### The neg burden is to prove that the aff won’t logically happen in the status quo, and the aff burden is to prove that it will.

#### Prefer:

#### 1] Text –

#### A] Ought is “used to express logical consequence” as defined by Merriam-Webster

(<http://www.merriam-webster.com/dictionary/ought>) //Massa

#### B] Oxford Dictionary defines ought as “used to indicate something that is probable.”

<https://en.oxforddictionaries.com/definition/ought> //Massa

#### 2] Debatability – A] it focuses debates on empirics about squo trends rather than irresolvable abstract principles that’ve been argued for years – resolvability is an independent voter cuz otherwise the judge can’t make a decision which means it’s a constraint on any burden because otherwise the round is impossible B] moral framework debate is impossible.

Joyce 02 Joyce, Richard. Myth of Morality. Port Chester, NY, USA: Cambridge University Press, 2002. p 45-47.

This distinction between what is accepted from within an institution, and “stepping out” of that institution and appraising it from an exterior perspective, is close to Carnap’s distinction between internal and external questions. 15 Certain **“linguistic frameworks”** (as Carnap calls them) **bring** with them **new** terms and **ways of talking: accepting the language of “things” licenses making assertions** like “The shirt is in the cupboard”; **accepting mathematics allows one to say “There is a prime number greater than one hundred”;** accepting the language of propositions permits saying “Chicago is large is a true proposition,” etc. Internal to the framework in question, confirming or disconfirming the truth of these propositions is a trivial matter. But traditionally **philosophers have interest**ed themselves **in** the external question – **the issue of the adequacy of the framework itself:** “Do objects exist?”, “Does the world exist?”, “**Are there numbers?”,** “Are the propositions?”, etc. Carnap’s argument is that **the** external **question,** as it has been typically construed, **does not make sense. From a perspective that accepts mathematics, the answer to the question “Do numbers exist?” is just** trivially **“Yes.”** From a perspective which has not accepted mathematics, Carnap thinks, the only sensible way of construing the question is not as a theoretical question, but as a practical one: “Shall I accept the framework of mathematics?”, and this pragmatic question is to be answered by consideration of the efficiency, the fruitfulness, the usefulness,etc., of the adoption. But the (traditional) **philosopher’s questions** – “But is mathematics true?”, “Are there really numbers?” – **are pseudo-questions.** By turning traditional philosophical questions into practical questions of the form “Shall I adopt...?”, Carnap is offering a noncognitive analysis of metaphysics. Since I am claiming that we can critically inspect morality from an external perspective – that we can ask whether there are any non-institutional reasons accompanying moral injunctions – and that such questioning would not amount to a “Shall we adopt...?” query, Carnap’s position represents a threat. What arguments does Carnap offer to his conclusion? He starts with the example of the “thing language,” which involves reference to objects that exist in time and space. **To** step out of the thing language and **ask “But does the world exist?” is a mistake,** Carnap thinks, **because the very notion of “existence” is a term which belongs to the thing language, and can be understood only within that framework, “hence this concept cannot be meaningfully applied to the system itself.”** 16 Moving on to the external question “Do numbers exist?” Carnap cannot use the same argument – he cannot say that “existence” is internal to the number language and thus cannot be applied to the system as a whole. Instead he says that philosophers who ask the question do not mean material existence, but have no clear understanding of what other kind of existence might be involved, thus such questions have no cognitive content. It appears that this is the form of argument which he is willing to generalize to all further cases: **persons who dispute** whether propositions exist, **whether properties exist,** etc., do not know what they are arguing over, thus they **are not arguing over the truth of a proposition,** but over the practical value of their respective positions. Carnap adds that this is so because there is nothing that both parties would possibly count as evidence that would sway the debate one way or the other.

#### 3] Neg definition choice – the aff should have defined ought in the 1ac because it was in the rez so it’s predictable contestation, by not doing so they have forfeited their right to read a new definition – kills 1NC strategy since I premised my engagement on a lack of your definition.

#### Now negate:

#### 1] Inherency – either a) the aff is non-inherent and you vote neg on presumption or b) it is and it isn’t going to happen since there are structural barriers that preclude. Also you don’t get to say in the 1ar that the aff is non inherent because you took a stance in the aff that it was which is an academic integrity issue.

## 3

#### Interpretation: affirmative debaters must delineate their enforcement mechanism by which they reduce in the 1AC.

#### There is no normal means since terms are negotiated contextually among member states.

WTO "Whose WTO is it anyway?" <https://www.wto.org/english/thewto_e/whatis_e/tif_e/org1_e.htm> //Elmer

**When WTO rules impose disciplines** on countries’ policies, that is the outcome of negotiations among WTO members. The rules are **enforced** **by** the **members themselves** under agreed procedures that they negotiated, including the possibility of trade sanctions. But those sanctions are imposed by member countries, and authorized by the membership as a whole. This is quite different from other agencies whose bureaucracies can, for example, influence a country’s policy by threatening to withhold credit.

#### Negate:

#### 1] Shiftiness- they can redefine what measure of reduction the 1ac defends in the 1ar which decks strategy and allows them to wriggle out of negative positions which strips the neg of specific politics DAs, process CPs, innovation DAs and case answers. They will always win on specificity weighing.

#### CX can’t resolve this and is bad because A] Not flowed B] Skews 6 min of prep C] They can lie and no way to check D] Debaters can be shady.

#### 2] Real World- policy makers will always specify what the object of change is. That outweighs since debate has no value without portable application. It also means zero solvency since the WTO, absent spec, can circumvent aff’s policy since they can say they didn’t know how to enforce it.

#### This spec shell isn’t regressive- it literally determines how the affirmative implements and who it affects

Fairness

Education

Competinginterps

Drop the debater

No rvis

## Case

### Uv

#### 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.

### framework

#### The appeal to util makes debate unsafe, since the logic of “the end justifies the means” can justify *any* reprehensible action.

**Anderson** Anderson, Kerby. [National Director of Probe Ministries International] “Utilitarianism: The Greatest Good for the Greatest Number.” *Probe*, 2004**. RP**

One problem with utilitarianism is that its leads to an ‘end justifies the means’ mentality. If any worthwhile end can justify the means to attain it, a true ethical foundation is lost. But we all know that the end does not justify the means. If that were so,then Hitler could justify the Holocaust because the end was to purify the human race. Stalin could justify his slaughter of millions because he was trying to achieve a communist utopia. The end never justifies the means. The means must justify themselves. A particular act cannot be judged as good simply because it may lead to a good consequence. The means must be judged by some objective and consistent standard of morality. Second, utilitarianism cannot protect the rights of minorities if the goal is the greatest good for the greatest number. Americans in the eighteenth century could justify slavery on the basis that it provided a good consequence for a majority of Americans. Certainly the majority benefited from cheap slave labor even though the lives of black slaves were much worse. A third problem with utilitarianism is predicting the consequences. If morality is based on results, then we would have to have omniscience in order to accurately predict the consequence of any action. But at best we can only guess at the future, and often these educated guesses are wrong. A fourth problem with utilitarianism is that consequences themselves must be judged. When results occur, we must still ask whether they are good or bad results. [Further][,] [u]tilitarianism provides no objective and consistent foundation to judge results because results are the mechanism used to judge the action itself. Inviolability is intrinsically valuable.

**Vote them down – this abhorrent discourse promotes terrible ideologies in the debate space.**

#### Additionally:

#### [1] Reversibility: once oppressive rhetoric is used it cannot be taken back

#### [2] Norm setting: we are part of a larger debate community with extensive norms – letting bad discourse be rampant kills the community

#### [3] Competition: debate is an educational competition with no place for offensive rhetoric – that kills access to the lasting benefit debate provides

#### Reject consequentialism:

#### 1. Problem of induction

Vickers 14, John Vickers, 2014, The Problem of Induction, https://plato.stanford.edu/entries/induction-problem/

The original problem of induction can be simply put. It concerns the support or justification of inductive methods; methods that predict or infer, in Hume's words, that “instances of which we have had no experience resemble those of which we have had experience” (THN, 89). Such methods are clearly essential in scientific reasoning as well as in the conduct of our everyday affairs. The problem is how to support or justify them and it leads to a dilemma: the principle cannot be proved deductively, for it is contingent, and only necessary truths can be proved deductively. Nor can it be supported inductively—by arguing that it has always or usually been reliable in the past—for that would beg the question by assuming just what is to be proved.

#### Takes out their offense since it is predicated on using past experiences.

#### 2. Prediction is impossible. Any action can lead to a domino effect that can have disastrous impacts in the end. For example, if I sneeze, it could lead to a butterfly effect that eventually causes my sneeze to form into a hurricane and kill thousands.

#### 3. Aggregate pleasure is impossible because pain is incommunicable – 5 headaches and a migraine can’t be compared since I don’t know how it feels for you versus me and if it’s the same or different, meaning weighing consequences is arbitrary. permissibility

#### 4. Consequentialism is irresolvable because if a bigger harm can outweigh a smaller, there’s always a non-zero chance of a bigger harm in the future and there’s no non-arbitrary point at which consequences stop being relevant

#### 5. No impact to anything – the universe is infinite.

Bostrom 11 Nick Bostrom (Professor, Faculty of Philosophy & Oxford Martin School Director, Future of Humanity Institute Director, Oxford Martin Programme on the Impacts of Future Technology University of Oxford) “Infinite Ethics” Analysis and Metaphysics, Vol. 10 (2011): pp. 9-59

In the standard Big Bang model, assuming the simplest topology (i.e., that space is singly connected), there are three basic possibilities: the universe can be open, flat, or closed. Current data suggests a flat or open universe, although the final verdict is pending. If the universe is either open or flat, then it is spatially infinite at every point in time and the model entails that it contains an infinite number of galaxies, stars, and planets. There exists a common misconception which confuses the universe with the (finite) “observable universe”. But the observable part—the part that could causally affect us—would be just an infinitesimal fraction of the whole. Statements about the “mass of the universe” or the “number of protons in the universe” generally refer to the content of this observable part; see e.g. [1]. Many cosmologists believe that our universe is just one in an infinite ensemble of universes (a multiverse), and this adds to the probability that the world is canonically infinite; for a popular review, see [2]. The “many worlds” of the Everett version of quantum physics, however, would not in any obvious way amount to the relevant kind of infinity; both because whether the “world”-count reaches infinity or merely a large finitude might be an artifact of convenient formalism rather than reflecting of physical reality, and also because the ethical significance of each Everettian “world” should, plausibly, be weighted by its associated measure (amplitude squared), which is a normalized; see e.g. [3].

### advantage

#### Evergreening is a myth.

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.

#### Feldman is a joke.

Risch 17 [Michael; “Data for the Evergreening Debate,” Written Description; 11/21/17; <https://writtendescription.blogspot.com/2017/11/data-for-evergreening-debate.html>] Justin

**Feldman and Wang** argue that the Orange Book has been used by companies to "evergreen" their drugs - that is, to extend exclusivity beyond patent expiration. The paper is on SSRN and the abstract is here:

Why do drug prices remain so high? Even in sub-optimally competitive markets such as health care, one might expect to see some measure of competition, at least in certain circumstances. Although anecdotal evidence has identified instances of evergreening, which can be defined as artificially extending the protection cliff, just how pervasive is such behavior? Is it simply a matter of certain bad actors, to whom everyone points repeatedly, or is the problem endemic to the industry?

This study examines all drugs on the market between 2005 and 2015, identifying and analyzing every instance in which the company added new patents or exclusivities. The results show a startling departure from the classic conceptualization of intellectual property protection for pharmaceuticals. Key results include: 1) Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. Every year, at least 74% of the drugs associated with new patents in the FDA’s records were not new drugs coming on the market, but existing drugs; 2) Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, almost 80% extended their protection at least once, with almost 50% extending the protection cliff more than once; 3) Once a company starts down this road, there is a tendency to keep returning to the well. Looking at the full group, 80% of those who added protections added more than one, with some becoming serial offenders; 4) The problem is growing across time.

I think the data the authors have gathered is extremely important, and I think that their study sheds important light on what happens in the pharmaceutical industry. That said, as I explain below, my takeaways from this paper are much different from theirs.

My concerns are fourfold. First, even assuming that every one of the efforts listed by the the study were an attempt to evergreen, I have no sense for whether evergreening actually happened. This study doesn't provide any data about generic entry or pricing. For example, the study describes 13 listings for OxyContin, but I'd bet dollars to donuts that there was plenty of generic oxycodone available. Similarly, many of the new listings are changes from Drug 1.0 to "new and improved!" Drug 2.0. This, of course, has been criticized as anti-competitive (since generics rely on auto-substitution laws), but the study presents no data about whether insurers refuse to pay for Drug 2.0 and instead require the generic, nor does it explain why generics can't do their own advertisements to get doctors to prescribe Drug 1.0.

Second, many of these listings and the new patents that go with them are for advances, like extended release and dissolvables. These can be critically important advances, and they are preferred by consumers. Thus, one person's "evergreening" is another person's innovation. I take extended release drugs (and expensive generic) to avoid side effects and I gave my son dissolvable Prevacid when he wouldn't stop crying with GERD (and was glad for it). Without consumer data or patent data, it is impossible to tell just how much evergreening is going on (or how harmful it is). Now, if these patents are obvious because making them dissolvable or extended is easy, I'm all for stripping protection - but that's a different issue.

Third, the article speaks of orphan drug approvals as if they are a bad thing. This made me bristle, quite frankly. My mother has an extremely rare autoimmune disease that is very painful. I often wondered, isn't there some incentive to develop drugs to treat it? Turns out there is, and though she got no relief, apparently a bunch of other rare diseases did, and that's the whole point behind orphan drug exclusivity. Concern about this exclusivity seems misguided anyway. If it turns out that drug companies are gaming it and nobody actually needs the drug, then the the loss is not too large, because it's a small population and nobody needs the generic anyway. And if it turns out that they do need it, the Orange Book only limits labeling, and doctors are free to prescribe a generic for off-label use. Without evidence that doctors refuse to do so, there's no real evidence that Orphan exclusivity does much harm. In another personal story, my wife was prescribed a generic drug in a different formulation than the patented tablet for off-label use.

Fourth, and most generally, the article speaks of new patents as if there is no innovation. New use discoveries are important. Many of our most important drugs are not for their original uses. As far as I know, generics are not barred from finding new uses and patenting them, either, though admittedly their hands are tied for patient use. So, where the authors see evergreening, I see innovation. Maybe. Maybe it's obvious. But we can't tell that from this high level, and I'm not ready to write it all off as evergreening. It is telling that I was able to provide four personal stories about how supposed evergreening efforts benefited, would have benefited, or did not increase costs for my family or me (and thankfully none of them involved oxycodone).

#### IP necessitates Secondary and Follow-on patents which are key to innovation.

IP Watch 18 9-21-2018 "Inside Views: Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection" <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> (a non-profit independent news service that provides professional coverage of global policymaking on intellectual property and innovation.)//Elmer

Why Protect Follow-On Innovation? The **attack on secondary** pharmaceutical **patents is based** in part **on** the **flawed premise** that **follow-on innovation is of marginal value** at best, and thus less deserving of protection than the primary inventive act of identifying and validating a new drug active ingredient. In fact, **follow-on innovation** **can play** a **critical role in transforming** **an interesting drug candidate into a safe and effective treatment option** for patients. A good example can be seen in the case of **AZT** (zidovudine), a drug ironically described in the Guidelines as the “first breakthrough in AIDS therapy.” AZT **began** its life **as a** failed attempt at a **cancer drug**, and it was **only years later** that its potential **application in the fight against AIDS** was realized. Follow-on research resulted in a method-of-use patent directed towards the use of AZT in the treatment of AIDS, and it was this patent that incentivized the investment necessary to bridge the gap between a promising drug candidate and a safe, effective, and FDA-approved pharmaceutical. Significantly, because of the long lag time between the first public disclosure of AZT and the discovery of its use in the treatment of AIDS, patent protection for the molecule per se was unavailable. In a world where follow-on innovation is unpatentable, there would have been no patent incentive to invest in the development of the drug, and without that incentive AZT might have languished on the shelf as simply one more failed drug candidate. Other examples of important drugs that likely never would have been made available to patients without the availability of a “secondary” patent include **Evista** (raloxifene, used in the treatment of osteoporosis and to reduce the risk of invasive breast cancer), **Zyprexa** (olanzapine, used in the treatment of schizophrenia), and an orally-administrable formulation of the antibiotic cefuroxime. **Pharmaceutical development** **is prolonged and unpredictable**, and frequently **a safe and effective drug** **occurs only as a result of** **follow-on innovation** occurring **long** **after the initial synthesis** and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be just as critical to the development of drugs as a patent on the active ingredient itself. The Benefits of Follow-On Innovation The criticism of patents on follow-on pharmaceutical innovation rests on an assumption that follow-on innovation provides little if any benefit to patients, and merely serves as a pretense for extending patent protection on an existing drug. In fact, there are many examples of follow-on products that represent significant improvements in the safety-efficacy profile. For example, the original formulation of Lumigan (used to treat glaucoma) had an unfortunate tendency to cause severe hyperemia (i.e., redeye), and this adverse event often lead patients to stop using the drug, at times resulting in blindness. Subsequent research led to a new formulation which largely alleviated the problem of hyperemia, an example of the type of follow-on innovation that significantly benefits patients but that which would be discouraged by a patent regime that does not reward follow-on innovation. Follow-on pharmaceutical innovation can come in the form of an extended-release formulation that permits the drug to be administered at less frequent intervals than the original formulation. Critics of secondary patents downplay the significance of extended-release formulations, claiming that they represent nothing more than a ploy to extend patent protection without providing any real benefit to patients. In fact, the availability of a drug that can be taken once a day has been shown to improve patient compliance, a significant issue with many drugs, particularly in the case of drugs taken by patients with dementia or other cognitive impairments. Extended-release formulations can also provide a more consistent dosing throughout the day, avoiding the peaks and valleys in blood levels experienced by patients forced to take an immediate-release drug multiple times a day. Other examples of improved formulations that provide real benefits to patients are orally administrable formulations of drugs that could previously only be administered by more invasive intravenous or intramuscular injection, combination products that combine two or more active pharmaceutical agents in a single formulation (resulting in improved patient compliance), and a heat-stable formulation of a lifesaving drug used to treat HIV infection and AIDS (an important characteristic for use in developing countries with a hot climate).