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#### CP text: The member nations of the World Trade Organization should add more stringent requirements for filing secondary patents by requiring secondary patent filers to demonstrate increased efficacy as compared to the original. Solves all your offense by reducing purely strategic patents while permitting R and D for companies.

Newsome 17, A [(JD candidate George Washington School of Law). (2017). Side effects of evergreening may include decreased competition & increased prices in the pharmaceutical industry. AIPLA Quarterly Journal, 45(4), 791-822] Justin

The current framework for evaluating a patent application, particularly the requirements of utility and nonobviousness, is insufficient for evaluating whether a secondary patent should be issued for a drug. Given that courts are tied to the low bar for utility and inconsistent with their application of nonobviousness,1 04 it is necessary to pass legislation creating a new utility requirement tailored to secondary pharmaceutical patents. This Note's Author proposes legislation language as follows: 35 U.S.C. § 106: Patentable Pharmaceutical Inventions

(a) Utility requirement for secondary patent: In the case of a pharmaceutical invention claiming an improvement on a patented invention, the applicant shall demonstrate through clear and convincing evidence in the written description that such invention has increased efficacy as compared to the original.

(b) Increased efficacy defined: As used in part (a), "increased efficacy" refers to a proven improvement in the mechanism of action, as disclosed in the patent claims. 0 5

(c) Mechanism of action defined: As used in part (b), "mechanism of action" refers to the process by which a drug functions to produce a therapeutic effect, as disclosed in the patent claims. 06

Under this legislation, the USPTO could grant a secondary patent only if the new formula's mechanism of action, or production of the intended pharmacological effect, in fact improves upon the patented drug's mechanism of action. For example, because VidaDrug is a chemotherapy drug, the new formula must include a change in the mechanism of action which causes an improvement in the efficacy of the drug's tumor-shrinking abilities to be eligible for a secondary patent. A formula tweak that reduces side effects is insufficient, because the underlying purpose of the drug - to treat cancer - remains unaffected.

Lowell provides some precedent for creating a higher utility standard. 07 This new standard would focus on a drug's overall improved efficacy, rather than a minor tweak in the formula that would mitigate or resolve a previously caused side effect. This standard would require holding the pharmaceutical industry to a higher standard than other industries, which could potentially conflict with the United States' TRIPS Agreement obligations with the WTO.

#### Solves best.

Newsome 17, A [(JD candidate George Washington School of Law). (2017). Side effects of evergreening may include decreased competition & increased prices in the pharmaceutical industry. AIPLA Quarterly Journal, 45(4), 791-822] Justin

Pharmaceutical patents are inherently different from software or manufacturing patents. 144 Pharmaceutical companies create life-saving drugs that carry a very serious benefit for a vulnerable group of consumers - patients. Because of this, the pharmaceutical industry should be held to a higher standard if its companies seek to prohibit affordable generic drugs from coming to the marketplace.

1. An Efficacy-Focused Standard Will Motivate Pharmaceutical Companies to Channel Resources to Creating Real Innovation Pharmaceutical companies argue that patent-life-cycle-management strategies (their preferred name for those tactics described herein as evergreening) are essential to ensuring they recoup R&D costs. 145 However, creation of a standard such as the one proposed here would ensure that pharmaceutical companies are properly incentivized to channel R&D resources to creating measurable change in the drugs, rather than creating minor changes that prolong the time they can profit off of monopolies at the expense of patients. For those industries in which R&D is more productive, like the pharmaceutical industry, "patent procedures should be refined to tighten the relationship between patents and the underlying inventions."14 6
2. A Higher Standard for Secondary Pharmaceutical Patents Will Increase Competition & Lead to Lower Prices The patent system enables pharmaceutical companies to retain market exclusivity for their drugs, allowing them to set high prices without an eye toward competition.1 47 The companies cite the need to recoup R&D costs as the driving factor for their pricing decisions,148 but critics say their main motivation is making a profit.'49 While the pharmaceutical companies' argument may hold weight, high prices for drugs have a negative impact on those patients who need those drugs, but cannot afford them.150 Tightening patent laws to prevent pharmaceutical companies from retaining patent protection for minor changes in their patented drugs will allow other companies to enter the marketplace sooner and drive prices down through competition. 5

# DA

#### Innovation high and evergreening is false – postdates your ev and we have stats

Ezell 20. Stephen Ezell, July 2020, “Ensuring U.S. Biopharmaceutical Competitiveness,” Information Technology and Innovation Foundation, <http://www2.itif.org/2020-biopharma-competitiveness.pdf> sean!

Medicines are critical to health. Since 2000, the FDA has approved more than 500 new medicines. 2 As of 2020, biopharmaceutical companies in the United States have more than 3,400 drugs under clinical development, accounting for almost half of the estimated 8,000 medicines under development globally (1,100 of which are being developed to treat various forms of cancers).3 And while some have asserted that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is that most of the drugs currently under development seek to tackle some of the world’s most intractable diseases, including Alzheimer’s, cancer, and communicable diseases. This includes 130 coronavirus vaccines under development globally as well as 144 active trials of coronavirus therapeutic agents, and another 457 development programs for new therapeutic agents, which the FDA is tracking through its Coronavirus Treatment Acceleration Program.4 Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first of their kind. For instance, in 2014, the FDA’s Center for Drug Evaluation and Research (CDER) approved 41 new medicines (the most since 1996 at that point), many of which were first-in-class medicines, meaning they represent a possible new pharmacological class for treating a medical condition.5 In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases. In 2018, CDER approved a record 59 novel drugs, and in 2019, 48 novel drugs, making 2019 the third-largest approval class in the past 25 years.6 As of 2020, 74 percent of medicines in clinical development in the United States are potentially first-in-class medicines, including 86 percent for Alzheimer’s, 70 percent for various forms of cancer, and 73 percent for cardiovascular diseases

#### The aff is a solution in search of a problem – they eviscerate the utility of follow on innovations and fail to target the root cause of high drug problems.

Holman 20 (Holman, Christopher M. “Why Pharmaceutical Follow-on Innovation Should Be Eligible for Patent Protection.” Geneva Network, 7 Feb. 2020, geneva-network.com/research/why-pharmaceutical-follow-on-innovation-should-be-eligible-for-patent-protection/. [Chris Holman joined C-IP2 as a Senior Scholar in 2014, and he became the Senior Fellow for Life Sciences at C-IP2 in August 2020. He is a Professor at the University of Missouri-Kansas City School of Law, where his primary research focus lies at the intersection of intellectual property and biotechnology. He has published numerous articles in law reviews and scientific publications such as Science, Cell, and Nature Biotechnology, and has authored amicus briefs in a number of important biotechnology patent cases at the Supreme Court and Federal Circuit. In 2008 he was awarded the Daniel L Brenner Faculty Publishing Award for an influential law review article on human gene patent litigation. Prior to becoming a law professor, Holman served as vice-president of intellectual property and patent counsel at several Silicon Valley biotechnology companies and worked as an associate at a major intellectual property law firm. He was also a tenure-track chemistry professor in the California State University system.])//LK [Accessed 8/23/2021]

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

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#### Despite growing rivalry, US-China economic interdependence strong now. Exchange of tech know-how, collaboration science research, and massive US-China STEM pipeline improving relations – but it can easily collapse.

Hass 8/12 [Ryan Hass (Senior Fellow - Foreign Policy, Center for East Asia Policy Studies, John L. Thornton China Center The Michael H. Armacost Chair Chen-Fu and Cecilia Yen Koo Chair in Taiwan Studies Nonresident Fellow, Paul Tsai China Center, Yale Law School), 8-12-2021, "The “new normal” in US-China relations: Hardening competition and deep interdependence," Brookings, <https://www.brookings.edu/blog/order-from-chaos/2021/08/12/the-new-normal-in-us-china-relations-hardening-competition-and-deep-interdependence/> // belle]

The intensification of U.S.-China competition has captured significant attention in recent years. American attitudes toward China have become more negative during this period, as anger has built over disruptions resulting from the COVID-19 pandemic, Beijing’s trampling of Hong Kong’s autonomy, human rights violations in Xinjiang, and job losses to China.

Amidst this focus on great power competition, two broader trends in the U.S.-China relationship have commanded relatively less attention. The first has been the widening gap in America’s and China’s overall national power relative to every other country in the world. The second has been the continuing thick interdependence between the United States and China, even amidst their growing rivalry. Even on economic issues, where rhetoric and actions around decoupling command the most attention, trade and investment data continue to point stubbornly in the direction of deep interdependence. These trends will impact how competition is conducted between the U.S. and China in the coming years.

SEPARATING FROM THE PACK

As America’s unipolarity in the international system has waned, there has been renewed focus on the role of major powers in the international system, including the European Union, Russia, India, and Japan. Each of these powers has a major population and substantial economic weight or military heft, but as my Brookings colleague Bruce Jones has observed, none have all. Only the United States and China possess all these attributes.

The U.S. and China are likely to continue amassing disproportionate weight in the international system going forward. Their growing role in the global economy is fueled largely by both countries’ technology sectors. These two countries have unique traits. These include world-class research expertise, deep capital pools, data abundance, and highly competitive innovation ecosystems. Both are benefitting disproportionately from a clustering effect around technology hubs. For example, of the roughly 4,500 artificial intelligence-involved companies in the world, about half operate in the U.S. and one-third operate in China. According to a widely cited study by PricewaterhouseCoopers, the U.S. and China are set to capture 70% of the $15.7 trillion windfall that AI is expected to add to the global economy by 2030.

The United States and China have been reinvesting their economic gains to varying degrees into research and development for new and emerging technologies that will continue to propel them forward. While it is not foregone that the U.S. and China will remain at the frontier of innovation indefinitely, it also is not clear which other countries might displace them or on what timeline. Overall, China’s economy likely will cool in the coming years relative to its blistering pace of growth in recent decades, but it is not likely to collapse.

DEEP INTERDEPENDENCE

At the same time, bilateral competition between the United States and China also is intensifying. Even so, rising bilateral friction has not – at least not yet – undone the deep interdependencies that have built up between the two powers over decades.

In the economic realm, trade and investment ties remain significant, even as both countries continue to take steps to limit vulnerabilities from the other. For example, Chinese regulators have been asserting greater control over when and where Chinese companies raise capital; Beijing’s recent probe of ride-hailing app Didi Chuxing provides but the latest example. China’s top leaders have been emphasizing the need for greater technology “self-sufficiency” and have been pouring billions of dollars of state capital into this drive. Meanwhile, U.S. officials have been seeking to limit American investments from going to Chinese companies linked to the military or surveillance sectors. The Security and Exchange Commission’s scrutiny of initial public offerings for Chinese companies and its focus on ensuring Chinese companies meet American accounting standards could result in some currently listed Chinese companies being removed from U.S. exchanges. Both countries have sought to disentangle supply chains around sensitive technologies with national security, and in the American case, human rights dimensions. U.S. officials have sought to raise awareness of the risks for American firms of doing business in Hong Kong and Xinjiang.

Even so, U.S.-China trade and investment ties remain robust. In 2020, China was America’s largest goods trading partner, third largest export market, and largest source of imports. Exports to China supported an estimated 1.2 million jobs in the United States in 2019. Most U.S. companies operating in China report being committed to the China market for the long term.

U.S. investment firms have been increasing their positions in China, following a global trend. BlackRock, J.P. Morgan Chase, Goldman Sachs, and Morgan Stanley have all increased their exposure in China, matching similar efforts by UBS, Nomura Holdings, Credit Suisse, and AXA. The Rhodium Group estimates that U.S. investors held $1.1 trillion in equities issued by Chinese companies, and that there was as much as $3.3 trillion in U.S.-China two-way equity and bond holdings at the end of 2020.

One leg of the U.S.-China economic relationship that has atrophied in recent years has been China’s flow of investment into the United States. This has largely been a product of tightened capital controls in China, growing Chinese government scrutiny of its companies’ offshore investments, and enhanced U.S. screening of Chinese investments for national security concerns.

Another area of U.S.-China interdependence has been knowledge production. As U.S.-China technology expert Matt Sheehan has observed, “With the rise of Chinese talent and capital, the exchange of technological know-how between the United States and China now takes place among private businesses and between individuals.” Leading technology companies in both countries have been building research centers in the other. Alibaba, Baidu, and Tencent have all opened research centers in the United States, just as Apple, Microsoft, Tesla, and other major American technology companies rely upon engineering talent in China.

In science collaboration, The Nature Index ranks the joint research between the two countries as the world’s most academically fertile. U.S.-China scientific collaboration grew by more than 10% each year on average between 2015 and 2019. Even following the global spread of COVID-19, American and Chinese experts collaborated more during the past year than over the previous five years combined. This has led to over 100 co-authored articles in leading scientific journals and frequent joint appearances in science-focused workshops and webinars.

China also is the largest source of international students in the United States. In the 2019-20 year, there were over 370,000 Chinese students in the U.S., representing 34% of international students in colleges and universities. Up until now, many of the top Chinese students have stayed in the United States following graduation and contributed to America’s scientific, technological, and economic development. It remains to be seen whether this trend will continue.

COMPETITIVE INTERDEPENDENCE

The scale of American and Chinese interests implicated will likely induce sobriety over time in Washington and Beijing as to how the relationship is managed. The U.S. policy focus for the foreseeable future is not likely to be seeking to “defeat” China or compel the collapse of the Chinese Communist Party. Rather, the focus will be on taking steps at home and with partners abroad to strengthen America’s long-term competitiveness vis-à-vis China. At the same time, American leaders will continue to push their Chinese counterparts to improve the treatment of their citizens. Such efforts are definitional to America’s self-identity as a champion of values.

The dense webs formed by trade, financial, scientific, and academic links between the United States and China will make it difficult for one side to inflict harm on the other without hurting itself in the process. As Joe Nye has written, “America can decouple security risks like Huawei from its 5G telecommunications network, but trying to curtail all trade with China would be too costly. And even if breaking apart economic interdependence were possible, we cannot decouple the ecological interdependence that obeys the laws of biology and physics, not politics.”

President Joe Biden likely will use the challenges posed by China as a spur for his domestic resilience agenda. He is not an ideologue, though, and is unlikely to limit his own flexibility by painting the world with permanent black and white dividing lines. The Biden team knows it will be harder to realize progress on serious global challenges like climate change, pandemics, and inclusive global economic recovery without pragmatic dealings with non-democratic states.

Major near-term improvements to the U.S.-China relationship are unlikely, barring an unexpected moderation in Beijing’s behavior. At the same time, the relationship is also unlikely to tip into outright hostility, barring an unforeseen dramatic event, such as a Chinese act of aggression against an American security partner.

U.S.-China relations are going to be hard-nosed and tense. Neither side is likely to offer concessions in service of smoother relations. At the same time, the balance of interests on both sides likely will control hostile impulses, placing the relationship in a state of hardening competition that coexists alongside a mutual awareness that both sides will be impacted — for good or ill — by their capacity to address common challenges.

#### Plan hurts US-China relations – means China goes back on it’s promise to regulate IP violations and draws in U.S. crackdown.

Shape 2/19 [Steven M. Shape; registered patent attorney and electrical engineer who has represented preeminent technology companies in complex, high-stakes Intellectual Property litigation; 2-19-2021, "IP Law Looms Large Over U.S.-China Relations," No Publication, [https://www.mondaq.com/trademark/1038030/ip-law-looms-large-over-us-china-relations //](https://www.mondaq.com/trademark/1038030/ip-law-looms-large-over-us-china-relations%20//) belle]

The U.S. and China were indisputably the two largest parties in the global trade war that consumed much of the last several years. Particularly between early 2018 and late 2019, it seemed as if one could hardly go a week, if that, without hearing something about tariffs, exports, imports, steel, soybeans, then-President Donald Trump, President Xi Jinping and the like. Accusations regarding violations of Intellectual Property law were among the biggest flashpoints, and ultimately, China announced new regulations concerning IP protection in November 2019 as a conciliatory move. Nearly 14 months later, newly inaugurated President Joe Biden has yet to fully clarify his administration's stance toward China. However, it is inevitable that IP rights and their preservation will factor into negotiations between the two economic giants. A look back at the proposed reforms (and their effects) Reports from CNN at the time claimed that China's prospective IP law reforms focused on making the penalties for IP infringement more strict. It would also put the government's increasingly modernized tech infrastructure to use in the discovery and prosecution of such crimes. Beyond that, the proposal carried few specifics. Although it is unclear whether Beijing's gambit worked as the deciding factor for Washington, it certainly did not fail. The two nations agreed in principle on "Phase One" of a new trade agreement December 12, 2019, per The Washington Post, and formalized the deal about a month later. The U.S. pledged not to impose further tariffs and roll back existing import taxes in return for China's IP reforms and agreement to buy American goods. In the 14 months that followed, so much changed. COVID-19's devastating impact on human life and the global economy made it difficult to gauge the positive effects of the tariff relief or IP reform. A report by the South China Morning Post found that China did not meet its import goal for 2020, with some analysts concluding the Phase One target was unrealistic. On the IP front, a Hong Kong news provider noted that Beijing had drafted some specific guidance to protect pharmaceutical patents, trade secrets and copyrights, but it was unclear how well they were being implemented. Additionally, a January 2021 report by the U.S. Patent and Trademark Office (USPTO) found that Chinese policies which offered subsidies for certain trademark and patent applications helped motivate a glut of fraudulent and bad-faith filings in the last few years. The bigger picture of China's IP law A casual observer or someone just learning of this issue might assume that until recently, China had little or no IP laws on the books. Of course, that is not true. However, there are many factors at play complicating the matter of Chinese IP protection policies. As noted in Harvard Business Review, China is quite strict in certain aspects of IP protection: Beijing allows (and encourages) all businesses to impose non-compete agreements to help protect trade secrets and other IP assets. In addition, according to the National Law Review, two new measures were passed in 2020 specifically to combat bad-faith trademark applications, in addition to the other new guidelines being imposed by the China National Intellectual Property Administration (CNIPA) in accordance with the Phase One agreement. All that said, it would be inaccurate to describe Chinese IP law as thoroughly protective for either domestic or foreign innovators. Along with the aforementioned trademark and patent subsidies, considerable controversy stems from "forced technology transfer" policies. According to the University of Oxford's Business Law Blog, foreign companies looking to do business in China must turn over their technology to local firms or be denied the right to operate within China. This effectively means turning over the blueprints (literal or otherwise) to such technology - which is all but equivalent to surrendering the IP. It creates considerable opportunities for infringement, fraud and corruption. Also, in disputes with foreign firms, some local IP courts still markedly favor domestic organizations. Chinese government representatives often resent such accusations of bias or corruption. In their view, the deals represent friendly agreements between businesses, and courts' decisions are not politically motivated. While Oxford noted that FTT guidelines are not as pervasive now as they were a few years ago, they have yet to disappear altogether. The Biden approach: Not dissimilar, but multilateral If the new U.S. Secretary of the Treasury, Janet Yellen, is to be believed, the Biden administration will not tolerate any signs of lapses in China's IP protections. "We need to take on China's abusive, unfair and illegal practices," Yellen said to the Senate Finance Committee at her confirmation hearings. As reported by Bloomberg, she added, "[China has] been stealing intellectual property and engaging practices that give it an unfair technological advantage, including forced technology transfers. And these . are practices that we're prepared to use the full array of tools to address." Biden had expressed similar sentiments during a December interview with The New York Times. However, he also said that they would work with ally nations to "develop a coherent strategy" for addressing cases of IP infringement and other issues - a stance Yellen echoed before the Senate - instead of taking China on in a unilateral and bellicose manner. This more nuanced approach could yield greater cooperation from Beijing and help repair U.S.-China trade relations, but we will likely not know one way or the other for some time. As we saw with the trade war, conflicts between the U.S. and China can quickly escalate and have ripple effects throughout the world. It would thus be wise for all organizations doing business in China to keep themselves abreast of the country's evolving IP regulations and work with a reliable IP services provider to help establish strong protection for their intangible assets.

#### Maintaining US-China relations key to confidence building, dialogue measures, and address mutual anxieties about nukes -- that prevents nuke war.

CSIS ’13 [CSIS (CSIS is a nonprofit organization headquartered in Washington, D.C. The Center’s 220 full- time staff and large network of affiliated scholars conduct research and analysis and develop policy initiatives that look into the future and anticipate change), March 2013, " Nuclear Weapons and U.S.-China Relations a way forward," Center for Strategic and International Studies, <https://csis-website-prod.s3.amazonaws.com/s3fs-public/legacy_files/files/publication/130307_Colby_USChinaNuclear_Web.pdf> // belle]

The United States has long seen China as a central factor in its strategy in Asia. Since the 1970s, U.S. policy has sought to encourage China’s economic reforms and development and to integrate China into the existing international political and economic order. While hopeful that China will develop into a constructive stakeholder, the United States and much of the Asia-Pacific region share continuing concerns about some aspects of China’s behavior that, it is feared, could undermine regional stability and U.S. interests in the Asia-Pacific.

Unfortunately, significant sources of tension and disagreement between the United States and its allies, on the one hand, and China, on the other, remain. These sources of discord could, in the worst case, lead to conflict. Needless to say, a large-scale conventional war between the United States and China would be incredibly dangerous and likely tremendously damaging. Nuclear war between the two would be devastating for all involved. Even though a conventional war between the two nations currently seems unlikely and nuclear war even more so, the possibility that war could break out, posing dramatic dangers and damage, clearly indicates that active steps should be taken to avoid conflict and successfully manage U.S.-China nuclear dynamics.

Significance and Objectives of U.S.-China Nuclear Relations

Maintaining stability in U.S.-China nuclear relations will be critical to the interests of the United States and those of its allies and security partners in the coming years. The Working Group judges that the nuclear dynamics between the United States and China are relatively stable at this time, primarily because both sides have or will soon have a nuclear deterrent of the size and scope they determine they need, and China appears committed to a relatively restrained posture oriented around a “lean and effective” nuclear force and its no-first-use policy. Yet the Working Group is concerned that the changing conventional military balance of power in the region, the current sources of tension and possible conflict, and the expansion of the quality and quantity of China’s nuclear arsenal raise serious questions about the future stability of U.S-China nuclear relations. The recommendations contained in this report are therefore focused on enhancing nuclear stabil- ity between the United States and China, primarily by advocating a series of both bilateral and unilat- eral policy and posture adjustments that would enhance crisis stability and arms race stability, while also laying the groundwork for future bilateral and multilateral nuclear engagement.

Because the current nuclear dynamics are broadly stabilizing and should be sustained, the Working Group recommends that U.S.-China nuclear relations be oriented toward sustaining these dynamics and avoiding decisions by either side that could erode stability. We therefore recommend a robust but realistically tailored program of engagement and dialogue on nuclear issues that reinforce China’s nuclear restraint and advance U.S. interests in stability, dialogue, transparency, and prog- ress toward arms control. The Working Group recognizes, however, the limited success attempts at dialogue and cooperation have thus far yielded. The Group’s recommendations are therefore de- signed to be ambitious but realistic, and are structured in such a way that, in the event that Beijing is unwilling to engage in earnest along the lines the Group advocates, the United States would be left with a powerful strategic capability and in the strong political position of having proffered a serious, fair-minded path forward in bilateral nuclear weapons relations that China had rebuffed.

The Working Group also recommends that the United States adopt a policy of accepting China’s possession of an assured second-strike nuclear capability, and thus avoid attempting to acquire the capability to negate China’s nuclear retaliatory capabilities. This judgment relies on the fundamental determination that the United States cannot realistically hope to deny China’s second-strike capability, that a failed attempt to deny it would be costly and counterproductive, and that Beijing’s possession of a reliable retaliatory capability promotes stability rather than detracts from it. In addition, this approach could reinforce China’s nuclear restraint. The Working Group is, however, divided on whether the United States should publicly and formally announce this acceptance.

The Working Group believes that some of the concepts associated with the idea of “strategic stability” provide an appropriate framework for U.S.-China engagement on nuclear weapons is- sues, although the specific meaning of the term is the subject of a long-running debate that has never been definitively settled. In order to gain the benefits of strategic stability, the Working Group believes that nuclear relations between the United States and China should emphasize two complementary approaches: crisis stability and arms race stability.

Stability can emerge between the United States and China if each fields forces that are capable of surviving a first strike and if each is able to credibly demonstrate to the other side that its cur- rent and future capabilities are not capable of denying the other side a viable strategic deterrent. As a result, fear of preemption and the need to launch weapons early become irrelevant, either as irri- tants in crisis or as dangers in conflict. In this way, the benefits of deterrence can be retained, while minimizing the chances of nuclear escalation and avoiding a competition in the development of offensive and defensive strategic arms that would intensify uncertainties for both sides.

Both sides could derive value from cooperation on nuclear weapons issues grounded in the stability concept. The United States worries about the composition of China’s nuclear force, China’s views on escalation and plans for nuclear use, and the future trajectory of China’s strategic posture. China, meanwhile, worries about the ability of the United States to deny it a second-strike capa- bility; the scope and sophistication of future U.S. nuclear, conventional prompt global strike, and missile defense programs; and U.S. unwillingness to acknowledge a condition of mutual vulner- ability between the two nations. A stability-grounded model could help address these anxiet- ies—on the U.S. side by providing greater insight into China’s current and future force structure and deeper insight into China’s ways of thinking about nuclear strategy, and on the Chinese side by providing similar insight into U.S. developments and a greater degree of assurance about U.S. acknowledgment of the survivability of the Chinese force. Concurrently, such an approach would have the added benefit of building confidence on both sides, thereby enhancing strategic trust more broadly. Finally, such a model could also provide a satisfactory way in which both nations could see something approximating their current force size, posture, and doctrine as satisfactory and compatible with stability.

#### US-China war causes extinction.

Wittner, PhD, 12

(Lawrence, History from Columbia, Professor Emeritus of History at SUNY Albany, <https://www.huffpost.com/entry/nuclear-war-china_b_1116556>) BW

Of course, the bottom line for those Americans convinced that nuclear weapons safeguard them from a Chinese nuclear attack might be that the U.S. nuclear arsenal is far greater than its Chinese counterpart. Today, it is estimated that the U.S. government possesses over 5,000 nuclear warheads, while the Chinese government has a total inventory of roughly 300. Moreover, only about 40 of these Chinese nuclear weapons can reach the United States. Surely the United States would “win” any nuclear war with China. But what would that “victory” entail? An attack with these Chinese nuclear weapons would immediately slaughter at least 10 million Americans in a great storm of blast and fire, while leaving many more dying horribly of sickness and radiation poisoning. The Chinese death toll in a nuclear war would be far higher. Both nations would be reduced to smoldering, radioactive wastelands. Also, radioactive debris sent aloft by the nuclear explosions would blot out the sun and bring on a “nuclear winter” around the globe — destroying agriculture, creating worldwide famine, and generating chaos and destruction. Moreover, in another decade the extent of this catastrophe would be far worse. The Chinese government is currently expanding its nuclear arsenal, and by the year 2020 it is expected to more than double its number of nuclear weapons that can hit the United States. The U.S. government, in turn, has plans to spend hundreds of billions of dollars “modernizing” its nuclear weapons and nuclear production facilities over the next decade. To avert the enormous disaster of a U.S.-China nuclear war, there are two obvious actions that can be taken. The first is to get rid of nuclear weapons, as the nuclear powers have agreed to do but thus far have resisted doing. The second, conducted while the nuclear disarmament process is occurring, is to improve U.S.-China relations. If the American and Chinese people are interested in ensuring their survival and that of the world, they should be working to encourage these policies.

# Case

#### 3 myths contribute to the evergreening lie; contrary to popular belief, patents cannot be extended, patents do not prevent competitors from bringing drugs to market, and automatic substitution simply reflects product advertising not an issue with the patent system

Lietzan 20 (Lietzan, Erika. “The Evergreening Myth.” CATO.org, CATO, 2020, [www.cato.org/regulation/fall-2020/evergreening-myth](http://www.cato.org/regulation/fall-2020/evergreening-myth). [Erika Lietzan is the William H. Pittman Professor of Law and Timothy J. Heinsz Professor of Law at the University of Missouri School of Law. This is condensed from her forthcoming article in the University of Akron Law Review.])//LK [Accessed 8/23/2021]

Three Myths of Evergreening The circumstances that trigger the “evergreening” label occur at the intersection of several complex bodies of law: the federal framework requiring premarket approval of new medicines and their copies, federal intellectual property laws, federal and state laws governing promotion of medicines, and federal laws and practices and state laws relating to prescribing and dispensing medicines. Many who propose aggressive government intervention because of evergreening give short shrift to this landscape, which allows the perpetuation of three myths that distort policymaking discussions. Before reviewing the myths, it will help to understand two points about the framework in which innovators compete with the companies that submit abbreviated applications. First, the FDA approves products, not active ingredients. And second, patents protect inventions, not products. Federal law states that every “new drug” requires an approved application. But at the FDA the term “drug” has more than one meaning. It includes a medicine’s active ingredient, to be sure. But it also includes drug products. A drug product is a medicine in its finished form, meaning the form that will be sold in the market and administered to patients. And the FDA approves a particular product described in a particular application — the specific combination of active and inactive ingredients (often called a drug’s “formulation”), in a particular dosage form (such as capsule or tablet), for a particular route of administration (such as oral or topical), at a particular strength, for particular medical uses (also known as the product’s “indications”), manufactured as described in the application, and accompanied by labeling written for prescribers based on the data in the application. Federal law allows a patent to issue for any new, useful, non‐​obvious invention, including a process, a composition of matter, and an improvement to an existing process or composition of matter. The patent usually expires 20 years after its application date. For any particular drug product approved by the FDA, the innovator might own patents on various types of inventions. The innovator usually owns a patent claiming the product’s active ingredient, and because the innovator generally files this patent before starting clinical trials, it is usually the first to expire. Other inventions protected by patent might include the product’s formulation or a dosage form and dosage of the active ingredient (or formulation). These inventions may emerge later in the premarket development process. If the resulting patent applications refer to the active ingredient patent, the patents will expire when the active ingredient patent expires, but otherwise they will expire later. The innovator may also own other patents claiming inventions embodied in the product, such as a patent claiming methods of using or administering the product, a patent claiming the manufacturing process, or a patent claiming a metabolite of the active ingredient. These, too, could expire later than the first patent — sometimes much later. These two points work together. A single active ingredient associated with a single brand name might be the subject of a half dozen, dozen, or more discrete products. Suppose an active ingredient was formulated into tablets and the innovator sold six strengths. Suppose the innovator also formulated an injectable version, which it sold in two strengths. Suppose it also developed a disintegrating tablet for oral administration, which it sold in four strengths. This innovator would sell 12 discrete products with the same active ingredient and probably (though not necessarily) the same brand name. And because a single product might incorporate many discrete inventions, the patents relevant to one product might differ from the patents relevant to another. Failure to realize this — and its regulatory significance — leads to three myths, as follows. Myth of evergreening patents / The first myth is that innovators extend their patents. This is legally impossible. In the United States, a patent expires 20 years after its application date. There are only two ways a patent’s expiration date can shift later in time: (1) When it issues a patent, the U.S. Patent and Trademark Office (PTO) adjusts the expiry date later to compensate for routine delays at the PTO. And (2), if the marketing application proposed a new active ingredient, then if the company asks the PTO for a patent term extension within 60 days of FDA approval, the PTO will use a statutory formula to extend one patent claiming the product to compensate partially for the lapse of patent life during premarket testing and regulatory review. There is no other mechanism by which a patent might be extended. In particular, a patent on one invention — no matter when it expires — does not extend the patent on another invention. Myth of blocked competitors / The second myth is that when an innovator holds patents that expire after its active ingredient patent, or when it introduces newer products to market, it can prevent its competitors from bringing their copies to market. Instead, once the initial patent and (if applicable) statutory exclusivity on the innovator’s active ingredient have expired, its competitors have substantial freedom to operate. This freedom reflects two facts that are often overlooked. First, the innovator’s competitor does not have to propose an exact copy. Federal law permits the competitor to rely on the innovator’s research but propose competing products that are not identical. To be sure, a competitor may submit an ANDA for a product that essentially duplicates the innovator’s product — that is, a generic. Ordinarily, the company shows in the ANDA that its product has the same active ingredient, route of administration, dosage form, strength, and labeling as the innovator’s product. The generic must also be “bioequivalent” to the original drug that it references, meaning that its active ingredient must reach the site of action in the body to the same extent and at the same rate as the active ingredient of the referenced product. But even a generic can be a little different. For example, it usually does not need the same inactive ingredients in the same quantities. And the generic competitor need not use the same manufacturing process. If a competitor wants to offer a different route of administration, dosage form, or strength — for instance, to avoid infringing a patent — it may still be able to use the generic drug approval pathway. It simply files a “suitability petition” asking the FDA’s permission. The agency will approve the petition unless more data are needed to establish the proposed product’s safety and effectiveness. And at this point, the competitor may file an ANDA. More significantly, though, a competitor can always use a different abbreviated application pathway: a “505(b)(2)” application for a product that differs more substantially from the innovator’s product. Although the changes proposed in this hybrid application must be supported by new data, the competitor otherwise relies on the innovator’s data, avoiding the expensive and time‐​consuming research and development process the innovator went through. In addition to using this mechanism to propose modifications that avoid a patent, a competitor might use the mechanism to propose innovations that will offer an advantage in the market — such as changes to the active ingredient and new medical uses. Second, an abbreviated application cites a specific innovative product, not the active ingredient or brand writ large. The competitor selects one innovative product as the reference product on which it relies — for instance, one of the 12 products in the hypothetical above. Its regulatory burden is tied to that specific product alone. The requirement to show sameness and bioequivalence (for an ANDA) and, critically, the obligation to contend with patents and wait for statutory exclusivity to expire are linked to the one specific product, alone. (In rare circumstances, when filing a hybrid application, a competitor might cite two innovative products, but the same point applies.) To be sure, the patents associated with the cited innovative product affect when the FDA may approve the abbreviated application. Whether it files an ANDA or a hybrid application, a competitor must address the unexpired patents listed in the FDA’s “Orange Book” for the specific innovative product it has chosen to cite. For each listed patent, it has two choices, and its selection dictates the timing of FDA approval as far as that patent is concerned. The competitor may state the date on which the patent will expire, signaling that it does not plan to market its product until expiry. This precludes final approval of its product until patent expiry. Or it may assert that the patent is invalid or will not be infringed by its product, notifying the innovator of this position. If the innovator sues within 45 days, the drug statute stays final approval of its abbreviated application for 30 months. Under changes to the law made in 2003, though, unless the competitor changes its position on a patent after filing its abbreviated application, approval of its application is stayed only once. At the end of the 30 months, the FDA must approve the abbreviated application if the approval standard is met, even if there is ongoing patent litigation. Although a competitor using the abbreviated application pathway must contend with the innovator’s patents and approval of its product may be delayed because of those patents, this is true of only the patents associated with the specific product that it references. The competitor does not have to contend with patents associated with other products that happen to contain the same active ingredient or bear the same brand name. Similarly, the competing applicant grapples with only the statutory exclusivity associated with the product it references. The drug statute provides five years of exclusivity in the data supporting new chemical entities and three years of exclusivity for most new products that are not new chemical entities. Separately, if an innovator introduces what the FDA calls a new “condition of approval” — such as a new strength or dosage form — the drug statute may provide three years of exclusivity. This delays approval of abbreviated applications proposing products with the same active ingredient for the same condition of approval. But a competitor that proposed a different strength or dosage form — or that cited a product with a different strength or dosage form (such as the innovator’s original product) — would not need to grapple with that exclusivity. This debunks the myth that an innovator with later‐​expiring patents and an innovator that introduces newer products can prevent its competitors from bringing copies to market. Instead, competitors have several options. For instance, empirical studies show that competitors file abbreviated applications as early as the law permits them to do so, arguing that the innovator’s patents are invalid or, if applicable, not infringed by the new drug. They tend to lose these arguments when the active ingredient patent is at issue, but they tend to win if a formulation patent is at issue. If a competitor believed it would infringe a patent or feared it would lose the patent infringement suit brought by the innovator, it could seek a license. Settlements of patent litigation between innovators and competitors seeking to market generic copies usually include a license allowing the competitor to bring its product to market earlier than the date of patent expiry. There are also other options. Once the patent on the active ingredient expires, a competitor can use the ingredient in its own product and file an abbreviated application, relying on the research performed and submitted by the innovator. Even in an ANDA, a true generic application, only the active ingredient must be the same. A competitor may be able to design around patents claiming other aspects of the innovator’s product (such as its strength and route of administration) and still file a true generic application. The competitor would simply file a suitability petition and, upon approval of that petition, a generic application proposing the difference that allowed it to avoid patent infringement. Then it would assert non‐​infringement in its application. If it could not file a generic application (for instance, because the FDA requested data to support the changes made), it could always file a hybrid application. It would still rely on the innovator’s research and it would similarly assert non‐​infringement in its application. In either case, the innovator might not sue if the competitor clearly avoided its patents. It is thus misleading for advocates of intervention to complain about the number of “patents” associated with a “drug.” A competitor filing an abbreviated application does not copy a “drug” in the broad sense of the term. Accurately describing a company’s freedom to operate in the market would require focusing on discrete products that can serve as references for abbreviated applications and on the number, scope, and breadth of the patent claims held by the innovator for those products. This would tell policymakers more about the market effects of a firm’s innovation and patenting practices than the number of patents associated with a particular brand name or the number of patents associated with the many finished products containing a particular active ingredient. Myth that automatic substitution is critical / The final myth of evergreening is that continuing innovation — especially when an innovator introduces a newer version of its product and stops selling its old version — precludes uptake of less expensive medicines by interfering with automatic pharmacy substitution under state pharmacy law. This myth reflects an assumption that competitors who file abbreviated applications depend on automatic pharmacy substitution — rather than the ordinary rough and tumble of a competitive marketplace — to obtain market share. The truth may be more complicated. Automatic pharmacy substitution arises through a combination of longstanding FDA practices and state pharmacy law. Once the agency has approved two products with the same active ingredient, it assesses whether they are “therapeutically equivalent.” Designating two as therapeutically equivalent means that they have the same clinical profile and that they can be “substituted”: either can be dispensed instead of the other. A true generic drug, an exact copy of the innovator’s product approved based on an ANDA, will be deemed therapeutically equivalent. Every state either permits or requires pharmacists to dispense a therapeutically equivalent generic drug when a doctor prescribes an innovator’s drug by its brand name, unless the doctor has said not to. The notion advanced by critics of alleged “evergreening” is that once an innovator introduces a newer version of its branded product, doctors will prescribe the newer version. And because the generic company instead copied the older version, pharmacists will not — cannot under state law — substitute the generic product when the patient presents a prescription for the newer innovator product. The problem with this argument is that actual dispensing decisions probably reflect a more complex interaction of prescriber decisions, payer preferences, and state law. To begin with, a doctor may specify either branded drugs or generic drugs. A doctor could write the brand name, to be sure, but the doctor could also simply identify the active ingredient, which will usually lead the pharmacist to dispense one of the available generic drugs. In theory, the doctor could even identify a particular generic company’s drug containing a particular active ingredient. And while drugmakers rarely promote generic drugs to doctors and patients, nothing prevents them from doing so. They do promote their therapeutically equivalent generic drugs to pharmacies and payers, focusing on the lower prices they offer. And a company that filed a hybrid application for a product that differed from the innovator’s product might brand its product and promote the distinguishing features, or (depending on the reason it filed the hybrid application) position the product as a near‐​duplicate of the more expensive branded alternatives and promote it as such. In short, an innovator’s newer product creates a new choice for doctors and payers. To be sure, if doctors select this product, pharmacists will dispense it rather than generic copies of the innovator’s older product. Doctors might shift their prescribing to the newer product for many reasons, including persuasive advertising and promotion — meaning they come to believe (based on advertising that, per FDA rules, must be truthful and not misleading) that there are benefits to the newer product. They might shift for other reasons, including experience treating patients with the two options. But companies may advertise and promote generic products to doctors and patients as well, and based on this advertising (or for other reasons, such as experience with the older innovative product that the competitor copied) doctors might not select the innovator’s newer product. They might specify the innovator’s older product (which would lead to automatic substitution, even if the innovator no longer markets the product) or, again, a generic product itself. Generic companies will be able to introduce copies of the innovator’s first product and they may or may not enjoy sales depending on the choices they make and the choices made by others in the market. The assumption that competing companies depend on automatic substitution for market share may be simplistic. Only a minority of states require substitution; most instead have permissive laws. In these states, if a generic product is therapeutically equivalent to the prescribed product and the payer requires its use, the permissive state pharmacy law makes it possible for a pharmacist to substitute, in accordance with the patient’s insurance, without consulting the physician. In these cases, the patient’s insurance drives the product selection. State law just makes it possible to comply with the insurance without contacting the doctor. If a payer perceives the innovator’s new product as less cost effective than available generic drugs containing the same active ingredient, it may decline to cover the product. A rational payer will adopt strategies that steer doctors and patients to less expensive products that are equally or adequately effective — not only those that are therapeutically equivalent, but also those that are not. In these cases, even if a doctor specifies a branded product, the patient’s insurance might prompt a conversation among the doctor, pharmacist, and patient, ultimately leading to modification of the prescription and dispensing of the cheaper copy of the innovator’s first‐​version product. In short, when an innovator introduces a new product into the market, generic companies will be able to introduce copies of the innovator’s first product and they may or may not enjoy sales depending on the choices they make and the choices made by others in the market. In this scenario, products compete for the business of rational payers based on their comparative benefits and cost. Substitution may play almost no true role, and whether the innovator still markets its older branded product may be irrelevant.

#### They don't solve their aff -- all they do is ensure companies only get one protection per invention -- either orphan drug rights, a patent, or data exclusivity -- but theres no brightline for whats a new or old invention, so they cant stop evergreening. Companies will just slightly modify their invention and get a separate new patent and the aff has no litmus test for when an invention is significantlly new/different enough from past inventions.

Also it’s chepaer for companies to sue than r&d.

#### Strong IPR is key to innovation – empirics and FDI

Ezell and Cory 19 [Stephen Ezell, BS from School of Foreign Service at Georgetown, VP of global innovation policy at Information Technology and Innovation Foundation. Nigel Cory, MA in public policy from Georgetown, BA in international business from Griffith University, Associate Director of trade policy at Information Technology and Innovation Foundation, former researcher in the Southeast Asia Program at the Center for Strategic and International Studies.] “The Way Forward for Intellectual Property Internationally,” Information Technology and Innovation Foundation, April 25, 2019, <https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally> TG

* FDI – foreign direct investment

IPRs Strengthen Innovation

Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that countries with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development.46

IPR reforms also introduce strong incentives for domestic innovation. Sherwood, using case studies from 18 developing countries, concluded that poor provision of intellectual property rights deters local innovation and risk-taking.47 In contrast, IPR reform has been associated with increased innovative activity, as measured by domestic patent filings, albeit with some variation across countries and sectors.48 For example, Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets.49 Park and Lippoldt also observed that the provision of adequate protection for IPRs can help to stimulate local innovation, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, local innovators are introduced to technologies first through the technology transfer that takes place in an environment wherein protection of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts.

The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that R&D to GDP ratios are positively related to the strength of patent rights, and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56

### AMR

#### ABR won’t get close to extinction, intervening actors solve it, their evergreening can’t

Ed Cara 17, science writer for The Atlantic, Newsweek, and Vocativ, 1/27/17, “The Attack Of The Superbugs,” http://www.vocativ.com/394419/attack-of-the-superbugs/

Antibiotic-resistant infections kill at least 700,000 people worldwide a year right now, according to an exhaustive report commissioned by the UK in 2014, and without any substantial medical breakthroughs or policy changes that slow down resistance, they may claim some 10 million deaths annually by 2050 — eclipsing cancer in general as a leading cause. These deaths largely won’t come from pan-resistant infections, just tougher ones. A preventable death there, a preventable death here. Leaving that aside, antibiotics, along with proper sanitation and nutrition, gird our entire way of living. Most every invasive surgery, pregnancy, organ transplant and chemotherapy session we go through will become riskier. Other diseases like HIV, malaria or influenza will become deadlier, since bacteria often exploit the opening in our immune system they leave behind. And already precarious populations like those living with cystic fibrosis, prisoners, and the poor will lose years off their lives. For all the warranted gloom, though, Farewell does think there are reasons to be hopeful. “I don’t think we are doing enough, but the scientific community along with many governmental and private foundations are very actively involved in finding not only new antibiotics, but new solutions to this problem,” she said. There’s been a noticeable change in attitude and increased urgency surrounding antibiotic resistance, she said, one that she hadn’t seen even five years ago, let alone twenty. Until recently, that attitude change could be seen from places as high up as the U.S. federal government. In 2014, former President Obama issued an executive order aimed at addressing antibiotic resistance, the first real acknowledgement of the problem from an administration, devoting funding and outlining a national action for combatting resistance. Through its federal agencies, the administration pushed to reduce antibiotic use on farms and encouraged doctors to stop using them in excess. “There has been a lot of work done the last couple of years, much of it spurned by [Obama’s] National Action Plan,” said Dr. David Hyun, a senior officer for Pew Charitable Trusts’ Antibiotic Resistance Project. The CDC, in particular, has used its funding to open up regional labs that allow them to better detect and respond to antibiotic-resistant outbreaks like the Nevada case, he said. They ultimately hope to create an expansive surveillance system that can easily keep track of resistance rates on a national, state and regional level. A parallel system also exists for monitoring resistance in the food chain, shepherded by the CDC and the U.S. Department of Agriculture. In fact, it was this sort of cooperation between national and local health agencies that enabled Nevada doctors to stop the worst from happening, said Dr. Lei Chen. The swift identification of a possible CRE strain by the hospital, coupled with the woman’s medical history, led to a precautionary quarantine, while also prompting Chen’s public health department and eventually the CDC into action. And it may help prevent future cases from spilling into the public. According to Chen, the CDC has allocated funding this year to all of Nevada’s state public health departments so they can better detect CRE and other dangerous resistant strains. Under the Trump administration, there’s no telling how these small victories will hold up or whether they will advance. All references to antibiotics once found on the Whitehouse.gov site have been removed, including a link to the Obama administration’s national action plan, and the fact that they’re already tried to bar USDA scientists from discussing their work with the public while stripping funding from other public health agencies isn’t encouraging. Even with the best public policy, however, there’s no clear light at the end of the tunnel. Antibiotic resistance has gradually been worsening, even within the last 15 to 20 years, when superbugs like methicillin-resistant Staphylococcus aureus (MRSA) first became widely known, said Hyun. The effort needed to develop new drugs has been in short supply, hamstrung by pharmaceutical companies’ inability to recoup the costs of bringing new antibiotics to market. That’s because, unlike the latest heart medication, any new antibiotics will have to be treated like the last drops of water during a drought, used as little as possible — the exact opposite way to make money off a new product. Yet, much like climate change, the financial toll of not doing anything will total in the trillions years down the road. And it already numbers in the billions now, according to the CDC. Of course, we need bacteria to survive. And most need or pay no mind to us in return. Even pan-resistant bacteria don’t really mean harm. Some have been found in perfectly healthy people, a fact that’ll either comfort you or keep you awake at night, only causing problems when our immune system wavers. There’s no army of sentient E. coli that will rise up and someday overthrow the human race. But barring the calvary showing up, a new fear of ours will learn to settle in, almost unnoticed. It’ll creep in when we pick our heads up from a nasty fall that scrapes our skin open or breaks our bones; when we wave goodbye to our loved ones before they enter an operating room, or when we cradle our newborns into a world teeming with the living infinitesimal, wishing there was still a way to shield them from it as our parents once could for us. A fear of naked vulnerability. The antibiotic apocalypse will be gentle, if it fully arrives, but it won’t be any less devastating to the human spirit.

### Hotspots

#### Hotspot escalation – vacuum – err neg on specificity

#### No 1AR theory

#### a] There is a 7-6-time skew after NC, negs get 1 less minute

#### b] They get new 2AR responses to 2NR counter-interps, that makes theory irresolvable because I don’t have a 3NR, and they win every theory debate because I can’t answer their responses

#### c] AC spikes solve there aren’t that many theory issues

#### d] deters 1NC abuse checking because of meta-theory, that means 6 minutes of aff abuse

#### e] infinite abuse doesn’t exist,

#### 1] 7 minutes if finite,

#### 2] resolvability is a pre-req to checking abuse, you cant check abuse on a irresolvable issue