# 1AC Lay AFF

#### I affirm the resolution, the member nations of the World Trade Organization ought to reduce intellectual property protections.

#### I value morality

**The value criterion is Maximizing well being Prefer:**

#### The standard is maximizing expected well-being. Prefer:

#### 1] Only pleasure and pain are intrinsically valuable – all other frameworks collapse.

Moen 16 [Ole Martin Moen, Research Fellow in Philosophy at University of Oslo “An Argument for Hedonism” Journal of Value Inquiry (Springer), 50 (2) 2016: 267–281] TDI

Let us start by observing, empirically, that a **widely shared judgment about intrinsic value and disvalue is that pleasure is intrinsically valuable and pain is intrinsically disvaluable. On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues.** This inclusion makes intuitive sense, moreover, for **there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels, and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have.** “Pleasure” and “pain” are here understood inclusively, as encompassing anything hedonically positive and anything hedonically negative.2 **The special value statuses of pleasure and pain are manifested in how we treat these experiences in our everyday reasoning about values.** If you tell me that you are heading for the convenience store, **I might ask: “What for?” This is a reasonable question, for when you go to the convenience store you usually do so,** not merely for the sake of going to the convenience store, but for **the sake of achieving something further that you deem to be valuable.** You might answer, for example: “To buy soda.” This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: “What is buying the soda good for?” This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: “Well, I want it for the pleasure of drinking it.” **If I then proceed by asking “But what is the pleasure of drinking the soda good for?” the discussion is likely to reach an awkward end. The reason is that the pleasure is not good for anything further; it is simply that for which going to the convenience store and buying the soda is good.**3 As Aristotle observes**: “We never ask [a man] what his end is in being pleased, because we assume that pleasure is choice worthy in itself**.”4 Presumably, a similar story can be told in the case of pains, for if someone says “This is painful!” we never respond by asking: “And why is that a problem?” We take for granted that if something is painful, we have a sufficient explanation of why it is bad. If we are onto something in our everyday reasoning about values, it seems that **pleasure and pain are both places where we reach the end of the line in matters of value.**

#### 2] If everyone has equal value, the rational solution is to maximize the lives and pleasure of as many as possible. We are all fundamentally equal, meaning some must give way for the sake of others.

#### 3] Actor specificity: A] Governments must aggregate since every policy benefit some and harms others, which also means side constraints freeze action. B] States lack wills or intentions since policies are collective actions. C] Actor-specificity comes first since different agents have different ethical standings.

**4] Uncertainty- if we’re unsure about which interpretation of the world is true, we should preserve the world to keep debating about it, extinction first.**

#### Observation – the affirmative’s obligation is to prove that as a whole, intellectual property protections for medicines are immoral. Even if there’s one intellectual property that is good, so long as the affirmative proves that in general, IP are bad, that is sufficient to affirm. For example, if I say the statement that dogs make good pets indicating a husky is bad pet doesn’t disprove the more holistic statement that dogs make good pets. P

## Contention One: Covid Medicines

#### Rich countries are blocking a WTO patent-waiver proposal necessary to boost global production of COVID vaccines.

Meredith 21. [(Sam Meredith is a Correspondent at CNBC in London, covering international politics, energy and business news) “Rich countries are refusing to waive the rights on Covid vaccines as global cases hit record levels,” CNBC, April 22, 2021. <https://www.cnbc.com/2021/04/22/covid-rich-countries-are-refusing-to-waive-ip-rights-on-vaccines.html>] TDI

LONDON — The U.S., Canada and U.K. are among some of the high-income countries actively **blocking a patent-waiver proposal** designed to **boost the global production of Covid-19 vaccines.** It comes as coronavirus cases worldwide surge to their highest level so far and the World Health Organization has repeatedly admonished a “**shocking imbalance” in the distribution of vaccines amid the pandemic.** Members of the World Trade Organization will meet virtually in Geneva, Switzerland on Thursday to hold informal talks on whether to temporarily waive intellectual property and patent rights on Covid vaccines and treatments. The landmark proposal, which was jointly submitted by India and South Africa in October, has been backed by more than 100 mostly developing countries. It aims to facilitate the manufacture of treatments locally and boost the global vaccination campaign. Six months on, the proposal continues to be **stonewalled by a small number of governments** — including the U.S., EU, U.K., Switzerland, Japan, Norway, Canada, Australia and Brazil. “In this Covid-19 pandemic, we are once again **faced with issues of scarcity**, which can be addressed through diversification of manufacturing and supply capacity and ensuring the **temporary waiver of relevant intellectual property**,” Dr. Maria Guevara, international medical secretary at Medecins Sans Frontieres, said in a statement on Wednesday. “It is about saving lives at the end, not protecting systems.” The **urgency and importance of waiving certain intellectual property rights amid the pandemic have been underscored** by the WHO, health experts, civil society groups, trade unions, former world leaders, international medical charities, Nobel laureates and human rights organizations. Why does it matter? The waiver, if adopted at the General Council, the WTO’s highest-level decision-making body, could **help countries around the world overcome legal barriers** preventing them from producing their own Covid vaccines and treatments. Advocates of the proposal have conceded the waiver is not a “silver bullet,” but argue that **removing barriers** toward the development, production and approval of vaccines is **vital in the fight to prevent, treat and contain the coronavirus.**

#### The pandemic is raging through developing economies and inflicting loss on a horrific scale and prolongs economic hardships – timeframe is fast.

Lindsey 21. [(Brink Lindsey) “Why intellectual property and pandemics don’t mix,” Brookings Institution, June 3, 2021. <https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/>] TDI

\*\*cut part about economic hardships

Although focusing on these immediate constraints is vital, we cannot confine our attention to the short term. First of all, the **COVID-19 pandemic is far from over**. Although Americans can now see the light at the end of the tunnel thanks to the rapid rollout of vaccines, most of the world isn’t so lucky. The virus is **currently raging in India and throughout South America, overwhelming health care systems and inflicting suffering and loss on a horrific scale**. And consider the fact that Australia, which has been successful in suppressing the virus, recently announced it was sticking to plans to keep its borders closed until mid-2022. Criticisms of the TRIPS waiver that focus only on the next few months are **therefore short-sighted**: this pandemic could well **drag on long enough for elimination of patent restrictions to enable new vaccine producers to make a positive difference.**

#### Critics of the IP waiver are wrong- it’s the most effective way to combat covid inequality, alternatives fail

Erfani et al, 21

(Parsa Erfani, Fogarty global health scholar1 2, Agnes Binagwaho, vice chancellor2, Mohamed Juldeh Jalloh, vice president3, Muhammad Yunus, chair4, Paul Farmer, professor57, Vanessa Kerry, associate professor810 Harvard Medical School, Boston, USA 2University of Global Health Equity, Rwanda 3Sierra Leone 4Yunus Centre, Bangladesh 5Global Health and Social Medicine, Harvard Medical School, Boston, USA 6Division of Global Health Equity, Brigham and Women’s Hospital, USA 7Partners In Health, USA 8Seed Global Health, USA 9Program in Global Public Policy and Social Change, Harvard Medical School, Boston, USA 10Division of Pulmonary and Critical Care Medicine, Massachusetts General Hospital, USA Intellectual property waiver for covid-19 vaccines will advance global health equity BMJ 2021; 374 doi: https://doi.org/10.1136/bmj.n1837 (Published 03 August 2021) Cite this as: BMJ 2021;374:n1837 https://www.bmj.com/content/374/bmj.n1837.full) The barrier to adequate vaccine supply today is not lack of vaccine options, nor even theoretical production capacity; the problem is the intellectual property (IP) protection governing production and access to vaccines—and ultimately, the political and moral will to waive these protections in a time of global crisis. Without such liberty, there will not be enough vaccine fast enough to prevent the spread of variants, the avoidable deaths, and the continued choking of low and middle income countries (LMICs) through poor health. Beyond donor based models of global vaccine equity As covid-19 became a pandemic, global efforts emerged to help ensure vaccines would be delivered across the globe to the highest risk populations. One of the first was Covax, a risk sharing mechanism in which countries, tiered by means, contribute to collectively source and equitably distribute vaccines globally. The effort, however laudable in intent, has been undercut by vaccine scarcity and underfunding. Covax aims to vaccinate 20% of the population in 92 low and middle income countries by the end of 2021. At the end of April, however, it had shipped only one fifth of its projected estimates and lacked critical resources for distribution.3 LMICs are wary about participating in well worn dynamics of global health aid. Instead, they are mobilising to overcome the fundamental paucity of available vaccines by challenging established global IP rules. At issue is the 1995 Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which established minimum protection standards for IP—including patents, industrial designs, trade secrets, and copyright—that all 164 members of the World Trade Organization (WTO) must respect.5 Subsequent rulings (such as the Doha declaration) have strived to clarify safeguards on patents, including compulsory licensing, which allows governments to license patents to a third party without consent (table 1).6 Today, these rules provide strong IP protection for vaccine technologies and affect the quantity and location of vaccine production and availability. Table 1 Licensing of intellectual property View popupView inline In October 2020, South Africa and India submitted a proposal to the WTO to temporarily waive certain provisions of the TRIPS agreement for covid-19 health products and technologies. The waiver would prevent companies that hold the IP for covid-19 vaccines from blocking vaccine production elsewhere on the grounds of IP and allow countries to produce covid-19 medical goods locally and import or export them expeditiously (table 1). Although the proposed IP waiver is supported by over 100 countries, WTO has not reached a consensus on the proposal because of opposition and filibustering by several high income countries, including the UK, Germany, and Japan.7 Waiver opponents argue that the limited capacity of LMICs to produce complex covid-19 vaccines safely is the true barrier to global production, not IP. They suggest that the TRIPS waiver would penalise drug companies, stifle biomedical innovation, and deter future investments in research and development—in sum, that it would reduce returns on investment and dismantle an IP system that provided the goods needed to end the pandemic. Others are concerned that an IP waiver would fuel supply chain bottlenecks for raw materials and undermine ongoing production. Moreover, policy makers argue that a waiver is unnecessary as company driven voluntary licensing—in which companies decide when and how to license their technologies—and existing TRIPS flexibilities (such as country determined compulsory licensing) should suffice in establishing production in LMICs (table 1). They suggest that waiving IP for covid-19 vaccines would provide no meaningful progress, but the data do not support this. What effect would a waiver have? Contrary to detractors’ concerns about the possible effect of a temporary TRIPS waiver, global health analyses suggest that it will be vital to equitable and effective action against covid-19. LMIC’s manufacturing capabilities have been underestimated, even though several LMICs have the scientific and manufacturing capacity to produce complex covid-19 vaccines. India, Egypt, and Thailand are already manufacturing viral vector or mRNA-based covid-19 vaccines,8910 and vaccine production lines could be established within months in some other LMICs,11 offering substantial benefit in a pandemic that will last years.11 Companies in India and China have already developed complex pneumococcal and hepatitis B recombinant vaccines, challenging existing vaccine monopolies.12 The World Health Organization launched an mRNA technology transfer hub in April 2021 to provide the logistical, training, and know-how support needed for manufacturers in LMICs to repurpose or expand existing manufacturing capacity to produce covid-19 vaccines and to help navigate accessing IP rights for the technology.13 Twenty five respondents from LMICs expressed interest, and South Africa was selected as the first hub, with plans to start producing the vaccine through the Biovac Institute in the coming months.14 Removing IP barriers through the waiver will facilitate these efforts, more rapidly enable future hubs, engage a greater number of manufacturers, and ultimately yield more doses faster. Moreover, as the waiver facilitates vaccine production, demand for raw materials and active ingredients will increase. Coupled with pre-emptive planning to anticipate and expand raw material production, the waiver—which encompasses the IP of all covid-19 vaccine-related technology— can offer a path to overcome bottlenecks and expand production of necessary vaccine materials. Current licensing mechanisms inadequate Voluntary licences have not and will not keep pace with public health demand. Since companies determine the terms of voluntary licences, they are often granted to LMICs that can afford them, leaving out poorer regions.10 For example, in South Asia, AstraZeneca has voluntarily licensed its vaccine to the Serum Institute of India, even though the region has multiple capable vaccine manufacturers.9 Many covid-19 vaccine developers have not taken steps towards licensing their technologies, simply because there is limited financial incentive to do so.11 To date, none have shared IP protected vaccine information with the WHO Covid-19 Technology Access Pool (C-TAP) established last year.15 Relying on the moral compass of companies that answer to shareholders to voluntarily license their technologies will have limited effect on vaccine equity. Their market is driven by profit margins, not public health. Compulsory licensing by LMICs will also be insufficient in rapidly expanding vaccine production, as each patent licence must be negotiated separately by each country and for each product based on its own merit. From 1995 to 2016, 108 compulsory licences were attempted and only 53 were approved.6 The case-by-case approach is slow and not suitable for a global crisis that requires swift action. In addition, TRIPS requires compulsory licences to be used predominantly for domestic supply, limiting exports of the licensed goods to nearby low income countries without production capacity.5 Although a “special” compulsory licence system was agreed in the Doha declaration to allow for expeditious exportation and importation (formalised as the article 31bis amendment to TRIPS in 2017), the provision is limited by cumbersome logistical procedures and has been rarely used.16 Governments may also be hesitant to pursue compulsory licences as high income countries have previously bullied them for doing so. Since India first used compulsory licensing for sorafenib tosylate in 2012 (reducing the cancer drug’s price by 97%), the US has consistently pressured the country not to use further compulsory licences.17 During this pandemic, Gilead sued the Russian government for issuing a compulsory licence for remdesivir.18 Furthermore, while compulsory licences are primarily for patents, covid-19 vaccines often have other types of IP, including trade secrets, that are integral for production.19 The emergency TRIPS waiver removes all IP as a barrier to starting production (not just patents) and negates the prolonged time, inconsistency, frequent failure, and political pressure that accompany voluntary licensing and compulsory licensing efforts. It also provides an expeditious path for new suppliers to import and export vaccines to countries in need without bureaucratic limitations. Finally, there is no compelling evidence that the proposed TRIPS waiver would dismantle the IP system and its innovation incentives. The waiver is restricted to covid-19 related goods and is time limited, helping to protect future innovation. It would, however, reduce profit margins on current covid-19 vaccines. With substantial earnings in the first quarter of 2021, many drug companies have already recouped their research and development costs for covid-19 vaccines.20 However, they have not been the sole investors in vaccine development, and they should not be the only ones to profit. Most vaccines received a substantial portion of their direct funding from governments and not-for-profit organisations—and for some, such as Moderna and Novavax, nearly all.21 Decades of publicly funded research have laid the groundwork for current innovations in the background technologies used for vaccines.22 Given that companies were granted upfront risk protection for covid-19 vaccine research and development, a waiver that advances global public health but reduces vaccine profits in a global crisis is reasonable. Knowledge transfer An IP waiver for covid-19 vaccines is integral to boosting vaccine supply, breaking vaccine monopolies, and making vaccines more affordable in LMICs. It is, however, only a first, but necessary, step. Originator companies must transfer vaccine technology and share know-how with C-TAP, transfer hubs, or individual manufacturers to help suppliers begin production.23 In addition, governments must leverage domestic law, private sector incentives, and contract terms with pharmaceutical companies to compel companies to cooperate with such transfers.24 If necessary, governments can require technology transfers in exchange for continuing enterprise in a country or avoiding penalties. Politicians and leaders are at a critical juncture: they will either take the necessary steps to make vaccine technology available to scale production, stimulate global collaboration, and create a path to equity or they will protect a hierarchical system based on an economic bottom line. The former will not only build a vaccination trajectory that puts equal value on the lives of the rich and the poor, but will also help stem the pandemic’s relentless momentum and quell the emergence of variants. We are in the middle of one of the largest vaccination efforts in human history. We cannot rely on companies to thread the needle of corporate social and moral responsibility with shareholder and stock value returns nor expect impacted governments to endure lengthy bureaucratic licensing processes in this time of crisis. It will be a legacy of apathy and unnecessary death. As the human impact of the proposed IP waiver becomes clear, consensus behind it is growing. Countries that previously opposed the waiver—such as the US and Brazil—now support written text based negotiations.7 Opposing countries must stop blocking the waiver, engage in transparent text negotiations, and commit to reaching consensus swiftly. The longer states stall, the more people die needlessly. Covid-19 has repeatedly shown that people without access to resources such as strong health systems, health workers, medicines, and vaccines will preferentially fall ill and die. For too long, this cycle has been “other people’s” problem. It is not. It is our problem.

## Contention Two: Evergreening

#### Innovation is low & companies are repurposing drugs rather than actually innovating. We control uniqueness – Up to 80% of new patents are not for new drugs, but existing ones.

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/.)//Lex](http://www.arnoldventures.org/stories/evergreening-stunts-competition-costs-consumers-and-taxpayers/.)//Lex) AW [Accessed 9/21/2021]

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 sustain**ing **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. **Limit**ing 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."**

#### Reject Neg Turns – They’re lies sold by Big pharma, the plan is pro-innovation not anti-patents

Radhakrishnan 16 Radhakrishnan , Priti. “Secondary Patent: Pharma's Secret Weapon to Keep Drug Prices High.” STAT, 14 June

2016, 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.

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. ADVERTISEMENT 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. Related: Gilead pricing for Sovaldi hepatitis C drug slammed by senators 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. ADVERTISEMENT 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**. Related: Inside the $100 million ad blitz for a $1,100-a-pill drug for hepatitis C **We support patents — just not those that are unmerited and that unjustly prolong companies’ market power** and prevent legitimate competition. It’s time to reevaluate and modernize the current standards for awarding all patents, but especially secondary patents. In the 10 years since we founded I-MAK, we have won multiple cases challenging secondary and other unmerited patents. This has helped government health programs and patients around the world access cheaper medicines and live better. As a result of public-interest intervention, China, Ukraine, and Egypt have already knocked down secondary patents for Sovaldi. By ensuring that patents are fairly awarded, governments can ensure that medicines are affordable and available to those who need them. This is especially important in the US, which is the only OECD nation with no government regulations on drug pricing. **Our patent system should reward only true inventions in science and medicine.** In the face of public health epidemics and out-of-control drug pricing, we need a patent system that achieves a better balance between the interests of corporations and the public.

## Contention Three: Solves for Existential threats

#### Innovation is key to solving bioterror, infectious disease, and antimicrobial threats – the response to COVID-19 is the exception not the standard.

Marjanovic & 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.m> Sonja Marjanovic directs RAND Europe’s portfolio of research in the field of healthcare innovation, industry and policy. She got her Ph.D., Judge Business School, University of Cambridge. Her work provides decisionmakers with evidence and insights to support innovation and improvement in healthcare systems, and to support the translation of innovation into societal benefits for healthcare services and population health. Previously, Marjanovic led RAND Europe's institutional partnership with The Healthcare Improvement Studies Institute at Cambridge University. She is also a member of the Cambridge Centre for Health Services Research and is an expert advisor on innovation to the NHS England and NHS Improvement cancer program. Carolina Feijao is an analyst working in the areas of science and emerging technology at RAND Europe. Previously, she worked for Frontiers, an Open Access scientific publisher, where she led the launch of and managed three peer-reviewed journals: Sustainable Food Systems, Forests and Global Change and Sustainable Cities. She gained experience in policy making through a placement at DEFRA and she has been a research associate for GenPol, a Cambridge-based think tank focusing on gender equality issues. She also participated in the Management of Technology & Innovation Programme at Cambridge Judge Business School and carried out consulting projects ranging from market entry strategies for a plant breeding company to pitching a business proposal on innovative wound dressing products. Feijao has a Ph.D. in biochemistry from the University of Cambridge, focused on crop biomass breakdown technologies for the bioenergy and food industries. She also has a M.Sc. in quantitative biology from Imperial College London where she worked on statistical models to assess the sustainability and economic feasibility of reptile meat production. She completed a B.Sc. in cellular biology and biotechnology at the University of Lisbon.

This perspective argues for the **need to establish** more sustainable and scalable ways of incentivising **pharmaceutical 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 sector. 2 It is therefore unsurprising that **we are seeing industry-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 compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials 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 accelerate 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 relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure 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 partners to see if they can be repurposed; accelerating trials 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 accelerate 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 relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure 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 indeveloping 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 combination product that is being tested for therapeutic potential 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, bioterrorism 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 immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious 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 contributions 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 innovation 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 industry 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 antimicrobial 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-related 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 reimbursement 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.

#### Bioterror & Disease leads to extinction – Mathematically proves magnitude ought to be weighed over probability.

**Millett & Snyder-Beattie 17** Millett, Piers, and Andrew Snyder-Beattie. “Existential Risk and Cost-Effective Biosecurity.” *Health security* vol. 15,4 (2017): 373-383. doi:10.1089/hs.2017.0028. Andrew leads Open Philanthropy’s work on biosecurity and pandemic preparedness. He previously spent five years at the Future o Humanity Institute (University of Oxford), where he worked as a program manager and later as Director of Research, developing programs across the institute including those in biosecurity and systemic risk. Prior to that, he was a researcher at a personalized medicine startup. He holds a PhD/DPhil in Zoology from the University of Oxford and is an alumnus of the Johns Hopkins Emerging Leaders in Biosecurity Initiative. Piers Millett is a Senior Research Fellow at the Future of Humanity Institute, where he focuses on pandemic and deliberate disease and the implications of biotechnology. Piers consults for the World Health Organization on research and development for public health emergencies. He spent more than a decade working for the Biological Weapons Convention, the international treaty that bans these weapons. He has collaborated with a wide range of international organizations dealing with human and animal health, humanitarian emergencies and International Humanitarian Law, law enforcement, international security. Piers holds advanced degrees in science policy, research methodology and international security. He has authored a wide range of policy, technical and peer reviewed documents across the full scope of health security and is a regular speaker at conferences, workshops and seminars around the world.

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 of state-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 **destroy**ing 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.** […] Human extinction would not only end the 7 billion lives in our current generation, but also cause the loss of all future generations to come. To calculate the humanitarian cost associated with such a catastrophe, one must therefore include the welfare of these future generations. While some have argued that future generations ought to be excluded or discounted when considering ethical actions,50 most of the in-depth philosophical work around the topic has concluded that future generations should not be given less inherent value.51-55 Therefore, for our calculations, we include future lives in our cost-effectiveness estimate.\*\*\*\* The large number of future generations at stake mean **that reducing existential risk even by a small amount may have very large expected value.** The Earth is thought to be habitable for roughly another billion years;56 our closest relative, homo erectus, lasted over 1.6 million years,57 and the typical mammalian species also lasts on the order of 1 to 2 million years.58 Following Matheny,29 if we were to assume that humanity would otherwise maintain a global population of 10 billion for the next 1.6 million years, human extinction would jeopardize on the order of 1.6 × 1016 life years. Including future generations into **our cost-effectiveness calculations demonstrates that reducing existential risks, even if they are improbable, can be incredibly cost-effective in expectation** (Table 2). Depending on the model used, we estimate that we can purchase 1 quality adjusted life-year in expectation for 10s of dollars (with outliers suggested around 12 cents to $1,600). Even with the most conservative estimates of existential risk, reducing the risk of human extinction is at least 100 times more cost-effective than standard biosecurity interventions, and possibly up to 1 million times more cost-effective.