# 1NC

## 1

#### Interpretation – the plan must directly reduce intellectual property rights for medicine

#### Violation: The plan doesn’t reduce an existing IPR but creates a new restriction, e.g. “by limiting drug innovators to one market exclusivity of their choice for their drug”

#### Vote neg for limits: there can be a thousand plans that create new restrictions which result in intellectual property right restriction. There’s no way to predict affs if they can tangentially result in ip reduction. Evaluate the plan text in a vacuum—it isn’t a reduction of an IPR, so they literally don’t defend the resolution which is the only stasis for limits and predictability.

#### Topicality should be a voting issue evaluated through competing interpretations—reasonability invites arbitrary judge intervention that takes the debate out of the hands of the debaters. Pre-round prep has already been skewed which means the only remedy is to drop the debater.

## 2

#### The TRIPs Council should vote to reduce intellectual property protections to reduce intellectual property protections for medicines by limiting drug innovators to one market exclusivity of their choice for their drug, amending TRIPs to mandate it

#### The United States should:

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

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

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

#### Counterplan competes ---

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

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

member nations

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

Sociology (1995)

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

Times, Sunday Times (2015)

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

Times, Sunday Times (2012)

Definition of 'nation'

nation

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

COUNTABLE NOUN

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

#### 2] Immediacy

#### Ought and should are used interchangeably.

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

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

#### “Should” is immediate

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

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

[CONTINUES – TO FOOTNOTE]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## 3

#### Economy’s recovering now – Delta and inflation are challenges but surmountable

Sully 8/19 - Evan Sully, 8/19/21, Reuters, U.S. leading indicator points to further economic recovery in July, https://www.reuters.com/world/us/us-leading-indicator-points-further-economic-recovery-july-2021-08-19/ WJ

(Reuters) -A gauge of future U.S. economic activity increased in July, suggesting the economy continued to expand from the recession caused by the coronavirus pandemic even in the face of a resurgence in cases fueled by the Delta variant.

The Conference Board on Thursday said its index of leading economic indicators (LEI) rose 0.9% last month to 116.0. Economists polled by Reuters had expected an increase of 0.8%.

Even though the U.S. economy is forecast to grow this year at its fastest pace since the 1980s, there are signs the recovery could be cooling off. Supply-chain bottlenecks continue to slow manufacturing growth, and consumer sentiment plummeted in early August to a decade-low as Americans gave faltering outlooks on everything from personal finances to inflation and employment.

Meanwhile, consumer price increases slowed in July, the Labor Department said last week, but inflation overall remained at a historically high level amid supply-chain disruptions as well as stronger demand for travel-related services.

"The U.S. LEI registered another large gain in July, with all components contributing positively," said Ataman Ozyildirim, the Conference Board's senior director of economic research. "While the Delta variant and/or rising inflation fears could create headwinds for the U.S. economy in the near term, we expect real GDP (gross domestic product) growth for 2021 to reach 6.0% year-over-year, before easing to a still robust 4.0% growth rate for 2022."

The LEI's coincident index, a measure of current economic conditions, rose 0.6% in July after increasing 0.4% in June.

But the lagging index increased 0.6% last month after being unchanged in June and increasing 0.8% in May.

"Even with more moderate growth in the second half of the year, the economy’s momentum remains encouraging with constraints on labor supply easing, a trove of excess savings still waiting to be drawn down, and strong vaccine numbers that will insulate the economy from the worsening health situation more so than prior waves," said Mahir Rasheed, U.S. economist at Oxford Economics.

#### Pharma collapses without strong IP protections

Buckland 17 - Danny Buckland (award-winning journalist who writes about health, general features and news, shortlisted for the prestigious Mind Media Awards for his work covering mental health issues), April 26, 2017, “Patents are lifeblood of pharmas”, https://www.raconteur.net/legal/intellectual-property/patents-are-lifeblood-of-pharmas/ WJ

Pharmaceutical companies are staffed by ranks of attorneys, and the intellectual property (IP) specialist is now a pivotal position in the research and development (R&D) cycle that keeps a company profitable and new drugs flowing to patients.

Tighter regulatory frameworks and even tighter purse strings controlled by healthcare systems are putting the squeeze on pharma returns and limiting R&D budgets. Figures from analysts Deloitte in 2016 reported projected return on investment was at a six-year low while development costs had risen by almost a third.

The litany of market changes is vexing for the industry. The generation of blockbuster drugs, with massive returns, has ended, national healthcare budgets are receding, traditional management methods are being challenged and new players, such as electronics and software companies, are entering the arena.

“For pharmaceutical companies, the patent system is its lifeblood and it simply wouldn’t survive without it,” says Simon Wright, a patent attorney with J A Kemp and chairman of the Chartered Institute of Patent Attorneys’ life sciences committee. “The cost of getting a product to market is high and there is a high failure rate, so you are not going to get investment unless you can protect your product and innovation. Quite frankly, it would all collapse without good IP.”

#### Bipoharma collapse causes economic meltdown – it’s far worse than previous recessions

Howrigon 17 -- Ron Howrigon “(President and Founder of Fulcrum Strategies. He earned a Bachelor's degree in Business Administration from Western Michigan University and a Master's in Economics from North Carolina State University, focusing in the area of Health Economics) http://www.kevinmd.com/blog/2017/01/health-care-crash-u-s-economy.html, January 19 2017, WJ

In recent history, the U.S. economy has experienced the near catastrophic failure of two major market segments. The first was the auto industry and the second was the housing industry. While each of these reached their breaking point for different reasons, they both required a significant government bailout to keep them from completely melting down. What is also true about both of those market failures is that, looking back, it’s easy to see the warning signs. What happens if health care is the next industry to suffer a major failure and collapse? It’s safe to say that a health care meltdown would make both the automotive and housing industries’ experiences seem minor in comparison. While that may be hard to believe, it becomes clear if you look at the numbers. The auto industry contributes around 3.5 percent of this country’s GDP and employs 1.7 million people. This industry was deemed “too big to fail” which is the rationale the U.S. government used to finance its bail out. From 2009 through 2014, the federal government invested around $80 billion in the U.S. auto industry to keep it from collapsing. Health care is five times larger than the auto industry in terms of its percentage of GDP, and is ten times larger than the auto industry in terms of the number of people it employs. The construction industry (which includes all construction, not just housing) contributes about 6 percent of our country’s GDP and employs 6.1 million people. Again, the health care market dwarfs this industry. It’s three times larger in terms of GDP production and, with 18 million people employed in the health care sector, it’s three times larger than construction in this area, too. These comparisons give you an idea of just how significant a portion health care comprises of the U.S. economy. It also begins to help us understand the impact it would have on the economy if health care melted down like the auto and housing industries did. So, let’s continue the comparison and use our experience with the auto and housing industries to suggest to what order of magnitude the impact a failure in the health care market would cause our economy. The bailout in the auto industry cost the federal government $80 billion over five years. Imagine a similar failure in health care that prompted the federal government to propose a similar bailout program. Let’s imagine the government felt the need to inject cash into hospital systems and doctors’ offices to keep them afloat like they did with General Motors. Since health care is five times the size of the auto industry, a similar bailout could easily cost in excess of $400 billion. That’s about the same amount of money the federal government spends on welfare programs. To pay for a bailout of the health care industry, we’d have to eliminate all welfare programs in this country. Can you imagine the impact it would have on the economy if there were suddenly none of the assistance programs so many have come to rely upon? When the housing market crashed, it caused the loss of about 3 million jobs from its peak employment level of 7.4 million in 1996. Again, if we transfer that experience to the health care market, we come up with a truly frightening scenario. If health care lost 40 percent of its jobs like housing did, it would mean 7.2 million jobs lost. That’s more than four times the number of people who are employed by the entire auto industry — an industry that was considered too big to be allowed to fail. The loss of 7.2 million jobs would increase the unemployment rate by 5 percent. That means we could easily top the all-time high unemployment rate for our country. OK, now it’s time to take a deep breath. I’m not convinced that health care is fated to unavoidable failure and economic catastrophe. That’s a worst-case scenario. The problem is that at even a fraction the severity of the auto or housing industry crises we’ve already faced, a health care collapse would still be devastating. Health care can’t be allowed to continue its current inflationary trending. I believe we are on the verge of some major changes in health care, and that how they’re implemented will determine their impact on the overall economic picture in this country and around the world. Continued failure to recognize the truth about health care will only cause the resulting market corrections to be worse than they need to be. I don’t want to diminish the pain and anguish that many people caught up in the housing crash experienced. I think an argument can be made, though, that if the health care market crashes and millions of people end up with no health care, the resulting fallout could be could be much worse than even the housing crisis.

#### Extinction

Tønnesson 15 Stein Research Professor, Peace Research Institute Oslo; Leader of East Asia Peace program, Uppsala University, 2015, “Deterrence, interdependence and Sino–US peace,” International Area Studies Review, Vol. 18, No. 3, p. 297-311

Several recent works on China and Sino–US relations have made substantial contributions to the current understanding of how and under what circumstances a combination of nuclear deterrence and economic interdependence may reduce the risk of war between major powers. At least four conclusions can be drawn from the review above: first, those who say that interdependence may both inhibit and drive conflict are right. Interdependence raises the cost of conflict for all sides but asymmetrical or unbalanced dependencies and negative trade expectations may generate tensions leading to trade wars among inter-dependent states that in turn increase the risk of military conflict (Copeland, 2015: 1, 14, 437; Roach, 2014). The risk may increase if one of the interdependent countries is governed by an inward-looking socio-economic coalition (Solingen, 2015); second, the risk of war between China and the US should not just be analysed bilaterally but include their allies and partners. Third party countries could drag China or the US into confrontation; third, in this context it is of some comfort that the three main economic powers in Northeast Asia (China, Japan and South Korea) are all deeply integrated economically through production networks within a global system of trade and finance (Ravenhill, 2014; Yoshimatsu, 2014: 576); and fourth, decisions for war and peace are taken by very few people, who act on the basis of their future expectations. International relations theory must be supplemented by foreign policy analysis in order to assess the value attributed by national decision-makers to economic development and their assessments of risks and opportunities. If leaders on either side of the Atlantic begin to seriously fear or anticipate their own nation’s decline then they may blame this on external dependence, appeal to anti-foreign sentiments, contemplate the use of force to gain respect or credibility, adopt protectionist policies, and ultimately refuse to be deterred by either nuclear arms or prospects of socioeconomic calamities. Such a dangerous shift could happen abruptly, i.e. under the instigation of actions by a third party – or against a third party. Yet as long as there is both nuclear deterrence and interdependence, the tensions in East Asia are unlikely to escalate to war. As Chan (2013) says, all states in the region are aware that they cannot count on support from either China or the US if they make provocative moves. The greatest risk is not that a territorial dispute leads to war under present circumstances but that changes in the world economy alter those circumstances in ways that render inter-state peace more precarious. If China and the US fail to rebalance their financial and trading relations (Roach, 2014) then a trade war could result, interrupting transnational production networks, provoking social distress, and exacerbating nationalist emotions. This could have unforeseen consequences in the field of security, with nuclear deterrence remaining the only factor to protect the world from Armageddon, and unreliably so. Deterrence could lose its credibility: one of the two great powers might gamble that the other yield in a cyber-war or conventional limited war, or third party countries might engage in conflict with each other, with a view to obliging Washington or Beijing to intervene.

## Case

#### Evergreening incentivizes innovation: turns the aff

Chris Holman, Febuary 7, 2020, "Why Pharmaceutical Follow-On Innovation Should Be Eligible For Patent Protection," Geneva Network, <https://geneva-network.com/research/why-pharmaceutical-follow-on-innovation-should-be-eligible-for-patent-protection/> //PHS AS

Why Protect Follow-On Innovation? The attack on secondary pharmaceutical patents is based in part on the flawed premise that follow-on innovation is of marginal value at best, and thus less deserving of protection than the primary inventive act of identifying and validating a new drug active ingredient. In fact, follow-on innovation can play a critical role in transforming an interesting drug candidate into a safe and effective treatment option for patients. A good example can be seen in the case of AZT (zidovudine), a drug ironically described in the Guidelines as the “first breakthrough in AIDS therapy.” AZT began its life as a failed attempt at a cancer drug, and it was only years later that its potential application in the fight against AIDS was realized. Follow-on research resulted in a method-of-use patent directed towards the use of AZT in the treatment of AIDS, and it was this patent that incentivized the investment necessary to bridge the gap between a promising drug candidate and a safe, effective, and FDA-approved pharmaceutical. Significantly, because of the long lag time between the first public disclosure of AZT and the discovery of its use in the treatment of AIDS, patent protection for the molecule per se was unavailable. In a world where follow-on innovation is unpatentable, there would have been no patent incentive to invest in the development of the drug, and without that incentive AZT might have languished on the shelf as simply one more failed drug candidate. Other examples of important drugs that likely never would have been made available to patients without the availability of a “secondary” patent include Evista (raloxifene, used in the treatment of osteoporosis and to reduce the risk of invasive breast cancer), Zyprexa (olanzapine, used in the treatment of schizophrenia), and an orally-administrable formulation of the antibiotic cefuroxime. Pharmaceutical development is prolonged and unpredictable, and frequently a safe and effective drug occurs only as a result of follow-on innovation occurring long after the initial synthesis and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be just as critical to the development of drugs as a patent on the active ingredient itself.

#### 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.

#### TURN - Evergreening allows for increased accessibility and innovation

Chris Holman, Febuary 7, 2020, "Why Pharmaceutical Follow-On Innovation Should Be Eligible For Patent Protection," Geneva Network, <https://geneva-network.com/research/why-pharmaceutical-follow-on-innovation-should-be-eligible-for-patent-protection/> //PHS AS

Inside View: Why Pharmaceutical Follow-On Innovation Should Be Eligible For Patent Protection By [Christopher M. Holman](https://cpip.gmu.edu/about/our-team/chris-holman/)\* Despite the important role of intellectual property rights in incentivizing innovation, the patenting of pharmaceutical innovation is frequently accused of impeding access to medicine. Criticism of the prevailing patent regime has focused in particular on patents directed towards follow-on innovation, i.e., innovation that seeks to improve upon existing pharmaceuticals and their use in treating patients. Patents on follow-on innovation are often derided as “secondary” patents, with the implication that the underlying inventions are somehow lesser in nature than the subject matter claimed in “primary” patents, i.e., the drug active ingredient per se. While implicitly acknowledging the legitimacy of primary patents, critics of so-called secondary patents contend that patents on follow-on innovation allow drug innovators to “evergreen” their products, i.e., to extend the period of patent exclusivity beyond the expiration of any original patent on the drug active ingredient, and in doing so contribute to the high cost of drugs, thereby limiting the ability of patients to access the drugs upon which they have come to rely. In 2015, the United Nations Development Programme (UNDP) issued a document entitled [Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective](http://www.undp.org/content/dam/undp/library/HIV-AIDS/UNDP_patents_final_web_2.pdf) (the “Guidelines”), which, in an effort to promote access to medicines, recommends that courts and patent offices implement newly heightened patentability requirements for follow-on pharmaceutical innovation that would be uniquely stringent and largely unprecedented. [1](https://geneva-network.com/article/follow-on-innovation/#note-3156-1) In 2017, I challenged many of the assertions made in the Guidelines in an article entitled [In Defense of Secondary Pharmaceutical Patents: A Response to the UN’s Guidelines for Pharmaceutical Patent Examination (“Defense of Secondary Patents”)](https://mckinneylaw.iu.edu/ilr/pdf/vol50p759.pdf), which provides numerous examples of so-called secondary patents that have withstood validity challenges in the courts and patent offices throughout the world and which were directed towards follow-on pharmaceutical innovation clearly meriting patent protection. [2](https://geneva-network.com/article/follow-on-innovation/#note-3156-2) More recently, I teamed up with legal scholars Timo Minssen and Eric Solovy in authoring [Patentability Standards for Follow-on Pharmaceutical Innovation (“Patentability Standards”)](https://www.liebertpub.com/doi/abs/10.1089/blr.2018.29073.cmh), an article that reiterates the important role of follow-on pharmaceutical innovation in addressing compelling human health concerns, and which proposes what we consider to be the appropriate standards and criteria to be applied in assessing the patentability of this sometimes underappreciated aspect of medical innovation. [3](https://geneva-network.com/article/follow-on-innovation/#note-3156-3)

#### No bioweapon threat – development obstacles

Morrow 17 (John, PhD in genetics, University of Washington, authored over 60 peer-reviewed publications reporting original research in genetics, immunology, developmental biology, evolution, cancer biology and animal science, “Bioweapons: An Existential Threat?” March 6, 2017, http://www.newportbiotech.com/pages/blog/entry/48/)

Today, large scale production, storage, protection and field testing of weaponized bacteria or viruses are beyond the abilities of a small group or a terrorist cell. However, a number of countries in the world have demonstrated the ability – and the will – to unleash horrific attacks upon their perceived enemies. They undoubtedly are following the current advances in gene manipulation technology with great interest. For now though, such advances in gene manipulation, while making the process faster, simpler and more accessible, are still quite a challenge to carry out.

CRISPR/Cas9 is the best of a new generation of tools for manipulating genes, and is being used to develop cures for diseases, improve agricultural products and engineer organisms that can carry out a variety of industrial processes. It is undergoing constant improvement, making it faster and easier to employ.

Fortunately, there are many obstacles to the execution of a credible biological warfare program, perhaps the greatest is the uncertainty of the behavior of these agents once released into the environment. In the commercial realm of engineered agricultural products (herbicides, pesticides, fertilizers), all manner of living and inert substances undergo arduous evaluation (usually for years) before they can be released to the environment; yet these new inventions still have phenomenal failure rates.

Given that engineered bacteria and viruses are lethal materials, their handling and use in battle would be extremely risky, and loading them with a burden of genetic modifications could affect their behavior outside of the laboratory in unpredictable ways. In order to be confident that the bioweapon would have its desired effect, it would be essential to have field data, which could require years of testing. Would a terrorist be content to keep deploying flawed product until hitting the motherlode?

#### No extinction from disease – global dispersion, countermeasures, and evolution

Farquhar 17

Sebastian Farquhar is the director of the Global Priorities Project, Masters degree in Physics and Philosophy from the University of Oxford, Project Manager at FHI, John Halstead, DPhil in political Philosophy from St Anne’s College, Oxford, Global Priorities Project, 2017, “Existential Risk Diplomacy and Governance”, https://www.fhi.ox.ac.uk/wp-content/uploads/Existential-Risks-2017-01-23.pdf

For most of human history, natural pandemics have posed the greatest risk of mass global fatalities.37 However, there are some reasons to believe that natural pandemics are very unlikely to cause human extinction. Analysis of the International Union for Conservation of Nature (IUCN) red list database has shown that of the 833 recorded plant and animal species extinctions known to have occurred since 1500, less than 4% (31 species) were ascribed to infectious disease.38 None of the mammals and amphibians on this list were globally dispersed, and other factors aside from infectious disease also contributed to their extinction. It therefore seems that our own species, which is very numerous, globally dispersed, and capable of a rational response to problems, is very unlikely to be killed off by a natural pandemic.

One underlying explanation for this is that highly lethal pathogens can kill their hosts before they have a chance to spread, so there is a selective pressure for pathogens not to be highly lethal. Therefore, pathogens are likely to co-evolve with their hosts rather than kill all possible hosts.39

#### Evergreening reflects an incomplete understanding of the patent system; inventiveness is a pre-req to a second patent and 95% of generics are available

Rory Moore, 7-6-2016, "Opinion: Patent Evergreening," Moore Intellectual Property, <http://www.moorepatent.co.za/opinion-patent-evergreening-a-valid-concern-in-south-africa/#easy-footnote-bottom-5>

The term “evergreening” is used pejoratively to refer to perceived attempts to extend the duration of patent protection by various means. Attempts by patent holders to obtain multiple patents covering different aspects of the same product are characterised by some observers as evergreening. Disapprobation is expressed regarding patents for improved versions of existing products, especially in the pharmaceutical sector. In our view the concept of evergreening is specious, especially in the South African context. It is based on an incomplete understanding of the patent system. South Africa is currently contemplating changes to its patent system. The Department of Trade and Industry published an Intellectual Property Consultative Framework (IPCF) on 6 July 2016.1 The IPCF seeks to promote public health and to balance the interests of the public and industry development by stimulating innovation. One of the proposed changes relates to South Africa’s simple “depositary” patent system whereby patent applications are subjected only to a rudimentary check of the documentary requirements. The IPCF proposes that South Africa do away with its depository system and replace it with infrastructure for the substantive search and examination (SSE) of patent applications. There has been a groundswell of opinion since 2011 advocating for substantive patent examination. The Fix the Patent Laws Coalition was launched in 2011, comprising 15 health institutions in South Africa such as Treatment Action Campaign, Doctors Without Borders and Section 27. The coalition advocates for reform of the South African laws to address issues that block access to affordable medicines in the country. The argument is that a substantive examination will ensure that patents are only granted on real innovations, thus limiting the grant of weak patents. In 2008, a survey was conducted between South Africa and Brazil (which examines patent applications). The statistics showed that South Africa granted 2 442 pharmaceutical patents in 2008 alone while Brazil only granted 278 patents from 2003 to 2008. The argument is that these disparities show that the bulk of South Africa’s patents relate to inventions not worthy of patent protection. It is also argued that the United States and Patent Office and the European Patent Office both rejected approximately 40% of the applications granted by South Africa.2 The calls for substantive examination, and some of the other proposed changes, appear to stem from a perception that pharmaceutical patents have an obstructive impact on the roll-out of health services in South Africa. Philip Stevens of the Geneva Network, a research organisation focusing on health, intellectual property and trade, provides the following insight into concerns relating to pharmaceutical patents:3 “Debates on how to improve healthcare in developing countries often start from the same premise: patents can potentially raise drug prices, so they should be abolished for better public health. “In the early 2000s, this argument drove the campaign against patents on HIV drugs in SA. This month, it anchors new nongovernmental organisation (NGO) campaigns against a proposed European Union (EU)-India Free Trade Agreement and the Regional Comprehensive Economic Partnership in Asia — both of which may include heightened intellectual property provisions. “NGO disquiet about drug patents has even led to the creation of a UN high-level panel on access to medicines…” South Africa’s achievements in the field of healthcare, especially in relation to HIV treatment, are laudable. It is not our intention to oppose the country’s ongoing work to make generic medicines widely and inexpensively available to those in need. However, it is our contention that the government’s proposed “fixes” to the South African patent system will not advance this cause and may in fact hinder it [availability]. The existing South African patent system promotes and encourages the development of both original and improved technologies. As long as an improvement upon a technology includes a new technical step, is non-obvious and is capable of being used in trade, industry or agriculture, such an improvement is eligible for patent protection. Any attempt to “evergreen” an invention by means of obvious and trivial improvements cannot pass muster under the scrutiny of South African patent law, and any such patents, even if granted under South Africa’s depositary system, are susceptible of revocation by the Court of the Commissioner of Patents. Opponents of evergreening sometimes argue along the following lines4: If an originator pharmaceutical firm files a patent application in 2020 claiming an active ingredient, the resulting patent will expire in 2040. If in 2025 that same company files a second, original patent application claiming an extended release formulation of that active ingredient and the application is granted, that second patent will not expire until 2045. However, inventiveness (non-obviousness) will always be a prerequisite for the grant of the second patent (the patent to the extended release formulation). This requirement means that trivial improvements with no value are already excluded by the patent system. If there is nothing inventive about the extended release formulation then a valid patent will not be available. If, on the other hand, there is an inventive step involved then it is appropriate for that new development to be protectable. Why should third party competitors (e.g. generic manufacturers) be empowered to exploit a newly developed, inventive formulation without having made any investment towards its development? In what way does a new and inventive formulation become somehow less so by virtue of the fact that its active ingredient is already known? At such time as the first patent expires, generic drug companies will be able to sell the original release formulation of the pharmaceutical. The marketplace will ultimately decide whether the higher costs associated with the extended release formulation are worthwhile expenditures. Opponents may try to rely on Section 39 of the South African Patents Act, in terms of which a patent for an improvement can be obtained even if the improvement is obvious having regard to the main invention. This argument is unfounded because Section 39 provides that the term of an improvement patent of this type (called a “patent of addition”) cannot extend beyond the date of expiry of the patent for the main invention. John R. Thomas5 has highlighted certain fallacies surrounding the concept of evergreening: “Some commentators … 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. “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. The ability of any innovator to obtain a patent is said to encourage competition among different firms, both in innovation and in the marketplace. “Industry experts further observe that patents on improvement inventions may not block competitors from marketing competing products that were covered by patents that have expired. In this respect, it should be appreciated that the scope of protection provided by a particular patent varies in accordance with the degree of technological advance provided by the patented invention. In particular, a patent that claims a new active ingredient for use in a pharmaceutical typically provides more robust proprietary rights than improvement patents.” There is also a fallacy in the basic underpinning of the argument that patents somehow block healthcare improvements in developing countries. In a 2016 study6, researchers investigated patents and how they affect access to medicines, by counting how many of the World Health Organisation’s (WHO’s) list of essential medicines were subject to patent protection in developing countries. The objective of the report was to identify which of the 375 items on the 2013 Model List of Essential Medicines (MLEM) of the World Health Organization (WHO) (18th edition) were patented and where. The MLEM is a list of medicines considered by WHO experts to be the most important. It was found that where patents were filed, this appeared to be more common in countries where there was market and manufacturing opportunity, namely, middle-income nations with larger populations, higher health spending per capita and pharmaceutical manufacturing capacity. The researchers found the following: (1) Patents for 95% medicines on the MLEM list had expired. The implication is that patents are not relevant to the vast majority of drugs typically used by physicians in developing countries. (2) Owners of patents for medicines either don’t register or do not enforce their patents in the poorest countries. According to report there was “a relative scarcity of patented medicines appearing on the 2013 MLEM and of those patents typically being filed in developing countries.” In summary, if the patent system were to be abolished it would make little difference to the cost or availability of most medicines used in developing countries. Even so, these medicines are frequently unavailable in public health systems. A study by the University of Utrecht in the Netherlands found that, on average, essential medicines were available in public sector facilities in developing countries only 40% of the time.7 According to Philip Stevens:8 “While generic medicines are cheap to make, with no royalties to pay, they are still too costly for most people in developing countries. … The reasons behind the expense and scarcity of essential medicines in developing countries are complex, but failures of governance loom large. Mark-ups along the distribution chain inflate the final price of medicines and include import tariffs, sales taxes, value-added taxes and retailers’ and wholesalers’ margins.” … Dysfunctional medicine supply chain management is another culprit. A 2015 survey by Medecins Sans Frontières (MSF) reported one in three health facilities in South Africa have shortages of crucial HIV and tuberculosis drugs. The drugs are imported in sufficient quantities, but fail to reach patients due to “local logistical and management problems, ranging from inaccurate forecasting to storage or transport issues”, said MSF.” “These are the major influences on access to medicines. Public health would be best served if the political focus were on these issues, rather than patents.” Evergreening cannot hold up to scrutiny as a justification for revisions of the South African patent system. The IPCF’s ambition to provide a substantive patent examination in South Africa is admirable but it will be difficult to implement, both logistically and financially. Patent examiners operate at the cutting edge of technology, meaning that post-graduate qualifications are required. This makes competent examiners expensive to hire even if they can be found in sufficient numbers. The process of examining even one patent application is a long and involved one, and often involves a protracted process of amendment, review, objection, argument, and further amendment. The South African Patent Office is currently only barely able to meet its commitments to the basic depositary system. It has had a long-standing service delivery shortfall relating to its filing service provider, with the result that patents open to public inspection cannot be accessed. Recordals of transactions in patents are behind and, as of the date of writing, some patents filed in 2014 have not yet been accepted despite acceptance being dependent only upon the need to satisfy formal requirements such as the submission of a Power of Attorney. The attempt to introduce a substantive examination is likely to exacerbate the current situation, and indeed may backfire by causing even longer delays in the grant of patents. This is not in the interests of South Africa’s competitiveness and attractiveness to investment. Para. 4.1.2.iv of the IPCF concedes that: “We are conscious that the implementation of [substantive search and examination] SSE like any new administrative procedure may have teething problems. For this reason, CIPC is considering entering into outsourcing arrangements with certain patent offices that are known to be highly efficient. This would be a contingency against the accumulation of inordinate backlogs.” That the European Patent Office rejects 40% of patent applications corresponding to those granted in South Africa is also not a cogent argument. The grant of a patent in South Africa does not preclude an interested party from applying for its revocation. In other words, a person who believes that he or she is entitled to exploit the subject matter of a patent, because he or she believes that the patent is invalid, may apply to the court for revocation of the patent. It is a relatively simple matter to check whether an equivalent European or U.S. patent was refused, or whether the scope of the claims had to be narrowed by comparison with the corresponding South African patent. Parties interested in the subject matter of such a patent may then either apply to court for revocation of the patent, or, since South African patent law adheres closely to global patent law principles, proceed on the understanding that the patent is invalid and that an infringement action on the basis of the patent would either not be in the interest of the patent holder to initiate or, if undertaken, would be likely to fail. An invalid patent cannot be infringed. Conversely, the introduction of a substantive examination cannot and will not stop the grant of valid patents, even for subject matter such as new formulations. Patents which claim new and inventive technical developments will still be valid even if they undergo examination. Thus, there are still going to be patents for secondary or improvement inventions. A patent for a new and inventive method of manufacture of a known drug, or a revised formulation, will still have to be granted. On the other side of the coin, even under South Africa’s existing, non-examining system a patent that fails to claim a new and inventive improvement is invalid even if it is accepted onto the Register. A patent of this type is invalid with or without an examination system in place. Put simply, the introduction of an examination system in South Africa will have no effect on the number of valid patents in South Africa, except in so far as the number of applications filed may decrease because of the increased burden of costs, administrative burden and length of time taken to obtain patents. Far from being an unfavourable feature of the South African patent system, the country’s depositary character is arguably favourable in the context of a developing country. The fact that examination is not substantive means that patents can be granted more quickly and less expensively than in most other countries. Yet quality is retained because the protection conferred by a patent remains constrained to the legal requirements. Indeed, an advantage of the existing South African patent system is that, since substantive decisions on novelty, obviousness, etc. are left to a specialist patent court rather than an examining division at a Patent Office, a more detailed and rigorous consideration of these matters can be undertaken in respect of those patents which are particularly important. The introduction of substantive examination will inevitably increase costs significantly since higher official fees will be payable to finance the examiners’ salary bills, and significant professional fees will become payable to patent attorneys for prosecution through examination (preparing responses to official actions, amending, etc.) Substantive examination will also inevitably expand the timeline from filing to grant significantly. One egregious consequence of this is that many potential patentees will be excluded from the system because of financial limitations. Already, the grant of patents to individual local inventors and SMME’s is a significant financial burden. An examination system will drive the protection of patents even further away from the general population and further into the arms of the large corporations, which become the only entities able to justify the costs of the system and the substantial financial risks that inevitably accompany embarking upon a patent programme. It is not sufficient to argue that financial backing can be sought by inventors. The procedural hurdles to be overcome to secure such funding are not insignificant and the award of the funds is uncertain. Futhermore, even where funding can be secured, it is often set up as part-funding with the inventor still being held responsible for a proportion of the costs. The end result is that, for the citizen of lower or even average income in South Africa a patent is out of reach or not worth the risk. This “innovation chasm” is likely to become deeper and wider with the introduction of an examining division at the Patent Office.