### 1AC - Framework

#### The Meta-Ethic is Moral Pluralism; Clashing viewpoints does not require the exclusion of one over another but instead the acceptance that both can be valuable ethical tools. Prefer

#### 1] Empirics- Quantum superposition proves different ethics can exist simultaneously.

MIT ’19 (Emerging Technology from the arXiv archive page; Covers latest ideas from blog post about arXiv; 03/12/2019; “Emerging Technology from the arXiv archive page”; <https://www.technologyreview.com/2019/03/12/136684/a-quantum-experiment-suggests-theres-no-such-thing-as-objective-reality/>; *MIT Technology Review*; accessed: 11/19/2020; MohulA)

Back in 1961, the Nobel Prize–winning physicist Eugene Wigner outlined a thought experiment that demonstrated one of the lesser-known paradoxes of quantum mechanics. The experiment shows how the strange nature of the universe allows two observers—say, Wigner and Wigner’s friend—to experience different realities. Since then, physicists have used the “Wigner’s Friend” thought experiment to explore the nature of measurement and to argue over whether objective facts can exist. That’s important because scientists carry out experiments to establish objective facts. But if they experience different realities, the argument goes, how can they agree on what these facts might be? That’s provided some entertaining fodder for after-dinner conversation, but Wigner’s thought experiment has never been more than that—just a thought experiment. Last year, however, physicists noticed that recent advances in quantum technologies have made it possible to reproduce the Wigner’s Friend test in a real experiment. In other words, it ought to be possible to create different realities and compare them in the lab to find out whether they can be reconciled. And today, Massimiliano Proietti at Heriot-Watt University in Edinburgh and a few colleagues say they have performed this experiment for the first time: they have created different realities and compared them. Their conclusion is that Wigner was correct—these realities can be made irreconcilable so that it is impossible to agree on objective facts about an experiment. Wigner’s original thought experiment is straightforward in principle. It begins with a single polarized photon that, when measured, can have either a horizontal polarization or a vertical polarization. But before the measurement, according to the laws of quantum mechanics, the photon exists in both polarization states at the same time—a so-called superposition. Wigner imagined a friend in a different lab measuring the state of this photon and storing the result, while Wigner observed from afar. Wigner has no information about his friend’s measurement and so is forced to assume that the photon and the measurement of it are in a superposition of all possible outcomes of the experiment. Wigner can even perform an experiment to determine whether this superposition exists or not. This is a kind of interference experiment showing that the photon and the measurement are indeed in a superposition. From Wigner’s point of view, this is a “fact”—the superposition exists. And this fact suggests that a measurement cannot have taken place. But this is in stark contrast to the point of view of the friend, who has indeed measured the photon’s polarization and recorded it. The friend can even call Wigner and say the measurement has been done (provided the outcome is not revealed). So the two realities are at odds with each other. “This calls into question the objective status of the facts established by the two observers,” say Proietti and co. That’s the theory, but last year Caslav Brukner, at the University of Vienna in Austria, came up with a way to re-create the Wigner’s Friend experiment in the lab by means of techniques involving the entanglement of many particles at the same time. The breakthrough that Proietti and co have made is to carry this out. “In a state-of-the-art 6-photon experiment, we realize this extended Wigner’s friend scenario,” they say. They use these six entangled photons to create two alternate realities—one representing Wigner and one representing Wigner’s friend. Wigner’s friend measures the polarization of a photon and stores the result. Wigner then performs an interference measurement to determine if the measurement and the photon are in a superposition. The experiment produces an unambiguous result. It turns out that both realities can coexist even though they produce irreconcilable outcomes, just as Wigner predicted. That raises some fascinating questions that are forcing physicists to reconsider the nature of reality. The idea that observers can ultimately reconcile their measurements of some kind of fundamental reality is based on several assumptions. The first is that universal facts actually exist and that observers can agree on them. But there are other assumptions too. One is that observers have the freedom to make whatever observations they want. And another is that the choices one observer makes do not influence the choices other observers make—an assumption that physicists call locality. If there is an objective reality that everyone can agree on, then these assumptions all hold. But Proietti and co’s result suggests that objective reality does not exist. In other words, the experiment suggests that one or more of the assumptions—the idea that there is a reality we can agree on, the idea that we have freedom of choice, or the idea of locality—must be wrong. Of course, there is another way out for those hanging on to the conventional view of reality. This is that there is some other loophole that the experimenters have overlooked. Indeed, physicists have tried to close loopholes in similar experiments for years, although they concede that it may never be possible to close them all. Nevertheless, the work has important implications for the work of scientists. “The scientific method relies on facts, established through repeated measurements and agreed upon universally, independently of who observed them,” say Proietti and co. And yet in the same paper, they undermine this idea, perhaps fatally. The next step is to go further: to construct experiments creating increasingly bizarre alternate realities that cannot be reconciled. Where this will take us is anybody’s guess. But Wigner, and his friend, would surely not be surprised.

#### 2] The rules of logic claim that the only time a statement is invalid is if the antecedent is true, but the consequent is false.

SEP [Stanford Encyclopedia of Philosophy.] “An Introduction to Philosophy.” Stanford University. <https://web.stanford.edu/~bobonich/dictionary/dictionary.html> TG Massa

Conditional statement: an “if p, then q” compound statement (ex. If I throw this ball into the air, it will come down); p is called the antecedent, and q is the consequent. A conditional asserts that if its antecedent is true, its consequent is also true; any conditional with a true antecedent and a false consequent must be false.  For any other combination of true and false antecedents and consequents, the conditional statement is true.

#### If the aff is winning, they get the ballot is a tacit ballot conditional which means denying the premise proves the conclusion that I should get the ballot.

#### 3] Principle of explosion is true.

**Wikiwand**. “Principle of Explosion.” Wikiwand, 0AD, [www.wikiwand.com/en/Principle\_of\_explosion](http://www.wikiwand.com/en/Principle_of_explosion). //Massa

A screenshot of a cell phone

Description automatically generated

The principle of explosion (Latin: ex falso (sequitur) quodlibet (EFQ), "from falsehood, anything (follows)", or ex contradictione (sequitur) quodlibet (ECQ), **"from contradiction, anything (follows)"), or the principle of**[**Pseudo-Scotus**](https://www.wikiwand.com/en/Pseudo-Scotus), is the law of [classical logic](https://www.wikiwand.com/en/Classical_logic), [intuitionistic logic](https://www.wikiwand.com/en/Intuitionistic_logic) and similar logical systems, according to which any statement can be proven from a contradiction.[[1]](https://www.wikiwand.com/en/Principle_of_explosion#citenote1) That is, once a contradiction has been asserted, any proposition (including their negations) can be inferred from it. This is known as **deductive explosion**.[[2]](https://www.wikiwand.com/en/Principle_of_explosion#citenote2)[[3]](https://www.wikiwand.com/en/Principle_of_explosion#citenote3) The proof of this principle was first given by 12th century French philosopher [William of Soissons](https://www.wikiwand.com/en/William_of_Soissons).[[4]](https://www.wikiwand.com/en/Principle_of_explosion#citenote4)

As a demonstration of the principle, **consider two contradictory statements – "All lemons are yellow" and "Not all lemons are yellow"**, and suppose that both are true. If that is the case, **anything can be proven**, e.g., **the assertion that "unicorns exist", by using the following argument:**

1. We know that **"All lemons are yellow"**, as it **has been assumed to be true.**
2. **Therefore**, the two-part statement **"All lemons are yellow OR unicorns exist” must also be true**, since the first part is true.
3. However, **since we know that "Not all lemons are yellow"** (as this has been assumed), **the first part is false, and hence the second part must be true, i.e., unicorns exist.**

#### 4] Dogmatism Paradox

Sorensen Sorensen, Roy, Professor of Philosophy at Washington University in St. Louis. "Epistemic Paradoxes.” Stanford Encyclopedia of Philosophy. 21 June 2006. <https://plato.stanford.edu/entries/epistemic-paradoxes/>. PeteZ

Saul Kripke’s ruminations on the surprise test paradox led him to a paradox about dogmatism. He lectured on both paradoxes at Cambridge University to the Moral Sciences Club in 1972. (A descendent of this lecture now appears as Kripke 2011). Gilbert Harman transmitted Kripke’s new paradox as follows:

If I know that h is true, I know that any evidence against h is evidence against something that is true; I know that such evidence is misleading. But I should disregard evidence that I know is misleading. So, once I know that h is true, I am in a position to disregard any future evidence that seems to tell against h. (1973, 148)

#### 5] Vote aff because it’s simple – evaluating responses to this is complicated so don’t

Baker 04’ [Baker, Alan, 10-29-2004, "Simplicity (Stanford Encyclopedia of Philosophy)," <https://plato.stanford.edu/entries/simplicity/>]

With respect to question (ii), there is an important distinction to be made between two sorts of simplicity principle. Occam's Razor may be formulated as an epistemic principle: if theory T is simpler than theory T\*, then it is rational (other things being equal) to believe T rather than T\*. Or it may be formulated as a methodological principle: if T is simpler than T\* then it is rational to adopt T as one's working theory for scientific purposes. These two conceptions of Occam's Razor require different sorts of justification in answer to question (iii). In analyzing simplicity, it can be difficult to keep its two facets—elegance and parsimony—apart. Principles such as Occam's Razor are frequently stated in a way which is ambiguous between the two notions, for example, “Don't multiply postulations beyond necessity.” Here it is unclear whether ‘postulation’ refers to the entities being postulated, or the hypotheses which are doing the postulating, or both. The first reading corresponds to parsimony, the second to elegance. Examples of both sorts of simplicity principle can be found in the quotations given earlier in this section.

#### 6] A trivial entity exists

**Kabay 08** [Paul Douglas Kabay, (PhD thesis, School of Philosophy, Anthropology, and Social Inquiry) "A Defense Of Trivialism" The University Of Melbourne, 2008, https://minerva-access.unimelb.edu.au/handle/11343/35203, DOA:10-25-2017]

Let us define a trivial entity as an entity that instantiates every predicate, i.e. an entity of which **everything is true.** One of the things true of **a trivial entity** is that it **exists in a reality in which trivialism is true. Hence, if a trivial entity exists, then trivialism is true.** But is it true that there exists a trivial entity? Here is an argument for thinking that it is true: **1) Every being (or entity or object) is either trivial or nontrivial 2) It is not the case that every being is nontrivial 3) Hence, there exists a trivial being**

#### 7] Negative arguments presuppose the aff being true since they begin with a descriptive premise about the affirmative such as the aff does x, and then justify why x is bad. However, if the aff does not have truth value, that entails the descriptive premise would also not have truth value, which is contradictory.

#### 8] Bonini’s Paradox – expanding debate’s parameters to the 1NC and onward makes the round irresolvable due to a lack of understanding so just vote aff

**Wikipedia** [Brackets Original. “Bonini's paradox”. Wikipedia. No Date. <https://en.wikipedia.org/wiki/Bonini%27s_paradox> ]

In modern discourse, the paradox was articulated by John M. Dutton and William H. Starbuck[2] "As a model of a complex system becomes more complete, it becomes less understandable. Alternatively, as a model grows more realistic, it also becomes just as difficult to understand as the real-world processes it represents".[3] This paradox may be used by researchers to explain why complete models of the human brain and thinking processes have not been created and will undoubtedly remain difficult for years to come. This same paradox was observed earlier from a quote by philosopher-poet Paul Valéry, "Ce qui est simple est toujours faux. Ce qui ne l’est pas est inutilisable".[4] ("A simple statement is bound to be untrue. One that is not simple cannot be utilized."[5]) Also, the same topic has been discussed by Richard Levins in his classic essay "The Strategy of Model Building in Population Biology", in stating that complex models have 'too many parameters to measure, leading to analytically insoluble equations that would exceed the capacity of our computers, but the results would have no meaning for us even if they could be solved.[6] (See Orzack and Sober, 1993; Odenbaugh, 2006)

#### 9] Liar’s Paradox – the resolution is always true

**Camus** [Albert Camus (existentialist). “The Myth of Sisyphus.” Penguin Books. 1975(originally published 1942). Accessed 12/11/19. Pg 22. Copy on hand. Houston Memorial DX]

The mind’s first step is to distinguish what is true from what is false. However, as soon as thought reflects on itself, what it first discovers is a contradiction. Useless to strive to be convincing in this case. Over the centuries no one has furnished a clearer and more elegant demonstration of the business than Aristotle: “The often ridiculed consequence of these opinions is that they destroy themselves. For by asserting that all is true we assert the truth of the contrary assertion and consequently the falsity of our own thesis (for the contrary assertion does not admit that it can be true). And if one says that all is false, that assertion is itself false. If we declare that solely the assertion opposed to ours is false or else that solely ours is not false, we are nevertheless forced to admit an infinite number of true or false judgments. For the one who expresses a true assertion proclaims simultaneously that it is true, and so on ad infinitum.”

#### 10] Overthinking paradox- the 1NC is a form of unnecessary overthinking that prevents decisions to be made so don’t evaluate it

**Wikipedia** [Brackets Original. “Analysis Paralysis”. Wikipedia. No Date. <https://en.wikipedia.org/wiki/Bonini%27s_paradox>]

Analysis paralysis (or paralysis by analysis) describes an individual or group process when overanalyzing or overthinking a situation can cause forward motion or decision-making to become [frozen] "paralyzed", meaning that no solution or course of action is decided upon. A situation may be deemed too complicated and a decision is never made, due to the fear that a potentially larger problem may arise. A person may desire a perfect solution, but may fear making a decision that could result in error, while on the way to a better solution. Equally, a person may hold that a superior solution is a short step away, and stall in its endless pursuit, with no concept of diminishing returns. On the opposite end of the time spectrum is the phrase extinct by instinct, which is making a fatal decision based on hasty judgment or a gut reaction.

#### 11] Affirm because either the neg is true meaning its bad for us to clash w/ it because it turns us into Fake News people OR it’s not meaning it’s a lie that you can’t vote on for ethics

#### 12] Decision Making Paradox- in order to judge we need a decision-making procedure to determine it is a good decision. But to chose a decision-making procedure requires another meta level decision making procedure leading to infinite regress so just vote aff to break the paradox.

#### 13] GCB- I am the greatest conceivable being so vote for me because I am infinitely good. To prove this, I will make them contest the aff and say they are not under my control.

#### 14] There are infinite worlds, the aff is logical in one which is sufficient.

**Vaidman 2** Vaidman, Lev, 3-24-2002, "Many-Worlds Interpretation of Quantum Mechanics (Stanford Encyclopedia of Philosophy)," No Publication, <https://plato.stanford.edu/entries/qm-manyworlds/>

-MWI: Multiple Worlds Interpretation

**The reason for adopting the MWI is that it avoids the collapse of the quantum wave.** (Other non-collapse theories are not better than MWI for various reasons, e.g., nonlocality of Bohmian mechanics; and the disadvantage of all of them is that they have some additional structure.) **The collapse postulate is a physical law that differs from all known physics in two aspects: it is genuinely random and it involves some kind of action at a distance**. According to the collapse postulate the outcome of a **quantum experiment is not determined by the initial conditions** of the Universe prior to the experiment: **only the probabilities are governed by the initial state**. Moreover, Bell 1964 has shown that there cannot be a compatible local-variables theory that will make deterministic predictions**. There is no experimental evidence in favor of collapse and against the MWI.**

#### 15] Negating affirms because it assumes that the 1ac is a statement that is worthy of contestation which means are arguments are legitimate.

#### **Only a pragmatic deliberative model accepts ongoing confrontation as legitimate rather than oppositional.** Thus, the standard is promoting pragmatic deliberation.

#### Additionally prefer

#### 1] Performativity- Responding to our framework concedes the validity of pragmatism since that in and of itself is a process of contestation that pragmatism would say is valuable and necessary for spaces like debate to function.

#### 2] TJFS- A] Inclusion – Pragmatism definitionally is a procedural for allowing almost any argumentation in the debate space which controls the internal link to inclusion which is an impact multiplier B] Resource Disparities- Discursive frameworks ensure big squads don’t have a comparative advantage since debates become about quality of arguments rather than quantity and require a higher level of analytic thinking that small schools have.

#### 3] Value – procedural decisions have infinite value because they allow agents to take steps to reduce harms under any index. To shut down an avenue for pragmatic discourse necessitates foreclosing all possible decisions in that situation except a static theory we can’t change. Kills the net most value – alternative theories with massive impacts can’t be considered.

#### 4] Value Pluralism- Other ethical theories rely on minimalistic criteria as their foundation, our framework resolves this by using these criteria to better inform our judgments

#### 5] Rule Following Paradox- There is nothing inherent to a rule that tells us how we ought to follow it, regardless of how correct the rule is. Only deliberation accounts for the diversity of interpretations of our norms.

#### **6]** Resolves Skepticism- a) Discussion between many bodies means that moral uncertainty can be deliberated and resolved. b) Truth only makes sense in groups of people so only they can prescribe action

### 1AC – Offense

#### The negative and I affirm the resolution resolved:  The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines

#### Counter solvency advcoates in the doc

<https://www.who.int/intellectualproperty/submissions/Pharmacoevolution.pdf?ua=1>

https://pubs.acs.org/doi/10.1021/acsmedchemlett.9b00497

#### Resolved is defined as[[1]](#footnote-1) firm in purpose or intent; determined and I’m determined.

#### Affirm means to express agreement[[2]](#footnote-2) and you already know I do.

#### 1] Reducing IP is a method of global solidarity by manifesting intra-country cooperation.

Jecker and Atuire 7/7 [Nancy S Jecker (professor of bioethics and philosophy at the University of Washington School of Medicine, Department of Bioethics and Humanities) and Caesar A Atuire (PhD in Philosophy from the Athenaeum Regina Apostolorum, Rome, Lecturer in the Department of Philosophy and Classics at the University of Ghana, Legon). “What’s yours is ours: waiving intellectual property protections for COVID-19 vaccines”. Journal of Medical Ethics. July 7 2021. Accessed 7/22/21. <https://jme.bmj.com/content/early/2021/07/06/medethics-2021-107555> //Xu]

We turn next to positive ethical arguments for temporarily waiving IP protections, which appeal to the values of globally solidarity and corporate responsibility. Global solidarity underscores that during the COVID-19 pandemic, each nation’s interests are entwined with the interests of every other.22 Just as it is impossible for any nation standing alone to address the threat to human health climate change raises, it is impossible for any single nation to meet the challenge that COVID-19 and future pandemics present. Instead, humanity must stand together. In the past, nations have failed to do so. The epidemic of HIV/AIDS in Africa illustrates. Shamefully, it took nearly a decade for the first antiretroviral drugs to reach the African continent, even though Africa was the hardest hit region and antiretroviral drugs provided 90% mortality reduction. Although the US government was an early investor in research that produced antiviral drugs for HIV, distribution was controlled by big pharmaceutical companies driven by profit. The USA and other wealthy countries repeated this mistake during the COVID-19 pandemic, supporting vaccine developers without requiring technology transfers and donations to COVAX (the multilateral partnership supplying vaccines to LMICs). Ethically, the task ahead is fixing a problem of human making. A second argument, based on corporate social responsibility, stresses expectations for and benefits of socially responsible behaviour by for-profit companies. Increasingly, companies appreciate the potential impact that socially responsible behaviour has on competitive advantage, reputation, retention of workers and customers, employee morale and relationships with stakeholders.23 IP protections shield pharmaceutical companies from competition, enabling them to monopolise markets and generate above-normal profits. During a pandemic, social responsibility requires temporarily limiting profits and requiring companies to give back, rather than allowing above-normal profits to accrue unchecked. Even Locke, who conceived of our modern notion of property rights, held that fundamental rights like property could be justly overridden under certain conditions, namely, when the goods are perishable and would go to waste or when their extraction may intrude on the common good, in which case they extend only to what leaves enough behind for others.24 Building on this analysis, we submit that displays of social responsibility fall along a continuum. During the COVID-19 pandemic, a high degree of responsibility would be shown by temporarily sharing patents for products aimed at preventing, containing, or treating COVID-19, which is India and South Africa’s proposal; moderate responsibility would be demonstrated by temporarily sharing licenses to manufacture COVID-19 vaccines, as the WTO Director General proposes; and minimal responsibility would be shown by sending vaccines directly to nations in response to pleas for help, which Pfizer did when it pledged up to 40 million doses of its vaccine to COVAX (which represents under 2% of the 2.5 billion doses Pfizer will produce in 2021).25

#### 2] IP laws prioritize uniformity and predictability as a method of homogenizing knowledge and refusing experimentation.

Wu 14 [Tim Wu (Julius Silver Professor of Law, Science and Technology at Columbia University). “Intellectual Property Experimentalism By Way of Competition Law”. Columbia Law School. 2014. Accessed 8/16/21. <https://scholarship.law.columbia.edu/cgi/viewcontent.cgi?article=2843&context=faculty_scholarship> //Xu]

The goals of uniformity and predictability has had its clearest implications at the international level. Unlike competition law, which varies significantly between OECD nations, over the last several decades all of the IP laws have become subject to a much stronger and geographically broader web of harmonizing international agreements, on multinational, regional and bilateral levels. The general aim of these treaties is to homogenize the world’s IP regimes, reducing or eliminating geographical variation. All of the major laws are the subject of longstanding global treaties specifying minimum protections (The Berne and Paris conventions), which were fortified in 1994 by the addition of an intellectual property agreement to the World Trade Organization, and further strengthened by numerous bilateral treaties since then. And of course the World Trade Organization, unlike the informal organizations common to competition law, has the power to punish deviations from the intellectual property treaties with serious trade sanctions. The pattern can also be observed at the national level. Both in Europe and the United States the last few decades have witnessed many important measures taken to create uniformity. In the United States, a single appeals court, the Federal Circuit, has heard the nation’s appeals in patent cases since 1982 in an effort to bring greater uniformity to the patent law. Though proposals for constructing a uniform patent court akin to the Federal Circuit in the European Union have been unsuccessful so far,26 the European Patent Convention, founded in 1973, provides a common application for the prosecution of patents in each of the member states.27 In short, stronger protection of uniform rights has been the clear trajectory of the intellectual property laws over the last few decades. That tendency is sharply at odds with the predispositions of the competition laws. The dichotomy I am suggesting here is, of course, not absolute. In certain areas of the competition law, one can sense the influence of a vested rights theory, in, for example, the resistance to breakups of dominant terms, even if the economic case for doing so might be quite strong. And there are areas in IP law, like the American fair use doctrine (a judicial and scholarly favorite), which have, in fact, served as important outlets for judicial tinkering in the face of changing conditions. For example the famous Sony decision, blessing the VCR, broke with prevalent copyright doctrine, arguably as a reaction to perceived technological necessity.28 Similarly, following a decade of bad press, Congress, the courts, and the American Patent Office have begun to make adjustments with American patent law. An example is the new post-grant review process, which includes a particular provision targeted at business method patents. Nonetheless it would be hard to describe the intellectual culture of either the intellectual property laws as truly committed to experimental improvement of the law. It would be even harder to describe competition law as devoted to the protection of fundamental rights. We are left with a divergence in intellectual cultures with broad implications for just about every advanced economy in the world. IV. USING ANTITRUST FOR PATENT EXPERIMENTALISM AT THE UNITED STATES SUPREME COURT I believe there is a need for a more experimentalist approach to the intellectual property laws, and particularly to the patent laws. The law, I believe, needs better mechanisms not simply to celebrate its successes, but to correct its errors, both specific and general. One way this might be achieved is to act within the structure and institutions of the laws themselves; as just discussed, this is a project underway in certain respects. But the other path is to rely on the competition laws as a kind of oversight and adjustment mechanism for the intellectual property laws.

### 1AC – Underview

#### 1] 1AR theory is legit – anything else means infinite abuse – drop the debater, competing interps, no rvis– 1AR is too short to make up for the time trade-off – no RVIs or 2NR theory and paradigm issues– 6 min 2NR means they can brute force me every time.

### 1AC - Advantage

#### We are in an innovation crisis

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.

#### Evergreening results 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

In 2011, Elsa Dixler was diagnosed with multiple myeloma. That August, she was prescribed Revlimid, a drug that had come on the market six years earlier. By January 2012, she went into full remission, where she has remained since. So long as Revlimid retains its effectiveness, she will take it for the rest of her life. “I was able to go back to work, see my daughter receive her Ph.D, and have a pretty normal life,” said Dixler, a Brooklyn resident who is now 74. “So, on the one hand, I feel enormously grateful.” But Dixler’s normal life has come at a steep financial cost to her family and to taxpayers. Revlimid typically costs nearly $800 per capsule, and Dixler takes one capsule per day for 21 days, then seven days off, and then resumes her daily dose, requiring 273 capsules a year. Since retiring from The New York Times at the end of 2017, she has been on Medicare. Dixler entered the Part D coverage gap (known as the donut hole) “within minutes,” she said. She estimates that adding her deductible, her copayment of $12,000, and what her Part D insurance provider pays totals approximately $197,500 a year. Revlimid should have **been subject to competition** from generic drug makers starting in 2009, bringing down its cost by many orders of magnitude. But by obtaining **27 additional patents**, eight orphan drug exclusivities and 91 total additional protections from the U.S. Food and Drug Administration (FDA) since Revlimid’s introduction in 2005, its manufacturer, Celgene, has extended the drug’s **monopoly** **period** **by 18 years** — through March 8, 2028. “I cannot fathom the immorality of a business that relies on **squeezing people with cancer**,” Dixler said, noting her astonishment that Revlimid has obtained orphan drug protections when it treats a disease that is not rare and does not serve a very limited population. She also observed that Revlimid’s underlying drug is thalidomide, which has been around for decades. “They didn’t invent a new drug, rather, they found a new use for it,” she said. “The cost of Revlimid has imposed constraints on our retirement,” Dixler said, “but when I hear other people’s stories, I feel very lucky. A lot of people have been devastated financially.” 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. Because these small changes to the injector have maintained its monopoly for so long, the cost of an EpiPen package (containing two injectors) has risen from $94 when Mylan purchased the device to between $650 and $700 today. For many people, especially parents of children with severe reactions to common allergens like peanuts, EpiPen’s increasing price tag imposes an onerous financial burden. What Can Be Done As the Evergreen Drug Patent Search makes clear, the positive impact of Hatch-Waxman has been steadily and severely eroded by a regulatory system vulnerable to increasingly sophisticated forms of manipulation. “You might say that the patent and regulatory system has been weaponized,” Feldman said. “When billions of dollars are at stake, there’s a lot of money available to look for ways to exploit the legal system. And companies have become adept at this, as our work has found.” There are several key steps that Congress could take to restore the balance between innovation and competition that is the key to a successful prescription drug regulatory process. These may include: Imposing restrictions on the number of patents that prescription drug manufacturers can defend in court to discourage the use of anticompetitive patent thickets. Limiting the patentability of so-called secondary patents — which don’t improve the safety or efficacy of a drug — through patent and exclusivity reform. Reforming the 180-day generic exclusivity, which can currently be abused to block other competitive therapies. “**The Evergreen Drug Patent Search provides the publicly available, evidence-based foundation that defines the extent of the problem**, and it can be used to develop policies that solve the problem of anti-competitive patent abuses,” said Kristi Martin, VP of Drug Pricing at Arnold Ventures. “Our incentives have gotten out of whack,” Martin said. “The luxury of monopoly protection should only be provided to innovations that provide meaningful benefits in saving lives, curing illnesses, or improving the quality of people’s lives. It should not be provided to those gaming the system. If we can change that, we can save consumers, employers, and taxpayers many billions of dollars while increasing the incentives for pharmaceutical companies to achieve breakthroughs."

#### 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.”

#### Extinction - generic defense doesn’t apply.

Srivatsa 17 Kadiyali Srivatsa 1-12-2017 “Superbug Pandemics and How to Prevent Them” <https://www.the-american-interest.com/2017/01/12/superbug-pandemics-and-how-to-prevent-them/> (doctor, inventor, and publisher. He worked in acute and intensive pediatric care in British hospitals)//Elmer

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

1. http://www.dictionary.com/browse/resolved [↑](#footnote-ref-1)
2. http://www.dictionary.com/browse/affirm [↑](#footnote-ref-2)