## 1ac

### 1AC – FW

#### The standard is maximizing expected well-being – Prefer

#### [1] Actor specificity – state actors can only use util – outweighs since different actors have different obligations.

#### A – Aggregation – all policies benefit some and hurts others – only util can resolve these cuz it gives a clear weighing mechanism

#### B – Collectivism – States are composed of many actors who inevitably disagree about intent means they can only use consequentialism because they don’t have to agree

#### [2] Extinction first –

#### a. Wager – if there is any chance of goodness existing, we ought to preserve our existence to maximize it.

#### b. Sequencing – if their framework is true, people dying is bad because it means those people can’t use their framework

### 1AC – Text

#### Plantext: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

### 1AC – Bioterror Adv

#### COVID-19 has heightened and exposed vulnerabilities for bioterror

Trushar and D’Souza 7/21

Trushar R. Patel Associate Professor and Canada Research Chair, and Michael Hilary D'Souza Masters Student. “Coronavirus Is Not a Bioweapon - but Bioterrorism Is a Real Future Threat.” The Conversation, 8 July 2021, theconversation.com/coronavirus-is-not-a-bioweapon-but-bioterrorism-is-a-real-future-threat-135984. // Phoenix

The pandemic’s effect on the world isn’t a conventional attack on government targets or the military. Rather, it’s a widespread and indiscriminate attack on [global citizens and the economy](https://www.bbc.com/news/business-51706225). This outbreak has directly impacted the lives of billions of people, making it the most effective model for future terrorist activities and a new model for circumventing the conventions of modern warfare.

Striking at international vulnerabilities

An act of bioterrorism could have the same effect on our lives and the economy. Terrorist organizations actively seek to cripple a target economy through the employment of simple technologies in coordinated and sophisticated attacks on key infrastructure. This has normally ranged between simple targeted shootings and improvised explosives but can also include biochemical weapons such as [mustard gas](https://www.theguardian.com/world/2017/jan/29/chemical-weapons-found-in-mosul-in-isis-lab-say-iraqi-forces).

Locally, we are aware that Canada’s economy is especially vulnerable to sudden global shockwaves. This is largely because of our subsistence on resource development projects like oil and natural gas, and our [bottle-necked relationships with the United States](https://nationalpost.com/news/canada/house-speaker-pelosi-announces-agreement-on-north-american-trade-pact-to-replace-nafta).

A little less than 10 per cent of Canada’s economy is dependent on mining, agriculture and [resource extraction](https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=3610043403), combined with another 10 per cent contributed by manufacturing. A strike to any of these industries would ripple insecurities across the country and hurt a fifth of Canada’s GDP.

For instance, a key infrastructure in Canada is the rail corridor that operates from coast-to-coast. The corridor is already overburdened with the transport of crude oil and mired in [rail derailments](https://www.cbc.ca/news/canada/saskatchewan/rail-slow-down-impact-1.5457262) that cause disruptions to the national economy. The combined price drop in oil and the Canadian National Rail blockades initiated by the [Wet’suwet’en solidarity movement](https://www.bbc.com/news/world-us-canada-51550821) against the Coastal GasLink Pipeline created [market volatility](https://www.cbc.ca/news/politics/tasker-teck-frontier-future-oilsands-1.5475658) and invariably shutdown Canada’s ability to transport goods, causing [temporary layoffs](https://www.thechronicleherald.ca/business/reuters/canada-loses-record-2-million-jobs-temporary-layoffs-add-more-pain-447387/) and concern from [foreign investors](https://business.financialpost.com/news/economy/choke-point-how-the-blockade-movement-has-sent-tremors-across-canadas-economy-and-beyond) developing the project.

Although the [economic impact](https://www.cbc.ca/news/politics/rail-blockades-economic-impact-1.5497236) of the blockades was low compared to the pandemic, the effect of disruption is important. It demonstrates the ease with which foreign and domestic terrorists can operate to undermine Canadian sovereignty and stability by targeting a few, important Canadian industries.

The effect of the blockades stalling trade and forcing [temporary layoffs](https://www.ctvnews.ca/business/cn-employees-heading-back-to-work-after-temporary-layoffs-as-blockades-wind-down-1.4836665) is similar in consequence to the imposed self-isolation preventing Canadians from working, generating income and consuming commodities.

Consistent [unemployment](https://www.macleans.ca/economy/economicanalysis/coronavirus-plunges-canadas-economy-into-the-abyss/) and spending reductions in Canada can also produce a snowball effect that inches towards recession. Regardless of its size, a targeted attack can disrupt a nation enough to create instability and panic, which is the intent of terrorist groups that cannot compete equally with industrially backed, modern militaries.

Opportunity and expertise

The feasibility of designing and dispersing biological weapons varies in difficulty depending on the biological agent in question. For instance, [Bacillus anthracis](https://www.cdc.gov/anthrax/index.html), an exceptionally deadly and versatile pathogenic bacterium that causes the disease anthrax, is naturally occurring in the environment and can infect humans and animals. Anthrax has recently emerged from [thawing permafrost due to the effects of climate change](https://www.theguardian.com/world/2016/oct/09/reindeer-to-be-culled-in-russias-far-north-due-to-anthrax-outbreak), and manages to persist in harsh climates and environments demonstrating its versatility.

Acquiring anthrax is relatively easy and its highly infectious spores can enter the body through inhalation of aerosols or ingestion via contaminated water supplies. Consequently, anthrax is considered one of the leading [potential bioweapons](https://www.medicalnewstoday.com/articles/321030#Bioterrorism:-Modern-concerns). In 2001, five people in the United States died after receiving mail contaminated with anthrax — [no one was caught or charged](https://www.npr.org/2011/02/15/93170200/timeline-how-the-anthrax-terror-unfolded).

Conversely, the employment of synthetic biology to engineer novel bioweapons from pre-existing pathogens using [CRISPR or DNA synthesis](https://cen.acs.org/biological-chemistry/synthetic-biology/Synthetic-biology-enable-bioweapons-development/96/i26) is far more demanding in terms of laboratory requirements and expertise.

The manipulation and handling of these agents have been made more accessible by biotechnology companies competing aggressively for the attention of academic, corporate and [government funding](https://www.theguardian.com/global-development/2014/feb/21/3d-printing-offer-developing-savings-replica-kit).

With strict deadlines and finite resources, researchers value methods that provide reproducible and reliable results. This has been especially encouraging for the development of new technologies like [CRISPR](https://www.scientificamerican.com/article/mail-order-crispr-kits-allow-absolutely-anyone-to-hack-dna/), whose competitive market has made gene-editing accessible and cost effective.

Researchers have also supplemented their laboratories [3D-printed equipment](https://www.nature.com/articles/d41586-018-07853-5), making complex instruments that were once costly and out-of-reach easily accessible to anyone interested in biotechnology. This allows the convenient development of weapons to occur anywhere from stringent, regulated laboratories to remote facilities and [even in one’s own garage](https://www.forbes.com/sites/fernandezelizabeth/2019/09/19/yes-people-can-edit-the-genome-in-their-garage-can-they-be-regulated/#7ff06edd768b).

While countries like the U.S. and [Russia](https://www.nti.org/learn/countries/russia/biological/) inherited advanced biological weapons programmes from the Cold War, rogue nations like [North Korea](https://www.nytimes.com/2019/01/15/science/north-korea-biological-weapons.html) and terrorist organisations like [al-Qaida](https://www.jstor.org/stable/26369585) are actively seeking to develop programs and infrastructure for their own use and deterrence against foreign interference. With easily obtainable and simple technologies, the ability to invest in an underground bioweapons program is widely available.

All that is necessary to bridge the gap is talent.

A common myth appears to exemplify terrorist members as being [uneducated individuals](https://www.theguardian.com/world/2016/oct/05/islamic-state-recruits-world-bank-study-education-boko-haram). However, at its peak, the Islamic State of Iraq and the Levant (ISIS) recruited a variety of educated professionals ranging from [engineers](https://www.macleans.ca/news/world/why-do-so-many-jihadis-have-engineering-degrees/) to [medical doctors](https://www.ctvnews.ca/world/recruiting-professionals-doctors-join-the-isis-fight-1.2295241). [ISIS operated](https://www.theguardian.com/cities/2018/jan/29/bureaucracy-evil-isis-run-city-mosul) in the Middle East as any nation state would, with municipal bureaucracies, tax collection, road-building, infrastructural developments and hospitals.

Terrorist organizations tend to have the same infrastructural and scientific capabilities as modern industrial nations, allowing them to potentially develop biochemical arsenals. The infrastructure requirements for biological weapons programs are also made easier by being [comparatively cheaper and more versatile than a nuclear arsenal](https://www.wired.com/2017/03/thank-goodness-nukes-expensive-complicated/). This is largely because they can be masked by developments in medical industry, health and [agricultural research](https://cosmosmagazine.com/biology/researchers-fear-us-agricultural-research-masks-bioweapons-development).

#### IPR gives patent holders complete control of solutions and forces responses to go through a deep, slow bureaucratic process creating a near-impossible obstacle course for any bioterror solutions

Oriola 7

Taiwo A. Oriola (Cardiff Law School, and the ESRC Centre for Business Relationships, Accountability, Sustainability, & Society, University of Cardiff, United Kingdom). “AGAINST THE PLAGUE: EXEMPTION OF PHARMACEUTICAL PATENT RIGHTS AS A BIOSECURITY STRATEGY.” JOURNAL OF LAW, TECHNOLOGY & POL‑ ICY. 2007.. [http://illinoisjltp.com/journal/wp‑content/uploads/2013/10/05‑05‑ 08\_Oriola\_AHW\_Formatted\_FINAL.pdf](http://illinoisjltp.com/journal/wpcontent/uploads/2013/10/0505%2008_Oriola_AHW_Formatted_FINAL.pdf) // Phoenix weird formatting probably due to OCR

B. The Propriety of Article 30 of the TRIPS Agreement for Bi0terrorism- Induced Diseases

Article 30 of the TRIPS Agreement allows for derogation from patent exclusivity on grounds of "exceptional use" by imposing three distinctive, but cumulative, exceptions on Article 28(1) of the TRIPS' patents exclusivity: (1) the exceptional use must be limited; (2) the exceptional use may not unreasonably conï¬‚ict with the normal exploitation of the patent; (3) the exceptional use may not unreasonably prejudice the legitimate interests of the patentee, taking into account the legitimate interests of third parties.28Â° The pertinent question is whether Article 30 of TRIPS could be used in sourcing crucial drugs and vaccines in bioterrorism-induced public health crises. The negotiating history of Article 30 and the Canada-Patent Protection cases offer some insights into the scope and usefulness of Article 30 in this respect. The Canada patent case will be analyzed in detail due to the significant light it sheds on the prospect of Article 30 being used as a tool for the procurement of critical drugs in a public health pandemic or bioterrorism crisis.

The negotiating history of Article 30 of TRIPS indicates that it was originally designed to accommodate a wide range of specific, authorized exceptions. This included prior users' rights; private and non-commercial acts; experimental acts; manual preparation by pharmacists and medical doctors in accordance with a prescription, or acts perfonned with a medicine so prepared; acts done in reliance upon such acts not being prohibited by a valid claim as initially granted in a patent, but subsequently prohibited by a valid claim of that patent as amended; and governmental acts performed for government uses. 82 Apparently, these specific exceptions never made it to the final provisions of Article 30 as it is presently construed.283

In the Canada-Patent Protection case, the European Community challenged the consistency of Sections 55.2(l) and 55.2(2) of the Canadian Patent Act with Articles 27.1, 28, 30, and 33 of TRIPS. 284 Section 55.2(l) of Canada's Patent Act provided that a patent shall not be infringed if the patented invention is used or sold for uses that reasonably relate to the development and submission of information required under any Canadian law.28 This is otherwise known as the "regulatory review exception,"286 which is akin to the United States' Bolar exception in the Hatch-Waxman Act.287 However, Canada's patent law went beyond the Bolar exception in Section 55.2(2), by authorizing third parties to manufacture and stockpile patented pharmaceuticals during regulatory review processes, six months prior to the expiration of the patent term. 288 The WTO panel report examined the validity of the twin exceptions in Sections 55.2(1) & (2) of Canada's Patent Act vis-a-vis Article 30 of TRIPS. The panel found that Section 55.2(1), which embodied the regulatory review Bolar-type exception, was consistent with Articles 27.1 and 28.1 of TRIPS because it was authorized by Article 30 of TRIPS?"

In effect, the WTO panel sanctioned acts of manufacturers and suppliers of active pharmaceutical components, as well as producers of generic pharmaceuticals, provided such acts were reasonably related to marketing approval of a generic pharmaceutical product.29Â° The WTO panel. however, found that the stockpiling exception under section 55.2(2) of the Canadian Patent Act ran afoul of Article 28.1 of TRIPS because it was outside of the ambit of allowable exceptions under Article 30 of TRIPS.29' Therefore, Article 30 was narrowly construed.292

The WTO panel's ruling, severing the stockpiling exception from the regulatory review exception of Canada's patent law, demonstrates the narrow ambit of the limited exceptions allowable under Article 30 for the production of generic pharmaceuticals. It also unequivocally demonstrates that Article 30 of TRIPS is improper for the challenges of bioterrorism emergency situations; drug stockpiling, though of limited practical use,293 is arguably an integral logistical measure of bioterrorism preparedness.

Although the "limited exceptions" provision was narrowly construed, the precise parameters were left undefined by the WTO panel ruling, rendering it vague and vulnerable to semantic arguments.294 While any number of patent- limiting provisions could theoretically fit into its narrow confines, in practice, only those that are less threatening to patented inventions, like the experimental use exception as opined by the WTO panel in the Canada-Patent Protection case, would pass muster. 295

The inappropriateness of Article 30 for bioterrorism emergencies is further underscored by the cumulative nature of its three conditions.296 Non- compliance with any of the three provisions contravenes Article 30 as a whole.297 The following paragraphs will examine conditions two and three in an attempt to shed more light on their usefulness for securing crucial medicines in any bioterrorism context.

1. Conflict with Normal Exploitation of a Patent

The second condition of Article 30 of TRIPS requires that exceptions to the rights conferred should not unreasonably conflict with a normal exploitation of the patent.298 While TRIPS does not define "normal exploitation," the WTO panel in the Canada-Patent Protection case defined "normal" as "a normative standard of entitlement" and "what is common within a relevant community."299 The Panel went on to define "exploitation" as the "commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent.” The panel summed up what it perceived as the essence of the second leg of Article 30 of TRIPS by stating that “[t]he normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent’s grant of market exclusivity.”

The panel's construction of the second prong of Article 30 was arguably too restrictive. Without a doubt, patent owners would love to exclude all forms of competition and breach stringent anti-competitive rules if they could do so. However, the TRIPS Agreement does not envisage an unbridled patent monopoly as evident in Article 3l(k), which enjoins against anti-competitive practice and would avail the grant of a compulsory license to loosen up any anti-competitive gridlock.3Â°2 If anything, the second condition of unreasonable conï¬‚ict with normal patent exploitation under Article 30 of TRIPS makes it nearly impossible to em loy the Article to acquire needed drugs in bioterrorism emergencies.3 3 Such a use would no doubt be an extreme measure vis-a-vis the stockpiling provision of section 55.2(2) (now repealed) of the Canadian Patent Act which the panel found invalid under Article 30 of TRIPS.

Furthermore, applying the second prong of Article 30 to the acquisition of crucial drugs for bioterrorism attacks could be complicated by a lack of a understanding of critical terms like limited exceptions, normal exploitation, or unreasonable conflict. The panel's proposition in this respect is too descriptive and very pro-patent. For instance, it is very unlikely that a WTO member could successfully parallel import crucial drugs for bioterrorism attacks via the second prong of Article 30. If Canada could fail to retain its drug stockpiling exception during the generic pharmaceuticals regulatory review process, any urgent measure aimed at securing crucial medicines for victims of bioterrorism attacks outside of the TRIPS systemic-bound provisions would be doomed to invalidity under Article 30 for unreasonably conflicting with the normal exploitation of the pharmaceutical patent in question.

#### **Biotech advancements allow for bioweapons to wipe out all of humanity by combining traits – the brink is now before the weapons are too powerful**

Millett and Snyder-Beattie 17 (Piers Millett and Andrew Snyder-Beattie; 2017; Health Security, Volume 15, Number 4; *“Existential Risk and Cost-Effective Biosecurity”*; accessed 8/13/21; <https://www.liebertpub.com/doi/pdf/10.1089/hs.2017.0028>; Piers Millett, PhD, is a Senior Research Fellow, and Andrew Snyder-Beattie, MS, is Director of Research; both at the University of Oxford, Future of Humanity Institute, Oxford, England.; page 374) HB rc // Phoenix

In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a long historical track record of state-run bioweapon research applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of staterun bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and mutually assured destruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25The possibility of a war between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27 Non-state actors may also pose a risk, especially those with explicitly omnicidal aims. While rare, there are examples. The Aum Shinrikyo cult in Japan sought biological weapons for the express purpose of causing extinction.28 Environmental groups, such as the Gaia Liberation Front, have argued that ‘‘we can ensure Gaia’s survival only through the extinction of the Humans as a species. we now have the specific technology for doing the job. several different [genetically engineered] viruses could be released’’(quoted in ref. 29). Groups such as R.I.S.E. also sought to protect nature by destroying most of humanity with bioweapons.30 Fortunately, to date, non-state actors have lacked the capabilities needed to pose a catastrophic bioweapons threat, but this could change in future decades as biotechnology becomes more accessible and the pool of experienced users grows.31,3

### 1AC – Drug Prices Adv

#### Drug prices are higher than ever

Bunis 6/21

Bunis, Dena. “Drug Price Increases Continue to Outpace Inflation.” AARP, 7 June 2021, [www.aarp.org/politics-society/advocacy/info-2021/prescription-price-increase-report.html. //](http://www.aarp.org/politics-society/advocacy/info-2021/prescription-price-increase-report.html.%20//) Phoenix

Retail prices for some of the most widely used brand name prescription drugs continue to increase twice as much as inflation, making these life-sustaining medicines potentially unaffordable to many older Americans, according to a new report from AARP’s Public Policy Institute.

In 2020, prices for 260 commonly used medications whose prices AARP has been tracking since 2006 increased 2.9 percent while the general rate of inflation was 1.3 percent, according to a recent [AARP “Rx Price Watch” report](https://www.aarp.org/content/dam/aarp/ppi/2021/06/trends-in-retail-prices-of-brand-name-prescription-drugs-widely-used-by-older-americans.10.26419-2Fppi.00143.001.pdf).

“It’s unfair that drug prices keep rising, even for medications that have been on the market for decades,” says Leigh Purvis, director of health care costs and access at AARP and coauthor of the reports. According to the June 7 report, the total retail prescription drug costs for the typical older American who takes four to five prescription drugs per month would be $31,000 per year — more than the $29,650 average annual income for Medicare beneficiaries.

#### IPR skyrockets prices by stifling competition and granting exclusivity

Hickey et. al 3/21

Hickey, Kevin, et al. Drug Pricing and Intellectual Property: The Legislative Landscape for the 117th Congress. 31 Mar. 2021. <https://sgp.fas.org/crs/misc/R46741.pdf> // Phoenix

Intellectual property (IP) rights play an important role in the development and pricing of pharmaceuticals, such as prescription drugs and biological products (biologics). To provide incentives for research and development (R&D), IP law grants innovators exclusive rights that may prevent others from making generic or biosimilar versions of a drug or biologic, enabling makers of brand-name pharmaceuticals to charge higher prices in some circumstances. In the pharmaceutical context, such higher-than-competitive prices are intended to allow pharmaceutical manufacturers an opportunity to recoup substantial R&D costs, including clinical trials and other tests necessary to obtain regulatory approval from the Food and Drug Administration (FDA). Although many factors other than IP rights contribute to the cost of prescription drugs and biologics, pharmaceutical products are frequently protected by IP rights, and IP rights are often among the most important factors driving high drug prices.

#### High prices kill accessibility

Bhatt ‘8

-- member at Landman Corsi Ballaine & Ford [Tina S., Amending TRIPS: A New Hope for Increased Access to Essential Medicines, 33 Brook. J. Int'l L., 2008, <https://brooklynworks.brooklaw.edu/bjil/vol33/iss2/6>, accessed 8-1-21] // rc Phoenix

Eighty percent of people in low- and middle-income countries that need antiretroviral therapy (“ART”) to treat HIV/AIDS do not have access to it.27 Eighty-three percent of sub-Saharan Africans and ninety-five percent of northern Africans and Middle Easterners do not receive needed medicines.28 In East, South, and Southeast Asia, eighty-four percent of those requiring ART do not receive it. In low- and middle-income countries in Europe and Central Asia, eighty-seven percent do not receive ART.29 In Latin America and the Caribbean, ART coverage is better but still inadequate at sixty-eight percent.30

While these statistics represent the situation in a substantial part of the world, they do not represent what the standard of care can be, especially considering that ART coverage in high-income countries, such as the United States, the United Kingdom, and France reaches above seventyfive percent.31 Also disconcerting is the fact that access to treatment is uneven between similarly situated countries. For example, Thailand’s coverage reaches up to sixty percent32 while in India, ART is accessible to a mere seven percent of those that need it.33 Botswana and Uganda have over fifty percent coverage while coverage in other sub-Saharan countries is well below ten percent.34One reason why essential medicines are not reaching all who need them is their high price.35 Though prices have dropped over the last few years in some low-income countries, they remain “unacceptably high in some countries” and have remained “almost stable” in middle-income countries.36 Additionally, drugs that have decreased in price represent mostly first-line treatment37 while second-line treatment (used after patients develop immunities to first-line drugs 38) costs are “prohibitive” in most countries 39 and vary greatly amongst countries of similar income level.40Brazil, where ART coverage is at eighty-three percent,41 presents a prime example of the dramatic effect drug prices have on access to treatment. Brazil was the first developing nation to provide universal free AIDS treatment and has “the best anti-AIDS program of any developing country.”42 It has been able to afford this by manufacturing generic versions of brand name drugs, thus reducing costs by up to almost half.43Generic manufacturers have been identified favorably as contributing to the price drops that have occurred within the last few years

#### Inaccessibility creates variants – the unvaccinated are petri dishes for mutations

Plater 8/21

Plater, Roz. “Unvaccinated People Are Fueling Coronavirus Variants.” Healthline, Healthline Media, 10 Aug. 2021, www.healthline.com/health-news/unvaccinated-people-are-increasing-the-chances-for-more-coronavirus-variants-heres-how#Millions-unvaccinated. // Phoenix

Experts say the number of unvaccinated people in the United States is a key reason coronavirus variants are emerging.

They explain that the virus replicates quicker in unvaccinated people, increasing the chance of mutations.

They’re concerned that new COVID-19 cases will continue to rise as variants spread and people still refuse to get vaccinated.

Chances are, the coronavirus variant known as [Epsilon](https://newsroom.uw.edu/news/epsilon-variant-mutations-contribute-covid-immune-evasion) might not be on your radar, but scientists sure are watching it.

First discovered in California last December, it’s now spreading in Pakistan.

“This is worrisome, as it is more transmissible than original strains of the virus,” said [Dr. Purvi Parikh](https://allergyasthmanetwork.org/about-us/our-team/), an allergist and immunologist with the Allergy and Asthma Network in New York City.

She added, “there is some early evidence” that the variant could be resistant to the vaccines.

So far, scientists in the United States say COVID-19 vaccines seem to be holding up against a new crop of variants that include Gamma, Lambda, Delta Plus, and even the Delta variant that’s responsible for 90 percent of [new cases](https://www.healthline.com/health-news/here-are-the-states-where-covid-19-is-increasing-2) in the country.

But some experts are worried the clock is ticking.

“It’s perhaps just a matter of time,” said [Dr. Michael Saag](https://www.uab.edu/medicine/diabetes/faculty/faculty-bios/194-michael-saag), a professor of medicine, infectious diseases, and virology at the University of Alabama at Birmingham.

“Let’s say, hypothetically, that a new variant could emerge where we won’t be so fortunate, and the existing vaccines won’t work,” Saag explained to Healthline.

“I call that hypothetical variant Omega. That’s the one we’re all fearing. It hasn’t happened yet, and we hope it doesn’t. But the longer this goes on with widespread transmission, the possibility increases with time,” he said.

Millions unvaccinated

The White House COVID-19 Response Team [noted](https://www.whitehouse.gov/briefing-room/press-briefings/2021/08/02/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-47/) that more than 165 million Americans are fully vaccinated.

However, there are still about 90 million who are eligible to be vaccinated but haven’t been.

Experts say the uptick in COVID-19 cases is happening largely because of the number of people who remain unvaccinated.

“They play a huge role. If everyone is vaccinated, eventually infections drop to zero and so do variants,“ Parikh said. “But if the virus has an easy host, such as an unvaccinated individual, then it is easy for it to mutate into a more contagious and virulent form.”

#### And COVID is an impact magnifier for the laundry list – climate change, overheating, and pandemic variants pull the trigger on extinction

McPherson 20

[Guy R McPherson, Professor Emeritus, University of Arizona, “Will COVID-19 Trigger Extinction of All Life on Earth?” Eart & Envi Scie Res & Rev, 2020, <https://opastonline.com/wp-content/uploads/2020/04/will-covid-19-trigger-extinction-of-all-life-on-earth-eesrr-20-.pdf>, y2k, reformatted by a^c]

The cooling effect is “nearly twice what scientists previously thought,” and the paper by Rosenfeld et al. [5] cites the conclusion by Levy et al. [4], indicating as little as **35% reduction** in **industrial activity** drives a 1 C global-average rise in **temperature**, thereby suggesting that as little as a 20% reduction in industrial activity will drive a 1 C spike in temperature within a few weeks [7]. Additional, recent support for the importance of the aerosol masking effect comes from [8, 9]. Furthermore, loss of **aerosols** exacerbates **heat waves** [10]. Human extinction might have been triggered several years ago when the global-average temperature of Earth exceeded 1.5 C above the 1750 baseline. According to a comprehensive overview published by European Strategy and Policy Analysis System in April, an “increase of 1.5 degrees is the maximum the planet can tolerate; … at worst, [such a rise in temperature above the 1750 baseline will cause] **the extinction of humankind** altogether” [11, 12]. Earth’s global-average temperature hit 1.73 C above the 1750 baseline by April, 2018 the highest global-average temperature experienced by Homo sapiens on Earth [13, 14]. By 13 March 2020, 2 C above the 1750 baseline was crossed [11]. In other words, human extinction via the death-by-a-thousandcuts route might be locked in with no further heating of Earth. In light of the ongoing pandemic, the ongoing Mass Extinction Event, and abrupt, irreversible climate change, it is pleasantly surprising that humans still occupy Earth. The pandemic-induced **reduction** in industrial activity may have already reduced the **aerosol masking effect** sufficiently to trigger **a 1 C temperature spike**. The outcome is not yet obvious because the timing of the outbreak of the novel coronavirus was favorable for human habitat. Trees produced leaves in the Northern Hemisphere spring of 2020 as a result of carbohydrates stored the previous year and grain crops were harvested before the novel coronavirus emerged. Results of the recent and ongoing rise in temperature, which have already been reported in China and India, will become obvious to most humans when many more trees die. Large-scale die-off of **trees** likely will approximately correspond with **catastrophic crop failure**. This might occur by the end of this year, although I would rather it not. Every civilization requires bread and circuses. There is little doubt the circuses attendant to industrial civilization will continue until the end of the planetary show for Homo sapiens. Bread, however, requires wheat. Wheat production requires a delicate balance of growing conditions that, like habitat for humans, teeters on the brink [15]. The path to **near-term** human **extinction** thus runs from a **tiny virus** underlying a **pandemic** through a **reduction of industrial activity** that **overheats** a planet already running a fever. The outbreak of COVID-19 could very well be the event that **accelerates** human **extinction** via reduction of industrial activity, hence **loss of habitat** for Homo sapiens. As a result of the **rapid environmental change** likely to follow, we are almost **certain** to **lose all life on Earth** [16]. History is replete with examples of **human hubris**. We thought we were mighty, and we certainly have left our mark on Earth. How embarrassing for the big-brained human species that **a microscopic virus** could pull the **trigger** on our **extinction** [15].

### 1AC – Variants – Econ

#### The pandemic is raging across the globe – vaccines are our only safeguard

Steenhuysen 7/21

Julie Steenhuysen, Alistair Smout and Ari Rabinovitch Reuters, 7-26, 21, How the Delta Variant Upends Assumptions About the Coronavirus, [https://www.usnews.com/news/top-news/articles/2021-07-26/how-the-delta-variant-upends-assumptions-about-the-coronavirus //](https://www.usnews.com/news/top-news/articles/2021-07-26/how-the-delta-variant-upends-assumptions-about-the-coronavirus%20//) Phoenix

The Delta variant is the fastest, fittest and most formidable version of the coronavirus that causes COVID-19 the world has encountered, and it is upending assumptions about the disease even as nations loosen restrictions and open their economies, according to virologists and epidemiologists. Vaccine protection remains very strong against severe disease and hospitalizations caused by any version of the coronavirus, and those most at risk are still the unvaccinated, according to interviews with 10 leading COVID-19 experts But the evidence is mounting that the Delta variant, first identified in India, is capable of infecting fully vaccinated people at a greater rate than previous versions, and concerns have been raised that they may even spread the virus, these experts said As a result, targeted use of masks, social distancing and other measures may again be needed even in countries with broad vaccination campaigns, several of them said. Israel recently reinstated mask-wearing requirements indoors and requires travelers to quarantine upon arrival. U.S. officials are considering whether to revise mask guidance for the vaccinated. Los Angeles County, the most populous in the United States, is again requiring masks even among the vaccinated in indoor public spaces. Even in Canada, where hospitalizations and COVID-19 cases continue to decline, national data from the Public Health Agency of Canada warns the Delta variant stands a chance of unravelling some of that progress. The data suggests that, despite ground gained on COVID-19 nationally, the Delta variant may result in “greater than previously expected resurgence this fall and winter.” “The biggest risk to the world at the moment is simply Delta,” said microbiologist Sharon Peacock, who runs Britain’s efforts to sequence the genomes of coronavirus variants, calling it the “fittest and fastest variant yet. The major worry about the Delta variant is not that it makes people sicker, but that it spreads far more easily from person to person, increasing infections and hospitalizations among the unvaccinated. Public Health England said on Friday that of a total of 3,692 people hospitalized in Britain with the Delta variant, 58.3 per cent were unvaccinated and 22.8 per cent were fully vaccinated In Canada, though COVID-19 cases are declining, Variants of Concern represent the majority of reported COVID-19 cases — approximately 70 per cent. For the week of June 20, 2021, cases of the Delta variant sat at 39 per cent, while Alpha cases sat around 38 per cent — the first time the two variant cases were reported in similar proportions. In Singapore, where Delta is the most common variant, government officials reported on Friday that three-quarters of its coronavirus cases occurred among vaccinated individuals, though none were severely ill. Israeli health officials have said 60 per cent of current hospitalized COVID-19 cases are in vaccinated people. Most of them are age 60 or older and often have underlying health problems. In the United States, which has experienced more COVID-19 cases and deaths than any other country, the Delta variant represents about 83 per cent of new infections. So far, unvaccinated people represent nearly 97 per cent of severe cases. Dr. Monica Gandhi, an infectious diseases doctor at the University of California, San Francisco, said many vaccinated people are “so disappointed” that they are not 100% protected from mild infections. But the fact that nearly all Americans hospitalized with COVID-19 right now are unvaccinated “is pretty astounding effectiveness,” she said “There is always the illusion that there is a magic bullet that will solve all our problems. The coronavirus is teaching us a lesson,” said Nadav Davidovitch, director of Ben Gurion University’s school of public health in Israel. The Pfizer Inc/BioNTech vaccine, one of the most effective against COVID-19 so far, appeared only 41% effective at halting symptomatic infections in Israel over the past month as the Delta variant spread, according to Israeli government data. Israeli experts said this information requires more analysis before conclusions can be drawn. “Protection for the individual is very strong; protection for infecting others is significantly lower,” Davidovitch said. MA study in China found that people infected with the Delta variant carry 1,000 times more virus in their noses compared with the original version first identified in Wuhan in 2019. “You may actually excrete more virus and that’s why it’s more transmissible. That’s still being investigated,” Peacock said. Virologist Shane Crotty of the La Jolla Institute for Immunology in San Diego noted that Delta is 50% more infectious than the Alpha variant first detected in the UK. “It’s outcompeting all other viruses because it just spreads so much more efficiently,” Crotty said. Genomics expert Eric Topol, director of the Scripps Research Translational Institute in La Jolla, California, noted that Delta infections have a shorter incubation period and a far higher amount of viral particles. “That’s why the vaccines are going to be challenged. The people who are vaccinated have got to be especially careful. This is a tough one,” Topol said. In the United States, the Delta variant has taken hold just as many Americans – vaccinated and not – have stopped wearing masks indoors. “It’s a double whammy,” Topol said. “The last thing you want is to loosen restrictions when you’re confronting the most formidable version of the virus yet.” The development of highly effective vaccines may have led many people to believe that once vaccinated, COVID-19 posed little threat to them. “When the vaccines were first developed, nobody was thinking that they were going to prevent infection,” said Carlos del Rio, a professor of medicine and infectious disease epidemiology at Emory University in Atlanta. The aim was always to prevent severe disease and death, del Rio added.The vaccines were so effective, however, that there were signs they also prevented transmission against prior coronavirus variants. “We got spoiled,” he said.

#### TRIPS creates unchecked variants and a deep inequality – waiver is needed

Gupta and Namboodiri 2021

[Vineeta, Sreenath, Health Affairs, "America And The TRIPS Waiver: You Can Talk The Talk, But Will You Walk The Walk?" July 13, <https://www.healthaffairs.org/do/10.1377/hblog20210712.248782/full/> // Phoenix

The TRIPS waiver is critical to combating the COVID-19 pandemic around the world. Demand for the vaccine has already surpassed supply, with high-income countries taking a large share of reserved doses. Given that no single vaccine manufacturer could produce enough vaccines to meet the demand of the entire globe, supporters of the waiver ponder the ethics of multinational manufacturers holding exclusive rights to information and technology, preventing other companies from entering the markets that are not being served—primarily in low- and middle-income countries. Sharing vaccine-related information will not only help get the pandemic in check now, but it could also encourage firms to develop the next round of vaccines that will be necessary to address new variants.

The TRIPS waiver is critical to ensuring an equitable distribution of vaccines around the globe. High-income countries already have widespread vaccination campaigns well underway, while many low-income countries have yet to administer a single dose. Without a TRIPS waiver, the gap between vaccination rates in high-income and low- and middle-income countries (LMIC) will only widen.

#### The brink is now to prevent lasting effects - Vaccine inequity kills economic recovery – developing countries can’t recover without protection against COVID

WHO 7/21

World Health Organization, July 22, 2021, <https://www.who.int/news/item/22-07-2021-vaccine-inequity-undermining-global-economic-recovery>, Vaccine inequity undermining global economic recovery // Phoenix

New Global Dashboard on COVID-19 Vaccine Equity finds low-income countries would add $38 billion to their GDP forecast for 2021 if they had the same vaccination rate as high-income countries. Global economic recovery at risk if vaccines are not equitably manufactured, scaled up and distributed. COVID-19 vaccine inequity will have a lasting and profound impact on socio-economic recovery in low- and lower-middle income countries without urgent action to boost supply and assure equitable access for every country, including through dose sharing, according to new data released today by the United Nations Development Programme (UNDP), the World Health Organization (WHO) and the University of Oxford An acceleration in scaling up manufacturing and sharing enough vaccine doses with low-income countries could have added $38 billion to their GDP forecast for 2021 if they had similar vaccination rates as high income countries. At a time when richer countries have paid trillions in stimulus to prop up flagging economies, now is the moment to ensure vaccine doses are shared quickly, all barriers to increasing vaccine manufacturing are removed and financing support is secured so vaccines are distributed equitably and a truly global economic recovery can take place.A high price per COVID-19 vaccine dose relative to other vaccines and delivery costs – including for the health workforce surge – could put a huge strain on fragile health systems and undermine routine immunization and essential health services and could cause alarming spikes in measles, pneumonia and diarrhea. There is also a clear risk in terms of foregone opportunities for the expansion of other immunization services, for example the safe and effective rollout of HPV vaccines. Lower income countries need timely access to sustainably priced vaccines and timely financial support.These insights come from the Global Dashboard for COVID-19 Vaccine Equity, a joint initiative from UNDP, WHO and the University of Oxford’s Blavatnik School of Government, which combines the latest information on COVID-19 vaccination with the most recent socio-economic data to illustrate why accelerating vaccine equity is not only critical to saving lives but also to driving a faster and fairer recovery from the pandemic with benefits for all. “In some low- and middle-income countries, less than 1 per cent of the population is vaccinated – this is contributing to a two-track recovery from the COVID-19 pandemic”, said UNDP Administrator, Achim Steiner. “It’s time for swift, collective action – this new COVID-19 Vaccine Equity Dashboard will provide Governments, policymakers and international organisations with unique insights to accelerate the global delivery of vaccines and mitigate the devastating socio-economic impacts of the pandemic. According to the new Dashboard, which builds on data from multiple entities including the IMF, World Bank, UNICEF and Gavi, and analysis on per capita GDP growth rates from the World Economic Outlook, richer countries are projected to vaccinate quicker and recover economically quicker from COVID-19, while poorer countries haven’t even been able to vaccinate their health workers and most at-risk population and may not achieve pre-COVID-19 levels of growth until 2024. Meanwhile, Delta and other variants are driving some countries to reinstate strict public health social measures. This is further worsening the social, economic and health impact, especially for the most vulnerable and marginalised people. Vaccine inequity threatens all countries and risks reversing hard won progress on the Sustainable Development Goals.

#### Econ collapse is the most probable scenario for war.

Elhefnawy 11 Nader Elhefnawy (professor of English at the University of Miami, writer on IR published in peer-reviewed journals including International Security, Astropolitics, and Survival). “Twenty Years After the Cold War: A Strategic Survey,” Parameters, The U.S. Army War College Quarterly. Spring 2011. <http://strategicstudiesinstitute.army.mil/pubs/parameters/Articles/2011spring/Ehlefnawy.pdf>

Relative calm has prevailed among the great powers since the demise of the Soviet Union. Large-scale warfare remains a possibility, but by and large interstate war has been confined to the margins of the international system, and limited in its intensity, with the operational realities of the world’s major armed forces characterized by alternative missions. Neoliberal globalization has been robust but economically problematic, characterized by slow growth, financial instability, and other factors contributing to social and political stress. East Asia, and especially China, constituted the principal exception to the slow growth characterizing these decades. East Asia has massively increased its share of world manufacturing, exports, and exchange reserves, while at the same time the EU expanded and consolidated the continent’s resources, with some “game-changing” implications (like the euro). Additionally, rising commodity prices have resulted in booms among resource exporters, particularly energy exporters, which have also permitted these nations to enjoy greater political leverage. As a result, while the United States remains in a class of its own with regard to military power, and its large national market, there have been some substantial shifts in economic power from the United States and Japan to other actors over the past two decades. This is particularly true of China, the EU, and a select number of energy exporters, resulting in a more complex and diffuse distribution of power. At the same time the relationships of the major powers are less defined by concerns related to traditional, state-centered threats than at any time since the nineteenth century, if not earlier. While these may not be the traditional threats, they do present an unprecedented array of non-traditional security concerns in areas like energy, the environment, and finance, and physical threats presented by non-state actors, such as international terrorism and high-seas piracy. Despite these mounting threats, cooperation has consistently fallen short of the levels hoped for in the early 1990s. Many of the current trends seem likely to continue through the foreseeable future. The interaction of the crises of the past several years (especially in energy and international finance) combined with long-mounting stresses in the global economy (slow growth, debt, ecological pressure) all raise the possibility of changes in some areas of development, particularly if these changes impact the world’s three principal loci of economic power: China, the European Union, and the United States. China may continue to grow rapidly, though perhaps less so as it matures, and begins to pursue goals beyond the mere maximizing of GDP. Even if the EU’s attempts at integration and expansion recede (as is plausible), Europe as a whole is likely to remain powerful, even if that power is less extensive and well-organized. Meanwhile the US position is not unlike what the “declinists” of the 1980s and early 1990s anticipated. The most significant direct challenges to the United States some twenty years after the Cold War are not military, but economic: deindustrialization, balance of payments problems, debt, and surviving inside an ever-more integrated global economy and strained ecosystem. Relations among the great powers may yet grow more intense, but economic crisis seems the most likely cause of any future conflict, with the less traditional dimensions of security presenting the most realistic obstacles to the United States’ freedom of action if such events ever do materialize.

#### Great power war goes nuclear

Talmadge 18 [Caitlin Talmadge is Associate Professor of Security Studies at the Edmund A. Walsh School of Foreign Service at Georgetown University. This essay is adapted from “Would China Go Nuclear? Assessing the Risk of Chinese Nuclear Escalation in a Conventional War With the United States,” International Security, Spring 2017. Beijing’s Nuclear Option: Why a U.S.-Chinese War Could Spiral Out of Control. 2018. https://www.foreignaffairs.com/articles/china/2018-10-15/beijings-nuclear-option]

As China’s power has grown in recent years, so, too, has the risk of war with the United States. Under President Xi Jinping, China has increased its political and economic pressure on Taiwan and built military installations on coral reefs in the South China Sea, fueling Washington’s fears that Chinese expansionism will threaten U.S. allies and influence in the region. U.S. destroyers have transited the Taiwan Strait, to loud protests from Beijing. American policymakers have wondered aloud whether they should send an aircraft carrier through the strait as well. Chinese fighter jets have intercepted U.S. aircraft in the skies above the South China Sea. Meanwhile, U.S. President Donald Trump has brought long-simmering economic disputes to a rolling boil.

A war between the two countries remains unlikely, but the prospect of a military confrontation—resulting, for example, from a Chinese campaign against Taiwan—no longer seems as implausible as it once did. And the odds of such a confrontation going nuclear are higher than most policymakers and analysts think.

Members of China’s strategic com­munity tend to dismiss such concerns. Likewise, U.S. studies of a potential war with China often exclude nuclear weapons from the analysis entirely, treating them as basically irrelevant to the course of a conflict. Asked about the issue in 2015, Dennis Blair, the former commander of U.S. forces in the Indo-Pacific, estimated the likelihood of a U.S.-Chinese nuclear crisis as “somewhere between nil and zero.”

This assurance is misguided. If deployed against China, the Pentagon’s preferred style of conventional warfare would be a potential recipe for nuclear escalation. Since the end of the Cold War, the United States’ signature approach to war has been simple: punch deep into enemy territory in order to rapidly knock out the opponent’s key military assets at minimal cost. But the Pentagon developed this formula in wars against Afghanistan, Iraq, Libya, and Serbia, none of which was a nuclear power.

#### Nuke war causes extinction

Edwards 17 [Paul N. Edwards, CISAC’s William J. Perry Fellow in International Security at Stanford’s Freeman Spogli Institute for International Studies. Being interviewed by EarthSky. How nuclear war would affect Earth’s climate. September 8, 2017. earthsky.org/human-world/how-nuclear-war-would-affect-earths-climate] **Note, we are only reading parts of the interview that are directly from Paul Edwards -- MMG**

In the nuclear conversation, what are we not talking about that we should be?

We are not talking enough about the climatic effects of nuclear war. The “nuclear winter” theory of the mid-1980s played a significant role in the arms reductions of that period. But with the collapse of the Soviet Union and the reduction of U.S. and Russian nuclear arsenals, this aspect of nuclear war has faded from view. That’s not good. In the mid-2000s, climate scientists such as Alan Robock (Rutgers) took another look at nuclear winter theory. This time around, they used much-improved and much more detailed climate models than those available 20 years earlier. They also tested the potential effects of smaller nuclear exchanges. The result: an exchange involving just 50 nuclear weapons — the kind of thing we might see in an India-Pakistan war, for example — could loft 5 billion kilograms of smoke, soot and dust high into the stratosphere. That’s enough to cool the entire planet by about 2 degrees Fahrenheit (1.25 degrees Celsius) — about where we were during the Little Ice Age of the 17th century. Growing seasons could be shortened enough to create really significant food shortages. So the climatic effects of even a relatively small nuclear war would be planet-wide. What about a larger-scale conflict? A U.S.-Russia war currently seems unlikely, but if it were to occur, hundreds or even thousands of nuclear weapons might be launched. The climatic consequences would be catastrophic: global average temperatures would drop as much as 12 degrees Fahrenheit (7 degrees Celsius) for up to several years — temperatures last seen during the great ice ages. Meanwhile, smoke and dust circulating in the stratosphere would darken the atmosphere enough to inhibit photosynthesis, causing disastrous crop failures, widespread famine and massive ecological disruption. The effect would be similar to that of the giant meteor believed to be responsible for the extinction of the dinosaurs. This time, we would be the dinosaurs. Many people are concerned about North Korea’s advancing missile capabilities. Is nuclear war likely in your opinion? At this writing, I think we are closer to a nuclear war than we have been since the early 1960s. In the North Korea case, both Kim Jong-un and President Trump are bullies inclined to escalate confrontations. President Trump lacks impulse control, and there are precious few checks on his ability to initiate a nuclear strike. We have to hope that our generals, both inside and outside the White House, can rein him in. North Korea would most certainly “lose” a nuclear war with the United States. But many millions would die, including hundreds of thousands of Americans currently living in South Korea and Japan (probable North Korean targets). Such vast damage would be wrought in Korea, Japan and Pacific island territories (such as Guam) that any “victory” wouldn’t deserve the name. Not only would that region be left with horrible suffering amongst the survivors; it would also immediately face famine and rampant disease. Radioactive fallout from such a war would spread around the world, including to the U.S. It has been more than 70 years since the last time a nuclear bomb was used in warfare. What would be the effects on the environment and on human health today? To my knowledge, most of the changes in nuclear weapons technology since the 1950s have focused on making them smaller and lighter, and making delivery systems more accurate, rather than on changing their effects on the environment or on human health. So-called “battlefield” weapons with lower explosive yields are part of some arsenals now — but it’s quite unlikely that any exchange between two nuclear powers would stay limited to these smaller, less destructive bombs.

### 1AC -- Solvency

#### The plan allows for mass production – solving bioterror crises

Oriola 7

Taiwo A. Oriola (Cardiff Law School, and the ESRC Centre for Business Relationships, Accountability, Sustainability, & Society, University of Cardiff, United Kingdom). “AGAINST THE PLAGUE: EXEMPTION OF PHARMACEUTICAL PATENT RIGHTS AS A BIOSECURITY STRATEGY.” JOURNAL OF LAW, TECHNOLOGY & POL‑ ICY. 2007.. [http://illinoisjltp.com/journal/wp‑content/uploads/2013/10/05‑05‑ 08\_Oriola\_AHW\_Formatted\_FINAL.pdf](http://illinoisjltp.com/journal/wpcontent/uploads/2013/10/0505%2008_Oriola_AHW_Formatted_FINAL.pdf) // Phoenix

Time is of the essence in getting crucial drugs to victims of bioterrorism attacks to save as many lives as possible, and authorities should be able to mass‑produce cru‑ cial drugs with minimal delay. Drug stockpiling is of limited practical value since most drugs and vaccines have limited shelf‑life,53 and no one knows for sure when terrorists would strike. Moreover, drug stockpiling is not a feasible bioterrorism policy option for resource‑poor countries that, unlike the United States and other wealthy nations,54 are already overwhelmed by HIV/AIDS, and lack functional public health infrastruc‑ tures and the resources to stockpile bioterrorism‑specific drugs for their populations.55 Nevertheless, securing crucial drugs in the shortest time possible for those infected in a bioterrorism attack is no less important than other public health preparedness mea‑ sures. It would undoubtedly minimize loss of life and effectively contain further spread of diseases and mass hysteria.56 However, the high propensity for intellectual property rights wrangling—as exemplified by the skirmishes over Bayer’s ciprofloxacin in the wake of the September 11, 2001 anthrax attacks in the United States —could stymie authorities’ efforts to mass produce or parallel import crucial patented drugs within the shortest time possible, especially in resource‑poor countries of Africa, Asia, and Latin America. This makes an effective bioterrorism‑specific pharmaceutical patent appro‑ priation clause in international and national patent laws bereft of the bureaucratic trappings of the contemporary patent regime, and the TRIPS access to medicines paradigms.

#### Competition causes a skydive in prices – empirics prove

Boustany ‘18

Charles Boustany is a retired physician and former congressman from Louisiana, August 9, 2018, <http://fortune.com/2018/08/09/trump-drugs-prices-pharmaceutical-research/> Americans Fund Most of the World’s Drug Research. Here’s How Trump Can End That // Phoenix

If U.S. companies earned more revenue from foreign nations, then the American companies could spend more on R&D. This ultimately would result in new treatments and inject more competition into the U.S. drug market, leading to lower prices for American patients. Just consider what happened with the numerous next-generation hepatitis C medicines released in recent years. These revolutionary drugs have been shown to cure 70-99% of patients. The first medicine gained FDA approval in late 2013 and debuted with a list price of $84,000 for a full course of treatment. Over the next four years, several competing drugs flooded the market. Prices subsequently dropped about 70% a few years later, as manufacturers heavily discounted their cures to win market share. For some of these drugs, a full course of therapy is now less expensive than the average treatment costs incurred by patients using interferon and ribavirin—the go-to prescription regimen for decades. Patients on interferon and ribavirin frequently suffered severe side effects; the new next-generation cures are comparatively painless. Or consider PCSK9 inhibitors. These drugs can sharply lower so-called bad cholesterol levels in patients at high risk of heart disease. A recent study found that one PCSK9 inhibitor, Praluent, reduced patients’ risk of cardiovascular disease by 15% and their risk of death by 29%. Despite the drug’s effectiveness, its manufacturer recently announced a 69% price cut to win market share. In short, free-market competition works. It delivers cutting-edge medicines at reasonable prices.

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

Erfani et al, 21

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