## 1AC – Framework

#### I value morality. The Meta-Ethic is Non-Naturalism.

#### [1] The open question argument – Suppose X represents a natural property like pleasure. If X is analytically equivalent to good, then the question “Is it true X is good” becomes “Is it true good is good.” This either means A) Naturalistic frameworks result in a tautology of “Good is good” or b) X is not the same as good in which case non-naturalism is true.

#### [2] Only a priori knowledge is epistemically reliable**. Descartes 41**,

René, 1641. Discourse On Method ; and, Meditations on First Philosophy, NPR

Yet from everything I have just listed, how do I know that there is not something else which does not allow even the slightest occasion for doubt**?** Is there not a God, or whatever I may call him, who puts into me the thoughts I am now having? But why do I think this, since I myself may perhaps be the author of these thoughts**?** In that case am not I, at least, something? But I have just said that I have no senses and no body. This is the sticking point: what follows from this? Am I not so bound up with a body and with senses that I cannot exist without them? But I have convinced myself that there is absolutely nothing in the world, no sky, no earth, no minds, no bodies. Does it now follow that I too do not exist? No: if I convinced myself of something then I certainly existed. But there is a deceiver of supreme power and cunning who is deliberately and constantly deceiving me**.** In that case I too undoubtedly exist**,** if he is deceiving me; and let him deceive me as much as he can, he will never bring it about that I am nothing so long as I think that I am something**. So** after considering everything very thoroughly**,** I must finally conclude that this proposition, I am, I exist, is necessarily true whenever it is put forward by me or conceived in my mind. ButI do not yet have a sufficient understanding of what this ‘I’ is, that now necessarily exists. So I must be on my guard against carelessly taking something else to be this ‘I’, and so making a mistake in the very item of knowledge that I maintain is the most certain and evident of all. I will therefore go back and meditate on what I originally believed myself to be, before I embarked on this present train of thought. I will then subtract anything capable of being weakened, even minimally, by the arguments now introduced, so that what is left at the end may be exactly and only what is certain and unshakeable.

#### There are three ways to categorize the substance of these non-natural properties: Internally, Externally, or from our Constitutive nature as beings. Internalism and Externalism fail – only constitutivism can solve their deficiencies. Kastafanas 14,

#### Kastafanas, Paul. "Constitutivism About Practical Reasons". *Philarchive.Org*, 2014, <https://philarchive.org/archive/KATCAP>. // Scopa

Consider a perfectly homely normative claim, such as “you have to go to the movies.” If we ask what would render this claim true, the answer seems clear: a fact about the agent’s motives. If the claim is true for Allen but false for Betty, this is due to the fact that Allen desires to see the film and Betty does not. It is natural to think that in just this way, reasons will be tied to facts about agent’s motives. But what about claims such as “you have reason not to murder”? That claim seems different. It purports to be universal, applying to all agents. Moreover, it does not seem to depend on the agent’s motives. Suppose Allen has many motives in favor of murdering his uncle (getting revenge for past slights, collecting an inheritance, etc.), and no motives that count against it (he’s a sociopath with no compunction about harming others, and he thinks he’s clever enough to contrive a plan that leaves him with no risk of getting caught). In this simplified case, all of Allen’s motives count in favor of murdering his uncle; none count against it. Nonetheless, most of us want to say that he has reason not to murder. So we face contrary pressures: in certain cases, the claim that reasons are grounded in motives looks exceedingly plausible, indeed obvious; in others, the same claim looks like it generates unacceptable consequences. And so we get a familiar, well-worn philosophical debate: internalists defend the claim that all normative claims are generated in facts about the agent’s motives, whereas externalists deny this. More precisely: (Internalism) Agent A has reason to φ iff A has, or would have after procedurally rational deliberation, a desire or aim whose fulfillment would be promoted by φ-ing. (Externalism) It can be true both that (i) agent A has reason to φ, and (ii) A does not have, and would not have after procedurally rational deliberation, a desire or aim whose fulfillment would be promoted by φ-ing. Each of these theories faces certain difficulties. Internalism has trouble with apparently universal normative claims, such as “you should not murder.” Externalism is tailor-made to capture universal normative claims. Nonetheless, it faces several challenges, including the much-discussed problems of practicality and queerness. First, consider practicality. Moral claims are supposed to be capable of moving us. Recognizing that φ-ing is wrong is supposed to be capable of motivating the agent not to φ. But we might wonder how a claim that bears no relation to any of our motives could have this motivational grip. As Bernard Williams puts it, “the whole point of external reasons statements is that they can be true independently of an agent’s motivations. But nothing can explain an agent’s (intentional) actions except something that motivates him so to act” (1981, 107). William’s suggestion is that if the fact that murder is wrong is to exert a motivational influence upon the person’s action, then the agent must have some motive that is suitably connected to not murdering. And this pushes us back in the direction of internalism. Second, consider Mackie’s argument from queerness. Motives are familiar things, so it seems easy enough to imagine that claims about reasons are claims about relations between actions and motives. Internalism therefore has little difficulty with Mackie’s argument. But what would the relata in an external reasons statement be? Are we to imagine that a claim about reasons is a claim about a relation between an action and some independently existing value? This would be odd: as Mackie puts it, “if there were objective values then they would be entities or relations of a very strange sort, utterly different than anything else in the universe” (1977, 38). For if such values existed, then it would be possible for a certain state of affairs to have “a demand for such-and-such an action somehow built into it” (1977, 40). And this, Mackie concludes, would be a decidedly queer property. In sum: both externalism and internalism have attractive features, yet incur substantial costs. Traditional internalism grounds normative claims in familiar features of our psychologies, yet for that very reason has trouble generating universal normative claims. Externalism generates universal normative claims with ease, yet encounters the problems of practicality and queerness. So we have a pair of unappealing options, and the debate continues. Constitutivism attempts to resolve this dilemma. To put it in an old-fashioned way, constitutivism sublates internalism and externalism, seeing each position as containing a grain of truth, but also as partial and one-sided. The constitutivist agrees with the internalist that the truth of a normative claim depends on the agent’s aims, in the sense that the agent must possess a certain aim in order for the normative claim to be true. However, the constitutivist traces the authority of norms to an aim that has a special status—an aim that is constitutive of being an agent. This constitutive aim is not optional; if you lack the aim, you are not an agent at all. So, while the constitutivist agrees with the internalist that reasons derive from the agent’s aims, the constitutivist holds that there is at least one aim that is intrinsic to being an agent. Accordingly, the constitutivist gets one of the conclusions that the externalist wanted: there are universal reasons for acting.13 Put differently, there are reasons for action that arise merely from the fact that one is an agent. Specifically, these are the reasons grounded in the constitutive aim. So constitutivism can be viewed as an attempt to resolve the dispute between externalists and internalists about practical reason, by showing that there are reasons that arise from non-optional aims.14 In so doing, it generates universal reasons while sidestepping the problems of practicality and queerness.

#### That requires practical reason as the basis for ethics:

#### 1] Bindingness: A theory is only binding when you can answer the question “why should I do this?” and not continue to ask “why”. Only practical reason provides a deductive foundation for ethics since the question “why should I be rational” already concedes the authoritative power of agency since your agency is at work. Bindingness ow.

#### 2] Action Theory: Every action can be broken down to infinite amounts of movements, i.e. me moving my arm can be broken down to the infinite moments of every state my arm is in. Only reason can unify these movements because we use practical reason to achieve our goals, means all actions collapse to reason.

#### 3] 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. TAKES OT NEG ARGUMENTS

#### That justifies a universal moral law –

#### 1] Absent universal ethics morality becomes arbitrary since it can be meaninglessly applied in different ways without reason. Non-arbitrariness is a side constraint – only non-arbitrary principles can hold agent culpable for their actions since otherwise we could make up ethical rules for different situations to punish people. Therefore err aff on risk of offense since anything else means ethics cannot serve it’s purpose.

#### 2] A priori principles like reason apply to everyone since they are independent of human experience. That means to allow one to violate a rule without another would be a contradiction. If we accept one contradiction we accept all statements as true.

#### 3] Key for following rules since rules 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 as enacted through the omnilateral will.

#### Prefer –

#### [1] Motivation – The categorical imperative is intrinsically motivational since it respects the nature of agency, which is the mechanism by which we can set and pursue any end – absent the motivation to pursue ends you would no longer be an agent, which means to be an agent necessitates being motivated to act.

[2] Theoretically prefer – [A] 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 [B] Resource Disparities – A focus on statistics and evidence rewards the debaters with the most preround prep which just increases the disparity between large schools with huge evidence files and lone wolves without coaches. A Kantian debate can easily be won without any preround prep as all that is need is analytical arguments.

#### [3] 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

## 1AC – Contention

#### [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.

## 1AC – 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.

#### 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.

## 1AC – 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 ow cuz its already harder for our side

Shah 19 [Sachin Shah, 2019, "A Statistical Analysis of Side-Bias on the 2019 January-February Lincoln-Douglas Debate Topic," NSD Update, http://nsdupdate.com/2019/a-statistical-analysis-of-side-bias-on-the-2019-january-february-lincoln-douglas-debate-topic/] AG accessed 6-22-2019

As a final note, it is also interesting to look at the trend over multiple topics. In the rounds from 93 TOC bid distributing tournaments (2017 – 2019 YTD), the negative won 52.99% of ballots (p-value < 0.0001) and 54.63% of upset rounds (p-value < 0.0001). This suggests the bias might be structural, and not topic specific, as this data spans six different topics.

#### 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] Presumption and Permissibility affirm- [a] – Freezes action: requiring pro-active justification for all our actions would make it impossible to make morally neutral claims like ‘I ought to drink water’ which means we always assume we can take an action absent a proactive reason not to. [b] – Epistemics: We could never start a strand of reasoning if we had to question that reasoning. [c] – If I told you my name was Vishnu you’d believe me