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### Top Level

#### Dr. Benjamin Mitra-Khan one a world renowned economist at the Australian patent office stated – “When it comes to intellectual property rights, not everything that glitters is gold.”

<https://www.quotemaster.org/intellectual+property+rights>

#### Thus I affirm the resolution Resolved – Member nations of the world trade organization ought to reduce intellectual property protections for medicines.

https://www.azquotes.com/picture-quotes/quote-there-are-a-lot-of-weapons-that-we-ve-developed-which-we-ve-pulled-back-from-biological-peter-singer-129-56-05.jpg

### Fwrk

#### My value is morality as per the word ought in the resolution

#### My value criterion is maximizing expected wellbeing

#### 1] 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.

#### 2] 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.

**3] 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 dog that is bad pet doesn’t disprove the more holistic statement that dogs make good pets.

### Contention 1 – Vaccine Inequality

#### The status quo ensures vaccine imperialism. Intellectual property law is the lynchpin of North-South health inequality and has empirically resulted in disparate life outcomes.

Vanni 21 – Dr. Amaka Vanni is Lecturer in Law at the University of Leeds. ("On Intellectual Property Rights, Access to Medicines and Vaccine Imperialism," 3-23-2021, <https://twailr.com/on-intellectual-property-rights-access-to-medicines-and-vaccine-imperialism/>) julian

While the response to COVID-19 has shown what can be accomplished when the world works together, it has also underscored three interrelated points. First, the neoliberal framework – including the critical role intellectual property (IP) law plays in constituting this form of civilisation – is an unsuitable model for delivering the goods needed to respond to global health emergencies. The current economic/market system does not allow for equitable responses to infectious diseases, particularly access to sufficient medical and health resources. This inequity was obvious in the early days of the pandemic when test kits, PPEs, and ventilation machines were being distributed on the basis of who could pay the most rather than who needed them the most. Second, the beggar-thy-neighbor response currently adopted by developed countries hurts everyone because failing to stop the spread of the virus globally allows more mutations, which makes existing vaccines less effective. As COVID-19 has shown, no one is safe until everyone is safe. Yet, despite this warning, the hoarding of vaccines by developed countries continues unabated and speaks to the wider racist capitalist system we live in. If anything, this crude accumulation of vaccines reinforces North-South economic and political dominance and marks, as Onur Ince observes, the conceptual locus of political violence operative in the global genealogy of capitalism. Third, while COVID-19 may endanger us all, it is far more costly to some than others. Numerous reports have shown how black and brown people are most impacted by the pandemic. In the United States, for example, indigenous Americans have the highest COVID-19 mortality rates nationwide while African American communities have COVID-19 mortality that is 2.3 times higher than the rate for Asians and Latinxs, and 2.6 times higher than the rate for Whites. Similar data is also emerging in the UK where people from black and minority ethnic groups are at greater risk of dying from coronavirus. This means those groups suffer higher loss of life compared to other racial groups due to inequities in healthcare access as well as higher rate of pre-existing conditions. In other parts of the world, the most vulnerable and the economically marginalized such as those working in the informal sector and living in shanty towns are feeling the effects of the pandemic the most. In Latin America and the Caribbean, 70 per cent of domestic workers have been affected by the pandemic where most have stopped receiving income. In Ghana, residents of slums at Old Fadama – a suburb in Accra – were made homeless when the government demolished their homes. The ensuing homelessness means there is little to no space of observing social distancing rules, access to running water and access to other resources to practice basic hygiene. Meanwhile in India, the pandemic has unsurprisingly hit the country along caste lines where the Dalits are most impacted because many are poor and have limited access to healthcare. As Kimberlé Williams Crenshaw reminds us, the high number of minority deaths is not new. Rather, this crisis simply amplified racism and other forms of structural inequality as a pre-existing condition – an intersectional issue – where those disproportionately hurt are those who are already structurally marginalized. Thus, while recognising a broken global IP regime that triggered the scramble for vaccines, the racialized impact of the pandemic cannot be ignored, and it points to the entangled roots of race and capitalism. The rest of this analysis takes a close look at some of the legal, political and economic forces that have animated IP rights and access to COVID-19 vaccine. It will focus on how the entanglement of corporate capture of global IP regime, state complicity and vaccine imperialism have come together to shape public health responses to the pandemic. It underscores how the law, in this case international IP law, consistently shelters capital and operates as an expression to further corporate pharmaceutical interests. If there is a lesson to be gleaned from this pandemic, it is that intellectual property is not failing us but is functioning the way it is set up to do. As the history of IP globalization has shown, the World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) is a transplant of the Euro-American model of property, driven by multinational corporations who used their respective national governments to underwrite and export their domestic IP claims. Therefore, it is unsurprising that this international legal regime employed to advance the interests of particular classes, nations and regions at the expense of others continues to reproduce extreme inequality with human costs.

#### This means COVID and future pandemics will reproduce untenable working conditions and racialized and classed life outcomes.

Sell 20 – Susan K. Sell is a Professor of Political Science and International Affairs at George Washington University. (“What COVID‑19 Reveals About Twenty‑First Century Capitalism: Adversity and Opportunity,” pg. 152-153) julian

The COVID-19 pandemic has revealed the lethal consequences of the sharp rise in economic inequality, the concentration of wealth in fewer and fewer hands and the increasing precarity of labour. For example, as COVID-19 slammed Manhattan, members of the top 1% flocked to their beach retreats in the Hamptons to ride out the contagion (Sellinger 2020). Meanwhile, ‘essential workers’ at the bottom of the contemporary economic hierarchy had no options but to continue to show up for work and face exposure to the deadly virus. First responders, bus drivers, nursing home workers, janitors, postal workers, grocery stockers, agricultural workers, Wal-Mart employees, Amazon warehouse workers, delivery drivers, and meat packers—many earning minimum wage and most without employer-subsidized health insurance or other benefits—had to keep working. As Bertha Bradley, a food service worker in North Carolina stated, ‘I don’t get health benefits, I don’t get sick time, I don’t get paid vacations, I don’t get a living wage’ (Jaffe and Chen 2020: 126). Katie Pine and Kate Henne refer to them as ‘new risk workers’, many of whom are given mandates for minimizing risk but few resources to implement them (Pine and Henne 2020). For example, in the John H. Stroger Hospital in Chicago, nurses were being told to reuse N95 masks, ‘sometimes up to forty-five days’ (Jaffe and Chen 2020: 138). By contrast, knowledge workers could work from the safety of their own homes and reduce their risks of becoming infected. COVID-19 has disproportionately attacked communities of colour, compounding economic inequality and systemic racism. It is clear that ‘race matters for the way that markets have been built historically and function today’ (McNamara and Newman 2020: 6). As Presidential candidate Joe Biden pointed out during the presidential debate in September 2020, 1 out of every one-thousand African Americans in the US has died from COVID-19. In Chicago about 70% of the COVID deaths were African Americans (Jaffe and Chen 2020: 140). The UN Secretary-General António Guterres pointed out that COVID-19 ‘is exposing fallacies and falsehoods everywhere … the delusion that we live in a post-racist world, the myth that we are all in the same boat’ (Guterres 2020). In September, Citigroup released a report that systemic racism, discrimination against African Americans, has cost the economy $16 trillion (Akala 2020). Many of the precariat are people of colour, recent immigrants and undocumented workers. By May 2020 slaughterhouses around the world became virus hot spots and exposed multiple layers of dysfunction. The meat processing industry is highly consolidated, dominated by global multinational corporations including Cargill, JBS, Smithfield and Tyson. Since the 1980s this industry has pursued the financialized model of consolidation and vertical integration, ‘aimed at increasing profits through efficiency and low wages’ (van der Zee et al. 2020). Many migrant workers in these plants live in communal housing; crowded working conditions, large plants and cramped housing, and lack of paid sick leave all exacerbate the spread of coronavirus in these environments. Indeed, Tyson was even offering workers $500 bonuses to keep working in the midst of plant outbreaks (van der Zee et al. 2020). Workers are shouldering all of the risk as slaughterhouse companies get the rewards. Structures of the global economy, including financialization and monopoly capitalism have amplified the dangers of the pandemic and pushed people further ‘into unequal groups that are not only divided by money but by matters of life and death’ (McNamara and Newman 2020: 11; Sell and Williams 2019).

#### 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.**

#### The plan reverse casually ensures the reduction of vaccine imperialism.

Vanni 21 – Dr. Amaka Vanni is Lecturer in Law at the University of Leeds. ("On Intellectual Property Rights, Access to Medicines and Vaccine Imperialism," 3-23-2021, <https://twailr.com/on-intellectual-property-rights-access-to-medicines-and-vaccine-imperialism/>) julian

Despite calls to make COVID-19 vaccines and related technologies a global public good, western pharmaceutical companies have declined to loosen or temporarily suspend IP protections and transfer technology to generic manufacturers. Such transfer would enable the scale-up of production and supply of lifesaving COVID-19 medical tools across the world. Furthermore, these countries are also blocking the TRIPS waiver proposal put forward by South Africa and India at the WTO despite being supported by 57 mostly developing countries. The waiver proposal seeks to temporarily postpone certain provisions of the TRIPS Agreement for treating, containing and preventing the coronavirus, but only until widespread vaccination and immunity are achieved. This means that countries will not be required to provide any form of IP protection on all COVID-19 related therapeutics, diagnostics and other technologies for the duration of the pandemic. It is important to reiterate the waiver proposal is time-limited and is different from TRIPS flexibilities, which are safeguards within the Agreement to mitigate the negative impact of patents such as high price of patented medicines. These safeguards include compulsory licenses and parallel importation. However, because of the onerous process of initiating these flexibilities as well as the threat of possible trade penalties by the US through the United States Trade Representative (USTR) “Special 301” Report targeting countries even in the absence of illegality, many developing countries are reluctant to invoke TRIPS flexibilities for public health purposes. For example, in the past, countries such as Colombia, India, Thailand and recently Malaysia have all featured in the Special 301 Report for using compulsory licenses to increase access to cancer medications. It is these challenges that the TRIPS waiver seeks to alleviate and, if approved, would also provide countries the space, without fear of retaliation from developed countries, to collaborate with competent developers in the R&D, manufacturing, scaling-up, and supply of COVID-19 tools. However, because this waiver is being opposed by a group of developed countries, we are grappling with the problem of artificially-created vaccine scarcity. The effect of this scarcity will further prolong and deepen the financial impact of this pandemic currently estimated to cost USD 9.2 trillion, half of which will be borne by advanced economies. Thus, in opposing the TRIPS waiver with the hopes of reaping huge financial rewards, developed countries are worsening pandemic woes in the long term. Another kind of scarcity caused by vaccine nationalism has also reduced equitable access. Vaccine nationalism is a phenomenon where rich countries buy up global supply of vaccines through advance purchase agreements (APA) with pharmaceutical companies for their own populations at the expense of other countries. But perhaps it is time to reorient our sight and call the ongoing practices of buying up global supply of vaccine what it truly is – vaccine imperialism. If we take seriously the argument put forward by Antony Anghie on the colonial origins of international law, particularly how these origins create a set of structures that continually repeat themselves at various stages, we will begin to see COVID-19 vaccine accumulation not only as political, but also as imperial continuities manifesting in the present. Take, for instance, the report released by the Duke Global Health Innovation Center that shows that high-income countries have already purchased nearly 3.8 billion COVID-19 vaccine doses. Specifically, the United States has secured 400 million doses of the Pfizer-BioNTech and Moderna vaccines, and has APAs for more than 1 billion doses from four other companies yet to secure US regulatory approval. The European Union has similarly negotiated nearly 2.3 billion doses under contract and is negotiating for about 300 million more. With these purchases, these countries will be able to vaccinate their populations twice over, while many developing states, especially in Africa, are left behind. In hoarding vaccines whilst protecting the IP interests of their pharmaceutical multinational corporations, the afterlife of imperialism is playing out in this pandemic. Moreover, these bilateral deals are hampering initiatives such as the COVID-19 Vaccine Global Access Facility (COVAX) – a pooled procurement mechanism for COVID-19 vaccine – aimed at equitable and science-led global vaccine distribution. By engaging in bilateral deals, wealthy countries impede the possibility of effective mass-inoculation campaigns. While the usefulness of the COVAX initiative cannot be denied, it is not enough. It will cover only the most vulnerable 20 per cent of a country’s population, it is severely underfunded and there are lingering questions regarding the contractual obligations of pharmaceutical companies involved in the initiative. For instance, it is not clear whether the COVAX contract includes IP-related clauses such as sharing of technological know-how. Still, even with all its faults, without a global ramping-up of production, distribution and vaccination campaigns via COVAX, the world will not be able to combat the COVID-19 pandemic and its growing variants. Health inequity and inequalities in vaccine access are not unfortunate outcomes of the global IP regime; they are part of its central architecture. The system is functioning exactly as it is set up to do. These events – the corporate capture of the global pharmaceutical IP regime, state complicity and vaccine imperialism – are not new. Recall Article 7 of TRIPS, which states that the objective of the Agreement is the ‘protection and enforcement of intellectual property rights [to] contribute to the promotion of technological innovation and to the transfer and dissemination of technology’. In similar vein, Article 66(2) of TRIPS further calls on developed countries to ‘provide incentives to enterprises and institutions within their territories to promote and encourage technology transfer to least-developed country’. While the language of ‘transfer of technology’ might seem beneficial or benign, in actuality it is not. As I discussed in my book, and as Carmen Gonzalez has also shown, when development objectives are incorporated into international legal instruments and institutions, they become embedded in structures that may constrain their transformative potential and reproduce North-South power imbalances. This is because these development objectives are circumscribed by capitalist imperialist structures, adapted to justify colonial practices and mobilized through racial differences. These structures are the essence of international law and its institutions even in the twenty-first century. They continue to animate broader socio-economic engagement with the global economy even in the present as well as in the legal and regulatory codes that support them. Thus, it is not surprising that even in current global health crisis, calls for this same transfer of technology in the form of a TRIPS waiver to scale up global vaccine production is being thwarted by the hegemony of developed states inevitably influenced by their respective pharmaceutical companies. The ‘emancipatory potential’ of TRIPS cannot be achieved if it was not created to be emancipatory in the first place. It also makes obvious the ways international IP law is not only unsuited to promote structural reform to enable the self-sufficiency and self-determination of the countries in the global south, but also produces asymmetries that perpetuate inequalities.

### Contention 2 – Insulin

#### US insulin prices are skyrocketing – lifesaving drugs for patients with diabetes are becoming more unaffordable.

Rajkumar 20 [S. Vincent Rajkumar, “The High Cost of Insulin in the United States: An Urgent Call to Action,” Mayo Clinic Proceedings, vol. 95, no. 1, Jan. 2020, pp. 22-28. Rajkumar, MD, is Consultant at the Division of Hematology, Department of Internal Medicine at the Mayo Clinic.] [CHSTM](file://CHSTM) recut //Lex VM

The most commonly used forms of analog insulin cost 10 times more in the United States than in any other developed country.3 There have been many other recent reports of deaths in patients with type 1 diabetes because of lack of affordable insulin.4,5 The high prevalence of diabetes, the chronic lifelong nature of the disease, and the fact that patients with type 1 diabetes will die without access to insulin make this an urgent problem that must be solved expeditiously. The price of insulin is also a stark and troubling example of the rising cost of prescription drugs in the United States and highlights a systemic problem with how drugs are priced compared with every other commodity.6,7 This commentary will address the reasons for the high cost of insulin and examine possible solutions. By understanding and solving this problem, we can create a roadmap that brings much needed reform and fairness to the existing system and helps make all prescription drugs more affordable.

The 3 main reasons cited by pharmaceutical companies for the high cost of new prescription drugs do not apply to insulin. First, the “high cost of development” is not relevant for a drug that is more than 100 years old; even the latest and most commonly used analog insulin products are all over 20 years old.8 Second, the pricing is not the product of a free market economy. Free market forces are clearly not operational; there is limited competition on price, the person who needs the product is not in a position to negotiate the price, and there is no relationship of price increases over time compared with overall market inflation. The price of insulin has risen inexplicably over the past 20 years at a rate far higher than the rate of inflation.9 One vial of Humalog (insulin lispro), which used to cost $21 in 1999, costs $332 in 2019, reflecting a price increase of more than 1000%.10-12 In contrast, insulin prices in other developed countries, including neighboring Canada, have stayed the same. Insulin pricing in the United States is the consequence of the exact opposite of a free market: extended monopoly on a lifesaving product in which prices can be increased at will, taking advantage of regulatory and legal restrictions on market entry and importation. Third, the arguments that high costs are needed for continued innovation and that attempts to lower or regulate the prices will hamper innovation are not a valid excuse.13 There is limited innovation when it comes to insulin; the more pressing need is affordability.

#### As a consequence there has been a surge in diabetes related deaths.

Terhune et al 8/12 [Chad Terhune, Robin Respaut, Deborah J. Nelson, "Special Report-How the pandemic laid bare America's diabetes crisis", U.S., 8-12-2021, https://www.reuters.com/article/us-usa-diabetes-covid-specialreport/special-report-how-the-pandemic-laid-bare-americas-diabetes-crisis-idUSKBN2FD13Q, accessed: 9-9-2021.] //Lex VM

The failure to effectively treat diabetes carries enormous consequences for patients, their families and society at large. Roughly 34 million people, or about 1 in 10 Americans, have diabetes. Treating them costs more than $230 billion a year – more than the U.S. Navy’s annual budget – much of that borne by taxpayers through government-sponsored Medicare insurance for the elderly and Medicaid for the poor. About 1.6 million people have type 1 diabetes, an autoimmune disease of unknown cause that requires lifelong insulin injections when the pancreas stops producing the hormone. Without insulin, cells are unable to absorb glucose, their primary source of energy, and the sugar builds up in the blood. But the vast majority of patients, accounting for most of the increase in new cases in recent years, have type 2 diabetes, a chronic condition linked to genetics, weight gain and inactivity. These patients’ bodies don’t make enough insulin or don’t use it well. Diet and exercise can help manage the disease, but many also need medication that helps them use the insulin their bodies produce. Many eventually require insulin injections. For all diabetes patients, life revolves around checking their numbers. That means testing their current blood glucose levels several times a day. And it means visiting a lab every few months to test their hemoglobin A1c, a measure of their glucose levels over the preceding three months. The higher the number, the worse it can be for a patient. Uncontrolled diabetes wreaks havoc on the body. Acute hyperglycemia can lead to coma or even death. Over time, the disease degrades blood vessels and damages major organs, leaving patients prone to heart disease, stroke, kidney failure, amputations and blindness. While the coronavirus battered diabetes patients around the world, the longer-term reversal of fortunes is a particularly American problem. The U.S. mortality rate for diabetes was 42% higher than the average among 10 other industrialized countries in 2017, according to the Organization for Economic Cooperation and Development. In the British medical journal Lancet, researchers in 2018 gave the United States a score of 62 out of 100 on the quality of diabetes care. Most Western European countries scored in the 90s. The United States trailed Libya, Iran and Vietnam. “Other countries have more of a safety net to get people through hard times,” said Steven Woolf, a professor at the Virginia Commonwealth University School of Medicine who studies death rates from diabetes and other causes. “People here are more vulnerable to the economic shocks of job losses, the last recession and now the pandemic.” Reversing the gloomy outlook for diabetes patients isn’t easy. Advances in medication and technology to help patients better manage their condition often fail to reach those whose access to care is hampered by their race, income or type of insurance, according to experts in diabetes and public health. And reducing those disparities, they said, would have to come with major investments in primary care and a coordinated effort to curb obesity and inactivity. “The current approach has failed,” said Dr David Kerr, director of research and innovation at the Sansum Diabetes Research Institute in Santa Barbara, California. “And just creating more expensive pharmaceuticals is not going to cut it at a population level.”

#### Generic competition arises as a patent expires – evergreening and stacked patents on Insulin delays it which drastically raises prices.

Christensen 20 [Connor Christensen, "The Evergreen Forests of Insulin Patents", Awakenwfu, The Creative Journal of Contemporary Bioethics, 9-14-2020, https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/, accessed: 9-7-2021.] //CHSTM and Lex VM

The prices of insulin have risen to unconscionable levels in just a little over two decades. What used to be a relatively minor expense for Americans with diabetes has, for some, become an insurmountable obstacle to living a normal life, or, in some cases living at all. The purpose of this brief commentary is to address just one of the many issues attributed to the stark increase in insulin prices: patent evergreening. People with Type I and Type II diabetes constantly depend on insulin injections to supplement their insufficient natural production of the blood-sugar regulating hormone in their pancreas.[1] Without this hormone, a diabetic person’s life expectancy is short and riddled with many serious health complications.[2] For many decades insulin was readily accessible and affordable for those who needed it. Recently, however, things have changed. In 1996, the list price of a single vial of insulin manufactured by Eli Lilly, a pharmaceutical firm, was only $25.[3] Since then, the formula for the same bottle of insulin hasn’t changed, but the list price has gone up to around $275 per vial.[4] This price increase alone is shocking, but it becomes even more unthinkable when you consider the fact that the average diabetic person uses between one and three vials per month.[5] Presently, a diabetic person without insurance requiring three vials per month could expect to pay at a minimum of $825 a month for just insulin alone.[6] Some people have even reported paying as much as $2880 for a month’s supply of insulin.[7] The exact reason for this stark increase in price is not uniformly agreed upon. Still, it’s speculated that it is a result of multiple “opaque” transactions among wholesalers, pharmacies, and manufacturers.[8] With figures this high, it is unsurprising that 27% of diabetics report that affording insulin has impacted their daily life.[9] The financially vulnerable are particularly put at risk by these exorbitant list prices. Being economically vulnerable and diabetic requires people to make sacrifices in other parts of their lives to keep affording insulin.[10] These sacrifices include staying at undesirable jobs, maintaining unhealthy relationships, foregoing higher education, selling valuables, and rationing food.[11] However, sometimes, even these sacrifices aren’t enough. In 2017, after aging out of his mother’s health insurance and despite making above minimum wage, Alec Smith, a 26-year-old diabetic man, died because he wasn’t able to afford enough insulin to live.[12] Tragic losses of life, like Alec’s, are entirely preventable, and there are a number of potential solutions that can fix or at least ameliorate the situation. Finding methods to prevent “patent evergreening ” is one of the possible solutions to the insulin crisis.[13] Evergreening occurs when brand-name companies patent “new inventions” that, in actuality, are simply old drugs with slight modifications.[14] Evergreening a patent can be done in various ways such as by “stacking patents,” (covering one drug with multiple patents) or by making small improvements to the drug and then pulling the old drug from the market.[15] Insulin, like many other drugs, has fallen prey to such evergreening.[16] Traditionally, patent monopolies on drugs eventually give way to generic competition after the patent expires. Upon expiration of the original patent other entities are allowed to produce the drug.[17] Evergreening, however, delays this process. The generic competition of once patented drugs is critical for consumers, consistently reducing the price of the drug by over 50%.[18] However, the unique development of insulin has allowed its formula and delivery to be continually improved upon since its discovery and first isolation.[19] Evergreening can essentially re-patent a drug, thus substantially extending the life of the monopoly granted to drug companies for their product.[20] As a consequence, by “evergreening” a patent, drug companies can effectively prevent biosimilar, or generic versions of that drug from being sold for far longer than the twenty years of a standard patent. Although there may be no protections remaining on the original formula, the “stacked” patents around that formula may cause it to be economically impossible to produce the original formula.[21] For example, Sanofi’s insulin, Lantus, has 74 patents associated with it, which will work together to protect it from generic competition for 37 years into the future.[22] Stacked patents not only discourage competition, but they also are incredibly effective at squashing potential patent infringers. Unsurprisingly, drug companies with multiple patents on their drugs are able to win 65% of the infringement cases against their drug.[23] Closing the loopholes that allow evergreening patents is a bipartisan issue. President Trump has even stated, “[o]ur patent system will reward innovation, but it will not be used as a shield to protect unfair monopolies.”[24] There is no question as to whether modern insulin is better than what we had in 1921; its formula, dosage, and administration improved beyond belief.[25] What used to be riddled with impurities is now a work-horse of a drug. However, it is highly questionable whether each small step in the lineage is deserving of patent protection.[26]

#### Reducing IP Rights on insulin medicines allows for equal access and reduces prices

Christensen 20 [Connor Christensen, "The Evergreen Forests of Insulin Patents", Awakenwfu, The Creative Journal of Contemporary Bioethics, 9-14-2020, https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/, accessed: 9-7-2021.] //CHSTM and Lex VM

A potential solution to prevent patent evergreening would be to modify the “inventiveness” standard required to obtain a new patent on drugs.[[27]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn27) By modifying this standard, the goal would be to stop non-inventive and commonly practiced pharmaceutical techniques from receiving patent protection.[[28]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn28) Moreover, each incremental improvement must be worth the burden on the consumer, especially in a country where the price of insulin has reached unconscionable levels.[[29]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn29) Therefore, to be considered inventive, the newer formula or methodology should be demonstratively safer or clearly more efficacious.[[30]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn30) Increasing the scrutiny would help control drug companies receiving patents on non-inventive, incremental improvements on insulin while still rewarding them for making sizable leaps forward.[31] Further, increasing the “inventiveness” standard would also encourage generic drug companies to enter the market. Previously, generic companies were precluded from producing generic insulins because patents protected the original formulas for such long periods of time that they were obsolete when it became possible to make a generic version.[[32]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn32) These obsolete versions of insulin were not viewed as a worthwhile investment to generic drug companies, so the market has been mostly devoid of generic versions.[[33]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn33) However, generic drug companies have shown some interest in creating generic versions of the next-generation of insulin. Reducing evergreening by raising the inventiveness standard required for new insulin patents could be enough to make manufacturing generics a worthwhile investment.[[34]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn34) Affording greater scrutiny to the issue of whether an incremental improvement is truly “inventive” is just one piece of the solution to reducing the price of insulin to affordable levels. Evergreens are a symbol of vitality; the irony is tangible that something of the same name can be depriving people of life.

## 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. We control Innovation not neg

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. 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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.