# 1NC

### 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 all” 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

### 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" \o "Definition of 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: The 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.

#### The PIC avoids the link to the innovation disad

Holman 17 (Christopher M.,) 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 Guidelines provide “recommendations” as to how patent examiners should examine these secondary pharmaceutical patent claims in a manner that would, according to the author of the Guidelines, “protect public health and promote access to medicines.” The recommendations generally call for 21 heightened patentability requirements, which, if implemented, would essentially deny patent protection to various types of pharmaceutical innovation that are currently afforded patent protection. The Working Paper has been widely cited 22 and used as the basis of arguing that heightened requirements of patentability should be applied to pharmaceutical inventions. No doubt the release of the 23 finalized Guidelines will serve to add more fuel to the fire.

One of the primary means by which the objective of the Guidelines would be accomplished is through a more rigorous application of the nonobviousness/inventive step requirements of patent law. In particular, the Guidelines postulate that many forms of pharmaceutical innovation are inherently routine, and that absent some sort of exceptional circumstance they should be treated as obvious/non-inventive, and hence unpatentable. In my experience, 24 though, the Guidelines’ assumption that many types of pharmaceutical inventions are inherently obvious and undeserving of patent protection is incorrect and based on an oversimplified view of how these inventions come about. This Article provides an evidence-based response to the Guidelines that refutes, or at least qualifies, some of the significant conclusions and recommendations set forth by its author.

I. MARKUSH CLAIMS

The Guidelines define a “Markush claim” as a patent claim which “consist[s] of a generic chemical structure with multiple alternatives that allow for the protection, under a single patent, of several variants of a claimed invention,” often encompassing “several million molecules.” The Working Paper came out 25 strongly against such patent claims, recommending that Markush claims “covering a large range of compounds should not be allowed.” This radical 26 recommendation seems to have been based upon a mistaken belief that it would be impossible to perform a prior art search for a claim encompassing so many permutations, with the Working Paper asserting, “Given that a search of prior art for millions of compounds is virtually impossible, the search of the patent office and the corresponding patent grant should be limited to what has been actually assessed and supported by the examples provided in the specification.” 27

In fact, such searches are performed routinely; it is part of the job description of a patent examiner working in the area of pharmaceutical chemistry. A Markush claim is defined by a central structural core, and it is possible for a patent examiner to use a chemical search tool to search for any molecules in the prior art that include that central core. If none can be found, it can be concluded that the 28 prior art does not encompass the large genus of molecules sharing that common core. Alternatively, if there are some molecules in the prior art that have that 29 core, they can be identified in the search and the examiner can assess whether the Markush group defined by the claim includes any members that overlap with this prior art. In short, this alleged inability of patent examiners to perform adequate 30 prior art search with Markush claims simply does not acknowledge the existence of chemical search tools that are available and used every day by patent examiners.

The author of the Guidelines apparently became aware of these tools after publication of the Working Paper, and added a couple of sentences in the Guidelines acknowledging their existence. But the Guidelines maintain that 31 these tools “do not permit a complete and accurate assessment,” and assert that “[s]everal computer-based tools may be required for a comprehensive retrieval, but their use is complex and they do not guarantee accurate results.” Somewhat 32 surprisingly, the Guidelines still retain the original language asserting that it is “virtually impossible to make prior art searches to establish novelty and inventive step for thousands or millions of compounds,” but at least the document has dropped the Working Paper’s recommendation that would have barred patent protection for any claim covering a “large range of compounds.” Significantly, 33 the Guidelines do not provide any evidence supporting their assertion that chemical search tools “do not permit a complete and accurate assessment” of the prior art, nor do they explain why a patent examiner with expertise in chemistry would not be expected to be able to effectively use “complex” computer-based tools. 34

In any event, the Guidelines maintain that the “coverage of the patent should be limited to the claimed embodiments that are actually enabled by the disclosure in the specification,” implying that the Guidelines would accept the patentability 35 of a Markush claim if all constituents covered by the claim are “actually enabled.” This recommendation might be fine, and entirely consistent with the current standard, depending upon what the author of the Guidelines means by the term “actually enabled.” Under U.S. law, a claim is only valid if it is “enabled” 36 (in the legal sense) across its full scope, and this would apply to Markush claims as much as to any other claim. However, there is no requirement under U.S. law 37 that an inventor has actually synthesized and characterized each and every molecule falling within the scope of the claim. So long as the inventor has 38 provided sufficient disclosure that would enable one of skill in the art to make and use the full scope of the invention without engaging in undue instrumentation, it is possible for a claim to be enabled even though it covers thousands or even millions of compounds, the vast majority of which have never been synthesized. 39

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

Holman 17 (Christopher M.,) 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

#### Secondary patents are key to pharmaceutical innovation – they read the impacts for us

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 bracketed for ableism

Pharmaceutical development is prolonged and unpredictable, and frequently a safe and effective drug occurs only as a result of follow-on innovation occurring long after the initial synthesis and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be just as critical to the development of drugs as a patent on the active ingredient itself.

The Benefits of Follow-On Innovation

The criticism of patents on follow-on pharmaceutical innovation rests on an assumption that follow-on innovation provides little if any benefit to patients, and merely serves as a pretense for extending patent protection on an existing drug. In fact, there are many examples of follow-on products that represent significant improvements in the safety-efficacy profile. For example, the original formulation of Lumigan (used to treat glaucoma) had an unfortunate tendency to cause severe hyperemia (i.e., redeye), and this adverse event often lead patients to stop using the drug, at times resulting in blindness. Subsequent research led to a new formulation which largely alleviated the problem of hyperemia, an example of the type of follow-on innovation that significantly benefits patients but that which would be discouraged by a patent regime that does not reward follow-on innovation.

Follow-on pharmaceutical innovation can come in the form of an extended-release formulation that permits the drug to be administered at less frequent intervals than the original formulation. Critics of secondary patents downplay the significance of extended-release formulations, claiming that they represent nothing more than a ploy to extend patent protection without providing any real benefit to patients. In fact, the availability of a drug that can be taken once a day has been shown to improve patient compliance, a significant issue with many drugs, particularly in the case of drugs taken by patients with dementia or other cognitive [patterns] ~~impairments~~. Extended-release formulations can also provide a more consistent dosing throughout the day, avoiding the peaks and valleys in blood levels experienced by patients forced to take an immediate-release drug multiple times a day.

Other examples of improved formulations that provide real benefits to patients are orally administrable formulations of drugs that could previously only be administered by more invasive intravenous or intramuscular injection, combination products that combine two or more active pharmaceutical agents in a single formulation (resulting in improved patient compliance), and a heat-stable formulation of a lifesaving drug used to treat HIV infection and AIDS (an important characteristic for use in developing countries with a hot climate).

“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. 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. Compatibility with TRIPS The heightened requirements of patentability proposed in the Guidelines not only pose a threat to important follow-on pharmaceutical innovation, but if they were to be adopted could constitute noncompliance with certain international treaties, including in particular the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”), which the 164 Members of the World Trade Organization (WTO) have agreed to abide by. The TRIPS Agreement requires WTO Members to provide certain minimum levels of protection for patentable inventions, thus placing substantive limitations on the ability of WTO Members to raise the bar for patentability. The TRIPS Agreement in no way sanctions subject matter-specific heightened requirements of patentability; to the contrary, the antidiscrimination provision in the TRIPS Agreement affirmatively precludes such measures. Unfortunately, this point is all too often lost in discussions of international and domestic patent policy. Best Practices for Evaluating the Patentability of Follow-On Pharmaceutical Inventions Patentable Subject Matter In Patentability Standards my co-authors and I endorse what we believe to be the proper standards for assessing the patentability of follow-on pharmaceutical innovation, which are essentially the same standards currently being applied in the US, Europe and other nations in compliance with the TRIPS Agreement. As a general matter, inventions arising out of follow-on pharmaceutical innovation, and in particular the categories of “secondary” invention identified in the Guidelines, should be deemed patentable subject matter so long as the various substantive requirements of patentability, including novelty, non-obviousness, and practical utility are satisfied. Although the US Supreme Court’s 2012 Mayo decision appears to have rendered many diagnostic inventions patent ineligible in the United States, the Court explicitly noted that the decision was not intended to adversely affect the patent eligibility of new methods of using drugs, and the patent eligibility of drugs and drug improvements remains generally noncontroversial in the US. In particular, the Guidelines’ recommendations that new methods of using a drug should be presumptively treated as patent ineligible “discoveries,” and that drug metabolites are not patent eligible because they can be produced by physiological processes, should be rejected. An inventive method of using a drug to treat disease is a significant advance in medicine, not a mere “discovery,” and it is a mistake to conflate naturally-occurring metabolites with drug metabolites, which as a general matter are not naturally-occurring molecules and which can in many instances constitute important contributions to medicine in and of themselves. Utility / Industrial Application The requirement of utility/industrial application likewise should generally not be an issue for follow-on pharmaceutical innovation, since by their nature these inventions involve a new form or mode of use of a pharmaceutically active chemical entity of known therapeutic potential. It is important to emphasize that compliance with the utility requirement does not require a showing that the follow-on invention provide some beneficial utility not otherwise provided by the prior art. If a follow-on pharmaceutical invention does not provide any significant benefit over the prior state-of-the-art, regulatory authorities and a well-functioning market should ensure that the patent will not significantly impact access to medicine. Novelty Under the TRIPS Agreement, an invention can be denied patent protection if, as of the effective filing date, it is not novel (i.e., new) relative to the “prior art,” as defined by statute and case law in domestic systems. The prior art consists of publications and other public disclosure of the invention, and under some circumstances encompasses certain non-public uses and offers for sale. Significantly, in order to have effect the prior art generally must enable one skilled in that field of technology to make and use a claimed invention without engaging in undue experimentation. For example, the generic disclosure of a large group of molecules comprising some common structural core does not necessarily destroy the novelty of each and every molecule encompassed by that disclosure. The rationale behind this approach, which is well-established in jurisdictions such as the US and Europe, is that while a generic disclosure can easily be defined so as to encompass millions and even billions of individual molecules, it does not meaningfully enable the identification, synthesis, and clinical use of a specific molecule falling within the genus that is later found to provide some specific utilitarian benefit not shared by other members of the group. The Guidelines would upset the status quo by declaring patents directed to inventions of this type (referred to in the Guidelines to as “selection patents”) as generally invalid for lack of novelty. But if a paper disclosure encompassing a large group of molecules, the vast majority of which have never been made or tested, is deemed sufficient to render every molecule falling within the group unpatentable, the incentive for drug companies to invest in identifying and developing a potentially safe and effective pharmaceutical compound falling within the group will be severely dampened. Identifying a specific molecule with the safety and efficacy profile required of a successful human therapeutic is a veritable search for a needle in a haystack, and without the potential for patent protection in cases in which a valuable needle is recovered too many haystacks will remain inadequately searched. Nonobviousness This brings us to what most would consider to be the most fundamental and important requirement of patentability, the nonobviousness requirement (i.e., the requirement that an invention embody an inventive step). Not surprisingly, the Guidelines focus heavily on the nonobviousness requirement, recommending that patent offices interpret and apply the requirement in a manner that would effectively render most follow-on pharmaceutical innovation presumptively unpatentable; some categories of follow-on innovation, such as a new polymorph with improved properties, or an isolated enantiomer that does not cause the adverse effects associated with the racemate, would be treated as per se obvious and thus entirely excluded from patent protection. These recommendations are based on an oversimplified and highly abstract understanding of pharmaceutical research, and fail to take into account the unpredictability and technical challenges inherent to the research and development of follow-on pharmaceutical innovation. The criterion for compliance with the nonobviousness requirement is straightforward when stated in the abstract: a claimed invention satisfies the requirement if, and only if, as of the relevant date, i.e. the effective filing date, the invention would not have been obvious to a person of skill in that area of technology, given the state-of-the-art at that time. In practice, the nonobviousness/inventiveness inquiry is highly fact-specific, decided on a case-by-case basis in view of the state-of-the-art at the time of the invention, the knowledge and skill of those working in the field at that time, the extent to which those working in the field would have been motivated to try to make the invention, and the unpredictability associated with that area of technology during the relevant timeframe. The question of compliance with the nonobviousness requirement must focus on the specifics of the invention at hand, rather than relying on the broad categorization of entire categories of invention as either per se or presumptively obvious, the approach advocated by the Guidelines. In assessing whether an invention would have been obvious at the time it was made, it is important to avoid the well-established tendency towards hindsight bias. In retrospect, once an invention has been made and proven successful, there is an inherent tendency of humans to look back and think “I could have thought of that.” This is particularly problematic in the context of follow-on pharmaceutical innovation, where it is tempting to assume that a new formulation or new method of using a drug would have been “obvious to try,” once that formulation or method has been made, tested, and proven safe and effective. When viewed in the abstract, by a person not actually engaged in pharmaceutical research and development, follow-on pharmaceutical innovation can appear deceptively simple. However, the path to meaningful follow-on innovation is tremendously challenging, unpredictable, and more often than not results in failure. This explains why so many courts and patent offices around the world have explicitly found patents directed to follow on pharmaceutical innovations nonobvious and patentable. An invention should only be deemed obvious if the prior art would have motivated one of skill in the art to attempt that invention and would have created a reasonable expectation of success in the attempt. It is not enough to merely show that the skilled person could have attempted the invention; the question is whether that person would have been motivated to make the attempt. In some cases, invention can lie in the identification and solution of a previously unidentified problem. In other cases, the problem is well known, but the solution requires the inventor to overcome technical challenges that stymied contemporaries in their attempts to solve the problem. Sometimes an invention occurs when the inventor tries an approach that runs entirely counter to conventional wisdom, ultimately proving that conventional wisdom to have been wrong. Defense of Secondary Patents provides numerous examples of inventions of this type, explaining how courts have determined such inventions to be nonobvious based on the specific factors at play in each individual case. Concluding Thoughts Patent law is primarily concerned with rewarding and enhancing the creation of useful inventions. It is not an instrument that has been specifically designed to address crucial problems relating to ethics, access, health, competition and human rights policies. This is particularly true for the bio-pharmaceutical sector. It is therefore crucial that patent offices and courts continue to assess the inventiveness of all inventions, including inventions arising out of follow-on pharmaceutical innovation, based on the specific features of that invention when compared to the relevant prior art, rather than adopting the sort of technology-specific presumptions against patentability endorsed by the Guidelines. In cases where there are legitimate concerns that patents are being misused in a manner that restricts access to medicine, then that misuse should be addressed directly, rather than through a broadside attack on the patenting of follow-on pharmaceutical innovation in toto.

If the patent system is being misused in a manner that is anticompetitive, then antitrust and competition laws should be invoked to address the problem directly. If certain specific types of patent enforcement activities are deemed problematic, they too can be addressed directly. The US patent statute, for example, already provides an exemption from liability for doctors who use a patented method of medical treatment. This addresses concerns about doctors potentially being sued without depriving medical innovators of patents (which would still be enforceable against a competing medical device company, for example). It would be a mistake to upset the delicate balance of innovation policy embodied in the current consensus patent regime – to do so poses a grave risk of greatly diminishing the pipeline of future medicinal breakthroughs.

#### Stopping Evergreening kills patent innovation

Christensen 20 [Connor Christensen, "The Evergreen Forests of Insulin Patents", Awakenwfu, The Creative Journal of Contemporary Bioethics, 9-14-2020, https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/, accessed: 9-7-2021.] //CHSTM and Lex VM

A potential solution to prevent patent evergreening would be to modify the “inventiveness” standard required to obtain a new patent on drugs.[[27]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn27) By modifying this standard, the goal would be to stop non-inventive and commonly practiced pharmaceutical techniques from receiving patent protection.[[28]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn28) Moreover, each incremental improvement must be worth the burden on the consumer, especially in a country where the price of insulin has reached unconscionable levels.[[29]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn29) Therefore, to be considered inventive, the newer formula or methodology should be demonstratively safer or clearly more efficacious.[[30]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn30) Increasing the scrutiny would help control drug companies receiving patents on non-inventive, incremental improvements on insulin while still rewarding them for making sizable leaps forward.[31] Further, increasing the “inventiveness” standard would also encourage generic drug companies to enter the market. Previously, generic companies were precluded from producing generic insulins because patents protected the original formulas for such long periods of time that they were obsolete when it became possible to make a generic version.[[32]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn32) These obsolete versions of insulin were not viewed as a worthwhile investment to generic drug companies, so the market has been mostly devoid of generic versions.[[33]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn33) However, generic drug companies have shown some interest in creating generic versions of the next-generation of insulin. Reducing evergreening by raising the inventiveness standard required for new insulin patents could be enough to make manufacturing generics a worthwhile investment.[[34]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn34) Affording greater scrutiny to the issue of whether an incremental improvement is truly “inventive” is just one piece of the solution to reducing the price of insulin to affordable levels. Evergreens are a symbol of vitality; the irony is tangible that something of the same name can be depriving people of life.

Reductions in protections kill medical innovation, economic

### 5

#### CP Text – the United States of America should

#### pass the Affordable Drug Manufacturing Act

#### Donate all extra drugs to low-income countries

#### Dedicate more money to innovation

#### Create a Pharma Innovation Fund to reward companies for therapeutic drugs, cost reducing innovations dan reward those who prove patents to be invalid

#### ADMA solves high prices

Scott 18 Dylan Scott [grew up in Ohio, lived in Las Vegas for a year and moved to Washington in 2011. I cover health care and other domestic policy.], 12-20-2018, "Elizabeth Warren’s ambitious new bill to lower generic drug prices, explained," Vox, <https://www.vox.com/policy-and-politics/2018/12/20/18146993/elizabeth-warren-2020-election-drug-prices-bill> DD AG  
The two lawmakers are targeting generic drugs — knockoff versions of brand-name medications that have lost their patent protections — specifically in their legislation. Generic drugs are supposed to lower drug prices by introducing cheaper alternatives to the brand-name version. But the generic drug industry has come under a lot of scrutiny in recent years, both for hiking generic prices and becoming the target of a historic lawsuit for anti-competitive practices. The system is often not working as intended.

Here’s what Warren and Schakowsky would propose to do: Under limited circumstances, the federal government would produce a more affordable generic version of certain drugs. These are the scenarios when the feds could start manufacturing their own medications:

* If no company is producing a generic version of the drug
* If only one or two companies are producing a drug and there is either a price hike or a drug shortage
* If only one or two companies are producing a drug, the price makes it difficult for some patients to afford, and the World Health Organization classifies it as an “essential medicine”

The bill allows the federal government to either produce the drugs itself or contract an outside company to do it. It would set “fair” prices to cover the costs of making the drugs. They also want the federal government to start producing insulin, which helps treat diabetes (which tens of millions of Americans have) and has seen its prices triple or so over the past decade.

“This proposal could be a helpful intervention for those generic drugs that have recently seen price spikes or are in shortage,” Rachel Sachs, who follows the drug pricing debate at Washington University in St. Louis, told me.

I heard the same from others — “an intriguing idea” as Craig Garthwaite, a health economist at Northwestern University, said.

Major hospitals had the same idea. They’ve set up a new nonprofit drug company, along with some philanthropic groups, that would produce drugs under similar circumstances as the Warren-Schakowsky bill. This is one of the hot ideas in health care right now.

There are some questions, of course, starting first and foremost with how well equipped the government is to make medications. The Food and Drug Administration previously forced the National Institutes of Health to shut down its drug manufacturing facilities over quality concerns — though this legislation notably allows the federal government to contract with private companies to do the actual drug producing.

#### Drug prices will drop significantly bc of prizes

Hollis 04

Aidan Hollis [Dr. Aidan Hollis is Professor in Economics at the University of Calgary, and President of Incentives for Global Health, a US-based NGO focused on the development of the Health Impact Fund proposal], 10 June 2004, “An Efficient Reward System for Pharmaceutical Innovation”, [https://www.who.int/intellectualproperty/news/Submission-Hollis6-Oct.pdf //](https://www.who.int/intellectualproperty/news/Submission-Hollis6-Oct.pdf%20//) AK

Prices of medicines under this proposal would fall to approximately the average cost of production. Based on experience with drugs facing generic competition today, this implies that patented drug prices would decrease by on average 50% to 80%. This would obviously be beneficial for consumers and insurers, with total savings in the US of on the order of $100bn annually. Globally, savings might be on the order of $200bn.25 Aside from the reduction in total expense to consumers, there would be a welfare gain from increased consumption of lower-priced medicines. The deadweight loss (DWL) from the current patent system is certainly immense in pharmaceutical markets. The gains from pricing drugs at approximately the average cost of production could easily be valued at $100bn, and gains in terms of saved lives would likely be very large.

### Case

#### 1] Neg turns on innovation aren’t lies – they’re the most qualified and key to testing things like the aff’s evidence

#### 2] Their ev is not causal on drug prices – this Hoban card just says generics aren’t accessible in low income countries, but doesn’t isolate evergreening as the root cause – even the lift mode ev is about people dying bc of expensive meds but the aff doesn’t solve that. The amin card is trash and is only about one cancer med lol

#### 3] Arnold Ventures--evergreening may create monopolies over specific drugs but not the drug market in general--that encourages innovation of new unpatented techniques or looking into more drugs which is good and what 1AC Hotez talks about--turns case and means they have zero internal link

#### 4] Radhakrishnan--Only warrant is “pharma companies don’t spend a lot on R&D” which 1] is not true, the ev says its 1/6 which is a ton for big companies 2] is non-unique

#### 5] Evergreening is just good – on things like insulin, epi pens and stuff wouldn’t exist without evergreening oops

#### 6] 1AR theory is bad and is irresolvable – their responses to my counter interp will always be new which makes you have to flip a coin to decide who wins. Worst case it’s just drop the arg. Don’t punish us for potential nc abuse

#### 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.

#### 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, the PTO will use a statutory formula to extend one patent claiming the product to compensate partially for the lapse of patent life during premarket testing and regulatory review. There is no other mechanism by which a patent might be extended. In particular, a patent on one invention — no matter when it expires — does not extend the patent on another invention.

#### 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.

#### The purpose of evergreening is to make money—medical advances are direct effects of the money big pharma makes.

Collier 13

Roger Collier (consultant specializing in health care policy issues, CEO of national healthcare consulting firm, Principal-in-Charge off KPMG’s national health and welfare consulting practice); “Drug patents: the evergreening problem”; CMAJ Vol. 185, Issue 9; June 11, 2013; <https://www.cmaj.ca/content/185/9/E385/tab-e-letters>; EMJ

“Typically, when you evergreen something, you are not looking at any significant therapeutic advantage. You are looking at a company’s economic advantage,” says Dr. Joel Lexchin, a professor in the School of Health Policy and Management at York University in Toronto, Ontario. “The response from the brand side is that they are trying to protect their markets so they can further invest in R&D [research and development]. And even if they make a modification to a drug, doctors are still quite able to prescribe the generic version of the older product. Having said that, the brand-name companies put an awful lot of money into marketing the newer version, and that marketing is designed to affect what doctors do.” Evergreening has been a hot topic of late because of the recent ruling by India’s Supreme Court to refuse to grant Swiss pharmaceutical company Novartis a patent for a new version of its cancer drug Gleevec (imatinib mesylate), or Glivec, as it’s known in some countries. Novartis claims the drug is more easily absorbed into the blood and, considering it is used to fight leukemia, that is enough of an improvement to warrant patent protection. But India’s trade and industry minister, Anand Sharma, has defended the decision, and was quoted by Agence France-Presse as saying it was “absolutely justified under the law” and that India’s patent law “does not accept evergreening.”

#### Squo solves—current patents check innovation and prevent evergreening.

Parker and Mooney 07

Scott Parker (senior associate in the Intellectual Property Group at Simmons & Simmons\*) and Kevin Mooney (partner in the Intellectual Property Group at Simmons & Simmons); Journal of Commercial Biotechnology, London Vol. 13, Iss. 4; August 7, 2007: 235. DOI:10.1057/palgrave.jcb.3050066; <https://www.proquest.com/docview/232906488/BEB34E662F134C80PQ/3>; EMJ

\*Simmons & Simmons is recognised worldwide as a pre-eminent law firm for the life sciences. It is Simmons &Simmons policy not to act for generic manufacturers in relation to patent expiry matters.

In summary, therefore, the patent system is inherently adapted to reflect how much innovation in fact takes place (by way of improvements to existing technology) and to prevent 'evergreening'. It allows the use of 'old' technology while protecting (and thus providing incentives for) improvements to that technology. Another factor to be taken into account in any debate on the patenting of 'minor variations' is that it is not only the company that owns the patents covering the originator product that can patent improvements thereto. Other companies (including generics) can (and do) do this, with the consequence that there may be a number of companies having similar products (some of which may for a variety of reasons be better suited to particular patients) and healthy competition in the marketplace.

#### growth, and knowledge building for the future – negative turns are Goldlocks – they explain that the aff is just wrong – we have the most qualled authors

McDole and Ezell 04/29 – Jaci McDole is a senior policy analyst covering intellectual property (IP) and innovation policy at ITIF. She focuses on IP and its correlations to global innovation and trade. Her work includes ITIF’s Innovate4Health Initiatives (2017–2019) and A Covid-19 TRIPS Waiver Makes No More Sense for Copyrights Than It Does for Patents (2021). McDole comes to ITIF from the Institute for Intellectual Property Research, an organization she cofounded to study and further robust global IP policies. Stephen J. Ezell is ITIF vice president for Global Innovation Policy. He focuses on science, technology, and innovation policy as well as international competitiveness and trade policy issues. He is the coauthor of Innovating in a Service Driven Economy: Insights Application, and Practice (Palgrave McMillan, 2015) and Innovation Economics: The Race for Global Advantage (Yale 2012). The Information Technology and Innovation Foundation (ITIF) is an independent, nonprofit, nonpartisan research and educational institute focusing on the intersection of technological innovation and public policy. Recognized by its peers in the think tank community as the global center of excellence for science and technology policy, ITIF’s mission is to formulate and promote policy solutions that accelerate innovation and boost productivity to spur growth, opportunity, and progress; April 29, 2021; “Ten Ways IP Has Enabled Innovations That Have Helped Sustain the World Through the Pandemic”; <https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through> //advay

Innovation can—and does—happen anywhere and at any time. As society ground to a halt in 2020, innovators around the world worked tirelessly to develop treatments, vaccines, and solutions to COVID-19 pandemic-related challenges. From personal protective equipment (PPE) to treatments and vaccines to autonomous delivery robots to remote and social distancing solutions for the workplace, intellectual property (IP) played an indispensable role in enabling research, development, and commercialization of many of the innovations meeting the challenges of the pandemic. IP enables start-ups to gain access to much-needed capital. IP gives innovators the confidence to invest in research and development (R&D) and provides incentives for commercialization. Indeed, it is difficult to innovate without the protection of ideas.

Despite this, some—particularly anti-business IP opponents—have blamed IP rights for a host of problems, including limited access to therapeutics, vaccines, and biotechnology. They offer seemingly simple solutions—weaken or eliminate IP rights—and innovation will flow like manna from heaven. Eliminating IP rights might accelerate the diffusion of some pre-existing innovations, but it would absolutely limit future innovations. Innovators, a bit like Charlie Brown kicking the football held by Lucy, would be wary of trusting governments who might say, “Well, this time we won’t take away your IP rights, so go ahead and invest large amounts of time and money.” Given the nature of COVID-19, nations around the world cannot afford to take this risk. Future pandemics and other challenges for which we will need to rely on IP-protected innovations to overcome are near certain to arise.

Moreover, the blame game usually ignores the real, underlying problems. For access to innovations to fight COVID-19, especially biotechnology, vaccines, and therapeutics, the underlying problems are regulatory delays and a lack of adequate and appropriate manufacturing infrastructure.1 The lack of infrastructure has resulted in supply chain bottlenecks in places where few are currently equipped to handle the manufacturing requirements.2 Meanwhile, regulatory delays have prevented vaccines, therapeutics, and diagnostics from entering certain markets.3

To better understand the role of IP in enabling solutions related to COVID-19 challenges, this report relies on 10 case studies drawn from a variety of nations, technical fields, and firm sizes. This is but a handful of the thousands of IP-enabled innovations that have sprung forth over the past year in an effort to meet the tremendous challenges brought on by COVID-19 globally. From a paramedic in Mexico to a veteran vaccine manufacturing company in India and a tech start-up in Estonia to a U.S.-based company offering workplace Internet of Things (IoT) services, small and large organizations alike are working to combat the pandemic. Some have adapted existing innovations, while others have developed novel solutions. All are working to take the world out of the pandemic and into the future.

The case studies are:

Bharat Biotech: Covaxin

Gilead: Remdesivir

LumiraDX: SARS-COV-2 Antigen POC Test

Teal Bio: Teal Bio Respirator

XE Ingeniería Médica: CápsulaXE

Surgical Theater: Precision VR

Tombot: Jennie

Starship Technologies: Autonomous Delivery Robots

Triax Technologies: Proximity Trace

Zoom: Video Conferencing

As the case studies show, IP is critical to enabling innovation. Policymakers around the world need to ensure robust IP protections are—and remain—in place if they wish their citizens to have safe and innovative solutions to health care, workplace, and societal challenges in the future.

THE ROLE OF INTELLECTUAL PROPERTY IN R&D-INTENSIVE INDUSTRIES

Intangible assets, such as IP rights, comprised approximately 84 percent of the corporate value of S&P 500 companies in 2018.4 For start-ups, this means much of the capital needed to operate is directly related to IP (see Teal Bio case study for more on this). IP also plays an especially important role for R&D-intensive industries.5

To take the example of the biopharmaceutical industry, it is characterized by high-risk, time-consuming, and expensive processes including basic research, drug discovery, pre-clinical trials, three stages of human clinical trials, regulatory review, and post-approval research and safety monitoring. The drug development process spans an average of 11.5 to 15 years.6 For every 5,000 to 10,000 compounds screened on average during the basic research and drug discovery phases, approximately 250 molecular compounds, or 2.5 to 5 percent, make it to preclinical testing. Out of those 250 molecular compounds, approximately 5 make it to clinical testing. That is, 0.05 to 0.1 percent of drugs make it from basic research into clinical trials. Of those rare few which make it to clinical testing, less than 12 percent are ultimately approved for use by the U.S. Food and Drug Administration (FDA).7

In addition to high risks, drug development is costly, and the expenses associated with it are increasing. A 2019 report by the Deloitte Center for Health Solutions concluded that since 2010 the average cost of bringing a new drug to market increased by 67 percent.8 Numerous studies have examined the substantial cost of biopharmaceutical R&D, and most confirm investing in new drug development requires $1.7 billion to $3.2 billion up front on average.9 A 2018 study by the Coalition for Epidemic Preparedness found similar risks and figures for vaccines, stating, “In general, vaccine development from discovery to licensure can cost billions of dollars, can take over 10 years to complete, and has an average 94 percent chance of failure.”10 Yet, a 2010 study found that 80 percent of new drugs—that is, the less than 12 percent ultimately approved by the FDA—made less than their capitalized R&D costs.11 Another study found that only 1 percent (maybe three new drugs each year) of the most successful 10 percent of FDA approved drugs generate half of the profits of the entire drug industry.12

To say the least, biopharmaceutical R&D represents a high-stakes, long-term endeavor with precarious returns. Without IP protection, biopharmaceutical manufacturers have little incentive to take the risks necessary to engage in the R&D process because they would be unable to recoup even a fraction of the costs incurred. Diminished revenues also result in reduced investments in R&D which means less research into cancer drugs, Alzheimer cures, vaccines, and more. IP rights give life-sciences enterprises the confidence needed to undertake the difficult, risky, and expensive process of life-sciences innovation secure in the knowledge they can capture a share of the gains from their innovations, which is indispensable not only to recouping the up-front R&D costs of a given drug, but which can generate sufficient profits to enable investment in future generations of biomedical innovation and thus perpetuate the enterprises into the future.13

#### All critiques of evergreening are wrong—it’s essential to encourage competition in the market, and improvements come in increments.

Thomas 09

John R. Thomas (Georgetown Law Center faculty, Visiting Scholar at the Congressional Research Service, inaugural Thomas Alva Edison Visiting Scholar at the U.S. Patent and Trademark Office);

Although the practice of evergreening has attracted considerable criticism, many observers believe these critiques are misplaced. Indeed, some consider the term “evergreening” to be inappropriate, and even derogatory in nature.62 They explain that the patent laws promote both original and improvement inventions, that most technological advance occurs incrementally, that improvements may be developed by competitors of the original innovator, that many improvement patents cover advances that are of considerable medical significance, and that patents on improvements may not impede the ability of competitors to market products that were covered by expired patents on original technologies. This report reviews these assertions in turn. First, these observers note that the patent system allows patents to be obtained on both original and improvement technologies. As a result, the patent law encourages the development of both kinds of inventions. They also explain that under the Patent Act, each invention must fulfill a number of requirements in order to be subject to patent protection. Among these criteria are that the invention must be novel,63 nonobvious,64 and fully disclosed in an application submitted to the USPTO.65 These statutory standards are applied neutrally to each kind of invention, whether it may be characterized as an “original” (such as a medication that has never been previously approved by the FDA) or an “improvement” (such as a new formulation of a known medication). Patent law experts believe that these legal standards appropriately recognize that most technological progress occurs on an incremental basis. Attorney Ivar Kaardal explains that “most patents ... are granted for incremental, or even insignificant, technological advances.”66 Some observers believe that, on an individual or collective basis, patents on more marginal improvements may provide the public with valuable sources of technological information. As Jeanne C. Fromer, a member of the Fordham Law School faculty, states: while there are a rising number of patents for incremental technical advances, which individually might not be commercially or informationally valuable, the collectivity of incremental advances provides essential information for further innovation in many areas… Some commentators also believe the critique that many “evergreen” patents represent trivial variations of earlier technologies is misplaced. They assert that many patented improvements provide significant practical benefits. For example, a new formulation may make a known medication easier to use, leading to greater patient compliance, or cause fewer side effects.68 Observers also note that the developer of the “original” product is not always the same entity as the developer of “improvement” technologies. Sometimes competitors of the “original” patent proprietor, including generic drug companies, develop and patent the improvements.69 The ability of any innovator to obtain a patent is said to encourage competition among different firms, both in innovation and in the marketplace.70