# 1ac

### fw 0:39

#### 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

#### C – Bureaucrats aren’t philosophers – policymakers do not have experience with dense frameworks so they don’t understand how to apply them to specific instances but they do understand that pain is bad and pleasure is good because it’s intrinsic to existing.

#### [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

#### c. Repugnance – if their framework cannot explain why people dying is bad – you should reject it because it cannot disavow of atrocities. You shouldn’t vote for a framework that can’t say the holocaust was a bad thing.

#### d. Performativity – us having a moral debate proves moral uncertainty because it means we are not certain about which framework is true - means we should preserve our ability to find the true framework

### plan [v2] – 0:05

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

### bioterror – 1:30

#### 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

### drug prices – 1:30

#### 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.”

#### Future mutations will cause extinction – it only takes one ‘super-spreader’

Bar-Yam 16

Yaneer Bar-Yam 7-3-2016 “Transition to extinction: Pandemics in a connected world” <http://necsi.edu/research/social/pandemics/transition> (Professor and President, New England Complex System Institute; PhD in Physics, MIT)//Elmer rc by Phoenix

Watch as one of the more aggressive—brighter red — strains rapidly expands. After a time it goes extinct leaving a black region. Why does it go extinct? The answer is that it spreads so rapidly that it kills the hosts around it. Without new hosts to infect it then dies out itself. That the rapidly spreading pathogens die out has important implications for evolutionary research which we have talked about elsewhere [1–7]. In the research I want to discuss here, what we were interested in is the effect of adding long range transportation [8]. This includes natural means of dispersal as well as unintentional dispersal by humans, like adding airplane routes, which is being done by real world airlines (Figure 2). When we introduce long range transportation into the model, the success of more aggressive strains changes. They can use the long range transportation to find new hosts and escape local extinction. Figure 3 shows that the more transportation routes introduced into the model, the more higher aggressive pathogens are able to survive and spread. As we add more long range transportation, there is a critical point at which pathogens become so aggressive that the entire host population dies. The pathogens die at the same time, but that is not exactly a consolation to the hosts. We call this the phase transition to extinction (Figure 4). With increasing levels of global transportation, human civilization may be approaching such a critical threshold. In the paper we wrote in 2006 about the dangers of global transportation for pathogen evolution and pandemics [8], we mentioned the risk from Ebola. Ebola is a horrendous disease that was present only in isolated villages in Africa. It was far away from the rest of the world only because of that isolation. Since Africa was developing, it was only a matter of time before it reached population centers and airports. While the model is about evolution, it is really about which pathogens will be found in a system that is highly connected, and Ebola can spread in a highly connected world. The traditional approach to public health uses historical evidence analyzed statistically to assess the potential impacts of a disease. As a result, many were surprised by the spread of Ebola through West Africa in 2014. As the connectivity of the world increases, past experience is not a good guide to future events. A key point about the phase transition to extinction is its suddenness. Even a system that seems stable, can be destabilized by a few more long-range connections, and connectivity is continuing to increase. So how close are we to the tipping point? We don’t know but it would be good to find out before it happens. While Ebola ravaged three countries in West Africa, it only resulted in a handful of cases outside that region. One possible reason is that many of the airlines that fly to west Africa stopped or reduced flights during the epidemic [9]. In the absence of a clear connection, public health authorities who downplayed the dangers of the epidemic spreading to the West might seem to be vindicated. As with the choice of airlines to stop flying to west Africa, our analysis didn’t take into consideration how people respond to epidemics. It does tell us what the outcome will be unless we respond fast enough and well enough to stop the spread of future diseases, which may not be the same as the ones we saw in the past. As the world becomes more connected, the dangers increase. Are people in western countries safe because of higher quality health systems? Countries like the U.S. have highly skewed networks of social interactions with some very highly connected individuals that can be “superspreaders.” The chances of such an individual becoming infected may be low but events like a mass outbreak pose a much greater risk if they do happen. If a sick food service worker in an airport infects 100 passengers, or a contagion event happens in mass transportation, an outbreak could very well prove unstoppable.

### solvency – 0:40

#### 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.

#### 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.

### Extra – 1:30

#### Reject innovation args

#### 1.] Courts clogged now – COVID, criminal suits, 6th amendment violations

Finnegan and Dolan 4/12

[(Michael Finnegan, Los Angeles Times reporter covering federal courts and law enforcement in California. Maura Dolan, California-based legal affairs writer for the Los Angeles Times) " Coronavirus shutdown of jury trials upends California's federal courts," Los Angeles Times, 4-12-2021, https://www.latimes.com/california/story/2021-04-12/coronavirus-federal-court-jury-trials-shutdown-california] TDI rc // Phoenix

Ronald Ware spent five months in a Santa Ana jail awaiting trial after his arrest in Brea last summer on a federal gun charge. His day in court never came. U.S. District Judge Cormac J. Carney dismissed the case in January, saying emergency rules that shut down federal jury trials during the pandemic had denied Ware his right to a speedy trial. “Nowhere in the Constitution is there an exception for times of emergency or crisis,” Carney wrote in the ruling that set Ware free. Carney has tossed criminal charges against a jewelry-store robbery suspect and [three others](https://www.latimes.com/socal/daily-pilot/entertainment/story/2021-02-25/u-s-judge-drops-charges-in-fifth-criminal-case-citing-suspects-right-to-a-speedy-trial) for the same reason. The decision to shut down all jury trials, he found, was excessive. The 13-month suspension of trials in the federal court system’s Central District of California, which includes Los Angeles and six neighboring counties, has disrupted the prosecution of hundreds of alleged drug dealers, tax cheats, cybercriminals, child porn purveyors and health insurance swindlers. It has clogged the courts with an unprecedented backlog of both criminal and civil cases. While many of those charged with crimes have been free on bail as they await trial, others have remained behind bars, enduring long stretches of solitude as detainees are kept apart to minimize spread of the coronavirus. Guan Lei, a Chinese scholar in the U.S. for research at UCLA, has been detained for eight months on a charge of [destroying a hard drive](https://www.latimes.com/california/story/2020-08-28/ucla-researcher-accused-of-destroying-evidence-latest-arrest-in-crackdown-on-visiting-chinese-scientists) in an attempt to obstruct a federal investigation. After two postponements, Guan’s scheduled May 4 trial will have to be delayed again, because Los Angeles federal court will not yet be open. Guan appeared at a court hearing Thursday by video from a downtown L.A. jail. “Mr. Guan, I’m very sorry it’s taken this long to give you a trial,” U.S. District Judge Michael W. Fitzgerald told him. Case dismissals have been rare; prosecutors have appealed Carney’s decisions. But an increasing number of defendants are alleging violations of their speedy trial rights, casting uncertainty over their cases as the pandemic subsides and federal courts prepare to reopen. Criminal defendants have the right to a trial within a set time period. In federal court, if they invoke that right, their trial generally must start within 70 days of when charges were filed. Typically, judges grant requests for more time to prepare for trial. Guan Lei and others charged with federal crimes have spent much of the pandemic detained at the Metropolitan Detention Center in downtown Los Angeles during a shutdown of federal jury trials. (Robyn Beck/AFP via Getty Images) One of the next defendants to seek dismissal of charges on speedy trial grounds in federal court will be Jerome Terry, who has been jailed for three years awaiting trial. He was arrested in connection with his alleged role in a sex-trafficking conspiracy in which two aspiring Canadian models were forced to work as prostitutes in the Hollywood Hills. Terry’s trial was most recently put off until July. “There’s this general feeling of purgatory,” said Meghan Blanco, his attorney. With nearly 20 million residents, California’s Central District is the country’s most populous federal judicial district, spanning Los Angeles, Orange, Riverside, San Bernardino, Ventura, Santa Barbara and San Luis Obispo counties. Even before the pandemic, vacancies on the bench had left overworked judges struggling to keep up with [growing caseloads.](https://www.cacd.uscourts.gov/sites/default/files/CACD_FY2019_Annual_Report.pdf) When jury trials stopped in March 2020, 10 of the district’s 28 judicial slots were unfilled. Six vacancies remain for President Biden to fill. In the year before the trial shutdown, more than 16,000 new cases were filed in the district: 15,514 civil lawsuits and 1,138 criminal prosecutions. Most criminal cases yield guilty pleas, and most civil lawsuits end in settlements. But nearly 150 trials typically occur each year in the district’s three courthouses — in Los Angeles, Santa Ana and Riverside. Pretrial hearings have kept moving over the last 13 months, thanks largely to Zoom. But the strongest incentive for guilty pleas and civil settlements often comes on the eve of a trial, so many cases that might have ended in normal times have instead lumbered along. “Once you open up the courthouse to trials, I think that, in and of itself, helps alleviate the backlog,” said U.S. District Judge Philip S. Gutierrez, the chief judge of the Central District. “There’s always going to be that 150 cases that you’re going to have to try, and those are backed up. So I think in the short term, we’re going to be working really hard and trying more cases than we would otherwise try once we get up to speed.” Criminal trials will have top priority, he said, starting with defendants in custody. With the recent decline in California’s coronavirus infections, jury summonses have been issued for federal trials to resume May 10 in Orange County. Gutierrez expects trials in Los Angeles and Riverside to start back up in June. Safety measures will be extensive. Jury selection will be tightly choreographed so it takes place in large courtrooms where everyone can stay six feet apart. Elevator use will be curtailed. Plexiglass will section off each judge, witness and court reporter. Masks will be mandatory, with possible exceptions for witnesses. In many other jurisdictions, trials have moved forward during the pandemic. Most visible is the ongoing murder trial in state court of former Minneapolis Police Officer Derek Chauvin in the death of George Floyd at a time when the coronavirus is far more widespread in Minnesota than in California. State courts in California have also pressed ahead with trials. In January and February, four employees of the [Los Angeles County Superior Court](https://www.latimes.com/california/story/2021-02-09/lawsuit-seeks-to-stop-l-a-courts-from-holding-some-civil-trials-due-to-covid-concerns) system died from COVID-19; it’s unclear whether they caught the coronavirus in court.

#### That alone means companies can’t enforce patents and investors lose certainty

Ball and Kesan 10

[(Gwendolyn G. Ball Research Fellow Business, Economics and Law Group Institute for Genomic Biology and Information Trust Institute University of Illinois Jay P. Kesan Professor and Mildred Van.Voorhis Jones Faculty Scholar College of Law Business, Economics and Law Group Institute of Genomic Biology University of Illinois) “Judges, Courts and Economic Development: the Impact of Judicial Human Capital on the Efficiency and Accuracy of the Court System” unpublished manuscript April 30, 2010] TDI rc // Phoenix

There is a long-standing consensus that the clear definition and enforcement of property rights is an important element in economic development.1 This consensus is of more than scholarly concern; the experience in the reforming socialist economies demonstrates that secure property rights play an major role in market economies.2 But well-designed laws and regulations cannot ensure property rights without an institution that will enforce those rights and settle disputes, and in nearly all countries the final forum for resolving property rights disputes is the court system. **Thus, a well-functioning court system is crucial for economic growth.** Following this line of reasoning, economists have considered the operations of court systems an important area of study. However, economic study of courts has usually focused on the design of incentive mechanisms to ensure an accountable and impartial judiciary. Much of this literature discusses the inherent tradeoff between judicial independence and judicial accountability.3 Nonetheless, some authors have noted that even if judicial incentives are perfectly designed, the organization of the court system and the rules under which it operates can have a dramatic impact on its effectiveness as an economic institution. While it is true that judges need to be protected from outside influences which could bias their decision, even unbiased decisions must accurately interpret the law. Inaccurate or well meaning but seemingly idiosyncratic decisions will decrease confidence in the legal system and increase uncertainty in economic activity.4 And accuracy alone is not sufficient for a high quality court system. Disputes must be resolved and decisions must be rendered in a timely manner **if they are to provide investors with the security and certainty necessary to promote investment.** Thus, a judicial system must not only be impartial, it must be accurate and efficient as well. International institutions promoting economic development, such as The World Bank, have recognized this link and launched technical assistance efforts to improve the administration of court systems around the developing world.5 Economic scholarship also recognizes the importance of a well-managed court system. In their study of the relationship between entrepreneurial investment and the “quality” of the legal systems across states in Mexico, Laeven and Woodruff, define “quality” not only as “the impartiality of judges” but also as “the quality of judges; the adequacy of judicial resources; the efficiency of enforcement of rulings; the efficiency of judicial administration more generally; the cost, ease of use and completeness of property registries and the adequacy of local legislation related to contract enforcement.”6 Rosales-Lopez explores the impact of recent reforms in the Spanish court system on its ability to resolve disputes, citing the “problems such as congestion, the high cost and delay of procedures [that weaken] the access and citizens’ equality before the law, as well as the enforcement of laws and the guarantees of property rights and contracts.”7 Choi, Gulati and Posner8 compare compare appointed and judges and find ambiguous results regarding the “independence” of the two judicial systems. However, they also evaluate both the “productivity” (as measured by the number of opinons written) and the “quality” (as measured by the number of citations received by such opinions) of judges in the two systems. Thus, to ensure public confidence and promote investment, courts must not only be impartial in administering justice, but also accurate and efficient in the resolution of disputes.9 . Finally, in their massive international study of adjudication of simple civil cases, Djankov, et. al.[3] analyze the importance of court procedures on both accountability and also on accuracy and case duration. Thus Recent economic scholarship has acknowledged the importance of case duration in analyzing the operation of court systems. However, what this literature generally neglects is that, just as there may be a trade-off between accountability and independence, there may be a trade-off between court reforms promoting accountability and those promoting increased judicial “human capital.”10 The various proposed measures to increase the“openness” and “accountability” of courts–election, versus appointment of judges; term limits; etc.–all involve the actual or threatened removal of judges from office. However, the job of managing a case docket is one which a judge must learn on the job. Presumably, a judge with many years on the bench should have developed a set of skills to keep cases flowing smoothly–scheduling the necessary court procedures, managing lawyers, etc. And previous legal experience may not have exposed a new judge to all the areas of the law s/he may see on the bench; as a judge sees more cases of a particular type, his/her knowledge of that area of the law should become deeper and richer, leading to more accurate decisions and rulings. Thus, the importance of general managerial skills and familiarity with special areas of the law can play a part in discussions of judicial term limits as well as whether judges should be elected or appointed. Maskin and Tirole note this problem by acknowledging that there may be a tradeoff between measures designed to create an unbiased court system and the “set up” costs of a new judge, including the “learning by doing” which occurs on the bench.11 And there is empirical verification that some policies designed to increase accountability may decrease experience and the resultant stock of human capital. In his study of state court judges, for example, Hanssen finds that appointed judges serve 50% longer on average than do elected judges.12 Thus, there is cause to worry that some legal reforms my reduce judicial experience due to a legal “switching cost” which kicks in when judges are removed from the bench. The possibility of such costs could be an important consideration in implementing reforms designed to increase the contribution of the courts to economic development. If the costs are great, reforms which lead to too much “churning” on the bench might be avoided. In fact, it might be worth pursuing policies which increase judicial experience and human capital, even if such changes might lead to a decrease in “impartiality.” For example, many countries employ specialized court systems which cover only one type of particularly complex case case. An argument for such specialized courts is that they lead to greater judicial human capital as judges specialize on one area of the law. But one argument against them is that judges and lawyers practicing in that area might become overly familiar, thereby decreasing impartiality.13 However, behind all the arguments about these potential tradeoffs between openness and experience lies one fact: this underlying hypothesis–that there is a positive relationship between judicial human capital and the accuracy and efficiency of the court system–must be empirically verified. This paper performs such an analysis, utilizing a class of litigation particulary suited to the question: litigation of patent infringement disputes in the United States. All U.S. patent cases must be filed in the U.S. Federal District Court system. Thus all patent cases are litigated using a uniform set of rules and procedures; data drawn form other types of litigation, which can be filed in both federal and state courts, has to account for a wide variety of legal statutes, precedents and procedural rules.14 In addition, all cases in U.S District Courts are randomly assigned to judges through a “round robin” system, freeing our analysis of experience from the type of endogeneity that plagues studies of education. Moreover, patent law is a highly specialized area of the law, allowing for a distinction between the “general” judicial human capital acquired through time on the bench and “specialized” human capital acquired through experience with a particular area of the law. Finally, examination of these issues with respect to patent cases has particular policy relevancy; as of this writing, the U.S. is contemplating the creation of a specialized patent trial court in order to increase the specialized knowledge of judges presiding over such cases. Thus, study of the relationship between judicial experience and the litigation of patent cases is both highly suitable and timely. The rest of the paper pursues this issue as follows. First, we provide some background on patent litigation in the United States and why it provides a good vehicle for the study of the impact of judicial human capital. Then, we outline the data collection procedure, including details about the data generating process which make unobserved heterogeneity a cause for concern, as well as the various methods for defining judicial experience. In the next section, we estimate the relationship between experience and efficiency using a duration model and using appropriate techniques for controlling for the impact of both observed and unobserved heterogeneity. Finally, we explore the relationship between experience and accuracy by analyzing the probability that a case will be reversed on appeal. Through these mechanisms we will examine the relationship between judicial human capital and the accuracy and efficiency of the court system. 2 Accurate and Efficient Patent Litigation and Judicial Human Capital. **While most economic scholarship analyzing the importance of the courts has focused on disputes over real property, the relationship between the court system and investment is no less strong for intellectual property.** And to a large extent, the relationship between the courts and the patent system depends on the quality of “judicial human capital.” In the United States, as in many countries, the courts are a crucial part of the patent system to the extent that the patent system is can be termed a two-stage process. In the first stage, the U.S. Patent and Trademark Office grants property rights to inventors. In the second stage, inventors can protect those rights through patent infringement suits in the courts and alleged infringers have the right to challenge improvidently granted patents and have them declared invalid. As a consequence, some authors have referred to patent rights as being “probabilistic,” depending not only on whether the innovation embodied in the patent has commercial value, but also on the refinement of that patent property right after litigation.15 **Just as with real property, the management of the court system has an impact on both patenting behavior and on investment in research and development**. **While the majority of all patents are not litigated, those that are disputed in the courts are among the most valuable**.16 **The rules governing the court system may even “feed back” into patenting behavior;** some authors have found evidence that the increasingly “patent friendly” rules17 adopted by the courts are a major factor in the surge in patenting since the 1980s.18 Moreover, the ability to define the “probabilistic” property rights is an important element in determining whether patents fulfill their purpose of promoting innovation.19 Finally, the costs associated with the patent systems can be reduced by an efficient court system; firms may hesitate to invest in new products and technologies which may infringe on existing patents, so any additional delay or cost in clarifying existent rights may slow the process of innovation. The more quickly and cheaply these rights are defined, the more beneficial the patent system will be in promoting and not inhibiting innovation and investment.

#### Biotech innovation is false

#### 1.] – limits out innovation from developing countries and suffocates new developments in bureaucracy

Chao and Mody 15

[(Tiffany E, Department of Surgery, Massachusetts General Hospital, Boston, Massachusetts, USA) (Gita N, Program in Global Surgery and Social Change, Harvard Medical School, Boston, Massachusetts, USA) “The impact of intellectual property regulation on global medical technology innovation,” BMJ Journals, 3/5/15. <https://innovations.bmj.com/content/1/2/49>] TDI rc // Phoenix

Technology innovation has the potential to expand equitable healthcare to underserved populations in global health. At the same time, device patents and their legislation can be barriers to innovation for developing countries. For example, the WHO has developed a ‘Compendium of innovative health technologies for low-resource settings’.1 Most of these technologies are inexpensive to develop, inexpensive to manufacture and relatively easy to use. Nevertheless, the WHO clearly states that inclusion in their Compendium does not necessarily mean “the use of the technologies is…in accordance with the national laws and regulations of any country, including…patent laws.” Of course, it would be a challenge to innovate in the absence of legislation on trademark laws and trade secrets. Since the profitability of devices depends on leveraging existing pathways for device development, manufacturing and distribution, intellectual property (IP) protection is a major aspect of commercialisation of technologies. Certainly investors in new start-ups look for IP protection as a high priority. Regulation of IP, therefore, is necessary to stimulate invention and new technologies. However, for technologies in low-resource settings, IP protection has historically been sparse. The World Intellectual Property Organisation reports that in 2012, high-income countries shared 64.5% of the world's total number of patents, while lower-middle-income countries held only 2.9%, with low-income countries owning only 0.4%.2 This disparity clearly demonstrates limited IP support for frugal innovation emerging from developing countries. Ironically, inventors in low-resource settings are presented with an abundance of important clinical needs and fewer established infrastructure constraints, so that there is a vast untapped potential for innovations to originate in these settings and move to the more developed world (known as reverse innovation).3 Inventors of healthcare devices for the developing world have varying interest in pursuing patent protection of their devices.i High cost, time and logistics are oft-cited reasons for not pursuing patents. Factors influencing the cost include not just the expense of filing (which can be thousands of dollars) but also fees for legal counsel and maintenance of the patent. These costs are a barrier in their own right, and they can also lead to increases in the price of the end product, which can be significant in a highly cost-sensitive market. An additional barrier is limited knowledge of complicated international patent laws with inadequate access to qualified IP lawyers. In cases where out-of-country universities are involved in patenting the technologies, the bureaucracy involved in dealing with the technology transfer office and their inexperience in executing foreign filings is a barrier (though there are counterexamples of very significant university partnerships in developing bottom-of-the-pyramid technologies). Another major reason for limited IP protection of technology for low-resource settings is the spirit behind the innovation in the first place; inventors designing for low-resource settings are often interested in keeping their device design open source, to maximise spread and impact. Also, consumers of the technologies are highly focused on affordability. Prosecution of infringement of IP laws in low-resource settings is limited, and violating IP laws is a pragmatic way for ‘copycats’ to reduce their investment costs in research and development, and quickly sell products, getting healthcare technology to those who need it. Most countries do operate under patent laws compliant with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, a framework that requires IP laws to resemble those of developed areas. This agreement applies to all WTO member countries. Therefore, unless a developing country wishes to withdraw from the WTO, its IP laws are required to resemble those in the USA or Europe, leaving little flexibility to tailor to local needs.4 This means that international IP laws are often in the economic interests of developed countries rather than in the innovation interests of other countries.5 As a result of these issues, the most prevalent strategy among global health technologies has often been to develop without regard for IP protection. A major advantage of this approach is that it can allow for open-source innovation, permitting technological learning through imitation. This approach can also eliminate the many costs of foreign protection or patent enforcement, allowing for a frugal approach to the initial development of the technology itself. Furthermore, this approach is most in line with the collaborative spirit of global health innovation. Nevertheless, there do exist some opportunities for frugal approaches to IP. Simplified legislation or pro bono opportunities for counsel allow an effective system of justice for inventors to take full advantage of legislation to promote innovation.6 Grants and other forms of non-dilutive funding enable inventors to develop global health technologies without being overly concerned about licensing or investment opportunities. Some potential legislative changes also could be made, such as creation of public–private partnerships that could facilitate government-funded research to be protected and disseminated at affordable cost in such countries.7 Other existing exemptions in international agreements could be implemented, including research exemptions for experimental uses of IP or government imposed non-exclusive or compulsory licensing.8 While there remains potential for more imaginative IP legislation in developing countries, original technologies continue to be developed in these settings. On the international stage, forums such as the WHO Global Forum on Medical Devices highlight emerging technologies that “impact the continuum of care ranging from screening to diagnosis, treatment and rehabilitation under the Universal Health Coverage Strategy.”9 These platforms demonstrate that despite the hurdles faced by developing economies in capturing the benefits of IP laws, global health technologies can be and will continue to be developed outside of these limitations.

#### 2.] by constraining competition

Lindsey 21 [Brink, vice president-Niskanean Center, Brookings Institute, "Why intellectual property and pandemics don't mix" June 6, <https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/> // rc Phoenix

Here is the basic bargain offered by patent law: encourage the creation of useful new ideas for the long run by slowing the diffusion of useful new ideas in the short run. The second half of the bargain, the half that imposes costs on society, comes from the temporary exclusive rights, or monopoly privileges, that a patent holder enjoys. Under U.S. patent law, for a period of 20 years nobody else can manufacture or sell the patented product without the permission of the patent holder. This allows the patent holder to block competitors from the market, or extract licensing fees before allowing them to enter, and consequently charge above-market prices to its customers. Patent rights thus slow the diffusion of a new invention by restricting output and raising prices.