### FW

#### All ethics is based on reason since to ask for a reason for reason is to concede the authority of reasons. Reasons must be universalizable since A) otherwise they’d be false because they wouldn’t apply to all applicable situations and B) 2+2 = 4 for all agents – if a reason can’t apply equally to all agents, it can’t provide a stable basis for ethics because it’s application is contingent on circumstance. Independently takes out consequentialist frameworks because they judge ethics based on matters of chance.

#### The standard is consistency with respecting liberty. Freedom violations aren’t because to violate one’s freedom you must freely will the act of violating another’s freedom, which is an action of using freedom to restrict it. Prefer –

#### 1] Unconditional value – the free will must be respected as an end in itself – all other goods are only conditionally valuable, and are granted objective value when humans confer that value upon them to justify their pursuit. Since nothing else is inherently good, violation of the free will can never be justified via external consequences.

#### 2] Action theory – ends are contingent on practical reason.

Stephen Engstrom 08 – professor of phil at university of Pittsburgh; before coming to the University of Pittsburgh in 1990, he taught at the University of Chicago and at Harvard, and since joining the Department he has held visiting positions at UCLA, the University of Leipzig, and the University of Chicago; “Universal Legislation As the Form of Practical Knowledge”. Academia.edu, 2008)

Kant holds that to set something as one’s end is to represent it in practical judgment as one’s effect, or, in other words, to represent oneself as its cause: “an end”, he says, “is the object of a concept, so far as the latter is regarded as the cause of the former (the real ground of its possibility)” (KU 220; cf. MS 384). Thus the act of practical representation that constitutes the setting of an object as an end essentially includes an understanding of itself as the cause whereby that object is to be brought about. It’s therefore essential to an end that to will something as one’s end is to regard oneself, in one’s representation of that end, as the cause that, through that same representation, is to realize it. Hence every representation of an end—and so every maxim15—contains two components: (i) the representation of the object, and (ii) the representation of the relation of causal dependency in which that object stands to the subject, as the latter’s effect, or (what comes to the same thing) the representation of the subject’s causal sufficiency in respect of the object, that is, the sufficiency of the subject’s action to produce it. And since what is represented in cognition must correspond to the cognition of it, to these two components in the representation of an end there must correspond two components in the end itself.

#### Consequentialism fails – it can only explain an act as movement with consequences since it only cares about consequences, but each act of agency can be reduced to an infinite series of subatomic movements and consequences.

#### Action theory outweighs – absent being able to coherently explain an act, you can never deem an act moral or immoral.

#### 3] TJF – frameworks are merely interpretations of the word ought in the resolution. Prefer my framework:

#### A. Accessibility – anyone can win a framework debate with analytics while other frameworks like util require mounds of prep. Accessibility is an impact filter for other goods – exclusion of particular people is the worst form of unfairness.

#### B. Resolvability – Kant debates are based on universal, a priori reasons, while other frameworks are based on contingent and thus unpredictable predictions. Outweighs – judges have to be able to make decisions.

#### 4] Actor specificity – governments must respect side constraints – the U.S. couldn’t donate all of its money to African states even if it would produce net more wellbeing for them than us – respecting freedom is enshrined in the constitution AND governments are structured to be mutual arbitrers of competing claims to rights in response to the conflicting rights claims of the state of nature – not to produce happiness.

#### 5] Performativity – the process of justifying any alternative framework relies upon freedom, and thus collapses to mine.

### 1AC: Plan

#### Plan – The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines by implementing a one-and-done approach for patent and exclusivity protection.

#### The Plan solves Evergreening.

Feldman 2 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.

### Contention

#### 1] The categorical imperative rejects the idea of intellectual property as it suppresses freedom by preventing others from innovating and suppressing speech in the name of a copyright.

Pievatolo 10 Pievatolo, Maria. “Freedom, Ownership and Copyright: Why Does Kant Reject the Concept of Intellectual Property?” *Freedom, Ownership and Copyright: Why Does Kant Reject the Concept of Intellectual Property?*, 7 Feb. 2010, bfp.sp.unipi.it/chiara/lm/kantpisa1.html. SJEP

In the Metaphysics of Morals, Kant seems to take for granted that the objects of real rights are only corporeal entities or res corporales: «Sache ist ein Ding, was keiner Zurechnung fähig ist. Ein jedes Object der freien Willkür, welches selbst der Freiheit ermangelt, heiß daher Sache (res corporalis)». [32](http://bfp.sp.unipi.it/chiara/lm/kantpisa1.html#ftn.id2478823) Theoretically, however, such a negative definition could have been appropriate to incorporeal things as well. According to Kant, the rightful possession of a thing should be distinguished from its sensible possession. Something external would be rightfully mine «only if I may assume that i could be wronged by another's use of a thing even though I am not in possession of it» (AA.06 [245:13-16](http://virt052.zim.uni-duisburg-essen.de/Kant/aa06/245.html)). The rightful possession is an intelligible, not sensible, relation. I can claim that my bicycle is mine only if I am entitled to require that nobody takes it even when I leave it alone in the backyard. Kant's theory of property is very different from Fichte's principle of property as explained in his 1793 essay, according to which we are the rightful owners of a thing, the appropriation of which by another is physically impossible. For this reason, according to Fichte, the originality of the exposition entitles an author to claim a rightful property on his work. Is it really so obvious that originality implies property? Property is a comfortable social convention that allows us to avoid to quarrel all the time over the use of material objects. It is so comfortable just because it is physically possible to appropriate things; we do not need to invoke property when something cannot be separated from someone. I say both that my fingerprints or my writing style are "mine" and that my bicycle is "mine". But these two "mine" have a different meaning: the former is the "mine" of attribution; the latter is the "mine" of property. The former can be used to identify someone, and conveys the historical circumstance that something is related exclusively to someone; the latter points only to an accidental relation with an external thing, if we consider it from a physical point of view. It is possible to lie on a historical circumstance, by plagiarizing a text, i.e. by attributing it to a person who did not wrote it. However, properly speaking, no one can "steal" the historical connection between "my" writing style and me: the convention of property is useless, in this case. Besides, if Fichte's principle were the only justification of property right, it would undermine the very concept of it: as it is physically possible to "attribute" my bicycle to another, when I leave it alone in the backyard, everyone would be entitled to take it for himself. As Kant would have said, a legal property right cannot be founded on sensible situations, but only on intelligible relations. Although he defines things as res corporales, Kant determines the rightful possession of a thing as a possession without detentio, by ignoring all its sensible facets. Such a possession - a possession of a thing without holding it - is exerted on an object that is "merely distinct from me", regardless of its position in space and time. Space and time, indeed, are sensible determinations and should be left out of consideration. According to the postulate of practical reason with regard to rights, property is justified by a permissive law of reason: [33](http://bfp.sp.unipi.it/chiara/lm/kantpisa1.html#ftn.id2533469) if a rightful possession were not possible, every object would be a res nullius and nobody would be entitled to use it. Kant implicitly denies that a res nullius can be used by everyone at the same time. His tacit assumption suggests that the objects of property, besides being distinct from the subjects, are excludable and rivalrous as well, just like the res corporales. Kant asserts that something external is mine if I would be wronged by being disturbed in my use of it even though I am not in possession of it (AA.6, [249:5-7](http://virt052.zim.uni-duisburg-essen.de/Kant/aa06/249.html)). If property is a merely intelligible relation with an object that is simply distinct from the subject, we have no reason to deny that such an object might be immaterial as well, just like the objects of intellectual property. Why, then, does Kant refrain from using the very concept of it? According to him, a speech is an action of a person: it belongs to the realm of personal rights. A person who is speaking to the people is engaging a relationship with them; if someone else engages such a relationship in his name, he needs his authorization. The reprinter, as it were, does not play with property: he is only an agent without authority. Speeches, by Kant, cannot be separated from persons: he has seen the unholy promised land of intellectual property without entering it. According to Kant, before the acquired rights, everyone has a moral capacity for putting others under obligation that he calls innate right or internal meum vel tuum (AA.06, [237:24-25](http://virt052.zim.uni-duisburg-essen.de/Kant/aa06/237.html)). The innate right is only one: freedom as independence from being constrained by another's choice, insofar it can coexist with the freedom of every other in accordance with a universal law. Freedom belongs to every human being by virtue of his humanity: in other words, it has to be assumed before every civil constitution, because it is the very possibility condition of law. Freedom implies innate equality, «that is, independence from being bound by others to more than one can in turn bind them; hence a human being's quality of being his own master (sui iuris), as well as being a human being beyond reproach (iusti) since before he performs any act affecting rights he has done no wrong to anyone, and finally his being authorized to do to others anything that does not in itself diminish what is theirs, so long as they do not want to accept it - such things as merely communicating his thoughts to them.» (AA.06, [237-238](http://virt052.zim.uni-duisburg-essen.de/Kant/aa06/237.html)) [34](http://bfp.sp.unipi.it/chiara/lm/kantpisa1.html#ftn.id2533617) In spite of his intellectual theory of property, [35](http://bfp.sp.unipi.it/chiara/lm/kantpisa1.html#ftn.id2533628) Kant does not enter in the realm of intellectual property for a strong systematic reason. Liberty of speech is an important part of the innate right of freedom. It cannot be suppressed without suppressing freedom itself. If the ius reale were applied to speeches, a basic element of freedom would be reduced to an alienable thing, making it easy to mix copyright protection and censorship.

[36](http://bfp.sp.unipi.it/chiara/lm/kantpisa1.html#ftn.id2533656) Property rights are based on the assumption that its objects are excludable and rivalrous and need to be appropriated by someone to be used. We cannot, however, deal with speeches as they were excludable and rivalrous things that need to be appropriated to be of some use, because excluding people from speeches would be like excluding them from freedom. Therefore, Kant binds speeches to the persons and their actions, and limits the scope of copyright to publishing, or, better, to the publishing of the age of print: the Nachdruck is unjust only when someone reproduces a text without the author's permission and distributes its copies to the public. If someone copies a book for his personal use, or lets others do it, or translates and elaborates a text, there is no copyright violation, just because it is not involved any intrinsic property right, but only the exercise of the innate right of freedom. The boundary of Kant's copyright is the public use of reason, as a key element of a basic right that should be recognized to everyone. Kant does not stick to the Roman Law tradition because of conservatism, but because of Enlightenment.

#### [2] IPP unjustifiably restricts agents from setting and pursuing ends in healthcare because patents prevent people from taking part in scientific advancements in medicine – that violates freedom in multiple ways

**Hale 18** (Zachary Hale, 4-4-2018, accessed on 8-22-2021, The Arkansas Journal of Social Change and Public Service, "Patently Unfair: The Tensions Between Human Rights and Intellectual Property Protection - The Arkansas Journal of Social Change and Public Service", <https://ualr.edu/socialchange/2018/04/04/patently-unfair/>) BHHS AK

Although the right to the protection of “moral and material interests resulting from any scientific, literary, or artistic production,”[32] is a human right as defined in the UDHR and the ICESCR, the current system of intellectual property protection conflicts with and even violates rights that are considered to be fundamental to human life. Although intellectual property instruments are certainly used to violate essential civil and political freedoms like the freedom of expression, and economic and social freedoms like the freedom to share in the scientific advancements of society, the most blatant violations of human rights caused by intellectual property protection occur in the fields of nutrition, healthcare, and culture.[33] Of these essential entitlements, the rights to food and health are made even more significant by their relationship to the most fundamental of all human rights: the right to life.

#### [3] IPP is inconsistent with free market principles

**Kinsella 11** (Stephan Kinsella, 5-25-2011, accessed on 8-23-2021, Foundation for Economic Education, "How Intellectual Property Hampers the Free Market | N. Stephan Kinsella", <https://fee.org/articles/how-intellectual-property-hampers-the-free-market/>) BHHS AK

But are they? There are good reasons to think that IP is not actually property—that it is actually antithetical to a private-property, free-market order. By intellectual property, I mean primarily patent and copyright. It’s important to understand the origins of these concepts. As law professor Eric E. Johnson notes, “The monopolies now understood as copyrights and patents were originally created by royal decree, bestowed as a form of favoritism and control. As the power of the monarchy dwindled, these chartered monopolies were reformed, and essentially by default, they wound up in the hands of authors and inventors.” Patents were exclusive monopolies to sell various goods and services for a limited time. The word patent, historian Patricia Seed explains, comes from the Latin patente, signifying open letters. Patents were “open letters” granted by the monarch authorizing someone to do something—to be, say, the only person to sell a certain good in a certain area, to homestead land in the New World on behalf of the crown, and so on. It’s interesting that many defenders of IP—such as patent lawyers and even some libertarians—get indignant if you call patents or copyright a monopoly. “It’s not a monopoly; it’s a property right,” they say. “If it’s a monopoly then your use of your car is a monopoly.” But patents are State grants of monopoly privilege. One of the first patent statutes was England’s Statute of Monopolies of 1624, a good example of truth in labeling. Granting patents was a way for the State to raise money without having to impose a tax. Dispensing them also helped secure the loyalty of favorites. The patentee in return received protection from competition. This was great for the State and the patentee but not for competition or the consumer. In today’s system we’ve democratized and institutionalized intellectual property. Now anyone can apply. You don’t have to go to the king or be his buddy. You can just go to the patent office. But the same thing happens. Some companies apply for patents just to keep the wolves at bay. After all, if you don’t have patents someone might sue you or reinvent and patent the same ideas you are using. If you have a patent arsenal, others are afraid to sue you. So companies spend millions of dollars to obtain patents for defensive purposes. Large companies rattle their sabers or sue each other, then make a deal, say, to cross-license their patents to each other. That’s fine for them because they have protection from each other’s competition. But what does it do to smaller companies? They don’t have big patent arsenals or a credible countersuit threat. So patents amount to a barrier to entry, the modern version of mercantilist protectionism. What about copyright? The roots literally lie in censorship. It was easy for State and church to control thought by controlling the scribes, but then the printing press came along, and the authorities worried that they couldn’t control official thought as easily. So Queen Mary created the Stationer’s Company in 1557, with the exclusive franchise over book publishing, to control the press and what information the people could access. When the charter of the Stationer’s Company expired, the publishers lobbied for an extension, but in the Statute of Anne (1710) Parliament gave copyright to authors instead. Authors liked this because it freed their works from State control. Nowadays they use copyright much as the State originally did: to censor and ban books. (More below.) IP, American Style The American system of IP began with the U.S. Constitution. Article 1, Section 8, Clause 8 authorizes (but doesn’t require) Congress “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” Despite modern IP proponents’ claims to the contrary, the American founders did not view intellectual property as a natural right but only as a policy tool to encourage innovation. Yet they were nervous about monopoly privilege, which is why patents and copyrights were authorized only for a limited time. Even John Locke, whose thought influenced the Founding Fathers, did not view copyright and patent as natural rights. Nor did he maintain that property homesteading applied to ideas. It applied only to scarce physical resources. Granted, some state constitutions had little versions of copyright before the American Constitution. (See Tom W. Bell, Intellectual Privilege: Copyright, Common Law, and the Common Good, part 1, chapter 3, section B.1.) On occasion, the language of natural rights was used to defend it, but this was just cover for the monopolies they granted to special interests. Natural rights do not expire after 15 years. Natural rights are not extended to Americans only. Natural rights wouldn’t exclude many types of innovation and intellectual creativity and cover only a few arbitrary types. And what is the result of this system? In the case of patents we have a modern statute administered by a huge federal bureaucracy that grants monopolies on the production and trade of various things, which means holders may ask the federal courts to order the use of force to stop competitors. But the competitors have not done anything that justifies force. They merely have used information to guide their actions with respect to their own property. Is that compatible with private property and the free market?

#### That affirms: Free market economies are the only ones that allow people to be free to pursue their own interests.

**Richman 12** [Sheldon Richman, 8-5-2012, "The Free Market Doesn't Need Government Regulation," Reason, <https://reason.com/2012/08/05/the-free-market-doesnt-need-government-r/>] // SJ AME

What regulates the conduct of these people? Market forces. (I keep specifying "in a freed market" because in a state-regulated economy, competitive market forces are diminished or suppressed.) Economically speaking, people cannot do whatever they want—and get away with it—in a freed market because other people are free to counteract them and it's in their interest to do so. That's part of what we mean by market forces. Just because the government doesn't stop a seller from charging $100 for an apple doesn't mean he or she can get that amount. Market forces regulate the seller as strictly as any bureaucrat could—even more so, because a bureaucrat can be bribed. Whom would you have to bribe to win an exemption from the law of supply and demand? (Well, you might bribe enough legislators to obtain protection from competition, but that would constitute an abrogation of the market.) It is no matter of indifference whether state operatives or market forces do the regulating. Bureaucrats, who necessarily have limited knowledge and perverse incentives, regulate by threat of physical force. In contrast, market forces operate peacefully through millions of cooperating participants, each with intimate knowledge of her own personal circumstances and looking out for her own well-being. Bureaucratic regulation is likely to be irrelevant or (more likely) inimical to what people in the market care about. Not so regulation by market forces.

### TT

#### The role of the ballot is truth testing

#### 1] Inclusion: Anything can function under truth testing insofar as it proves the resolution either true or false. Specific role of the ballots exclude all offense besides those that follow from their framework which shuts out people without the technical skill or resources to prep for it.

#### 2] Textuality – Five Dictionaries[[1]](#footnote-1) define to affirm as to prove true[[2]](#footnote-2) and negate as to deny the truth of which means the sole judge jurisdiction is to vote on the resolution’s truth or falsity. This outweighs on common usage – it is abundantly clear that our roles are verified.

#### 3] Co-opts their role of the ballot any comparison between worlds requires proving a statement “X world is more desirable than the Y world” true. It collapses because all statements assume the truth value of such statement.

### Underview

#### 1] We are in an innovation crisis – new drugs are not being developed in favor of re-purposing old drugs to infinitely extend patent expiration.

Feldman 1 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

Drug companies **have brought great innovations** to market. Society rewards innovation with patents, or with non-patent exclusivities that can be obtained for activities such as testing drugs in children, undertaking new clinical studies, or developing orphan drugs. The rights provided by patents or non-patent exclusivities provide a defined time period of protection so companies can recoup their investments by charging monopoly prices. When patents end, lower-priced competitors should be able to jump into the market and drive down the price. **But that’s not happening**. Instead, drug companies build massive patent walls around their products, extending the protection **over and over again**. Some modern drugs have an avalanche of U.S. patents, with expiration dates **staggered across time**. For example, the rheumatoid arthritis drug Humira is **protected by more than 100 patents**. Walls like that **are insurmountable**. Rather than rewarding innovation, our patent system is now largely repurposing drugs. Between 2005 and 2015, **more than three-quarters** of the drugs associated with new patents **were not new ones** coming on the market but existing ones. In other words, we are mostly churning and recycling. Particularly troubling, new patents can be **obtained on minor tweaks** such as adjustments to dosage or delivery systems — a once-a-day pill instead of a twice-a-day one; a capsule rather than a tablet. Tinkering like this may have some value to some patients, but it nowhere near justifies the rewards we lavish on companies for doing it. From society’s standpoint, incentives should drive scientists back to the lab to look for new things, not to recycle existing drugs for minimal benefit.

#### 2] We control Uniqueness – 78% of New Drugs aren’t innovative.

PFAD 21 Patients for Affordable Drugs 2-3-2021 “BIG PHARMA’S BIG LIE: THE TRUTH ABOUT INNOVATION & DRUG PRICES” <https://patientsforaffordabledrugs.org/2021/02/03/innovation-report/> (a patient advocacy and lobbying organisation based in Washington, D.C. founded by David Mitchell who suffers from multiple myeloma. Ben Wakana is the executive director. It focuses on policies to lower drug prices.)//Elmer

The drug industry talks a lot about how reforms to lower prices threaten cutting-edge breakthroughs, but in reality, **only a fraction of new medications are truly innovative**. **Since 1975**, **only 10** to 15 **percent** of drugs entering the market **represented** **therapeutic advances**; **instead**, **drug companies prioritized the development of existing drugs with minor variations that lack clinical significance**.21 Drug patents offer a stark illustration of this point. Between 2005 and 2015, **78 percent of drug patents were related to drugs already on the market.**22 **Instead of investing in R&D that could lead to new** breakthrough **therapies**, **drug companies spend resources obtaining patents on old drugs** — not to improve user experience — but **to extend patent protection**, prolong monopoly pricing periods, and keep generic competitors off the market. So if we understand that new drugs are not the same as new cures, a small reduction in new drugs doesn’t pose a threat to innovation. Harvard economist Richard Frank summed it up this way: “If drug companies claim lowering drug prices means somewhat fewer new drug launches, remember that there are **numerous new products sold every year whose elimination would have little to no impact on the health of Americans**.”23 If our current system of drug development does not result primarily in truly innovative drugs, we can’t let the pharmaceutical industry use the threat of R&D cuts as a scapegoat to thwart reforms. We can create a system that incentivizes valuable innovation that delivers meaningful clinical benefit to patients — instead of repurposing old drugs.

#### 3] The only major study confirms our Internal Link – Evergreening decimates competition by resulting in functional monopolies

Arnold Ventures 20 9-24-2020 "'Evergreening' Stunts Competition, Costs Consumers and Taxpayers" <https://www.arnoldventures.org/stories/evergreening-stunts-competition-costs-consumers-and-taxpayers/> (Arnold Ventures is focused on evidence-based giving in a wide range of categories including: criminal justice, education, health care, and public finance)//Elmer

Revlimid is a case study in a process known as “evergreening” — artificially sustaining a monopoly for years and even decades by manipulating intellectual property laws and regulations. Evergreening is most commonly used with blockbuster drugs generating the highest prices and profits. **Of the roughly 100 best-selling drugs, more than 70 percent have extended their protection** from competition at least once. More than half have extended the protection cliff multiple times. The true scope and cost of evergreening has been brought into sharper focus by a groundbreaking, publicly available, comprehensive database released Thursday by the Center for Innovation at the University of California Hastings College of Law and supported by Arnold Ventures. **The Evergreen Drug Patent Search is the first database to exhaustively track the patent protections filed by pharmaceutical companies**. Using data from 2005 to 2018 on brand-name drugs listed in the FDA’s Orange Book — a listing of relevant patents for brand name, small molecule drugs — it demonstrates the full extent of how evergreening has been used by Big Pharma to prolong patents and delay the entry of generic, lower-cost competition. “Competition is the backbone of the U.S. economy,” said Professor Robin Feldman, Director of the UC Hastings Center for Innovation, who spearheaded the database’s creation. “But it’s not what we’re seeing in the drug industry. “With evergreening, pharmaceutical companies repeatedly make slight, often trivial, modifications to drugs, dosage levels, delivery systems or other aspects to obtain new protections,” she said. “They pile these protections on over and over again — so often that 78 percent of the drugs associated with new patents were not new drugs coming on the market, but existing drugs.” Competition is the backbone of the U.S. economy. But it’s not what we’re **seeing in the drug industry**. Professor Robin Feldman Director of the UC Hastings Center for Innovation In recent decades, evergreening has systematically undermined the Drug Price Competition and Patent Term Restoration Act of 1984, which created the generic drug industry. Commonly known as the Hatch-Waxman Act, it established a new patent and market exclusivity regime in which new drugs are protected from competition for a specified period of time sufficient to allow manufacturers to recoup their investments and earn a reasonable profit. When that protection expires, generic drug makers are incentivized to enter the market through a streamlined regulatory and judicial process. Drug prices typically drop by as much as 20 percent when the first generic enters the market**, and with more than one generic manufacturer, prices can plummet by 80 to 85 percent**. “Hatch-Waxman created an innovation/reward/competition cycle, but it’s been distorted into an innovation/reward/more reward cycle,” Feldman said. “To paraphrase something a former FDA commissioner once said, the greatest creativity in Big Pharma should come from the research and development departments, not from the legal and marketing departments.” Feldman led the development of the Evergreen Drug Patent Search in response to repeated requests from Congressional committees, members of Congress, state regulators and journalists for information about specific drugs and companies. “We want to make it so anyone can have the question about drug protections at their fingertips whenever they want,” Feldman said. “It’s designed to be easy and user-friendly, and to enhance public understanding about how competition may be limited rather than enhanced through the drug patent system.” The **database** was **created through** a painstaking process of **combing** through **160,000 data points** **to examine every instance where a pharmaceutical company added a new drug patent or exclusivity**. “Most of it was done by hand,” Feldman said, “with multiple people reviewing it at every stage. And along the way we repeatedly made conservative choices. **We erred on the side of underrepresenting the evergreen gain**

to be sure we were as fair and reasonable as possible.” Among the 2,065 drugs covered in Evergreen Drug Patent Search, there are many examples of the evergreening strategy used by pharma to delay the entry of competition, especially generics, often for widely prescribed drugs, including those used to treat heartburn, chronic pain, and opioid addiction. Nexium Before Nexium, there was Prilosec, a popular drug to treat gastroesophageal reflux disease (GERD). But its patent exclusivity was due to expire in April 2001. In the late 1990s, with a precipitous drop in revenue looming, Prilosec’s manufacturer, AstraZeneca, decided to develop a replacement drug. Using “one-half of the Prilosec molecule — an isomer of it,” the result was Nexium, which received approval in February 2001. Essentially an evergreened version of Prilosec, Nexium’s exclusivity was then extended by more than 15 years, as AstraZeneca received 97 protections stemming from 16 patents. These included revised dosages, compounds, and formulations. Feldman said that tinkering changes such as Nexium’s do not involve the substantial research and development required for a new drug, nor do they constitute true innovations, yet for a decade and a half, patients and taxpayers were forced to pay far more than was warranted for GERD relief. In fact, in 2016 — one year after patent exclusivity expired — Nexium still topped all drugs in Medicare Part D spending, totaling $1.06 billion. Suboxone Use of this combination of buprenorphine and naloxone for treating opioid addiction has exploded in the wake of the opioid epidemic. Since its approval, Suboxone’s manufacturer, Reckitt Benckiser (now operating as Indivior), extended its protection cliff eight times, gaining nearly two extra decades of exclusivity through early 2030. The drug maker gained six patents for creating a film version of the drug — notably around the time protection was expiring for its tablet version. (The therapeutic benefits of the film and tablet are identical.) An earlier version of Suboxone also obtained an orphan drug designation, despite an opioid epidemic that has expanded Suboxone’s customer base to millions of potential customers. Suboxone generates more than $1 billion in annual revenue and ranks among the 40 top-selling drugs in the U.S. Truvada When Truvada, commonly referred to as PrEP, was approved in 2004, this HIV-prevention drug was a breakthrough. But 16 years later — and 14 years after its original exclusivity was to expire — it retains its monopoly status. Truvada’s manufacturer, Gilead, has received 15 patents and 120 protections since it came on the market, extending its exclusivity for more than 17 years, until July 3, 2024. In countries where generic Truvada is available, PrEP costs $100 or less per month, compared to $1,600 to $2,000 in the U.S. As a result, Truvada is unaffordable to many people **who need protection from HIV**. Barred from access, they are left vulnerable to infection. “We’re establishing a precedent that a pharmaceutical company can charge whatever it wants even as it allows an epidemic to continue, and the government refuses to intervene,” said James Krellenstein, co-founder of the group PrEP4All. “That should scare every American. If it’s HIV today, it will be another disease tomorrow.” EpiPen First approved in 1987, the EpiPen has saved the lives of countless numbers of people with deadly allergies. But it is protected from competition until 2025 — 38 years after its introduction — because its owner, Mylan, has filed five patents, four since 2010, all involving tweaks to the automatic injector. The actual medication used, epinephrine, has existed for more than a century — the innovation here is in the delivery device.

#### 3 impacts:

#### 1] Only innovation now solves AMR super-bugs -- timeframe’s key.

Sobti 19 [Dr. Navjot Kaur Sobti is an internal medicine resident physician at Dartmouth-Hitchcock-Medical Center/Dartmouth School of Medicine and a member of the ABC News Medical Unit. May 1, 2019. “Amid superbug crisis, scientists urge innovation”. <https://abcnews.go.com/Health/amidst-superbug-crisis-scientists-urge-innovation/story?id=62763415>] Dhruv

[The United Nations](https://abcnews.go.com/Politics/amal-clooney-angelina-jolie-speak-us-weighed-vetoing/story?id=62574726) has called antimicrobial resistance a “global crisis.” With the [rise in superbugs](https://abcnews.go.com/Health/superbug-fungus-global-health-threat-600-us-infected/story?id=62297532) across the globe, common infections are becoming harder to treat, and lifesaving procedures riskier to perform. Drug-resistant infections result in about 700,000 deaths per year, with at least 230,000 of those deaths due to multidrug resistant tuberculosis, [according to a groundbreaking report from the World Health Organization (WHO).](https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG_final_report_EN.pdf?ua=1) Given that antibiotic resistance is present in every country, antimicrobial resistance (AMR) now represents a global health crisis, according to the UN, which has urged immediate, coordinated and global action to prevent a potentially devastating health and financial crisis. With the rising rates of AMR -- including antivirals, antibiotics, and antifungals -- estimates from the WHO show that AMR may cause 10 million deaths every year by 2050, send 24 million people into extreme poverty by 2030, and lead to a financial crisis as severe as the on the U.S. experienced in 2008. Antimicrobial resistance develops when germs like bacteria and fungi are able to “defeat the drugs designed to kill them,” according to the Centers for Disease Control and Prevention. Through a biologic “survival of the fittest,” germs that are not killed by antimicrobials and continue to grow. WHO explains that “poor infection control, inadequate sanitary conditions and inappropriate food handling encourage the spread” of AMR, which can lead to “superbugs.” Those superbugs require powerful and oftentimes more expensive antimicrobials to treat. Examples of superbugs are far and wide, and can range from drug-resistant bacteria like Pseudomonas aeruginosa and Staphylococcus aureus to fungi like Candida. These bugs can cause illnesses that range from pneumonia to urinary tract and sexually transmitted infections. According to the WHO, AMR has caused complications for nearly 500,000 people with tuberculosis, and a number of people with HIV and malaria. The people at the [highest risk for AMR](https://www.who.int/news-room/detail/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed) are those with chronic diseases, people living in nursing homes, hospitalized in the ICU or undergoing life-saving treatments such as organ transplantation and cancer therapy. These people often develop infections, which can become antimicrobial-resistant, rendering them difficult, if not impossible, to treat. [(MORE: Melissa Rivers talks about her father's suicide with Dr. Jennifer Ashton)](https://abcnews.go.com/Health/melissa-rivers-talks-fathers-suicide-dr-jennifer-ashton/story?id=62733179&cid=clicksource_26_null_headlines_hed) The CDC notes that “antibiotic resistance has the potential to affect people at any stage of life,” including the “healthcare, veterinary, and agriculture industries, making it one of the world’s most urgent public health problems." AMR can cause prolonged hospital stays, billions of dollars in healthcare costs, disability, and potentially, death. “The most important thing is to understand and embrace the interconnectedness of all of this,” said Dr. Robert Redfield, director of the CDC, in a recent interview with ABC News’ Dr. Jennifer Ashton. It’s not just our countries that are connected.” Research has shown that superbugs like Candida auris “came from multiple places, at the same time. It wasn’t just one organism that [evolved]” in a single location, Redfield added. Given longstanding concerns about antimicrobial misuse leading to AMR, physicians have embraced a medical approach called antibiotic stewardship. This encourages physicians to carefully evaluate which antibiotic is most appropriate for their patient, and discontinue it once it is no longer medically needed. WHO has also highlighted that the inappropriate use of antimicrobials in agriculture -- such as on farms and in animals -- may be an underappreciated cause of AMR. Noting these trends, the WHO has urged for “coordinated action...to minimize the emergence and spread of antimicrobial resistance.” It urges all countries to make national action plans, with a focus on the development of new antimicrobial medications, vaccines, and careful antimicrobial use. Redfield emphasized the importance of vaccination during the global superbug crisis, stating that “the only way we have to eliminate an infection is vaccination.” He added that investing in innovation is key to solving the crisis. While WHO continues to advocate for superbug awareness, they warn that AMR has reversed “a century of progress in health.” The WHO added that “the challenges of antimicrobial resistance” are “not insurmountable,” and that coordinated action will “help to save millions of lives, preserve antimicrobials for generations to come and secure the future from drug-resistant diseases.”

#### Evolving superbugs trigger extinction.

Srivatsa ’17 (Kadiyali; specialist in pediatric intensive and critical care medicine in the UK. Invented the bacterial identification tool ‘MAYA’; 1-12-2017; "Superbug Pandemics and How to Prevent Them", American Interest; https://www.the-american-interest.com/2017/01/12/superbug-pandemics-and-how-to-prevent-them/, Accessed: 8-31-2021; AU)

It is by now no secret that the human species is locked in a race of its own making with “superbugs.” Indeed, if popular science fiction is a measure of awareness, the theme has pervaded English-language literature from Michael Crichton’s 1969 Andromeda Strain all the way to Emily St. John Mandel’s 2014 Station Eleven and beyond. By a combination of massive inadvertence and what can only be called stupidity, we must now invent new and effective antibiotics faster than deadly bacteria evolve—and regrettably, they are rapidly doing so with our help. I do not exclude the possibility that bad actors might deliberately engineer deadly superbugs.1 But even if that does not happen, humanity faces an existential threat largely of its own making in the absence of malign intentions. As threats go, this one is entirely predictable. The concept of a “black swan,” Nassim Nicholas Taleb’s term for low-probability but high-impact events, has become widely known in recent years. Taleb did not invent the concept; he only gave it a catchy name to help mainly business executives who know little of statistics or probability. Many have embraced the “black swan” label the way children embrace holiday gifts, which are often bobbles of little value, except to them. But the threat of inadvertent pandemics is not a “black swan” because its probability is not low. If one likes catchy labels, it better fits the term “gray rhino,” which, explains Michele Wucker, is a high-probability, high-impact event that people manage to ignore anyway for a raft of social-psychological reasons.2 A pandemic is a quintessential gray rhino, for it is no longer a matter of if but of when it will challenge us—and of how prepared we are to deal with it when it happens. We have certainly been warned. The curse we have created was understood as a possibility from the very outset, when seventy years ago Sir Alexander Fleming, the discoverer of penicillin, predicted antibiotic resistance. When interviewed for a 2015 article, “The Most Predictable Disaster in the History of the Human Race,” Bill Gates pointed out that one of the costliest disasters of the 20th century, worse even than World War I, was the Spanish Flu pandemic of 1918-19. As the author of the article, Ezra Klein, put it: “No one can say we weren’t warned. And warned. And warned. A pandemic disease is the most predictable catastrophe in the history of the human race, if only because it has happened to the human race so many, many times before.”3 Even with effective new medicines, if we can devise them, we must contain outbreaks of bacterial disease fast, lest they get out of control. In other words, we have a social-organizational challenge before us as well as a strictly medical one. That means getting sufficient amounts of medicine into the right hands and in the right places, but it also means educating people and enabling them to communicate with each other to prevent any outbreak from spreading widely. Responsible governments and cooperative organizations have options in that regard, but even individuals can contribute something. To that end, as a medical doctor I have created a computer app that promises to be useful in that regard—of which more in a moment. But first let us review the situation, for while it has become well known to many people, there is a general resistance to acknowledging the severity and imminence of the danger. What Are the Problems? Bacteria are among the oldest living things on the planet. They are masters of survival and can be found everywhere. Billions of them live on and in every one of us, many of them helping our bodies to run smoothly and stay healthy. Most bacteria that are not helpful to us are at least harmless, but some are not. They invade our cells, spread quickly, and cause havoc that we refer to generically as disease. Millions of people used to die every year as a result of bacterial infections, until we developed antibiotics. These wonder drugs revolutionized medicine, but one can have too much of a good thing. Doctors have used antibiotics recklessly, prescribing them for just about everything, and in the process helped to create strains of bacteria that are resistant to the medicines we have. We even give antibiotics to cattle that are not sick and use them to fatten chickens. Companies large and small still mindlessly market antimicrobial products for hands and home, claiming that they kill bacteria and viruses. They do more harm than good because the low concentrations of antimicrobials that these products contain tend to kill friendly bacteria (not viruses at all), and so clear the way for the mass multiplication of surviving unfriendly bacteria. Perhaps even worse, hospitals have deployed antimicrobial products on an industrial scale for a long time now, the result being a sharp rise in iatrogenic bacterial illnesses. Overuse of antibiotics and commercial products containing them has helped superbugs to evolve. We now increasingly face microorganisms that cannot be killed by antibiotics, antifungals, antivirals, or any other chemical weapon we throw at them. Pandemics are the major risk we run as a result, but it is not the only one. Overuse of antibiotics by doctors, homemakers, and hospital managers could mean that, in the not-too-distant future, something as simple as a minor cut could again become life-threatening if it becomes infected. Few non-medical professionals are aware that antibiotics are the foundation on which nearly all of modern medicine rests. Cancer therapy, organ transplants, surgeries minor and major, and even childbirth all rely on antibiotics to prevent infections. If infections become untreatable we stand to lose most of the medical advances we have made over the past fifty years.

#### 2] Pharma spills-over – has cascading global impacts that are necessary for human survival.

NAS 8 National Academy of Sciences 12-3-2008 “The Role of the Life Sciences in Transforming America's Future Summary of a Workshop” //Re-cut by Elmer

Fostering Industries to Counter Global Problems The life sciences have applications in areas that range far beyond human health. Life-science based approaches could **contribute to advances in** many industries, from energy production and pollution remediation, to clean manufacturing and the production of new biologically inspired materials. In fact, biological systems could provide the basis for new products, services and industries that we cannot yet imagine. Microbes are already producing biofuels and could, through further research, provide a major component of future energy supplies. Marine and terrestrial organisms extract carbon dioxide from the atmosphere, which suggests that biological systems could be used to help manage climate change. Study of the complex systems encountered in biology is decade, it is really just the beginning.” Advances in the underlying science of plant and animal breeding have been just as dramatic as the advances in genetic can put down a band of fertilizer, come back six months later, and plant seeds exactly on that row, reducing the need for fertilizer, pesticides, and other agricultural inputs. Fraley said that the global agricultural system needs to adopt the goal of doubling the current yield of **crops while reducing key inputs like pesticides, fertilizers, and water** by one third. “It is more important than putting a man on the moon,” he said. Doubling agricultural yields would “change the world.” Another billion people will join the middle class over the next decade just in India and China as economies continue to grow. And all people need and deserve secure access to food supplies. Continued progress will require both basic and applied research, The evolution of life “put earth under new management,” Collins said. Understanding the future state of the planet will require understanding the biological systems that have shaped the planet. Many of these biological systems are found in the oceans, which cover 70 percent of the earth’s surface and have a crucial impact on weather, climate, and the composition of the atmosphere. In the past decade, new tools have become available to explore the microbial processes that drive the **chemistry of the oceans**, observed David Kingsbury, Chief Program Officer for Science at the Gordon and Betty Moore Foundation. These technologies have revealed that a large proportion of the planet’s genetic diversity resides in the oceans. In addition, many organisms in the oceans readily exchange genes, creating evolutionary forces that can have global effects. The oceans are currently under great stress, Kingsbury pointed out. Nutrient runoff from agriculture is helping to create huge and expanding “dead zones” where oxygen levels are too low to sustain life. Toxic algal blooms are occurring with higher frequency in areas where they have not been seen in the past. Exploitation of ocean resources is disrupting ecological balances that have formed over many millions of years. Human-induced changes in the chemistry of the atmosphere are changing the chemistry of the oceans, with potentially catastrophic consequences. “If we are not careful, we are not going to have a sustainable planet to live on,” said Kingsbury. Only by understanding the basic biological processes at work in the oceans can humans live sustainably on earth.

#### Climate change destroys the world.

Specktor 19 [Brandon writes about the science of everyday life for Live Science, and previously for Reader's Digest magazine, where he served as an editor for five years] 6-4-2019, "Human Civilization Will Crumble by 2050 If We Don't Stop Climate Change Now, New Paper Claims," livescience, <https://www.livescience.com/65633-climate-change-dooms-humans-by-2050.html> JW

\*\*Cites and talks about the Spratt and Dunlop study

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](https://www.livescience.com/55129-how-heat-waves-kill-so-quickly.html), 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."

1. <http://dictionary.reference.com/browse/negate>, <http://www.merriam-webster.com/dictionary/negate>, <http://www.thefreedictionary.com/negate>, <http://www.vocabulary.com/dictionary/negate>, <http://www.oxforddictionaries.com/definition/english/negate> [↑](#footnote-ref-1)
2. *Dictionary.com – maintain as true, Merriam Webster – to say that something is true, Vocabulary.com – to affirm something is to confirm that it is true, Oxford dictionaries – accept the validity of, Thefreedictionary – assert to be true* [↑](#footnote-ref-2)