### 1

#### Interpretation – the Aff may not specify a specific IP protection

#### IP Protections is a generic bare plural

**Leslie and Lerner 16** [Sarah-Jane Leslie (Ph.D., Princeton, 2007) is the dean of the Graduate School and Class of 1943 Professor of Philosophy. She has previously served as the vice dean for faculty development in the Office of the Dean of the Faculty, director of the Program in Linguistics, and founding director of the Program in Cognitive Science at Princeton University. She is also affiliated faculty in the Department of Psychology, the University Center for Human Values, the Program in Gender and Sexuality Studies, and the Kahneman-Treisman Center for Behavioral Science and Public Policy], and Adam Lerner, Ph.D, Postgraduate Research Associate in the Department of Philosophy at Princeton University, 4-24-2016, accessed 9-4-2021, "Generic Generalizations (Stanford Encyclopedia of Philosophy)," <https://plato.stanford.edu/entries/generics/>] HWIC

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

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

#### It applies to this topic – “Member nations ought to reduce IP for medicines– therefore, member nations ought to reduce protections for medicines” is illogical

#### 1] Limits: There’s inf intellectual property protections they could specify, coupled with various types of countries

#### 2] TVA Solves – just read your aff as an advantage to a whole rez aff. We aren’t stopping them from reading new FWs, mechanisms, or advantages.

Drop the debater bc you can’t drop the arg on their advocacy

No rvis – they can dump on theory in the 1ar, chilling us from checking abuse

Competing interps – reasonability is arbitrary and causes race to the bottom

No 1ar theory – it’s irresolvable since their responses to my interp will always be new. Worst case, use reasonability on 1ar theory to avoid substance crowdout since they don’t need ballot implications on CPs

### 2

#### CP: The TRIPs Council should vote to reduce intellectual property protections for [PLAN], amending TRIPs to mandate the [PLAN]

#### The United States should:

#### --Publicly rescind support for the WTO waiver

#### -- Veto this motion and refuse to comply

#### The remaining member nations should initiate proceedings against the United States through the World Trade Organization Dispute Settlement Body which ought to find against the United States. The United States ought to comply with this ruling.

#### Counterplan competes ---

#### 1] The plan has the “member nations” act individually, while the counterplan is the WTO through the Council and eventually the DSB.

**Collins Dictionary n.d.** “member nations” RJP, DebateDrills https://www.collinsdictionary.com/us/dictionary/english/member-nations

member nations

The [United](https://www.collinsdictionary.com/us/dictionary/english/unite) [Nations](https://www.collinsdictionary.com/us/dictionary/english/nation) is an [international](https://www.collinsdictionary.com/us/dictionary/english/international) organization [comprised](https://www.collinsdictionary.com/us/dictionary/english/comprise) of about 180 member nations.

Sociology (1995)

At the Nato [summit](https://www.collinsdictionary.com/us/dictionary/english/summit), he called on all the member nations to [pledge](https://www.collinsdictionary.com/us/dictionary/english/pledge) to [spend](https://www.collinsdictionary.com/us/dictionary/english/spend) at least 2% of their [national](https://www.collinsdictionary.com/us/dictionary/english/national) [income](https://www.collinsdictionary.com/us/dictionary/english/income) on [defence](https://www.collinsdictionary.com/us/dictionary/english/defence).

Times, Sunday Times (2015)

The [beneficiaries](https://www.collinsdictionary.com/us/dictionary/english/beneficiary) will not be [limited](https://www.collinsdictionary.com/us/dictionary/english/limit) to EU member nations, but [worldwide](https://www.collinsdictionary.com/us/dictionary/english/worldwide).

Times, Sunday Times (2012)

Definition of 'nation'

nation

(neɪʃən)[Explore 'nation' in the dictionary](https://www.collinsdictionary.com/us/dictionary/english/nation)

COUNTABLE NOUN

A nation is an individual country considered together with its social and political structures.

#### 2] Immediacy

#### Ought and should are used interchangeably.

Anastasia **Koltai 18**. CEO of MyEnglishTeacher, “Difference Between Ought to and Should,” MyEnglishTeacher, September 25, 2018, <https://www.myenglishteacher.eu/blog/difference-between-ought-to-and-should/>, RJP, DebateDrills.

In most cases, SHOULD and OUGHT TO are used interchangeably today. Both SHOULD and OUGHT TO are used to express advice, obligation, or duty.

#### “Should” is immediate

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

¶4 The legal question to be resolved by the court is whether the word "should"[13](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn13) in the May 18 order connotes futurity or may be deemed a ruling *in praesenti*.[14](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn14) The answer to this query is not to be divined from rules of grammar;[15](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn15) it must be governed by the age-old practice culture of legal professionals and its immemorial language usage. To determine if the omission (from the critical May 18 entry) of the turgid phrase, "and the same hereby is", (1) makes it an in futuro ruling - i.e., an expression of what the judge will or would do at a later stage - or (2) constitutes an in in praesenti resolution of a disputed law issue, the trial judge's intent must be garnered from the four corners of the entire record.[16](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn16)

[CONTINUES – TO FOOTNOTE]

[13](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker2fn13) "*Should*" not only is used as a "present indicative" synonymous with *ought* but also is the past tense of "shall" with various shades of meaning not always easy to analyze. See 57 C.J. Shall § 9, Judgments § 121 (1932). O. JESPERSEN, GROWTH AND STRUCTURE OF THE ENGLISH LANGUAGE (1984); St. Louis & S.F.R. Co. v. Brown, 45 Okl. 143, 144 P. 1075, 1080-81 (1914). For a more detailed explanation, see the Partridge quotation infra note 15. Certain contexts mandate a construction of the term "should" as more than merely indicating preference or desirability. Brown, supra at 1080-81 (jury instructions stating that jurors "should" reduce the amount of damages in proportion to the amount of contributory negligence of the plaintiff was held to imply an *obligation* *and to be more than advisory*); Carrigan v. California Horse Racing Board, 60 Wash. App. 79, [802 P.2d 813](http://www.oscn.net/applications/oscn/deliverdocument.asp?box1=802&box2=P.2D&box3=813) (1990) (one of the Rules of Appellate Procedure requiring that a party "should devote a section of the brief to the request for the fee or expenses" was interpreted to mean that a party is under an *obligation* to include the requested segment); State v. Rack, 318 S.W.2d 211, 215 (Mo. 1958) ("should" would mean the same as "shall" or "must" when used in an instruction to the jury which tells the triers they "should disregard false testimony"). [14](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker2fn14) *In praesenti* means literally "at the present time." BLACK'S LAW DICTIONARY 792 (6th Ed. 1990). In legal parlance the phrase denotes that which in law is *presently* or *immediately effective*, as opposed to something that *will* or *would* become effective *in the future [in futurol*]. See Van Wyck v. Knevals, [106 U.S. 360](http://www.oscn.net/applications/oscn/deliverdocument.asp?box1=106&box2=U.S.&box3=360), 365, 1 S.Ct. 336, 337, 27 L.Ed. 201 (1882).

#### The plan would require US companies to disclose information and waive IP protections---the counterplan has the US resist to avoid political backlash, but that violates WTO disclosure requirements.

Jorge Contreras 21. Presidential Scholar and Professor of Law at the University of Utah with an adjunct appointment in the Department of Human Genetics, JD @ Harvard, “US Support for a WTO Waiver of COVID-19 Intellectual Property – What Does it Mean?” Bill of Health Harvard Law, May 7, 2021, <https://blog.petrieflom.law.harvard.edu/2021/05/07/wto-waiver-intellectual-property-covid/>, RJP, DebateDrills

The proposed WTO IP waiver is significant because it includes trade secrets. Thus, under the waiver’s original language, a country that wished to suspend trade secret protection for COVID-19 technology could do so without violating the TRIPS Agreement. Such a country could also, presumably, mandate that foreign companies operating in the country disclose their proprietary manufacturing, storage, and testing information to local producers under a compulsory license.

The details of this disclosure requirement, and any compensation payable to the originator of the information, would need to be worked out in whatever waiver is eventually adopted by the WTO, but the prospect for a mandatory trade secret transfer — something that would be unprecedented in the international arena — is worth watching carefully. [As reported by Intellectual Asset Management on May 4, 2021](https://www.iam-media.com/coronavirus/brazilian-senate-passes-compulsory-covid-19-know-how-licensing-bill), the Brazilian Congress is currently considering legislation that would nullify the patents of any company that fails to disclose know-how and data related to a compulsory COVID-19 patent license. It will also be interesting to see whether the United States stands behind such a requirement, which goes far beyond the compulsory licensing of patents.

Will the U.S. require companies to share their know-how with others?

As noted above, under the waiver, a country could impose a trade secret disclosure requirement on companies operating within its jurisdiction. But that requirement would have little effect on U.S. vaccine producers who do not, themselves, have material operations overseas. Only the U.S. government could require a U.S.-based company to disclose its trade secrets. Would the U.S. impose such a requirement? This is not known, but I think it’s unlikely. It is one thing for the U.S. to agree not to challenge other countries’ compulsory licensing regimes as violations of TRIPS, but a very different thing for the U.S. to issue a compulsory licensing order of its own, particularly in the area of trade secrets, where it would be met with significant internal opposition.

#### DSB is underutilized currently but using it for major dispute settlement shores it up---that’s key to combat Chinese IP violations.

James **Bacchus 18**. Member of the [Herbert A. Stiefel Center for Trade Policy Studies](https://www.cato.org/herbert-stiefel-center-trade-policy-studies), the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida. He was a founding judge and was twice the chairman—the chief judge—of the highest court of world trade, the Appellate Body of the World Trade Organization in Geneva, Switzerland. “How the World Trade Organization Can Curb China’s Intellectual Property Transgressions,” CATO, March 22, 2018, <https://www.cato.org/blog/how-world-trade-organization-can-curb-chinas-intellectual-property-transgressions>, RJP, DebateDrills.

Quite rightly, President Donald Trump and his Administration are targeting the transgressions of China against US intellectual property rights in their unfolding trade strategy. But why not use the WTO rules that offer a real remedy for the United States without resorting to illegal unilateral action outside the WTO?  
  
Seventeen years after China joined the WTO, China still falls considerably short of fulfilling its WTO obligations to protect intellectual property. About 70 percent of the software in use in China, valued at nearly $8.7 billion, is pirated. The annual cost to the US economy worldwide from pirated software, counterfeit goods, and the theft of trade secrets could be as high as $600 billion, with China at the top of the IP infringement list. China is the source of 87 percent of the counterfeit goods seized upon entry into the United States.  
  
One possible response by the United States is the one the Trump Administration seems to be taking: slapping billions of dollars of tariffs on imports of more than 100 Chinese products through unilateral trade action. Given its protectionist predilections, taking this approach is surely tempting to the Trump Administration. Doing so will, however, harm American workers, businesses, and consumers, and contribute to further turmoil in the global economy.

The results will likely include retaliation by China against the goods and services of American companies and workers; lawful economic sanctions imposed by China on American exports to China after the US lost to China in WTO cases; the hidden tax of higher prices for American consumers; less competitiveness in the US market and in other markets for American companies that depend on Chinese imports as intermediate goods in production; and doubtless still more American and global economic landmines from the downward spiral of tit-for-tat in international trade confrontations.  
  
These tariffs are not only self-defeating and counter-productive; they are also illegal under international law. Where an international dispute falls within the scope of coverage of the WTO treaty, taking unilateral action without first going to WTO dispute settlement for a legal ruling on whether there is a WTO violation is, in and of itself, a violation of the treaty. The WTO treaty establishes mandatory jurisdiction for the WTO dispute settlement system for all treaty-related disputes between and among WTO Members. The WTO Appellate Body has explained, “Article 23.1 of the (WTO Dispute Settlement Understanding) imposes a general obligation to redress a violation of obligations or other nullification or impairment of benefits under the covered agreements only by recourse to the rules and procedures of the DSU, and not through unilateral action.”  
  
Thus, the United States is not permitted by the international rules to which it has long since agreed to be the judge and the jury in its own case. Imposing tariffs on Chinese products without first obtaining a WTO ruling that Chinese actions are inconsistent with China’s WTO obligations is a clear violation by the United States of its WTO obligations to China – as WTO jurists will doubtless rule when China responds to the tariffs by challenging the tariffs in the WTO.  
  
Such a legal loss by the United States, with all its unforeseeable economic and geopolitical consequences, can be avoided while still confronting Chinese IP violations effectively. Before resorting to unilateral action outside the WTO and in violation of international law, the United States should take a closer look at the substantial rights it enjoys under the WTO treaty for protecting US intellectual property against abuse.  
  
Potential remedies in the WTO exist and should not be ignored. These remedies can be enforced through the pressure of WTO economic sanctions. WTO rules do not yet cover all the irritants that must be addressed in US-China trade relations. Even so, instead of just concluding that there are no adequate remedies under WTO rules to help stop IP infringement, the United States should first try to use the remedies in rules we have already negotiated that bind China along with all other WTO Members.  
  
A number of these rules have not yet been tested against China or any other country – which is not proof they will not work. Generally, when tried for the first time, WTO rules have been found to work, and, generally, when China has been found to be acting inconsistently with its WTO obligations, it has complied with WTO rulings. The actual extent of Chinese compliance with WTO judgments can be questioned; in some instances it is seen by some as only “paper compliance.” But whether any one WTO rule can in fact be enforced cannot be known if no WTO Member bothers to try to enforce it.  
  
The WTO rules in the WTO Agreement on the Trade-related Aspects of Intellectual Property Rights – the so-called TRIPS Agreement – are unique among WTO rules because they impose affirmative obligations. Yet, this affirmative aspect of WTO intellectual property rules has been largely unexplored in WTO dispute settlement. In particular, WTO Members have so far refrained from challenging other WTO Members for failing to enforce intellectual property rights.  
  
On enforcement, Article 41.1 of the TRIPS Agreement imposes an affirmative obligation on all WTO Members: “Members shall ensure that enforcement procedures… are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.”  
  
Note that this “shall” be done by all WTO Members; it is mandatory for compliance with their WTO obligations. And yet what does this obligation mean by requiring that effective actions against infringements must be “available”? Is this obligation fulfilled by having sound laws on the books, as is generally the case with China? Or must those laws also be enforced effectively in practice, which is often not the case with China?  
  
The Appellate Body has said that “making something *available* means making it ‘obtainable,’ putting it ‘within one’s reach’ and ‘at one’s disposal’ in a way that has sufficient form or efficacy.” Thus, simply having a law on the books is not enough. That law must have real force in the real world of commerce. This ruling by the Appellate Body related to the use of the word “available” in Article 42 of the TRIPS Agreement and to a legal claim seeking fair and equitable access to civil judicial procedures. Yet the same reasoning applies equally to the enforcement of substantive rights under Article 41.  
  
In the past, the United States has challenged certain parts of the overall Chinese legal system for intellectual property protection – and successfully – in WTO dispute settlement. Despite its overall concerns about enforcement by China of US intellectual property rights, the United States has not, however, challenged the Chinese system as a whole in the WTO. Instead of indulging in the illegality of unilateral tariffs outside the legal framework of the WTO, the Trump Administration should initiate a comprehensive legal challenge in the WTO, not merely, as before, to the bits and pieces of particular Chinese IP enforcement, but rather *to the entirety of the Chinese IP enforcement system*.  
  
To be sure, a systemic challenge by the United States to the application of all China’s inadequate measures relating to intellectual property protection would put the WTO dispute settlement system to a test. It would, what’s more, put both China and the United States to the test of their commitment to the WTO and, especially, to a rules-based world trading system.  
  
As Trump’s trade lawyers will hasten to say, a systemic IP case against China in the WTO would also involve a perhaps unprecedented amount of fact-gathering. It would necessitate an outpouring of voluminous legal pleadings. It would, furthermore, force the WTO Members and the WTO jurists to face some fundamental questions about the rules-based trading system. Yet it could also provide the basis for fashioning a legal remedy that would in the end be mutually acceptable to both countries, and could therefore help prevent commercial conflict and reduce a significant obstacle to mutually beneficial US-China relations.

#### Stopping tech stealing is key to avoid war

Timothy R. **Heath 18**. RAND Senior Defense and International Analyst, “Avoiding “Avoiding U.S.-China Competition Is Futile: Why the Best Option Is to Manage Strategic Rivalry”; Asia Policy; Vol 13 No 2; April 2018, RJP, DebateDrills

This article argues that the structural drivers of U.S.-China competition are too deep to resolve through cooperative engagement and that policymakers must instead accept the reality of strategic rivalry and aim to manage it at a lower level of intensity. main argument Rising tensions between China and the U.S. have spurred fears that the two countries could end up in conflict or recreate the Cold War. To avoid these outcomes, analysts have proposed ways to defuse competition and promote cooperation. However, because these arguments do not address the structural drivers underpinning U.S.-China competition, such proposals are unlikely to end the rivalry. Conflict is not inevitable, however, and aggressive strategies that unnecessarily aggravate the sources of rivalry are likely to prove dangerously counterproductive. The best option at this point is, paradoxically, for the U.S. to accept the reality of the growing strategic rivalry and manage it at a lower level of intensity. policy implications • Maintaining a technological edge is critical for the U.S. to successfully manage the rivalry with China. Policies should be pursued to ensure that the U.S. continues to attract and nurture the best science and technology talent and retains its status as the global leader in technology. • To compete with China’s narrative about leading regional integration, the U.S. should both put forth a compelling vision for the region that encompasses widely held economic, security, and political values and continue to bolster its diplomatic and military positions in Asia. • To maintain the U.S.-China rivalry at a stable level, policymakers in both countries should prioritize measures that discourage the mobilization of popular sentiment against the other country and encourage cultural exchanges. • U.S.-China competition will likely become increasingly entwined with rivalries between China and U.S. allies and partners such as Japan and India. U.S. policymakers will need to take into account the independent dynamics of those separate rivalries when managing relations with China. The United States and China find themselves increasingly enmeshed in a strategic rivalry, the basic nature of which remains poorly understood in the United States. To be sure, disagreements between the two countries have gained widespread attention. Disputes involving Chinese confrontations with U.S. allies and partners such as Japan, the Philippines, and Taiwan have frequently grabbed the headlines. At other times, disagreements over Chinese trade practices and U.S. military activities in the South China Sea have occasioned discord. All these sources of conflict are genuine, but they mask the main drivers of rivalry, which are twofold. First, the United States and China are locked in a contest for primacy—most clearly in Asia and probably globally as well. The United States has been the dominant power, and China seeks to eventually supplant it. By definition, two different states cannot simultaneously share primacy at either the regional or global level. Second, economic, demographic, and military trajectories suggest that China has the potential to contend in a significant way for leadership at the global systemic level. At this level, the most decisive competition will be for technological leadership. Should China supplant the United States as the world’s premier country in terms of technology, its claim to regional and global supremacy will be difficult to deny. And once it has gained that supremacy, China will be well positioned to restructure institutional arrangements to privilege itself and disadvantage the United States. Although this competition is occurring simultaneously at both levels, observers have focused primarily on the struggle for primacy at the regional level and overlooked or downplayed the competition at the global systemic level.1 To counter China’s pursuit of regional primacy, the United States has bolstered its alliances in Asia (albeit inconsistently), expanded diplomatic outreach to China and rising powers in Southeast Asia, and revised its military posture—efforts captured by President Barack Obama’s “rebalance to Asia.” President Donald Trump may have abandoned the rebalance, but many of the related initiatives remain more or less in place.2 China’s challenge at the global systemic level, especially in the field of technology, has received less attention. Confidence in the proven U.S. ability to produce new technologies and facile assumptions about the difficulties China will face in promoting innovation in new industries have led many to dismiss the challenge posed by China. **But the contest for technological leadership is actually even more consequential than that for regional primacy.** Should China succeed in surpassing the United States as the world’s technological leader, U.S. diplomacy and military power will not suffice to hold the line either in Asia or around the globe**.** Under those conditions, countries throughout the world, including U.S. allies in Asia, will be forced to come to terms with the new leading economy. Military power projection could be far less relevant as China moves to consolidate its leading status at both the regional and global levels in such a scenario. Accordingly, although the United States cannot abandon its efforts to bolster its diplomatic and military position in Asia, the country must step up its efforts to strengthen its faltering lead in new technology development. While China clearly grasps the stakes, it is not clear that the United States does. For example, China’s government has promoted R&D into quantum computing. The investment appears to be paying off, as the country has leaped ahead of the United States in developing quantum communications.3 Similarly, the U.S. Congress has proposed to dispense with subsidies for the purchase of electric vehicles, even as China pushes ahead in its plan to become the lead producer of this technology.4 And while the U.S. government seeks to restrict immigration and discourage foreign students from attending U.S. universities (and staying after they receive their advanced training), China has revised its policies to welcome foreigners, prioritizing those with science and technology expertise. Moreover, Chinese investment in basic R&D is rapidly catching up to that of the United States.5 Studies have also noted a shrinking U.S. lead in science and technology as such investment is beginning to bear fruit.6 Similarly, the United States has lost its once-undisputed lead in the per capita number of engineers and scientists.7 Understanding the nature of the U.S.-China rivalry at the regional and global systemic levels, as well as how these two levels interact with one another, is essential if the United States is to successfully manage the challenge posed by China in a manner that avoids war. This study aims to contribute to that understanding. The article is organized into the following sections: u pp. 95–102 provide an overview of the growing rivalry between China and the United States, including a discussion of the meaning and role of strategic rivalry in interstate conflict and a comparison with the U.S.-China rivalry during the Cold War. u pp. 102–4 review the dynamics of the rivalry at the regional systemic level. u pp. 104–10 analyze the dynamics of the rivalry at the global systemic level. u pp. 110–15 examine why proposals to avoid rivalry through cooperation or aggressive competition are unlikely to succeed. u pp. 115–19 discuss the idea of strategic rivalry management and offer recommendations on ways to sustain the rivalry at a lower level of intensity the growing rivalry between the united states and china Strains between China and the United States have deepened in the past few years over a proliferating array of issues. President Trump has stepped up accusations against China of unfair trade practices and inadequate pressure on North Korea. He also provoked controversy early in his term when he floated the idea of increasing official contacts with Taiwan, which Beijing considers a renegade province.8 These disputes add to tensions that had expanded under President Obama, who moved to strengthen U.S. alliances in Asia, promote a regional trade pact, criticize Chinese behavior in the cyber and maritime domains, and shift more military assets to the Asia-Pacific as part of the rebalance to Asia strategy.9 China has in turn dismissed U.S. concerns about the construction of artificial islands in the South China Sea, intensified its criticism of U.S. security leadership in Asia, and tightened its grip on disputed maritime territories.10 The baleful state of bilateral relations has spurred plenty of finger-pointing. On the Chinese side, officials denounce the United States’ “Cold War mindset” and warn of conflict if Washington does not adjust its policies.11 A 2015 defense white paper described an “intensifying competition” between the great powers.12 Military officials and many Chinese analysts regard increasing tension between the two countries as unavoidable, although they do not regard war as likely. People’s Liberation Army (PLA) deputy chief of staff Qi Jianguo commented that “no conflict and no confrontation does not mean no struggle” between China and the United States.13 According to Chinese official media, polls in China suggest a large majority believes that the United States intends to pursue a containment policy.14 Reflecting this point of view, Niu Xinchun, a scholar at the China Institutes of Contemporary International Relations, argued that the “greatest obstacle to the further integration of emerging countries such as China into the international system comes from the United States.”15 Western officials and commentators tend to blame China for current strains. Senior U.S. leaders have criticized “assertive” Chinese behavior, while some analysts blame Xi Jinping for pushing a more confrontational set of policies.16 Other Western observers worry that a further souring of relations could lead to conflict.17 But even if war remains unlikely, the deepening tensions increase the risks of miscalculation, crises, and potential military clashes involving the world’s two largest powers. Echoing a view widely held among U.S. foreign policy experts and officials, former CIA director General Michael Hayden has warned that mishandling the U.S.-China relationship could be “catastrophic.”18 Rivalry at the Heart of the U.S.-China Relationship This widespread concern reflects a realistic appraisal of the dangers inherent in the U.S.-China relationship. But developing successful policies to manage an increasingly sensitive and complex situation requires an accurate assessment of the phenomenon of interstate rivalry that lies at the heart of that relationship. Rivalry is a concept that, while widely acknowledged, remains poorly understood. To be sure, most experts take for granted the idea that powerful nations compete for status and influence, and they acknowledge the danger posed by a rising power’s challenge to a status quo power. Yet investigation into the phenomenon of rivalry too often stops at these well-trodden findings. Less often discussed are the conclusions regarding the dynamics of rivalry that experts on conflict studies have arrived at within the past few years. Much of this scholarship draws from improvements to the analyses and data regarding interstate crisis and conflict.19 This research has generated useful and interesting insights regarding the start and conclusion of rivalries, crises, and war, although these remain largely unexplored outside academic circles. Analysts have established, for example, that rivalry is perhaps the most important driver of interstate conflict. As defined by political scientists, “rivals” are states that regard each other as “enemies,” sources of real or potential threat, and as competitors. At the root of rivalries thus lie disputes over incompatible goals and perceptions that countries possess both the ability (real or potential) and the intention to harm each other. Wars have historically tended to be fought by pairings of these states and their allies. Rivals have opposed each other in 77% of wars since 1816 and in over 90% of wars since 1945.20 Not only are rivals more likely to fight than non-rivals, but rivals also have a tendency to be recidivists because they are unable to resolve their political differences on the battlefield. Yet that does not always discourage them from trying to do so repeatedly. Rivals that cannot prevail due to parity frequently compete for advantage by building internal strength through arms racing or by leveraging external power through the strengthening of alliances and partnerships. Rivals are also prone to serial militarized crises**.** Mutual perceptions of each other as hostile enemies and the inconclusive outcome of previous militarized disputes typically fuel a pattern of recurrent crises characterized by deepening resentment, distrust, and growing willingness to risk escalation. Studies have also established that the risk of conflict increases sharply after three episodes of militarized crises.21 Rivalries do not progress in a linear direction, however. Their intensity can wax and wane in response to shocks and other important developments. Periods of relative stability can alternate with turbulent periods of tension and conflict. Similarly, cooperative activities can be interspersed with periods of acute tension and hostility. Nevertheless, the link between rivalry, crises, and interstate conflict is pervasive. Drawing from these sources, one can describe the Sino-U.S. relationship as a rivalry characterized as a competition between two major powers over incompatible goals regarding their status, leadership, and influence over a particular region—in this case principally the Asia-Pacific. The dynamics of this type of strategic rivalry differ in significant ways from the far more numerous rivalries over territory that have characterized conflict between so many countries, especially weaker and poorer ones. In contrast with rivalries over territories, strategic rivals do not necessarily share borders, although allies of one power may be engaged in a territorial dispute with the other major power. Strategic rivalries among major powers tend to be especially long-lived, with the average enduring for about 55 years.22 Strategic rivalries are incredibly complex phenomena that include overlapping and often reinforcing layers of disputes over leadership, status, and territory between the principal rivals and their allies. Such rivalries are almost always multilateral affairs that also involve allies and partners, some of which have their own rivalries with the other side. Competition in the economic, political, and military domains can serve as expressions as well as drivers of rivalry, as can sports and cultural competition. Strategic rivalries can be confined to one region, with the basic conflict reducible in some respects to which rival will occupy the top rung of the regional hierarchy. In other cases, however, a rivalry can span regional and global domains either sequentially or simultaneously. The U.S.-China rivalry, for instance, is already both a regional and, to a lesser extent, a global rivalry, but there is still considerable room for competition to expand. The complex and overlapping nature of the disputes makes strategic rivalries extremely crisis- and conflict-prone. Strategic rivalries come in a grim package deal that includes strained and hostile relations, serial crises, and in some cases wars. The comprehensive and multifaceted nature of the disputes also explains why such rivalries have proved so durable and why their wars have been so devastating. Conflict between strategic rivals has historically occasioned the most destructive wars, of which World Wars I and II are the most recent examples. The fact that experts at the time of each historic episode of systemic conflict consistently underestimated the duration or extent of war offers cold comfort to analysts today who seek to predict the trajectory of any conflict that might involve China and the United States. Comparisons of the Current Environment with the U.S.-China Rivalry during the Cold War How did the two countries arrive at this position? The most widely accepted narrative argues that China’s rapid economic growth has provided the resources with which it can press demands on long unresolved issues such as unification with Taiwan. China and the United States may have enjoyed stable relations in the 1980s when they cooperated on a limited basis against the Soviet Union, but that foundation of cooperation eroded considerably once the Soviet bloc dissolved in the early 1990s. Moreover, China’s rapid growth in economic power has given the country fresh resources to press its own demands on the United States and U.S. allies. By 2010, China’s economy had outpaced that of Japan to become the second-largest in the world.23 The persistence of long-standing sources of antagonism, such as the U.S. security partnership with Taiwan, has both reflected and aggravated a broader competition for leadership. For its own reasons, Washington has resisted Beijing’s demands, and the result has been growing fear and distrust.24 The intensifying rivalry between the rising power and the status quo leader is as old as antiquity itself. Indeed, Graham Allison coined the term “Thucydides trap” to describe such a situation, a term that he subsequently applied to the current U.S.-China situation.25 The popular narrative is not entirely incorrect, yet in some ways it remains incomplete. A closer look at history reminds us that antagonism between China and the United States is not unprecedented. In the 1950s and 1960s, the two countries engaged in an intense strategic competition for status and influence in Asia, one that occasionally burned hot, as it did when they clashed on the Korean Peninsula or more indirectly in Vietnam. This Cold War–era rivalry saw a complex network of competing alliances and partnerships, principally in Asia. The United States supported Taiwan and South Korea in bitter disputes with China and its allies, North Korea and the Soviet Union. This rivalry terminated in the 1970s primarily due to Beijing’s decision to counter a growing Soviet menace and the United States’ decision to pursue China as a potential partner for its own rivalry with the Soviet Union. But the existence of a period of intense U.S.-Chinese tension and competition provides a helpful baseline of comparison. What requires explanation is not the fact that the United States and China are engaged in a rivalry but the difference between today’s rivalry and that of the Cold War. What distinguishes the rivalry today from that of the earlier period is both the closer parity in relative power—albeit still more potential than real—between the two countries and the comprehensiveness, complexity, and systemic nature of the disputes between them. Paradoxically, these features make the current rivalry potentially far more threatening to the United States, despite the fact that so far U.S.-China relations have remained peaceful, and even though the U.S. and Chinese militaries fought each other in the Korean War. The dangerous potential of the current rivalry ultimately owes to the risk that China could rise to the position of global system leader and subordinate the United States accordingly. As has happened in previous power transitions, China as a system leader could exploit existing arrangements to its benefit and to the detriment of the outgoing leader, the United States. Due to the enormous rewards that accrue to a systemic leader and the high costs for the state that loses this position**,** struggles for global leadership have historically proved to be especially destructive. The possibility that China and the United States could find themselves in a similar struggle, while unlikely at this point, cannot be ruled out given the reality of the relative decline in U.S. power and the concomitant increase in Chinese comprehensive national power. At the most basic level, this fact may be measured superficially by the U.S. share of world GDP, which eroded from 40% in 1950 to 16% in 2014, adjusted for purchasing power parity. Over the same period, China’s share expanded from around 5% to 17%.26 An important consequence of the narrowing of the gap in comprehensive power has been an intensifying competition for leadership in the international economic and political order. In this way, the popular discussion of the Thucydides trap correctly recognizes the dangers of the U.S.-China competition. This feature contrasts sharply with the previous episode of rivalry. In the 1950s and 1960s, the asymmetry in power meant that the United States and China competed for influence and even clashed militarily in countries along China’s borders, but rarely elsewhere. As a largely rural, impoverished country, China had little stake in the system of global trade promoted by the industrialized West. Excluded from the United Nations, Maoist China also lacked the institutional ability to influence geopolitics and project power much beyond its immediate environs—and even that capability was sorely handicapped. Outside Asia, the United States faced minimal competition from China and generally regarded the Soviet Union as a more pressing threat. By contrast, the current competition features a China fully enmeshed in a political and economic order led by the United States. While generally supportive of this order, China is also seeking to revise aspects of the regional and international order that it regards as obstacles to the country’s revitalization as a great power. The main theater of this competition for influence and leadership is the Asia-Pacific, as it was in the Cold War, but U.S.-China rivalry increasingly is expanding globally. Moreover, unlike the largely military, regional, and ideological Cold War competition, the current contest is far more multifaceted and comprehensive in nature; it includes military, economic, technological, and political dimensions. The following two sections review the state of the competition at both the regional and the global systemic levels. the u.s.-china rivalry at the regional level At the regional level, U.S.-China competition spans the political, economic, and military realms. Politically, the two countries have feuded over the role of liberal values and ideals, a dispute that widened after the 1989 Tiananmen Square massacre. However, the 1996 Taiwan Strait crisis elevated the potential threat of conflict between the two countries and may therefore be regarded as the starting point of the current rivalry. Coinciding with impressive gains in China’s economic and military power following two decades of market reforms, the standoff saw Washington and Beijing deploy military assets to back up their respective positions regarding Taiwan’s right to hold a presidential election, elevating the risk of a clash. Since then, the competition for political influence and leadership has intensified. In 2011, the United States announced its rebalance to Asia, which was aimed in part at shoring up U.S. alliances, partnerships, and influence.27 Although on the surface Washington has abandoned the effort, the Trump administration has reintroduced a vision for Asia’s economic and security order premised on values favorable to U.S. interests.28 The 2017 National Security Strategy stated, for example, that the United States upholds a “free and open Indo-Pacific.”29 Beijing, by contrast, has increased its efforts to advance a vision for a regional order premised on Chinese leadership. In recent years, China has promoted major economic and geostrategic initiatives to deepen Asia’s economic integration through the Belt and Road Initiative, Asian Infrastructure Investment Bank (AIIB), and other initiatives.30 In 2017, China for the first time issued a white paper that outlined the government’s vision for Asia-Pacific security. The paper stated that China takes the advancement of regional prosperity and stability “as its own responsibility.”31 These policies build on directives issued by Xi Jinping in 2013, when he called for policies to bolster China’s attractiveness as a regional leader.32 Economically, the two countries are competing over the evolution of Asia’s economic future—a region anticipated to drive global growth in coming decades. Both countries are also competing to shape the terms of trade. President Trump may have abandoned the Trans-Pacific Partnership (TPP), but his advisers have advocated other measures to shape favorable trade terms.33 Meanwhile, China has stepped up advocacy of the Regional Comprehensive Economic Partnership, a proposed free trade agreement for the region that excludes the United States.34 China also has promoted the AIIB, while the United States and Japan continue to instead support the Asian Development Bank.35 Militarily, the growing arms race and the establishment of rival security institutions stand among the most obvious manifestations of an increasing competition in this domain. China and the United States have designed an array of military capabilities and doctrines partly aimed at each other. The PLA has developed weapons systems to counter potential U.S. intervention in any contingency along China’s periphery, which the United States has in turn sought to counter with its own innovations, such as the Joint Operational Access Concept.36 U.S. secretaries of defense Chuck Hagel and Ashton Carter outlined a “third offset” strategy to compete with China and Russia in military technology.37 To promote regional security, the United States has strengthened its military alliances and partnerships, while China has strengthened ties with Russia and argued that regional security is best protected through the Shanghai Cooperation Organisation, the Conference on Interaction and Confidence Building Measures in Asia, and other Chinese-led institutions. In 2014, Xi indirectly rebuked the United States for seeking to bolster its security leadership in the region, stating that “it is for the people of Asia to uphold the security of Asia.”38

### 3

#### Text: Member nations of the World Trade Organization ought to enforce antitrust laws against pharmaceutical companies blocking generic competition, ban pharmaceutical lobbying of doctors, and eliminate the suit immunity provided to doctors who use patented products.

#### Solves without hurting innovation

Holman 18 (Christopher M., Professor of Law @ University of Missouri-Kansas City School of Law) Inside Views: Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection, 9/21/18, <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> EE

For example, if a drug company is found to have engaged in some anticompetitive activity to block generic competition in the market for the original product once it has gone off patent, then antitrust and competition laws should be invoked to address that problem. If doctors are prescribing an expensive new formulation of a drug that provides little benefit compared to a cheaper, unpatented original product, then that is a deficiency in the market that should be addressed directly, rather than through a broadside attack on follow-on innovation. In short, if is found that secondary patents are being used in a manner that creates an unwarranted extension of patent protection, it is that misuse of the patent system which should be addressed directly, rather than through what amounts to an attack on the patent system itself.

### 4

#### CP Text: 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 and exclusivity protection except for Markush claims.

#### Eliminating Markush claims shreds innovation

Holman JD and PhD 18 (Christopher M. Holman, Professor of Law @ University of Missouri-Kansas City School of Law, PhD in biochemistry from UC Davis; Timo Minssen, Professor of Law at the University of Copenhagen; and Eric M. Solovy, partner at Sidney Austin LLP, JD Harvard Law School, DC Circuit Bar member)

Biotechnology Law Report.Jun 2018.131-161. http://doi.org/10.1089/blr.2018.29073.cmh EE

There is one category of secondary patent discussed in the Guidelines, so-called “selection patents,” which deserves mention in this regard, since the Guidelines improperly suggest an interpretation of the novelty requirement that is entirely inconsistent with established practice and good policy. The Guidelines define a “selection patent” as a patent claiming:

a subgroup of elements … selected from a larger group and claimed on the grounds that a new, unexpected property has been found. For instance, if a Markush claim was admitted in relation to a set of pharmaceutical compounds, the patent owner might later file a new patent application covering one or more of such compounds.80

The Guidelines recommend that selection patents should not be granted, asserting that the “selection of elements included in the disclosed group lacks novelty, such as in the case of compounds disclosed in a prior generic chemical structure or included within a numerical range.”81 To the contrary, it is well-established in multiple jurisdictions that disclosure of a genus of structurally related molecules, either in the context of a Markush claim or otherwise, is not necessarily sufficient to render a subsequent claim directed to one or more species of the genus on the basis of lack of novelty or obviousness.82 The rationale behind this principle of patent law is that, as a practical matter, a paper disclosure of many structurally related molecules does not necessarily provide sufficient direction for one of skill in the art to identify a specific member of the genus possessing a desirable pharmaceutical property, especially a property not shared by most other members of the genus. At the same time, the selection of a specific member or members of a genus that possess a property to a greater degree than most members of the genus can constitute a patentable invention of great benefit to patients.

Identifying this potentially groundbreaking pharmaceutical agent from an astronomical pool of candidates can be like finding a needle in a haystack. Although a disclosure of thousands or millions of chemical compounds might in some hyper-literal sense disclose each compound, practically speaking it does not in any way put society in possession of those rare needles that might provide very real health benefits. It is very easy to disclose on paper that an astronomically large genus is of structurally related molecules, but such a disclosure does not put the public in possession of particular members that have exceptional pharmaceutical properties, which are in many cases only identified through painstaking research.

#### Markush claims are also key to avoiding copycats which kill innovation

Holman 17 (Christopher M., Professor of Law @ University of Missouri-Kansas City School of Law) In Defense of Secondary Pharmaceutical Patents: A Response to the UN's Guidelines for Pharmaceutical Patent Examination Professor of Law @ University of Missouri-Kansas City School of Law 5/12/17 <http://journals.iupui.edu/index.php/inlawrev/article/view/21522> EE

The rationale behind this longstanding practice is that there is a certain degree of predictability in chemistry, and certain substitutions at various sites of a relatively complex core molecular structure can be predicted to result in a molecule that retains the utility of other molecules in the genus that have been synthesized and tested. Given this predictability, there can be a relatively high 40 likelihood that many of the molecules in a claimed genus will share this activity. If an inventor was only permitted to patent molecules that had actually been synthesized and tested, the patent claims would be quite narrow and in many cases quite easy to circumvent. Someone could simply use the disclosure of the patent as a template for designing and synthesizing unpatented analogs sharing the pharmaceutical utility of the claimed molecules. A genus claim 41 encompassing these variations prevents this sort of easy circumvention by a copyist.

Although a million compounds sounds like a lot, it must be recognized that when there are multiple sites for substitution on a complex molecule, and multiple possible substitutions at each of the sites, the number of possibilities grows exponentially. For example, if there are ten sites of substitution, and ten possible substituents at each of the sites, then there are ten to the 10th power, or 10 billion possible drugs that share the same core as the molecules that have been tested and found to be pharmaceutically active. Of course, it is impossible for an inventor to actually synthesize and test anything approaching this number of compounds, but if she is not allowed to obtain a claim encompassing them, a copyist can easily circumvent a narrow patent and develop an analogous molecule to compete with the original inventor. The Guidelines seem to totally disregard the valid policy basis behind the allowance of Markush claims. 42

#### The counterplan competes – it’s a secondary patent

Holman 17 (Christopher M., Professor of Law @ University of Missouri-Kansas City School of Law) In Defense of Secondary Pharmaceutical Patents: A Response to the UN's Guidelines for Pharmaceutical Patent Examination Professor of Law @ University of Missouri-Kansas City School of Law 5/12/17 <http://journals.iupui.edu/index.php/inlawrev/article/view/21522> EE

The heart of the Guidelines is a category-by-category examination of twelve types of pharmaceutical patent claims: Markush claims; selection patents; 4 5 polymorphs; enantiomers; salts; ethers and esters; compositions; doses; 6 7 8 9 10 11 combinations; prodrugs; metabolites; and new medical uses. Patents with 12 13 14 15 claims of this type are sometimes referred to as “secondary” pharmaceutical patents, distinguished from “primary” patents directed toward a novel active ingredient. There are those who consider secondary pharmaceutical patent 16 claims somehow less legitimate and worthy of protection than primary claims, and less necessary for incentivizing pharmaceutical innovation. Some 17 developing countries have sought to curtail their patentability. For example, 18 India excludes from patentability 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. 19 Brazil and South Africa are reportedly considering legislation along similar lines. 20

#### Rising R&D costs mean that pharma is on the brink of losing monetary incentive to innovate

Gassmann et al 16-- Schuhmacher, Alexander, Oliver Gassmann [Professor of Technology management at University of St. Gallen], and Markus Hinder. "Changing R&D models in research-based pharmaceutical companies." Journal of translational medicine 14.1 (2016): 1-11. (AG DebateDrills)

The costs for pharmaceutical R&D increased in the past decades significantly. Munos [[3](https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-0838-4#ref-CR3)] reported an annual inflation-adjusted increase of R&D costs of 8.6 % for the period of 1950–2009 [[3](https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-0838-4#ref-CR3)]. Other studies support this view: while the costs per NME were published to be USD 250 million before the 1990s, the average out-of-the-pocket costs per NME have been calculated to be USD 403 million (2000s) and USD 873 million (2010), respectively [[12](https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-0838-4#ref-CR12), [28](https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-0838-4#ref-CR28), [29](https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-0838-4#ref-CR29)]. The low success rates and the respective costs of failed drug projects are causal for the high out-of-the-pocket costs. In addition, the use of new technologies to reduce the timelines and to increase success rates in drug discovery, such as combinatorial chemistry, DNA sequencing, high-throughput-screening (HTS) or computational drug design, may have further increased R&D costs just as larger clinical trial sizes and better clinical infrastructure. Split to the phases of R&D, Paul et al. [[12](https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-0838-4#ref-CR12)] reported that drug discovery and preclinical development account for 33 % of the total cost per NME (USD 281 million), clinical development (phase I to submission) represents 63 % (USD 548 million) and submission to launch costs 5 % (USD 44 million) of the overall expenditures per NME [[12](https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-0838-4#ref-CR12)]. In view of the long time intervals, these out-of-the-pocket costs add together in extraordinary high capitalized costs of reported of USD 1.778 billion (2010) per NME [[12](https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-0838-4#ref-CR12), [19](https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-0838-4#ref-CR19), [28](https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-0838-4#ref-CR28)]. Such cost calculations do not include all expenditures associated directly and indirectly with drug R&D. Costs for basic research, phase IV trials, regulatory approvals in non-US markets or product life-cycle management need to be added. Exemplified by data from the 2014 CMR Factbook that 25.7 % of all costs of R&D are dedicated to the international roll-out and line extensions, the actual costs per new drug are higher than the analyzed USD 1.778 billion. Potentially, the results provided by Harper [[30](https://translational-medicine.biomedcentral.com/articles/10.1186/s12967-016-0838-4#ref-CR30)] illustrate the real costs, as he analyzed the expenditures per NME launched by leading pharmaceutical companies to be USD 3-12 billion. And he investigated that the top pharmaceutical companies, defined as those that have launched more than four NMEs between 2002–2011, invested more than USD 5 billion per new drug.

#### Secondary patents are vital in producing safe and effective drugs

Holman 18 (Christopher M., Professor of Law @ University of Missouri-Kansas City School of Law) Inside Views: Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection, 9/21/18, <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> EE

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.

#### Secondary patents are necessary to incentivize research of both initial active ingredients and follow on innovations, this controls the internal link to all of their innovation impacts—also competitor litigation controls the negative effects well

Foor 21-- Meredith Foor; JD candidate at University of New Hampshire; “INCENTIVIZING INNOVATION AND RECLAIMING BALANCE IN THE PHARMACEUTICAL INDUSTRY: A CASE FOR SECONDARY PATENTS”; HeinOnline; May 2021; <https://law.unh.edu/sites/default/files/media/2021/05/foor_final.pdf>. (AG DebateDrills)

Patents remain a primary focus for the pharmaceutical industry as a means to protect new drug inventions and to provide an opportunity to recover some of the expended upfront costs of the extensive preclinical and clinical testing phases.76 Primary patents are often robust and serve to initially protect the invention.77 However, this initial patent term is not enough to allow a patent owner to effectively recover from the upfront time lost from the initial filing date and the high likelihood of failure in bringing a new drug product from early stage development to market.78 The FDA’s Hatch-Waxman Act solution of allowing for a patent restoration term, adding up to an additional five years of patent life onto the natural end of the patent, seeks to remedy this initial time lost as a result of the regulatory approval process.79 However, this extension still may not provide for enough time or incentive for brand companies to expend such extensive resources on new product research and development when the chance of failure for bringing a new product through the FDA approval process is so high. This is where the use of secondary patents comes in. The name “secondary patent” leaves the notion in a reader’s mind that these types of patents are not as important as “primary patents.”80 This is not an accurate depiction of the relative connection between primary and secondary patents. Rather, the first patent filed for a product which often covers the new molecule or new active pharmaceutical ingredient is simply referred to as the “primary patent,” while additional patents covering other aspects of the same product or follow-on innovation are referred to as the secondary patents.81 The categorization of primary verses secondary patents arises solely out of the timeline of when the patents for a given drug product are filed and ultimately obtained. However, regardless of the informal category given to the various types of pharmaceutical patents, a patent will not issue unless it satisfies the requirements of patentability as determined by the United States Patent and Trademark Office (USPTO).82 In that sense, an application is required to meet all patentability requirements before the patent will be issued. Therefore, a secondary patent should not be deemed lesser than a primary patent in that respect. It is true that the subject matter of secondary patents may be deemed “weaker.”83 This categorization, however, is based on the idea that it is easier to invalidate and “invent around” these patents in comparison to the patent covering the very specific new molecule or active ingredient itself.84 The categorization should not take away the importance of secondary patents for brand companies or the subject matter covered in the patents. Opponents of secondary patents in the industry suggest that pharmaceutical companies use these patents as a means of extending protection on the initial product itself.85 This argument stems from the idea that secondary patents can essentially be used to double-patent, or patent the exact same invention twice.86 However, as the USPTO will not issue a patent unless the requirements of patentability are met, specifically that the invention must be novel, the existence of secondary patents is not equivalent to double patenting.87 There are also steps that competitors can take to invalidate a patent that it believes to be an attempt at patenting the same idea twice.88 In fact, competitors do take advantage of the opportunities afforded to them to invalidate patents. For example, they often choose to litigate. Because a majority of these litigation challenges target brand companies’ secondary patents, this suggests that competitors are effectively policing the improper use of secondary patents.89 Therefore, there is little evidence that double patenting is as significant an issue as some allege that it may be.

Continuing

Another misconception regarding secondary patents is the idea that the subject matter is but the same original invention covered by the primary patent with a simple and insignificant change.101 This is incorrect. Why would the USPTO grant a patent on an invention that was neither novel nor new, thus not meeting all criteria of patentability? Clearly, in a perfect world, the USPTO would not grant a patent on something that added no innovation to what previously existed. While, from an outside perspective, “pharmaceutical innovation can appear deceptively simple,” in reality, “the path to meaningful follow-on innovation is tremendously challenging, unpredictable, and more often than not results in failure.”102 In addition, breakthroughs have been made by essentially recycling old failed products and attempting to implement them in a new treatment field. Without some sort of incentive to allow for financial gain, why would a company undertake a highly expensive and challenging project that is prone to failure? Secondary patents play a critical role in encouraging companies to face the risk of uncertainty in exploring different applications and means of improving current or failed drug products because they allow brand companies a greater opportunity to recoup their costs, make a profit, and recycle their profits into new groundbreaking research and innovation.

## Case

### Drug Prices

#### 7] They’re just wrong – evergreening doesn’t crowdout innovation – we read green

1AC 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 legislationmay 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.

#### 8] Feldman’s study sucks and patent extensions are necessary for innovation.

**Risch 17** [Michael Risch, 11-21-2017, "Data for the Evergreening Debate," No Publication, <https://writtendescription.blogspot.com/2017/11/data-for-evergreening-debate.html>] //DD PT

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).

#### 9] Companies are collaborating to stop AMR in the squo.

**Jones and Holland 20** [Abigail Jones, Silas Holland, 7-9-2020, "New AMR Action Fund steps in to save collapsing antibiotic pipeline with pharmaceutical industry investment of US$1 billion," BusinessWire, <https://www.businesswire.com/news/home/20200709005154/en/%C2%A0New-AMR-Action-Fund-steps-in-to-save-collapsing-antibiotic-pipeline-with-pharmaceutical-industry-investment-of-US1-billion>] //DD PT

Today, more than 20 leading biopharmaceutical companies [have] announced the launch of the AMR Action Fund, a ground-breaking partnership that aims to bring 2-4 new antibiotics to patients by 2030. These treatments are urgently needed to address the rapid rise of antibiotic-resistant infections – also called antimicrobial resistance, or AMR. The companies have raised so far nearly US$1 billion new funding to support clinical research of innovative new antibiotics that are addressing the most resistant bacteria and life-threatening infections. Through the AMR Action Fund, pharmaceutical companies will join forces with philanthropies, development banks, and multilateral organizations to strengthen and accelerate antibiotic development. The Fund will focus on urgent public health needs. It will provide much needed financial resources, as well as important technical support to help biotech companies bring novel antibiotics to patients. The AMR Action Fund, an initiative of the international body representing the R&D pharmaceutical industry (International Federation of Pharmaceutical Manufacturers & Associations, IFPMA), was announced at simultaneous virtual launch events in Berlin, Germany, and Washington, D.C., USA, with a third event in Tokyo, Japan taking place on July 10. AMR is a looming global crisis that has the potential to dwarf COVID-19 in terms of deaths and economic costs. While tragically the death toll of COVID-19 continues to rise, each year 700,000 people are dying from AMR. In some of the most alarming scenarios, it is estimated that by 2050 AMR could claim as many as 10 million lives per year. “Unlike COVID-19, AMR is a predictable and preventable crisis. We must act together to rebuild the pipeline and ensure that the most promising and innovative antibiotics make it from the lab to patients,” said Thomas Cueni, Director General of the IFPMA, one of the organizers of the new fund. He adds: “The AMR Action Fund is one of the largest and most ambitious collaborative initiatives ever undertaken by the pharmaceutical industry

to respond to a global public health threat”. The world urgently needs new antibiotics, but there are few in the pipeline because of a paradox: despite the huge societal costs of AMR, there is currently no viable market for new antibiotics. New antibiotics are used sparingly to preserve effectiveness, so in recent years, a number of antibiotic-focused biotechs have declared bankruptcy or exited this space due to the lack of commercial sustainability, resulting in the loss of valuable expertise and resources. The consequence is a huge public health need for new antibiotics, but a lack of funding available for antibiotic R&D, particularly the later stages of clinical research. This creates a “valley of death” between discovery and patient access. “With the AMR Action Fund, the pharmaceutical industry is investing nearly US$1 billion to sustain an antibiotic pipeline that is on the verge of collapse, a potentially devastating situation that could affect millions of people around the world,” said David Ricks, Chairman and CEO of Eli Lilly and Company and President of IFPMA. “The AMR Action Fund will support innovative antibiotic candidates through the most challenging later stages of drug development, ultimately providing governments time to make the necessary policy reforms to enable a sustainable antibiotic pipeline.” While the AMR Action Fund is an important step in addressing the challenge of AMR, policymakers across the globe must enact market-based reforms, including reimbursement reform and new pull incentives, to revitalize the antibiotics market and drive sustainable investments in antibiotic R&D. Until then, the biopharmaceutical industry is taking action now to support the current pipeline of antibiotics. With this investment from leading biopharmaceutical companies, the AMR Action Fund will be the largest collective venture ever created to address AMR. The AMR Action Fund will: Invest in smaller biotech companies focused on developing innovative antibacterial treatments that address the highest priority public health needs, make a significant difference in clinical practice, and save lives. Provide technical support to portfolio companies, giving them access to the deep expertise and resources of large biopharmaceutical companies, to strengthen antibiotic development, and support access and appropriate use of antibiotics. Bring together a broad alliance of industry and non-industry stakeholders, [through] including philanthropies, development banks, and multilateral organizations, and help encourage governments to create market conditions that enable sustainable investment in the antibiotic pipeline. The AMR Action Fund expects to invest more than US$1 billion with the support of future partners into a portfolio of companies to address the funding gap for the financing of antibiotic development. The Fund is expected to be operational during the fourth quarter of 2020.

#### 10] Evergreening doesn’t block generics

Holman 18 (Christopher M., Professor of Law @ University of Missouri-Kansas City School of Law) Inside Views: Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection, 9/21/18, <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> EE

“Evergreening” – an Incoherent Concept

Drug innovators are often accused of using secondary patents to “evergreen” the patent protection of existing drugs, based on an assumption that a secondary patent somehow extends the patent protection of a drug after the primary patent on the active ingredient is expired. As a general matter, this is a false assumption — a patent on an improved formulation, for example, is limited to that improvement and does not extend patent protection for the original formulation.

Once the patents covering the original formulation have expired, generic companies are free to market a generic version of the original product, and patients willing to forgo the benefits of the improved formulation can choose to purchase the generic product, free of any constraints imposed by the patent on the improvement. Of course, drug innovators hope that doctors and their patients will see the benefits of the improved formulation and be willing to pay a premium for it, but it is important to bear in mind that ultimately it is patients, doctors, and third-party payers who determine whether the value of the improvement justifies the costs.

#### 11] Evergreening is false – patents legally can’t be extended more than 20 years

Lietzan 20

Erika Lietzan [Law professor at the University of Missouri School of Law, where she researches, writes, and teaches primarily in the areas of FDA regulation, intellectual property, and administrative law], 2020 Fall, “https://www.cato.org/regulation/fall-2020/evergreening-myth”, <https://www.cato.org/regulation/fall-2020/evergreening-myth#three-myths-evergreening> // AK

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, t

he 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.

**12] Their own card isolates alt causes – we read blue**

1AC Arnold Ventures 20 9-24-2020 "'Evergreening' Stunts Competition, Costs Consumers and Taxpayers" <https://www.arnoldventures.org/stories/evergreening-stunts-competition-costs-consumers-and-taxpayers/> (Arnold Ventures is focused on evidence-based giving in a wide range of categories including: criminal justice, education, health care, and public finance)//Elmer

In 2011, Elsa Dixler was diagnosed with multiple myeloma. That August, she was prescribed Revlimid, a drug that had come on the market six years earlier. By January 2012, she went into full remission, where she has remained since. So long as Revlimid retains its effectiveness, she will take it for the rest of her life. “I was able to go back to work, see my daughter receive her Ph.D, and have a pretty normal life,” said Dixler, a Brooklyn resident who is now 74. “So, on the one hand, I feel enormously grateful.” But Dixler’s normal life has come at a steep financial cost to her family and to taxpayers. Revlimid typically costs nearly $800 per capsule, and Dixler takes one capsule per day for 21 days, then seven days off, and then resumes her daily dose, requiring 273 capsules a year. Since retiring from The New York Times at the end of 2017, she has been on Medicare. Dixler entered the Part D coverage gap (known as the donut hole) “within minutes,” she said. She estimates that adding her deductible, her copayment of $12,000, and what her Part D insurance provider pays totals approximately $197,500 a year. Revlimid should have **been subject to competition** from generic drug makers starting in 2009, bringing down its cost by many orders of magnitude. But by obtaining **27 additional patents**, eight orphan drug exclusivities and 91 total additional protections from the U.S. Food and Drug Administration (FDA) since Revlimid’s introduction in 2005, its manufacturer, Celgene, has extended the drug’s **monopoly** **period** **by 18 years** — through March 8, 2028. “I cannot fathom the immorality of a business that relies on **squeezing people with cancer**,” Dixler said, noting her astonishment that Revlimid has obtained orphan drug protections when it treats a disease that is not rare and does not serve a very limited population. She also observed that Revlimid’s underlying drug is thalidomide, which has been around for decades. “They didn’t invent a new drug, rather, they found a new use for it,” she said. “The cost of Revlimid has imposed constraints on our retirement,” Dixler said, “but when I hear other people’s stories, I feel very lucky. A lot of people have been devastated financially.” Revlimid is a case study in a process known as “evergreening” — artificially sustaining a monopoly for years and even decades by manipulating intellectual property laws and regulations. Evergreening is most commonly used with blockbuster drugs generating the highest prices and profits. **Of the roughly 100 best-selling drugs, more than 70 percent have extended their protection** from competition at least once. More than half have extended the protection cliff multiple times. The true scope and cost of evergreening has been brought into sharper focus by a groundbreaking, publicly available, comprehensive database released Thursday by the Center for Innovation at the University of California Hastings College of Law and supported by Arnold Ventures. **The Evergreen Drug Patent Search is the first database to exhaustively track the patent protections filed by pharmaceutical companies**. Using data from 2005 to 2018 on brand-name drugs listed in the FDA’s Orange Book — a listing of relevant patents for brand name, small molecule drugs — it demonstrates the full extent of how evergreening has been used by Big Pharma to prolong patents and delay the entry of generic, lower-cost competition. “Competition is the backbone of the U.S. economy,” said Professor Robin Feldman, Director of the UC Hastings Center for Innovation, who spearheaded the database’s creation. “But it’s not what we’re seeing in the drug industry. “With evergreening, pharmaceutical companies repeatedly make slight, often trivial, modifications to drugs, dosage levels, delivery systems or other aspects to obtain new protections,” she said. “They pile these protections on over and over again — so often that 78 percent of the drugs associated with new patents were not new drugs coming on the market, but existing drugs.” Competition is the backbone of the U.S. economy. But it’s not what we’re **seeing in the drug industry**. Professor Robin Feldman Director of the UC Hastings Center for Innovation In recent decades, evergreening has systematically undermined the Drug Price Competition and Patent Term Restoration Act of 1984, which created the generic drug industry. Commonly known as the Hatch-Waxman Act, it established a new patent and market exclusivity regime in which new drugs are protected from competition for a specified period of time sufficient to allow manufacturers to recoup their investments and earn a reasonable profit. When that protection expires, generic drug makers are incentivized to enter the market through a streamlined regulatory and judicial process. Drug prices typically drop by as much as 20 percent when the first generic enters the market**, and with more than one generic manufacturer, prices can plummet by 80 to 85 percent**. “Hatch-Waxman created an innovation/reward/competition cycle, but it’s been distorted into an innovation/reward/more reward cycle,” Feldman said. “To paraphrase something a former FDA commissioner once said, the greatest creativity in Big Pharma should come from the research and development departments, not from the legal and marketing departments.” Feldman led the development of the Evergreen Drug Patent Search in response to repeated requests from Congressional committees, members of Congress, state regulators and journalists for information about specific drugs and companies. “We want to make it so anyone can have the question about drug protections at their fingertips whenever they want,” Feldman said. “It’s designed to be easy and user-friendly, and to enhance public understanding about how competition may be limited rather than enhanced through the drug patent system.” The **database** was **created through** a painstaking process of **combing** through **160,000 data points** **to examine every instance where a pharmaceutical company added a new drug patent or exclusivity**. “Most of it was done by hand,” Feldman said, “with multiple people reviewing it at every stage. And along the way we repeatedly made conservative choices. **We erred on the side of underrepresenting the evergreen gain** to be sure we were as fair and reasonable as possible.” Among the 2,065 drugs covered in Evergreen Drug Patent Search, there are many examples of the evergreening strategy used by pharma to delay the entry of competition, especially generics, often for widely prescribed drugs, including those used to treat heartburn, chronic pain, and opioid addiction. Nexium Before Nexium, there was Prilosec, a popular drug to treat gastroesophageal reflux disease (GERD). But its patent exclusivity was due to expire in April 2001. In the late 1990s, with a precipitous drop in revenue looming, Prilosec’s manufacturer, AstraZeneca, decided to develop a replacement drug. Using “one-half of the Prilosec molecule — an isomer of it,” the result was Nexium, which received approval in February 2001. Essentially an evergreened version of Prilosec, Nexium’s exclusivity was then extended by more than 15 years, as AstraZeneca received 97 protections stemming from 16 patents. These included revised dosages, compounds, and formulations. Feldman said that tinkering changes such as Nexium’s do not involve the substantial research and development required for a new drug, nor do they constitute true innovations, yet for a decade and a half, patients and taxpayers were forced to pay far more than was warranted for GERD relief. In fact, in 2016 — one year after patent exclusivity expired — Nexium still topped all drugs in Medicare Part D spending, totaling $1.06 billion. Suboxone Use of this combination of buprenorphine and naloxone for treating opioid addiction has exploded in the wake of the opioid epidemic. Since its approval, Suboxone’s manufacturer, Reckitt Benckiser (now operating as Indivior), extended its protection cliff eight times, gaining nearly two extra decades of exclusivity through early 2030. The drug maker gained six patents for creating a film version of the drug — notably around the time protection was expiring for its tablet version. (The therapeutic benefits of the film and tablet are identical.) An earlier version of Suboxone also obtained an orphan drug designation, despite an opioid epidemic that has expanded Suboxone’s customer base to millions of potential customers. Suboxone generates more than $1 billion in annual revenue and ranks among the 40 top-selling drugs in the U.S. Truvada When Truvada, commonly referred to as PrEP, was approved in 2004, this HIV-prevention drug was a breakthrough. But 16 years later — and 14 years after its original exclusivity was to expire — it retains its monopoly status. Truvada’s manufacturer, Gilead, has received 15 patents and 120 protections since it came on the market, extending its exclusivity for more than 17 years, until July 3, 2024. In countries where generic Truvada is available, PrEP costs $100 or less per month, compared to $1,600 to $2,000 in the U.S. As a result, Truvada is unaffordable to many people **who need protection from HIV**. Barred from access, they are left vulnerable to infection. “We’re establishing a precedent that a pharmaceutical company can charge whatever it wants even as it allows an epidemic to continue, and the government refuses to intervene,” said James Krellenstein, co-founder of the group PrEP4All. “That should scare every American. If it’s HIV today, it will be another disease tomorrow.” EpiPen First approved in 1987, the EpiPen has saved the lives of countless numbers of people with deadly allergies. But it is protected from competition until 2025 — 38 years after its introduction — because its owner, Mylan, has filed five patents, four since 2010, all involving tweaks to the automatic injector. The actual medication used, epinephrine, has existed for more than a century — the innovation here is in the delivery device. Because these small changes to the injector have maintained its monopoly for so long, the cost of an EpiPen package (containing two injectors) has risen from $94 when Mylan purchased the device to between $650 and $700 today. For many people, especially parents of children with severe reactions to common allergens like peanuts, EpiPen’s increasing price tag imposes an onerous financial burden. What Can Be Done As the Evergreen Drug Patent Search makes clear, the positive impact of Hatch-Waxman has been steadily and severely eroded by a regulatory system vulnerable to increasingly sophisticated forms of manipulation. “You might say that the patent and regulatory system has been weaponized,” Feldman said. “When billions of dollars are at stake, there’s a lot of money available to look for ways to exploit the legal system. And companies have become adept at this, as our work has found.” There are several key steps that Congress could take to restore the balance between innovation and competition that is the key to a successful prescription drug regulatory process. These may include: Imposing restrictions on the number of patents that prescription drug manufacturers can defend in court to discourage the use of anticompetitive patent thickets. Limiting the patentability of so-called secondary patents — which don’t improve the safety or efficacy of a drug — through patent and exclusivity reform. Reforming the 180-day generic exclusivity, which can currently be abused to block other competitive therapies. “**The Evergreen Drug Patent Search provides the publicly available, evidence-based foundation that defines the extent of the problem**, and it can be used to develop policies that solve the problem of anti-competitive patent abuses,” said Kristi Martin, VP of Drug Pricing at Arnold Ventures. “Our incentives have gotten out of whack,” Martin said. “The luxury of monopoly protection should only be provided to innovations that provide meaningful benefits in saving lives, curing illnesses, or improving the quality of people’s lives. It should not be provided to those gaming the system. If we can change that, we can save consumers, employers, and taxpayers many billions of dollars while increasing the incentives for pharmaceutical companies to achieve breakthroughs."

12] **Alt causes -- evergreening doesn't extend patent for the original product**

**Holman 20** [Chris Holman, Senior Fellow for Life Sciences & Senior Scholar @ Center for Intellectual Property x Innovation Policy, Professor at the University of Missouri-Kansas City School of Law. "Why Pharmaceutical Follow-On Innovation Should Be Eligible For Patent Protection", Geneva Network, 2-7-2020, accessed 9-5-2021, https://geneva-network.com/research/why-pharmaceutical-follow-on-innovation-should-be-eligible-for-patent-protection/] HWIC

Drug innovators are often accused of using secondary patents to “evergreen” the patent protection of existing drugs, based on an assumption that a secondary patent somehow extends the patent protection of a drug after the primary patent on the active ingredient is expired. As a general matter, this is a false assumption — a patent on an improved formulation, for example, is limited to that improvement and does not extend patent protection for the original formulation.

Once the patents covering the original formulation have expired, generic companies are free to market a generic version of the original product, and patients willing to forgo the benefits of the improved formulation can choose to purchase the generic product, free of any constraints imposed by the patent on the improvement. Of course, drug innovators hope that doctors and their patients will see the benefits of the improved formulation and be willing to pay a premium for it, but it is important to bear in mind that ultimately it is patients, doctors, and third-party payers who determine whether the value of the improvement justifies the costs.

Of course, this assumes a reasonably well-functioning pharmaceutical market. If that market breaks down in a manner that forces patients to pay higher prices for a patented new version of a drug that provides little real improvement over the original formulation, then it is the deficiency in the market which should be addressed, rather than the patent system itself.

For example, if a drug company is found to have engaged in some anticompetitive activity to block generic competition in the market for the original product once it has gone off patent, then antitrust and competition laws should be invoked to address that problem. If doctors are prescribing an expensive new formulation of a drug that provides little benefit compared to a cheaper, unpatented original product, then that is a deficiency in the market that should be addressed directly, rather than through a broadside attack on follow-on innovation. In short, if is found that secondary patents are being used in a manner that creates an unwarranted extension of patent protection, it is that misuse of the patent system which should be addressed directly, rather than through what amounts to an attack on the patent system itself.