### Quick underview at the bottom!

### Advantage 1 is Innovation:

#### We are in an innovation crisis – new patents are not new drugs but old ones.

**Feldman 18** [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 recut Adam recut //cohn

**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.

#### Most recent evidence concludes aff – innovation turns are big pharma’s lies

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

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

#### The only wholistic 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 recut //cohn

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."**

#### Companies don’t even spend on R&D anymore

AT Advantage CPs to solve Drug Prices

**Radhakrishnan 16** Priti Radhakrishnan 6-14-2016 "Pharma’s secret weapon to keep drug prices high"<https://www.statnews.com/2016/06/14/secondary-patent-gilead-sovaldi-harvoni/> (Priti Radhakrishnan is cofounder and director of the Initiative for Medicines, Access & Knowledge (I-MAK), a US-based nonprofit group of scientists and lawyers working globally to get people lifesaving medicines. Before founding I-MAK, she worked as a health attorney in the US, Switzerland, and India.)//Elmer recut //cohn

**Skyrocketing drug prices are forcing states to take unprecedented measures to rein in health care spending.** Vermont just became the nation’s first state to require prescription drug pricing transparency. The New York and Massachusetts attorneys general have launched investigations into major pharmaceutical companies’ and insurers’ drug pricing policies and strategies. **These are important steps. But they ignore a key driver of the problem: secondary patents.** **Familiar to only a few people inside the insular world of intellectual property law, secondary patents work like this: Companies file for additional, defensive patents to thicken the protection around their original base patents. These additional patents rarely represent anything new in terms of science. Instead, their purpose is to prolong a company’s monopoly and, along with that, its ability to charge high prices for its drugs.** Some drugs have dozens of secondary patents. Abbott Labs, for example, has over 108 patents on its HIV drug Kaletra. Take the case of Sovaldi, a treatment for hepatitis C developed by Gilead Sciences. In the United States, Gilead prices Sovaldi at up to $1,000 a pill, or about $84,000 for a complete course of treatment. This pricing strategy helped Gilead clear $18 billion in profits last year, while taxpayer-funded Medicaid programs, state health programs, and patients have trouble affording this astronomically priced drug. Sovaldi is comprised of a base compound — sofosbuvir — for which the pharma giant has filed three patents. On top of that, Gilead has pursued an additional 24 patents, with more likely to come. My organization, the Initiative for Medicines, Access & Knowledge (I-MAK), aims to ensure that people with hepatitis C and HIV around the world get the medicines they need to survive and lead healthy lives. We have evaluated Gilead’s patent portfolio and found that, based on US and international patent law, Gilead does not deserve any of its 27 patents for Sovaldi. Both the base and secondary patents for the drug are based on old science and commonly known techniques. Yet because of its defensive patenting strategy, Gilead will maintain an iron lock on its market share and charge exorbitantly high prices to Americans with hepatitis C until well into the 2030s. Harvoni, another medication that treats hepatitis C, combines sofosbuvir and a drug called ledipasvir. Currently, Harvoni has 27 secondary patents. If these were removed, people in the US could access far cheaper versions of the same drug as soon as 10 years earlier. Based on I-MAK’s conservative estimates, this could open access to treatment for millions of people in the US, saving patients and payers like Medicare and Medicaid $5 billion over an eight-year period. **In the US, Harvoni is priced at $94,000 for a course of treatment. In middle-income, high-population countries like Argentina, Brazil, and China, people are forced to pay thousands of dollars for sofosbuvir.** Stripping away unmerited patents would reduce drug costs and increase access for millions of people in the US and around the world. **Pharmaceutical companies love to claim that winnowing their armada of patents would be a disincentive to innovation and would limit research into new drugs. Don’t believe it. The industry devotes shockingly little funding to research and development**. **Companies spend roughly one-third of their revenues on marketing and only half as much on research and development, while spending big on armies of lawyers to devise and defend secondary patents and other so-called “life cycle management” strategies. Drug research funding has been declining for more than a decade, while strategies of secondary patenting have steadily increased.** We support patents — just not those that are unmerited and that unjustly prolong companies’ market power and prevent legitimate competition.

#### Only innovation now solves superbugs -- 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 recut //cohn

The United Nations has called antimicrobial resistance a “global crisis.” With the **rise in superbugs** 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). 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 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. **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.”**

#### AMR Pandemics are a predictable crisis and cause Extinction - shrugs off generics just like AMRs shrug off current cures,

**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 recut //cohn

**It is by now no secret that the human species is locked in a race of its own making with “superbugs.”** Indeed, if popular science fiction is a measure of awareness, the theme has pervaded English-language literature from Michael Crichton’s 1969 Andromeda Strain all the way to Emily St. John Mandel’s 2014 Station Eleven and beyond. By a combination of massive inadvertence and what can only be called stupidity, **we must now invent new and effective antibiotics faster than deadly bacteria evolve**—and regrettably, they are rapidly doing so with our help. I do not exclude the possibility that bad actors might deliberately engineer deadly superbugs.1 But even if that does not happen, **humanity faces an existential threat** largely **of its own making** in the absence of malign intentions. **As threats go, this one is entirely predictable.** The concept of a “black swan,” Nassim Nicholas Taleb’s term for low-probability but high-impact events, has become widely known in recent years. Taleb did not invent the concept; he only gave it a catchy name to help mainly business executives who know little of statistics or probability. Many have embraced the “black swan” label the way children embrace holiday gifts, which are often bobbles of little value, except to them. **But the threat of inadvertent pandemics is not a “black swan” because its probability is not low. If one likes catchy labels, it better fits the term “gray rhino,” which, explains Michele Wucker, is a high-probability, high-impact event that people manage to ignore anyway for a raft of social-psychological reasons**.2 A pandemic is a quintessential gray rhino, for **it is no longer a matter of if but of when it will challenge us**—and of how prepared we are to deal with it when it happens. We have certainly been warned. The curse we have created was understood as a possibility from the very outset, when seventy years ago Sir Alexander Fleming, the discoverer of penicillin, predicted antibiotic resistance. When interviewed for a 2015 article, “The Most Predictable Disaster in the History of the Human Race, ” Bill Gates pointed out that one of the costliest disasters of the 20th century, worse even than World War I, was the Spanish Flu pandemic of 1918-19. As the author of the article, Ezra Klein, put it: “**No one can say we weren’t warned. And warned. And warned. A pandemic disease is the most predictable catastrophe in the history of the human race, if only because it has happened to the human race so many, many times before.”**3 Even with effective new medicines, if we can devise them, we must contain outbreaks of bacterial disease fast, lest they get out of control. In other words, we have a social-organizational challenge before us as well as a strictly medical one. That means getting sufficient amounts of medicine into the right hands and in the right places, but it also means educating people and enabling them to communicate with each other to prevent any outbreak from spreading widely. Responsible governments and cooperative organizations have options in that regard, but even individuals can contribute something. To that end, as a medical doctor I have created a computer app that promises to be useful in that regard—of which more in a moment. But first let us review the situation, for while it has become well known to many people, there is a general resistance to acknowledging the severity and imminence of the danger. What Are the Problems? Bacteria are among the oldest living things on the planet. They are masters of survival and can be found everywhere. Billions of them live on and in every one of us, many of them helping our bodies to run smoothly and stay healthy. Most bacteria that are not helpful to us are at least harmless, but some are not. They invade our cells, spread quickly, and cause havoc that we refer to generically as disease. Millions of people used to die every year as a result of bacterial infections, until we developed antibiotics. These wonder drugs revolutionized medicine, but one can have too much of a good thing. Doctors have used antibiotics recklessly, prescribing them for just about everything, and in the process helped to create strains of bacteria that are resistant to the medicines we have. We even give antibiotics to cattle that are not sick and use them to fatten chickens. Companies large and small still mindlessly market antimicrobial products for hands and home, claiming that they kill bacteria and viruses. They do more harm than good because the low concentrations of antimicrobials that these products contain tend to kill friendly bacteria (not viruses at all), and so clear the way for the mass multiplication of surviving unfriendly bacteria. Perhaps even worse, hospitals have deployed antimicrobial products on an industrial scale for a long time now, the result being a sharp rise in iatrogenic bacterial illnesses. Overuse of antibiotics and commercial products containing them has helped superbugs to evolve. We now increasingly face microorganisms that cannot be killed by antibiotics, antifungals, antivirals, or any other chemical weapon we throw at them. Pandemics are the major risk we run as a result, but it is not the only one. Overuse of antibiotics by doctors, homemakers, and hospital managers could mean that, in the not-too-distant future, something as simple as a minor cut could again become life-threatening if it becomes infected. Few non-medical professionals are aware that antibiotics are the foundation on which nearly all of modern medicine rests. Cancer therapy, organ transplants, surgeries minor and major, and even childbirth all rely on antibiotics to prevent infections. If infections become untreatable we stand to lose most of the medical advances we have made over the past fifty years. And the problem is already here. In the summer of 2011, a 43-year-old woman with complications from a lung transplant was transferred from a New York City hospital to the Clinical Center at the National Institutes of Health (NIH), in Bethesda, Maryland. She had a highly resistant superbug known as Klebsiella pneumoniae carbapenemase (KPC). The patient was treated and eventually discharged after doctors concluded that they had contained the infection. A few weeks later, a 34-year-old man with a tumor and no known link to the woman contracted KPC while at the hospital. During the course of the next few months, several more NIH patients presented with KPC. Doctors attacked the outbreak with combinations of antibiotics, including a supposedly powerful experimental drug. A separate intensive care unit for KPC patients was set up and robots disinfected empty rooms, but the infection still spread beyond the intensive care area. Several patients died and then suddenly all was silent on the KPC front, with doctors convinced they had seen the last of the dangerous bacterium. They couldn’t have been more mistaken. A year later, a young man with complications from a bone marrow transplant arrived at NIH. He became infected with KPC and died. This superbug is now present in hospitals in most, if not all U.S. states. This is not good. This past year an outbreak of CRE (carbapenem-resistant enterobacteriaceae) linked to contaminated medical equipment infected 11 patients and killed two in Los Angeles area hospitals. This family of bacteria has evolved resistance to all antibiotics, including the powerful carbapenem antibiotics that are often used as a last resort against serious infections. They are now so resilient that it is virtually impossible to remove them from medical tools such as catheters and breathing tubes placed into the body, even after cleaning. Then we have gonorrhea, chlamydia, and other sexually transmitted diseases that we cannot treat and that are spreading all over the world. Anyone who has sex can catch these infections, and because most people may not exhibit any symptoms they spread infections without anyone knowing about it. Sexually transmitted diseases used to be treatable with antibiotics, but in recent years we have witnessed the rise of multi-drug resistant STDs. Untreated gonorrhea can lead to infertility in men and women and blindness and other congenital defect in babies. As is well known, too, we have witnessed many cases of drug-resistant pneumonia. These problems have arisen in part because of simple mistakes healthcare professionals repeatedly make. Let me explain. Neither superbugs nor common bacterial infections produce any special symptoms indicative of their cause. Rashes, fevers, sneezing, runny noses, ear pain, diarrhea, vomiting, coughing, fatigue, and weakness are signs of common and minor illnesses as well as uncommonly deadly ones. Therefore, the major problem for clinicians is to identify a common symptom that may potentially be an early sign of a major infection that could result in an epidemic. We know that dangerous infections in any given geographical area do not start at the same time. They start with one victim and gradually spread. But that victim is only one among hundreds of patients a doctor will typically see, so many doctors will miss patients presenting with infections that are serious. They will probably identify diseases that kill fast, but slow-spreading infections such as skin infections that can lead to septicemia are rarely diagnosed early. In addition, I have seen doctors treating eczema with antibiotic cream, even though they know that bacteria are resistant to the majority of these drugs. This sort of action encourages simple infections to spread locally, because patients are therefore not instructed to take other, more useful precautions. On top of that, some people are frivolous about infections and assume doctors are exaggerating the threat. And some people are selfish. Once I was called to see a passenger during a flight who had symptoms consistent with infection. He boarded the plane with these symptoms, but began to feel much worse during the flight. I was scared, knowing how infections such as Ebola can spread. This made me think about a way to screen passengers before they board a flight. Airlines could refund a traveler’s ticket, or issue a replacement, in case of sickness—which is not the policy now. We currently have no method to block infectious travelers from boarding flights, and there are no changes in the incentive system to enable conscientious passengers to avoid losing their money if they responsibly miss a flight because of illness. Speaking of selfishness, I once saw a mother drop her daughter off at school with a serious bout of impetigo on her face. When I asked her why she had brought her daughter to school with a contagious infection, she said she could not spare the time to keep her at home or take her to the doctor. By allowing this child to contact other children, a simple infection can become a major threat. Fortunately, I could see the rash on the girl’s face, but other kids in schools may have rashes we cannot see. Incorrect diagnosis of skin problems and mistaken use of antibiotics to treat them is common all over the world, and so we are continually creating superbugs in our communities. Similarly, chest infections, sore throats, and illnesses diagnosed as colds that unnecessarily treated with antibiotics are also a major threat. By prescribing antibiotics for viral infections, we are not only helping bacteria develop resistance, but we are also polluting the environment when these drugs are passed in urine and feces. All of this helps resistant bacteria to spread in the community and become an epidemic. Ebola is very difficult to transmit because people who are contagious have visible and unusual symptoms. However, the emerging infections and pandemics of the future may not have visible symptoms, and they could break out in highly populous countries such as India and China that send thousands of travelers all over the world every day. When a person is infected with a contagious disease, he or she can expect to pass the illness on to an average of two people. This is called the “reproduction number.” Two is not that high a number as these things go; some diseases have far greater rates of infection. The SARS virus had a reproduction number of four. Measles has a reproduction number of 18. One person traveling as an airplane passenger and carrying an infection similar to Ebola can infect three to five people sitting nearby, ten if he or she walks to the toilet. The study that highlighted this was published in a medical journal a few years ago, but the airline industry has not implemented any changes or introduced screening to prevent the spread of infections by air travel passengers, a major vehicle for the rapid spread of disease. It is scary to think that nobody knows what will happen when the world faces a lethal disease we’re not used to, perhaps with a reproduction number of five or eight or even ten. What if it starts in a megacity? What if, unlike Ebola, it’s contagious before patients show obvious symptoms? Past experience isn’t comforting. In 2009, H1N1 flu spread around the world before we even knew it existed. The Questions Remains Why do seemingly intelligent people repeatedly do such collectively stupid things? How did we allow this to happen? The answer is disarmingly simple. It is because people are incentivized to prioritize short-term benefits over long-term considerations. It is what social scientists have called a “logic of collective action” problem. Everyone has his or her specialized niche interest: doctors their patients’ approval, business and airline executives their shareholders’ earnings, hospitals their reputations for best-practice hygienics, homemakers their obligation to keep their own families from illness. But no one owns the longer-term consequences for hundreds of millions of people who are irrelevant to satisfying these short-term concerns. Here is an example. At a recent Superbug Super Drug conference in London that I attended, scientists, health agencies, and pharmaceutical companies were vastly more concerned with investing millions of dollars in efforts to invent another antibiotic, claiming that this has to be the way forward. Money was the most pressing issue because, as everyone at the conference knew, for many years pharmaceutical companies have been pulling back from antibiotics research because they can’t see a profit in it. Development costs run into billions of dollars, yet there is no guarantee that any new drug will successfully fight infections. At the same conference Dr. Lloyd Czaplewski spoke about alternatives to antibiotics, in case we cannot come up with new ones fast enough to outrun superbug evolution. But he omitted mention of preventive strategies that use the internet or communication software to help reduce the spread of infections among families, communities, and countries. It is madness that we don’t have a concrete second-best alternative to new antibiotics, because we need them and we need them quickly. Of course, this is why we have governments, which have been known occasionally in the past as commonwealths. Governments are supposed to look out for the wider, common interests of society that niche-interested professionals take no responsibility for, and that includes public health. It is why nearly every nation’s government has an official who is analogous to the U.S. Surgeon General, and nearly every one has a public health service of some kind. Alas, national governments do not always function as they should. Several years ago physician and former Republican Senator Bill Frist submitted a proposal to the Senate for a U.S. Medical Expeditionary Corps. This would have been a specialized organization that could coordinate and execute rapid responses to global health emergencies such as Ebola. Nothing came of it, because Dr. Frist’s fellow politicians were either too shortsighted or too dimwitted to understand why it was a good idea. Or perhaps they simply realized that they could not benefit politically from supporting it. Plenty of mistakes continue to be made. In 2015, a particularly infectious form of bird flu ripped through 14 U.S. states, leading farmers to preventively slaughter nearly 40 million birds. The result of such callous and unnecessary acts is that, instead of exhausting themselves in the host population of birds, the viruses quickly find alternative hosts in which to survive, and could therefore easily mutate into a form that can infect humans. Earlier, during the 1980s, AIDS garnered more public attention because a handful of rich and famous people were infected, and because the campaign to eradicate it dovetailed with and boosted the political campaign on behalf of homosexual rights. Methicillin resistant Staphylococcus aureus (MRSA) in hospitals, by far the bigger threat at the time, was virtually ignored. Some doctors knew that MRSA would bring us to our knees and kill millions of people worldwide, but pharmaceutical companies and device and equipment manufacturers ignored these doctors and the thousands of patients dying in hospitals as a result of MRSA. They prioritized the wrong thing, and government did not correct the error. And that is partly how antibiotic-resistant infection went from an obscure hospital problem to an incipient global pandemic. Politics well outside the United States plays several other roles in the budding problem that we are confronting. Countries often will not admit they have a problem and request help because of the possible financial implications in terms of investment and travel. Guinea did not declare the Ebola epidemic early on and Chinese leaders, worried about trade and tourism, lied for months in 2002 about the presence of the SARS virus. In 2004, when avian influenza first surfaced in Thailand, officials there displayed a similar reluctance to release information. Hospitals in some countries, including India, are managed and often owned by doctors. They refuse to share information about existing infections and often categorically deny they have a problem. Reporting infections to public health authorities is not mandatory, and so hospitals that fail to say anything are not penalized. Even now, the WHO and the CDC do not have accurate and up-to-date information about the spread of E. coli or other infections, and part of the reason is that for-profit hospitals are reluctant to do anything to diminish their bottom line. Syria and Yemen are among those countries that are so weak and fragmented that they cannot effectively coordinate public healthcare. But their governments are also hostile to external organizations that offer relief. Part of the reason is xenophobia, but part is that this makes the government look bad. Relatedly, most poor-nation governments do not trust the efficacy of international institutions, and think that cooperating with them amounts to a re-importation of imperialism. They would rather their own people suffer and die than ask for needed help. That brings us to the level of international public health governance. Alas, sometimes poor-country governments estimate the efficacy of international institutions accurately. The WHO’s Ebola response in 2014-15 was a disaster. The organization was slow to declare a public health emergency even after public warnings from Médecins Sans Frontières, some of whose doctors had already died on the front line. The outbreak killed more than 28,000 people, far more than would have been the case had it been quickly identified. **This isn’t just an issue of bureaucratic incompetence. The WHO is under-resourced for the problems it is meant to solve. Funding comes from voluntary donations, and there is no mechanism by which it can quickly scale up its efforts during an emergency. The result is that its response to the next major disease outbreak is likely to be as inadequate as were its responses to Ebola, H1N1, and SARS.** Stakeholders admit that we need another mechanism, and most experts agree that the world needs some kind of emergency response team for dangerous diseases. But no one knows how to set one up amid the dysfunctional global governance structures that presently exist. Maybe they should turn to Bill Frist, whose basic concept was sound; if the U.S. government will not act, perhaps some other governments will, and use the UN system to do so. But as things stand, we lack a health equivalent of the military reserve. Neither government leaders nor doctors can mobilize a team of experts to contain infections. People who want to volunteer, whether for government or NGO efforts, are not paid and the rules, if any, are sketchy about what we do with them when they return from a mission. Are employers going to take them back? What are the quarantine rules? It is all completely ad hoc, meaning that humanity lacks the tools it needs to protect itself. And note, by the way, the contrast between how governments prepare for facing pandemics and how they prepare for making war. War is not more deadly to the human race than pandemics, but national defense against armed aggression is much better planned for than defense against threats to public health. There is a wealth of rules regarding it, too. Human beings study and plan for war, which kills people both deliberately and accidentally, but they do not invest comparable effort planning for pandemics, which are liable to kill orders of magnitude more people. To the mind of a medical doctor, this is strange. **Creating Conditions for Infections to Spread Superbug infections spread for several interlocking reasons. Some are medical-epidemiological. Most of the infections of the past thirty years have started in one place and in one family. As already noted, they spread because many infectious diseases are highly contagious before the onset of symptoms, and because it is difficult to prevent patients who know they are sick from going to hospitals, work, and school, or from traveling further afield.** But again, one reason for the problem is political, not medical. Many governments have no strategies in place to prevent pandemics because they are unwilling to tell their people how infections spread. They don’t want to worry people with such talk; it will make them, they fear, unpopular. So governments may have mountains of bureaucracy with great heaps of rules and regulations concerning public health, but they are generally unwilling to trust their own citizens to use common sense on their own behalf. This, too, seems very strange. Until now, no one has come forward to help us develop strategies to educate people how to identify and prevent the spread of infection to their families and communities. The majority of stakeholders have also been oblivious to the use of new technologies to help reduce the spread of these infections. There are some exceptions. In a fun blog post called Preparedness 101: Zombie Apocalypse, the CDC uses the threat of a zombie outbreak as a metaphor to encourage people to prepare for emergencies, including pandemics. It is well meaning and insightful, yet when my colleagues and I try to discuss ways of scaling up the CDC’s example with doctors and nurses, they shut down. Nobody plans for an actual crisis partly because it is too scary and hence paralyzing to think about. But it is also because it is not most health professionals’ job; it is not what they are trained and paid to do. It is always someone else’s job, except that it has turned out to be nobody’s job. **Worse, the situation is not static. While we sit [frozen]~~paralyzed~~, superbugs are evolving. Epidemiological models now predict how an algorithmic process of disease spread will move through the modern world. All urban centers around the entire globe can become infected within sixty days because we move around and cross borders much more than our ancestors did, thanks to air travel. A new pandemic could start crossing borders before we even know it exists. A flu-like disease could kill more than 33 million people in 250 days.3**

#### AMR Pandemics are a GAME OVER issue for humanity

**Pamlin and Armstrong 15** Dennis Pamlin and Stuart Armstrong February 2015 “Global Challenges: 12 Risks that threaten human civilization: The case for a new risk category” https://web.archive.org/web/20171006070112/https://api.globalchallenges.org/static/wp-content/uploads/12-Risks-with-infinite-impact.pdf (Dennis Pamlin, Executive Project Manager Global Risks, Global Challenges Foundation, and Stuart Armstrong, James Martin Research Fellow, Future of Humanity Institute, Oxford Martin School, University of Oxford)//Re-cut by Elmer recut //cohn

3.1 Current risks Pandemic 3.1.4 Global **A pandemic** (from Greek πᾶν, pan, “all”, and δῆμος demos, “people”) **is an epidemic of infectious disease that has spread through human populations across a large region; for instance several continents, or even worldwide.** Here only worldwide events are included. A widespread endemic disease that is stable in terms of how many people become sick from it is not a pandemic. 260 84 Global Challenges – Twelve risks that **threaten human civilisation** – The case for a new category of risks 3.1 Current risks 3.1.4.1 Expected impact disaggregation 3.1.4.2 Probability Influenza subtypes266 **Infectious diseases have been one of the greatest causes of mortality in history.** **Unlike many other global challenges pandemics have happened recently, as we can see where reasonably good data exist.** Plotting historic epidemic fatalities on a log scale reveals that these tend to follow a power law with a small exponent: many plagues have been found to follow a power law with exponent 0.26.261 These kinds of power laws are heavy-tailed262 to a significant degree.263 In consequence most of the fatalities are accounted for by the top few events.264 **If this law holds for future pandemics as well,265 then the majority of people who will die from epidemics will likely die from the single largest pandemic**. Most epidemic fatalities follow a power law, with some extreme events – such as the Black Death and Spanish Flu – being even more deadly.267 **There are other grounds for suspecting that such a highimpact epidemic will have a greater probability than usually assumed.** **All the features of a**n extremely **devastating disease already exist in nature**: **essentially incurable (Ebola268), nearly always fatal (rabies269), extremely infectious (common cold270), and long incubation periods (HIV271). If a pathogen were to emerge that somehow combined these features (and influenza has demonstrated antigenic shift, the ability to combine features from different viruses272),** its **death toll would be extreme.** Many relevant features of the world have changed considerably, making past comparisons problematic. The modern world has better sanitation and medical research, as well as national and supra-national institutions dedicated to combating diseases. Private insurers are also interested in modelling pandemic risks.273 **Set against this is the fact that modern transport and dense human population allow infections to spread much more rapidly274, and there is the potential for urban slums to serve as breeding grounds for disease**.275 Unlike events such as nuclear wars, pandemics would not damage the world’s infrastructure, and initial survivors would likely be resistant to the infection. And there would probably be survivors, if only in isolated locations. **Hence the risk of a civilisation collapse would come from the ripple effect of the fatalities and the policy responses**. **These would include political and agricultural disruption as well as economic dislocation and damage to the world’s trade network (including the food trade). Extinction risk is only possible if the aftermath of the epidemic fragments and diminishes human society to the extent that recovery becomes impossible**277 **before humanity succumbs to other risks (such as climate change or further pandemics)**. Five important factors in estimating the probabilities and impacts of the challenge: 1. What the true probability distribution for pandemics is, especially at the tail. 2. The capacity of modern international health systems to deal with an extreme pandemic. 3. How fast medical research can proceed in an emergency. 4. How mobility of goods and people, as well as population density, will affect pandemic transmission. 5. Whether humans can develop novel and effective anti-pandemic solutions.

### Advantage 2 is India

#### Pressure for IP protection from WTO & Flawed US System is damaging India’s pharma industry - preventing the production of cures

**Washington 17** Jessica Washington 27 Sep 2017 “'This is about life and death': Pharmaceutical patents threaten India's generic drug industry” <https://www.abc.net.au/news/2017-09-28/what-india-pfizer-patent-decision-means-for-region-health/8981206> (writer for ABC news) //cohn

**India's decision to grant a patent on a pneumonia vaccine to US pharma giant Pfizer will further damage the country's generic drug industry, which saves thousands of lives across the developing world, medical groups have warned.** The Indian Patent Office last month granted Pfizer patent authorisation for Prevenar 13, which gives the company exclusive rights to distribute the vaccine within India until 2026 and blocks Indian manufacturers from making a generic version of the life-saving vaccine for export. **Prior to 2005, India did not grant patents** **on medicines** — a situation **that bolstered the generic drug manufacturing industry, which** exports medicines to **treat diseases like HIV**/AIDS, **malaria** **and t**u**b**erculosis **around the world.** **That put the South Asian nation in the sights of large pharmaceutical companies from the US and Europe, who say that patent protection and the profits it generates are crucial for funding further research.** **After becoming a signatory to World Trade Organisation agreements, India began to recognise private ownership of intellectual property — including of pharmaceutical products.** "This current flash point is really a manifestation of larger battles over intellectual property, trade, and human rights," said Matthew Rimmer, a professor of intellectual property and innovation at the Queensland University of Technology. The right to health needs to be recognised as a human right, says academic **Matthew Rimmer.(ABC: James Bennett) According to a Medecins Sans Frontieres (MSF) report from 2005, India's generic therapies led to the cost of certain AIDS therapies dropping from as much as US$10,000, to around US$200. As the report put it: "Sick people around the world depend on Indian producers to manufacture affordable generic versions of new medicines."** "We knew back in 2005 that there would be some long-term pain associated with this system," said Leena Menghaney, the access campaign manager at MSF India. **"A large number of medicines and vaccines are now patented in India — so we're going to see, within the next decade or two, India not being able to produce a number of life-saving treatments."** **Intense pressure from drug producers** Each year, the Office of the US Trade Representative releases a Priority Watch List of countries regarded as having harmful records on "protection, enforcement, or market access". Despite the Pfizer decision, **India remains on the Priority Watch List because of its intellectual property framework. India is identified as one of the countries which will "be the subject of intense bilateral engagement during the coming year" — lobbying, in other words.** **According to Ms Menghaney, the watch list is a "pressure tactic". "The United States is very successfully using trade pressure on countries like India," she said. "Their bilateral forums constantly reiterate the need to protect intellectual property, irrespective of the impact on human life."** Dr Rimmer believes the Trump administration has upped the ante when it comes to pressuring India about generic drug manufacturing. "Increasingly, there are larger trade pressures being brought to bear on India," he said. "The new Trump administration has very strong views about intellectual property and trade, and that's caused an amount of friction between the Trump administration and other superpowers like China and India." What happens now? MSF is seeking advice about the feasibility of legally challenging the patent that was granted to Pfizer — a process Ms Menghaney said could "take years". "**We are painfully aware of the dark reality. This is not just about an industry — this is about the life or death of patients."** In the meantime, she hopes Indian manufacturers can find a way to move past the challenges posed by pharmaceutical patents to ensure that people around the developing world have access to affordable health treatments. Dr Rimmer said **the global pharmaceutical industry needs to rethink the role of patent law in the way it operates. "There's a need to recognise the right to health as a human right," he said. "Patent law is also a very crude way of providing an incentive for research and development. So we need to think about alternative means of encouraging development." Pfizer** said in a statement to Saturday Extra that it delivers the pneumococcal conjugate vaccine to the world's poorest countries at a lower price than in higher income countries, through its partnership with GAVI, the Vaccine Alliance. The company also said it is keen to work with the Indian government to "scale up deployment" of the Prevenar 13 vaccine in India.

#### Evergreening restricts Generic production by artificially extending Patents.

**Moir and Gleeson 14** Hazel Moir and Deborah Gleeson 11-5-2014 "Explainer: evergreening and how big pharma keeps drug prices high"<https://theconversation.com/explainer-evergreening-and-how-big-pharma-keeps-drug-prices-high-33623> (Adjunct Associate Professor; economics of patents, copyright and other "IP", Australian National University AND Lecturer in Public Health, La Trobe University)//Elmer recut //cohn

Efforts by pharmaceutical companies to extend their patents cost taxpayers millions of dollars each year. In some cases they also mean people are subjected to unnecessary clinical trials. **Big pharma** makes big profits. Their useful new **drugs are patented**, **protecting them from competition** and allowing them to charge high prices.

When the patent ends, other companies are allowed to supply the previously patented drug. These are **known as generics**. The prices of generic drugs are much lower than the prices of in-patent drugs – it has been suggested that for widely used drugs price falls can be as much as 95%. Pharmaceutical companies want to get their new products listed on the Pharmaceutical Benefits Scheme (PBS), because they will sell in much higher volumes. Taxpayers have an interest in ensuring that these drugs move from the high in-patent price to the much lower off-patent price as early as possible. On average, a patent provides effective protection from competition for about 14 years. But, of course, **companies** like monopolies and would like to **extend the patent period**. Over the past few decades they have **used** a process known as evergreening to keep generic companies out of the market for longer. How evergreening works **Evergreening** is achieved by seeking extra patents on variations of the original drug – new forms of release, new dosages, new combinations or variations, or new forms. Big pharma refers to this as “lifecycle management”. Even if the patent is dubious, the company can earn more from the higher prices than it pays in legal fees to keep the dubious patent alive. Evergreening is possible because in Australia the standard required to get a patent is very low. Different methods of delivering drugs (such as extended release, for example) have been known for decades. But when one of these known delivery methods is combined with a known drug, the patent office considers this sufficiently inventive to grant a new 20-year patent. Another favourite evergreening strategy is to patent a slight variation of the drug. Brand pharmaceutical companies argue that these “lifecycle management” patents provide improved health outcomes to the community. They meet the (very low) patentability thresholds of novelty and inventiveness. Critics argue that the claimed improved health outcomes are small or non-existent. An evergreening story: from Efexor to Efexor-XR to Pristiq An example is useful. In the case of the depression drug **venlafaxine** (marketed as Efexor), the original version had major side-effects. However, when provided in extended release form these side-effects were substantially reduced. Naturally the extended release form (Efexor-XR) became preferred. Although it might seem obvious to combine venlafaxine with an extended release form to overcome the side-effect problem, the patent office **granted two new patents** for extended release versions of venlafaxine. One of these was written in such a broad form that it **delayed generic entry by two and a half years**, while legal wrangling took place. Eventually the evergreening patent was declared invalid. But the cost to taxpayers of this delay is estimated at $209 million. Pfizer has a second evergreening strategy for venlafaxine. When venlafaxine is taken, the human body converts it to desvenlafaxine. In other words desvenlafaxine is a variant of the original active pharmaceutical ingredient venlafaxine. Clearly the two compounds are closely related. So it is astonishing that desvenlafaxine passed the tests for getting a patent. Desvenlafaxine is marketed as Pristiq. Pristiq entered the market early in the two-and-a-half-year period of legal wrangling over the extended release venlafaxine (Efexor-XR) patent. Pfizer’s marketing of Pristiq in February 2009 was so lavish that it attracted the attention of investigative journalists. Pristiq has no additional benefits for patients. Despite this, during the first six months of 2014 half of prescriptions were written for Pristiq rather than for the clinically identical Efexor-XR. But Pristiq costs between $A22.32 and $A26.50 more than Efexor-XR, depending on the dose. Based on reported prescription volumes in 2013-14, the cost to the taxpayer of doctors prescribing Pristiq rather than Efexor-XR exceeds $21 million a year. Unless generic companies challenge the desvenlafaxine patent, there will be **no generic versions of Pristiq until after August 2023**, when the patent expires.

#### Indian generic exporting strength is key to their soft power

**Jha 16** Prem Shankar Jha 11-5-2016 “Let India unleash its soft power”<https://www.thehindu.com/opinion/lead/Let-India-unleash-its-soft-power/article13292272.ece> (Writer at the Hindu)//Elmer

And why stop at food grains? In drought-struck regions, contaminated water kills much faster than hunger and takes the very young and the very old first. The **Indian pharmaceuticals** industry **is the envy of the world**, **because it produces and sells** **medicines at a tenth to a thirtieth** of the **retail prices abroad**. **Can Delhi not buttress its** **food aid with medicines** and vitamins? This will give **an entirely new meaning to** the concept of **Soft Power for**, **unlike the West** in its present incarnation, **it would be seeking to build influence by protecting** and preserving, **not destroying**; by expanding peoples' futures instead of ending them in darkness. We have been relatively **slow to realise** our **full potential** for the exercise of soft power. This could be because of our too-ready acceptance of a concept that was created by an American to address American foreign policy concerns. In Joseph Nye's original definition, soft power originated in the capacity to attract others to your country's culture, values and institutions. Indian policymakers have taken this to heart and relied mainly upon India's open society, democratic institutions, lack of aggressive intent and willingness to share the burden of U.N. peacekeeping and policing the global commons, to garner respect and support in the international community. It is only in the last half-decade, as the Westphalian international order crumbled and India's neighbourhood became increasingly unstable, that New Delhi has begun to explore the economic dimensions of ‘soft power' seriously. Afghanistan has been the focus of its initial efforts, and its success is attested to by the threat (irrational though it is) that Pakistan feels from it.

#### Successful India Soft Power solves Extinction

**Kamdar 7**, Mira. Planet India: How the fastest growing democracy is transforming America and the world. Simon and Schuster, 2007. (Bernard Schwartz Fellow at the Asia Society in 2008)//Elmer

**No other country matters more to the future of our planet than India**. There is no challenge we face, no opportunity we covet where India does not have critical relevance. **From combating global terror to finding cures for dangerous pandemics, from dealing with the energy crisis to averting the worst scenarios of global warming**, from rebalancing stark global inequalities to spurring the vital innovation needed to create jobs and improve lives—**India is now a pivotal player**. The world is undergoing a process of profound recalibration in which the rise of Asia is the most important factor. India holds the key to this new world. India is at once an ancient Asian civilization, a modern nation grounded in Enlightenment values and democratic institutions, and a rising twenty-first-century power. With a population of 1.2 billion, India is the world’s largest democracy. It is an open, vibrant society. India’s diverse population includes Hindus, Muslims, Sikhs, Christians, Buddhists, Jains, Zoroastrians, Jews, and animists. There are twenty-two official languages in India. Three hundred fifty million Indians speak English. India is the world in microcosm. Its geography encompasses every climate, from snowcapped Himalayas to palm-fringed beaches to deserts where nomads and camels roam. A developing country, India is divided among a tiny affluent minority, a rising middle class, and 800 million people who live on less than $2 per day. India faces all the critical problems of our time—extreme social inequality, employment insecurity, a growing energy crisis, severe water shortages, a degraded environment, global warming, a galloping HIV/AIDS epidemic, terrorist attacks—on a scale that defies the imagination. **India’s goal is** breathtaking in scope: transform a developing country of more than 1 billion people into a developed nation and global leader by 2020, and do this as a democracy in an era of resource scarcity and environmental degradation. The world has to cheer India on. If India fails, there is a real risk that **our world will become hostage to political chaos, war over dwindling resources, a poisoned environment, and galloping disease**. Wealthy enclaves will employ private companies to supply their needs and private militias to protect them from the poor massing at their gates. But, if India succeeds, it will demonstrate that it is possible to lift

hundreds of millions of people out of poverty. It will prove that multiethnic, multireligious democracy is not a luxury for rich societies. It will **show us how to save our environment, and how to manage in a fractious, multipolar world**. India’s gambit is truly the venture of the century.

### Thus The Plan

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

#### The Plan solves Evergreening. (solvency advocate)

**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 + cohn (cuz im the best)

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.

#### Reforming the Patent Process would lower Drug Prices and incentivize Pharma Innovation by revitalizing the Market.

**Stanbrook 13**, Matthew B. "Limiting “evergreening” for a better balance of drug innovation incentives." (2013): 939-939. (MD (University of Toronto) PhD (University of Toronto))//Elmer modified //cohn

At issue in the Indian case was “evergreening,” a now widespread practice by the pharmaceutical industry designed to extend the monopoly on an existing drug by modifying it and seeking new patents.2 Currently, half of all drugs patented in Canada have multiple subsequent patents, extending the lifetime of the original patent by about 8 years.3 Manufacturers, in defence of these practices, predictably tout the advantages of new versions of their products, which often represent more potent isomers or salts of the original drugs, longer-lasting formulations or improved delivery systems that make adherence easier or more convenient. But the new versions are by definition “**me too” drugs**, and demonstration that the resulting **incremental benefits** in efficacy and safety are clinically meaningful **is often lacking**. Moreover, the original drugs have often been “blockbusters” used for years to improve the health of millions of patients. It seems hard to argue convincingly why such beneficial drugs require an upgrade, often just before their patents expire. Rather than the marginal benefits accrued from tinkering with already effective agents, patients worldwide are in desperate need of new classes of pharmaceuticals for the great many health conditions for which treatments are presently inadequate or entirely lacking. But developing truly innovative

drugs is undeniably a high-risk venture. It is important and necessary that pharmaceutical companies continue to take these risks, because they are usually the only entities with sufficient resources to do so. Therefore, companies must continue to perceive **sufficient incentives** to continue investing in innovation. Indeed, there is evidence that the prospect of future evergreening has become part of the incentive calculation for innovative drug development.4 But surely it is perverse to extend unpredictably a period of patent protection that the government intended to be clearly defined and predictable, and to maintain incentives that drive companies to divert their **drug-development resources away from innovation**. **Current patent legislation may not be optimal** for striking the right balance between encouraging innovation and facilitating profiteering. Given the broad societal importance of patent legislation, ongoing research to enable active governance of this issue should be a national priority. In the last decade, Canada’s laws have been among the friendliest toward evergreening in the world.5 We should now reflect on whether this is really in our national interest. Governments, including Canada’s, would do well to take inspiration from India’s example and tighten regulations that currently facilitate evergreening. This might involve **denying future patents for modifications** that currently would receive one. An overall reduction in the duration of all secondary patents on a therapy might also be considered. Globally, a more flexible and individualized approach to the length of drug patents might be a more effective strategy to align corporate incentives with population health needs. Limits on evergreening would likely reduce the **extensive patent litigation** that contributes to the **high prices of generic drugs** in Canada.3 Reducing economic pressure on generic drug companies may facilitate current provincial initiatives to lower generic drug prices. **As opportunities to generate revenue from evergreening are eliminated**, research-based **pharmaceutical companies would be left with no choice but to invest more in innovative drug development to maintain their profits.**

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### Framing

**The standard is maximizing expected wellbeing or act hedonistic util.**

**Prefer:**

#### 1] TJFS

#### a) Ground – non-util philosophies conclude overwhelmingly on one side of most topics – for example, Kant won every neg round on the national service topic. Only util generates robust debates with equitable ground.

#### b) Real-world – abstract debates about philosophy have much less grounding in the real world than util – discussing consequences gives students education about fopo, economics, IR, etc. Outweighs since portable skills are the ultimate goal of debate.

#### c) Predictability - Most articles about IP are written through util – it’s a stasis point for the topic

#### 2] Death is bad and outweighs – a) agents can’t act if they fear for their bodily security which constrains every ethical theory, b) it destroys the subject itself – kills any ability to achieve value in ethics since life is a prerequisite which means it’s a side constraint since we can’t reach the end goal of ethics without life

#### 3] Intent-foresight distinction is fake– if I foresee a consequence, then it becomes part of my deliberation since its intrinsic to my action

#### No **Intent-foresight for states**

**Enoch 07** Enoch, D [The Faculty of Law, The Hebrew Unviersity, Mount Scopus Campus, Jersusalem]. (2007). INTENDING, FORESEEING, AND THE STATE. Legal Theory, 13(02). doi:10.1017/s1352325207070048 https://www.cambridge.org/core/journals/legal-theory/article/intending-foreseeing-and-the-state/76B18896B94D5490ED0512D8E8DC54B2

The general difficulty of the intending-foreseeing distinction here stemmed, you will recall, from the feeling that **attempting to pick and choose among the foreseen consequences of one’s actions those one is more and those one is less responsible for looks more like the preparation of a defense than like a genuine attempt to determine what is to be done. Hiding behind the intending-foreseeing distinction seems like an attempt to evade responsibility, and so thinking about the distinction in terms of responsibility serves** 39. Anderson & Pildes, supra note 38. I will use this text as my example of an expressive theory here. 40. See id. at 1554, 1564. 41. For a general critique, see Mathew D. Adler, Expressive Theories of Law: A Skeptical Overview, 148 U. PA. L. REV. 1363 (1999–2000). 42. As Adler repeatedly notes, the understanding of expression Anderson & Pildes work with is amazingly broad, so that “To express an attitude through action is to act on the reasons the attitude gives us”; Anderson & Pildes, supra note 38, at 1510. If this is so, it seems that expression drops out of the picture and everything done with it can be done directly in terms of reasons. 43. This may be true of what Anderson and Pildes have in mind when they say that “expressive norms regulate actions by regulating the acceptable justifications for doing them”; id. at 1511. http://journals.cambridge.org Downloaded: 03 Aug 2014 IP address: 134.153.184.170 Intending, Foreseeing, and the State 91 **to reduce even further the plausibility of attributing to it intrinsic moral significance. This consideration—however weighty in general—seems to me very weighty when applied to state action and to the decisions of state officials**. For perhaps it may be argued that individuals are not required to undertake a global perspective, one that equally takes into account all foreseen consequences of their actions. Perhaps, in other words, individuals are entitled to (roughly) settle for having a good will, and beyond that let chips fall where they may. But this is precisely what stateswomen and statesmen—and certainly **states—are not entitled to settle** for.**44 In making policy decisions, it is precisely the global (or at least statewide, or nationwide, or something of this sort) perspective that must be undertaken**. Perhaps, for instance, an individual doctor is entitled to give her patient a scarce drug without thinking about tomorrow’s patients (I say “perhaps” because I am genuinely not sure about this), but surely **when a state committee tries to formulate rules for the allocation of scarce medical drugs and treatments, it cannot hide behind the intending-foreseeing distinction, arguing that if it allows45 the doctor to give the drug to today’s patient, the death of tomorrow’s patient is merely foreseen and not intended. When making a policy-decision, this is clearly unacceptable.** Or think about it this way (I follow Daryl Levinson here):46 perhaps restrictions on the responsibility of individuals are justified because individuals are autonomous, because much of the value in their lives comes from personal pursuits and relationships that are possible only if their responsibility for what goes on in the (more impersonal) world is restricted. But none of this is true of **states and governments.** **They have no special relationships and pursuits, no personal interests, no autonomous lives to lead in anything like the sense in which these ideas are plausible when applied to individuals persons. So there is no reason to restrict the responsibility of states in anything like the way the responsibility of individuals is arguably restricted.47 States and state officials have much more comprehensive responsibilities than individuals do. Hiding behind the intending-foreseeing distinction thus more clearly constitutes an evasion of responsibility in the case of the former. So the evading-responsibility worry has much more force against the intending-foreseeing distinction when applied to state action than elsewhere.**

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### Underview

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