# 1NC

### 1NC – CP

#### CP: The member nations of the World Trade Organization should allow market 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 and exclusivity 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

#### 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.

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#### Interp – the aff must only defend that the member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

#### Intellectual property is

Brewer 19 [(Trevor, advises clients on business structuring and sale transactions, regulatory compliance, third-party contracts, liability protection and general matters facing small business owners. His focus extends beyond legal advice and includes business strategy and wealth preservation.) “WHAT ARE THE FOUR BASIC TYPES OF INTELLECTUAL PROPERTY RIGHTS?” Brewer Long, 5/16/19. <https://brewerlong.com/information/business-law/four-types-of-intellectual-property/>] RR

There are four types of intellectual property rights and protections (although multiple types of intellectual property itself). Securing the correct protection for your property is important, which is why consulting with a lawyer is a must. The four categories of intellectual property protections include:

TRADE SECRETS

Trade secrets refer to specific, private information that is important to a business because it gives the business a competitive advantage in its marketplace. If a trade secret is acquired by another company, it could harm the original holder.

Examples of trade secrets include recipes for certain foods and beverages (like Mrs. Fields’ cookies or Sprite), new inventions, software, processes, and even different marketing strategies.

When a person or business holds a trade secret protection, others cannot copy or steal the idea. In order to establish information as a “trade secret,” and to incur the legal protections associated with trade secrets, businesses must actively behave in a manner that demonstrates their desire to protect the information.

Trade secrets are protected without official registration; however, an owner of a trade secret whose rights are breached–i.e. someone steals their trade secret–may ask a court to ask against that individual and prevent them from using the trade secret.

PATENTS

As defined by the U.S. Patent and Trademark Office (USPTO), a patent is a type of limited-duration protection that can be used to protect inventions (or discoveries) that are new, non-obvious, and useful, such a new process, machine, article of manufacture, or composition of matter.

When a property owner holds a patent, others are prevented, under law, from offering for sale, making, or using the product.

COPYRIGHTS

Copyrights and patents are not the same things, although they are often confused. A copyright is a type of intellectual property protection that protects original works of authorship, which might include literary works, music, art, and more. Today, copyrights also protect computer software and architecture.

Copyright protections are automatic; once you create something, it is yours. However, if your rights under copyright protections are infringed and you wish to file a lawsuit, then registration of your copyright will be necessary.

TRADEMARKS

Finally, the fourth type of intellectual property protection is a trademark protection. Remember, patents are used to protect inventions and discoveries and copyrights are used to protect expressions of ideas and creations, like art and writing.

Trademarks, then, refer to phrases, words, or symbols that distinguish the source of a product or services of one party from another. For example, the Nike symbol–which nearly all could easily recognize and identify–is a type of trademark.

While patents and copyrights can expire, trademark rights come from the use of the trademark, and therefore can be held indefinitely. Like a copyright, registration of a trademark is not required, but registering can offer additional advantages.

#### A one-and-done approach affects orphan drug designations – their solvency advocate card

1AC Feldman 19 Robin Feldman 2-11-2019 "‘One-and-done’ for new drugs could cut patent thickets and boost generic competition" <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/> (Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation)//SidK + Elmer

I believe that one period of protection **should be enough**. We should make the legal changes necessary to prevent companies **from building patent walls** and piling up mountains of rights. This could be accomplished **by** a “one-and-done” approach for patent protection. Under it, a drug would receive just one period of exclusivity, and no more. The choice of which “one” could be left entirely in the hands of the pharmaceutical company, with the election made when the FDA approves the drug. Perhaps development of the drug went swiftly and smoothly, so the remaining life of one of the drug’s patents is of greatest value. Perhaps development languished, so designation as an orphan drug or some other benefit would bring greater reward. The choice would be up to the company itself, based on its own calculation of the maximum benefit. The result, however, is that a pharmaceutical company chooses whether its period of exclusivity would be a patent, an orphan drug designation, a period of data exclusivity (in which no generic is allowed to use the original drug’s safety and effectiveness data), or something else — but not all of the above and more. Consider Suboxone, a combination of buprenorphine and naloxone for treating opioid addiction. The drug’s maker has extended its protection cliff eight times, including obtaining an orphan drug designation, which is intended for drugs that serve only a small number of patients. The drug’s first period of exclusivity ended in 2005, but with the additions its protection now lasts until 2024. That makes almost two additional decades in which the public has borne the burden of monopoly pricing, and access to the medicine may have been constrained. Implementing a one-and-done approach in conjunction with FDA approval underscores the fact that these problems and solutions are designed for pharmaceuticals, not for all types of technologies. That way, one-and-done could be implemented through **legislative changes to the FDA’s drug approval system**, and would apply to patents granted going forward. One-and-done would apply to both patents and exclusivities. A more limited approach, a baby step if you will, would be to invigorate the existing patent obviousness doctrine as a way to cut back on patent tinkering. Obviousness, one of the five standards for patent eligibility, says that inventions that are obvious to an expert or the general public can’t be patented. Either by congressional clarification or judicial interpretation, many pile-on patents could be eliminated with a ruling that the core concept of the additional patent is nothing more than the original formulation. Anything else is merely an obvious adaptation of the core invention, modified with existing technology. As such, the patent would fail for being perfectly obvious. Even without congressional action, a more vigorous and robust application of the existing obviousness doctrine could significantly improve the problem of piled-up patents and patent walls. Pharmaceutical companies have become adept at maneuvering through the system of patent and non-patent rights to create mountains of rights that can be applied, one after another. This behavior lets drug companies keep competitors out of the market and beat them back when they get there. We shouldn’t be surprised at this. Pharmaceutical companies are profit-making entities, after all, that face pressure from their shareholders to produce ever-better results. If we want to change the system, we must change the incentives driving the system. And right now, the incentives for creating patent walls are just too great.

#### Orphan drug designation goes beyond IP

FDA “Designating an Orphan Product: Drugs and Biological Products” No Date <https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-orphan-product-drugs-and-biological-products> SM

Supporting the development and evaluation of new treatments for rare diseases is a key priority for the FDA. The FDA has authority to grant orphan-drug designation to a drug or biological product to prevent, diagnose or treat a rare disease or condition. Orphan drug designation qualifies sponsors for incentives including:

Tax credits for qualified clinical trials

Exemption from user fees

Potential seven years of market exclusivity after approval

#### Reducing orphan drug designation standards is widely extra-topical – it affects companies’ abilities to obtain tax credits, grants, regulatory assistance, fee waivers, and more. Market exclusivity is just one aspect.

Nuventra 4/21 Nuventra Pharma Sciences [Our consultants translate complex data into actionable insights across the entire drug development spectrum. With more than 1,000 years of combined experience in pharmaceutical development, we enable our clients to make better strategic decisions and improve their clinical and nonclinical studies.] “FDA Orphan Drug Designation for Rare Diseases” April 21, 2021 <https://www.nuventra.com/resources/blog/orphan-drug-products/> SM

Incentives of Orphan Drug Designation

One of the biggest challenges for companies developing drugs for rare diseases is that due to the small target population size, sponsors are unlikely to recoup the cost of research, development, and approval from the orphan drug product. In response to this, the FDA has created multiple incentives to make orphan drug development more financially possible for companies to pursue. Some of the incentives include:

7-year marketing exclusivity to sponsors of approved orphan products

25% federal tax credit for expenses incurred in conducting clinical research within the United States

Tax credits may be applied to prior year or applied over as many as 20 years to future taxes

Waiver of Prescription Drug User Fee Act (PDUFA) fees for orphan drugs

A value of approximately $2.9 million in 2021

Ability to qualify to compete for research grants from the Office of Orphan Products Development (OOPD) to support clinical studies for orphan drugs

Eligibility to receive regulatory assistance and guidance from the FDA in the design of an overall drug development plan

#### Vote neg for limits – allowing extra topicality explodes the prep burden to every possible incentive granted to pharma companies – reciprocal prep burdens are key to engagement

#### No plan text in a vacuum for this arg specifically – a] their plan text says “a one-and-done approach for patent and exclusivity protection” which is defined as including orphan drugs PER THEIR OWN solvency ev so the plan text violates b] vote neg on presumption – there’s zero way you’d know what a “one-and-done approach” is absent reading their evidence which means evaluating their plan text absent the Feldman card is incoherent and illogical

### 1NC – DA

#### Reconciliation passes now which unites House Democrats around Infrastructure—there’s zero margin of error.

Lisa Hagen 10-25-2021, [Lisa Hagen is a politics reporter for U.S. News & World Report covering Congress, elections, and the Supreme Court], “Democrats Inch Closer to Deal on Massive Social Spending Plan,” U.S. News & World Report, <https://www.usnews.com/news/politics/articles/2021-10-25/democrats-inch-closer-to-deal-on-massive-social-spending-plan> //SLC PK

Democrats say they're getting closer to clinching a deal on their massive social spending plan, one that seeks to bring together warring factions of the party and help deliver on President Joe Biden's two-part economic agenda.

The White House and congressional leaders are working on firming up the final details and spending cuts with two key holdouts in the Senate and to reach a framework that'll appease both the progressive and moderate wings of the party. Democrats need to greatly downsize their bill which could end up in the $1.5 trillion to $1.9 trillion range. While making concessions on party priorities has been largely contentious, Democrats believe they're closer than ever to a compromise on legislation that'll deliver benefits for parents, children, families and seniors.

If they can settle on a framework this week, Democrats plan to promptly hold a vote on the trillion-dollar bipartisan infrastructure bill that has stalled in the House. Last month, progressives banded together and withheld their support for the bipartisan legislation until getting commitments from Sen. Joe Manchin of West Virginia and Sen. Kyrsten Sinema of Arizona on the Democrat-only social safety net package. Because they're using the budget reconciliation process to pass the spending bill with a simple majority and no GOP votes, all 50 Senate Democrats need to vote for it.

After a weekend trip to Delaware to continue negotiations on the reconciliation bill, known as the Build Back Better Act, Senate Majority Leader Chuck Schumer of New York said Democrats are "on track" to reach a deal. He met with Biden and Manchin on Sunday and is consistently speaking with House Speaker Nancy Pelosi of California and rank-and-file members. Schumer told reporters at the Capitol they need to keep working on "three or four outstanding issues," but he noted much of the reconciliation bill is already written.

"No one ever said passing transformational legislation like this would be easy, but we are on track to get this done," Schumer said Monday afternoon from the Senate floor. "Because it's so important and it is what the American people need and what they want."

"The progress of last week illustrated if we stick together, work towards finding that legislative sweet spot, then we can get big things done for the American people," he added.

Before departing for New Jersey on Monday morning, Biden said he wants to secure a deal before he travels abroad to attend a United Nations climate change conference in Scotland starting next week. The president has been traveling around the country to tout both pieces of his agenda – the bipartisan bill and the reconciliation legislation – especially with two high-stakes governors' elections next Tuesday, particularly in Virginia. Some Democrats have urged the party to immediately take up the bipartisan infrastructure bill as a boost to former Gov. Terry McAuliffe, who is seeking a second term but is in a tight race with Republican businessman Glenn Youngkin despite Virginia's Democratic streak in recent elections.

"It would be very, very positive to get it done before the trip," Biden told reporters, referring to his foreign trip that begins on Thursday.

Since Democrats' initial $3.5 trillion bill will likely be at least slashed in half, some programs have been completely taken out – like tuition-free community college for two years. Others will be scaled back – like the child tax credit, which will now only get a one-year extension. And the fate of some programs are still unknown – like paid family and medical leave and expanded Medicare benefits. But other key provisions may remain unscathed – like universal pre-kindergarten.

Plus, Democrats are still finalizing the tax portion of their bill that'll pay for the years of new spending. After Sinema's objections, the party will no longer rely on increasing corporate and individual tax rates with large corporations and wealthier Americans.

While the timeline for a deal and an infrastructure vote are still a bit murky and hurdles still exist, Democrats voiced confidence over the weekend and again on Monday that they can get there within a matter of days.

Democrats set a new deadline of securing a framework for the reconciliation bill and passing bipartisan infrastructure legislation by Oct. 31 since surface transportation funding runs out. But if they blow past the deadline for a second time, they're likely to pass a short-term extension again to give them more time.

Manchin appeared optimistic that a framework could be finalized this week. And while pieces of the reconciliation bill still concern him – like a paid leave program and Medicare and Medicaid expansion – he sounded open to tax ideas to fund the bill, such as a billionaire wealth tax and a minimum tax for corporations, saying he's "open to any type of thing that makes people pay who are not paying now."

At the same time, he still seems committed to his $1.5 trillion top-line spending as others in the party, especially progressives, try to settle on a price tag closer to $2 trillion. But Manchin signaled that Democrats are now in a better spot than they've been in for months.

"I think that we've got a good understanding of each other," Manchin told reporters, "better than we've ever had."

#### Attacks on pharmaceutical profits triggers Mod Dem Backlash – it disrupts unity.

Cohen 9-6 Joshua Cohen 9-6-2021 "Democrats’ Plans To Introduce Prescription Drug Pricing Reform Face Formidable Obstacles" <https://www.forbes.com/sites/joshuacohen/2021/09/06/democrats-plans-to-introduce-prescription-drug-pricing-reform-face-obstacles/?sh=37a269917395> (independent healthcare analyst with over 22 years of experience analyzing healthcare and pharmaceuticals.)//Elmer

There’s considerable uncertainty regarding passage with a simple majority of the 2021 massive budget reconciliation bill. Last week, Senator Joe Manchin called on Democrats to pause pushing forward the budget reconciliation bill. If Manchin winds up saying no to the bill, this would scuttle it as the Democrats can’t afford to lose a single Senator. And, there’s speculation that provisions to reduce prescription drug prices may be watered down and not incorporate international price referencing. Additionally, reduced prices derived through Medicare negotiation may not be able to be applied to those with employer-based coverage. While the progressive wing of the Democratic Party supports drug pricing reform, **several key centrist Democrats** in both the House and Senate appear to be **uncomfortable** **with** particular aspects of the budget reconciliation bill, including a potential deal-breaker, namely the potential **negative impact of drug price controls on the domestic pharmaceutical industry**, as well as long-term patient access to new drugs. A paper released in 2019 by the nonpartisan Congressional Budget Office found that the proposed legislation, H.R. 3, would reduce global revenue for new drugs by 19%, leading to 8 fewer drugs approved in the U.S. between 2020 and 2029, and 30 fewer drugs over the next decade. And, a new report from the CBO reinforces the message that drug pricing legislation under consideration in Congress could lead to fewer new drugs being developed and launched. **Intense lobbying efforts from biopharmaceutical industry groups** **are underway**, **warning of** what they deem are **harms from price controls in** the form of diminished patient **access to new innovations**. The argument, based in part on assumptions and modeling included in the CBO reports, asserts that price controls would dampen investment critical to the biopharmaceutical industry’s pipeline of drugs and biologics. **This** won’t sway most Democrats, but has been a traditional talking point in the Republican Party for decades, and **may convince some centrist Democrats to withdraw backing** of provisions **that** in their eyes **stymie pharmaceutical innovation.** If the budget reconciliation bill would fail to garner a majority, a pared down version of H.R. 3, or perhaps a new bill altogether, with Senator Wyden spearheading the effort, could eventually land in the Senate. But, a similar set of provisos would apply, as majority support in both chambers would be far from a sure thing. In brief, Democrats’ plans at both the executive and legislative branch levels to introduce prescription **drug pricing reform** **encounter challenges** which may prevent impactful modifications from taking place.

#### Sinema specifically jumps ship.

Hancock and Lucas 20 Jay Hancock and Elizabeth Lucas 5-29-2020 "A Senator From Arizona Emerges As A Pharma Favorite" <https://khn.org/news/a-senator-from-arizona-emerges-as-a-pharma-favorite/> (Senior Correspondent, joined KHN in 2012 from The Baltimore Sun, where he wrote a column on business and finance. Previously he covered the State Department and the economics beat for The Sun and health care for The Virginian-Pilot of Norfolk and the Daily Press of Newport News. He has a bachelor’s degree from Colgate University and a master’s in journalism from Northwestern University.)//Elmer

Sen. Kyrsten **Sinema formed** a **congressional caucus to raise** “**awareness of the benefits of personalized medicine**” in February. Soon after that, employees of **pharmaceutical companies** **donated** $35,000 to her campaign committee. Amgen gave $5,000. So did Genentech and Merck. Sanofi, Pfizer and Eli Lilly all gave $2,500. Each of those companies has invested heavily in personalized medicine, which promises individually tailored drugs that can cost a patient hundreds of thousands of dollars. **Sinema** is a first-term Democrat from Arizona but has nonetheless **emerged as a pharma favorite in Congress** as the industry steers through a new political and economic landscape formed by the coronavirus. She is a **leading recipient of pharma campaign cash** even though she’s not up for reelection until 2024 and lacks major committee or subcommittee leadership posts. For the 2019-20 election cycle through March, political action committees run by employees of drug companies and their trade groups gave her $98,500 in campaign funds, Kaiser Health News’ Pharma Cash to Congress database shows. That stands out in a Congress in which a third of the members got no pharma cash for the period and half of those who did got $10,000 or less. The contributions give companies a chance to cultivate Sinema as she restocks from a brutal 2018 election victory that cost nearly $25 million. Altogether, pharma PACs have so far given $9.2 million to congressional campaign chests in this cycle, compared with $9.4 million at this point in the 2017-18 period, a sustained surge as the industry has responded to complaints about soaring prices. Sinema’s pharma haul was twice that of Sen. Susan Collins of Maine, considered one of the most vulnerable Republicans in November, and approached that of fellow Democrat Steny Hoyer, the powerful House majority leader from Maryland. It all adds up to **a bet by drug companies that** the 43-year-old **Sinema**, first elected to the Senate in 2018, **will** gain influence in coming years and **serve as an industry ally** in a party that also includes many lawmakers harshly critical of high drug prices and the companies that set them.

#### Infrastructure reform solves Existential Climate Change – it results in spill-over.

USA Today 7-20 7-20-2021 "Climate change is at 'code red' status for the planet, and inaction is no longer an option" <https://www.usatoday.com/story/opinion/todaysdebate/2021/07/20/climate-change-biden-infrastructure-bill-good-start/7877118002/> //Elmer

**Not long ago**, **climate change** for many Americans **was** like **a distant bell**. News of starving polar bears or melting glaciers was tragic and disturbing, but other worldly. Not any more. **Top climate scientists** from around the world **warned of a "code red for humanity**" in a report issued Monday that says severe, human-caused global warming is become unassailable. Proof of the findings by the United Nations' Intergovernmental Panel on Climate Change is a now a factor of daily life. Due to **intense heat waves and drought**, 107 wildfires – including the largest ever in California – are now raging across the West, consuming 2.3 million acres. Earlier this summer, hundreds of people died in unprecedented triple-digit heat in Oregon, Washington and western Canada, when a "heat dome" of enormous proportions settled over the region for days. Some victims brought by stretcher into crowded hospital wards had body temperatures so high, their nervous systems had shut down. People collapsed trying to make their way to cooling shelters. Heat-trapping greenhouse gases Scientists say the event was almost **certainly made worse and more intransigent by human-caused climate change**. They attribute it to a combination of warming Arctic temperatures and a growing accumulation of heat-trapping greenhouse gases caused by the burning of fossil fuels. The **consequences of** what mankind has done to the atmo**sphere are now inescapable**. Periods of **extreme heat** are projected to **double** in the lower 48 states by 2100. **Heat deaths** are far **outpacing every other form of weather killer** in a 30-year average. A **persistent megadrought** in America's West continues to create tinder-dry conditions that augur another devastating wildfire season. And scientists say **warming oceans** are **fueling** ever **more powerful storms**, evidenced by Elsa and the early arrival of hurricane season this year. Increasingly severe weather is causing an estimated $100 billion in damage to the United States every year. "It is honestly surreal to see your projections manifesting themselves in real time, with all the suffering that accompanies them. It is heartbreaking," said climate scientist Katharine Hayhoe. **Rising seas** from global warming Investigators are still trying to determine what led to the collapse of a Miami-area condominium that left more than 100 dead or missing. But one concerning factor is the corrosive effect on reinforced steel structures of encroaching saltwater, made worse in Florida by a foot of rising seas from global warming since the 1900s. The clock is ticking for planet Earth. While the U.N. report concludes some level of severe climate change is now unavoidable, there is still a window of time when far more catastrophic events can be mitigated. But mankind must act soon to curb the release of heat-trapping gases. Global **temperature** has **risen** nearly **2 degrees** Fahrenheit since the pre-industrial era of the late 19th century. Scientists warn that in a decade, it could surpass a **2.7**-degree increase. That's **enough** warming **to cause catastrophic climate changes**. After a brief decline in global greenhouse gas emissions during the pandemic, pollution is on the rise. Years that could have been devoted to addressing the crisis were wasted during a feckless period of inaction by the Trump administration. Congress must act Joe Biden won the presidency promising broad new policies to cut America's greenhouse gas emissions. But Congress needs to act on those ideas this year. Democrats cannot risk losing narrow control of one or both chambers of Congress in the 2022 elections to a Republican Party too long resistant to meaningful action on the climate. So what's at issue? A trillion dollar **infrastructure bill** negotiated between Biden and a group of centrist senators (including 10 Republicans) is a start. In addition to repairing bridges, roads and rails, it would **improve access** by the nation's power infrastructure **to renewable energy sources,** **cap millions of abandoned oil and gas wells spewing greenhouse gases**, **and harden structures against climate change**. It also **offers tax credits for** the **purchase of electric vehicles** and funds the construction of charging stations. (**The nation's largest source of climate pollution are gas-powered vehicles**.) Senate approval could come very soon. Much **more is needed** if the nation is going to reach Biden's necessary goal of cutting U.S. climate pollution in half from 2005 levels by 2030. His ideas worth considering include a federal clean electricity standard for utilities, federal investments and tax credits to promote renewable energy, and tens of billions of dollars in clean energy research and development, including into ways of extracting greenhouse gases from the skies. Another idea worth considering is a fully refundable carbon tax. **The vehicle** for these additional proposals **would be a second infrastructure bill**. And if Republicans balk at the cost of such vital investment, Biden is rightly proposing to pass this package through a process known as budget reconciliation, which allows bills to clear the Senate with a simple majority vote. These are drastic legislative steps. But drastic times call for them. And when Biden attends a U.N. climate conference in November, he can use American progress on climate change as a mean of persuading others to follow our lead. Further delay is not an option.

#### Warming guarantees extinction – multiple scenarios

Specktor 19 [Brandon Specktor] “Human Civilization Will Crumble by 2050 If We Don't Stop Climate Change Now, New Paper Claims.” Live Science. June 4, 2019. <https://www.livescience.com/65633-climate-change-dooms-humans-by-2050.html> TG

It seems every week there's a scary new report about how man-made climate change is going to cause the collapse of the world's ice sheets, result in the extinction of up to 1 million animal species and — if that wasn't bad enough — make our [beer very, very expensive](https://www.livescience.com/63832-climate-change-will-ruin-beer.html). This week, a new policy paper from an Australian think tank claims that those other reports are slightly off; the risks of climate change are actually much, much worse than anyone can imagine.

[According to the paper](https://docs.wixstatic.com/ugd/148cb0_b2c0c79dc4344b279bcf2365336ff23b.pdf), climate change poses a "near- to mid-term existential threat to human civilization," and there's a good chance society could collapse as soon as 2050 if serious mitigation actions aren't taken in the next decade.

Published by the Breakthrough National Centre for Climate Restoration in Melbourne (an independent think tank focused on climate policy) and authored by a climate researcher and a former fossil fuel executive, the paper's central thesis is that climate scientists are too restrained in their predictions of how climate change will affect the planet in the near future. [[Top 9 Ways the World Could End](https://www.livescience.com/36999-top-scientists-world-enders.html)]

The current climate crisis, they say, is larger and more complex than any humans have ever dealt with before. General climate models — like the one that the [United Nations' Panel on Climate Change](https://www.ipcc.ch/sr15/) (IPCC) used in 2018 to predict that a global temperature increase of 3.6 degrees Fahrenheit (2 degrees Celsius) could put hundreds of millions of people at risk — fail to account for the sheer complexity of Earth's many interlinked geological processes; as such, they fail to adequately predict the scale of the potential consequences. The truth, the authors wrote, is probably far worse than any models can fathom.

How the world ends

What might an accurate worst-case picture of the planet's climate-addled future actually look like, then? The authors provide one particularly grim scenario that begins with world governments "politely ignoring" the advice of scientists and the will of the public to decarbonize the economy (finding alternative energy sources), resulting in a global temperature increase 5.4 F (3 C) by the year 2050. At this point, the world's ice sheets vanish; brutal droughts kill many of the trees in the [Amazon rainforest](https://www.livescience.com/57266-amazon-river.html) (removing one of the world's largest carbon offsets); and the planet plunges into a feedback loop of ever-hotter, ever-deadlier conditions.

"Thirty-five percent of the global land area, and 55 percent of the global population, are subject to more than 20 days a year of lethal heat conditions, beyond the threshold of human survivability," the authors hypothesized.

Meanwhile, droughts, floods and wildfires regularly ravage the land. Nearly one-third of the world's land surface turns to desert. Entire ecosystems collapse, beginning with the planet's coral reefs, the rainforest and the Arctic ice sheets. The world's tropics are hit hardest by these new climate extremes, destroying the region's agriculture and turning more than 1 billion people into refugees.

This mass movement of refugees — coupled with [shrinking coastlines](https://www.livescience.com/51990-sea-level-rise-unknowns.html) and severe drops in food and water availability — begin to stress the fabric of the world's largest nations, including the United States. Armed conflicts over resources, perhaps culminating in nuclear war, are likely.

The result, according to the new paper, is "outright chaos" and perhaps "the end of human global civilization as we know it."

### 1NC – 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

#### 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

#### 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

#### They don’t have a bioweapons scenario and disease won’t cause extinction—