# Framing

#### The standard is maximizing expected wellbeing

#### Prefer utilitarianism because

#### States don’t have the ability to look to individual experiences—can only evaluate averages and aggregates.

**Goodin 90.** Robert Goodin 90, [professor of philosophy at the Australian National University college of arts and social sciences], “The Utilitarian Response,” pgs 141-142

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

#### Existential risk first – prefer utilitarianism

**Bostrom 12** (Nick, Professor of Philosophy at Oxford, directs Oxford's Future of Humanity Institute and winner of the Gannon Award, Interview with Ross Andersen, correspondent at The Atlantic, 3/6, “We're Underestimating the Risk of Human Extinction”, <http://www.theatlantic.com/technology/archive/2012/03/were-underestimating-the-risk-of-human-extinction/253821/>)

Bostrom, who directs Oxford's Future of Humanity Institute, has argued over the course of several papers that human extinction risks are poorly understood and, worse still, severely underestimated by society. Some of these existential risks are fairly well known, especially the natural ones. But others are obscure or even exotic. Most worrying to Bostrom is the subset of existential risks that arise from human technology, a subset that he expects to grow in number and potency over the next century.¶ Despite his concerns about the risks posed to humans by technological progress, Bostrom is no luddite. In fact, he is a longtime advocate of transhumanism---the effort to improve the human condition, and even human nature itself, through technological means. In the long run he sees technology as a bridge, a bridge we humans must cross with great care, in order to reach new and better modes of being. In his work, Bostrom uses the tools of philosophy and mathematics, in particular probability theory, to try and determine how we as a species might achieve this safe passage. What follows is my conversation with Bostrom about some of the most interesting and worrying existential risks that humanity might encounter in the decades and centuries to come, and about what we can do to make sure we outlast them.¶ Some have argued that we ought to be directing our resources toward humanity's existing problems, rather than future existential risks, because many of the latter are highly improbable. You have responded by suggesting that existential risk mitigation may in fact be a dominant moral priority over the alleviation of present suffering. Can you explain why? ¶ Bostrom: Well suppose you have a moral view that counts future people as being worth as much as present people. You might say that fundamentally it doesn't matter whether someone exists at the current time or at some future time, just as many people think that from a fundamental moral point of view, it doesn't matter where somebody is spatially---somebody isn't automatically worth less because you move them to the moon or to Africa or something. A human life is a human life. If you have that moral point of view that future generations matter in proportion to their population numbers, then you get this very stark implication that existential risk mitigation has a much higher utility than pretty much anything else that you could do. There are so many people that could come into existence in the future if humanity survives this critical period of time---we might live for billions of years, our descendants might colonize billions of solar systems, and there could be billions and billions times more people than exist currently. Therefore, even a very small reduction in the probability of realizing this enormous good will tend to outweigh even immense benefits like eliminating poverty or curing malaria, which would be tremendous under ordinary standards.

# Climate DA

#### In the status quo, climate patents are high. However, any form of IP reduction sets the precedent for appropriations of the law – the threat alone deters investors into climate tech

**Brand 21** Brand, Melissa. “Trips Ip Waiver Could Establish Dangerous Precedent for Climate Change and Other Biotech Sectors.” *IPWatchdog.com | Patents & Patent Law*, 26 May 2021, www.ipwatchdog.com/2021/05/26/trips-ip-waiver-establish-dangerous-precedent-climate-change-biotech-sectors/id=133964/. // FC

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](https://www.ipwatchdog.com/2021/04/19/waiving-ip-rights-during-times-of-covid-a-false-good-idea/id=132399/)), can we really feel confident that this or some future Administration will not apply the same logic to the climate crisis? And, without the confidence in the underlying IP for such solutions, what does this mean for U.S. innovation and economic growth? United States Trade Representative (USTR) [Katherine Tai](https://www.ipwatchdog.com/2021/05/05/tai-says-united-states-will-back-india-southafrica-proposal-waive-ip-rights-trips/id=133224/) was subject to questioning along this very line during a recent Senate Finance Committee hearing. And while Ambassador Tai did not affirmatively state that an IP waiver would be in the future for climate change technology, she surely did not assuage the concerns of interested parties.

International Pressure May Be Influencing Domestic IP Policy

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.

Forced Tech Transfer Could Be on The Table

When being questioned about the scope of a potential TRIPS IP waiver, Ambassador Tai invoked the proverb “Give a man a fish and you feed him for a day. Teach a man to fish and you feed him for a lifetime.” While this answer suggests primarily that, in times of famine, the Administration would rather give away other people’s fishing rods than share its own plentiful supply of fish (here: actual COVID-19 vaccine stocks), it is apparent that in Ambassador Tai’s view waiving patent rights alone would not help lower- and middle-income countries produce their own vaccines. Rather, they would need to be taught how to make the vaccines and given the biotech industry’s manufacturing know-how, sensitive cell lines, and proprietary cell culture media in order to do so.

In other words, Ambassador Tai acknowledged that the scope of the current TRIPS IP waiver discussions includes the concept of forced tech transfer. In the context of climate change, the idea would be that companies who develop successful methods for producing new seed technologies and sustainable biomass, reducing greenhouse gases in manufacturing and transportation, capturing and sequestering carbon in soil and products, and more, would be required to turn over their 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 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.

Necessary Investment Could Diminish

Developing climate change solutions is not an easy endeavor and bad policy positions threaten the likelihood that they will materialize. These products have long lead times from research and development to market introduction, owing not only to a high rate of failure but also rigorous regulatory oversight. Significant investment is required to sustain and drive these challenging and long-enduring endeavors. For example, synthetic biology companies critical to this area of innovation [raised over $1 billion in investment in the second quarter of 2019 alone](https://www.bio.org/sites/default/files/2021-04/Climate%20Report_FINAL.pdf). If investors cannot be confident that IP will be in place to protect important climate change technologies after their long road from bench to market, it is unlikely they will continue to invest at the current and required levels.

#### Private investment is critical to closing the Paris gap and fighting climate change – government action comes too little, too late

**Vandenbergh and Gilligan 17** Vandenbergh, Michael, and Jonathan M Gilligan. “Government Action Isn't Enough for Climate Change. the Private Sector Can CUT Billions of Tons of Carbon.” *The Conversation*, 21 June 2017, theconversation.com/government-action-isnt-enough-for-climate-change-the-private-sector-can-cut-billions-of-tons-of-carbon-79728. // FC

But one thing is clear: Even if all the remaining participating nations do their part, governments alone can’t substantially reduce the risk of [catastrophic](https://www.epa.gov/sites/production/files/2014-12/documents/incorporating_catastrophic_climate-change_into_policy_analysis.pdf) climate change.

We’ve studied the role of the [private sector in addressing climate change](http://www.powells.com/book/beyond-politics-9781316632482), and we’re convinced that the next stage is going to require more than just political agreement. What is needed is a concerted effort to mobilize private action – not just corporations but also religious and civic organizations, colleges and universities, investors and households – to help narrow the gap that remains after the Paris Agreement.

The Paris gap

Under current policies, global emissions are on a path toward a world with temperatures more than [3 degrees Celsius](http://climateactiontracker.org/publications/publication/154/Analysis-of-current-greenhouse-gas-emission-trends.html) (5.4 degrees Fahrenheit) above preindustrial temperatures. The Paris Agreement emphasized the need to keep warming “well below” 2°C and ideally reach a reduction of 1.5°C. The accord includes national pledges to reduce emissions, which are to be updated every five years to move the world closer to the temperature target. Under current policies, global emissions are on a path toward a world with temperatures more than [3 degrees Celsius](http://climateactiontracker.org/publications/publication/154/Analysis-of-current-greenhouse-gas-emission-trends.html) (5.4 degrees Fahrenheit) above preindustrial temperatures. The Paris Agreement emphasized the need to keep warming “well below” 2°C and ideally reach a reduction of 1.5°C. The accord includes national pledges to reduce emissions, which are to be updated every five years to move the world closer to the temperature target. Although the agreement takes a significant first step, without additional steps the world will fall [far short](http://climateactiontracker.org/assets/publications/briefing_papers/CAT_2017_Tracking_Progress.pdf) of even the more modest goal. This is the Paris gap – the difference between the goals of the Paris Agreement and what it will actually achieve over the next decade, even if all countries fully comply with their commitments. [A detailed scientific assessment](http://infographics.pbl.nl/indc/) by the PBL Netherlands Environmental Assessment Agency found that by 2030 this gap would reach 12-14 billion tons per year even if all countries including the U.S. meet their targets.

The Paris Agreement sets up a process for countries to add new commitments for the period after 2025, but here’s the catch: The Paris gap is so large that waiting until then brings risks. Although no one can predict all the effects of a global temperature increase of 3°C or more, an increase in this range will [almost certainly](https://www.nap.edu/catalog/21852/attribution-of-extreme-weather-events-in-the-context-of-climate-change) amplify the [frequency and severity of deadly heat waves around the world](http://news.nationalgeographic.com/2017/06/heatwaves-climate-change-global-warming/). It will also increase the likelihood of crossing tipping points that could make the consequences of climate change, such as sea level rise, much worse. Waiting a decade for additional national commitments is a [risky option](https://theconversation.com/managing-climate-risk-in-trumps-america-67746?sr=8).

So how should we close the Paris gap? Until now, global climate change efforts have largely focused on actions by national, regional and local governments – all of which will be [critical](https://theconversation.com/are-we-overreacting-to-us-withdrawal-from-the-paris-agreement-on-climate-78741) to closing the gap. But governments are not the only actors that can make a difference: corporations, citizens and nonprofits can make an important, and perhaps essential, contribution, even if they cannot solve the entire problem.

We’ve already seen private actors respond to the U.S. withdrawal from the Paris Agreement. For example, the [We Are Still In initiative](http://wearestillin.com/) is a coalition of businesses, colleges and universities, and cities and counties. And on June 20, the [Climate Leadership Council](https://www.clcouncil.org/) – a collection of big businesses, environmental advocacy groups and individuals – launched, calling for policy action on climate change.

Our assessment finds that private actions can close 10 percent to 30 percent of the Paris gap over the next decade. This can reduce the cost of climate mitigation and allow the politic consensus to catch up with the scientific consensus, although it is not a substitute for government action.

Vast potential

Private actors – including corporations, civic and advocacy groups, private citizens, and even the Catholic Church – played an important role in pushing nations to make commitments in Paris, but lobbying for government action is not the only role for the private sector. These private actors are sources of emissions that can reduce emissions directly and independently of government policies.

#### Climate change causes extinction

**Sprat** **and Dunlop** **19** (David Spratt and Ian Dunlop, \*Research Director for Breakthrough National Centre for Climate Restoration and co-author of Climate Code Red: The case for emergency action; \*\*member of the Club of Rome AND formerly an international oil, gas and coal industry executive, chairman of the Australian Coal Association, chief executive of the Australian Institute of Company Directors, and chair of the Australian Greenhouse Office Experts Group on Emissions Trading, "Existential climate-related security risk: A scenario approach," Breakthrough National Centre for Climate Restoration, 5-30-2019, https://docs.wixstatic.com/ugd/148cb0\_90dc2a2637f348edae45943a88da04d4.pdf, Date Accessed: 7-5-2019, SB)

2050: By 2050, there is broad scientific acceptance that system tipping-points for the West Antarctic Ice Sheet and a sea-ice-free Arctic summer were passed well before 1.5°C of warming, for the Greenland Ice Sheet well before 2°C, and for widespread permafrost loss and large-scale Amazon drought and dieback by 2.5°C. **The “hothouse Earth” scenario has been realised**, and Earth is headed for another degree or more of warming, especially since human greenhouse emissions are still significant. While sea levels have risen 0.5 metres by 2050, the increase may be 2–3 metres by 2100, and it is understood from historical analogues that seas may eventually rise by more than 25 metres. Thirty-five percent of the global land area, and 55 percent of the global population, are subject to more than 20 days a year of lethal heat conditions, **beyond the threshold of human survivability.** The destabilisation of the Jet Stream has very significantly affected the intensity and geographical distribution of the Asian and West African monsoons and, together with the further slowing of the Gulf Stream, is impinging on life support systems in Europe. North America suffers from **devastating weather extremes including wildfires, heatwaves, drought and inundation.** The summer monsoons in China have failed, and water flows into the great rivers of Asia are severely reduced by the loss of more than one-third of the Himalayan ice sheet. Glacial loss reaches 70 percent in the Andes, and rainfall in Mexico and central America falls by half. Semi-permanent El Nino conditions prevail. Aridification emerges over more than 30 percent of the world’s land surface. Desertification is severe in southern Africa, the southern Mediterranean, west Asia, the Middle East, inland Australia and across the south-western United States. Impacts: A number of **ecosystems collapse**, including coral reef systems, the Amazon rainforest and in the Arctic. Some poorer nations and regions, which lack capacity to provide artificially-cooled environments for their populations, become unviable. Deadly heat conditions persist for more than 100 days per year in West Africa, tropical South America, the Middle East and South-East Asia, which together with land degradation and rising sea levels contributes to 21 perhaps a billion people being displaced. Water availability decreases sharply in the most affected regions at lower latitudes (dry tropics and subtropics), affecting about two billion people worldwide. **Ag**riculture **becomes nonviable** in the dry subtropics. Most regions in the world see a significant drop in food production and increasing numbers of **extreme weather events**, including heat waves, floods and storms. **Food production is inadequate** to feed the global population and food prices skyrocket, as a consequence of a one-fifth decline in crop yields, a decline in the nutrition content of food crops, a catastrophic decline in insect populations, desertification, monsoon failure and **chronic water shortages**, and conditions **too hot for human habitation** in significant food-growing regions. The lower reaches of the agriculturally-important river deltas such as the Mekong, Ganges and Nile are inundated, and significant sectors of some of the world’s most populous cities — including Chennai, Mumbai, Jakarta, Guangzhou, Tianjin, Hong Kong, Ho Chi Minh City, Shanghai, Lagos, Bangkok and Manila — are **abandoned**. Some small islands become **uninhabitable**. Ten percent of Bangladesh is inundated, displacing 15 million people. According to the Global Challenges Foundation’s Global Catastrophic Risks 2018 report, even for 2°C of warming, more than a billion people may need to be relocated due to sea-level rise, and In high-end scenarios “the scale of destruction is beyond our capacity to model, with **a high likelihood of human civilisation coming to an end**”. 22

# Generic Drugs DA

#### IP is key to combatting counterfeit and generic drugs

**FIFARMA 21** FIFARMA. “This Is How We Fight Counterfeit Medicines with Intellectual Property.” *FIFARMA*, 28 Apr. 2021, fifarma.org/en/this-is-how-we-fight-counterfeit-medicines-with-intellectual-property/. // FC

In addition to functioning as a tool to maintain constant innovation in the industry, IP helps reducing counterfeit medicines because medicines have better technologies and ingredients are more difficult to copy. This means that, through market incentives, the industry manages to have high quality infrastructure, new technology and trained personnel, to create specialized and specific medicines and therapies, which is why they are difficult to replicate.

On the other hand, political will functions as another important axis, as it must prosecute those who are making counterfeit medicines. This is achieved through a constant conversation between industry and governments. Therefore, it will be absolutely clear how to identify the authenticity of medicines.

In short, IP allows quality standards to be clearer and stricter, and regulators to have greater knowledge and traceability of each product that enters the market. Through IP, you can establish a record of all products globally, which makes it easier to find possible counterfeit medicines.

Consequently, the best way to fight counterfeit medicines is through accessing the best quality medicines and for this to happen, an ecosystem between countries, regulators and industry is needed. This ecosystem shall take into account the structural deficiencies of each country and addresses them in a holistic manner, to provide the best quality medicines.

#### Counterfeit drug companies send their worst quality drugs where risk of inspection is the lowest. There, poor quality medications don’t treat the patients and lead to microbial resistance

**Eban 19** [Katherine Eban, an investigative journalist and the author of the New York Times bestseller Bottle of Lies: The Inside Story of the Generic Drug Boom, May 17 2019, “How Some Generic Drugs Could Do More Harm Than Good,” Time Magazine, <https://time.com/5590602/generic-drugs-quality-risk/> ]

For the 16 years that Dr. Brian Westerberg, a Canadian surgeon, worked volunteer missions at the Mulago National Referral Hospital in Kampala, Uganda, scarcity was the norm. The patients usually exceeded the 1,500 allotted beds. Running water was once cut off when the debt-ridden hospital was unable to pay its bills. On some of his early trips, Westerberg even brought over drugs from Canada in order to treat patients. Butas low-cost generics made in India and China became widely available through Uganda’s government and international aid agencies in the early 2000s, it seemed at first like the supply issue had been solved. Then on February 7, 2013, Westerberg examined a feverish 13-year-old boy who had fluid oozing from an ear infection. He suspected bacterial meningitis, though he couldn’t confirm his diagnosis because the CT scanner had broken down. The boy was given intravenous ceftriaxone, a broad-spectrum antibiotic that Westerberg believed would cure him. But after four days of treatment, the ear had only gotten worse**.** As Westerberg prepared to operate, the boy had a seizure. With the CT scanner working again, Westerberg ordered an urgent scan, which revealed small abscesses in the boy’s skull, likely caused by the infection. When a hospital neurosurgeon looked at the images and confidently declared that surgery was unnecessary and the swelling and abscesses would abate with effective antibiotic treatment, Westerberg was confused. They had already treated the boy with intravenous ceftriaxone, which hadn’t worked. His confusion deepened when his colleague suggested that they switch the boy to a more expensive version of the drug. Why swap one ceftriaxone for another? Most people assume that a drug is a drug — that Lipitor, for example, or a generic version, is the same anywhere in the world, so long as it’s made by a reputable drug company that has been inspected and approved by regulators. That, at least, is the logic that has driven the global generic-drug revolution: that drug companies in countries like India and China can make low-cost, high-quality drugs for markets around the world. These companies have been hailed as public-health heroes and global equalizers, by making the same cures available to the wealthy and impoverished. PAID PARTNER CONTENT 6 Prepaid Funeral Plan Myths: Learn More BY DIGNITY MEMORIALBut many of the generic drug companies that Americans and Africans alike depend on, which I spent a decade investigating, hold a dark secret: they routinely adjust their manufacturing standards depending on the country buying their drugs, a practice that could endanger not just those who take the lower-quality medicine but the population at large. These companies send their highest-quality drugs to markets with the most vigilant regulators, such as the U.S. and the European Union. They send their worst drugs — made with lower-quality ingredients and less scrupulous testing — to countries with the weakest review. The U.S. drug supply is not immune to quality crises — over the last ten months, dozens of versions of the generic blood pressure drugs valsartan, losartan and irbesartan have been subject to sweeping recalls. The active ingredients in some, manufactured in China, contained a probable carcinogen once used in the production of liquid rocket fuel**.** But the patients who suffer most are those in so-called “R.O.W. markets” — the generic-drug industry’s shorthand for “Rest of World.” In swaths of Africa, Southeast Asia and other areas with developing markets, some generic drug companies have made a cold calculation: they can sell their cheapest drugs where they will be least likely to get caught. In Africa, for instance, pharmaceuticals used to come from more developed countries, through donations and small purchases. So when Indian drug reps offering cheap generics started arriving, the initial feeling was positive**.** But Africa soon became an avenue “to send anything at all,” said Kwabena Ofori-Kwakye, associate professor in the pharmaceutics department at the Kwame Nkrumah University of Science and Technology in Kumasi, Ghana**.** The poor quality has affected every type of medication, and the adverse impact on health has been “astronomical,”he told me. Multiple doctors I spoke to throughout the continent said they have adjusted their medical treatment in response, sometimes tripling recommended doses to produce a therapeutic effect. Dr. Gordon Donnir, former head of the psychiatry department at the Komfo Anokye teaching hospital in Kumasi, treats middle-class Ghanaians in his private practice and saysthat almost all the drugs his patients take are substandard, leading him to increase his patients’ doses significantly. While his European colleagues typically prescribe 2.5 milligrams of haloperidol (a generic form of Haldol) several times a day to treat psychosis, he’ll prescribe 10 milligrams, also several times a day, because he knows the 2.5 milligrams “won’t do anything.”Donnir once gave ten times the typical dose of generic Diazepam, an anti-anxiety drug, to a 15-year-old boy, an amount that should have knocked him out. The patient was “still smiling,” Donnir said. Many hospitals also keep a stash of what they call “fancy” drugs — either brand-name drugs or higher-quality generics — to treat patients who should have recovered after a round of treatment but didn’t. Confronted with the ailing boy at the Mulago hospital, Westerberg’s colleagues swapped in the more expensive version of ceftriaxone and added more drugs to the treatment plan. But it was too late. In the second week of his treatment, the boy was declared brain dead. Westerberg’s Ugandan colleagues were not surprised. Their patients frequently died when treated with drugs that should have saved them. And there were not enough “fancy” drugs to go around, making every day an exercise in pharmaceutical triage. It was also hard to keep track of which generics were safe and which were not to be trusted, said one doctor in Western Uganda: “It’s anesthesia today, ceftriaxone tomorrow, amoxicillin the next day.” Westerberg, shaken by his newfound knowledge, flew back to Canada and teamed up with a Canadian respiratory therapist, Jason Nickerson, who’d had similar experiences with bad medicine in Ghana. They decided to test the chemical properties of the generic ceftriaxone that had been implicated in the Ugandan boy’s death. Another of Westerberg’s colleagues brought him a vial from the Mulago hospital pharmacy. The drug had been made by a manufacturer in northern China, which also exported to the U.S. and other developed markets. But when they tested the ceftriaxone at Nickerson’s lab, it contained less than half the active drug ingredient stated on the label. At such low concentration, the drug was basically useless, Nickerson said. He and Westerberg published a case report in the CDC’s Morbidity and Mortality Weekly Report. Although they couldn’t say with certainty that the boy had died due to substandard ceftriaxone, their report offered compelling evidence that he had. Some companies claim that, while their drugs are all high-quality, there may be some variance in how they are produced because regulations differ from market to market. But Patrick H. Lukulay, former vice president of global health impact programs for USP (formerly U.S. Pharmacopeia), one of the world’s top pharmaceutical standard-setting organizations, calls that argument “totally garbage.” For any given drug, he says, “There’s only one standard, and that standard was set by the originator,” meaning the brand-name company that developed the product. It’s not just those in developing markets who should be alarmed**.** Often, substandard drugs do not contain enough active ingredient to effectively cure sick patients. But they do contain enough to kill off the weakest microbes while leaving the strongest intact. These surviving microbes go on to reproduce, creating a new generation of pathogens capable of resisting even fully potent, properly made medicine. In 2011, during an outbreak of drug-resistant malaria on the Thailand-Cambodia border, USP’s chief of party in Indonesia Christopher Raymond strongly suspected substandard drugs as a culprit**.** Treating patients with drugs that contain a little bit of active ingredient, as he put it, is like “putting out fire with gasoline.**”** USP is so concerned about this issue that in 2017 it launched a center called the Quality Institute, which funds research into the link between drug quality and resistance. In late 2018, Boston University biomedical engineering professor Muhammad Zaman studied a commonly used antibiotic called rifampicin that, if not manufactured properly, yields a chemical substance called rifampicin quinone when it degrades. When Zaman subjected bacteria to this substance, it developed mutations that helped it resist rifampicin and other similar drugs. Zaman concluded from his work that substandard drugs are an “independent pillar” in the global menace of drug resistance.The low cost of generic drugs makes them essential to global public health. But if those bargain drugs are of low quality, they do more harm than good**.** For years, politicians, regulators and aid workers have focused on ensuring access to these drugs. Going forward, they must place equal value on quality, through an exacting program of unannounced inspections, routine testing of drugs already on the market and strict legal enforcement against companies manufacturing subpar medicine. One model is the airline industry, which through international laws and treaties, has established clear global standards for aviation safety.Without something similar for safe and effective drugs, the twin forces of subpar medicine and growing drug resistance will be so destructive that developed countries won’t be able to ignore them. As Elizabeth Pisani, an epidemiologist who has studied drug quality in Indonesia, put it, “The fact is, pathogens know no borders.”

#### Microbial resistance causes extinction

**Davies 08** (Julian Davies, “Resistance redux. Infectious diseases, antibiotic resistance and the future of mankind,” EMBO reports 9, S1, S18–S21 (2008), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3327549/)

For many years, antibiotic-resistant pathogens have been recognized as one of the main threats to human survival, as some experts predict a return to the pre-antibiotic era. So far, national efforts to exert strict control over the use of antibiotics have had limited success and it is not yet possible to achieve worldwide concerted action to reduce the growing threat of multi-resistant pathogens: there are too many parties involved. Furthermore, the problem has not yet really arrived on the radar screen of many physicians and clinicians, as antimicrobials still work most of the time—apart from the occasional news headline that yet another nasty superbug has emerged in the local hospital. Legislating the use of antibiotics for non-therapeutic applications and curtailing general public access to them is conceivable, but legislating the medical profession is an entirely different matter.

…microbes are formidable adversaries and, despite our best efforts, continue to exact a toll on the human race

In order to meet the growing problem of antibiotic resistance among pathogens, the discovery and development of new antibiotics and alternative treatments for infectious diseases, together with tools for rapid diagnosis that will ensure effective and appropriate use of existing antibiotics, are imperative. How the health services, pharmaceutical industry and academia respond in the coming years will determine the future of treating infectious diseases. This challenge is not to be underestimated: microbes are formidable adversaries and, despite our best efforts, continue to exact a toll on the human race.

### Case

#### The WTO can’t enforce the aff- causes circumvention.

Lamp 19 [Nicholas; Assistant Professor of Law at Queen’s University; “What Just Happened at the WTO? Everything You Need to Know, Brink News,” 12/16/19; <https://www.brinknews.com/what-just-happened-at-the-wto-everything-you-need-to-know/>]

Nicolas Lamp: For the first time since the establishment of the WTO in 1995, the Appellate Body cannot accept any new appeals, and that has knock-on effects on the whole global trade dispute settlement system. When a member appeals a WTO panel report, it goes to the Appellate Body, but if there is no Appellate Body, it means that that panel report will not become binding and will not attain legal force.

The absence of the Appellate Body means that members can now effectively block the dispute settlement proceedings by what has been called appealing panel reports “into the void.”

The WTO panels will continue to function as normal. When a panel issues a report, it will normally be automatically adopted — unless it is appealed. And so, even though the panel is working, the respondent in a dispute now has the option of blocking the adoption of the panel’s report. It can, thereby, shield itself from the legal consequences of a report that finds that the member has acted inconsistently with its WTO obligations.

#### Lack of IP protection makes medical research prohibitively risky and expensive.

Grabowski et al 15 [(Henry, Professor of Economics, member of the faculty for the Health Sector Management Program, and Director of the Program in Pharmaceuticals and Health Economics at Duke University) “The Roles of Patents and Research And Development Incentives In Biopharmaceutical Innovation,” Health Affairs, 2/2015]

The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term. Several economic characteristics make patents and intellectual property protection particularly important to innovation incentives for the biopharmaceutical industry. **5** The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a billion dollars in out-of-pocket costs. **6** Only approximately one in eight drug candidates survive clinical testing. **6** As a result of the high risks of failure and the high costs, research and development must be funded by the few successful, on-market products (the top quintile of marketed products provide the dominant share of R&D returns). **7**,**8** Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market. Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents. New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment. Patents play an essential role in the economic “ecosystem” of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. **11** The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms.