# Neg

### Framework

#### The value criterion must be maximizing well-being for everyone.

#### There are two main reasons for this:

#### 1] Death is bad and outweighs – a] agents can’t act if they fear for their bodily security which constrains every ethical theory, b] it destroys the subject itself – kills any ability to achieve value in ethics since life is a prerequisite which means it’s a side constraint since we can’t reach the end goal of ethics without life

#### 2] Existential threats outweigh – all life has infinite value and extinction eliminates the possibility for future generations – err negative, because of innate cognitive biases that prevent policymaking to solve extinction

Also default util bc they didn’t read a fw and its abusive to read a new one in the 1ar

## biotech da

#### Continued biotech innovation is key to cutting emissions by half and prevent the 2 degree tipping point

Heath 21, Michelle Mcmurry-Heath May 21, 2021, 5-21-2021, "To help solve climate change, look to the biosciences," STAT, https://www.statnews.com/2021/05/21/climate-change-solutions-from-biosciences/ tw

President Biden’s pledge to cut U.S. greenhouse gas emissions in half by 2030 is an admirable and ambitious undertaking. It’s nearly double the goal set by President Obama in 2015. And it establishes the United States as a world leader in battling climate change. The biosciences, including biotechnology, will play a pivotal role in the fight against climate change. It is already leading the way on several fronts. According to a report from BIO, the organization I work for, the biotech industry’s green initiatives could mitigate the equivalent of 3 billion tons of carbon dioxide every year by 2030, or about half of the country’s annual CO2 emissions. Food consumption — and production — is central to human existence. Global food production accounts for one-quarter of greenhouse gas emissions. A recent report from an international team of researchers concluded that even if all other fossil fuel emissions were eliminated, emissions from food production alone would prevent us from reaching a key goal of the climate change agreement signed in Paris: preventing the global temperature from rising more than 2 degrees Celsius. Halting food production isn’t an option, so biotech companies are helping farmers become part of the climate solution. Take, for example, Boston-based Joyn Bio. It is [are] engineering bacteria that pull nitrogen directly from the atmosphere. These microbes then pass the nitrogen to crops like wheat and corn, reducing the need to make, transport, and apply nitrogen fertilizers, which reduces greenhouse gas emissions. Biotechnology can also help protect food from climate change. As fungal and bacterial infections accelerated by human-driven environmental disturbances threaten to wipe out Cavendish bananas, Tropic Biosciences in the United Kingdom is using CRISPR gene-editing technology to engineer infection-resistant bananas. Fuel is another target for biotechnology. Transportation accounts for the highest percentage of U.S. greenhouse gas emissions. While electric cars are gaining popularity, and the $174 billion allocated to support the transition to electrics in Biden’s American Jobs Plan is important, biofuels — which are carbon neutral — will be needed to help reduce emissions in transportation and need comparable support. The biotech company Synthetic Genomics, for instance, is utilizing saltwater algae, which [and] convert sunlight and carbon dioxide into biomass, to make sustainable auto fuel. By 2025, 10,000 barrels of the algal biofuel could be produced per day for commercial use. Biotech firms are already stepping up. Companies like Neste, Gevo, and World Energy are using everything from algae to used or wasted cooking oil to create sustainable jet fuels. LanzaTech recycles carbon from industrial emissions and other sources and turns it into aviation fuel — and has recently partnered with other corporations to bring that fuel to market for commercial airline use. With help from biotechnology, the U.S. can achieve the climate change goals outlined by the Biden administration and the Paris Agreement. Human progress and technology got us into this mess. That same ingenuity can help get us out.

#### Biotech patents are high now and solving warming but waivers set an alarming precedent – the threat is enough to kill investment and devastate international cooperation

Brand 21, Melissa Brand, 5-26-2021, "TRIPS IP Waiver Could Establish Dangerous Precedent for Climate Change and Other Biotech Sectors," IPWatchdog, https://www.ipwatchdog.com/2021/05/26/trips-ip-waiver-establish-dangerous-precedent-climate-change-biotech-sectors/id=133964/ tw

While the discussions around waiving intellectual property (IP) rights set forth in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) are currently (and somewhat amorphously) limited to COVID-19 related drug and medical products, it is probably shortsighted to ignore the implications for other technologies critical to sustaining our environment and advancing a more healthful world. In fact, if we want to ensure continued investment in these technologies, we should be very concerned about the message conveyed by the international political tide: if you overcome a challenging scientific problem and your solution has the potential to save lives, be prepared to be subjected to intense political pressure and to potentially hand over your technology without compensation and regardless of the consequences. The biotech industry is making remarkable advances towards climate change solutions, and it is precisely for this reason that it can expect to be in the crosshairs of potential IP waiver discussions. President Biden is correct to refer to climate change as an existential crisis. Yet it does not take too much effort to connect the dots between President Biden’s focus on climate change and his Administration’s recent commitment to waive global IP rights for Covid vaccines (TRIPS IP Waiver). “This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures.” If an IP waiver is purportedly necessary to solve the COVID-19 global health crisis (and of course we dispute this notion), can we really feel confident that this or some future Administration will not apply the same logic to the climate crisis? And, without the confidence in the underlying IP for such solutions, what does this mean for U.S. innovation and economic growth? United States Trade Representative (USTR) Katherine Tai was subject to questioning along this very line during a recent Senate Finance Committee hearing. And while Ambassador Tai did not affirmatively state that an IP waiver would be in the future for climate change technology, she surely did not assuage the concerns of interested parties. The United States has historically supported robust IP protection. This support is one reason the United States is the center of biotechnology innovation and leading the fight against COVID-19. However, a brief review of the domestic legislation arguably most relevant to this discussion shows just how far the international campaign against IP rights has eroded our normative position. The Clean Air Act, for example, contains a provision allowing for the mandatory licensing of patents covering certain devices for reducing air pollution. Importantly, however, the patent owner is accorded due process and the statute lays out a detailed process regulating the manner in which any such license can be issued, including findings of necessity and that no reasonable alternative method to accomplish the legislated goal exists. Also of critical importance is that the statute requires compensation to the patent holder. Similarly, the Atomic Energy Act contemplates mandatory licensing of patents covering inventions of primary importance in producing or utilizing atomic energy. This statute, too, requires due process, findings of importance to the statutory goals and compensation to the rights holder. A TRIPS IP waiver would operate outside of these types of frameworks. There would be no due process, no particularized findings, no compensation, and no recourse. Indeed, the fact that the World Trade Organization (WTO) already has a process under the TRIPS agreement to address public health crises, including the compulsory licensing provisions, with necessary guardrails and compensation, makes quite clear that the waiver would operate as a free for all. In other words, Ambassador Tai acknowledged that the scope of the current TRIPS IP waiver discussions includes the concept of forced tech transfer. In the context of climate change, the idea would be that companies who develop successful methods for producing new seed technologies and sustainable biomass, reducing greenhouse gases in manufacturing and transportation, capturing and sequestering carbon in soil and products, and more, would be required to turn over their proprietary know-how to global competitors. While it is unclear how this concept would work in practice and under the constitutions of certain countries, the suggestion alone [which] could be devastating to voluntary international collaborations. Even if one could assume that the United States could not implement forced tech transfer on its own soil, what about the governments of our international development partners? It is not hard to understand that a U.S.-based company developing climate change technologies would be unenthusiastic about partnering with a company abroad knowing that the foreign country’s government is on track – with the assent of the U.S. government – to change its laws and seize proprietary materials and know-how that had been voluntarily transferred to the local company. Developing climate change solutions is not an easy endeavor and bad policy positions threaten the likelihood that they will materialize. These products have long lead times from research and development to market introduction, owing not only to a high rate of failure but also rigorous regulatory oversight. Significant investment is required to sustain and drive these challenging and long-enduring endeavors. For example, synthetic biology companies critical to this area of innovation raised over $1 billion in investment in the second quarter of 2019 alone. If investors cannot be confident that IP will be in place to protect important climate change technologies after their long road from bench to market, it is unlikely they will continue to invest at the current and required levels. It is quite reasonable to be worried about the broad implications of a TRIPS IP waiver precedent. International campaigns to weaken IP rights seem to be taking hold in U.S. domestic policy. The TRIPS IP waiver discussions will not conclude in the near term and will not yield more shots in people’s arms. This is not even truly disputed, as our own administration acknowledges that the goal here is technology transfer abroad. Given the signaling that our Administration believes waiving IP rights is an appropriate measure to end global crises, it is proper to worry that facets of the biotech sector addressing climate change may be next on the chopping block.

#### Climate change is a threat multiplier and causes extinction

Torres 16, Phil Torres, 7-22-2016, "Op-ed: Climate Change Is the Most Urgent Existential Risk," Future of Life Institute, https://futureoflife.org/2016/07/22/climate-change-is-the-most-urgent-existential-risk/?cn-reloaded=1

Climate change and biodiversity loss may pose the most immediate and important threat to human survival given their indirect effects on other risk scenarios. As such, they have the capacity to raise or lower the probability of other risks scenarios unfolding. Ask yourself the following: are wars more or less likely in a world marked by extreme weather events, megadroughts, food supply disruptions, and sea-level rise? Are terrorist attacks more or less likely in a world beset by the collapse of global ecosystems, agricultural failures, economic uncertainty, and political instability? Both government officials and scientists agree that the answer is “more likely.” For example, the current Director of the CIA, John Brennan, recently identified “the impact of climate change” as one of the “deeper causes of this rising instability” in countries like Syria, Iraq, Yemen, Libya, and Ukraine. Similarly, the former Secretary of Defense, Chuck Hagel, has described climate change as a “threat multiplier” with “the potential to exacerbate many of the challenges we are dealing with today — from infectious disease to terrorism.” The Department of Defense has also affirmed a connection. In a 2015 report, it states, “Global climate change will aggravate problems such as poverty, social tensions, environmental degradation, ineffectual leadership and weak political institutions that threaten stability in a number of countries.” Scientific studies have further shown a connection between the environmental crisis and violent conflicts. For example, a 2015 paper in the Proceedings of the National Academy of Sciences argues that climate change was a causal factor behind the record-breaking 2007-2010 drought in Syria. This drought led to a mass migration of farmers into urban centers, which fueled the 2011 Syrian civil war. Some observers, including myself, have suggested that this struggle could be the beginning of World War III, given the complex tangle of international involvement and overlapping interests. The study’s conclusion is also significant because the Syrian civil war was the Petri dish in which the Islamic State consolidated its forces, later emerging as the largest and most powerful terrorist organization in human history. The point is that climate change and biodiversity loss could very easily push societies to the brink of collapse. This will exacerbate existing geopolitical tensions and introduce entirely new power struggles between state and nonstate actors. At the same time, advanced technologies will very likely become increasingly powerful and accessible. As I’ve written elsewhere, the malicious agents of the future will have bulldozers rather than shovels to dig mass graves for their enemies. If the conversation were to end here, we’d have ample reason for placing climate change and biodiversity loss at the top of our priority lists. But there are other reasons they ought to be considered urgent threats. I would argue that they could make humanity more vulnerable to a catastrophe involving superintelligence and even asteroids. Now imagine trying to solve these problems amidst a rising tide of interstate wars, civil unrest, terrorist attacks, and other tragedies? The societal stress caused by climate change and biodiversity loss will almost certainly compromise important conditions for creating friendly AI, such as sufficient funding, academic programs to train new scientists, conferences on AI, peer-reviewed journal publications, and communication/collaboration between experts of different fields, such as computer science and ethics.

## pharma da

#### Investment and innovation are high now, $$ is key

**Swagel 21** Phillip L. Swagel, Director of the Congressional Budget Office, 4/2021, "Research and Development in the Pharmaceutical Industry," Congressional Budget Office, https://www.cbo.goc/publication/57126#\_idTextAnchor020 wr tw

Policymakers have considered policies that would lower drug prices and reduce federal drug expenditures. Such policies would probably reduce the industry’s incentive to develop new drugs. The pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation. The share of revenues that drug companies devote to R&D has also grown: On average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses in 2019, which is almost twice as large a share of revenues as they spent in 2000. That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On average, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), which are costly to develop, hard to imitate, and frequently have high prices. Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA. In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug. Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and during that time the company does not receive a financial return on its investment in developing that drug. Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. In particular, spending on drug R&D increased by nearly 50 percent between 2015 and 2019. Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. In real terms, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, the trend is broadly representative of R&D spending by the industry as a whole.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3 Although total R&D spending by all drug companies has trended upward, small and large firms generally focus on different R&D activities. Small companies not in PhRMA devote a greater share of their research to developing and testing new drugs, many of which are ultimately sold to larger firms (see Box 1). By contrast, a greater portion of the R&D spending of larger drug companies (including those in PhRMA) is devoted to conducting clinical trials, developing incremental “line extension” improvements (such as new dosages or delivery systems, or new combinations of two or more existing drugs), and conducting postapproval testing for safety-monitoring or marketing purposes.

#### **Strong IPRs are key to risk taking and innovation**

Ezell and Cory 19, Stephen Ezell, Nigel Cory. 2019. "The Way Forward For Intellectual Property Internationally". Information Technology And Innovation Foundation. https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally.

Robust intellectual property rights spur innovative activity by increasing the appropriability of the returns to innovation, enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks. By raising the private rate of return closer to the social rate of return, intellectual property rights address the knowledge-asset incentive problem, allowing inventors to realize economic gain from their inventions, thereby catalyzing investment in knowledge creation. If innovators know that most of the benefits from their innovations would go to others without compensation, they would be much less likely and capable of engaging in future innovations. In addition, as they capture a larger portion of the benefits of their innovative activity, innovating companies obtain the resources to pursue the next generation of innovative activities. IP thus produces a number of positive benefits, including: 1) [by] creating powerful incentives for domestic innovation; 2) inducing knowledge spillovers that help others to innovate; 3) ensuring a country’s companies can focus on operating productively and innovating, instead of having to devote an undue amount of their time and resources to protecting their IP in an environment where it’s at risk; 4) promoting the international diffusion of technology, innovation, and knowhow; and 5) boosting a country’s levels of research and development, inbound foreign direct investment (FDI), and exports of goods and services.24 The evidence shows that strong intellectual property rights protections are vitally important for both developed and developing countries alike. As the definitive 2010 OECD review of the effects of intellectual property rights protections on developing countries, “Policy Complements to the Strengthening of IPRs in Developing Countries” found, “The results point to a tendency for IPR reform to deliver positive economic results.”25 The OECD study found that developing-country IPR reforms concerning patent protection have tended to deliver the most substantial results, although the results for copyright reform and trademark reform are also positive and significant. But to have the greatest impact on economic growth, IPR reforms must occur concomitantly with other positive complements, particularly ones regarding inputs for innovative and productive processes and the ability to conduct business. These include policies that influence the macro-environment for firms as well as the availability of resources (e.g., related to education), a country’s legal and institutional conditions, and fiscal incentives.26 Strengthening IPR protection has been shown to correlate with increased trade.27 For instance, Fink and Primo Braga found that IPR protection is positively associated with international trade flows, in particular of manufactured, non-fuel imports.28 Other studies have found a positive association between IPR protection and trade flows in high-technology products.29 Likewise, strengthening of IPR protection has also been connected with increased inflows of FDI. Cavazos Cepeda et al. found that a 1 percent increase in the protection of IPRs as measured by the Patent Rights Index (a measure of the strength of countries’ IPR regimes) is associated with a 2.8 percent increase in the inflow of FDI.30 Similarly, a 1 percent increase in trademark protection levels is associated with a 3.8 percent increase in incoming FDI; and a 1 percent increase in copyright protection yields a 6.8 percent increase in FDI.31 Moreover, the researchers identified a virtuous cycle between FDI and protection of IP, whereby improvements in the IPR environment are associated with improved economic performance—in particular with respect to FDI—and, in turn, further improvements in the IPR environment. Park and Lippoldt showed that stronger IPRs in developing countries are associated with an increase of technology-intensive FDI, while Awokuse and Yin provided a concrete example concerning the relationship of IPR protection in China to FDI inflows, concluding that IPR reforms in China have had a positive and significant effect on inbound FDI.32 There is also evidence that countries with similar levels of intellectual property protection trade more with one another.33 The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that R&D to GDP ratios are positively related to the strength of patent rights, and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56

#### **Innovation is necessary to solve future pandemics, antimicrobial diseases, and bioterror.**

Marjanovic and Fejiao 20 Marjanovic, Sonja, and Carolina Feijao. SonjaMarjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." (2020).

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions. Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions. The COVID-19 pandemic is a game-changer among global public health threats. The risk to human life (both in terms of morbidity and quality of life), the economic risks, the epidemiology of the disease and speed of escalation have led to a crisis-response by many governments around the world. This has in turn influenced the immediate industry efforts. Many other infectious disease threats may not manifest as crises in the short term and in the same way as COVID-19, but they could nevertheless escalate. They are not considered to be crises from a short term perspective because they are contained to specific regions and affect fewer people at present – or are re-emerging (e.g. Ebola) – or their impacts have not yet materialised at a scale that would qualify as an immediate crisis (e.g. growing risks of antimicrobial resistance to some infectious pathogens). However, such diseases and issues are recognised as global threats that could become crises in the future.

#### Covid magnifies the bioterror threat which risks extinction

Walsh 20, Bryan Walsh, 5-14-2020, "The coronavirus pandemic reawakens bioweapon fears," Axios, https://www.axios.com/coronavirus-pandemic-pathogen-bioweapon-45417c86-52aa-41b1-8a99-44a6e597d3a8.html

The immense human and economic toll of the COVID-19 pandemic only underscores the threat posed by pathogens that could be deliberately engineered and released. Why it matters: New technology like gene editing and DNA synthesis has made the creation of more virulent pathogens easier. Yet security and regulation efforts haven't kept pace with the science. That doesn't mean the threat from bioweapons isn't dire. Along with AI, engineered pandemics are widely considered the biggest existential risk facing humanity. That's in part because a pathogen could be engineered in a lab for maximum contagiousness and virulence, well beyond what would arise through natural selection. Case in point: a 2018 pandemic simulation put on by the Johns Hopkins Center for Health Security featured a fictional engineered virus called Clade X that combined the contagiousness of the common cold with the virulence of the real-life Nipah virus, which has a mortality rate of 40-75%. The resulting simulated global outbreak killed 150 million people. COVID-19 isn't anywhere near that fatal, but the pandemic has shown the vulnerability of the U.S. and the world to biological threats both natural and manmade. "Potential adversaries are of course seeing the same things we’re seeing," says Richard Pilch of the Middlebury Institute of International Studies. "Anyone looking for a radical leveling approach — whether a state actor like North Korea or a motivated terrorist organization — may be influenced by COVID-19 to consider pursuing a biological weapons capability." While earlier bioweapons fears focused on the possibility that a state or terror group could try to weaponize a known dangerous agent like smallpox — which would require somehow obtaining restricted pathogens — new technology means that someone could obtain the genetic sequence of a germ online and synthesize it in the lab. The democratization of biotechnology could unleash a wave of creativity and innovation, just as the democratization of personal computing did. But it also increases the number of people who could potentially make a dangerous engineered virus, whether deliberately or by accident.

# case

## a2 access

#### Innovation is a prereq: no innovation means there won’t be drugs to access in the first place.

#### Turn: IPRs are key to providing quality access drugs – that outweighs because bad quality drugs -> death.

Lybercker 16, Kristina M. L. Acri NéE Lybecker, 6-27-2016, "Counterfeit Medicines and the Role of IP in Patient Safety," IPWatchdog, https://www.ipwatchdog.com/2016/06/27/counterfeit-medicines-ip-patient-safety/id=70397/

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Counterfeits are a worldwide problem, but the OECD estimates that the United States is the hardest hit, followed by Italy and France.  Of the estimated $461 billion in counterfeit trade in 2013, goods with registered intellectual property rights in the U.S. represented 20 percent, or $92 billion, of the OECD estimate.”[1] As the author of the chapter on illicit trade in counterfeit medicines within the OECD report, I worry that global policymakers may be working against each other when it comes to battling counterfeit drugs, especially in the context of intellectual property rights. While the Senate Hearing and the OECD report highlight the importance of strong IP protection in combating the growing threat of counterfeit goods, their efforts coincide with an initiative by the UN Secretary-General that has the potential to greatly worsen the problems of counterfeit pharmaceuticals.   UN Secretary General Ban Ki Moon’s High Level Panel on Access to Medicines proposes “to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”[2] The High Level Panel is a thinly veiled attempt to undermine the intellectual property rights architecture that incentivizes pharmaceutical innovation and protects patients from counterfeit medicines. While patents and other forms of intellectual property rights are widely recognized as fostering pharmaceutical innovation, they also serve to inhibit counterfeiting. The World Health Organization has determined that counterfeiting is facilitated where “there is weak drug regulatory control and enforcement; there is a scarcity and/or erratic supply of basic medicines; there are extended, relatively unregulated markets and distribution chains, both in developing and developed country systems; price differentials create an incentive for drug diversion within and between established channels;  there is lack of effective intellectual property protection; due regard is not paid to quality assurance”.[3] According to INTERPOL estimates, approximately 30 percent of drugs sold worldwide are counterfeit.[4] However, as is the case with many other counterfeit trade statistics, the origins of this figure are somewhat uncertain, as is the methodology used to make the calculation. Perhaps the most widely-cited statistic originates from the World Health Organization, which estimates that **10 percent of the global market for pharmaceuticals is comprised of counterfeits and reports place the share in some developing countries as high as 50-70%.**[5] While difficult to measure, estimates do exist on the extent of the market for counterfeit drugs and the harm done to human health. As noted in my chapter in the OECD report, “INTERPOL estimates that more than one million people die each year from counterfeit drugs.[6] While counterfeit drugs seem to primarily originate in Asia, Asian patients are also significantly victimized by the problem. A 2005 study published in PLoS Medicine estimate that 192,000 people are killed in China each year by counterfeit medicines.[7] According to work done by the International Policy Network, an estimated 700,000 deaths from malaria and tuberculosis are attributable to fake drugs. [8] The World Health Organization presents a much more modest number noting that malaria claims one million lives annually and as many as 200,000 may be attributed to counterfeit medicines which would be avoidable if the medicines available were effective, of good quality and used correctly.[9] Even this number is double that presented by academic researchers Amir Attaran and Roger Bate who claim that each year more than of 100,000 people around the world may die from substandard and counterfeit medications.[10]” [11] Given the devastating impact of counterfeit medicines on patients and the importance of intellectual property protection in combating pharmaceutical counterfeiting, it is troubling that the UN High Level Panel seems poised to prevent a series of recommendations that will undermine public health under the guise of enhancing access. **Without the assurance of quality medicines, access is meaningless**.

#### The aff is insufficient: there are additional causes to lack of access to medicine that ip reductions don’t solve. Lybeck continues,

Lybecker continues Moreover, while falsely presenting intellectual property rights as the primary obstacle to global health care, the High Level Panel downplays a host of other factors that prevent developing country patients from getting the drugs they need:  inadequate medical infrastructure, insufficient political will, a shortage of clinical trials in nations where neglected diseases are endemic, poverty, and insufficient market incentives. If the United Nations is serious about addressing the critical need for access to medicines, the Secretary General must come to terms with the reality surrounding the challenges of access to medicine. Although the international patent system may be in need of improvement, it is overly simplistic to blame drug patents, international trade agreements and the global pharmaceutical industry for the access problem. The problem is far more nuanced and complicated than portrayed by the High Level Panel. As the WHO, OECD and Senator Hatch recognize, intellectual property rights (iprs) are part of the solution. To truly address the access problem, we must move beyond blaming IPRs and begin the difficult work of grappling with structural deficiencies and poverty.

#### They don’t solve for hesitancy which turns the solvency; reducing patents doesn’t mean people are actually willing to take the vaccine – that’s why Nicki Minaj refused to get the vaccine, and that’s why we are seeing in lics like Africa.

Sallam 21, Malik Sallam, 2-26-2021, "COVID-19 Vaccine Hesitancy Worldwide: A Concise Systematic Review of Vaccine Acceptance Rates," PubMed Central (PMC), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7920465/

Utility of vaccine campaigns to control coronavirus 2019 disease (COVID-19) is not merely dependent on vaccine efficacy and safety. Vaccine acceptance among the general public and healthcare workers appears to have a decisive role in the successful control of the pandemic. The aim of this review was to provide an up-to-date assessment of COVID-19 vaccination acceptance rates worldwide. A systematic search of the peer-reviewed English survey literature indexed in PubMed was done on 25 December 2020. Results from 31 peer-reviewed published studies met the inclusion criteria and formed the basis for the final COVID-19 vaccine acceptance estimates. Survey studies on COVID-19 vaccine acceptance rates were found from 33 different countries. Among adults representing the general public, the highest COVID-19 vaccine acceptance rates were found in Ecuador (97.0%), Malaysia (94.3%), Indonesia (93.3%) and China (91.3%). However, the lowest COVID-19 vaccine acceptance rates were found in Kuwait (23.6%), Jordan (28.4%), Italy (53.7), Russia (54.9%), Poland (56.3%), US (56.9%), and France (58.9%). Only eight surveys among healthcare workers (doctors and nurses) were found, with vaccine acceptance rates ranging from 27.7% in the Democratic Republic of the Congo to 78.1% in Israel. In the majority of survey studies among the general public stratified per country (29/47, 62%), the acceptance of COVID-19 vaccination showed a level of ≥70%. Low rates of COVID-19 vaccine acceptance were reported in the Middle East, Russia, Africa and several European countries. This could represent a major problem in the global efforts to control the current COVID-19 pandemic. More studies are recommended to address the scope of COVID-19 vaccine hesitancy. Such studies are particularly needed in the Middle East and North Africa, Sub-Saharan Africa, Eastern Europe, Central Asia, Middle and South America. Addressing the scope of COVID-19 vaccine hesitancy in various countries is recommended as an initial step for building trust in COVID-19 vaccination efforts. Vaccine hesitancy is an old phenomenon that represents a serious threat to the global health, as shown by the resurgence of some infectious diseases (e.g., outbreaks of measles and pertussis) [[76](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7920465/#B76-vaccines-09-00160),[77](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7920465/#B77-vaccines-09-00160),[78](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7920465/#B78-vaccines-09-00160),[79](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7920465/#B79-vaccines-09-00160),[80](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7920465/#B80-vaccines-09-00160)]. The huge leaps in developing efficacious and safe COVID-19 vaccines within a short period were unprecedented [[81](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7920465/#B81-vaccines-09-00160),[82](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7920465/#B82-vaccines-09-00160),[83](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7920465/#B83-vaccines-09-00160)]. Nevertheless, COVID-19 vaccine hesitancy can be the limiting step in the global efforts to control the current pandemic with its negative health and socio-economic effects [[43](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7920465/#B43-vaccines-09-00160),[84](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7920465/#B84-vaccines-09-00160),[85](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7920465/#B85-vaccines-09-00160)]. However, vaccine hesitancy can be a decisive factor that would hinder the successful control of the current COVID-19 pandemic [[43](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7920465/#B43-vaccines-09-00160),[92](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7920465/#B92-vaccines-09-00160)]. Thus, estimates of vaccine acceptance rates can be helpful to plan actions and intervention measures necessary to increase the awareness and assure people about the safety and benefits of vaccines, which in turn would help to control virus spread and alleviate the negative effects of this unprecedented pandemic [[93](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7920465/#B93-vaccines-09-00160),[94](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7920465/#B94-vaccines-09-00160)]. Evaluation of attitudes and acceptance rates towards COVID-19 vaccines can help to initiate communication campaigns that are much needed to strengthen trust in health authorities [[24](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7920465/#B24-vaccines-09-00160)]. The widespread prevalence of COVID-19 vaccine hesitancy mandates collaborative efforts of governments, health policy makers, and media sources, including social media companies. It is recommended to build COVID-19 vaccination trust among the general public, via the spread of timely and clear messages through trusted channels advocating the safety and efficacy of currently available COVID-19 vaccines.

#### **The disad solves case: Biotech mRNA innovation uniquely solves infectious diseases that disproportionately affects developing countries**

Anderson 21, Kelly Anderson, 8-23-2021, "The Innovation Ecosystem Behind COVID Vaccines is Now Targeting HIV/AIDS," IPWatchdog, https://www.ipwatchdog.com/2021/08/23/innovation-ecosystem-behind-covid-vaccines-now-targeting-hiv-aids/id=136982/

Kelly Anderson serves as senior director of health and drug policy at the U.S. Chamber’s Global Innovation Policy Center (GIPC). Anderson is primarily responsible for leading the Chamber’s Discover & Deliver campaign, which tells the story of the innovative biopharmaceutical industry’s capacity to respond to evolving health threats, such as COVID-19.

June marked the 40th anniversary of the first reported AIDS case. On the anniversary, UNAIDS released a strategy to end HIV/AIDS by 2030, a goal that seemed unthinkable over 40 years ago. Yet since 1981, the innovative scientific community has delivered a series of treatments that revolutionized the outlook for HIV/AIDS patients. An HIV vaccine has escaped the innovative scientific community with good reason: the HIV virus is both complicated and evasive. Dr. Fauci noted that the challenge with HIV lies in the fact that the virus mutates quickly and rapidly integrates into the genomes of cells. Yet, recent clinical trials of an mRNA vaccine offered promising early-stage results. In February 2021, the International AIDS Vaccine Initiative (IAVI) and Scripps University in California announced the results of their Phase I trial of an mRNA HIV vaccine candidate. The study found that the vaccine lead to the production of rare immune cells needed to create antibodies against HIV.in 97% of participants. IAVI and Scripps now plan to partner with Moderna – the newest household name in the mRNA field – for additional clinical trials to further refine the technology. Both the evolution of treatments for HIV/AIDS and response to the global pandemic shed light on the transformative power of innovation and America’s thriving innovation ecosystem, empowered by public-private sector collaboration. Over the last year, the biopharmaceutical industry, academic community, the government, and non-profit sector condensed every avenue for innovation into one: defeating COVID-19. That partnership resulted in multiple effective vaccines in less than a year’s time. This success gives us new hope that, working together, organizations like IAVI, Scripps University, and Moderna may be able to make concrete progress towards the ever-elusive HIV vaccine, building off of the lessons learned on the application of mRNA during the global pandemic. It is clear that working together, we can achieve more. But we need the right legal and regulatory framework in place to do so. Effective intellectual property (IP) protection supports America’s thriving innovation ecosystem by providing the legal certainty that high-risk, high-capital innovations will be protected.