# Loyola Round 3 – Solebury LN vs Westwood BJ

#### 1ac: evergreening

#### 1nc: T – Vaccines, DA – FDI, NC – Kant

#### 2NR: T – Vaccines

#### RFD – no ci gg

# 1AC – Evergreening V2

## Advantage

#### Innovation low now – secondary patents gut the incentive and skyrocket price of Naloxone, HIV meds, insulin, and even basic allergy drugs – the only comprehensive study

AV 20 (“‘Evergreening’ Stunts Competition, Costs Consumers and Taxpayers.” Arnold Ventures, Arnold Foundation, 24 Sept. 2020, [www.arnoldventures.org/stories/evergreening-stunts-competition-costs-consumers-and-taxpayers/.)//LK](http://www.arnoldventures.org/stories/evergreening-stunts-competition-costs-consumers-and-taxpayers/.)//LK) [Accessed 8/23/2021]

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.” 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."

#### They’re endemic to the industry & 80% of patents were not for new drugs – their stats ignore the quality of the innovation which is nonexistant

Robin 18 (Robin Feldman, 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 [Robin Feldman, Hastings College of the Law, University of California])//LK](https://doi.org/10.1093/jlb/lsy022%20%5bRobin%20Feldman,%20Hastings%20College%20of%20the%20Law,%20University%20of%20California%5d)//LK) [Accessed 8/23/21]

IV.A. Overview 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](javascript:;) 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. IV.B. Number of drugs that had patents and/or exclusivities added to them in the Orange Book, compared to the total number of drugs available As an initial inquiry, we wanted to determine the extent to which companies are adding patents and exclusivities to drugs. Is this a limited activity, confined to well-worn anecdotes that everyone repeats, or does it occur throughout the industry? Our results demonstrate that adding patents and exclusivities is a common behavior, endemic to pharmaceuticals. In fact, between 2005 and 2015, almost 40% of all drugs available on the market had patents, exclusivities, or other changes added to them. Table [1](javascript:;) shows the total number of FDA-approved drugs available on the market in each year of our study. Table [2](javascript:;) shows the number of drugs that had a patent or exclusivity added to them as a percentage of the total number of drugs. The figure is broken down in terms of the number of drugs with an added patent, the number of drugs with an added exclusivity, and the number of drugs that had any relevant change made to it (which includes not only adding a patent and/or exclusivity, but also other significant changes such as adding a use code.)

#### Secondary patents are the root cause & less than 1/6 of revenues go to R&D – ignore their lies told by big pharma

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 //LK [RCT]

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.

#### Independently, it’s the root cause of AIDS backsliding – kills millions each year

Frontline AIDS (“How Patents Affect Access to Hiv Treatment.” Frontline AIDS, 2 October 2019, frontlineaids.org/how-patents-affect-access-to-hiv-treatment/)//LK [Accessed 8/25/2021] \*pppy = per person per year

Since the world acknowledged the global AIDS epidemic in the 1980s much has changed. With better treatment and prevention options, AIDS is no longer seen as a death sentence. Better treatment for co-infections, particularly multi-drug resistant tuberculosis (MDR-TB) and for viral hepatitis have also emerged in the past decade. However, despite the huge progress made, 1.7 million people acquired HIV last year and 770,000 died of AIDS-related illness. For those people – the parents, children, siblings, and friends who unnecessarily lost their lives – the declarations of success are hollow. UNAIDS, which NGOs have been criticising for years for its unduly optimistic reporting, has now acknowledged in its 2019 Epidemic Update that “the annual number of HIV infections has increased in three regions: Eastern Europe and Central Asia (29% increase), Middle East and North Africa (10% increase) and Latin America (7% increase)”. HIV advances that had been made, are now reversing. The over-positive reporting resulted in a serious side-effect. Donors, with competing priorities, bought into the success narrative, and overall global funding for AIDS was reduced. Investment in the HIV responses of low- and middle-income countries decreased by $900 million in just one year. We must act now to ensure the response is fully funded and barriers to accessing medicines, including to second and third line HIV treatment and co-infection treatments, are effectively tackled. Frontline AIDS and the International Treatment Preparedness Coalition (ITPC) have released a joint report looking at one of these crucial barriers – the problem with patents in middle-income countries (MICS). In 2019, people aren’t dying because the drugs for treating HIV, MDR-TB, hepatitis C and many other diseases don’t exist. People are dying because they can’t access them. With an increasing focus on voluntary mechanisms to provide access to medicines, the problem with patents in MICs is being seriously over-looked; as are the legitimate tools that governments can use to increase access and availability and decrease prices. The use of legal mechanisms like TRIPS flexibilities by governments has proven highly effective; in the use of these legal tools, governments, global health agencies and civil society all have an essential role to play. It will not be possible to achieve a sustainable response to HIV without tackling intellectual property (IP) barriers, particularly in MICs. The problem with patents One of the most critical barriers that has existed since treatment for HIV was first approved relates to patents. Patenting of medicines has increased considerably since 2005. More worrying is the trend of ‘evergreening’ patents. Evergreening is a tactic used by pharmaceutical companies to extend their exclusivity over a medicine by applying for, and usually getting, multiple, overlapping patents on a single medicine. Most medicines are covered by several patents, known as patent ‘thickets’ and are used to delay or complicate generic production. Over-pricing as a result of unmerited and extended monopolies puts a huge strain on health budgets. While in theory a government may commit to universal access, in reality the budget may not stretch. Prices for HIV treatment can vary from under $100 to tens of thousands of dollars per person per year (pppy) – for the same drug. Take dolutegravir (DTG) for example. In July 2019, the World Health Organization (WHO) recommended all countries immediately adopt DTG-based regimens as the preferred first-line treatment for HIV. Prices pppy range from $75 for countries that are in a ‘voluntary license’, up to $9656 for those that are not. Middle-income, high burden Typically, MICs are worst affected by the patent problem. Nearly 38 million people live with HIV and a majority of them live in MICs. The countries’ income classification means they are frequently left out of pricing deals or voluntary agreements and have funding reduced by health and development agencies, and so face the dual burden of high prevalence and high costs. Evergreening is just one of the tactics employed by pharmaceutical companies to maintain monopolies and pave the way for this arbitrary pricing. Our report details other tactics as well as how they can be legitimately challenged. Within the Sustainable Development Goals themselves our recommendations are backed. SDG3b reaffirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) regarding flexibilities to protect public health, and, in particular, provide access to medicines for all. Unless TRIPS flexibilities are more routinely put into practice we risk undermining the commitments made to the HIV response.

#### We control uniqueness – innovation is low now and it solves disease, bioterror & antimicrobial resistance. The response to COVID is the exception, not the rule.

Marjanovic and Feijao 20 (Marjanovic, Sonja and Carolina Feijao, Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement. Santa Monica, CA: RAND Corporation, 2020. <https://www.rand.org/pubs/perspectives/PEA407-1.html)//LK> [Accessed 8/30/31]

We need to ensure scalable and sustainable approaches for pharmaceutical innovation in response to infectious disease threats to public health As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism con-text.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterror-ism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions. The COVID-19 pandemic is a game-changer among global public health threats. The risk to human life (both in terms of morbidity and quality of life), the economic risks, the epidemiology of the disease and speed of escalation have led to a crisis-response by many governments around the world. This has in turn influenced the immediate indus-try efforts. Many other infectious disease threats may not manifest as crises in the short term and in the same way as COVID-19, but they could nevertheless escalate. They are not considered to be crises from a short term perspective because they are contained to specific regions and affect fewer people at present – or are re-emerging (e.g. Ebola) – or their impacts have not yet materialised at a scale that would qualify as an immediate crisis (e.g. growing risks of antimi-crobial resistance to some infectious pathogens). However, such diseases and issues are recognised as global threats that could become crises in the future.13 The emerging threats raise important policy questions about how government and the pharmaceutical industry can work together to ensure that pharmaceutical industry innovation is incentivised sustainably and at scale. This is important to help mitigate against current and emerging threats becoming crises further down the line. At present, there are no clear and specific criteria to determine when a disease can trigger the types of healthcare-innovation-re-lated policy actions that have been deployed in response to the COVID-19 crisis. For example, this applies to criteria for securing financial resources for innovation-related activities, reforming regulation to accelerate trials and regulatory approval processes, and securing reimburse-ment mechanisms that help enable industry engagement and the search for rapid solutions. The WHO guidance on what constitutes a pandemic phase does provide guidance on national policy response options, but not specifically as they relate to healthcare innovation activity.14 There are also questions as to whether such policy initiatives and incentives should only be applied in crisis situations, or also as part of proactive government and industry efforts to innovate in the areas of public health threats in order to prevent future global calamities. A crisis and ‘emergency mode’ response may be inevitable for some diseases, but more can be done to mitigate against the need for such a response – especially in cases where emerging threats and their consequences can be foreseen and are known to be a risk. We need to anticipate and act now in terms of how we plan and incentivise better for the future, and how we distinguish between different types of infectious disease threats and phases in framing incentives and regulation.

#### 3 Impacts:

#### 1] Antimicrobial resistance triggers extinction.

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

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

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

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

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

#### Climate change destroys the world.

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

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

The current climate crisis, they say, is larger and more complex than any humans have ever dealt with before. General climate models — like the one that the [United Nations' Panel on Climate Change](https://www.ipcc.ch/sr15/) (IPCC) used in 2018 to predict that a global temperature increase of 3.6 degrees Fahrenheit (2 degrees Celsius) could put hundreds of millions of people at risk — fail to account for the sheer complexity of Earth's many interlinked geological processes; as such, they fail to adequately predict the scale of the potential consequences. The truth, the authors wrote, is probably far worse than any models can fathom.

How the world ends

What might an accurate worst-case picture of the planet's climate-addled future actually look like, then? The authors provide one particularly grim scenario that begins with world governments "politely ignoring" the advice of scientists and the will of the public to decarbonize the economy (finding alternative energy sources), resulting in a global temperature increase 5.4 F (3 C) by the year 2050. At this point, the world's ice sheets vanish; brutal droughts kill many of the trees in the [Amazon rainforest](https://www.livescience.com/57266-amazon-river.html) (removing one of the world's largest carbon offsets); and the planet plunges into a feedback loop of ever-hotter, ever-deadlier conditions.

"Thirty-five percent of the global land area, and 55 percent of the global population, are subject to more than 20 days a year of [lethal heat conditions](https://www.livescience.com/55129-how-heat-waves-kill-so-quickly.html), beyond the threshold of human survivability," the authors hypothesized.

Meanwhile, droughts, floods and wildfires regularly ravage the land. Nearly one-third of the world's land surface turns to desert. Entire ecosystems collapse, beginning with the planet's coral reefs, the rainforest and the Arctic ice sheets. The world's tropics are hit hardest by these new climate extremes, destroying the region's agriculture and turning more than 1 billion people into refugees.

This mass movement of refugees — coupled with [shrinking coastlines](https://www.livescience.com/51990-sea-level-rise-unknowns.html) and severe drops in food and water availability — begin to stress the fabric of the world's largest nations, including the United States. Armed conflicts over resources, perhaps culminating in nuclear war, are likely.

The result, according to the new paper, is "outright chaos" and perhaps "the end of human global civilization as we know it."

#### 3] Disease and bioweapons cause extinction – mathematically outweighs, even if they win mitigation.

Millett & Snyder-Beattie ‘17. Millett, Ph.D., Senior Research Fellow, Future of Humanity Institute, University of Oxford; and Snyder-Beattie, M.S., Director of Research, Future of Humanity Institute, University of Oxford. 08-01-2017. “Existential Risk and Cost-Effective Biosecurity,” Health Security, 15(4), PubMed

In the decades to come, advanced bioweapons could threaten human existence. Although the probability of human extinction from bioweapons may be low, the expected value of reducing the risk could still be large, since such risks jeopardize the existence of all future generations. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios. How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity's favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9 In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a long historical track record ofstate-run bioweapon research applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and mutually assured destruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The possibility of a war between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27 Non-state actors may also pose a risk, especially those with explicitly omnicidal aims. While rare, there are examples. The Aum Shinrikyo cult in Japan sought biological weapons for the express purpose of causing extinction.28 Environmental groups, such as the Gaia Liberation Front, have argued that “we can ensure Gaia's survival only through the extinction of the Humans as a species … we now have the specific technology for doing the job … several different [genetically engineered] viruses could be released”(quoted in ref. 29). Groups such as R.I.S.E. also sought to protect nature by destroying most of humanity with bioweapons.30 Fortunately, to date, non-state actors have lacked the capabilities needed to pose a catastrophic bioweapons threat, but this could change in future decades as biotechnology becomes more accessible and the pool of experienced users grows.31,32 What is the appropriate response to these speculative extinction threats? A balanced biosecurity portfolio might include investments that reduce a mix of proven and speculative risks, but striking this balance is still difficult given the massive uncertainties around the low-probability, high-consequence risks. In this article, we examine the traditional spectrum of biosecurity risks (ie, biocrimes, bioterrorism, and biowarfare) to categorize biothreats by likelihood and impact, expanding the historical analysis to consider even lower-probability, higher-consequence events (catastrophic risks and existential risks). In order to produce reasoned estimates of the likelihood of different categories of biothreats, we bring together relevant data and theory and produce some first-guess estimates of the likelihood of different categories of biothreat, and we use these initial estimates to compare the cost-effectiveness of reducing existential risks with more traditional biosecurity measures. We emphasize that these models are highly uncertain, and their utility lies more in enabling order-of-magnitude comparisons rather than as a precise measure of the true risk. However, even with the most conservative models, we find that reduction of low-probability, high-consequence risks can be more cost-effective, as measured by quality-adjusted life year per dollar, especially when we account for the lives of future generations. This suggests that despite the low probability of such events, society still ought to invest more in preventing the most extreme possible biosecurity catastrophes.

## Advocacy

#### Thus, the plan: the member nations of the World Trade Organization ought to reduce intellectual property protections for medicines by limiting drug innovators to one market exclusivity of their choice for their drug.

#### Solves better than any counterplan – only the aff tackles incentives

Feldman 19 (Feldman, Robin. “Drug Patent Protection: It's Time for a 'One-and-Done' Approach.” STAT, 11 Feb. 2019, [www.statnews.com/2019/02/11/drug-patent-protection-one-done/. [Robin Feldman is professor of law and director of the Institute for Innovation Law at UC Hastings College of the Law in San Francisco and author of “Drugs, Money, and Secret Handshakes” (Cambridge University Press, March 2019).])//LK](http://www.statnews.com/2019/02/11/drug-patent-protection-one-done/.%20%5b%5d)//LK) [Accessed 8/25/2021]

In a perfect world, the system for conveying medications from their makers to patients should be designed to deliver the lowest-cost drugs. The system in the U.S. doesn’t even come close. Insurers should provide the lowest-cost and highest-quality drug benefit for each plan, public or private. But they don’t. Pharmacy benefit managers should use their volume buying power to obtain rebates that individuals could never obtain on their own and pass those rebates along to patients. But they don’t. Pharmacists, who know the prices of the drugs in their stock and who see patients’ cost-sharing amounts at the cash register, should be motivated to provide their customers with information on how to find the best deal so they can afford their medicines. But they aren’t. Doctors should make medication decisions that are in the best interests of their patients. But they often don’t. All of this occurs against the backdrop of a national conversation to lower drug costs and a policy to expedite and encourage vigorous competition in the pharmaceutical industry through the rapid entry of generic drugs as soon as patents expire. But even though the vast majority of prescriptions are filled with generic drugs, rising prices on existing brand-name drugs and sky-high prices for new drugs are swamping the savings from generics. Why isn’t the system working as it should? Related: Behind the patent thicket: tactics AbbVie allegedly used to thwart biosimilar versions of Humira Some experts believe the U.S. can rein in drug process with value-based pricing, which aims to tie the prices we pay for drugs to the benefits they provide, either in terms of longer life or better quality of life. Others call for dismantling pharmacy benefit managers. Still others want large groups like Medicare to negotiate with drug companies for better drug prices. While each of these might help, they cannot solve the problem alone. Why? Because they do not reach the heart of the problem. As I explain in my new book, “Drugs, Money, and Secret Handshakes,” the government itself is giving pharmaceutical companies the power they are wielding through overly generous drug patent protection. Effective solutions must address that problem. 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. Related: WATCH: What is a biosimilar, exactly? 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. Related: Extraordinary tactics, perverse incentives: Makers of top-selling drugs hike prices in lockstep, and patients bear the cost 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.

## Framing --- Util

#### The standard is maximizing expecting well being.

#### 1] Actor specificity

#### ---A] Aggregation – every policy benefits some and harms others, which also means side constraints freeze action.

#### ---B] No act-omission distinction – choosing to omit is an act itself – governments actively decide not to act so there is no omission

#### 2] Util is a lexical pre-requisite to any other framework: Threats to life preclude the ability for moral actors to effectively utilize and act upon other moral theories since they are in a constant state of crisis –

#### that inhibits the ideal moral conditions which other theories presuppose.

#### 3] Extinction matters under any framework:

#### ---A] It precludes the possibility of any kind of moral value – we can’t confer value onto anything if we’re not alive.

#### ---B] Future generations means infinite magnitude – we have to look towards future lives too

## Underveiw

#### 1AR theory –

#### ---A] AFF gets it because otherwise the neg can engage in infinite abuse, making debate impossible. No 2n theory – kills resolvability because judge has to intervene in weighing interp and 2ar counterinterp.

#### ---B] drop the debater – the short 1AR irreparably skewed from abuse on substance and time investment on theory.

#### ---C] no RVIs – the 6-minute 2nr can collapse to a short shell and get away with infinite 1nc abuse via sheer brute force and time spent on theory.

#### ---D] Use competing interps – 1AR interps aren’t bidirectional and the neg should have to defend their norm since they have more time.

#### Yes Aff RVIs

#### ---A] I have a 4 minute 1AR to answer T or Theory which skews my time from other arguments. T bites out of a higher percentage of my rebuttal time.

#### ---B] No risk issue for the negative, you can go for it in the 2nr if I undercover but if I overallocate you can just kick it.

# 1nc

## mina



here u go asher

## 1

#### Interpretation: The affirmative debater must defend reducing intellectual property protections for substances that treat diseases. To clarify, they may not defend substances that prevent diseases.

#### Violation: They defend vaccines

#### Medicines treat diseases

Webster (Merriam Webster is America's leading and most-trusted provider of language information, accessed on 6-30-21, Merriam Webster, "Definition of MEDICINE,” https://www.merriam-webster.com/dictionary/medicine)// ww pbj

Definition of medicine 1a: a substance or preparation used in treating disease cough medicine

#### Treatment is different than prevention

Pflanzer 20 (Lydia Ramsey Pflanzer is a healthcare editor for Business Insider. She joined Business Insider in 2015 after graduating from Northwestern University, 4-29-2020, accessed 6/30/21, "Scientists are racing to discover ways to treat and prevent coronavirus. Here's the difference between a treatment and a vaccine.," Business Insider, <https://www.businessinsider.com/whats-the-difference-between-a-vaccine-and-a-treatment-2020-4)//ww> pbj

Vaccines are used to prepare the body's immune system to fight off infections. They work by giving the body a small taste of what the virus is like so that way it can produce antibodies that fight off an intruding virus, ideally keeping people from falling ill. Some vaccines protect better than others, and they're typically administered across broad populations. There are vaccines for some infectious diseases, like the flu, smallpox, measles, and chickenpox. But others, like HIV and hepatitis C, don't have vaccines that protect against them. Vaccines that protect against two other deadly outbreaks, MERS and SARS, have yet to be approved after the outbreaks subsided. There are more than 70 potential coronavirus vaccines in the works, with a number in early human trials. Drugmakers are looking into ways to produce the billions of doses that might be needed to suppress the pandemic. Read more: There are more than 70 potential coronavirus vaccines in the works. Here are the top efforts to watch, including the 16 vaccines set to be tested in people this year. FILE - In this March 2020 photo provided by Gilead Sciences, a vial of the investigational drug remdesivir is visually inspected at a Gilead manufacturing site in the United States. Given through an IV, the medication is designed to interfere with an enzyme that reproduces viral genetic material. (Gilead Sciences via AP) FILE - In this March 2020 photo provided by Gilead Sciences, a vial of the investigational drug remdesivir is visually inspected at a Gilead manufacturing site in the United States. Given through an IV, the medication is designed to interfere with an enzyme that reproduces viral genetic material. (Gilead Sciences via AP) Associated Press Treatments, on the other hand, are meant to do just that: treat COVID-19, helping patients sickened by the virus survive and recover more quickly. Treatments for disease are there to lessen symptoms and ultimately improve the outcomes of a particular disease. Sometimes, medications can be used preventatively. For instance, patients with high cholesterol might be prescribed a medication called a statin to prevent heart attacks. Some potential coronavirus treatments are being studied to see if they can prevent people from contracting the virus in the first place. For COVID-19, researchers are testing everything from antimalarial medications to antivirals, to even common heartburn medications in hospitalized patients with the hopes that more patients will survive severe forms of the illness and potentially recover faster. Some are looking at ways to use patients' own bodies to fight the virus with antibody treatments.

#### Standards:

#### [1] Limits – they explode the topic to include tons of substances that prevent disease rather than treat them like soap, medical supplies, or food and make it so there is *no* unified neg generics. The aff still gets the core of the topic lit: they get medicine, innovation, and global inequality. Explosion of aff ground makes neg prep burden impossible, either killing neg ground or forcing the neg to read generics that barely link, always letting aff win. Force the 1AR to read a definition card with a clear list of what’s included and excluded – otherwise, vote neg since they can’t put a clear limit on the topic. Our interp solves – it establishes a clear bright-line for that gives the neg a chance to predict and prepare for every aff ahead of time. At best, the aff’s extra-T still links to all our offense since they can get extra-T advantages to solve disads and defend whatever they want, magnifying limits.

#### [2] Precision – not defending the text of the resolution justifies the affirmative doing away with random words in the resolution which a] means they’re not within the topic which is a voter for jurisdiction since you can only vote affirmative on the resolution and this debate never should have happened, b] they’re unpredictable and impossible to engage in so we always lose

#### Drop the Debater –

#### [1] sets a precedent that debaters wont be abusive

#### [2] DTA is the same since you drop the aff

#### Voters:

#### [1] Fairness – constitutive to the judge to decide the better debater, only fairness is in your jurisdiction because it skews decision making

#### [2] Education – the only portable education from debate that we care about

#### DTD:

#### [1] it drops the whole AC so dta is the same thing.

#### [2] deters future abuse since wins and losses determine the activity’s direction.

#### Competing Interps:

#### [1] reasonability on t is incoherent: you’re either topical or you’re not – it’s impossible to be 77% topical, links to all limits offense

#### [2] functionally the same as reasonability – we debate over a specified briteline which is a counter interp

#### [3] judge intervention – judge has to intervene on what’s reasonable, creates a race to the bottom where debaters exploit judge tolerance for questionable argumentation.

#### No RVIs

#### [1] illogical for you to get offense just for being fair – it’s the 1ac’s burden

#### [2] baiting - rvi’s incentivize debaters to read abusive positions to win off theory

#### [3] discourages checking abuse since debaters will be afraid to lose on theory

## 2

#### First, Practical Reason exists—

#### [A] An agent’s will acts on a law that it gives to itself. If pleasure were a law, then you would straightaway do the pleasurable act, but since you’re autonomous, you can reason about taking the action. Thus a condition of action is that the will is self-determined. Without practical reason, moral reason and action could not exist

#### Korsgaard

“Self-Constitution in the Ethics of Plato and Kant” by Christine M. Korsgaard

“Now I’m going to argue that that sort of willing is impossible. The first step is this: : **to conceive** of **yourself as the cause of your actions is to identify with** **the principle of choice on which you act.** A rational will is a self-conscious causality, and a self-conscious causality is aware of itself as a cause. To be aware of yourself as a cause is to identify yourself with something in the scenario that gives rise to the action, and this must be the principle of choice. For instance**, suppose you experience a conflict** of desire: you have a desire to do both A and B, and they are incompatible. You have **some principle** that **favors** **A over B,** so you exercise this principle, and **you choose** to do **A. In this** kind of **case**, you do not regard yourself as a mere passive spectator to the battle between A and B. **You regard the choice as yours**, as the product of your own activity, **because you regard the principle** of choice **as expressive**, or representative, **of yourself.** You must do so, for **the** only **alternative** to identifying with the principle of choice **is regarding the principle** of choice **as some third** **thing in you**, another force on a par with the incentives to do A and to do B, which happened to throw in its weight in favor of A, in a battle at which you were, after all, a mere passive spectator. **But then you are not the cause** **of the action.** Self-conscious or rational agency, then, requires identification with the principle of choice on which you act.” (123)

#### Second, a rational will must set ends with reciprocal constraints—

#### [A] Anything else justifies that someone could impede your ability to achieve your end in the first place and would restrict self-sufficiency, the root cause of action, which also means reason contains end-based framework.

**Engstrom**, Stephen [“Universal Legislation As the Form of Practical Knowledge. University of Pittsburgh, ND]

I’ll begin with the case of natural justice. **Since this obligation is founded on the practical knowledge of self-sufficiency as an end, and since self-sufficiency, according to its very idea, can never be augmented, but only restricted, by the actions of others, the maxim we have to consider is one prescribing action that restricts others’ self-sufficiency**. This restriction can be more precisely characterized, however, as the **limitation of what Kant calls outer freedom**. For as I’ll now try to explain, outer freedom is just what self-sufficiency requires, as a negative condition, in relation to others. Kant describes outer freedom as an “**independence from the necessitating power of choice of another**” (MS237). In other words, **outer freedom lies in the independence of one’s capacity to pursue one’s ends from hindrance to its exercise stemming from the power of choice of 19another.** That one’s capacity to pursue one’s ends can be subject to such hindrance from another is, of course, clear. Where diverse persons share a practical world, where in other words they are present together in the world in such a way that it’s possible for any one of them both to know what action another of them intends and also to act in ways that prevent or hinder that action (or, as we might also say, where mutual recognition and mutual influence are possible), **the outer freedom of one such person is limited to the extent that another chooses to prevent or to hinder the former’s action and succeeds in the attempt.** Where a person’s actions constitute such hindrances they can accordingly be described—to borrow a phrase from Kant—as “assaults on the freedom... of others” (G430).**19 Now since the material ends a person pursues in acting are all united in the fundamental end of happiness, generically conceived, outer freedom amounts to independence from hindrances by others to one’s pursuit of that basic end. Thus any assault on this freedom, to the extent that it’s successful, is a limitation of a person’s capacity to realize this end. And since this capacity is just what self-sufficiency consists in, this freedom is nothing other than the independence from other persons requisite for self-sufficiency, and it can therefore be regarded,** in a negative sense**, as self-sufficiency itself in relation to others.** Given the preceding considerations, it’s a straightforward matter to see how a maxim of action that assaults the freedom of others with a view to furthering one’s own ends results in a contradiction when we attempt to will it as a universal law in accordance with the foregoing account of the formula of universal law. **Such a maxim would lie in a practical judgment that deems it good on the whole to act to limit others’ outer freedom, and hence their self-sufficiency, their capacity to realize their ends, where doing so** augments, or **extends, one’s own outer freedom and so also one’s own self-sufficiency.** 20Now on the interpretation we’ve been entertaining, applying the formula of universal law involves considering whether it’s possible for every person—every subject capable of practical judgment—to share the practical judgment asserting the goodness of every person’s acting according to the maxim in question. **Thus in the present case the application of the formula involves considering whether it’s possible for every person to deem good every person’s acting to limit others’ freedom, where practicable, with a view to augmenting their own freedom. Since here all persons are on the one hand deeming good both the limitation of others’ freedom and the extension of their own freedom, while on the other hand, insofar as they agree with the similar judgments of others, also deeming good the limitation of their own freedom and the extension of others’ freedom, they are all deeming good both the extension and the limitation of both their own and others’ freedom. These judgments are inconsistent insofar as the extension of a person’s outer freedom is incompatible with the limitation of that same freedom**.

#### [B] If we are under that authority of reason, we act since we reason action is good. Actions can only be good because we have rationally chosen them. Respecting someone as a rational being means respecting their right to make decisions on their actions. That forbids infringing on other’s freedoms because it undermines value to action in the first place because every agent must be able to attribute value to an end. Anything else fails to attribute value to an action – making it impossible to determine moral action.

#### Thus, the standard is respecting a system of inner and outer freedom

#### Prefer:

#### Action Theory: Only reason can explain why we take transitional action to an overall end. For example, setting the end of tea provides me a reason to unify the necessary actions to produce tea, like getting a pot, filling it with water, etc. Any other explanation fails since it can’t give meaning to why we take transitioning action – freezing action. 2 Impacts—

#### That’s a side constraint on the AC—ethics is a guide to action so it must appeal to a structure of action.

#### Bindingness—reason is intrinsic to actions since only it can provide value to transitioning action, which justifies universality

#### Presume freedom since it allows each of us to pursue our individual search for ethics so the NC co-opts every reason your framework is good, but adds an additional side constraint. This also serves as a tiebreaker

### Offense

#### [1] Negates, reducing intellectual property violates rights to property

Riccardo Pozzo 06 [January 2006, "Immanuel Kant on intellectual property," https://www.researchgate.net/publication/250048266\_Immanuel\_Kant\_on\_intellectual\_property] // WW DL

**\*We do not endorse the author’s gendered language**

Corpus mysticum, opus mysticum, propriété incorporelle, proprietà letteraria, geistiges Eigentum. All these terms mean intellectual property, the existence of which is intuitively clear because of the unbreakable bond that ties the work to its creator. The book belongs to whomever has written it, the picture to whomever has painted it, the sculpture to whomever has sculpted it; and this independently from the number of exemplars of the book or of the work of art in their passages from owner to owner. The initial bond cannot change and it ensures the author authority on the work. Kant writes in section 31/II of the Metaphysics of Morals: “Why does unauthorized publishing, which strikes one even at first glance as unjust, still have an appearance of being rightful? Because on the one hand a book is a corporeal artifact (opus mechanicum) that can be reproduced (by someone in legitimate possession of a copy of it), so that there is a right to a thing with regard to it. On the other hand a book is also a mere discourse of the pub 1 Lecturer (Full Professor) of History of Philosophy at University of Verona. Article received on oct/ 06 and approuved for publication on dec/06. 12 Trans/Form/Ação, São Paulo, 29(2): 11-18, 2006 lisher to the public, which the publisher may not repeat publicly without having a mandate from the author to do so (praestatio operae), and this is a right against a person. The error consists in mistaking one of these rights for the other” (Kant, 1902, t.6, p.290). The corpus mysticum, the work considered as an immaterial good, remains property of the author on behalf of the original right of its creation. The corpus mechanicum consists of the exemplars of the book or of the work of art. It becomes the property of whoever has bought the material object in which the work has been reproduced or expressed. Seneca points out in De beneficiis (VII, 6) the difference between owning a thing and owning its use. He tells us that the bookseller Dorus had the habit of calling Cicero’s books his own, while there are people who claim books their own because they have written them and other people that do the same because they have bought them. Seneca concludes that the books can be correctly said to belong to both, for it is true they belong to both, but in a different way. The peculiarity of intellectual property consists thus first in being indeed a property, but property of an action; and second in being indeed inalienable, but also transferable in commission and license to a publisher. The bond the author has on his work confers him a moral right that is indeed a personal right. It is also a right to exploit economically his work in all possible ways, a right of economic use, which is a patrimonial right. Kant and Fichte argued that moral right and the right of economic use are strictly connected, and that the offense to one implies inevitably offense to the other. In eighteenth-century Germany, the free use came into discussion among the presuppositions of a democratic renewal of state and society. In his Supplement to the Consideration of Publishing and Its Rights, Reimarus asked writers “instead of writing for the aristocracy, to write for the tiers état of the reader’s world.” (Reimarus, 1791b, p.595). He saluted with enthusiasm the claim of disenfranchising from the monopoly of English publishers expressed in the American Act for the Encouragement of Learning of May 31, 1790. Kant, however, was firm in embracing intellectual property. Referring himself to Roman Law, he asked for its legislative formulation not only as patrimonial right, but also as a personal right. In Of the Illegitimity of Pirate Publishing, he considered the moral faculties related to intellectual property as an “inalienable right (ius personalissimum) always himself to speak through anyone else, the right, that is, that no one may deliver the same speech to the public other than in his (the author’s) name” (Kant, 1902, t.8, p.85). Fichte went farther in the Demonstration of the Illegitimity of Pirate Publishing. He saw intellectual property as a part of his metaphysical construction of intellectual activity, which was based on the principle that thoughts “are not transmitted hand to hand, they are not paid with shining cash, neither are they transmitted to us if we take home the book Trans/Form/Ação, São Paulo, 29(2): 11-18, 2006 13 that contains them and put it into our library. In order to make those thoughts our own an action is still missing: we must read the book, meditate – provided it is not completely trivial – on its content, consider it under different aspects and eventually accept it within our connections of ideas” (Fichte, 1964, t.I/1, p.411).

## 3

#### FDI is expected to recover but is tentative – uncertainties from pandemic and economic recovery

UNCTAD 7/21, 6-21-2021, [United Nations Conference on Trade and Development "Global foreign direct investment set to partially recover in 2021 but uncertainty remains," UNCTAD, https://unctad.org/news/global-foreign-direct-investment-set-partially-recover-2021-uncertainty-remains]//anop

Looking ahead, global FDI flows are expected to bottom out in 2021 and recover some lost ground with an increase of 10% to 15% (Figure 2). “This would still leave FDI some 25% below the 2019 level. Current forecasts show a further increase in 2022 which, at the upper bound of projections, bring FDI back to the 2019 level,” said UNCTAD’s director of investment and enterprise, James Zhan. Figure 2 - Foreign direct investment outflows, top 20 home economies, 2017 and 2018 (Billions of dollars) Figure 2 - Foreign direct investment outflows Source: UNCTAD, World Investment Report 2021. Prospects are highly uncertain and will depend on, among other factors, the pace of economic recovery and the possibility of pandemic relapses, the potential impact of recovery spending packages on FDI, and policy pressures. The relatively modest recovery in global FDI projected for 2021 reflects lingering uncertainty about access to vaccines, the emergence of virus mutations and the reopening of economic sectors. “Increased expenditures on both fixed assets and intangibles will not translate directly into a rapid FDI rebound, as confirmed by the sharp contrast between rosy forecasts for capex and still-depressed greenfield project announcements,” Mr. Zhan said. The FDI recovery will be uneven. Developed economies are expected to drive global growth in FDI, both because of strong cross-border mergers and acquisitions (M&A) activity and large-scale public investment support. FDI inflows to Asia will remain resilient as the region has stood out as an attractive destination for international investment throughout the pandemic. A substantial recovery of FDI to Africa and to Latin America and the Caribbean is unlikely in the near term.

#### The plan decreases foreign direct investment from negative signals – turns case

Kogan 11, Lawrence A [Lawrence A. Kogan is founder and Managing Attorney of The Kogan Law Group, P.C., a New York City–based multidisciplinary professional services firm specialized in identifying and addressing emerging regulatory, policy and trade risks posed to multinational company assets, operations and supply-chains. (2011), "Commercial High Technology Innovations Face Uncertain Future Amid Emerging “BRICS” Compulsory Licensing and IT Interoperability Frameworks" San Diego International, https://digital.sandiego.edu/cgi/viewcontent.cgi?article=1091&context=ilj]//anop

Similarly, the enactment of national laws and regulations promoting the availability and flexible use by governments of a compulsory licensing mechanism as an exception or limitation to the patent right to secure foreign companies’ patented high technologies at less than their fair market value can increase economic risks and result in acts of regulatory arbitrage and protectionist opportunism by home country as well as foreign companies operating pursuant to divergent business models. The security of property rights has been placed into question where compulsory licenses have been issued or threatened against foreign patented high technologies. Studies have shown that a corresponding reduction in the flow of knowledge-based foreign direct investment (FDI) will follow.81 82 [T]he practice of compulsory licensing comes with a price: the temporary or permanent deprivation of some part of a patent owner’s right to exclude disrupts the investment-backed expectation of the property right. In the future, pharmaceutical companies and other industries dependent upon intellectual property rights may mistrust licensing nations’ promises to protect and enforce patent rights, not to mention copyrights, and trademarks. As a result, industries that find the security of property rights lacking in a given nation may avoid engaging in foreign direct investment with that nation. Because foreign direct investment (FDI) is a major potential source of economic growth for recipient nations, the loss of such investment resources arising from compulsory licensing practices could force developing nations to pay a particularly heavy cost for providing needed medicines for its citizens.83 While government patent policy by itself is an incomplete measurement of a country’s market and investment friendliness, it is generally agreed that such legal protections reflect a country’s interest in fostering business and technology development. Through effective deterrence of imitation, “patents reduce the costs of enforcing contracts and at the same time increase the expected returns on FDI and licensing, which will have a positive effect on technology transfer. Patent rights encourage technology transfer by providing owners with legal certainty.”84 Consequently, the passage of IP laws that do not include a provision for compulsory licensing, for example, may favorably signal to foreign investors that a government is willing to allow strategic business decisions without undue interference and ensure more transparent and unbiased application of commercial laws with the prospect of reduced government corruption.85 “There is little doubt that developing countries who issue compulsory licenses also face additional risks in attracting global capital. Particularly, for MDC’s [middle developing countries], a compulsory license can trigger the loss of significant FDI.”86 If patent ownership rights indicate to prospective investors a firm’s proper regard for its intellectual property security, then surely a company’s willingness to engage in a foreign market where the government has decided to adopt or enforce anti-patent measures will convey negative signals to the investment community about the company, the quality of its management, and the strength and economic value of its patents and associated projected revenue streams. Just as the sale of a product through a low-status selling channel of a product can signal a diminution in brand status to the consumer, exposure of a patent to an uncertain legal environment can signal that the firm may not consider the patent to be as valuable as others believe. Even the threat of an ‘anti-patent’ such as a compulsory license can impair firm equity, thereby reducing the attractiveness of a country as an investment partner. Any firm calculating its returns from FDI will have to account for the possibility of these signaling-based losses.87

#### FDI is key to long term economic stability – it dictates future investments and industries

Susic et al 17 [I Susic1 , M Stojanovic-Trivanovic2 and M Susic3 1University of Business Studies, Jovan Ducic Street, No 23A, 78000 Banja Luka, Bosnia and Herzegovina 2 Independent University Banjaluka, Veljka Mladjenovica Street No 12E, 78000 Banja Luka, Bosnia and Herzegovina 3Enterprise Fructa Trade – Kort, Marije Bursac Street No 70, 74400 Derventa, Bosnia and Herzegovina 2017 IOP Conf. Ser.: Mater. Sci. Eng. 200 012019. https://iopscience.iop.org/article/10.1088/1757-899X/200/1/012019/pdf]//anop

Foreign direct investments (FDI) represent such a form of investment in which foreign investor keeps the ownership right, provides the control and the management of the firm in which they invested the funds, in order to achieve long-term interests. These investments are the most important instrument of foreign capital inflow because they represent a direct inflow from abroad, i.e. direct inflow of the capital in the economic system of the host country. Foreign direct investment, as a form of international capital mobility, represents an important contributor to more efficient activities in the economy. They provide faster exit to the international market and as the aftermath are ensuring improved the living standard of the society. Evaluation of investment efficiency is the basis for making investment decisions from one country to another, which will consequently lead to improvement of the economy. Foreign investments are a key development factor in the modern economy, and jointly with the trade, represent the most important leverage of an enterprise, organization of production, supplying goods and services on a global scale. FDI are supporting the companies in organizing production on a global scale, providing an efficient supply of raw materials, energy, labor as the input, and are facilitating the placement of products and services as the output in the most important markets in a profitable way. On the basis of such activities, the companies can on optimal way use its advantages in technology, expertise, and economies of scale. Developing countries having high state debt and unfavorable economic situation show huge interest in gaining as higher foreign investments as possible. It has been especially important after bank loans and various financial aid ceased to arrive in some countries. Countries in transition, aiming to integrate into the world economic system, can overcome negative economic tendencies with the help of international capital inflow. Developed countries, faced with a financial crisis, have been also interested in an increased inflow of foreign capital, since the foreign investments are the most important element of development strategies in general. With foreign direct investment is not coming just the capital from one country to another, but also the investment package containing new technologies, managerial skills and new markets. In addition, bearing higher risks, FDIs are significantly increasing the opportunities for making profits. Foreign direct investments are autonomous transactions of long-term capital movements, motivated by economic interests, with the profit at the first place.\

#### Continued recession causes war – stats support transition wars, resource conflicts, terrorism, and diversionary wars – other authors don’t base their analysis on global studies

Royal ’10 [Jedediah, Director of Cooperative Threat Reduction at the U.S. Department of Defense, “Economic Integration, Economic Signaling and the Problem of Economic Crises”, 2010, Economics of War and Peace: Economic, Legal and Political Perspectives, ed. Goldsmith and Brauer, p. 213-215]PM

Less intuitive is how periods of economic decline may increase the likelihood of external conflict. Political science literature has contributed a moderate degree of attention to the impact of economic decline and the security and defence behaviour of interdependent slates. Research in this vein has been considered at systemic, dyadic and national levels. Several notable contributions follow. First, on the systemic level. Pollins (2008) advances Modelski and Thompson's (19%) work on leadership cycle theory, finding that rhythms in the global economy are associated with the rise and fall of a pre-eminent power and the often-bloody transition from one pre-eminent leader to the next. As such, exogenous shocks such as economic crises could usher in a redistribution of relative power (sec also Gilpin. 1981) that leads to uncertainty about power balances, increasing the risk of miscalculation (Fearon, 1995). Alternatively, even a relatively certain redistribution of power could lead to a permissive environment for conflict as a rising power may seek to challenge a declining power (Werner, 1999). Separately. Pollins (1996) also shows that global economic cycles combined with parallel leadership cycles impact the likelihood of conflict among major, medium and small powers, although he suggests that the causes and connections between global economic conditions and security conditions remain unknown. Second, on a dyadic level. Copeland's (1996. 2000) theory of trade expectations suggests that 'future expectation of trade' is a significant variable in understanding economic conditions and security behaviour of states. He argues that interdependent states are likely to gain pacific benefits from trade so long as they have an optimistic view of future trade relations. However, if the expectations of future trade decline, particularly for difficult to replace items such as energy resources, likelihood for conflict increases. as states will be inclined to use force to gain access to those resources. Crises could potentially be the trigger for decreased trade expectations either on its own or because it triggers protectionist moves by interdependent states.4 Third, others have considered the link between economic decline and external armed conflict at a national level. Blomberg and Hess (2002) find a strong correlation between internal conflict and external conflict, particularly during periods of economic downturn. They write, The linkages between internal and external conflict and prosperity are strong and mutually reinforcing. Economic conflict tends to spawn internal conflict, which in turn returns the favour. Moreover, the presence of a recession lends to amplify the extent to which international and external conflicts self-reinforce each other. (Blomberg & I less. 2002. p. 89) Economic decline has also been linked with an increase in the likelihood of terrorism (Blomberg. Hess. & Wccrapana. 2004). which has the capacity to spill across borders and lead to external tensions. Furthermore, crises generally reduce the popularity of a sitting government. "Diversionary theory' suggests that, when facing unpopularity arising from economic decline, sitting governments have increased incentives to fabricate external military conflicts to create a 'rally around the flag' effect. Wang (1996), DcRoucn (1995), and Blomberg. Mess, and Thacker (2006) find supporting evidence showing that economic decline and use of force are at least indirectly correlated. Gelpi (1997), Miller (1999), and Kisangani and Pickering (2009) suggest that the tendency towards diversionary tactics are greater for democratic states than autocratic states, due to the fact that democratic leaders are generally more susceptible to being removed from office due to lack of domestic support. DcRoucn (2000) has provided evidence showing that periods of weak economic performance in the United States, and thus weak Presidential popularity, are statistically linked to an increase in the use of force. In summary, recent economic scholarship positively correlates economic integration with an increase in the frequency of economic crises, whereas political science scholarship links economic decline with external conflict at systemic, dyadic and national levels.5 This implied connection between integration, crises and armed conflict has not featured prominently in the economic-security debate and deserves more attention. This observation is not contradictory to other perspectives that link economic interdependence with a decrease in the likelihood of external conflict, such as those mentioned in the first paragraph of this chapter. Those studies tend to focus on dyadic interdependence instead of global interdependence and do not specifically consider the occurrence of and conditions created by economic crises. As such, the view presented here should be considered ancillary to those views.

## Case

### Fw

#### Top Level

#### [1] Infinite consequences—each action has a consequence which leads to another consequence—if I drop a pen, that could lead to a hurricane so there is no consequence that can be predicted

#### [2] Culpability—it stretches agents too much and makes us responsible for mistakes—util would say it is bad for me to give a peanut butter sandwich to a homeless guy if he dies bc he has a peanut allergy, even if I didn’t know that and was trying to help—also a side constraint on calc bc we don’t know the outcome and are afraid to act

#### LBL

#### Off Actor Spec

#### [1] Is-ought fallacy; just because states use util doesn’t mean they should

#### [2] Empirically denied – corruption and self-interest disprove, look at Trump

#### [3] Constitution and Germany’s government prove inherent rights are protected and are unalienable

#### Off no act omission distinction

#### [1] Inaction in the context of policymaking is not presenting a bill in the first place

#### [2] Reliant on them winning consequences matter – there’s no impact to omission absent that

#### Off lexical pre-req/extinction

#### [1] Fallacy of origin – just because we need to live to understand morality doesn’t eman it’s the focus of morality, i.e. oxygen is required to live but oxygen isn’t the start of our moral reasoning.

#### [2] Only the NC explains why life is good – the fact we can take action and choose things we like to have a pleasurable life

#### [3] Assumes you’re winning consequences are true which is the fw debate

### Adv

#### Companies will adapt –

#### [a] shell companies will market the same drug in different market just through different companies

#### [b] FDA rules still apply – secondary drugs will be created to bypass the restrictions, empirically proven with Allegra which was created originally a sinus treatment but shifted to other markets once it was discovered to treat for fevers

#### [c] they’ll just have trade secrecy and not disclose their practices which means it’s impossible to compete with BigPharma

#### [d] they’ll just dominate their market – pay for delay tactics to create lawsuits that delay market access or product hopping

#### They definitely don’t get to solve for warming – too many alt causes, oil, carbon, fracking. No quantifiable claim to how much biotech helps – be highly skeptical.

Can’t solve antibiotic

#### COVID accelerated biopharma R&D

Neil Lesser and Sonal Shah 20, Shah is senior manager with the Deloitte Center for Health Solutions within Deloitte Services LP and leads the center’s life sciences research, “Seeds of change,” https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/measuring-return-from-pharmaceutical-innovation.html

The COVID-19 pandemic has had a significant disruptive effect on clinical trial operations, with biopharma companies, clinical research organizations (CROs), and other research organizations being forced to shut down trials, suspend enrollment, or delay planned study startups or completions (an estimated 1,210 trials have been negatively affected across the industry). However, the pandemic has also accelerated the adoption of new approaches to R&D with the development of a number of novel COVID-19 vaccines and therapies in record time through extraordinary collaboration and partnerships, as well as a wider use of transformative approaches such as master protocols and adaptive trial design and the use of real-world data (RWD). The positive learnings arising from the COVID-19 pandemic have sown the seeds of change for a more productive future for biopharma R&D. Moreover, the accelerated development of COVID-19 therapies and vaccines is expected to have a positive impact on the internal rate of return (IRR) over the coming years.

#### Weakening patents is worse – eliminates funds for R&D and halts pharma innovations that prevents an effective development of a right to health.

Sarah Joseph 11, Professor of Human Rights Law, and the Director of the Castan Centre for Human Rights Law at Monash University, Sarah, “Blame it on the WTO?” http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780199565894.001.0001/acprof-9780199565894-chapter-8#acprof-9780199565894-note-1350

IP protection restricts trade and competition, so IP clauses are somewhat anomalous in trade agreements, which are normally designed to decrease trade barriers. What is the justification for IP protection?44 Due to their relevance to this chapter, I will concentrate on arguments in favour of patents.45 Patents reward people for their inventions, thus encouraging creativity and innovation. Patents operate on the assumption that people are not inherently altruistic, and expect rewards for their endeavours, especially when those endeavours are risky as they may, and often do, result in costly failure.46 Furthermore, the money raised from patent protection is said to be necessary to fund the considerable costs of research and development (R&D).47 Therefore, without patents, innovation in the pharmaceutical field (or any industrial field) might grind to a standstill. While it is true that the high prices generated by patent protection may render access to drugs selective, (p.221) it is nevertheless better that a drug is available to some rather than non-existent and available to no one. The global extension of patent law mandated by TRIPS helps to ensure that patents are not undermined by the sale of competing pirated copies. Furthermore, global IP regimes should theoretically encourage greater technology transfer between countries, greater foreign direct investment, and greater local innovation within compliant states.48 All of these outcomes should accelerate the economic development of poor countries, with positive knock-on effects for human rights. Thus, perhaps it is arguable that pharmaceutical patents are justifiable under international human rights law, as they promote R&D which is essential for the future enhancement of rights to life and health. Furthermore, to the extent that they are held by natural persons, they are one way of protecting that person’s rights under Article 15(1)(c) of the ICESCR.

#### TRIPS IP rights are key for innovation

James Bacchus 20, adjunct scholar at CATO, “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines,” December 16th, 2020, <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#does-novel-virus-present-novel-issues>

Technically, IP rights are exceptions to free trade. A long‐​standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion. The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long‐​term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”18 The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know‐​how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth in the 21st century is increasingly ideas‐​based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation. In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.19

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#### Natural pandemics won’t cause human extinction

Sebastian Farquhar 1/23/17, director at Oxford's Global Priorities Project, Owen Cotton-Barratt, a Lecturer in Mathematics at St Hugh’s College, Oxford, John Halstead, Stefan Schubert, Haydn Belfield, Andrew Snyder-Beattie, "Existential Risk Diplomacy and Governance", GLOBAL PRIORITIES PROJECT 2017, https://www.fhi.ox.ac.uk/wp-content/uploads/Existential-Risks-2017-01-23.pdf

1.1.3 Engineered pandemics For most of human history, natural pandemics have posed the greatest risk of mass global fatalities.37 However, there are some reasons to believe that natural pandemics are very unlikely to cause human extinction. Analysis of the International Union for Conservation of Nature (IUCN) red list database has shown that of the 833 recorded plant and animal species extinctions known to have occurred since 1500, less than 4% (31 species) were ascribed to infectious disease.38 None of the mammals and amphibians on this list were globally dispersed, and other factors aside from infectious disease also contributed to their extinction. It therefore seems that our own species, which is very numerous, globally dispersed, and capable of a rational response to problems, is very unlikely to be killed off by a natural pandemic. One underlying explanation for this is that highly lethal pathogens can kill their hosts before they have a chance to spread, so there is a selective pressure for pathogens not to be highly lethal. Therefore, pathogens are likely to co-evolve with their hosts rather than kill all possible hosts.39

#### Genetic variations and adaption solves – plus, no known disease has the potential to kill everyone

Amesh Adalja 16, infectious-disease physician at the University of Pittsburgh, 6/17/16, “Why Hasn't Disease Wiped out the Human Race?,” https://www.theatlantic.com/health/archive/2016/06/infectious-diseases-extinction/487514/

But when people ask me if I’m worried about infectious diseases, they’re often not asking about the threat to human lives; they’re asking about the threat to human life. With each outbreak of a headline-grabbing emerging infectious disease comes a fear of extinction itself. The fear envisions a large proportion of humans succumbing to infection, leaving no survivors or so few that the species can’t be sustained. I’m not afraid of this apocalyptic scenario, but I do understand the impulse. Worry about the end is a quintessentially human trait. Thankfully, so is our resilience. For most of mankind’s history, infectious diseases were the existential threat to humanity—and for good reason. They were quite successful at killing people: The 6th century’s Plague of Justinian knocked out an estimated 17 percent of the world’s population; the 14th century Black Death decimated a third of Europe; the 1918 influenza pandemic killed 5 percent of the world; malaria is estimated to have killed half of all humans who have ever lived. Any yet, of course, humanity continued to flourish. Our species’ recent explosion in lifespan is almost exclusively the result of the control of infectious diseases through sanitation, vaccination, and antimicrobial therapies. Only in the modern era, in which many infectious diseases have been tamed in the industrial world, do people have the luxury of death from cancer, heart disease, or stroke in the 8th decade of life. Childhoods are free from watching siblings and friends die from outbreaks of typhoid, scarlet fever, smallpox, measles, and the like. So what would it take for a disease to wipe out humanity now? In Michael Crichton’s The Andromeda Strain, the canonical book in the disease-outbreak genre, an alien microbe threatens the human race with extinction, and humanity’s best minds are marshaled to combat the enemy organism. Fortunately, outside of fiction, there’s no reason to expect alien pathogens to wage war on the human race any time soon, and my analysis suggests that any real-life domestic microbe reaching an extinction level of threat probably is just as unlikely. Any apocalyptic pathogen would need to possess a very special combination of two attributes. First, it would have to be so unfamiliar that no existing therapy or vaccine could be applied to it. Second, it would need to have a high and surreptitious transmissibility before symptoms occur. The first is essential because any microbe from a known class of pathogens would, by definition, have family members that could serve as models for containment and countermeasures. The second would allow the hypothetical disease to spread without being detected by even the most astute clinicians. The three infectious diseases most likely to be considered extinction-level threats in the world today—influenza, HIV, and Ebola—don’t meet these two requirements. Influenza, for instance, despite its well-established ability to kill on a large scale, its contagiousness, and its unrivaled ability to shift and drift away from our vaccines, is still what I would call a “known unknown.” While there are many mysteries about how new flu strains emerge, from at least the time of Hippocrates, humans have been attuned to its risk. And in the modern era, a full-fledged industry of influenza preparedness exists, with effective vaccine strategies and antiviral therapies. HIV, which has killed 39 million people over several decades, is similarly limited due to several factors. Most importantly, HIV’s dependency on blood and body fluid for transmission (similar to Ebola) requires intimate human-to-human contact, which limits contagion. Highly potent antiviral therapy allows most people to live normally with the disease, and a substantial group of the population has genetic mutations that render them impervious to infection in the first place. Lastly, simple prevention strategies such as needle exchange for injection drug users and barrier contraceptives—when available—can curtail transmission risk. Ebola, for many of the same reasons as HIV as well as several others, also falls short of the mark. This is especially due to the fact that it spreads almost exclusively through people with easily recognizable symptoms, plus the taming of its once unfathomable 90 percent mortality rate by simple supportive care. Beyond those three, every other known disease falls short of what seems required to wipe out humans—which is, of course, why we’re still here. And it’s not that diseases are ineffective. On the contrary, diseases’ failure to knock us out is a testament to just how resilient humans are. Part of our evolutionary heritage is our immune system, one of the most complex on the planet, even without the benefit of vaccines or the helping hand of antimicrobial drugs. This system, when viewed at a species level, can adapt to almost any enemy imaginable. Coupled to genetic variations amongst humans—which open up the possibility for a range of advantages, from imperviousness to infection to a tendency for mild symptoms—this adaptability ensures that almost any infectious disease onslaught will leave a large proportion of the population alive to rebuild, in contrast to the fictional Hollywood versions. While the immune system’s role can never be understated, an even more powerful protector is the faculty of consciousness. Humans are not the most prolific, quickly evolving, or strongest organisms on the planet, but as Aristotle identified, humans are the rational animals—and it is this fundamental distinguishing characteristic that allows humans to form abstractions, think in principles, and plan long-range. These capacities, in turn, allow humans to modify, alter, and improve themselves and their environments. Consciousness equips us, at an individual and a species level, to make nature safe for the species through such technological marvels as antibiotics, antivirals, vaccines, and sanitation. When humans began to focus their minds on the problems posed by infectious disease, human life ceased being nasty, brutish, and short. In many ways, human consciousness became infectious diseases’ worthiest adversary. None of this is meant to allay all fears of infectious diseases. To totally adopt a Panglossian viewpoint would be foolish—and dangerous. Humans do face countless threats from infectious diseases: witness Zika. And if not handled appropriately, severe calamity could, and will, ensue. The West African Ebola outbreak, for instance, festered for months before major efforts to bring it under control were initiated. When it comes to infectious diseases, I’m worried about the failure of institutions to understand the full impact of outbreaks. I’m worried about countries that don’t have the infrastructure or resources to combat these outbreaks when they come. But as long as we can keep adapting, I’m not worried about the future of the human race.