#### I affirm, resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

## Definitions

#### **Intellectual property is defined by the NCBI as the following:**

Saha and Bhattacharya 11, Chandra Nath Saha, Sanjib Bhattacharya, associate professor of HRDC & physics, at the JUiversity of North Bengal, "Intellectual property rights: An overview and implications in pharmaceutical industry," April-June 2011, National Center for Biotechnology Information, accessed 24 August 2021, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/> brackets for gender ~ST~

Intellectual property (IP) pertains to any original creation of the human intellect such as artistic, literary, technical, or scientific creation. Intellectual property rights (IPR) refers to the legal rights given to the inventor or creator to protect his invention or creation for a certain period of time.[[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/#ref1)] These legal rights confer an exclusive right to the inventor/creator or his assignee to fully utilize ~~his~~ [their] invention/creation for a given period of time. It is very well settled that IP play a vital role in the modern economy. It has also been conclusively established that the intellectual labor associated with the innovation should be given due importance so that public good emanates from it. There has been a quantum jump in research and development (R&D) costs with an associated jump in investments required for putting a new technology in the market place.[[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/#ref2)] The stakes of the developers of technology have become very high, and hence, the need to protect the knowledge from unlawful use has become expedient, at least for a period, that would ensure recovery of the R&D and other associated costs and adequate profits for continuous investments in R&D.[[3](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/#ref3)] IPR is a strong tool, to protect investments, time, money, effort invested by the inventor/creator of an IP, since it grants the inventor/creator an exclusive right for a certain period of time for use of his invention/creation. Thus IPR, in this way aids the economic development of a country by promoting healthy competition and encouraging industrial development and economic growth. Present review furnishes a brief overview of IPR with special emphasis on pharmaceuticals.

#### Since medicines are inventions, they are under patent, which is defined by the Oxford Dictionary as the following:

Oxford Dictionary no date Oxford Dictionary, "PATENT English Definition and Meaning," no date, accessed 9 October 2021, <https://www.lexico.com/en/definition/patent?locale=en> ~ST~

A government authority or license conferring a right or title for a set period, especially the sole right to exclude others from making, using, or selling an invention.

## Framework

#### Now, on framework.

#### I value morality because the word “ought” implies a moral obligation.

#### The value criterion is maximizing well-being, also known as utilitarianism. Prefer this for 3 reasons:

#### [1] No policy action is perfect in all respects, which makes maximizing the universal good of pleasure the only way to resolve tradeoffs between different people.

#### [2] Utilitarianism is uniquely good in the context of government action since they are only able to use generalities.

Goodin 90 Goodin, Robert, fellow in philosophy, Australian National Defense University, THE UTILITARIAN RESPONSE, 1990, p. 141-2 http://open-evidence.s3-website-us-east-1.amazonaws.com/files/Morality\_Starter\_Pack\_\_\_SDI\_2012.docx

My larger argument turns on the proposition that there is something special about the situation of public officials that makes utilitarianism more probable for them than private individuals. Before proceeding with the large argument, I must therefore say what it is that makes it so special about public officials and their situations that make it both more necessary and more desirable for them to adopt a more credible form of utilitarianism. Consider, first, the argument from necessity. Public officials are obliged to make their choices under uncertainty, and uncertainty of a very special sort at that. All choices – public and private alike – are made under some degree of uncertainty, of course. But in the nature of things, private individuals will usually have more complete information on the peculiarities of their own circumstances and on the ramifications that alternative possible choices might have for them. Public officials, in contrast, [they] are relatively poorly informed as to the effects that their choices will have on individuals, one by one. What they typically do know are generalities: averages and aggregates. They know what will happen most often to most people as a result of their various possible choices, but that is all. That is enough to allow[s] public policy-makers to use the utilitarian calculus – assuming they want to use it at all – to choose general rules or conduct.

#### [3] Decision-making always takes place with positive endpoints as the focal consideration. For example, when I make arguments, it is because I believe doing so will allow me to achieve the endpoint of winning the round, meaning good consequences are intrinsic to taking action.

#### Thus, prefer utilitarianism as the criterion.

## Offense

### C1: Vaccines

#### The COVID-19 pandemic has devastated people across the globe, and increasing manufacturing capacity for vaccines is critical for the current pandemic as well as ensuring preparedness for future pandemics.

Jecker & Atuire 21 Dr Nancy S Jecker, Department of Bioethics & Humanities, University of Washington School of Medicine. Department of Philosophy, University of Johannesburg, Auckland Park, Gauteng, South Africa. Caesar A Atuire, Department of Philosophy and Classics, University of Ghana, Accra, Accra, Ghana. All Souls College, University of Oxford, Oxford, Oxfordshire, UK. Journal of Medical Ethics 2021;47:595-598. “What’s yours is ours: waiving intellectual property protections for COVID-19 vaccines.” 2021, accessed 8 October 2021 <https://jme.bmj.com/content/47/9/595> brett

Since consequentialist justifications treat the value of IP as purely instrumental, they are also vulnerable to counterarguments showing that a sought-after goal is not the sole or most important end. During the COVID-19 pandemic, we submit that the vaccinating the world is an overriding goal. With existing IP protections intact, the world has fallen well short of this goal. Current forecasts show that at the current pace, there will not be enough vaccines to cover the world’s population until 2023 or 2024.15 IP protections further frustrate the goal of universal access to vaccines by limiting who can manufacturer them. The WHO reports that 80% of global sales for COVID-19 vaccines come from five large multinational corporations.16 Increasing the number of manufacturers globally would not only increase supply, but reduce prices, making vaccines more affordable to LMICs. It would stabilise supply, [and] minimising disruptions of the kind that occurred when India halted vaccine exports amidst a surge of COVID-19 cases.

It might be objected that waiving IP protections will not increase supply, because it takes years to establish manufacturing capacity. However, since the pandemic began, we have learnt it takes less time. Repurposing facilities and vetting them for safety and quality can often happen in 6 or 7 months, about half the time previously thought.17 Since COVID-19 will not be the last pandemic humanity faces, expanding manufacturing capacity is also necessary preparation for future pandemics. Nkengasong, Director of the African Centres for Disease Control and Prevention, put the point bluntly, ‘Can a continent of 1.2 billion people—projected to be 2.4 billion in 30 years, where one in four people in the world will be African—continue to import 99% of its vaccine?’18

#### Decreasing IP protections for vaccines will save lives.

Krishtel 21 Priti Krishtel, health justice lawyer and co-founder of I-MAK, "Suspend intellectual property rights for covid-19 vaccines," 28 May 2021, BMJ, accessed 8 October 2021, <https://www.bmj.com/content/373/bmj.n1344> ~ST~

Inadequate access to essential vaccines is predictable in a system that prioritises monopolies—and this will repeat itself in the absence of an intellectual property waiver for covid-19 vaccines.

Key features

A successfully negotiated waiver would meet four important criteria. The waiver’s primary aim should be to save as many lives as possible. The Biden administration wants the waiver to focus on vaccines. This constraint should be removed. The original proposal applies to all medical technologies related to covid-19, including diagnostics, medicines, and ventilators. Many people are likely to become sick even if vaccination rates improve worldwide.

Secondly, negotiations should be completed quickly. Governments should make substantial progress ahead of the WTO meeting on 8 June 2021. Thirdly, any waiver should be straightforward, unambiguous, for a reasonable duration, and limit manufacturers’ ability to file legal challenges that impede access.

Finally, negotiating texts should be fully disclosed, with negotiations transparent to ensure all countries negotiate as equals. In the past, powerful nations have used their leverage to extract concessions from less powerful countries behind closed doors.14

Opponents of a waiver question whether manufacturers in lower income countries have the required capabilities. This argument was also made in the 1980s when Merck and GSK dominated the market for complex recombinant hepatitis B vaccines. It was discredited in 1997, when Indian manufacturer Shantha Biotechnics launched a vaccine that reduced the cost of a dose from up to $23 to just $1. Many millions of people worldwide have since been successfully immunised.15 Manufacturers in low and middle income countries are already critical to overall immunisation efforts worldwide: in 2018, they provided over half of the 2.4 billion vaccine doses procured by Unicef.16

Suppliers worldwide are gearing up to meet this moment. New mRNA vaccines are under development in India17 and China,18 and several companies in middle income countries are already manufacturing covid-19 vaccines.1920 WHO is establishing a technology transfer hub to support local production of mRNA vaccines.21 Although follow-on manufacturers can produce complex vaccines without support from holders of technology, sharing knowledge would save time and lives.

As we enter into a new era of global pandemics, we must fundamentally rethink the global intellectual property system. The ability to respond swiftly to global crises cannot be left to a handful of private companies in a few wealthy countries. We need a more cooperative global response to this and future public health emergencies.

#### COVID has brought and will bring significant harms to everyone around the world without the aff.

**Lindsey 21** Brink Lindsey, Vice President and Director of the Open Society Project at the Niskanen Center, “Why intellectual property and pandemics don’t mix,” Brookings Institution, June 3, 2021. Accessed 15 October 2021 <https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/> TDI

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

#### **The severity of the pandemic also causes decades-long increases of extreme poverty.**

Kharas and Dooley 21 Homi Kharas, fellow in the Center for Sustainable Development at Brookings Institute, Meagan Dooley, senior research analyst in the Center for Sustainable Development at Brookings Institute, "Long-run impacts of COVID-19 on extreme poverty," 2 June 2021, Brookings, accessed 15 October 2021, <https://www.brookings.edu/blog/future-development/2021/06/02/long-run-impacts-of-covid-19-on-extreme-poverty/> ~ST~

Global poverty had been declining before COVID-19. By our calculations, extreme poverty, defined as those living in households spending less than $1.90 per person per day in 2011 PPP terms, had fallen from 1.9 billion people in 1990 to 648 million in 2019, and was on pace to reach 537 million by 2030. COVID-19 interrupted this trend. The absolute number of people living in extreme poverty rose for the first time since 1997, and, absent other measures, we would not expect global poverty headcounts to fall below 2019 levels until 2023. As a result of long-term scarring, we estimate that by 2030, 588 million people could still live in extreme poverty, an additional 50 million people compared with pre-COVID-19 estimates.

### C2: Insulin

#### Insulin patents severely restrict lifesaving medication.

Belluz 19 Julia Belluz, MIT science journalism fellow, senior health correspondent at Vox, "The absurdly high cost of insulin, explained," 3 April 2019, Vox, accessed 8 October 2021, <https://www.vox.com/2019/4/3/18293950/why-is-insulin-so-expensive> ~ST~

The cost of the four most popular types of insulin has tripled over the past decade, and the out-of-pocket prescription costs patients now face have doubled. By 2016, the average price per month rose to $450 — and costs continue to rise, so much so that as many as one in four people with diabetes are now skimping on or skipping lifesaving doses.

Members of Congress have been pressuring drug companies and pharmacy benefit managers to bring insulin costs under control — and there have been several promising moves. In May, Colorado took the unusual step of capping the price of insulin in the state: A new law says people with diabetes won’t have to shell out more than $100 per monthly copay for the drug, regardless of how much they use. The state’s attorney general will also investigate rising insulin prices and make recommendations for other legislative changes.

Before that, the insurance behemoth Cigna, and its pharmacy benefit arm Express Scripts, announced a program that’ll cap the 30-day cost of insulin at $25. That’s a 40 percent reduction from the $41.50-per-month fee people with Express Scripts benefits were paying in 2018. The program is also expected to launch later this year for insurance plans that work with Express Scripts benefits. And by next year, all diabetes patients on Cigna plans will be able to join, according to the Washington Post.

Federal fixes to reduce insulin prices have also been proposed — like the Affordable Drug Manufacturing Act, introduced by Senator Elizabeth Warren (D-MA) and Representative Jan Schakowsky (D-IL). It would have, among other things, allowed the federal government to manufacture drugs or hire an outside contractor, and set fair prices for essential medicines, such as insulin. But the bill didn’t go anywhere.

While these measures suggest the problem of insulin price gouging is finally being tackled, there are several catches to consider. Colorado is just one state, and people with diabetes live in every state in America. The cap also only applies to people who have health insurance coverage. As for Cigna’s plan, patients can only participate if their employers opt into the change in plan, Stat reported. Cigna is just one of many insurance companies out there, covering less than 1 percent of the 23 million living with diabetes in America. And new federal laws haven’t passed.

“As solutions to the insulin-cost crisis are being considered,” a new New England Journal of Medicine editorial argues, “there is value in remembering that when the patent for insulin was first drafted in 1923, Banting and Macleod declined to be named on it. Both felt that insulin belonged to the public. Now, nearly 100 years later, insulin is inaccessible to thousands of Americans because of its high cost.”

Most patients with diabetes remain vulnerable to the whims of drug company pricing, since companies can still set whatever prices they wish. And no drug is better for understanding how that happened than insulin.

How the companies justify their price increases

With Type 1 diabetes, which affects about 5 percent of people with diabetes in the US, the immune system attacks the insulin-producing cells in the pancreas, leaving the body with little or none of the hormone. In Type 2 diabetes, the pancreas still makes insulin, but the body has grown resistant to its effects. In both cases, patients rely on insulin medication to keep energy from food flowing into their bodies.

The US is a global outlier on money spent on the drug, representing only 15 percent of the global insulin market and generating almost half of the pharmaceutical industry’s insulin revenue. According to a recent study in JAMA Internal Medicine, in the 1990s Medicaid paid between $2.36 and $4.43 per unit of insulin; by 2014, those prices more than tripled, depending on the formulation.

Medicaid reimbursement trends for covered insulin products from 1991 to 2014. JAMA Internal Medicine

The doctors and researchers who study insulin say it is yet another example — along with EpiPens and decades-old generic drugs — of companies raising the cost of their products because of the lax regulatory environment around drug pricing. “They are doing it because they can,” Jing Luo, a researcher at Brigham and Women’s Hospital, told Vox in 2017, “and it’s scary because it happens in all kinds of different drugs and drug classes.”

In countries with single-payer health systems, governments exert much more influence over the entire health care process.

In England, for example, the government has an agency that negotiates directly with pharmaceutical companies. The government sets a maximum price it will pay for a drug, and if companies don’t agree, they simply lose out on the entire market. This puts drugmakers at a disadvantage, driving down the price of drugs.

The US doesn’t do that. Instead, America has long taken a free market approach to pharmaceuticals.

Drug companies haggle separately over drug prices with a variety of private insurers across the country. Meanwhile, Medicare, the government health program for those over age 65 — it’s also the nation’s largest buyer of drugs — is barred from negotiating drug prices.

That gives pharma more leverage, and it leads to the kind of price surges we’ve seen with EpiPens, recent opioid antidotes — and insulin.

Insulin manufacturers say the increases are just the price tag that comes with innovation — creating more effective insulin formulations for patients.

According to a 2017 Lancet paper on insulin price increases, “Older insulins have been successively replaced with newer, incrementally improved products covered by numerous additional patents.” The result is that more than 90 percent of privately insured patients with Type 2 diabetes in America are prescribed the latest and costliest versions of insulin.

But soaring prices for these newer formulations is out of step with how much they improve treatment for patients, said Yale endocrinologist Kasia Lipska. For Type 1 diabetes, newer formulations appear to be more effective at controlling blood sugar than older formulations. “For Type 2 diabetes, it’s less clear — the benefits are not as strong.”

So, Lipska asked, “Are [the new insulins] 20 times better? I’m not sure.”

Luo, the Lancet paper’s lead author, doesn’t find the “cost of innovation” argument very convincing. In his research, he’s come across many examples of the same insulin products that have been continuously available for years without improvements, yet their price tags have gone up at a much higher rate than inflation.

“The list price of these products are already out of reach for most Americans living with diabetes — in some cases, over $300 a vial,” he said. “It is also strange to see Humulin still priced at over $150 a vial considering this product was first sold in the US in 1982.”

Drugmakers do this because they can

So insulin’s drug pricing problem is much bigger than anything one state — or drug company — alone can fix. But more changes in the market may be on the horizon.

The three major insulin makers — Eli Lilly, Novo Nordisk, and Sanofi — testified before the House Energy and Commerce’s oversight subcommittee last April, focusing more attention on the issue. Lawmakers, including Sens. Chuck Grassley (R-IA) and Ron Wyden (D-OR), have also been investigating the problem and sending letters to drug companies asking them to account for their outrageous price hikes.

But while the pressure around insulin may be mounting, we’re also seeing the terrible impact of rising insulin prices on patients: people being forced to taper off insulin so they can pay their medical bills, and winding up with kidney failure, blindness, or even death.

Some are forced to head to Canada, where drug prices are more heavily regulated and, according to the new NEJM editorial, where a carton of insulin costs $20 instead of the $300 patients often pay in the US. “Of course, there isn’t enough insulin in all of Canada to make large-scale importation feasible,” the editorial authors wrote.

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.

#### **Generic insulin would not only provide a cheaper option, but also drastically increase overall affordability.**

Aitken 16 Murray Aitken, executive of the IQVIA Institute for Human Data Science and visiting professor at the London School of Economics and Political Science, "Price Declines after Branded Medicines Lose Exclusivity in the U.S.," January 2016, IMS Institute for Healthcare Informatics, accessed 9 October 2021, pg. 2, <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf> ~ST~

Generic drugs greatly reduce the price of medicines. Generics enter the market at substantially lower prices than the brands for which they are substituted, and their prices continue to fall in subsequent years. This creates savings for patients, payers, and the healthcare system as a whole.

Generics that entered the market between 2002 and 2014 reduced the price of medicines by 51% in the first year and 57% in the second year following loss of exclusivity. Prices of oral medicines were reduced further, by 66% in the first year and 74% in the second year after generic entry. Within five years, prices of generic oral medicines fell to 80% from their pre-expiry brand prices.

#### This has a large impact because there has been a disproportional surge in deaths from diabetes.

Terhune et al 21 Chad Terhune, Robin Respaut, Deborah J. Nelson, "Special Report-How the pandemic laid bare America's diabetes crisis", Reuters, 12 August 2021, https://www.reuters.com/article/us-usa-diabetes-covid-specialreport/special-report-how-the-pandemic-laid-bare-americas-diabetes-crisis-idUSKBN2FD13Q, accessed: 9 September 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.”

#### **That means the removal of patents would introduce generic insulin to the market, providing much-needed affordability to insulin patients.**

### C3: Bioterrorism

#### **Bioterrorism is an increasingly likely form of attack in which terrorists create biological weapons to use against civilian populations. Terrorists are becoming increasingly interested in manufacturing bioweapons due to the immense consequences of the COVID-19 pandemic.**

Pavel and Venkatram 21 Barry Pavel, senior vice president and director of the Scowcroft Center for Strategy and Security, former senior director for defense policy and strategy on the National Security Council, Vikram Venkatram, Young Global Professional in the Scowcroft Center for Strategy and Security, "Facing the future of bioterrorism," 7 September 2021, Atlantic Council, accessed 9 October 2021, <https://www.atlanticcouncil.org/commentary/article/facing-the-future-of-bioterrorism/> ~ST~

Bioterrorism is not a new phenomenon, though past cases have been limited in scope. In the 1990s, a Japanese cult known as Aum Shinrikyo attempted to engineer an aerosolized strain of anthrax or, in other words, a strain of anthrax capable of infecting people through inhalation. The cult’s members were ultimately unsuccessful in their attempts to do so and resorted to releasing sarin gas (a chemical weapon, rather than a biological one) in Tokyo’s subway system on March 20, 1995, which killed thirteen people and sickened thousands of others. Their goal was to release an infectious pathogen in the hopes of causing an epidemic and stimulating a world war that would have allowed them to seize power. They were stymied by a lack of expertise—though cult members included former biologists and some with medical credentials.

A decade before, in Oregon, a cult known as the Rajneeshees spread salmonella in the hopes of incapacitating opposing candidates in local government elections. Cult members ultimately caused food poisoning in more than seven hundred and fifty people, marking the largest bioterrorism incident in US history. In 1998, al-Qaeda publicly declared its intent to pursue weapons of mass destruction, including bioweapons. The organization later conducted training courses on the use of such weapons and recruited biologists to help develop a bioweapons program. In the wake of the attacks on the United States on September 11, 2001, anthrax-laced letters were sent by mail, killing five people.

Greater access to cheap but powerful biotechnology tools—and a reduced need for expertise in operating those tools—… is making it easier for malicious actors to utilize that technology for ill.

As these cases illustrate, terrorists have already demonstrated a willingness to use biological weapons, without regard for the indiscriminate danger those weapons pose to the entire globe. As COVID-19 has shown, diseases can cross borders, particularly in the globalized world we live in today. A bioweapon released in Tokyo could spread across the world in short order, even if the initial attack is limited in scope (i.e., targeted at a specific group or starting with a relatively small volume of pathogen). These potential large-scale effects of attempted bioterrorism have been mitigated in the past by terrorists’ lack of expertise, and the inherent challenge of using biotechnology to make and release dangerous pathogens. Now, as people gain greater access to this technology and it becomes easier to use, the challenge is easing. Further, COVID-19 has shown that pandemics can have an extraordinary political impact, preying upon and worsening existing fractures in society and among nations. To terrorists, who conduct violence to achieve political aims, this reinforces the fact that a bioweapon could serve their purposes. Thus, incidents of bioterrorism soon will become more prevalent.

#### **Current patent law acts as a barrier to creating countermeasures against bioterrorist attacks and must therefore be reduced to save lives during sudden attack.**

Oriola 13 Taiwo A. Oriola, Ph.D in law from the University of Cardiff, senior lecturer in law at the University of Derby Law School, programme leader for LLM Intellectual Property and Information Technology Law, "Against the Plague: Exemption of Pharmaceutical Patent Rights as a Biosecurity Strategy," 5 October 2013, University of Illinois Journal of Law, Technology, and Policy, accessed 9 October 2021, pg. 342-343, <http://illinoisjltp.com/journal/wp-content/uploads/2013/10/05-05-08_Oriola_AHW_Formatted_FINAL.pdf> ~ST~

This Article proposes the inclusion of a bioterrorism-specific pharmaceutical patents appropriation clause in national and international patent regimes. The thesis is predicated on the impropriety of the current bureaucracy-prone access to medicines paradigms in international and national patent regimes for bioterrorism-induced public health crises situations. Using highly plausible, worst-case scenarios of bioterrorism attacks, this Article argues that vast swathes of the population could become simultaneously vulnerable to deadly bioweapons, exposing millions of people to inevitable deaths, in a comparatively shorter time span than naturally-occurring diseases like HIV/AIDS or tuberculosis. In this circumstance, time is of utmost essence in saving as many lives as possible. This makes it imperative for authorities to override patents on crucial drugs or vaccines without the consent of patent holders, thus avoiding lengthy negotiations that might be destined for failure. Moreover, this Article deems a bioterrorism-specific appropriation clause in global patents regimes expedient, in light of the pervasive and dominant pro-patents forces intent on a stronger intellectual property regime. This regime rationalizes patent protection solely on utilitarianism, and would cast attempts at proportionality of rights as campaigns against innovation. A fortiori, absent a bioterrorism-specific pharmaceutical patent appropriation clause, authorities could be bogged down by political and economic expediencies of pharmaceutical patent appropriation, fostering indecision that would make securing critical medicines in bioterrorism pandemics situations nigh impossible. This article justifies the case for bioterrorism-specific pharmaceutical patents appropriation on ethical grounds, overriding public interests, and fundamental rights to health and life.

### C4: Innovation

#### **Medical innovation is needed for a high quality of life, especially during the current pandemic.**

Regelsberger 21 Jan Regelsberger, department chair of neurosurgery at Diakonissenkrankenhaus Flensburg, "The Need for Innovation in Healthcare," 5 July 2021, Olympus Europa, accessed 11 October 2021, <https://www.olympus-europa.com/medical/en/stories-detail/2021-07-05/The-Need-for-Innovation-in-Healthcare.html> ~ST~

Healthcare decision-makers are consistently under a huge amount of pressure to deliver quality care with limited resources. Factors such as an aging population, sharp rises in long term conditions, reduced funding, increased patient expectations and of course, the current COVID-19 pandemic, make this even more difficult and highlight a constant need for innovation in healthcare.

Shortages in the availability of skilled staff is also a serious challenge for healthcare providers, who must appear as attractive as possible to appeal to the most talented and sought-after potential employees. Groundbreaking technologies and the ever-growing digitalization of healthcare can help provide this much-needed innovation, creating opportunities to boost attractiveness to patients and staff while improving patient outcomes and efficiency.

#### **However, the current patent system is proven to decrease innovation for much-needed medicines.**

Feldman 18 Robin Feldman 18, May your drug price be evergreen, Journal of Law and the Biosciences, Volume 5, Issue 3, December 2018, accessed 15 October 2021 Pages 590–647, <https://doi.org/10.1093/jlb/lsy022> Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation (Study Notes: Presenting the first comprehensive study of evergreening, this article examines the extent to which evergreening behavior—which can be defined as artificially extending the protection cliff—may contribute to the problem. The author analyses all drugs on the market between 2005 and 2015, combing through 60,000 data points to examine every instance in which a company added a new patent or exclusivity.)//sid

The study results demonstrate definitively that the pharmaceutical industry has strayed far from the patent system's intended design. The patent system is not functioning as a time-limited opportunity to garner a return, followed by open competition. Rather, companies throughout the industry seek and obtain repeated extensions of their competition-free zones. Moreover, the incidence of such behavior has steadily increased between 2005 and 2015, especially on the patent front and for certain highly valuable exclusivities. Most troubling, the data suggest that the current state of affairs is harming innovation in tangible ways. Rather than creating new medicines—sallying forth into new frontiers for the benefit of society—drug companies are focusing their time and effort extending the patent life of old products. This, of course, is not the innovation one would hope for. The greatest creativity at pharmaceutical companies should be in the lab, not in the legal department.115 The following sections describe the results obtained through our analysis in detail, but below are the key takeaways from the study: Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. In fact, 78% of the drugs associated with new patents in the FDA’s records were not new drugs coming on the market, but existing drugs. In some years, the percentage reached as high as 80%. Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, more than 70% extended their protection at least once, with more than 50% extending the protection cliff more than once. Looking at the full group, almost 40% of all drugs available on the market created additional market barriers by having patents or exclusivities added to them. Many of the drugs adding to the Orange Book are ‘serial offenders’—returning to the well repeatedly for new patents and exclusivities. Of the drugs that had an addition to the Orange Book, 80% of those had an addition to the Orange Book on more than one occasion, and almost half of these drugs had additions to the Orange Book on four or more occasions. The number of drugs with a high quantity of added patents in a single year has substantially increased. For example, the number of drugs with three or more patents added to them in one year has doubled. Similarly, the number of drugs with five or more added patents has also doubled. Overall, the quantity of patents added to the Orange Book has more than doubled, increasing from 349 patents added in the year 2005 to 723 in 2015. The number of drugs that had a patent added to them in the Orange Book almost doubled. There were striking increases in certain exclusivities, such as orphan drug exclusivity, new patient population exclusivity, and new product exclusivity. In particular, the number of drugs with an added orphan drug exclusivity tripled. In addition, the number of times a use code was added to a patent more than tripled, suggesting that this has become a new favored game. To provide a broad sense of the types of metrics we are using, some could be characterized as ‘intensity’ measures, which capture the breadth and depth of patent and exclusivity activity in the industry. Another set of our metrics can be characterized as ‘temporal’ measures, which evaluate whether there are any trends in the behavior under examination across time during our 11-year timeframe from 2005 to 2015.

#### Because patents prevent true innovation by taking over rights on old medicines, people are negatively harmed by the unavailability of new medicines.

### C5: Developing Countries

#### We debate from a Western point of view, which ignores the needs of everyone else. The patent system results in disease and suffering for half the entire world population.

Gold et al. 10 E. Richard Gold, Director at the Centre for Intellectual Property Policy, Professor of Human Genetics McGill University, "Are Patents Impeding Medical Care and Innovation?," 5 January 2010, National Center for Biotechnology Information, accessed 11 October 2021, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2795161/> ~ST~

If patents represent a bargain between the claimant to intellectual property (IP) and the state, and on balance should benefit society, a key question in this age of globalization is “which society?” The United Kingdom's Royal Society, an independent academy of science, rightly argues that “uses of intellectual property that benefit people in one part of the world but conspicuously fail to benefit others, or even act to their detriment, are not what the [patent] system is supposed to be about” [40].

For developing countries, patents can impede medical care by pricing medicines and other health care technologies (HCTs) out of the reach of patients or their health care systems. Pharmaceutical companies have little interest in pricing drugs for developing country markets because they are seeking to maximize global not national profits, and do not want to set a low price precedent that would increase demand in wealthy countries for similar low prices [41]. For those with a purchasing power less than what is needed to meet minimal needs—i.e., most of the 3.8 billion people who live on less than US$2 per day [42]—access to HCTs is little more than a discomforting dream. Further, if a treatment is too expensive, other factors that can affect medicines availability, such as drug distribution systems and rational drug use policies, become moot. Indeed, it was only when generic competition lowered the price of antiretroviral therapy for HIV—from more than US$15,000 per patient per year in 2001 to less than US$99 in 2007—that the policy debate shifted from whether such therapy was possible in resource-poor settings to how to strengthen health infrastructure to provide comprehensive HIV health care for people in such settings [43],[44].

To increase access to existing HCTs, governments can make use of fully legal safety provisions of the World Trade Organization's Trade in Intellectual Property Rights Agreement (TRIPS). These provisions include compulsory licensing, which allows a government to force a drug company to license its patent to a local generic producer who must pay a royalty to the patent holder. But a government is allowed to issue a compulsory license only after price negotiations with the patent holder have failed. Nevertheless, compulsory licensing remains a valuable tool, as memorably shown in 2001 when South Africa issued compulsory licenses to produce selected anttiretroviral drugs. Although 39 pharmaceutical companies attempted to sue South Africa's government for allegedly infringing on their patent rights, they ultimately chose to withdraw this lawsuit in the face of immense public pressure [45]. The confrontation led the World Trade Organization to issue its November 2001 Doha Declaration, which affirmed that “the TRIPS Agreement does not and should not prevent members from taking measures to protect public health” [46].

Current patent laws also skew biomedical research to products that yield high profits rather than to global priority health needs in both developed and developing countries. Currently, malaria, pneumonia, diarrhea, and tuberculosis, which together account for 21% of the global disease burden, receive 0.31% of all public and private funds devoted to heath research [47],[48]. More than 1 billion people—the overwhelming majority of whom are in the developing world—suffer from neglected tropical diseases, those for which there are inadequate or nonexistent treatments and a paucity of research and development [49]. Of the 1,556 new pharmaceutical compounds that appeared on the market between 1975 and 2004, just twenty of these drugs—1.3%—were for tropical diseases and tuberculosis [50].

The international debate around patents has been largely framed in terms of “protection for” versus “access to” IP. If the framing of the debate shifts to a focus on research and development, this is likely to strengthen the leverage of developing countries to change the dynamics of IP negotiations in trade agreements [51]. Entirely shifting the debate from IP rights to the R&D gap may help tackle the fundamental problem of a monopoly-based innovation and access system. One example is nonexclusive licensing practices, such as those used by the not-for-profit Drugs for Neglected Diseases Initiative (http://www.dndi.org/). The initiative finances R&D up front and offers the outcome of its research on a nonexclusive basis to generic producers, allowing for technology transfer and competition among multiple producers [51]. Furthermore, universities currently hold important patents on many life-saving drugs, including the antiretroviral drugs stavudine (Yale University), abacavir (University of Minnesota), lamivudine (Emory University), and enfuvirtide (Duke University) [52]. In recognition of these university patents, Universities Allied for Essential Medicines (http://www.essentialmedicine.org) proposes that “when a university licenses a promising new drug candidate to a pharmaceutical company, it should require that the company allow the drug to be made available in poor countries at the lowest possible cost” [53]. Another alternative to overcoming current patent barriers is the use of patent pools, as proposed by the WHO, Médecins Sans Frontières, and UNITAID [54],[55]. Here, a number of patents held by different entities, such as companies, universities, or research institutes, are pooled and made available to others for production or further development—of, for example, pediatric formulations or fixed-dose formulations. The patent holders receive royalties that are paid by those who use the patents. The pool manages the licenses, the negotiations with patent holders, and the receipt and payment of royalties.

Other innovative policy proposals, such as the Heath Impact Fund (a strategy to create a publicly funded “pot of gold” that would attract the private sector to create R&D innovations that effectively address priority global heath needs) [56], should be implemented. However, using patents as the financial incentive to encourage the pharmaceutical industry to develop drugs for the world's poor is of limited use where the market is nonexistent because neither governments nor patients can afford the end product [57]. Instead, framing the issue around global R&D, as opposed to international IP rights, will aid in developing public–private partnerships and a set of novel policy alternatives that support approaches to addressing the public health needs of developing nations [58].

The patent system as it affects access to and innovation for HCTs is broken. The system must be reformed so that public goods—such as genuine innovation and access to HCTs—are not sacrificed on the altar of private gain. This reform must prioritize the public good, use innovative policy tools to harness the private sector where it is possible to do so, and create public R&D capacity where market forces and actors are likely to continue to fail.

#### **Thus, I affirm and stand ready for cross-examination.**