# --- CSUF Round 2 1AC – 10/16/2021 ---

## 1AC

### ADV---Evergreening

#### Advantage 1 is Evergreening

#### We are in an innovation crisis – new drugs are not being developed in favor of re-purposing old drugs to infinitely extend patent protection.

Feldman 19 [Robin Feldman, Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation, 2-11-2019, "‘One-and-done’ for new drugs could cut patent thickets and boost generic competition" <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/>]/SidK + Elmer, recut by Cogito

In a perfect world, the system for conveying medications from their makers to patients should be designed to deliver the lowest-cost drugs. The system in the U.S. doesn’t even come close. Insurers should provide the lowest-cost and highest-quality drug benefit for each plan, public or private. But they don’t. Pharmacy benefit managers should use their volume buying power to obtain rebates that individuals could never obtain on their own and pass those rebates along to patients. But they don’t. Pharmacists, who know the prices of the drugs in their stock and who see patients’ cost-sharing amounts at the cash register, should be motivated to provide their customers with information on how to find the best deal so they can afford their medicines. But they aren’t. Doctors should make medication decisions that are in the best interests of their patients. But they often don’t. All of this occurs against the backdrop of a national conversation to lower drug costs and a policy to expedite and encourage vigorous competition in the pharmaceutical industry through the rapid entry of generic drugs as soon as patents expire. But even though the vast majority of prescriptions are filled with generic drugs, rising prices on existing brand-name drugs and sky-high prices for new drugs are swamping the savings from generics. Why isn’t the system working as it should? Some experts believe the U.S. can rein in drug process with value-based pricing, which aims to tie the prices we pay for drugs to the benefits they provide, either in terms of longer life or better quality of life. Others call for dismantling pharmacy benefit managers. Still others want large groups like Medicare to negotiate with drug companies for better drug prices. While each of these might help, they cannot solve the problem alone. Why? Because they do not reach the heart of the problem. As I explain in my new book, “Drugs, Money, and Secret Handshakes,” the government itself is giving pharmaceutical companies the power they are wielding through overly generous drug patent protection. Effective solutions must address that problem. Drug companies **have brought great innovations** to market. Society rewards innovation with patents, or with non-patent exclusivities that can be obtained for activities such as testing drugs in children, undertaking new clinical studies, or developing orphan drugs. The rights provided by patents or non-patent exclusivities provide a defined time period of protection so companies can recoup their investments by charging monopoly prices. When patents end, lower-priced competitors should be able to jump into the market and drive down the price. But that’s not happening. Instead, drug companies build massive patent walls around their products, extending the protection **over and over again**. Some modern drugs have an avalanche of U.S. patents, with expiration dates staggered across time. For example, the rheumatoid arthritis drug Humira is **protected by more than 100 patents**. Walls like that **are insurmountable**. Rather than rewarding innovation, our patent system is now largely repurposing drugs. Between 2005 and 2015, **more than three-quarters** of the drugs associated with new patents **were not new ones** coming on the market but existing ones. In other words, we are mostly churning and recycling. Particularly troubling, new patents can be **obtained on minor tweaks** such as adjustments to dosage or delivery systems — a once-a-day pill instead of a twice-a-day one; a capsule rather than a tablet. Tinkering like this may have some value to some patients, but it nowhere near justifies the rewards we lavish on companies for doing it. From society’s standpoint, incentives should drive scientists back to the lab to look for new things, not to recycle existing drugs for minimal benefit. I believe that one period of protection should be enough. We should make the legal changes necessary to prevent companies **from building patent walls** and piling up mountains of rights. This could be accomplished **by a “one-and-done” approach** for patent protection. Under it, a drug would receive just one period of exclusivity, and no more. The choice of which “one” could be left entirely in the hands of the pharmaceutical company, with the election made when the FDA approves the drug.

#### Err aff – 80% of patents aren’t new, but minimal variations on old patents to artificially extend monopoly power

Bluhm 19 [Michael Bluhm, educator at GWU for IR with a PhD, 12-2019, “The Role of Monopoly in America’s Prescription Drug Crisis,” Open Markets, https://static1.squarespace.com/static/5e449c8c3ef68d752f3e70dc/t/5ea4d29f9bc8f31a1117feec/1587860128096/WhitePaper\_DrugPrices\_Bluhm.pdf]/Kankee

THICKETS OF EVERGREEN PATENTS Drug manufacturers retain the exclusive rights to produce and sell a patented drug during the 20-year length of a patent. To be fair to pharmaceutical firms, they generally patent new drug formulations during clinical trials, so drugs coming to market usually wind up with an average of 8 to 12 years of patent protection remaining.71 But drugmakers today rarely apply for only a single patent for their new drugs. Instead, they game the regulatory system by registering thickets of similar patents around a single brand drug for minor tweaks devoid of innovation. These patent thickets lock in monopoly rents well beyond the 20 years of patent protection. Drugmakers deploy multiple, overlapping strategies to abuse the patent system this way. Pharmaceutical firms commonly file additional patents for individual features of a product, such as isomers, polymorphs, metabolites, or intermediates.72 Drugmakers also claim patents for minimal variations in methods of use, dosage schedules, or the method of manufacture.73 The bases for these patents might sound dubious, but any potential market competitor would have to go through expensive, lengthy litigation to challenge a single patent.74 To ward off competition, drugmakers cobble together a complex scaffolding of patents around each brand drug. The scope of the abuse of the patent system is breathtaking. Almost 80 percent of drugs receiving U.S. patents from 2005 to 2015 were not new drugs, but drugs that already enjoyed patent protection.75 The total number of additional patents for existing drugs soared from 349 additional patents in 2005 to 723 additional patents in 2015.76 More recent data show a stark increase in drugs with multiple patents and exclusivities.77 As of 2018, almost 40 percent of all drugs on the market had walled off competition through multiple patents or exclusivities.78 Almost half of all available drugs were shielded by at least four additional patents, and some drugs were cocooned by more than 20 additional patents.79 Drugmakers build patent thickets to extend monopoly rents, and this motivation is obvious in the size of the thickets protecting best-selling drugs. A blockbuster drug usually brings in billions of dollars each year in revenue, so extending monopoly protection by even a few months will produce hundreds of millions of dollars in extra revenue.80 Each of the 12 best-selling drugs of 2018 was shielded by an average of 71 patents and 125 patent applications, with three of the 12 drugs having more than 200 patent applications.81 Thanks to these dozens of patents, each best-selling drug had, on average, an effective patent protection period of 38 years, nearly double the 20-year monopoly granted by a patent.82 Because all 12 drugs remain under patent protection, these total numbers of patents and years of monopoly could still grow. Industry insiders also refer to this practice as evergreening, when drugmakers claim fresh patents for drugs whose original patents are about to expire. Similarly, drug manufacturers also engage in producthopping, when they marginally change a product shortly before its patent expires, and then they pressure doctors to prescribe the newer version, to keep patients from using a generic alternative to the original brand formulation.83

#### Secondary patents create legal “minefields” that deter generic market entry

Gurgula 20 [Olga Gurgula, lecturer of intellectual property law at Brunel University London, 10-28-2020, "Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?," IIC - International Review of Intellectual Property and Competition Law, https://link.springer.com/article/10.1007/s40319-020-00985-0]/Kankee

Strategic patenting also has a chilling effect on follow-on innovation by generic competitors in the form of developing alternative versions of an off-patent compound. As was discussed earlier, the expiry of a basic patent that protects an active compound facilitates generic competition. This is because even if the product is still protected by process, specific form or formulation patents, generic companies may develop alternative ways of producing or formulating the product and start competing with the originator. In the absence of strategically accumulated patents by the originator, generic companies are typically open to innovating to launch alternative generic products as soon as the basic patent expires. However, by pursuing strategic patenting, originators may discourage generics from engaging in follow-on innovation because of the uncertainty about the patent protection and a fear of infringing on one of the numerous patents.Footnote96 In its Sector Inquiry Report, the Commission cited the following quote from one of the originators: The entire point of the patenting strategy adopted by many originators is to remove legal certainty. The strategy is to file as many patents as possible on all areas of the drug and create a “minefield” for the generics to navigate. All generics know that very few patents in that larger group will be valid and infringed by the product they propose to make, but it is impossible to be certain prior to launch that your product will not infringe and you will not be the subject of an interim injunction.Footnote97 Therefore, as a result of creating an impenetrable ring of patent protection by the originator,Footnote98 generic competitors may be prevented from developing alternative generic versions of an off-patent compound. One of the examples revealed by the Commission during its Pharmaceutical Sector Inquiry was the filing by an originator company of “more than 30 patent families translating into several hundreds of patents in the Member States in relation to one product”, many of which were filed after the introduction of the product.Footnote99 This affected the intentions of several generic companies that planned to develop and bring their generic versions of the original product to the market.Footnote100 As a result, in addition to the already high barriers to entry into the pharmaceutical market due to patents that protect an existing product and the need to obtain a marketing authorisation, strategic patenting raises these entry barriers further, making it very difficult for generic companies to overcome them. This strategy, therefore, “may without further enforcement action by originator companies, … delay generic entry until the patent situation is clearer or even discourage more risk-sensitive generic companies from entering altogether”.Footnote101 Consequently, the fact that actual or potential competitors of originators would not be able to develop alternative generic products means that no one could enter the market and challenge originators’ monopoly positions. This results in a weakening of competition in the relevant market and a strengthening of the originator’s already dominant position. As Maggiolino put it, “patent accumulation … may work as a pre-emptive entry-deterrence strategy to protect monopoly power and … lower consumer welfare by allowing dominant firms to keep on charging over-competitive prices”.Footnote102 Therefore, when an array of accumulated secondary patents “blocks monopolists’ rivals from producing follow-on innovations, this strategy prevents the whole society from enjoying … these further innovations”.Footnote103 While practices that facilitate innovation are encouraged by competition law, practices that are aimed at blocking follow-on innovation by competitors should raise competition law concerns. Strategic Patenting is Considered Lawful Under the Current Approach

#### Indefinite monopolies through patents decks competition, the key driver of pharma innovation

Gurgula 20 [Olga Gurgula, lecturer of intellectual property law at Brunel University London, 10-28-2020, "Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?," IIC - International Review of Intellectual Property and Competition Law, https://link.springer.com/article/10.1007/s40319-020-00985-0]/Kankee

Strategic Patenting Impairs Originators’ Incentives to Innovate While originator companies typically argue that the competition law intervention into their patenting practices will reduce their incentives to innovate,Footnote81 this article asserts that strategic patenting itself reduces originators’ incentives. Thus, in a properly functioning system, when a patent protecting a product is close to expiration the originator would be encouraged to innovate further in order to introduce a new product on the market and maintain its competitive position. However, by engaging in strategic patenting, the originator’s incentive to innovate diminishes as it enjoys its monopoly position by merely procuring numerous secondary patents that shield its current product from generic competition. Therefore, when companies engage in such strategic patenting, they are merely protecting themselves from the competitive pressures that competition law aims to establish. Maintaining that this practice is lawful, originators argue that strong patent protection is essential for recouping their investments, as well as for incentivising them to engage in further innovation.Footnote82 Such a position may find some support in the arguments put forward by Joseph Schumpeter and his followers, who claimed that since monopoly increases the reward of the innovator, monopolists are more prone to innovation.Footnote83 However, as Lowe noted:Footnote84 the empirical evidence of the past few decades has worked against Schumpeter and in favor of Kenneth Arrow, who contends that in favoring monopolies Schumpeter underestimated the incentives for innovation that competition can offer. Monopolists tend to want to keep their monopolies by resorting to any measures that can keep new entrants out. Firms under competitive pressure from actual or potential competition, on the other hand, are less complacent and know that inventing a new product is their best strategy for maintaining and increasing their market share. In the same vein, the Commission emphasises the importance of competition for the incentives to innovate, stating that: “[r]ivalry between undertakings is an essential driver of economic efficiency, including dynamic efficiencies in the form of innovation. In its absence the dominant undertaking will lack adequate incentives to continue to create and pass on efficiency gains.”Footnote85 Evidence from the pharmaceutical industry confirms that strategic patenting reduces incentives to engage in genuine and meritorious innovation. In many cases, strategically accumulated secondary patents are of marginal quality and are typically the result of routine research activities.Footnote86 For example, in Perindopril the European Commission revealed that most of the secondary patents, procured as part of the originator company’s anti-generic strategy, were seen by the company as “blocking” or “paper”, some of which it considered involved “zero inventive step”Footnote87 and a purely editorial task.Footnote88 Moreover, these follow-on pharmaceutical inventions are specifically timed around the expiration of the basic patent and can be developed on demand.Footnote89 In AstraZeneca the Commission noted that the company designed to “[f]ile a patent-cloud of mixtures, uses, formulations, new indications, and chemistry” in relation to its blockbuster product omeprazole to slow down generic entry at a specifically defined time, close to the expiration of the basic patent.Footnote90 The main aim of these patents is to increase uncertainty for generic companies as to the possibility of their market entry.Footnote91 Therefore, while many of these secondary patents may be trivial and potentially invalid, the originator pursues them to protect its current successful product from generic competition.Footnote92 Even if a company continues to engage in innovation in parallel to pursuing strategic patenting, it still protects itself from the pressures of competition, which would have forced the company to innovate faster and would thus provide consumers with better products and/or access to cheaper generic versions earlier. As Ullrich argues:Footnote93 A slowdown in the transition of the new medicines from the protected status of a proprietary medicine to the status of generic products manufactured and distributed in open competition does not simply mean a loss of static efficiency, namely a loss of consumer well-being due to a slowdown in the reduction of process. Rather, such a slowdown also involves the risk of a loss of dynamic efficiency in that it extends the duration of a monopoly rent situation, thus reducing the pressure to innovate more quickly. Following the rationale of the General Court’s statement in AstraZeneca, the practice of the originator that extends its market monopoly by relying on the patent system “potentially reduces the incentive to engage in innovation, since it enables the company in a dominant position to maintain its exclusivity beyond the period envisaged by the legislator”.Footnote94 Such practices, according to the Court, act “contrary to the public interest”.Footnote95 Therefore, the practice of strategic patenting that protects originators’ monopolies from competitive pressures and significantly reduces their incentives to engage in genuine innovation is contrary to the rationale of the patent system, has a significant negative effect on competition and should raise competition law concerns. Strategic Patenting Impairs Follow-on Innovation of Generic Companies

#### Follow-on patents are minor modifications, not innovative breakthroughs, and don’t improve health outcomes – consensus of studies prove

Naci et al. 15 [Huseyin Naci, assistant professor of health policy at the LSE Health analysis center at the Department of Social Policy for the London School of Economics and Political Science, Alexander W Carter policy fellow, at the Institute of Global Health Innovation, Imperial College London, Elias Mossialos, professor of health policy, at the LSE Health analysis center at the Department of Social Policy for the London School of Economics and Political Science, 10-23-2015, “Why the drug development pipeline is not delivering better medicines,” BMJ, https://sci-hub.se/https://www.bmj.com/content/351/bmj.h5542.full]/Kankee

Many in the pharmaceutical sector suggest that the industry is in crisis. Industry analysts fret that financial rewards are no longer sufficient for companies to maintain the investment needed to develop clinically useful drugs.1 Despite these concerns, regulators in the US and Europe granted marketing authorisations to a record number of new medicines in 2014. However, the majority of new medicines offer few clinical advantages over existing alternatives. We discuss how both government and drug company practices contribute to the ongoing innovation deficit in the sector. Paucity of clinically superior medicines Patients and clinicians commonly understand innovation to mean a medicine that has transformed management and treatment,2 either by providing treatments for conditions with no current (satisfactory) remedies or by offering meaningful improvement over existing options. In recent years, however, industry analysts have adopted other definitions to measure innovation (box 1).3 Currently, the most common approach to measure innovation is to count the number of new drug approvals.3 The number of drug approvals has increased over the past five decades, culminating in 41 approvals in the US and 40 in Europe in 2014 alone; this compares with a 50 year average of 20 approvals a year.4 5 Large numbers of new drugs have been taken as a proxy for the innovative capacity of the industry. Unfortunately, rather than new breakthroughs, most of the new drugs are relatively minor modifications of existing treatments.6 Studies evaluating the clinical importance of new drugs over the past decades consistently report a negative trend.7-11 Regardless of differences in analytical approach and time period, all characterise only a minority of new drugs as clinically superior to existing alternatives.3 Luijn found that 10% of 122 new medicines on the European market between 1999 and 2005 were superior to drugs already on offer.12 Among drugs reviewed by German authorities between 2012 and 2013, about 20% were concluded to offer some benefit over existing alternatives and none was deemed to offer major benefit.13 Between 1990 and 2003, only 6% of 1147 drugs approved in Canada provided a substantial improvement over existing drug products,14 and Canadian authorities considered 10% of new drugs approved between 2004 and 2009 as highly innovative.15 Despite the paucity of clinically superior drugs, the pharmaceutical market grew by a factor of 2.5 in real terms between 1990 and 2010 (fig 1⇓). Much of the increased expenditure on drugs was the result of increasing industry investment in “me-too” medicinesrather than clinically superior medications.14 Drug companies have remained profitable over this period while the proportion of health spending on drugs has increased and drugs have become less affordable.16 17 Over the past 30 years, firms lost their number one position in the Fortune 500 ranking of US companies only in 2003, coming third behind oil and financial companies. In 2012, the top five pharmaceutical companies included in the Fortune 500 earned over $50bn (£30bn; €40bn) in net profits.

#### Pharma innovation is key to prevent devastating pandemics, bioterror, and ABR

Marjanovic and Fejiao 20 [Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge, and Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon, 2020, "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." RAND Corporation, https://www.rand.org/pubs/perspectives/PEA407-1.html]/Kankee

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a **bioterrorism con-text**.1 The general threat to public health that is posed by **antimicrobial resistance** is also **well-recognised** as an area **in need of pharmaceutical innovation**. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an **indispensable** partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is **essential** for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to **benefit patients** and wider **population health**. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other **infectious diseases**, **bioterror-ism** agents **and antimicrobial resistance**) are **urgently in need of pharmaceutical innovation**, **even if their impacts are not as visible** to society **as COVID**-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still **low**.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions.

### ADV---Solvency

#### Advantage 2 is Solvency

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

#### The Plan solves Evergreening.

Feldman 19 Robin Feldman 2-11-2019 "‘One-and-done’ for new drugs could cut patent thickets and boost generic competition" <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/> (Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation)//SidK + Elmer

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

#### Reforming the Patent Process would lower Drug Prices and incentivize Pharma Innovation by revitalizing the Market.

Stanbrook 13, Matthew B. "Limiting “evergreening” for a better balance of drug innovation incentives." (2013): 939-939. (MD (University of Toronto) PhD (University of Toronto))//Elmer

At issue in the Indian case was “evergreening,” a now widespread practice by the pharmaceutical industry designed to extend the monopoly on an existing drug by modifying it and seeking new patents.2 Currently, half of all drugs patented in Canada have multiple subsequent patents, extending the lifetime of the original patent by about 8 years.3 Manufacturers, in defence of these practices, predictably tout the advantages of new versions of their products, which often represent more potent isomers or salts of the original drugs, longer-lasting formulations or improved delivery systems that make adherence easier or more convenient. But the new versions are by definition “**me too” drugs**, and demonstration that the resulting **incremental benefits** in efficacy and safety are clinically meaningful **is often lacking**. Moreover, the original drugs have often been “blockbusters” used for years to improve the health of millions of patients. It seems hard to argue convincingly why such beneficial drugs require an upgrade, often just before their patents expire. Rather than the marginal benefits accrued from tinkering with already effective agents, patients worldwide are in desperate need of new classes of pharmaceuticals for the great many health conditions for which treatments are presently inadequate or entirely lacking. But developing truly innovative drugs is undeniably a high-risk venture. It is important and necessary that pharmaceutical companies continue to take these risks, because they are usually the only entities with sufficient resources to do so. Therefore, companies must continue to perceive **sufficient incentives** to continue investing in innovation. Indeed, there is evidence that the prospect of future evergreening has become part of the incentive calculation for innovative drug development.4 But surely it is perverse to extend unpredictably a period of patent protection that the government intended to be clearly defined and predictable, and to maintain incentives that drive companies to divert their **drug-development resources away from innovation**. **Current patent legislation may not be optimal** for striking the right balance between encouraging innovation and facilitating profiteering. Given the broad societal importance of patent legislation, ongoing research to enable active governance of this issue should be a national priority. In the last decade, Canada’s laws have been among the friendliest toward evergreening in the world.5 We should now reflect on whether this is really in our national interest. Governments, including Canada’s, would do well to take inspiration from India’s example and tighten regulations that currently facilitate evergreening. This might involve **denying future patents for modifications** that currently would receive one. An overall reduction in the duration of all secondary patents on a therapy might also be considered. Globally, a more flexible and individualized approach to the length of drug patents might be a more effective strategy to align corporate incentives with population health needs. Limits on evergreening would likely reduce the **extensive patent litigation** that contributes to the **high prices of generic drugs** in Canada.3 Reducing economic pressure on generic drug companies may facilitate current provincial initiatives to lower generic drug prices. As opportunities to generate revenue from evergreening are eliminated, research-based pharmaceutical companies would be left with no choice but to invest more in innovative drug development to maintain their profits.

### ADV---Framing

#### Advantage 3 is Framing

#### The standard is maximizing expected well-being.

#### 1] Actor Specificity

#### a) Different actors have distinct responsibilities – governments are abstract entities lacking personal identity and can’t know their impact on specific individuals

#### b) Aggregation – governments evaluate policy tradeoffs and degrees of wrongness of actions

#### 2] Fairness and Education – frameworks are topicality interpretations of the word “ought” so they must be theoretically justified –

#### a) Util doesn’t arbitrarily moot 6 minutes of 1AC offense and forcing a 1AR restart

#### b) Real World – policymakers use util to model impacts – outweighs since education is the reason schools fund debate

#### \*3] Prefer Aff Reasonability –

#### a) Substance crowd-out – competing interps leads to endless frivolous theory with arbitrary self-serving interps instead of stopping actual abuse

#### b) 1AR Time Skew – 4 minutes is too short to reasonably answer T and substance given the 6 minute 2NR collapse to 1 argument

#### 4] No RVIs

#### a) Chilling Effect – RVIs make worse theory debaters fear theory debates in the face of actual abuse

#### b) Logic – You shouldn’t win a chess match by *not* flipping the chess board