### 1

#### Climate Patents and Innovation high now and solving Warming but the plan sets a dangerous precedent for appropriations - the mere threat is sufficient is enough to kill investment.

Brand 5-26, Melissa. “Trips Ip Waiver Could Establish Dangerous Precedent for Climate Change and Other Biotech Sectors.” IPWatchdog.com | Patents & Patent Law, 26 May 2021, www.ipwatchdog.com/2021/05/26/trips-ip-waiver-establish-dangerous-precedent-climate-change-biotech-sectors/id=133964/. //sid

The biotech industry is making remarkable advancestowards climate change solutions, and it is precisely for this reason that it can expect to be in the crosshairs of potential IP waiver discussions. President Biden is correct to refer to climate change as an existential crisis. Yet it does not take too much effort to connect the dots between President Biden’s focus on climate change and his Administration’s recent commitment to waive global IP rights for Covid vaccines (TRIPS IP Waiver). “This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures.” If an IP waiver is purportedly necessary to solve the COVID-19 global health crisis (and of course [we dispute this notion](https://www.ipwatchdog.com/2021/04/19/waiving-ip-rights-during-times-of-covid-a-false-good-idea/id=132399/)), can we really feel confident that this or some future Administration will not apply the same logic to the climate crisis? And, without the confidence in the underlying IP for such solutions, what does this mean for U.S. innovation and economic growth? United States Trade Representative (USTR) [Katherine Tai](https://www.ipwatchdog.com/2021/05/05/tai-says-united-states-will-back-india-southafrica-proposal-waive-ip-rights-trips/id=133224/) was subject to questioning along this very line during a recent Senate Finance Committee hearing. And while Ambassador Tai did not affirmatively state that an IP waiver would be in the future for climate change technology, she surely did not assuage the concerns of interested parties. The United States has historically supported robust IP protection. This support is one reason the United States is the center of biotechnology innovation and leading the fight against COVID-19. However, a brief review of the domestic legislation arguably most relevant to this discussion shows just how far the international campaign against IP rights has eroded our normative position. The Clean Air Act, for example, contains a provision allowing for the mandatory licensing of patents covering certain devices for reducing air pollution. Importantly, however, the patent owner is accorded due process and the statute lays out a detailed process regulating the manner in which any such license can be issued, including findings of necessity and that no reasonable alternative method to accomplish the legislated goal exists. Also of critical importance is that the statute requires compensation to the patent holder. Similarly, the Atomic Energy Act contemplates mandatory licensing of patents covering inventions of primary importance in producing or utilizing atomic energy. This statute, too, requires due process, findings of importance to the statutory goals and compensation to the rights holder. A TRIPS IP waiver would operate outside of these types of frameworks. There would be no due process, no particularized findings, no compensationand no recourse. Indeed, the fact that the World Trade Organization (WTO) already has a process under the TRIPS agreement to address public health crises, including the compulsory licensing provisions, with necessary guardrails and compensation, makes quite clear that the waiver would operate as a free for all. Forced Tech Transfer Could Be on The Table When being questioned about the scope of a potential TRIPS IP waiver, Ambassador Tai invoked the proverb “Give a man a fish and you feed him for a day. Teach a man to fish and you feed him for a lifetime.” While this answer suggests primarily that, in times of famine, the Administration would rather give away other people’s fishing rods than share its own plentiful supply of fish (here: actual COVID-19 vaccine stocks), it is apparent that in Ambassador Tai’s view waiving patent rights alone would not help lower- and middle-income countries produce their own vaccines. Rather, they would need to be taught how to make the vaccines and given the biotech industry’s manufacturing know-how, sensitive cell lines, and proprietary cell culture media in order to do so. In other words, Ambassador Tai acknowledged that the scope of the current TRIPS IP waiver discussions includes the concept of forced tech transfer. In the context of climate change, the idea would be that companies who develop successful methods for producing new seed technologies and sustainable biomass**,** reducing greenhouse gases in manufacturing and transportation, capturing and sequestering carbon in soil and products, and more, would be required to turn over their proprietaryknow-how to global competitors. While it is unclear how this concept would work in practice and under the constitutions of certain countries, the suggestion alone could be devastating to voluntary internationalcollaborations. Even if one could assume that the United States could not implement forced tech transfer on its own soil, what about the governments of our international development partners? It is not hard to understand that a U.S.-based company developing climate change technologies would be unenthusiastic about partnering with a company abroad knowing that the foreign country’s government is on track – with the assent of the U.S. government – to change its laws and seize proprietary materials and know-how that had been voluntarily transferred to the local company. Necessary Investment Could Diminish Developing climate change solutions is not an easy endeavor and bad policy positions threaten the likelihood that they will materialize. These products have long lead times from research and development to market introduction, owing not only to a high rate of failure but also rigorous regulatory oversight. Significant investment is required to sustain and drive these challenging and long-enduring endeavors. For example, synthetic biology companies critical to this area of innovation [raised over $1 billion in investment in the second quarter of 2019 alone](https://www.bio.org/sites/default/files/2021-04/Climate%20Report_FINAL.pdf). If investors cannot be confident that IP will be in place to protect important climate change technologies after their long road from bench to market, it is unlikely they will continue to investat the current and required levels**.**

#### Climate Patents are critical to solving Warming – only way to stimulate Renewable Energy Technology Investment.

Aberdeen 20 Arielle Aberdeen October 2020 "Patents to climate rescue: how intellectual property rights are fundamental to the development of renewable energy" <https://www.4ipcouncil.com/application/files/4516/0399/1622/Intellectual_Property_and_Renewable_Energy.pdf> (Caribbean Attorney-at-Law with extensive experience in legal research and writing.)//Elmer

**Climate change is** the **most pressing** global **challenge** and with the international commitment to reduce greenhouse gas emissions under the Paris Agreement,1 there **needs to be a global energy revolution** and transition.2 This is where **innovative technology can help** meet the challenge of reducing our dependency on finite natural capital resources. The development and deployment of innovative technology play a pivotal role in enabling us to replace fossil fuel use with more sustainable energy solutions. **Patents** have **facilitated** the **development of such innovative technologies** thus far **and** will **continue to be the catalyst for this transition**. Patents are among a group of intellectual property rights (‘IPRs’). 3 These are private and exclusive rights given for the protection of different types of intellectual creations. IPRs are the cornerstone of developed and knowledge-based economies, as they encourage innovation, drive the investment into new areas and allow for the successful commercialisation of intellectual creations. IPRs are the cornerstone of developed and knowledge-based economies. Empirical evidence has shown that a **strong IPRs** system **influences** both the **development and diffusion of technology**. Alternatively, **weak IPRs** protection has been shown to **reduce** **innovation**, **reduce investment** and prevent firms from entering certain markets.4 Once patent protection has been sought and granted, it gives a time-limited and exclusive rights to the creator of an invention. This allows the inventor or patentor the ability to restrict others from using, selling, or making the new invented product or process. Thereby allowing a timelimited monopoly on the exploitation of the invention in the geographical area where it is protected. During the patent application procedure, the patentor must make sufficient public disclosure of the invention. This will allow others to see, understand and improve upon it, thereby spurring continuous innovation. Therefore, the patent system through providing this economic incentive is a successful tool which has encouraged the development and the dissemination of technology. Patents like all IPRs are key instruments in the global innovation ecosystem.5 When developing innovative technology, patents play a role throughout the “technological life cycle”,6 as shown in Figure 1. This lifecycle involves the invention, research and development (‘R&D’), market development and commercial diffusion. Patents are most effective when sought at the R&D stage. Once a patent has been granted, it becomes an asset which can then be used to7: Gain Market Access: Patents can create market advantages; to develop and secure market position; to gain more freedom to operate within a sector and reduce risks of infringing on other patents; protect inventions from being copied, and removes delaying by innovative firms to release new or improved technology and encourage the expansion of their markets. Negotiation leverage: Patents can build a strong brand or company reputation which can enhance the company’s negotiation power and allow for the creation of equal partnerships. Funding: Patents can generate funding and revenue streams for companies. Having a strong patent portfolio especially in small businesses or start-ups can be used to leverage investor funding; while also be a source of revenue for companies through licensing fees, sales, tax incentives, collateral for loans and access to grants and subsidies. Strategic value: Patents can be used to build “synergistic partnerships”8 through which collaboration on R&D and other partnerships; be used to improve in-house R&D and build and/ or develop more products. As such, obtaining and managing patent as part of a patent and broader IPRs strategy are key tools for business success, especially within highly innovative and technology-driven industries.9 Renewable Energy: The Basics Renewable energy is derived from natural unlimited sources which produce little to no harmful greenhouse gases and other pollutants. 10 Innovative renewable energy technologies (‘RETs’) have created the ability to tap into these sources and convert them to energy which can then be stored, distributed, and consumed at a competitive cost. RETs have developed into a technology ecosystem which consists of alternative energy production, energy conservation and green transportation.11 For energy production, RETs have been developed to generate energy from six main sources. These are: Wind energy: Technology, via off-shore and/or on-shore wind turbines, harnesses the energy produced by the wind. Solar energy: Technology either through concentrated solar power (‘CSP’)and solar photovoltaic (‘PV’) harnesses the energy produced by the sun. Hydropower: Technology either through large-scale or small-scale hydropower plants, captures energy from flowing water. Bioenergy: Technology is used to convert organic material into energy either through burning to produce heat or power or through converting it to a liquid biofuel. Geothermal: Technology is used to capture the energy from the heat produced in the earth’s core. Ocean/Tidal energy: Technology is used to capture the energy produced from waves, tides, salinity gradient energy and ocean thermal energy conversion. Out of these six sources, the wind, solar and hydropower energy sectors are the biggest, the most developed and the most widely used. While geothermal and ocean energy sources are used in a more limited capacity. In particular, the RETs in ocean energy is still at its infancy and thus presents an opportunity for future innovation and commercialisation. Renewable energy is the fastest-growing energy source, with the electricity sector showing the fastest energy transition. 12 In 2016, renewable energy accounted for 12% of final global energy consumption and in 2018, a milestone was reached with renewables being used to generate 26% of global electricity. The source of this energy has been driven by renewable hydropower, as shown in Figure 2, with wind and solar energy trailing behind in energy production. However, the International Energy Agency (‘IRENA’) forecasts that Solar PV will lead RETs to increase capacity in the upcoming years. 13 This rise in renewable energy is due to the increased investment into the sector and the development, diffusion and deployment of innovative RETs. For the period between 2010 and 2019, there were 2.6 trillion US dollars invested in renewable energy. 14 The majority of which being focused on solar energy. 15 This investment has surpassed the investment made into the traditional fossil fuel energy 16 and has been heavily driven by the private sector. 17 The International Energy Agency recent report showed that its members increased the public budgets for energy technology R&D, with the biggest increase in the low-carbon sectors.18 The geographic sources of this investment shown in Figure 3, reveals that the European Union, the United States and Japan are part of the largest investors. This reflects the historic involvement these countries have had in the renewable energy arena and the development of RETs. However, there is now the emergence of China, India and Brazil as large investors in this field. This trend in investment has also coincided with the increase in patenting technology in renewable energy compared to fossil fuels.19 Reports from the World Intellectual Property Office (WIPO), have shown that there has been a **steady increase in patent filing rates in RETs since the mid-1990s**.20 This increase has occurred in the four major renewable sectors, 21 where RETs patents applications were growing steadily from 2005 until reaching a peak in 2013.22 Post-2013, there has been a slight decline in patent filings, which can indicate a maturing of sectors and deployment of technologies.23 Each renewable energy sector is at a different stage of maturity and thus there is a variation of patent ownership. The wind sector is the most mature and consequently has the highest intellectual property ownership and patent grants compared to that of the biofuel sector. 24 IRENA also provides a comprehensive and interactive database for RETs patents. As seen in Figure 4 below, they have collected patent data from the major patent filing jurisdiction25 which shows the breakdown of the patents per type. This information reveals that there is a dominance of patent filings focused on solar technology. This data corresponds to the focus of the investment in renewable energy into solar energy. Upon closer look at the data, the geographic source of these patents shows that RETs patents have been concentrated in a few developed OECD countries and China. This also corresponds to the source of investment shown in Figure 3 and reflects the historical concentration of RETs innovation within these countries. 26 The latest WIPO report for 2019, which looks at the data for PCT patent applications, shows that 76 % of all PCT patent application came from the United States, Germany, Japan, the Republic of Korea and China.27 China is the newest entry into the top ten list and has made one of the largest jumps to become one of the biggest RETs patent filers at the PCT. This geographic data is also mirrored by IRENA’s statistics, as shown in Figure 5 below. This data also reflects China’s emerging renewable dominance. China is heavily **investing in solar energy** **technology** and has filed numerous patents in this area and the underlying technologies.28 The successful flow of investment in this sector can only **occur in** the **presence of a strong IPRs system** and protection. Government policies and initiatives to improve the **patent system** can be used to promote the development of RETs and drive private capital and investment into this area.29 This direct **effect on RETs** through policies was **shown in** the United States with the ‘**Green Tech Pilot Program’**.30 This was a special accelerated patent application procedure developed by the United States Patent and Trademark Office for inventions falling under the green technology category. This program ran from 2009-2011 and led to a boost in RETs patent applications, with the office issuing 1062 RETs patents from the programme. Other jurisdictions, such as the European Union and China have used policy and incentives to promote the development of RETs and the advancement of their renewable energy sector. In particular, the European Union and China began the renewable energy path at different starting points but are now both dominant players in this area.

#### Climate change destroys the world.

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

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

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

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

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

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

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

#### TC

**IPCC 14**, Intergovernmental Panel on Climate Change, (“Summary for Policymakers”, <http://ipcc-wg2.gov/AR5/images/uploads/WG2AR5_SPM_FINAL.pdf>, 2014) Kerwin

Livelihoods and poverty Throughout the 21st century, climate-change impacts are projected to slow down economic growth, make poverty reduction more difficult, further erode food security, and prolong existing and create new poverty traps, the latter particularly in urban areas and emerging hotspots of hunger (medium confidence). Climate-change impacts are expected to exacerbate poverty in most developing countries and create new poverty pockets in countries with increasing inequality, in both developed and developing countries. In   urban and rural areas, wage-labor-dependent poor households that are net buyers of food are expected to be particularly affected due to food price increases, including in regions with high food insecurity and high inequality (particularly in Africa), although the agricultural selfemployed could benefit. Insurance programs, social protection measures, and disaster risk management may enhance long-term livelihood resilience among poor and marginalized people, if policies address poverty and multidimensional inequalities.66

#### 2] Extinction outweighs

#### **a] Moral uncertainty – if we’re unsure about which interpretation of the world is true – we ought to preserve the world to keep debating about it.**

#### **b] Forecloses improvement – we can never improve society because our impact is irreversible.**

#### **c] Turns suffering – mass death causes suffering because people can’t get access to resources and basic necessities.**

#### **d] Moral obligation – allowing people to die is unethical and should be prevented because it creates ethics towards other people.**

### 2

#### Text – Member states of the World Trade Organization ought to domestically establish single-payer national health insurance individually domestically.

#### Single Payer solves High Drug Prices.

Rotolo 19 Shannon Rotolo 11-18-2019 "Letters: ‘Medicare for All’ would drive down drug costs" <https://www.chicagotribune.com/opinion/letters/ct-letters-vp-111819-20191118-3q6k5toz6fgmvafspzylpbs2ca-story.html> (pharmacist and member of the Illinois Single-Payer Coalition, Chicago)//Elmer

In 2017, a study found that more than 15% of people living in the United States went without a needed medication because of its cost. This is significantly higher than the nonadherence in a majority of European countries. While there are multiple bills at the state and federal level aimed at reducing drug prices for single classes of drugs, such as insulin, or targeting high-cost drugs as a category, **none of these bills has the potential to make the same impact as a switch to a single-payer system**, commonly known as “Medicare for All.” Creation of a single-payer system has the **ability to drive down drug prices by consolidating negotiating power**. This is something we’ve been told pharmacy benefit managers (PBMs), middlemen in our current system, could achieve. But despite their presence, drug costs have continued to skyrocket. A single-payer system, on the other hand, is **projected to reduce** brand name **drug prices by about 50%.** These changes in average wholesale price (AWP) or any other price measures used by the industry or in retail pharmacies aren’t necessarily tied to the copay you see at the pharmacy counter, though. Medicare for All would address that piece as well, **with no copays or deductibles** in one proposed version, and a maximum of $200 per year on prescriptions in the other. Another unique advantage of Medicare for All is that it would **restore patient choice in pharmacy**. **Private insurance** and PBMs **ensure** greater **profits** for themselves **by restricting choice**, **driving prescriptions to the chains they own.** When they do permit patients to use alternative pharmacies, the reimbursement to those small businesses can be so low that prescriptions are often filled at a loss. The end **result is** the **pharmacy deserts** we see on the South and West sides of Chicago, and closing of independent pharmacies in the Chicago area in general. Medication only helps if you can take it, and you can only take it if you can afford it. Everyone deserves to get the medication they need from a pharmacy they trust. I encourage everyone who takes medication or loves someone who takes medication to learn more about Medicare for All and to support the candidates who will fight for it.

### 3

#### Counterplan Text – Member states of the World Trade Organization ought to consult the World Health Organization on whether or not to [do the Plan]. The World Health Organization ought to publicly declare that their decision on [the Plan] will represent their future decisions on all intellectual property protections on medicines.

#### The Plan’s unilateral action by the WTO on medical IP undermines WHO legitimacy – forcing a perception of WHO action against Patents is key to re-assert it.

Rimmer 4, Matthew. "The race to patent the SARS virus: the TRIPS agreement and access to essential medicines." Melbourne Journal of International Law 5.2 (2004): 335-374.

<https://law.unimelb.edu.au/__data/assets/pdf_file/0007/1681117/Rimmer.pdf> (BA (Hons), LLB (Hons) (Australian National University), PhD (New South Wales); Lecturer at ACIPA, the Faculty of Law, The Australian National University)//SidK + Elmer

The WHO has been instrumental in coordinating the international network of research on the SARS virus. It has emphasised the need for collaboration between the network participants. The WHO presented the containment of the SARS virus as ‘one of the biggest success stories in public health in recent years’.206 However, it **was less active in the debate over patent law** and public health epidemics. The 56th World Health Assembly considered the relationship between intellectual property, innovation and public health. It stressed that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination.207 However, there was much disagreement amongst the member states as to what measures would be appropriate. The WHO has made a number of **aspirational statements** about patent law and access to essential medicines. Arguably, though, the organisation could be a much more informed and vocal advocate. Initially, the WHO did not view the patent issues related to SARS as being within its field of activities. The agency **did not even seem aware of the patent proceedings**, leaving individual research institutions without guidance. Spokesman Dick Thompson said: ‘What we care about is [that] the international collaboration continues to function. Patents, they don’t really concern us’.208 The director of WHO’s Global Influenza project, Klaus Stöhr, expressed his opinion that the patent filings would not interfere with the international cooperation on the SARS research: ‘I don’t think this will undermine the collaborative spirit of the network of labs’.209 However, he believed that, after the international network of researchers had identified the coronavirus, it was necessary to rely upon companies to commercialise such research. Klaus Stöhr conceded: ‘At a certain point of time you have to give way for competitive pharmaceutical companies’.210 On a policy front, the WHO **remained deferential** to the WTO over the debate over patent law and access to essential medicines, observing: Owing to the inconclusive nature of the studies conducted to date, and because of the effect that potentially significant price increases could have on access to drugs in poor countries, WHO is currently monitoring and evaluating the effects of TRIPS on the prices of medicines. It is also monitoring the TRIPS impact on other important issues such as transfer of technology, levels of research and development for drugs for neglected diseases, and the evolution of generic drug markets.211 In such a statement, the WHO appears diffident, **unwilling to take on more than a spectator** role. Such a position is arguably too timid, given the gravity of national emergencies, such as the SARS virus. The organisation could take a much stronger stance on the impact of the **TRIPS** Agreement on public health concerns. The WHO has since enunciated a position statement on the patenting of the SARS virus. A number of high ranking officials from the organisation have commented on the need to ensure that international research into the SARS virus is not impeded by competition over patents. Arguably though, the **WHO should not be limited to a mere spectator role in such policy discussions. It needs to play an active advocacy role in the debate over patent law and access to essential medicines**. The WHO released a position statement on ‘Patent Applications for the SARS Virus and Genes’ on 29 May 2003.212 The organisation stressed that it had no per se objection to the patenting of the SARS virus: Some people have objected to the SARS patent applications on the ground that the virus and its genes should not be patentable because they are mere discoveries, not inventions. This distinction no longer prevents the granting of patents; the novel claim rests not with the virus itself but with its isolation, and likewise with the identification of the genetic sequence not its mere occurrence. Many patents have been issued on viruses and genetic sequences, though the appropriate policies to follow in such cases — particularly as genomic sequencing becomes more routine and less ‘inventive’ — remain matters of dispute.213 Furthermore, it recognised that public institutions could legitimately use patents as a defensive means to prevent undue commercial exploitation of the research: The “defensive” use of patents can be a legitimate part of researchers’ efforts to make their discoveries (and further discoveries derived therefrom) widely available to other researchers, in the best collaborative traditions of biomedical science.214 The WHO affirmed the need for further cooperation between research organisations in respect of the SARS virus: ‘For continued progress against SARS, it is essential that we nurture the spirit of the unprecedented, global collaboration that rapidly discovered the novel virus and sequenced its genome’.215 The WHO announced its intention to monitor the effects of patents (and patent applications) on the speed with which SARS diagnostic tests, treatments, and vaccines are developed and made available for use, and on the manner in which prices are set for these technologies. It observed: In the longer term, the manner in which SARS patent rights are pursued could have a profound effect on the willingness of researchers and public health officials to collaborate regarding future outbreaks of new infectious diseases. WHO will therefore examine whether the terms of reference for such collaborations need to be modified to ensure that the credit for any intellectual property developed is appropriately attributed, that revenues derived from licensing such property are devoted to suitable uses, and that legitimate rewards for innovative efforts do not impose undue burdens on efforts to make tests, therapies, and preventive measure available to all.216 It maintained that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination.219 The Assembly requested that the Director-General continue to support Member States in the exchange and transfer of technology and research findings, according high priority to access to antiretroviral drugs to combat HIV/AIDS and medicines to control tuberculosis, malaria and other major health problems, in the context of paragraph 7 of the Doha Declaration which promotes and encourages technology transfer.220 The WHO also considered a report on the emergence of the SARS virus and the international response to the infectious disease.221 It was ‘deeply concerned that SARS ... poses a serious threat to global health security, the livelihood of populations, the functioning of health systems, and the stability and growth of economies’.222 The Committee on Infectious Diseases requested that the Director-General ‘mobilize global scientific research to improve understanding of the disease and to develop control tools such as diagnostic tests, drugs and vaccines that are accessible to and affordable by Member States’.223 The Director-General of the WHO, Dr Gro Harlem Brundtland, **told the World Health** Assembly that there was a need to build trust and forge solidarity in the face of public health epidemics: ‘**Ensuring that patent regimes stimulate research and do not hinder international scientific cooperation** is a critical challenge — whether the target is SARS or any other threat to human health’.224 Similarly, Dr Marie-Paule Kieny, Director of the WHO Initiative for Vaccine Research, said: If we are to develop a SARS vaccine more quickly than usual, we have to continue to work together on many fronts at once, on scientific research, intellectual property and patents issues, and accessibility. It is a very complicated process, involving an unprecedented level of international cooperation, which is changing the way we work.225 She emphasised that patents and intellectual property issues and their safeguards can help rather than hinder the rapid development of SARS vaccines and ensure that, once developed, they are available in both industrialised and developing countries.226 C Summary The WHO should play a much more active role in the policy debate over patent law and access to essential medicines. James Love, the director of the Consumer Project on Technology, run by Ralph Nader, is critical of the WHO statement on ‘Intellectual Property Rights, Innovation, and Public Health’.227 He maintains that the Assembly could have addressed ‘practical examples, like SARS’ and cites the report in The Washington Post that notes that a number of commercial companies are investing in SARS research.228 The non-government organisation Médecins Sans Frontières has been critical in the past of the passive role played by the WHO in the debate over access to essential medicines: ‘As the world’s leading health agency, and armed with the clear mandate of recent World Health Assembly resolutions, the WHO can and should **do much more’**.229 The WHO should become a vocal advocate for public health concerns at the WTO and its TRIPS Council — especially in relation to patent law and the SARS virus. It must staunchly defend the rights of member states to incorporate measures in their legislation that protect access to medicines — such as compulsory licensing, parallel imports, and measures to accelerate the introduction of generic pharmaceutical drugs. It needs to develop a clearer vision on global equity pricing for essential medicines. The race to patent the SARS virus seems to be an inefficient means of allocating resources. A number of public research organisations — including the BCCA, the CDC and HKU — were compelled to file patents in respect of the genetic coding of the SARS virus. Such measures were promoted as ‘defensive patenting’ — a means to ensure that public research and communication were not jeopardised by commercial parties seeking exclusive private control. However, there are important drawbacks to such a strategy. The filing of patents by public research organisations may be prohibitively expensive. It will also be difficult to resolve the competing claims between the various parties — especially given that they were involved in an international research network together. Seth Shulman argues that there is a need for international cooperation and communication in dealing with public health emergencies such as the SARS virus: The success of a global research network in identifying the pathogen is an example of the huge payoff that can result when researchers put aside visions of patents and glory for their individual laboratories and let their work behave more like, well, a virus. After all, the hallmark of an opportunistic virus like the one that causes SARS is its ability to spread quickly. Those mounting a response need to disseminate their information and innovation just as rapidly.230 There is a danger that such competition for patent rights may undermine trust and cooperation within the research network. Hopefully, however, such concerns could be resolved through patent pooling or joint ownership of patents. Furthermore, a number of commercial companies have filed patent applications in respect of research and development into the SARS virus. There will be a need for cooperation between the public and private sectors in developing genetic tests, vaccines, and pharmaceutical drugs that deal with the SARS virus. There is also a need to reform the patent system to deal with international collaborative research networks — such as that created to combat the SARS virus. Several proposals have been put forward. There has been a renewed debate over whether patents should be granted in respect of genes and gene sequences. Some commentators have maintained that the SARS virus should fall within the scope of patentable subject matter — to promote research and development in the field. However, a number of critics of genetic technology have argued that the SARS virus should not be patentable because it is a discovery of nature, and a commercialisation of life. There has been a discussion over the lack of harmonisation over the criteria of novelty and inventive step between patent regimes. As Peter Yu comments, ‘[w]hile [the] US system awards patents to those who are the first to invent, the European system awards patents to those who are the first to file an application’.231 There have been calls for the requirement of utility to be raised. There have also been concerns about prior art, secret use and public disclosure. Representative Lamar Smith of Texas has put forward the CREATE Act, which recognises the collaborative nature of research across multiple institutions. Such reforms are intended to ensure that the patent system is better adapted to deal with the global nature of scientific inquiry. The race to patent the SARS virus also raises important questions about international treaties dealing with access to essential medicines. The public health epidemic raises similar issues to other infectious diseases — such as AIDS, malaria, tuberculosis, influenza, and so forth. The WHO made a public statement about its position on the patenting of the SARS virus. It has stated that it will continue to monitor developments in this field. Arguably, there is a need for the WHO to play a larger role in the debate **over patent law and** access to essential medicines. **Not only could it mediate legal disputes** over patents in respect of essential medicines, it could be a vocal advocate in policy discussions. The WTO has also played an important role in the debate over patent law and access to essential medicines. A number of public interest measures could be utilised to secure access to patents relating to the SARS virus including compulsory licensing, parallel importation and research exceptions. The appearance of the SARS virus shows that there should be an open-ended interpretation of the scope of diseases covered by the Doha Declaration on the TRIPS Agreement and Public Health. Important lessons should be learned from the emergence of the SARS virus, and the threat posed to global health. As the World Health Report 2003 notes: SARS will not be the last new disease to take advantage of modern global conditions. In the last two decades of the 20th century, new diseases emerged at the rate of one per year, and this trend is certain to continue. Not all of these emerging infections will transmit easily from person to person as does SARS. Some will emerge, cause illness in humans and then disappear, perhaps to recur at some time in the future. Others will emerge, cause human illness and transmit for a few generations, become attenuated, and likewise disappear. And still others will emerge, become endemic, and remain important parts of our human infectious disease ecology.232 Already, in 2004, there have been worries that pharmaceutical drug companies and patent rights are impeding efforts to prevent an outbreak of bird flu — avian influenza.233 There is a need to ensure that the patent system is sufficiently flexible and adaptable to cope with the appearance of new infectious diseases.234

#### They say yes

Alison Brunier, 4-1-2021, ("New WHO Global Compact to speed up action to tackle diabetes," No Publication, <https://www.who.int/news/item/14-04-2021-new-who-global-compact-to-speed-up-action-to-tackle-diabetes>) Adam

The World Health Organization’s  new Global Diabetes Compact aims to bring a much-needed boost to efforts to prevent diabetes and bring treatment to all who need it  ̶  100 years after the discovery of insulin.

The Compact is being launched today at the Global Diabetes Summit, which is co-hosted by WHO and the Government of Canada, with the support of the University of Toronto. During the event, the President of Kenya will join the Prime Ministers of Fiji, Norway and Singapore; the WHO Global Ambassador for Noncommunicable Diseases and Injuries, Michael R. Bloomberg; and ministers of health from a number of countries as well as diabetes experts and people living with diabetes, to highlight the ways in which they will support this new collaborative effort. Other UN agencies, civil society partners and representatives of the private sector will also attend.

The risk of early death from diabetes is increasing

“The need to take urgent action on diabetes is clearer than ever,” said Dr Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization. “The number of people with diabetes has quadrupled in the last 40 years.  It is the only major noncommunicable disease for which the risk of dying early is going up, rather than down. And a high proportion of people who are severely ill in hospital with COVID-19 have diabetes. The Global Diabetes Compact will help to catalyze political commitment for action to increase the accessibility and affordability of life-saving medicines for diabetes and also for its prevention and diagnosis.”

“Canada has a proud history of diabetes research and innovation. From the discovery of insulin in 1921 to one hundred years later, we continue working to support people living with diabetes,” said the Honourable Patty Hajdu, Minister of Health, Canada. “But we cannot take on diabetes alone. We must each share knowledge and foster international collaboration to help people with diabetes live longer, healthier lives — in Canada and around the world.”

Urgent action needed on increasing access to affordable insulin

One of the most urgent areas of work is to increase access to diabetes diagnostic tools and medicines, particularly insulin, in low- and middle-income countries.

The introduction of a pilot programme for WHO prequalification of insulin in 2019 has been an important step. Currently the insulin market is dominated by three companies. Prequalification of insulin produced by more manufacturers could help increase the availability of quality-assured insulin to countries that are currently not meeting demand. In addition, discussions are already underway with manufacturers of insulin and other diabetes medicines and diagnostic tools about avenues that could help meet demand at prices that countries can afford.

Insulin is not the only scarce commodity:  many people struggle to obtain and afford blood glucose metres and test strips as well.

In addition, about half of all adults with type 2 diabetes remain undiagnosed and 50% of people with type 2 diabetes don’t get the insulin they need, placing them at avoidable risk of debilitating and irreversible complications such as early death, limb amputations and sight loss.

Innovation will be one of the core components of the Compact, with a focus on developing and evaluating low-cost technologies and digital solutions for diabetes care.

#### WHO Cred key to Global Right to Health – medicine access is critical.

* Note the Bottom Paragraph is at the bottom of the PDF – I put a paragraph break to indicate it as such – no words are missing.

Bluestone 3, Ken. "Strengthening WHO's position should be a priority for the new Director-General." The Lancet 361.9351 (2003): 2. (Senior Policy Adviser, Voluntary Service Overseas (VSO))//Elmer

To meet these challenges, WHO must strengthen its resolve to maintain its **independence and lead its member states**, **even at the risk of causing controversy**. A meaningful example is the role that WHO can have in **ensuring access to medicines** for the world’s poorest people. WHO is the only global institution that has the **remit to drive this agenda forward**, yet has failed to do so convincingly. The new Director-General must support and reinvigorate the advocacy efforts of the organisation and provide a proper counterbalance to the interests of the pharmaceutical industry and wealthy member states. As the new Director-General takes office, they will face the dual challenge of **seeing that** the broadest possible public health interpretation of the World Trade Organization’s Doha Agreement on Trade Related Aspects on Intellectual Property Rights (TRIPS) **is not lost, and** of seizing an opportunity to bring about an international framework for sustainable and predictable tiered pricing of medicines. Without the active intervention of a public health advocate at the level of WHO, there is a risk that both of these initiatives **could founder.** Some people in positions of power still do not have high expectations of WHO or its new Director-General. But for the world’s poorest people, the overwhelming majority of whom live in developing countries, this person’s legacy could literally make the difference between life and death. Ken Bluestone Senior Policy Adviser, Voluntary Service Overseas (VSO)

New leader should re-establish WHO’s credibility The credibility of WHO’s advocacy of the right to health for all has been eroded in recent years. A large reason is WHO’s **failure to challenge the pharmaceutical** industry on access to medicines for people with HIV/AIDS and other diseases. WHO’s collaboration with the industry in the “Accelerated Access” programme on antiretroviral medicines sounds good. In fact, the programme has served as a cover for the organisation’s frequent acceptance of industry arguments for restricting treatment access. To re-establish WHO’s credibility, the new Director-General must lead the organisation to stand consistently with those most deprived of health services. Kenneth Roth, Executive Director, Human Rights Watch.

#### Right to Health solves Nationalist Populism.

Friedman 17 Eric Friedman March 2017 “New WHO Leader Will Need Human Rights to Counter Nationalistic Populism” <https://www.hhrjournal.org/2017/03/new-who-leader-will-need-human-rights-to-counter-populism/> (JD, Project Leader of the Platform for a Framework Convention on Global Health at the O’Neill Institute for National and Global Health Law at the Georgetown University Law Center in Washington, DC)//Elmer

The need for WHO leadership on human rights—and for global leadership on health and human rights beyond WHO—has always been present, yet has become ever more pressing. A reactionary, nationalist populism has been gaining momentum, particularly in the United States and parts of Europe, and some of its most disturbing features, such as xenophobia and disregard for international law and institutions, are surfacing elsewhere. Persisting health challenges—such as immense national and **global health inequities**, with universal health coverage and the Sustainable Development Goals offering some hope of lessening them—and growing threats such as outbreaks of infectious disease, worsening antimicrobial resistance, and climate change demand the type of leadership that the right to health entails. In this immensely challenging environment, WHO needs to become a 21st century institution that has the gravitas and credibility to carve a path through these obstacles towards global health justice. The next WHO Director-General, to be elected in May, must lead the organization there. The right to health can light the way ahead, with reforms to, and driven by, WHO. These reforms must develop an internal governance that is far more welcoming of civil society, with WHO member states significantly increasing contributions so work on the social determinants of health can expand, and with enhanced transparency and accountability. Furthermore, reforms are needed so that WHO leads on global health equity and human rights, including through national health equity strategies and, above all, the Framework Convention on Global Health (FCGH). The FCGH could help bring the right to health to the next level by capturing core aspects of the right to health, such as: 1) participation and accountability, setting clear standards for people’s participation in health policy-making at all levels, and establishing multi-layered health accountability frameworks with standards to which all nations would be held; 2) equity, including by catalyzing national health equity strategies—which must be developed through broad participation, itself a potentially empowering process—and advancing data disaggregation and more equitable financing; 3) financial resources, with global norms on national and international health financing responsibilities; and 4) respecting and promoting the right to health in all policies, from setting standards on health impact assessments—including participatory processes in developing them, human rights standards, an equity focus, and follow-up processes—to firmly ensuring the primacy of the right to health in other legal regimes that may undermine. From an earlier WHO treaty, the Framework Convention on Tobacco Control, we know the power of international law to significantly advance health, with the transformative power of legally binding global health norms. As a treaty, the FCGH would increase political accountability and accountability through the courts, while helping protect health other treaty-based international regimes, such as trade. It would also be a bold assertion of global solidarity for global justice, as so urgently needed, “demonstrating that the community of **nations are indeed stronger together**.” One candidate for the WHO Director-General election, David Nabarro, has recognized the value and civil society support that FCGH has already received, and the need to further explore the treaty (mentioned at 1:46:38 mark). A good first step would be establishing a WHO working group on the FCGH, with broad participation, particularly from states, civil society, and representatives of communities most affected by health inequities, along with relevant international agencies. We see signs of **resistance of the dangerous nationalist populism**, from protests that persist and judicial checks on one of the administration’s vilest acts (an immigration and refugee travel ban, with its effects falling heaviest on Muslims) in the United States to the rejection of the far-right candidate in the elections in the Netherland. Such resistance can prevent some of the worst impacts on the right to health, from discrimination against migrants to cuts to programs vital for health. Meanwhile, let’s construct an edifice for the future of health and human rights, even as we stand against its destruction. WHO, right to health, and FCGH leadership ought to be a core part of that endeavor.

#### Populism is an existential threat.

de Waal 16 Alex de Waal 12-5-2016 “Garrison America and the Threat of Global War” <http://bostonreview.net/war-security-politics-global-justice/alex-de-waal-garrison-america-and-threat-global-war> (Executive Director of the World Peace Foundation at the Fletcher School at Tufts University)//Elmer

Polanyi recounts how economic and financial crisis led to global calamity. Something similar could happen today. In fact we are already in a steady unpicking of the liberal peace that glowed at the turn of the millennium. Since approximately 2008, the historic decline in the number and lethality of wars appears to have been reversed. Today’s wars are not like World War I, with formal declarations of war, clear war zones, rules of engagement, and definite endings. But they are wars nonetheless. What does a world in global, generalized war look like? We have an unwinnable “war on terror” that is metastasizing with every escalation, and which has blurred the boundaries between war and everything else. We have deep states—built on a new oligarchy of generals, spies, and private-sector suppliers—that are strangling liberalism. We have emboldened middle powers (such as Saudi Arabia) and revanchist powers (such as Russia) rearming and taking unilateral military action across borders (Ukraine and Syria). We have massive profiteering from conflicts by the arms industry, as well as through the corruption and organized crime that follow in their wake (Afghanistan). We have impoverishment and starvation through economic warfare, the worst case being Yemen. We have “peacekeeping” forces fighting wars (Somalia). We have regional rivals threatening one another, some with nuclear weapons (India and Pakistan) and others with possibilities of acquiring them (Saudi Arabia and Iran). Above all, today’s generalized war is a conflict of destabilization, with big powers intervening in the domestic politics of others, buying influence in their security establishments, bribing their way to big commercial contracts and thereby corroding respect for government, and manipulating public opinion through the media. Washington, D.C., and Moscow each does this in its own way. Put the pieces together and a global political market of rival plutocracies comes into view. Add virulent reactionary populism to the mix and it resembles a war on democracy. What more might we see? Economic liberalism is a creed of optimism and abundance; reactionary protectionism feeds on pessimistic scarcity. If we see punitive trade wars and national leaders taking preemptive action to secure strategic resources within the walls of their garrison states, then old-fashioned territorial disputes along with accelerated state-commercial grabbing of land and minerals are in prospect. We could see mobilization against immigrants and minorities as a way of enflaming and rewarding a constituency that can police borders, enforce the new political rightness, and even become electoral vigilantes. Liberal multilateralism is a system of seeking common wins through peaceful negotiation; case-by-case power dealing is a zero-sum calculus. We may see regional arms races, nuclear proliferation, and opportunistic power coalitions to exploit the weak. In such a global political marketplace, we would see middle-ranking and junior states rewarded for the toughness of their bargaining, and foreign policy and security strategy delegated to the CEOs of oil companies, defense contractors, bankers, and real estate magnates. The United Nations system appeals to leaders to live up to the highest standards. The fact that they so often conceal their transgressions is the tribute that vice pays to virtue. A cabal of plutocratic populists would revel in the opposite: applauding one another’s readiness to tear up cosmopolitan liberalism and pursue a latter-day mercantilist naked self-interest. Garrison America could opportunistically collude with similarly constituted political-military business regimes in Russia, China, Turkey, and elsewhere for a new realpolitik global concert, redolent of the early nineteenth-century era of the Congress of Vienna, bringing a façade of stability for as long as they collude—and war when they fall out. And there is a danger that, in response to a terrorist outrage or an international political crisis, President Trump will do something stupid, just as Europe’s leaders so unthinkingly strolled into World War I. The multilateral security system is in poor health and may not be able to cope. Underpinning this is a simple truth: the plutocratic populist order is a future that does not work. If illustration were needed of the logic of hiding under the blanket rather than facing difficult realities, look no further than Trump’s readiness to deny climate change. We have been here before, more or less, and from history we can gather important lessons about what we must do now. The importance of defending civility with democratic deliberation, respecting human rights and values, and maintaining a commitment to public goods and the global commons—including the future of the planet—remain evergreen. We need to find our way to a new 1945—and the global political settlement for a tamed and humane capitalism—without having to suffer the catastrophic traumas of trying everything else first.

### Case FW

#### Reject 1AR theory- A] 7-6 time skew means it’s endlessly aff biased B] I don’t have a 3nr which allows for endless extrapolation C] 1AR theory is skewed to the aff because they have a 2ar judge psychology warrant which is also a reason why they shouldn’t get 2ar weighing

#### Infinite abuse claims are wrong- A] Spikes solve-you can just preempt paradigms in the 1AC B] Functional limits- 1nc is only 7 minutes long

#### Reasonability on 1AR shells – 1AR theory is very aff-biased because the 2AR gets to line-by-line every 2NR standard with new answers that never get responded to– reasonability checks 2AR sandbagging by preventing really abusive 1NCs while still giving the 2N a chance.

#### DTA on 1AR shells - They can blow up a blippy 20 second shell to 3 min of the 2AR while I have to split my time and can’t preempt 2AR spin which necessitates judge intervention and means 1AR theory is irresolvable so you shouldn’t stake the round on it.

ROB and roj

Reject impact justified

No 1AR implications

AT medina—just says excluding perspectives is bad—this is a double turn with the aff bc state action and lobbying inev excludes the voices and empowers big pharma ie rollback of policies

AT last piece of ev

Proabbilist claim and debate solve

Reject generic ev that’s old literally from psycho card and he even says nuke war will happen--

### 1NC – IP not Key [Insulin Specific] – Read IP not Key Generic Too

#### Political Lobbying, Marketing Schemes, and Payment for Influence/Silence are all huge Alt Causes to the Aff.

T1I International 19 1-20-2019 "8 Reasons Why Insulin is so Outrageously Expensive" <https://www.t1international.com/blog/2019/01/20/why-insulin-so-expensive/> (global type 1 diabetes charity advocating for sustainable access to supplies, care & #insulin4all.)//Elmer

5. Politics Companies are not in the habit of throwing money away, and they are not in the habit of staying out of politics. Eli Lilly, Novo Nordisk, and Sanofi collectively rake in several billions of dollars in profits. That’s not millions, but billions – with a B. We know they spend millions on marketing, but they also spend millions on lobbying politicians and donating to our decision-makers so that they keep quiet about price gouging. Check if your representatives receive contributions from one of the ‘big three’ insulin manufacturers or any pharmaceutical company. Chances are, they do. Not to mention, the revolving door between pharma companies and US Government positions. Our current secretary of Health and Human Services was previously an Eli Lilly executive. Obviously, his interests are not with people, but with power. This is why independent patient voices are so important. 6. Price Fixing These Business Insider graphs pretty much say it all. Several lawsuits alleging some form price-fixing are currently in the works. You can read more here and here. 7. Pharma Marketing Schemes Physicians in the United States and some other countries are allowed to collect fees from pharmaceutical companies for talks, advice, and more. Supposedly, these are to compensate physicians for their expertise and time. However, they can create loyalty to a company and may influence prescribing habits – a belief shared by some pharmaceutical salespeople. In some countries like India, physicians are allowed to sell and profit off insulin directly through patients, or through pharmacies they themselves own, cutting out middlemen and the retail pharmacies. Thus, they lose the incentive to find the lowest price insulin for their patients. Insulin companies also focus on ‘insulin-starts’, or the insulin the physician diagnosing patients begins with. As patients are reluctant to change, a number of marketing and financial incentives are employed to influence this decision. 8. Payment for Influence (or Silence) Many major key opinion leaders, influencers, and patient advocacy organizations take pharma cash. For example, the two biggest diabetes organizations – The American Diabetes Association and The Juvenile Diabetes Research Foundation – have accepted huge sums from insulin manufacturers. Other groups were actually created by money from the ‘big three’, like the World Diabetes Foundation which is funded by Novo Nordisk, and other supposed advocacy groups that are actually doing pharma’s bidding, or at least are highly influenced by them. If this issue is important to you, check the funders of an organization you want to support, and if it’s not transparent, you can ask if they take industry money.

### 1NC – Follow-On Innovation Good

#### Follow-On Innovation is critical for Public Health – specifically in Insulin.

Cohen and Kaitin 8, Joshua, and Kenneth Kaitin. "Follow-on drugs and indications: the importance of incremental innovation to medical practice." American journal of therapeutics 15.1 (2008): 89-91. (Tufts Center for the Study of Drug Development, Tufts University, Boston, MA.)//Elmer

Over the past several decades, biopharmaceutical **innovation has resulted in** **substantial improvements in medical treatment and care**. New medicines, diagnostic tools, and drug–device combinations have increased the length and **improved** the **quality of millions of patients’ lives**. Health economists, however, caution that such technologic advances are an important cause of rising healthcare expenditures.1 Tension has arisen between the drive to stimulate biopharmaceutical innovation on the one hand and the need to bring rising healthcare costs under control on the other. As the biopharmaceutical armamentarium expands, physicians and patients are faced with **important choices regarding** **which innovations to use and when**. Similarly, third party payers confront a major challenge deciding which drugs to reimburse, under what kinds of cost-sharing arrangements, and with what formulary restrictions. **Biopharmaceutical innovation is comprised of** two components. The first is research and development leading to the production of novel treatments and firstin-class medicines. The second is the much more common but equally important creation of **incremental improvements** over existing therapies leading to the development of **follow-on medicines and new uses for existing medicines** (ie, supplemental indications). Breakthrough or first-in-class biopharmaceuticals attract the public’s attention, because such drugs may address unmet medical needs or provide treatments for indications in which current therapies are inadequate. Accordingly, payers and policymakers are inclined to view breakthrough medicines favorably, which is typically reflected in the products’ comparatively swift and generous reimbursement.2 On the other hand, payers may question the value of incremental innovation and follow-on drugs. In some cases, this may be reflected in delays in reimbursement after marketing approval as well as in the imposition of formulary restrictions.2 A novel therapeutic entity or first-in-class drug can be seen as providing stimulus for the evolution of new classes of drugs. In time, other drugs with similar chemical properties (ie, follow-ons) will likely be approved for marketing for the same or similar indications. Moreover, research suggests that increasingly, follow-on drugs were already in late stages of development when the first-in-class drug was approved.3 Typically, there is a race among competing developers to be first to market with a new class of compounds. Obviously, only the first approved product will be considered the first-inclass drug; all subsequent approvals will be considered follow-on products. In fact, one may argue that the distinction between breakthrough and follow-on drugs is not particularly meaningful; the development of new products can best be characterized as a race among candidates rather than post hoc imitation. Nonetheless, critics of the drug industry opine that research-based companies **devote too many resources to developing and marketing follow-on drugs and indications rather than creating more breakthrough drugs**. As a corollary, some critics contend that follow-on research yields drugs with negligible added value. For example, the global alliance Health Action International asserts, ‘‘few medicines on the market are the product of innovation and new research. . . . The industry churns out mostly copycats . . . that offer little or no added therapeutic value over breakthrough drugs.’’4 Others argue, however, that **follow-on drugs** and indications **provide therapeutic options**, **which** frequently **offer improved safety and efficacy profiles and enhance patient compliance**. Wertheimer et al, for example, suggest, ‘‘the **availability of** a **broad** **range of medicines enables physicians to treat with precision the individual needs of diverse patients** and provides options when the first agent used is either ineffective or not tolerated.’’5 To evaluate the public health impact of follow-on research and development, one must first consider the value it currently provides to patients. Using the World Health Organization’s Essential Drug List (EDL) as a benchmark, we examined the role follow-on drugs and innovations play on the formulary. We chose the EDL as a basis for analysis because of its global acceptance as a standard of medically essential therapy. The primary criteria used by the World Health Organization for placement of a drug on the EDL are the product’s safety and efficacy data. Secondary criteria include the prevalence of the disease targeted by the drug as well as cost. Our study found that 63% of the drugs on the 2005 EDL are follow-on drugs. This figure represents a continuation of an upward trend since the establishment of the EDL in 1977, when 47% of drugs on the EDL were follow-on products. Moreover, 49% of the followon drugs on the EDL received a priority rating from the U.S. Food and Drug Administration (FDA), indicating that the FDA considered these drugs to represent a significant therapeutic gain over existing therapy. In addition, 15% of the recommended indications in the EDL guidelines are for follow-on indications. This number has been fairly steady over the past 30 years. In light of the fact that the EDL includes only those therapies deemed medically necessary, the high numbers of follow-on drugs and indications on the EDL are a clear reflection of their vital importance to public health. **Follow-on drugs provide** therapeutic **alternatives** and choice **when patients do not respond** to a particular drug, **when their response is suboptimal**, **or when side effects and toxicities preclude the use of that drug**. As an illustration, ciprofloxacin, a follow-on antibacterial, was added to the EDL in response to growing concerns of increased microbial resistance to older drugs. Another illustration is the HIV/AIDS combination product lopinavir/ritonavir, which was added to the EDL because of an improved safety and tolerability profile compared with the first-in-class drug, ritonavir. Further examples include the cardiovascular medications atenolol and amlodipine, which were important additions to the beta-blocker and calcium channel blocker therapeutic classes, respectively. In certain instances, follow-on products may provide backup in case a first-in-class drug is withdrawn from the market. For example, when dicumarol was recalled, it was replaced by warfarin on the EDL, a drug superior in its safety and efficacy profile as well as in its versatility. Beyond drug development within a particular class, the history of biopharmaceutical development is replete with examples highlighting the evolution of new therapeutic classes resulting from incremental innovation. The following drugs and therapeutic classes on the EDL point to this kind of evolution: Sulfonamide antibiotics, diuretics, and oral antidiabetic agents are derived from the drug prontosil6 ; Molecular changes to mercaptopurine produced allopurinol, a xanthine oxidase inhibitor used to treat gout, and azathioprine, an immunosuppressant6 ; and Research on norepinephrine’s chemical structure led to development of alpha-methyldopa, an antihypertensive.6 It is reasonable to ask how our study on the World Health Organization’s EDL relates to follow-ons in industrialized or developed economies, where the percentage of follow-ons in use on hospital and outpatient formularies may approach 85%.7 Moreover, a lower, although still significant, percentage—one third—of follow-ons are priority-rated.3 Although in industrialized nations, a wider range of drugs (than the one suggested by EDL) will generally be regarded as medically necessary, and therefore justifying reimbursement and use, the basic principle in drawing up formularies is the same as that which applies to the EDL. There have been numerous followon biopharmaceutical advances in the past year that have been added to formularies in developed economies while not (yet) gaining entry to the EDL. Some of these follow-ons have built on previous breakthroughs, whereas others were developed independently of the first-in-class drugs. Four examples follow: 1) a medicine with a more convenient form of dosing for patients with AIDS; 2) a novel insulin delivery system for patients with diabetes; 3) more potent drugs for patients with leukemia; and 4) a follow-on indication for a breast cancer medication. 1. In July 2006, the FDA approved the first-ever oncea-day AIDS treatment combining three existing drugs into one pill. The two biopharmaceutical companies that produce the medicines worked together to combine their drugs.8 The pill, named Atripla (Bristol–Myers Squibb, New York, NY and Gilead, Foster City, CA), combines a regimen of three previously approved drugs, efavirenz, tenofovir disoproxil fumarate, and emtricitabine, the most common treatment combination for patients with HIV. The single-pill treatment regimen is a marked improvement over the original AIDS treatments developed in the 1990s. 2. In January 2006, the **FDA approved** the **first-ever inhaled insulin,** a powdered form of insulin administered through an inhaler. It **presents** an **alternative to injections** for nearly five million Americans who rely on insulin to control their diabetes. In clinical trials, this form of insulin was shown to have a **more rapid onset of action** than other forms of injected insulin.9 3. In June 2006, Dasatinib (Sprycel, Bristol–Myers Squibb, New York, NY) was approved for marketing by the FDA. It represents the first in the next generation of imatinib-related drugs.10 Dasatinib builds on the imatinib breakthrough and was approved to treat patients with chronic myeloid leukemia, or Philadelphia chromosome-positive acute lymphoblastic leukemia, who do not respond to imatinib. 4. Findings from five recently conducted clinical trials evaluating trastuzumab in early-stage breast cancer suggest the drug’s beneficial effect on recurrence and mortality rates.11 An application for regulatory approval of that follow-on indication was submitted to the European Medicines Agency in February 2006 and was approved in May 2006. Subsequently, the FDA approved the new indication in November 2006. Beyond the therapeutic benefits provided by followon drugs and supplemental indications, there are economic benefits associated with these forms of incremental innovation as well. Research by DiMasi, for example, has shown that more drugs within a therapeutic class spark price competition with new drugs entering existing classes typically priced at a discount from the first-in-class product as well as the price leader in the class.12 CONCLUSION Although some follow-on drugs may turn out to be ‘‘best-in-class’’ and may become first-line therapy for certain indications, others may simply provide critical treatment alternatives to patients who respond suboptimally, who are nonresponsive, who stop responding, or who experience unacceptable toxicity to the first-line treatment. Follow-on drugs also ensure an uninterrupted supply of needed medications if, for safety reasons, the lead drug in a class is withdrawn from the market or, as in the case of antiinfectives, resistance to current therapy develops. As we have shown, follow-on drugs and indications provide physicians and patients with invaluable options that help to extend the length and the quality of patients’ lives. Moreover, follow-ons provide significant direct as well as indirect, economic benefits. The development of follow-on drugs and indications is a critical component of innovation. As policymakers debate mechanisms to stimulate the development of novel medicines while containing the growth in overall healthcare spending, they should be cautious to avoid policies and programs that create disincentives for conducting incremental innovation. The therapeutic and economic consequences of such policies would undoubtedly be dire. On the contrary, sound public policy to improve health care while controlling costs should include adequate incentives to ensure that both breakthrough product development and incremental innovation continue.

### 1NC – Medicine not Key [Insulin Specific]

#### Medicine solely refers to drugs.

American Heritage Dictionary of Medicine 18 The American Heritage Dictionary of Medicine 2018 by Houghton Mifflin Harcourt Publishing Company <https://www.yourdictionary.com/medicine> //Elmer

"A **substance**, **especially a drug**, **used to treat** the signs and symptoms of a **disease**, condition, or injury."

#### That thumps the Aff – Insulin itself isn’t patented – thickets surrounding non-active ingredients and associated devices keep the prices high.

Belluz 19 Julia Belluz 11-7-2019 "The absurdly high cost of insulin, explained" <https://www.vox.com/2019/4/3/18293950/why-is-insulin-so-expensive> (Julia Belluz is Vox's senior health correspondent, focused on medicine, science, and public health. She's covered topics as varied as the anti-vaccine movement, America's staggering maternal mortality problem, how dark chocolate became a health food, and what makes America's sickest county so unhealthy. She has also debunked numerous medical misinformation peddlers such as Dr. Oz, Gwyneth Paltrow, and Alex Jones.)//Elmer

**One real solution** to the problem, however, **would be to bring a generic version of insulin** to the market. There are currently no true generic options available (though there are several rebranded and biosimilar insulins). This is in part because companies have made those incremental improvements to insulin products, which has allowed them to keep their formulations under patent, and because older insulin formulations have fallen out of fashion. But **not all insulins are patent-protected**. For example, **none of Eli Lilly’s insulins are**, according to the drugmaker. **In those cases**, Luo said, **potential manufacturers may be deterred by secondary patents on non-active ingredients in insulins or on associated devices (such as insulin delivery pens).**

#### Patents are not the issue w/ patents for Insulin – this evidence is phenomenal.

HAI 16 Health Action International April 2016 “FACT SHEET Insulin Patent Profile” <https://haiweb.org/wp-content/uploads/2015/05/HAI_ACCISS_factsheet_insulinpatent.pdf> (a non-profit organization based in The Netherlands. Established in 1981, HAI works to expand access to essential medicines through research, policy analysis and intervention projects)//Elmer

The Insulin Patent Profile, published in April 2016, contributes to a better understanding of whether patents could be a barrier to access to insulin. This fact sheet provides an overview of the key findings of this research. Publicly-accessible **databases** **from** the **US, European, Chinese and Indian patent offices**, and the US Food and Drug Administration (Orange Book) and Health Canada, **were reviewed to determine** the **patent status of** human and analogue **insulins**. The profile and related fact sheet is the result of the mapping work completed in phase one of the Addressing the Challenge and Constraints of Insulin Sources and Supply (ACCISS) Study and is one of several profiles on the global insulin market to be published. The Leona M. and Harry B. Helmsley Charitable Trust and Stichting ICF are funding the ACCISS Study. The analysis included in this fact sheet is that of the authors alone and does not necessarily reflect the views of the Helmsley Charitable Trust or Stichting ICF. All references and conclusions are intended for educational and informative purposes and do not constitute an endorsement or recommendation from the Helmsley Charitable Trust or Stichting ICF. Patents on Insulin Products Already on the Market • **There are no patents on any formulations of human insulins**. • Based on the filing date and a 20 year patent period, patents on analogue insulins already on the market in the US and Canada have expired or will soon expire in these countries and elsewhere (Figure 1). • Four companies, Eli Lilly, Sanofi, Novo Nordisk, and Pfizer, own these patents. • The patents were most commonly filed in North America, Europe, Australia, and China. Patents on Insulin in Development • Across the four companies, the patent expiration dates of insulins in development are generally later than those of insulin products already on the market. Any insulin patents that might eventually be granted will expire as late as the 2030’s (Figure 2). • The patents and patent applications were filed in more regions of the world compared to the filings of insulin products already on the market. [Figure 1 omitted] Other Insulin Manufacturers • Patent applications for insulin were found for only four other companies: Biocon and Wockhardt (India), and Tonghua Dongbao, and Zhuhai United Laboratories (China). Recent work by Luo and Kesselheim in The Lancet Diabetes & Endocrinology on this topic in the US highlighted 1: • 19 active patents on insulin in 2014 with 10 of these filed by Novo Nordisk, six by Sanofi, and three by Eli Lilly. • **More than half of patents were for insulin-containing devices** **rather than** the active **ingredient**. (See also reference 2). • **At the end of 2015**, **there will be no patent protection on 11 common insulin products sold in the US.** • Intellectual property cannot be seen as a barrier to entry for biosimilar manufacturers. This data confirms that **for insulin products already marketed**, **the expiration of key patents** on analogues **has already taken place** or will soon take place (albeit some patents filed by Sanofi have later expiration dates than their competitors). A different picture is seen for insulin in development where there is no obvious patent cliff. Patents, if granted, will extend into the future particularly for Novo Nordisk and Sanofi products. **Of concern** **should be the increase in patents on devices**, **which might tie individuals to certain types of insulin**. That said, **unlike other medicines where i**ntellectual **p**roperty **could be seen as a barrier to access this is not the case for human insulin**. Certain limitations in the search methodology should be noted, including the exclusion of products marketed outside of North America. Additionally, publicly disclosing patent information with Health Canada is optional and listing patents may be delayed as they first screen and review them.

### 1NC – DIY Insulin Solves

#### DIY insulin solves.

Berning 21 Jack Berning 6-26-2021 "Biohackers take aim at big pharma’s stranglehold on insulin" <https://www.freethink.com/series/just-might-work/how-to-make-insulin> //Elmer

Biohackers to Share How To Make Insulin With the Public A group of dedicated biohackers believes that making insulin more accessible requires taking the monopoly away from the big three pharmaceutical companies that produce it. So they’ve started the Open Insulin Foundation, a non-profit with plans to develop the world’s first open-source insulin production model. The team consists of dozens of volunteers led by founder Anthony DiFranco, a type I diabetic. They’re now able to produce the microorganisms needed for insulin with a bioreactor. They’re also working to develop equipment that can purify the proteins produced by the bioreactor. With open-source hardware equivalent to proprietary bioreactors, the foundation hopes to give labs across the world access to the equipment needed to produce the insulin protein on a small scale. “Very few people really have any concrete ideas about how to solve these problems,” says DiFranco. “At the level of the technical fundamentals, it’s clear that we can do this. And if we can, we must.” But the process hasn’t been easy. For six years, DiFranco’s team has attempted to reverse-engineer the production of insulin with volunteer-led experiments at their community labs in cities like Oakland, Baltimore, and Sunnyvale, CA. Today, they’re beginning to see hopeful signs of a major breakthrough — like getting an FDA-approved protocol for making injectables. The team estimates that costs will be 98% cheaper than big pharma, reaching prices as low as $5-15 per vial. The best part? They’re willing to give away their plans for how to make insulin for free. “Our plan is to have a system for local production that can operate anywhere in the world that there is a need for it,” explains DiFranco. Open Insulin has already partnered with community labs, academic institutions, patient advocacy groups, and NGOs across the country and beyond. They hope their work eventually leads to the distribution of insulin in countries that don’t currently have access to it. “There was a time for being angry,” says DiFranco. “Now that we can actually see an end to this soon, it’s not anger anymore. It’s just determination.”

#### DIY Insulin is possible and safe.

Gallegos and Peccoud 18 Jenna E. Gallegos and Jean Peccoud 9-13-2018 "After a century, insulin is still expensive – could DIYers change that?" <https://theconversation.com/after-a-century-insulin-is-still-expensive-could-diyers-change-that-99822> (Postdoctoral Researcher in Chemical and Biological Engineering, Colorado State University and Professor, Abell Chair in Synthetic Biology, Colorado State University)//Elmer + Xu

Democratizing insulin production Some people are taking matters into their own hands, tinkering to meet their medical needs. In 2015, patients and hobby scientists launched an initiative known as the Open Insulin Project. As in winemaking, the specific know-how required for insulin production is a guarded secret. The goal of the Open Insulin Project is to figure out a patent-free method and release the information, so that competing companies can manufacture “generic” insulin. Given the cost of regulatory approval, it is more likely that the project could enable patients to “home brew” their own diabetic treatments. There is currently no structure for regulating drugs that are not produced commercially. One report estimates that as many as 2,000 patients have already reverse engineered their own insulin pumps and electronic monitoring systems. The insulin itself could be next. Is it possible to make biologic drugs like insulin more affordable without compromising safety? One suggestion that has been gaining steam is to scale down biomanufacturing. Right now, biologic medicines like insulin are cooked up in giant batches. Ensuring that those batches are consistent and free of contamination is a major challenge. Think about the meat department in your grocery store. Many big-box stores stock hamburger that was ground in a central processing plant and then distributed. If an E. coli outbreak occurs in the plant, it’s going to spread to all of the stores downstream, potentially infecting hundreds or thousands of people. The meat is also exposed to more potential contamination events through storage and transport. And, if contaminated meat is identified in one store, it won’t be immediately clear whether or not all the others are safe. Now, consider a small local butcher who grinds meat in-house. Any safety risk is going to be isolated to the customers of that one store and the source will be obvious. Similarly, producing medications in smaller batches reduces the potential impact of any one safety event. Pharmacy compounding provides an example. In compounding, drugs are specially mixed or produced for a very small number of patients. Compounded medications are not subject to clinical trials. If insulin were made in smaller batches, manufacturers might be able to forego clinical trials and use simpler and less expensive tests to confirm that each batch of insulin produced is safe and comparable to previously approved insulins. It would be like using chemical tests to identify important flavor compounds in two vintages of wine instead of organizing taste tests. This model could also apply to other expensive biologic drugs such as those that treat cancer, HIV and rheumatoid arthritis. The technology necessary for small-batch insulin production already exists. Future research could help automate and streamline small batch medicine production in order to minimize safety risks. The future of medicine The pharmaceutical industry is ripe for disruption. In the coming decades, drugs might be produced in very different settings. Hospitals have already begun plans to make their own medicines. DIY biologists could provide patients with the knowledge needed to produce for themselves the drugs their lives depend on. As the industry and regulatory agencies gain more experience with biologic drugs, it is also possible regulations will ease up, lowering the cost of approval. This would enable the emergence of small-scale drug manufacturers that could provide off-brand drugs at a lower cost. One thing is certain, the future of medicine will not be “business as usual.” Biomanufacturing technologies will continue to evolve. These changes could enable decentralized production of life-saving drugs. How the regulatory system and pharmaceutical industry will adjust to that future is yet to be determined.