### Framework

#### Ethics must begin apriori

#### [1] Uncertainty – our experiences are inaccessible to others which allows people to say they don’t experience the same, however a priori principles are universally applied to all agents.

#### [2] Bindingness – I can keep asking “why should I follow this” which results in relativism since obligations are predicated on ignorantly accepting rules. Only reason solves since asking “why reason?” requires reason which concedes its authority and equally proves agency as constitutive.

#### [3] Action theory: only evaluating action through reason solves since reason is key to evaluate intent, otherwise we could infinitely divide actions. For example: If I was brewing tea, I could break up that one big action into multiple small actions. Only our intention, to brew tea unifies these actions if we were never able to unify action, we could never classify certain actions as moral or immoral since those actions would be infinitely divisible.

#### [4] All arguments by definition appeal to reason – otherwise you are conceding they have no warrant to structure them and are by definition baseless. Thus reason is an epistemic constraint on evaluating neg arguments.

#### That implies universality

#### [1] Apriori truths are true for everyone, i.e. the sum of interior angles in a triangle equaling 180 can’t only be true for me but not you

#### [2] Principle of equality- There is nothing apriori distinct between agents thus our obligations should be equal, which means even if we aren’t bound to the categorical imperative, universality is still a side constraint on other frameworks.

#### Freedom follows

#### [1] Its impossible to will a violation of freedom, since it necessarily entails a violation of your own freedom thus violating your will.

#### [2] We could not hold agents responsible for their actions if we did not assume them to have the freedom to control their actions for themselves.

#### [3] Key for action guidance-obligations are arbitrary since the agent can form a unique interpretation and understanding which makes it impossible to verify a violation. Only universality solves since universalizing a violation of freedom entails a violation of your own freedom, thus a recognizable violation appears

#### Thus, the standard is consistency with the categorical imperative.

#### Prefer the standard:

#### [1] Resource Disparities- a focus on evidence and statistics privileges debaters with the most preround prep which excludes lone-wolfs who lack huge evidence files. A debate under my framework can easily be won without any prep since huge evidence files aren’t required.

#### [2] Real World Education – Governments operate in consistency to Kantian conceptions of the state. Empirically proven – legitimate states have deontic side constraints like a bill of rights or constitutional courts, but no state is allowed to violate citizens’ liberties for the purpose of the greater good

#### [3] Performativity—freedom is the key to the process of justification of arguments. Willing that we should abide by their ethical theory presupposes that we own ourselves in the first place. Thus, it is logically incoherent to justify the neg arguments/standard without first willing that we can pursue ends free from others.

#### [4] Consequences Fail- [A] Every action has infinite stemming consequences, because every consequence can cause another consequence. [B] Induction is circular because it relies on the assumption that nature will hold uniform and we could only reach that conclusion through inductive reasoning based on observation of past events. [C] Aggregation Fails – suffering is not additive can’t compare between one migraine and 10 headaches [D] Predictions are impossible because anything could lead to a butterfly effect of unexpected consequences i.e. sneezing becoming a tornado and killing thousands

#### [5] Abstraction is necessary and inevitable in ethics- the alternative is unchecked egoism.

**Farr 2** Arnold Farr (prof of phil @ UKentucky, focusing on German idealism, philosophy of race, postmodernism, psychoanalysis, and liberation philosophy). “Can a Philosophy of Race Afford to Abandon the Kantian Categorical Imperative?” JOURNAL of SOCIAL PHILOSOPHY, Vol. 33 No. 1, Spring 2002, 17–32

To avoid ethical egoism one must abstract from (think beyond) one’s own personal interest and subjective maxims. That is, the categorical imperative requires that I recognize that I am a member of the realm of rational beings. Hence, I organize my maxims in consideration of other rational beings. Under such a principle other people cannot be treated merely as a means for my end but must be treated as ends in themselves. The merit of the categorical imperative for a philosophy of race is that it contravenes racist ideology to the extent that racist ideology is based on the use of persons of a different race as a means to an end rather than as ends in themselves. Embedded in the formulation of an end in itself and the formula of the kingdom of ends is the recognition of the common hope for humanity. That is, maxims ought to be chosen on the basis of an ideal, a hope for the amelioration of humanity. This ideal or ethical commonwealth (as Kant calls t in the Religion) is the kingdom of ends.34 Although the merits of Kant’s moral theory may be recognizable at this point, we are still in a bit of a bind. It still seems problematic that the moral theory of a racist is essentially an antiracist theory. Further, what shall we do with Henry Louis Gates’s suggestion that we use the Observations on the Feeling of the Beautiful and Sublime to deconstruct the Grounding? What I have tried to suggest is that instead of abandoning the categorical imperative we should attempt to deepen our understanding of it and its place in Kant’s critical philosophy. A deeper reading of the Grounding and Kant’s philosophy in general may produce the deconstruction35 suggested by Gates. However, a text is not necessarily deconstructed by reading it against another. Texts often deconstruct themselves if read properly. To be sure, the best way to understand a text is to read it in context. Hence, if the Grounding is read within the context of the critical philosophy, the tools for a deconstruction of the text are provided by its context and the tensions within the text. Gates is right to suggest that the Grounding must be deconstructed. However, this deconstruction requires much more than reading the Observations on the Feeling of the Beautiful and Sublime against the Grounding. It requires a complete engagement with the critical philosophy. Such an engagement discloses some of Kant’s very signiﬁcant claims about humanity and the practical role of reason. With this disclosure, deconstruction of the Grounding can begin. What deconstruction will reveal is not necessarily the inconsistency of Kant’s moral philosophy or the racist or sexist nature of the categorical imperative, but rather, it will disclose the disunity between Kant’s theory and his own feelings about blacks and women. Although the theory is consistent and emancipatory and should apply to all persons, Kant the man has his own personal and moral problems. Although Kant’s attitude toward people of African descent was deplorable, it would be equally deplorable to reject the categorical imperative without ﬁrst exploring its emancipatory potential.

### Offense

#### [1] IPP is nonuniversalizable – universalizing the act of restricting the production of a certain medicine terminates in a contradiction because it entails that you restrict your own ability to produce the medicine

#### [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] Evergreening – exploitation of patents is anti-ethical to the intrinsic nature of medical duty – that affirms.

McHenry 6, Leemon. "Ethical issues in psychopharmacology." Journal of Medical Ethics 32.7 (2006): 405-410.

It is often claimed that corporations that are profit driven could not be expected to behave in any other manner than they do. The nature of business demands maximisation of the market share and shareholder value. **Pharmaceutical companies**, however, **present** themselves **as responsible producers of healthcare products**. The **very nature** of the product **involves trust** in the science that produced it **and** an **ethical commitment to** the **wellbeing of the patients** who are their consumers. Despite appearances, nothing of this sort is true in the pharmaceutical industry. As we have seen above, the serotonin hypothesis sold to consumers of pharmaceuticals is flawed. Making questionable claims for the efficacy and safety of SSRIs involves the pharmaceutical companies in further deception. Expanding the market for these drugs by creating dubious disease categories and then luring vulnerable individuals into SSRI therapy by direct to consumer advertising would represent, if perpetrated by a doctor, an abuse of the trust implicit in the relationship between patient and doctor. I do not argue that SSRIs should be withdrawn from the market thus depriving clinicians and patients of this therapeutic option. Rather I argue that **full disclosure** of the data for efficacy and safety **is a basic moral obligation** of the pharmaceutical industry. Until such data is available to the public, prescribing clinicians and patients are relying on drug promotion rather than rigorous science. When **Kant discusses** the **motivation of acting from duty** **as opposed to** the motivation of **self interest**, he mentions the case of the merchant who keeps a fixed price for everyone so that a child who buys from him pays the same price as everyone else.53 The **only actions that have moral worth are those done from the motive of duty alone**. And similarly, **only when** the **pharmaceutical companies act from** the motive of **duty** in fully disclosing all information they possess about the risks and benefits of their drugs **do their actions have any moral worth**. The SSRI marketing story provides a lens through which we can view a much larger problem. The **integrity of medicine is endangered by** an industry that profits from illness and distorts the process of scientific inquiry by marketing strategy, public relations campaigns, and the **sheer power of buying influence** in high places. The House of Commons health committee in the UK has made the point: “It is not in the long term interest of industry for prescribers and the public to lose faith in it. We need an industry which is led by the values of scientists not those of its marketing force” (House of Commons health committee,23 p 6). Medicine desperately needs to win back the territory lost to business. If and when it does, it is not likely to be a result of industry and government regulators facing up to the problems, but rather a matter of the sheer weight of legal actions filed by victims and public outcry about the moral concerns of the sort raised in this paper.

### Advantage

#### The advantage is Innovation

#### 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.

#### We control Uniqueness – up to 80% of all new patents are not new drugs but old ones.

Feldman 2 Robin Feldman 18, May your drug price be evergreen, Journal of Law and the Biosciences, Volume 5, Issue 3, December 2018, Pages 590–647, <https://doi.org/10.1093/jlb/lsy022> Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation (Study Notes: Presenting the first comprehensive study of evergreening, this article examines the extent to which evergreening behavior—which can be defined as artificially extending the protection cliff—may contribute to the problem. The author analyses all drugs on the market between 2005 and 2015, combing through 60,000 data points to examine every instance in which a company added a new patent or exclusivity.)//sid

The study results demonstrate definitively that the pharmaceutical industry has strayed far from the patent system's intended design. The patent system is not functioning as a time-limited opportunity to garner a return, followed by open competition. Rather, companies throughout the industry seek and obtain repeated extensions of their competition-free zones. Moreover, the incidence of such behavior has steadily increased between 2005 and 2015, especially on the patent front and for certain highly valuable exclusivities. Most troubling, the data suggest that the current state of affairs **is harming innovation** in tangible ways. Rather than creating new medicines—sallying forth into new frontiers for the benefit of society—drug companies are focusing their time and effort extending the patent life of old products. This, of course, is not the innovation one would hope for. The greatest creativity at pharmaceutical **companies should be in the lab, not in the legal department**.115 The following sections describe the results obtained through our analysis in detail, but below are the key takeaways from the study: Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. In fact, 78% of the drugs associated with new patents in the FDA’s records were not new drugs coming on the market, but existing drugs. In some years, the percentage reached as high as 80%. Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, more than 70% extended their protection at least once, with more than 50% extending the protection cliff more than once. Looking at the full group, almost 40% of all drugs available on the market created additional market barriers by having patents or exclusivities added to them. Many of the drugs adding to the Orange Book are ‘serial offenders’—returning to the well repeatedly for new patents and exclusivities. Of the drugs that had an addition to the Orange Book, 80% of those had an addition to the Orange Book on more than one occasion, and almost half of these drugs had additions to the Orange Book on four or more occasions. The number of drugs with a high quantity of added patents in a single year has substantially increased. For example, the number of drugs with three or more patents added to them in one year has doubled. Similarly, the number of drugs with five or more added patents has also doubled. Overall, the quantity of patents added to the Orange Book has more than doubled, increasing from 349 patents added in the year 2005 to 723 in 2015. The number of drugs that had a patent added to them in the Orange Book almost doubled. There were striking increases in certain exclusivities, such as orphan drug exclusivity, new patient population exclusivity, and new product exclusivity. In particular, the number of drugs with an added orphan drug exclusivity tripled. In addition, the number of times a use code was added to a patent more than tripled, suggesting that this has become a new favored game. To provide a broad sense of the types of metrics we are using, some could be characterized as ‘intensity’ measures, which capture the breadth and depth of patent and exclusivity activity in the industry. Another set of our metrics can be characterized as ‘temporal’ measures, which evaluate whether there are any trends in the behavior under examination across time during our 11-year timeframe from 2005 to 2015.

#### 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

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 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.

### 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 protection.

#### The Plan solves Evergreening.

Feldman 3 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.

### Underview

#### 1] AFF theory is no RVI, Drop the debater, competing interps, and the highest layer of the round under an interp that aff theory is legit regardless of voters a) infinite abuse since otherwise it would be impossible to check NC abuse b) it would justify the aff never getting to read theory which is a reciprocity issue c) Time crunched 1ar means it becomes impossible to justify paradigm issues and win the shell. d) the 2n can dump on a script to a CI and go for RVI’s making it impossible to check abuse e) The 1ar is too short to win theory and substance f) The 2n can always create infinite reasonability arguments the 2ar can’t get through

#### 2] AFF fairness issues come prior to NC arguments a) The 1ar can’t engage on multiple layers if there is a skew since the speech is already time-crunched b) Sets up an invincible 2n since there are a million of unfair things you can collapse to to win every round.

#### 3] No 2n theory arguments and paradigm issues. a) overloads the 2AR with a massive clarification burden b) it becomes impossible to check NC abuse if you can dump on reasons the shell doesn't matter in the 2n.

#### 4] The role of the ballot is to determine the truth or falsity of the resolution

#### the ballot says vote aff or neg based on a topic and five dictionaries[[1]](#footnote-1) define to negate as to deny the truth of and affirm[[2]](#footnote-2) as to prove true which means it’s constitutive and jurisdictional. Text comes first – a) Controls the internal link to fairness since it’s the basis of things like predictability and prep b) Key to jurisdiction since the judge can only endorse what is within their burden c) Even if another role of the ballot is better for debate, that is not a reason it ought to be the role of the ballot, just a reason we ought to discuss it.

### Extra

#### [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.

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)