### 1NC – T

#### Interpretation: “intellectual property protections” is a generic bare plural. The aff may not defend WTO member nations reducing a subset of intellectual property protections for medicines.

Leslie and Lerner 16 [Sarah-Jane Leslie, Ph.D., Princeton, 2007. Dean of the Graduate School and Class of 1943 Professor of Philosophy. Served as the vice dean for faculty development in the Office of the Dean of the Faculty, director of the Program in Linguistics, and founding director of the Program in Cognitive Science at Princeton University. Adam Lerner, PhD Philosophy, Postgraduate Research Associate, Princeton 2018. From 2018, Assistant Professor/Faculty Fellow in the Center for Bioethics at New York University. Member of the [Princeton Social Neuroscience Lab](http://psnlab.princeton.edu/).] “Generic Generalizations.” Stanford Encyclopedia of Philosophy. April 24, 2016. <https://plato.stanford.edu/entries/generics/> TG

1. Generics and Logical Form

In English, generics can be expressed using a variety of syntactic forms: bare plurals (e.g., “tigers are striped”), indefinite singulars (e.g., “a tiger is striped”), and definite singulars (“the tiger is striped”). However, none of these syntactic forms is dedicated to expressing generic claims; each can also be used to express existential and/or specific claims. Further, some generics express what appear to be generalizations over individuals (e.g., “tigers are striped”), while others appear to predicate properties directly of the kind (e.g., “dodos are extinct”). These facts and others give rise to a number of questions concerning the logical forms of generic statements.

1.1 Isolating the Generic Interpretation

Consider the following pairs of sentences:

(1)a.Tigers are striped.

b.Tigers are on the front lawn.

(2)a.A tiger is striped.

b.A tiger is on the front lawn.

(3)a.The tiger is striped.

b.The tiger is on the front lawn.

The sentence pairs above are prima facie syntactically parallel—both are subject-predicate sentences whose subjects consist of the same common noun coupled with the same, or no, article. However, the interpretation of first sentence of each pair is intuitively quite different from the interpretation of the second sentence in the pair. In the second sentences, we are talking about some particular tigers: a group of tigers in ([1b](https://plato.stanford.edu/entries/generics/#ex1b)), some individual tiger in ([2b](https://plato.stanford.edu/entries/generics/#ex2b)), and some unique salient or familiar tiger in ([3b](https://plato.stanford.edu/entries/generics/#ex3b))—a beloved pet, perhaps. In the first sentences, however, we are saying something general. There is/are no particular tiger or tigers that we are talking about.

The second sentences of the pairs receive what is called an existential interpretation. The hallmark of the existential interpretation of a sentence containing a bare plural or an indefinite singular is that it may be paraphrased with “some” with little or no change in meaning; hence the terminology “existential reading”. The application of the term “existential interpretation” is perhaps less appropriate when applied to the definite singular, but it is intended there to cover interpretation of the definite singular as referring to a unique contextually salient/familiar particular individual, not to a kind.

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

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

#### **Violation – they only defend one added condition to IPP**

#### Vote neg: limits – you can pick anything from patent evergreening to patent delays to data exclusivity to EU trade secrets to copyright and there’s no universal disad since each one has a different function and implication for health, tech, and relations – explodes neg prep and leads to random IP of the week affs which makes cutting stable neg links impossible.

#### Competing interpretations—Reasonability is arbitrary and unpredictable, inviting a race to the bottom and we’ll win it links to our offense.

#### Drop the debater to deter future abuse and because the 2N doesn’t get new disads to whole rez so it’s permanently skewed.

### 1NC – CP

#### Member nations of the WTO should:

#### Institute value-based pricing for new medicines

#### Allow health service agencies to negotiate over drug prices

#### Institute price increase caps on existing drugs to an international reference price

#### Set aside public funding in the form of Development Impact Bonds and cash-on-delivery tied to health gain and encourage risk-sharing for NTD research

#### Engage in health diplomacy where richer nations share medicines and information to poorer nations to combat neglected diseases

#### Planks 1-3 solve drug prices but avoids the patent good turns.

**Rajkumar 2020** (S. Vincent Rajkumar, MD, Division of Hematology, Mayo Clinic, Rochester, MN (S.V.R.). “The high cost of prescription drugs: causes and solutions” *Blood Cancer Journal* volume 10, Article number: 71 2020)DR 21

Value-based pricing

Unlike other developed countries, the United States does not negotiate over the price of a new drug based on the value it provides. This is a fundamental problem that allows drugs to be priced at high levels, regardless of the value that they provide. Thus, almost every new cancer drug introduced in the last 3 years has been priced at more than $100,000 per year, with a median price of approximately $150,000 in 2018. The lack of value-based pricing in the United States also has a direct adverse effect on the ability of other countries to negotiate prices with manufacturers. It greatly reduces leverage that individual countries have. Manufacturers can walk away from such negotiations, knowing fully well that they can price the drugs in the United States to compensate. A governmental or a nongovernmental agency, such as the Institute for Clinical and Economic Review (ICER), must be authorized in the United States by law, to set ceiling prices for new drugs based on incremental value, and monitor and approve future price increases. Until this is possible, the alternative solution is to cap prices of lifesaving drugs to an international reference price.

Medicare negotiation

In addition to not having a system for value-based pricing, the United States has specific legislation that actually prohibits the biggest purchaser of oral prescription drugs (Medicare) from directly negotiating with manufacturers. One study found that if Medicare were to negotiate prices to those secured by the Veterans Administration (VA) hospital system, there would be savings of $14.4 billion on just the top 50 dispensed oral drugs[17](https://www.nature.com/articles/s41408-020-0338-x#ref-CR17).

Cap on price increases

The United States also has a peculiar problem that is not seen in other countries: marked price increases on existing drugs. For example, between 2012 and 2017, the United States spent $6.8 billion solely due to price increases on the existing brand name cancer drugs; in the same period, the rest of the world spent $1.7 billion less due to decreases in the prices of similar drugs[18](https://www.nature.com/articles/s41408-020-0338-x#ref-CR18). But nothing illustrates this problem better than the price of insulin[19](https://www.nature.com/articles/s41408-020-0338-x#ref-CR19). One vial of Humalog (insulin lispro), that costs $21 in 1999, is now priced at over $300. On January 1, 2020, drugmakers increased prices on over 250 drugs by approximately 5%[20](https://www.nature.com/articles/s41408-020-0338-x#ref-CR20). The United States clearly needs state and/or federal legislation to prevent such unjustified price increases [21](https://www.nature.com/articles/s41408-020-0338-x#ref-CR21).

#### Plank 4 and 5 solves NTDs and Health diplomacy BUT pharma profits are key—NTD research is high-risk and capital-intensive

**Barofksy and Schneider 2017** (Jeremy Barofsky, Sc.D., M.A. is a non-resident Fellow in Governance Studies at the Brookings Institution and a Research Associate at Tulane University’s Commitment to Equity (CEQ) Institute. He received his doctorate from Harvard University’s T.H. Chan School of Public Health in Global Health and Population (Economics) and holds an M.A. in Economics from Boston University. and Jake Schneider, Research Assistant - The Brookings Insitution “Promoting Private Sector Involvement in Neglected Tropical Disease Research and Development” *The Brookings Private Sector Global Health R&D Project* https://www.brookings.edu/wp-content/uploads/2017/12/br\_health4\_optimized\_final.pdf December 2017)DR 21

Based on this analysis, we make several recommendations for future action:

1. Alignment of public funding with social return. Our analysis shows the restricted circumstances in which private sector R&D generates a positive return on investment in the current policy environment. To increase the range of activities that receive private funding, **we propose public funding that is explicitly tied to health gain** (disability adjusted life years [DALYs] averted). There are various financing mechanisms that have been developed that would allow governments to pay for results, including Development Impact Bonds and cash-on-delivery models. These arrangements allow public funders to provide financing contingent on results, as verified by a third party, and do not require outlays otherwise.
2. Private sector late-stage investment and risk sharing. Our quantitative analysis finds that the most important drivers of private sector development cost are long development timelines and failure risk. Complementary to recommendation #1, we therefore propose additional private sector investment focused on phase III clinical trials to minimize risk-adjusted, capitalized private sector costs. In addition, to further minimize risk, private sector **biopharmecutical firms could enter into investment agreements that would spread the risk** and benefits of these trials. This risk-sharing arrangement would be particularly oriented toward social impact investors that want to both diversify market risk (R&D risk being orthogonal to market risk) and generate positive social returns.
3. Public funding coordination and stewardship. Our case studies indicated the importance of stewardship and coordination of product development partnerships by non-profit entities. Greater stewardship from governments to determine priority areas for NTD investment as well as coordinate joint funding of early stage R&D with nonprofit actors would both increase the likelihood of private sector involvement in late stage R&D as well as increase the likelihood that innovation maximizes public health.
4. Advanced market commitment for hookworm and schistosomiasis: Our analysis highlighted the challenges for NTD vaccine development and the mismatch in scale between current resources compared to the funding necessary for successful development. The creation of an advanced market commitment ensuring a set price for certain number of treatments purchased would increase the likelihood of private involvement in vaccine development.
5. Tiered PRV based on social return and clinical stage: One specific policy change that may be more feasible in the near term to align financial incentives and health impact includes an adjustment to the PRV such that the PRV varies based on the level of innovation produced compared to current clinical practice.

### 1NC – DA

#### Climate Patents and Innovation high now and solving Warming but patent reductions and campaign against IP protections set a dangerous precedent for appropriations - the mere threat is sufficient is enough to kill investment.

Brand 5-26, Melissa. “Trips Ip Waiver Could Establish Dangerous Precedent for Climate Change and Other Biotech Sectors.” IPWatchdog.com | Patents & Patent Law, 26 May 2021, www.ipwatchdog.com/2021/05/26/trips-ip-waiver-establish-dangerous-precedent-climate-change-biotech-sectors/id=133964/. //sid//recut PW

The biotech industry is making remarkable advances towards climate change solutions, and it is precisely for this reason that it can expect to be in the crosshairs of potential IP waiver discussions. President Biden is correct to refer to climate change as an existential crisis. Yet it does not take too much effort to connect the dots between President Biden’s focus on climate change and his Administration’s recent commitment to waive global IP rights for Covid vaccines (TRIPS IP Waiver). “This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures.” If an IP waiver is purportedly necessary to solve the COVID-19 global health crisis (and of course [we dispute this notion](https://www.ipwatchdog.com/2021/04/19/waiving-ip-rights-during-times-of-covid-a-false-good-idea/id=132399/)), can we really feel confident that this or some future Administration will not apply the same logic to the climate crisis? And, without the confidence in the underlying IP for such solutions, what does this mean for U.S. innovation and economic growth? United States Trade Representative (USTR) [Katherine Tai](https://www.ipwatchdog.com/2021/05/05/tai-says-united-states-will-back-india-southafrica-proposal-waive-ip-rights-trips/id=133224/) was subject to questioning along this very line during a recent Senate Finance Committee hearing. And while Ambassador Tai did not affirmatively state that an IP waiver would be in the future for climate change technology, she surely did not assuage the concerns of interested parties. The United States has historically supported robust IP protection. This support is one reason the United States is the center of biotechnology innovation and leading the fight against COVID-19. However, a brief review of the domestic legislation arguably most relevant to this discussion shows just how far the international campaign against IP rights has eroded our normative position. The Clean Air Act, for example, contains a provision allowing for the mandatory licensing of patents covering certain devices for reducing air pollution. Importantly, however, the patent owner is accorded due process and the statute lays out a detailed process regulating the manner in which any such license can be issued, including findings of necessity and that no reasonable alternative method to accomplish the legislated goal exists. Also of critical importance is that the statute requires compensation to the patent holder. Similarly, the Atomic Energy Act contemplates mandatory licensing of patents covering inventions of primary importance in producing or utilizing atomic energy. This statute, too, requires due process, findings of importance to the statutory goals and compensation to the rights holder. A TRIPS IP waiver would operate outside of these types of frameworks. There would be no due process, no particularized findings, no compensation and no recourse. Indeed, the fact that the World Trade Organization (WTO) already has a process under the TRIPS agreement to address public health crises, including the compulsory licensing provisions, with necessary guardrails and compensation, makes quite clear that the waiver would operate as a free for all. Forced Tech Transfer Could Be on The Table When being questioned about the scope of a potential TRIPS IP waiver, Ambassador Tai invoked the proverb “Give a man a fish and you feed him for a day. Teach a man to fish and you feed him for a lifetime.” While this answer suggests primarily that, in times of famine, the Administration would rather give away other people’s fishing rods than share its own plentiful supply of fish (here: actual COVID-19 vaccine stocks), it is apparent that in Ambassador Tai’s view waiving patent rights alone would not help lower- and middle-income countries produce their own vaccines. Rather, they would need to be taught how to make the vaccines and given the biotech industry’s manufacturing know-how, sensitive cell lines, and proprietary cell culture media in order to do so. In other words, Ambassador Tai acknowledged that the scope of the current TRIPS IP waiver discussions includes the concept of forced tech transfer. In the context of climate change, the idea would be that companies who develop successful methods for producing new seed technologies and sustainable biomass, reducing greenhouse gases in manufacturing and transportation, capturing and sequestering carbon in soil and products, and more, would be required to turn over their proprietary know-how to global competitors. While it is unclear how this concept would work in practice and under the constitutions of certain countries, the suggestion alone could be devastating to voluntary international collaborations. Even if one could assume that the United States could not implement forced tech transfer on its own soil, what about the governments of our international development partners? It is not hard to understand that a U.S.-based company developing climate change technologies would be unenthusiastic about partnering with a company abroad knowing that the foreign country’s government is on track – with the assent of the U.S. government – to change its laws and seize proprietary materials and know-how that had been voluntarily transferred to the local company. Necessary Investment Could Diminish Developing climate change solutions is not an easy endeavor and bad policy positions threaten the likelihood that they will materialize. These products have long lead times from research and development to market introduction, owing not only to a high rate of failure but also rigorous regulatory oversight. Significant investment is required to sustain and drive these challenging and long-enduring endeavors. For example, synthetic biology companies critical to this area of innovation [raised over $1 billion in investment in the second quarter of 2019 alone](https://www.bio.org/sites/default/files/2021-04/Climate%20Report_FINAL.pdf). If investors cannot be confident that IP will be in place to protect important climate change technologies after their long road from bench to market, it is unlikely they will continue to invest at the current and required levels.

#### Climate change is a threat multiplier that increases the risk of every other extinction scenarios – biggest impact in the round

Torres 16 [Phil Torres, conservationist, science advocate, and educator, with a BS in entomology from Cornell, working on a PhD at Rice University in tropical conservation biology, he is a biologist, science communicator, photographer, and television host based in New York City who works projects all over the globe, Institute for Ethics and Emerging Technologies Affiliate Scholar, 8-7-2016, IEET, "Climate Change Is the Most Urgent Existential Risk", <https://ieet.org/index.php/IEET2/more/Torres20160807>] someone//PW

Humanity faces a number of formidable challenges this century. Threats to our collective survival stem from asteroids and comets, supervolcanoes, global pandemics, climate change, biodiversity loss, nuclear weapons, biotechnology, synthetic biology, nanotechnology, and artificial superintelligence. With such threats in mind, an informal survey conducted by the Future of Humanity Institute placed the probability of human extinction this century at 19%. To put this in perspective, it means that the average American is more than a thousand times more likely to die in a human extinction event than a plane crash.\* So, given limited resources, which risks should we prioritize? Many intellectual leaders, including Elon Musk, Stephen Hawking, and Bill Gates, have suggested that artificial superintelligence constitutes one of the most significant risks to humanity. And this may be correct in the long-term. But I would argue that two other risks, namely climate change and biodiveristy loss, should take priority right now over every other known threat. Why? Because these ongoing catastrophes in slow-motion will frame our existential predicament on Earth not just for the rest of this century, but for literally thousands of years to come. As such, they have the capacity to raise or lower the probability of other risks scenarios unfolding. Multiplying Threats Ask yourself the following: are wars more or less likely in a world marked by extreme weather events, megadroughts, food supply disruptions, and sea-level rise? Are terrorist attacks more or less likely in a world beset by the collapse of global ecosystems, agricultural failures, economic uncertainty, and political instability? Both government officials and scientists agree that the answer is “more likely.” For example, the current Director of the CIA, John Brennan, recently identified “the impact of climate change” as one of the “deeper causes of this rising instability” in countries like Syria, Iraq, Yemen, Libya, and Ukraine. Similarly, the former Secretary of Defense, Chuck Hagel, has described climate change as a “threat multiplier” with “the potential to exacerbate many of the challenges we are dealing with today — from infectious disease to terrorism.” The Department of Defense has also affirmed a connection. In a 2015 report, it states, “Global climate change will aggravate problems such as poverty, social tensions, environmental degradation, ineffectual leadership and weak political institutions that threaten stability in a number of countries.” Scientific studies have further shown a connection between the environmental crisis and violent conflicts. For example, a 2015 paper in the Proceedings of the National Academy of Sciences argues that climate change was a causal factor behind the record-breaking 2007-2010 drought in Syria. This drought led to a mass migration of farmers into urban centers, which fueled the 2011 Syrian civil war. Some observers, including myself, have suggested that this struggle could be the beginning of World War III, given the complex tangle of international involvement and overlapping interests. The study’s conclusion is also significant because the Syrian civil war was the Petri dish in which the Islamic State consolidated its forces, later emerging as the largest and most powerful terrorist organization in human history. A Perfect Storm The point is that climate change and biodiversity loss could very easily push societies to the brink of collapse. This will exacerbate existing geopolitical tensions and introduce entirely new power struggles between state and nonstate actors. At the same time, advanced technologies will very likely become increasingly powerful and accessible. As I’ve written elsewhere, the malicious agents of the future will have bulldozers rather than shovels to dig mass graves for their enemies. The result is a perfect storm of more conflicts in the world along with unprecedentedly dangerous weapons. If the conversation were to end here, we’d have ample reason for placing climate change and biodiversity loss at the top of our priority lists. But there are other reasons they ought to be considered urgent threats. I would argue that they could make humanity more vulnerable to a catastrophe involving superintelligence and even asteroids. The basic reasoning is the same for both cases. Consider superintelligence first. Programming a superintelligence whose values align with ours is a formidable task even in stable circumstances. As Nick Bostrom argues in his 2014 book, we should recognize the “default outcome” of superintelligence to be “doom.” Now imagine trying to solve these problems amidst a rising tide of interstate wars, civil unrest, terrorist attacks, and other tragedies? The societal stress caused by climate change and biodiversity loss will almost certainly compromise important conditions for creating friendly AI, such as sufficient funding, academic programs to train new scientists, conferences on AI, peer-reviewed journal publications, and communication/collaboration between experts of different fields, such as computer science and ethics. It could even make an “AI arms race” more likely, thereby raising the probability of a malevolent superintelligence being created either on purpose or by mistake. Similarly, imagine that astronomers discover a behemoth asteroid barreling toward Earth. Will designing, building, and launching a spacecraft to divert the assassin past our planet be easier or more difficult in a world preoccupied with other survival issues? In a relatively peaceful world, one could imagine an asteroid actually bringing humanity together by directing our attention toward a common threat. But if the “conflict multipliers” of climate change and biodiversity loss have already catapulted civilization into chaos and turmoil, I strongly suspect that humanity will become more, rather than less, susceptible to dangers of this sort. Context Risks We can describe the dual threats of climate change and biodiversity loss as “context risks.” Neither is likely to directly cause the extinction of our species. But both will define the context in which civilization confronts all the other threats before us. In this way, they could indirectly contribute to the overall danger of annihilation — and this worrisome effect could be significant. For example, according to the Intergovernmental Panel on Climate Change, the effects of climate change will be “severe,” “pervasive,” and “irreversible.” Or, as a 2016 study published in Nature and authored by over twenty scientists puts it, the consequences of climate change “will extend longer than the entire history of human civilization thus far.” Furthermore, a recent article in Science Advances confirms that humanity has already escorted the biosphere into the sixth mass extinction event in life’s 3.8 billion year history on Earth. Yet another study suggests that we could be approaching a sudden, irreversible, catastrophic collapse of the global ecosystem. If this were to occur, it could result in “widespread social unrest, economic instability and loss of human life.” Given the potential for environmental degradation to elevate the likelihood of nuclear wars, nuclear terrorism, engineered pandemics, a superintelligence takeover, and perhaps even an impact winter, it ought to take precedence over all other risk concerns — at least in the near-term. Let’s make sure we get our priorities straight.

### 1NC – CP

#### CP: The member nations of the World Trade Organization should allow exclusivity to be extended indefinitely for antimicrobial drugs per Salmieri. The member nations of the World Trade Organization should reduce intellectual property protections for all other medicines by implementing a one-and-done approach for patent protection.

Salmieri 18 “INTELLECTUAL PROPERTY AND THE FREEDOM NEEDED TO SOLVE THE CRISIS OF RESISTANT INFECTIONS” 2018 Gregory Salmieri [Ph.D., Philosophy, 2008, University of Pittsburgh; B.A. 2001, The College of New Jersey. Fellow, The Anthem Foundation for Objectivist Scholarship; Lecturer, Philosophy Department, Rutgers University] <http://georgemasonlawreview.org/wp-content/uploads/2019/04/26-1_7-Salmieri.pdf> SM

This Article suggests another sort of solution, which might be described as a way of incentivizing, by means of a single policy change, both the development of new antimicrobials and the responsible stewardship of these drugs. In its simplest form, the solution is to make the patent terms on these drugs extremely long. The solution has been proposed in this form by Professor John Horowitz and Brian Moehring32 as well as Professor Eric Kades,33 and it is occasionally mentioned in the existing literature.34 However, the case for this broad sort of solution has not been adequately articulated or appreciated. The next part develops the case for a solution of this sort and proposes an alternative version of the solution that is better tailored to the problem and better situated within a theory of IP. Finally, Part III addresses some concerns faced by any solution of this sort.

II. THE RIGHT TO THE VALUE CREATED BY RESPONSIBLE STEWARDSHIP

Consider how the two-fold problem of growing resistance to our current antimicrobial drugs and the dearth of new antimicrobials under development looks once the specifics are omitted. Forget for a moment that the subject is drugs and microbes—or even inventions as opposed to other sorts of property—and just focus on the structure of the predicament.35 There is a resource of immense value that is being used myopically in a way that destroys existing stocks of the resource, and little is being done to find or develop new stocks of it.

This is a pattern one expects to see with unowned resources, but not with owned ones. It is the classic “tragedy of the commons.” When a patch of grazing land is owned in common by everyone—which is just to say it is unowned—everyone has an incentive to make what use of it he can, leading to its overuse and destroying its value. By contrast, an owner can use land judiciously in ways that preserve its value or even to invest in improving the land. This is possible because the owner has exclusive control of the land in the present and therefore can control its uses, and because the owner expects to reap the benefit of the land’s future value. If deeds to land expired after twenty years, with the land reverting to the commons, land owners would have no financial incentives to preserve or enhance the land’s value past the twenty-year window. In this scenario, they could not afford to forgo shortterm gains that came at the expense of the land’s later value. Nor could they afford to invest in long-term improvement projects, such as clearing new land for grazing. This is the predicament with antimicrobial drugs. The profligate use of such drugs in the present destroys their value in a future in which they are unowned.

This suggests the simple solution of extending the patent terms for antimicrobial drugs. So long as the drug remains under patent, the patent holder has both an interest in preserving its usefulness and the ability to control its use so as to preserve its value. How long should the patent term be extended? The five years of extra market exclusivity offered by the GAIN Act is calculated with a view to incentivizing companies to invest in developing new drugs. The aim of the present proposal is different. It is to enable the creators of drugs to profitably exercise their rights over the drugs in a manner that preserves the drugs’ effectiveness over time—ideally into the indefinite future. This requires extending the term of exclusivity not just a few years or decades, but as far into the future as there is reason to hope that the drugs’ effectiveness can be maintained.

There are various ways in which this suggestion could be further developed; perhaps the most promising is simply to allow patents on antimicrobial drugs to be renewed indefinitely, so long as the drugs’ continued effectiveness can be demonstrated. (How exactly continued effectiveness should be demonstrated is a matter of detail, but likely by showing resistance to be below a certain threshold—perhaps 20 percent—in clinical isolates of interest.36) This would allow for a potentially infinite patent term. “Perpetual patents” have occasionally been proposed, 37 but the lack of a fixed term may do violence to the notion of a patent, so it may be better to conceive of this as a proposal for a new type of IP right that combines features of patents and trademarks. Conceptualizing the relevant right in this way highlights its basis. Like a patent, the right would pertain to an invention and would confer market exclusivity; like a trademark, however, it would be renewable in perpetuity on the grounds that the continued value of the property depends on the owner taking continuous action to maintain it. In the case of the right under consideration, the relevant actions would be those of stewarding the drug in such a manner as to prolong its continued effectiveness in the face of resistance.

This new sort of property right could, in principle, be applied to drugs that are already off patent or otherwise ineligible for patent protection. The Chatham House Working Group proposes granting “delinkage rewards” to “firms registering a new antibiotic without patent protection (such as new uses for old drugs),”38 and it may be that the sort of IP protection proposed here would be applicable in such cases as well. If so, the right would be justified by the discovery of the new use for the drug and by the fact that intelligent management of this use is required for it to retain its value. A more difficult case is granting such rights to already known antibiotics that have gone off patent and are now available as generics. Removing these drugs from the commons would make it possible for an owner to profit by stewarding them responsibly. The difficulty here is determining who would own them. Professor Kades considers the possibility of granting a new patent to the original patent holder, but suggests “auctioning the patent rights [to such drugs] to the highest bidder.”39 Both are plausible solutions. Another option, in light of the issue of cross-resistance (which will be discussed in Part III) would be to apportion the IP rights to the relevant drugs among the owners of other drugs with similar mechanisms of action.

Instituting the sort of property right described here (whether or not it is extended to drugs that are currently unpatentable and/or in the public domain) would create an environment in which pharmaceutical companies and other private entities can compete to develop new policies and business models that maximize the total value derived from antimicrobial drugs over time. An important advantage of this proposal is that it does not require policymakers (or authors of law review articles) to know in advance which specific practices would have this auspicious effect. However, some obvious possibilities suggest themselves.

Pharmaceutical companies could sell new antimicrobials at a price high enough to make it prohibitive to use them as anything other than treatments of last resort. In addition to extending the drugs’ useful lives, the high prices would compensate for the lower initial volume of sales, and the drugs could eventually be repriced for wider use as second- and then first-line treatments. This repricing would have to be paced both to the growth of the resistant bacterial population and to the development of new antimicrobial drugs to take their predecessors’ place as treatments of last resort. One can imagine many variations of this strategy with different price points and development cycles.

Pharmaceutical companies could also extend the effective lifespan of their antimicrobials through contractual arrangements with healthcare providers, which restrict the latter’s use of the drugs to certain protocols or best practices. Imagine the new business practices whereby pharmaceutical companies might profit from drugs that are never or hardly ever used. Licensing plans like the one proposed by Commissioner Gottlieb might be employed in innovative ways.40 For example, healthcare providers or insurance companies might pay a monthly fee for the right to use these drugs should it ever become necessary to do so. Or the various parties might negotiate a system whereby a pharmaceutical company (or an entity that has licensed drugs from multiple companies) charges a fixed price for treatment in accordance with a proprietary antimicrobial protocol that makes use of several of their drugs, specifying which drugs can used under which conditions.

The suggestions in the last paragraph all amount to ways in which revenues from the creation of a new drug might be “delinked” from sales volume. In principle, this delinkage could occur simply through market forces, without any additional policy interventions, but since governments and multinational organizations account for most of the spending in the healthcare sector in much of the world, their adopting policies favoring delinkage would likely stimulate the development of these sorts of business models under an IP regime of the sort suggested. Indeed, such delinkage–promoting policies would likely fare better under the proposed IP regime than under the current IP system because, as The Chatham House Working Group observes, “patent expiry” creates some difficulties for such policies.

Obligations for responsible use can be carefully crafted and functional when monopoly rights are in place, but are likely to fail once generic antibiotics are introduced upon the termination of the period of exclusivity. Generic manufacturers ordinarily rely on volume-based rewards, and low prices and large volume of sales without appropriate measures to conserve the antibiotics may be an important driver of indiscriminate use and resistance. A sustainable system will require controls on market entry after termination of the patent, and regulation of the way the generic products are marketed and prescribed.41

It bears emphasizing at this point that the best stewardship policies for antimicrobial drugs remain to be discovered. The Chatham House Working Group report (quoted several times above) represents the cutting edge of research on this issue, and it offers precious few details about the new “delinked” business model it says “needs to be developed.” Successful business models are rarely if ever specified from on high by public policy makers. Securing a long-range IP right to antimicrobial drugs would create the conditions in which the healthcare industry as a whole could invest the resources required to discover the practices, protocols, and business models that maximize the value of these substances. In addition, the ability to capture this value as profit would create an incentive to develop new drugs as needed.

IP rights, and patents in particular, are sometimes understood as bargains between creators and society. The proposal under consideration grants a lot more to the developers of any new antimicrobial drugs than they are granted under current law, but it asks a lot of these developers in return—for it requires them to become good stewards of their drugs by discovering and implementing the means necessary to preserve the drugs’ value over time, so that the maximum potential benefit from them is realized.42 This is work that needs to be done by someone, and the sort of IP regime proposed here would enable those people and firms most qualified to do this work to profit by doing it.

This leads to a deeper point. Although IP rights are often understood as special privileges granted by government and justified on utilitarian grounds, the dominant strand in early American jurisprudence, taking its inspiration from John Locke, regards all property rights as securing to a creator the fruits of his productive work.43 Among the reasons why patents and copyrights are finite in duration, whereas rights to chattels or land can be passed on from generation to generation indefinitely, is that chattels and land generally need to be maintained in order to retain their economic value over time, whereas this is not true of the economic value of an artwork or a method.44 But the case under consideration reveals that the continued economic value of certain methods does depend on an ongoing process of intelligent management by which one uses the method sparingly. It is this very fact that (according to the argument of this Part) justifies extending the IP right to the drug indefinitely. This raises the question of whether there are structurally similar cases in other fields, where the continued commercial value of a potential invention depends on its judicious use. If so, it may be that there are other values being destroyed (or never created) because of tragedies of the commons that could be rectified by policies analogous to the one suggested here.

#### Even if the aff incentivizes innovation they cannot incentivize innovation in anti-microbial research – the problem right now is lack of profit incentives for innovation and responsible stewardship.

Salmieri 18 “INTELLECTUAL PROPERTY AND THE FREEDOM NEEDED TO SOLVE THE CRISIS OF RESISTANT INFECTIONS” 2018 Gregory Salmieri [Ph.D., Philosophy, 2008, University of Pittsburgh; B.A. 2001, The College of New Jersey. Fellow, The Anthem Foundation for Objectivist Scholarship; Lecturer, Philosophy Department, Rutgers University] <http://georgemasonlawreview.org/wp-content/uploads/2019/04/26-1_7-Salmieri.pdf> SM

According to a 2013 report by the Center for Disease Control (“CDC”), two million people in the United States annually contract infections that are “resistant to one or more of the antibiotics designed to treat those infections”; the result is at least 23,000 deaths and (direct and indirect) economic losses that have been estimated at $55 billion (in 2008 dollars).2 The United Kingdom’s Antimicrobial Resistance Review estimates that, worldwide, there will be as many as ten million deaths annually from such infections by 2050.3 A 2017 report by the World Bank Group anticipates the financial toll:

In the optimistic case of low AMR [antimicrobial resistance] impacts, the simulations found that, by 2050, annual global gross domestic product (GDP) would likely fall by 1.1 percent, relative to a base-case scenario with no AMR effects; the GDP shortfall would exceed $1 trillion annually after 2030. In the high AMR-impact scenario, the world will lose 3.8 percent of its annual GDP by 2050, with an annual shortfall of $3.4 trillion by 2030.4

There are two related aspects to this crisis: (1) bacterial populations are evolving resistance to the antimicrobial drugs currently in use, and (2) there are few new drugs in the developmental pipeline that promise to be effective against these bacteria.5 It is widely understood that both aspects are caused or exacerbated by the economic incentives faced by the pharmaceutical industry and the healthcare industry more broadly.6

The eventual obsolescence of any conventional antimicrobial drug is inherent in its use, but it is hastened when the drug is liberally prescribed.7 Such liberal prescription is driven by incentives for both physicians and pharmaceutical companies. Patients’ expectations for prompt treatment sometimes lead doctors to prescribe broad-spectrum antibiotics in cases where it would be more prudent to await testing and prescribe a more targeted antimicrobial—or to prescribe antibiotics for viral infections where they are ineffective. 8 Pharmaceutical companies have an incentive to sell as much volume as possible in the period between the drug’s Food and Drug Administration (“FDA”) approval and the end of its twenty-year patent term.

The problem of liberal prescription of antibiotics has been much discussed in medical and policy circles. 9 It is widely agreed that an important part of the solution is antimicrobial stewardship, which the Infectious Diseases Society of America defines as follows:

Antimicrobial stewardship refers to coordinated interventions designed to improve and measure the appropriate use of antimicrobials by promoting the selection of the optimal antimicrobial drug regimen, dose, duration of therapy, and route of administration. The major objectives of antimicrobial stewardship are to achieve optimal clinical outcomes related to antimicrobial use, to minimize toxicity and other adverse events, to reduce the costs of health care for infections, and to limit the selection for antimicrobial resistant strains.10

The most dramatic outcome thus far of the policy discussion, in the United States at least, is that the Centers for Medicare and Medicaid Services updated its “Conditions of Participation.”11 These updated “Conditions of Participation” (issued as a result of an executive order by President Obama in 2014) require all hospitals participating in Medicare and Medicaid to establish and maintain “antibiotic stewardship programs.”12 These conditions are already in effect for acute care hospitals and are expected to go into effect generally by the end of 2018.13

An additional incentive for too liberal use of antibiotics comes from outside of the healthcare industry. These drugs are useful as a growth promoter for livestock, and it has been shown that this use can lead to the growth of resistant bacteria, which can then infect human beings. 14 Such use of most antibiotics is now banned in the European Union member states, Mexico, New Zealand, and South Korea.15 In the United States and Canada, regulatory agencies have issued guidelines against this use of antibiotics that are deemed medically important.16

The second aspect of the crisis is the dearth of new antimicrobial drugs in development. A 2017 World Health Organization report projects that approximately ten new antibiotics and biologicals will be approved in the next ten years but warns that “these new treatments will add little to the already existing arsenal” because most of them will be “modifications of existing antibiotic classes,” which are “only short term solutions as they usually cannot overcome multiple existing resistance mechanisms and do not control the growing number of pan-resistant pathogens.”17

Few new antimicrobial drugs are in development because there is a low return on the investment needed to discover such drugs and shepherd them through the approval process. This is the reason why Aventis, Bristol-Myers, Squibb, Eli Lilly, Glaxo SmithKline, Proctor and Gamble, Roche, and Wyeth all “greatly curtailed, wholly eliminated or spun off their antibacterial research” between 1999 and 2003.18 The already low return on investment will dwindle as stewardship guidelines are adopted and the drugs are prescribed more judiciously.19

The Chatham House Working Group on New Antibiotic Business Models summarizes the situation thusly:

Today, few large pharmaceutical companies retain active antibacterial drug discovery programmes. One reason is that it is scientifically challenging to discover new antibiotics that are active against the antibiotic-resistant bacterial species of current clinical concern. Another core issue, however, is diminishing economic incentives. Increasingly, there are calls to conserve the use of truly novel antibiotics, which might limit sales severely and discourage greater investment in R&D. Meanwhile, unless they see evidence of superiority, healthcare payers are unwilling to pay prices that would directly support the cost of development, provide a competitive return on investment and reflect the value to society of maintaining a portfolio of antibiotics adequate to overcome growing resistance.

A principal reason for this is the mismatch between the current business model for drugs and combating resistance. The current business model requires high levels of antibiotic use in order to recover the costs of R&D. But mitigating the spread of resistance demands just the opposite: restrictions on the use of antibiotics. Economic incentives play a key role in the global resistance problem, leading to overuse of these precious drugs at the same time as companies are abandoning the field; and the increasing restrictions on inappropriate use of antibiotics make them relatively unprofitable compared with other disease areas.20

### Case

#### 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

#### Your author pulls warrants from a misleading and incomplete database – dates aren’t updated, protections are misidentified, and years are wrong.

**C-Ip 3/4** (C-Ip2, 3-4-2021, "UC Hastings’ Evergreen Drug Patent Search Database: A Look Behind the Statistics Reveals Problems with this Approach to Identifying and Quantifying So-Called “Evergreening”," Center for Intellectual Property x Innovation Policy, <https://cip2.gmu.edu/2021/03/04/uc-hastings-evergreen-drug-patent-search-database-a-look-behind-the-statistics-reveals-problems-with-this-approach-to-identifying-and-quantifying-so-called-evergreening/#_ftn1>)The problems we have identified with the statistics provided by the Evergreening Database are numerous and multifaceted, and it would be beyond the scope of a single blog post to try to address them all. Instead, we have decided to focus on a single drug, ranolazine, which is used to treat angina and marketed by Gilead under the tradename Ranexa. There is nothing particularly unique about ranolazine—the problems with its statistics are representative of what we have generally observed to be pervasive throughout the Database. The ranolazine entry caught our attention because it purports to show that the drug was a subject of a relatively large number of “protections” (24 of them) and 13 years of “additional protection time,” even though the total time between the approval of the drug and expiration of all associated patents and exclusivities was only a little more than 13 years—about five years less than the average term of a U.S. patent. We will start with an initial explanation of the methodology underlying the Evergreening Database. As mentioned above, the statistics are derived from out-of-date versions of the FDA’s Orange Book, which is published on the FDA’s website and provides information on patents and “exclusivities” associated with FDA-approved drugs. The exclusivities can be any of a variety of non-patent regulatory exclusivities that Congress created to reward innovators that have achieved certain outcomes that Congress sought to incentivize. Examples include the “NCE exclusivity”—five years of data exclusivity awarded for the initial approval of a new active ingredient, i.e., a “new chemical entity”—and the seven years of orphan drug exclusivity awarded to an innovator that develops a drug for a rare disease or condition. The Orange Book provides a listing of these exclusivities, as well as a list of patents relating to the approved drug (i.e., patents claiming the drug’s active ingredient, formulations of the drug, and methods of using the drug). It also provides expiration dates for the patent and exclusivities. The FDA periodically revises the Orange Book, and when it does, it removes from the lists any patents and exclusivities that have expired. The creators of the Evergreening Database compiled this historical data in a Comma Separated Values file (“the CSV file”). The Database uses the patents and exclusivities derived from the CSV file to generate various statistics for each drug, including a total number of “protections” and “extensions,” as well as the “earliest protection date,” “latest protection date,” and the number of “months of additional protection” (which is the time between the earliest protection date and the latest protection date). Presumably, these statistics are intended to shed some light on the purported evergreening practices of pharmaceutical companies. Now let us turn to ranolazine. The Evergreening Database entry for ranolazine provides the New Drug Application (“NDA”) number for the drug (21526), the branded product name (Ranexa), the name of the innovator company associated with the branded drug (Gilead), and the date of FDA approval (January 27, 2006). The ranolazine entry also provides various statistics derived from the raw data, including the number of “protections” (26) and the amount of “additional protection time” (156 months, i.e., 13 years). This seems to provide an example of evergreening. The statistics appear to show that Gilead gamed the system to “artificially extend the protection horizon of its patents” by 13 years. However, a closer examination of the raw data tells a quite different story. First, what are the 26 purported “protections” that Gilead has apparently secured with respect to Ranexa? Eleven of them are patents that were once listed in the Orange Book for the drug. All the listed patents have expired, so none appear in the current Orange Book. While the Database lists the patents, it does not include expiration dates, which are necessary to understand the “protection time” statistics. Worse, the Database provides no information with respect to the other 15 “protections,” i.e., non-patent exclusivities. With some effort, the missing information can be found in the CSV file. The following step-by-step instructions will hopefully make it easier for others interested in following this path. Beginning on the homepage for the Evergreening Database, click on the “About the Data” hyperlink, which will take you to another page which states: To download the original dataset, that was used to develop the results for the article May Your Drug Price Be Evergreen, along with information about researching the FDA’s Orange Book, please see:

#### Secondary patents are necessary for innovation of otherwise mediocre drugs—core to cancer and HIV treatments

**Holman 2018** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law. “Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection” <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> September 21, 2018)DR 21

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.**

#### One and done model kills innovation—chilling effect

**Magiera 2021** (Melissa S., J.D. Candidate, 2021, Indiana UniversityRobert H. McKinney School of Law; B.S. 2017, Indiana University Purdue University Indianapolis – Indianapolis, Indiana. Recipient of the Papke Prize for Best Note in Volume 54, endowed by and named in honor of David R. Papke, former R. Bruce Townsend Professor of Law and faculty advisor to the Indiana Law Review “Leaving the Evergreening Problem to the Patent Experts--The USPTO, the PTAB, and the Federal Circuit” Indiana Law Review, 54(1), 195-220.)DR 21

Additionally, the pharmaceutical industry spends millions of dollars in researching new uses or safer ways to administer known drugs.94 A new use or method of administering or making a known drug should be rewarded with a patent; if not, many pharmaceutical companies will treat the discovered drugs as “one-and-dones.” 95 Patents are meant to be issued for innovations, not for products.96 Just because a patent is granted on a medicine does not mean that the innovation relating to the drug ends; in fact, many pharmaceutical companies continue to research “new ways to make the medicine, new populations who can benefit from its use, better ways to get it to and into patients, and new versions that expand options for patents.” 97 The effect of this legislation, if enacted, likely would be to focus on lowering the price of medicine for patients at the cost of denying rightful patents to pharmaceutical companies that could have made new medical advances for the good of society. 98 Any pharmaceutical company would be scrutinized for any additional innovation of a drug and may be subject to penalties.99 Eventually, this means that the pharmaceutical companies could halt further research on any patented drug, even if there is a better, undiscovered use for that drug. 100 If enacted, the legislation could also “erode[] incentives and threaten[] innovation,” which is what the patent system was created to protect. 101

#### Minor tweaks of drugs are key to ensure adequate treatment- otherwise patients skip doses or medicines fail in hot climates

**Holman 2018** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law. “Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection” <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> September 21, 2018)DR 21

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 **oral**ly 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).

#### There’s a reason the aff’s authors are blogs not lawyers – Evergreen doesn’t prolong patents -- secondary patents *only* cover the improvement, but the original patent dies regardless.

**Holman 2018** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law. “Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection” <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> September 21, 2018)DR 21

“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.

#### That solves pricing and monopoly- the improvement might be patented but generics of the original compound become incredibly cheap

**Holman 2016** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law; J.D., University of California, Berkeley; Ph.D., University of California, Davis. “IN DEFENSE OF SECONDARY PHARMACEUTICAL PATENTS: A RESPONSE TO THE UN’S GUIDELINES FOR PHARMACEUTICAL PATENT EXAMINATION” *Indiana Law Review* 50, 2016)DR 21

Rather than the blanket presumption against patents on new formulations endorsed by the Guidelines, which would tend to deny patent protection for both minor improvements and highly significant improvements, the needs of patients would be better served if the market and the judgment of patients and healthcare providers were allowed to determine the value of a new formulation on an existing drug. If the improvement is of such significance that it justifies a substantial cost premium, then society has benefited from the development of this improved mode of drug delivery, and payment of the premium is justified, in the same way that it is by development of a therapeutically useful new active ingredient. If the improvement is nominal, then payers should refuse to pay the premium, which they can do by simply purchasing the original formulation from generic companies at a discounted price. If there are market inefficiencies that somehow induce payers to pay the premium even though the improvement is minimal, then those market inefficiencies should be addressed, rather than attempting to address it by changing the standard for patentability in a discriminatory manner that targets specific categories of inventions.

#### It's illegal to extend a patent on the same drug—only new compounds can be patented

**Holman 2020** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law; J.D., University of California, Berkeley; Ph.D., University of California, Davis “Congress should decline ill-advised legislative proposals aimed at evergreening of pharmaceutical patent protection” *University of the Pacific Law Review*, 51(3), 493-524)DR 21

When critics of the pharmaceutical industry initially began talking about "evergreening," the discussion often seemed to imply that pharmaceutical companies were literally re-patenting the same product. However, those more familiar with patent law have responded by pointing out that, as a general matter, pharmaceutical companies are not simply re-patenting a product, and that various doctrines of patent law work in conjunction to prevent a company from obtaining new patents on a product that is **already on the market**. For example, at a May 7 Congressional Hearing entitled Intellectual Property and the Price of Prescription Drugs: Balancing Innovation and Competition, Professor David Olson of the Boston College Law School explained to lawmakers that:

It is axiomatic patent law doctrine that a later-filed patent (other than a continuation) cannot cover an earlier invention. Thus, no patent that covers an earlier composition or biologic is valid. To the extent that a patent owner says that a later-filed patent, with a later priority date and expiration date covers the same subject matter as an earlier-filed patent, that person is plainly wrong .... New patents can be filed on different formulations of a previous drug, on different manufacturing processes, and on new uses of previous drugs. Although some may call this "evergreening," new uses of drugs and new ways of producing them are the kinds of innovations that the patent system is designed to encourage. It would be a very significant change in patent law to change the law to not allow these kinds of patents in the pharmaceutical field.

If, on the other hand, a patent owner files new method patents and then asserts that a competitor cannot make the originally-claimed drug without infringing the new method, **the new patent** is either **invalid** or being asserted too broadly. If the patent owner uses trade secret methods to produce its drug, and later seeks to patent those trade secret methods, then the patent owner is seeking an invalid patent and can be liable for fraud on the patent office if the patent owner did not disclose that the method was used as a trade secret for more than a year before filing. 9

#### Economics is the key internal link which short IP terms exacerbate.

Plackett 20 “Why big pharma has abandoned antibiotics” October 21, 2020, Benjamin Plackett [science journalist based in London and the Middle East] <https://www.nature.com/articles/d41586-020-02884-3> SM

Why big pharma has abandoned antibiotics

A lack of financial incentive has meant large pharmaceutical companies have left the market

When scientists, public-health bodies and governments around the world warn that antimicrobial resistance is the next great health crisis, they have good reason. Since the 1960s, bacteria and other microorganisms have become increasingly resistant to antimicrobial drugs, leading to more and more people dying.

Drug-resistant diseases kill around 700,000 people each year, but a United Nations interagency group on antimicrobial resistance estimates that this could swell to 10 million a year by 2050 if no action is taken. This is more than the number of people who currently die from cancer worldwide every year.

Despite the clear need for more antimicrobial agents, such drugs have not been forthcoming. Fewer new antibiotics are reaching the market; the last entirely original class of antibiotic was discovered in the late 1980s. One reason is that discovering and bringing antibiotics to market is often not profitable for pharmaceutical companies.

A 2017 estimate puts the cost of developing an antibiotic at around US$1.5 billion1. Meanwhile, industry analysts estimate that the average revenue generated from an antibiotic’s sale is roughly $46 million per year. “That’s tiny and nowhere near the amount needed to justify the investment,” says Kasim Kutay, chief executive of Novo Holdings, an investment firm in Hellerup, Denmark, focused on the life sciences.

As a result, many large pharmaceutical firms have dropped out of the market in favour of pursuing profitable lines of drug development, such as cancer treatments (see ‘Low approval ratings’). In their place, smaller companies and funding bodies are striving to fill the gap. But fixing the economics of drug development might take a radical approach.

Pipeline problem

Deaths caused by infectious diseases have fallen by 70% since antibiotics were introduced on a large scale in the 1940s, according to the UK biomedical funding charity Wellcome. This could be in jeopardy unless the economics of the market can be re-imagined.

A 2017 review found that in one strain of bacteria, the prevalence of resistance to levofloxacin, an antibiotic used to treat a wide variety of infections, grew from roughly 2% before 2000 to 27% between 2011 and 2015 in the Asia Pacific region2.

“The problem is terrible and not too far away,” warns Asad Khan, a microbiologist at the Aligarh Muslim University in Aligarh, northern India. “I think many governments and funding bodies haven’t yet understood the scale of what we’re facing.”

Many economists have also been slow to act. One review found that only 55 of more than 1 million peer-reviewed economics articles in the EconLit database were related to antimicrobial resistance3. Papers on climate change, by comparison, totalled around 16,000. Yet economics has a significant role in the lack of antibiotics coming to market.

Any type of pharmaceutical development is an expensive process, but for antibiotics it is especially hard. One issue is that the cost–benefit ratio — how much profit will result from an investment — is much less favourable than for other drugs. “Profit is basically volume multiplied by price,” says Richard Smith, a health economist at the University of Exeter, UK. For antibiotics, neither element is high enough to offset the cost of development.

Prices are low because in many countries government agencies have a role in assessing the price, not the manufacturer alone. In the United Kingdom, for instance, the National Institute for Health and Care Excellence (NICE) assesses the clinical strength and cost-effectiveness of new medicines. “The point of NICE is to try and keep drug prices low,” says Smith.

Other countries have a similar set-up. For a new drug to be included in the Australian government’s Pharmaceutical Benefits Scheme, which subsidizes the cost of medication, it has to be approved by a committee of health professionals and economists, who evaluate whether the drug offers value for money. Canada also regulates the price of patented medicines to keep prices low.

At the same time, physicians avoid prescribing new antibiotics to help delay the development of bacterial resistance. This means that governments and health agencies are even less likely to accept a premium for new antibiotics, says Smith. “Antibiotics used to be profitable back in the 1960s when you didn’t have to consider resistance as an issue,” he says. Typically, a drug is granted a 5–10 year exclusivity period, during which the manufacturer is shielded from competition from any generic versions that might be developed. But even this isn’t enough to recoup the vast development costs. Once the exclusivity period expires, other drug makers can enter the market — and, without the need to account for large research expenditures, they can drop the price.

According to a policy review4 by the UK Office of Health Economics, the relatively short treatment cycle for a course of antibiotics reduces the volume that can be sold. Antibiotics are typically prescribed for a couple of weeks, whereas therapies for chronic diseases are taken for months or even years.

In a 2003 study, researchers found that an injectable antibiotic is roughly three times less profitable than are drugs used for the treatment of cancer5. Drugs for musculoskeletal conditions, meanwhile, are around 11 times more lucrative.

#### Number of patents has no bearing on innovation or competition– tech proves

**Holman 2020** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law; J.D., University of California, Berkeley; Ph.D., University of California, Davis “Congress should decline ill-advised legislative proposals aimed at evergreening of pharmaceutical patent protection” *University of the Pacific Law Review*, 51(3), 493-524)DR 21

Edited for ableist language in brackets []

It is generally recognized that an advanced smart phone, such as Apple's iPhone, is covered by literally thousands of patents. 0 In his opening remarks before the May 7, 2019, Senate Judiciary hearing Senator Thom Tillis noted this fact, pointing out that "[]ust like an iPhone has thousands of patents, so does a complex pharmaceutical product.""' In his written testimony prepared for that same hearing, Professor Olson pointed out that while some might expect the large number of patents on smart phones to create a "significant drag on innovation," in fact "there is no conclusive evidence that smartphone or other high-tech innovation is being ~~retarded~~ [slowed] by the large numbers of patents that may cover these devices. 8 2 He goes on to point out that "[t]he number of patents that cover any particular drug or biologic, in comparison, are quite low, ranging from the single digits to perhaps one hundred. This is not enough patents to constitute a substantial patent thicket that will deter innovation. 83

Similarly, in recent testimony before the House Judiciary Committee, USPTO Director Andrei Iancu was asked about the issues of "evergreening" and "patent thicketing" in the context of pharmaceutical drugs, and he defended his office's practice of issuing multiple patents to the same drug, stating that each application is evaluated for whether the claimed invention "actually presents novel and nonobvious innovation vis-i-vis what's come beforehand. 84

#### Companies would just file a dozen patents upfront instead of secondary patents

**Holman 2020** (Christopher, Professor of Law, University of Missouri-Kansas City School of Law; J.D., University of California, Berkeley; Ph.D., University of California, Davis “Congress should decline ill-advised legislative proposals aimed at evergreening of pharmaceutical patent protection” *University of the Pacific Law Review*, 51(3), 493-524)DR 21

Under this interpretation of the bill, pharmaceutical companies would be motivated to dramatically change their patent filing practices. Instead of filing an application with claims that might be found to be directed towards two or more distinct inventions-and thus subject to a restriction requirement-the pharmaceutical company would need to file many patent applications simultaneously, each with claims directed towards the different inventions. For example, if this was the law at the time Amgen filed its initial patent application in 1983, it would have likely responded by filing at least seven applications with claims directed towards various methods, reagents, and products, rather than filing a single application that ultimately resulted in seven patents.

Cant solve econ, not reverse causal