# 1AC

**1AC – Framing**

**The standard is maximizing expected well-being.**

**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] Extinction first --- moral uncertainty.**

**Bostrom 12** [(Nick Bostrom, Faculty of Philosophy & Oxford Martin School University of Oxford) “Existential Risk Prevention as Global Priority.” Global Policy, 2012] TDI

These reflections on moral uncertainty suggest an alternative, complementary way of looking at existential risk; they also suggest a new way of thinking about the ideal of sustainability. Let me elaborate. **Our** present **understanding** of axiology **might** well **be confused**. We may not now know — at least not in concrete detail — what outcomes would count as a big win for humanity; we might not even yet be able to imagine the best ends of our journey. **If we are** indeed profoundly **uncertain about our** ultimate aims, **then we should** recognize that there is a great option **value** in preserving — and ideally improving — **our ability to** recognize value and to **steer the future accordingly. Ensuring** that there will be **a future** version **of humanity** with great powers and a propensity to use them wisely is plausibly the best way available to us to increase the probability that the future will contain a lot of value. To do this, **we must prevent any existential catastrophe**.

**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.**

**Offense**

**Thus, I affirm the resolution Resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.**

**Definitions:**

**WTO -- the only global international organization dealing with the rules of trade between nations**

<https://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm>

**Intellectual property protections -- protection for inventions, literary and artistic works, symbols, names, and images created by the mind**

<https://www.upcounsel.com/intellectual-property-protection>

**Reduce -- to diminish in size, amount, extent, or number**

<https://www.merriam-webster.com/dictionary/reduce>

**Medicine -- a substance or preparation used in treating disease**

<https://www.merriam-webster.com/dictionary/medicine>

**My value is morality because of the word “ought” in the resolution.**

**Contention 1: COVID-19 vaccines**

**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.

**Incentivizing pharma medicine development during future pandemics is crucial.**

**Lindsey 21** Brink Lindsey is Vice President and Director of the Open Society Project at the Niskanen Center. Previously he was the Cato Institute's vice president for research [Brink Lindsey, 6-3-2021, "Why intellectual property and pandemics don’t mix," Brookings, <https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/>] //Lex AKo

On May 5 the Biden administration announced that it would support waiving intellectual property protections for COVID-19 vaccines under the World Trade Organization’s Agreement on Trade-Related Intellectual Property Rights (TRIPS). Predictably, the move drew fiery condemnation from drug companies. In addition, many disinterested observers criticized the support for a TRIPS waiver as empty symbolism, arguing that vaccine patents are not the major obstacle hindering the currently flagging drive to make vaccines available around the world. Waiving patent protections is certainly no panacea. **What is needed most urgently is a massive drive of technology transfer**, capacity expansion, and supply line coordination **to bring vaccine supply in line with global demand. Dispensing with patents in no way obviates the need for governments to fund and oversee this** effort. 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. Furthermore, and probably even more important, **this is almost certainly not the last pandemic** we will face. Urbanization, the spread of factory-farming methods, and globalization all combine to increase the odds that **a new virus will** make the jump from animals to humans and then **spread rapidly around the world**. Prior to the current pandemic, the 21st century already saw outbreaks of SARS, H1N1, MERS, and Ebola. Everything we do and learn in the current crisis should be viewed from the perspective of getting ready for next time. THE NATURE OF THE PATENT BARGAIN When we take the longer view, we can see a fundamental mismatch between the policy design of intellectual property protection and the policy requirements of effective pandemic response. Although **patent law**, properly restrained, **constitutes one important element of a well-designed national innovation system**, the way it goes about encouraging technological progress **is singularly ill-suited to the emergency conditions** of a pandemic or other public health crisis. Securing a TRIPS waiver for COVID-19 vaccines and treatments would thus establish a salutary precedent that, in emergencies of this kind, **governments should employ other, more direct means to incentivize the development of new drugs.** Here is the basic bargain offered by patent law: encourage the creation of useful new ideas for the long run by slowing the diffusion of useful new ideas in the short run. The second half of the bargain, the half that imposes costs on society, comes from the temporary exclusive rights, or monopoly privileges, that a patent holder enjoys. Under U.S. patent law, for a period of 20 years nobody else can manufacture or sell the patented product without the permission of the patent holder. This allows the **patent holder to block competitors from the market**, or extract licensing fees before allowing them to enter, and consequently charge above-market prices to its customers. Patent rights thus slow the diffusion of a new invention by restricting output and raising prices. **The imposition** of these short-run costs, however, **can bring net long-term benefits by sharpening the incentives to invent new products**. In the absence of patent protection, **the prospect of easy imitation by later market entrants can deter would-be innovators from incurring the up-front fixed costs of research and development**. But with a guaranteed period of market exclusivity, inventors can proceed with greater confidence that they will be able to recoup their investment. For the tradeoff between costs and benefits to come out positive on net, patent law must strike the right balance. **Exclusive rights should be valuable enough to encourage greater innovation, but not so easily granted or extensive in scope or term that this encouragement is outweighed by output restrictions** on the patented product and discouragement of downstream innovations dependent on access to the patented technology. Unfortunately, the U.S. patent system at present is out of balance. Over the past few decades, the expansion of patentability to include software and business methods as well as a general relaxation of patenting requirements have led to wildly excessive growth in these temporary monopolies: the number of patents granted annually has skyrocketed roughly fivefold since the early 1980s. One unfortunate result has been the rise of “non-practicing entities,” better known as patent trolls: firms that make nothing themselves but buy up patent portfolios and monetize them through aggressive litigation. As a result, a law that is supposed to encourage innovation has turned into a legal minefield for many would-be innovators. In the pharmaceutical industry, firms have abused the law by piling up patents for trivial, therapeutically irrelevant “innovations” that allow them to extend their monopolies and keep raising prices long beyond the statutorily contemplated 20 years. Patent law is creating these unintended consequences because policymakers have been caught in an ideological fog that conflates “intellectual property” with actual property rights over physical objects. Enveloped in that fog, they regard any attempts to put limits on patent monopolies as attacks on private property and view ongoing expansions of patent privileges as necessary to keep innovation from grinding to a halt. In fact, patent law is a tool of regulatory policy with the usual tradeoffs between costs and benefits; like all tools, it can be misused, and as with all tools there are some jobs for which other tools are better suited. **A well-designed patent system**, in which benefits are **maximized and costs kept to a minimum, is just one of various policy options that governments can employ to stimulate technological advance—including tax credits for R&D, prizes for targeted inventions**, and direct government support. PUBLIC HEALTH EMERGENCIES AND DIRECT GOVERNMENT SUPPORT For pandemics and other public health emergencies, patents’ mix of costs and benefits is misaligned with what is needed for an effective policy response. The basic patent bargain, even when well struck, is to pay for more innovation down the road with slower diffusion of innovation today. In the context of a pandemic, that bargain is a bad one and should be rejected entirely. Here the imperative is to accelerate the diffusion of vaccines and other treatments, not slow it down. Giving drug companies the power to hold things up by blocking competitors and raising prices pushes in the completely wrong direction. What approach to encouraging innovation should we take instead? How do we incentivize drug makers to undertake the hefty R&D costs to develop new vaccines without giving them exclusive rights over their production and sale? **The most effective approach** during a public health crisis **is direct government support: public funding of R&D, advance purchase commitments by the government to buy large numbers of doses at set prices, and other, related payouts**. And when we pay drug makers, we should not hesitate to pay generously, even extravagantly: **we want to offer drug companies big profits so that they prioritize this work** above everything else, and so that they are ready and eager to come to the rescue again the next time there’s a crisis.

**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)

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.

**Monopolization of the insulin market and lack of competing alternatives drives high cost – patent evergreening erects barriers to entry and gives major companies exclusive control of the product.**

**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)

Second, there is virtual monopoly on insulin that has been sustained for decades. Three companies, Novo Nordisk, SanofiAventis, and Eli Lilly control most of the market.2 Until recently, almost every insulin product sold in the United States was made by these 3 companies. They still continue to have a monopolistic hold on an essential product, with limited competition, and no regulations in effect to cap or control prices.

Third, there is the problem of patent evergreening.15 For a drug that was first made in 1921, it is hard to imagine that insulin is still under patent protection. However, as Table 2 points, from 1921 to early 2000s, there has been a continued improvement in insulin formulations. Each new formulation provided more reliable control of diabetes, provided more convenience, but also came with new patents. Newer formulations have prolonged the patent life and extended the monopoly on these products to the present day. In addition to prolonging patent life, with the introduction of improved analog versions of insulin, pharmaceutical companies have resorted to filing and securing multiple patents on the same drug.15 For example, 70 patents have been filed for Lantus since the drug was first introduced, which can technically provide more than 30 additional years of monopoly protection. Even more worrisome are lawsuits filed to prevent new competition alleging patent violation16 and possible “pay-for-delay” schemes in which competitors are paid money to delay market entry.

**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]

**Covid has left many unemployed exacerbating the difficulty for low-income diabetic patients from affording insulin – absent constant insulin intake diabetics risk death.**

**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.”

**No UQ for innovation – insulin revenue goes to shareholders not R&D.**

**Collington 20** [Rosie Collington is a Junior Researcher with the Academic-Industry Research Network and MSc student at the University of Copenhagen. She has previously worked in health policy and advocacy at medical research and patient organizations in the UK., "Who Benefits When the Price of Insulin Soars?", Institute for New Economic Thinking, 4-16-2020, https://www.ineteconomics.org/perspectives/blog/who-benefits-when-the-price-of-insulin-soars, accessed: 9-9-2021.] //Lex VM

Contrary to pharmaceutical company claims, revenue from high insulin prices are going to shareholders, not R&D The coronavirus pandemic has brought drug development processes under the spotlight. But the pitfalls of pharmaceutical company corporate governance models that **prioritize value for shareholders over** the interests of **patients and innovation** capabilities are nothing new – as the case of insulin shows. The list price of analogue insulin medicines in the United States has soared in recent years. A study published in March found that the list prices of seven branded insulin drugs increased by 262% between 2007-2018. The consequences of list price increases are serious, and potentially affect millions of Americans. Today, approximately 1.25 million adults and children in the United States live with type-1 diabetes, an autoimmune condition that leads to kidney failure, blindness and diabetic ketoacidosis (DKA) if left untreated. This means that for type-1 diabetics, inability to access insulin can be fatal, and recent data suggests that some patients are struggling to afford their prescription. In the United States, the amount that individuals pay for their insulin prescription depends on their health insurance plans, whether provided by an employer, individual subscription, Medicaid or Medicare. Although patients covered by insurance plans tend not to pay the full list price for their prescription medicines, increases in list prices of prescription medicines can result in higher costs of insurance coverage in the form of deductibles, co-pays and premiums. Despite an overall reduction in the number of uninsured Americans following the introduction of the Affordable Care Act (ACA) in 2010, there remain many individuals who are not covered by an insurance plan. And in most cases, uninsured individuals need to pay out-of-pocket for healthcare costs. In 2018, researchers at Yale found that one in four of the diabetes patients surveyed experienced cost-related insulin underuse. Patient organization T1International details numerous, tragic cases of type-1 diabetes patients dying after attempting to ration an insulin prescription to cut costs. Insulin can also be prescribed as a treatment for type-2 diabetes, a condition that is on the rise in the United States, with the Centers for Disease Control and Prevention reporting that approximately 34.2 million people across the country had a form of diabetes – approximately 10.5% of the population. With the potential consequences of insulin unaffordability so clear for patients, it begs the question: who benefits when the price of insulin soars? How have the rising profits from higher-priced insulin medicines been distributed? My new paper addresses these questions. Cui bono? Over the past year, William Lazonick and I have studied the flows of profits and payments across the insulin supply chain. This study is continuing, but there is enough data now to draw some important conclusions. Our review of the evidence suggests that contrary to some claims, the three manufacturers that dominate the insulin market – Eli Lilly, Novo Nordisk and Sanofi – have indeed seen higher net revenues from insulin product lines during the past decade as list prices have increased. Data available from financial reports of the companies show that annual net revenue from insulin products was on average 44% higher than 2009 for the years 2010-2018. These data reflect Hernandez et al.’s recently published data on net price increases of branded insulin products. Pharmaceutical companies have long argued that high drug prices are needed to augment investment in innovation, and the industry has attributed the growing list prices of many new drugs to rising costs of drug development. In the case of insulin, analysis of the companies’ cash flows suggests that shareholders of Eli Lilly, Novo Nordisk and Sanofi have seen huge gains as the list price of insulin has grown. The companies have collectively distributed a total of **$122 billion to shareholders** in the form of share buybacks and cash dividends over the period 2009-2018. Alternative models A “retain-and-reinvest” model of corporate governance, where profits are invested in research and development, could be conducive to innovation within a pharmaceutical company. In any case, most pharmaceutical companies today do not adopt such an approach. Lazonick and colleagues have shown that most of the largest US pharmaceutical companies in fact use high prices to maximize shareholder value and boost stock prices. And **even if the insulin manufacturing companies** had directed most of their profits from the sale of insulin into R&D activities, the question remains whether higher prices for existing medicines **should be funding investment** in future medicines. Alternatively, the cost of subsidizing the development of new medicines could be socialized; with R&D spending no longer contingent at all on the price of drugs, there would be no justification for hiking the prices of life-saving medicines. Fundamentally, **if a funding model** to develop new medical technologies **requires higher list prices** that reduce patients’ access to existing treatments, we have to question to **what extent it is worth pursuing** or even constitutes ‘**innovation’ at al**l. A closer examination of the Denmark-based company, Novo Nordisk, illustrates this point. Constituting 66% of its total net revenue between 2009-2018, insulin sales in the United States have been an important source of income for the company. Novo Nordisk traces its roots back to the early years of insulin development in the 1920s, when Professor August Krogh brought the novel discovery of the protein as a treatment for type-1 diabetes back to Denmark from the University of Toronto. Historically, the company has maintained a focus on manufacturing insulin, gradually becoming the world leader and today holding a 45% share of the modern and new-generation insulin market. Like other large companies in Denmark, Novo Nordisk operates on the basis of an industrial foundation model of corporate governance. Control over company decisions is maintained by a non-profit institution, the Novo Nordisk Foundation, which holds 76.1% of votes and 28.1% of capital through its shares in Novo Nordisk. The remaining votes and capital are in shares held by institutional and private shareholders. Studies of industrial foundations suggest that the corporate governance model provides relative stability through the development of long-term capital. The working paper suggests that while this may be true, in the case of Novo Nordisk, the company has an interest in keeping insulin prices high in the United States. Some profits yielded through cash dividends and share repurchasing within the Novo Group have been distributed to what can broadly be considered R&D activities through investments in small and medium enterprise (SME) biotech companies by Novo Holdings. Novo Holdings also holds a portfolio of largely liquid investments, comprised predominantly of equities. However, the development of that long-term capital in recent years has been contingent on the list price increases of insulin medicines in the United States. Financialization in the context of insulin pricing could thus be considered to be in tension with the affordability of products that are on the market now, because higher treatment costs for diabetes patients in the United States are a foundation of the Danish company’s long-term capital for future innovation.