# Plano West R3 – 1NC v Strake BL

## 1

#### Climate innovation happening rapidly now, but strong investment is key to reducing CO2 emissions

Henderson 20 (Chris Henderson is a Research Analyst at the Global Climate Action at World Resources Institute. Graduate from The George Washington University), “Investing in innovation is key to net-zero emissions”, Center for Climate and Energy Solutions, 7-28-20, <https://www.c2es.org/2020/07/investing-in-innovation-is-key-to-net-zero-emissions/> NT

Collectively, the world needs to reach net-zero emissions by 2050 in order to remain at 1.5 degrees C, or by 2070 to keep global temperature rise to 2 degrees C. However, many crucial technologies are not yet fully developed (see figure below). The report finds that 35 percent of the carbon dioxide emissions reductions necessary to meet the Paris Agreement’s 2-degree goal are dependent on technologies, such as CCUS for natural gas and hydrogen power turbines, which are still prototypes or in the early demonstration phase of development. A further 40 percent of reductions depend on technologies, including solar and wind power, electric vehicles and heat pumps, which are still in the “early-adoption” phase. These technologies **require significant R&D support** to reduce costs and improve operational efficiency. It can take a long time for technologies to move from basic research to wide-spread commercial adoption. Solar photovoltaic panels were first developed by Bell Labs in the 1950s, and only in the last decade have policy and technological advancements enabled the cost declines necessary for them to proliferate. Moreover, companies working on new technologies must navigate a period known as the ‘valley of death,’ in which they face the twin challenges of high costs and low investment in their technology. Without government policy intervention, many of these technologies may not mature quickly enough to deploy before it is too late. Investment in R&D can also produce additional public benefits, such as pollution reduction or the advancement of scientific knowledge, that companies cannot fully capture. **This makes public investments critical** to maximizing the potential of technological innovation.

#### Reducing IP for medicines spills over to climate solutions, which could force tech transfers between competitors, decimating investment in the green economy

Brand 5-26-21 (Melissa Brand is Assistant General Counsel and Director of Intellectual Property at the Biotechnology Innovation Organization (BIO), a major trade association with over 1,000 members in the biotechnology industry. In her role at BIO, Ms. Brand advocates on domestic and international intellectual property matters, with a particular emphasis on patent law and policy.), “TRIPS IP Waiver Could Establish Dangerous Precedent for Climate Change and Other Biotech Sectors”, Intellectual Property Watchdog, <https://www.ipwatchdog.com/2021/05/26/trips-ip-waiver-establish-dangerous-precedent-climate-change-biotech-sectors/id=133964/> NT

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. 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. 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. Next on the Chopping Block 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.

#### Solving warming is not all-or-nothing – every additional fraction of a degree is irreversible and costs millions of lives—prefer IPCC assessments that are the gold standard for warming consensus

David Wallace-Wells 19 [National Fellow at New America. He is deputy editor of New York Magazine, where he also writes frequently about climate and the near future of science and technology, including his widely read and debated 2017 cover story on worst-case scenarios for global warming], *The Uninhabitable Earth: A Story of the Future* (Kindle Edition: Allen Lane, 2019), pg. 8-30, beckert

* Every degree key – each bit 🡪 hundreds of millions of lives
* IPCC🡪 best ev b/c conservative estimate + still really big impact
* Now key – not reversible, feedback loops 🡪 speeds up later

There is almost no chance we will avoid that scenario. The Kyoto Protocol achieved, practically, nothing; in the twenty years since, despite all of our climate advocacy and legislation and progress on green energy, we have produced more emissions than in the twenty years before. In 2016, the Paris accords established two degrees as a global goal, and, to read our newspapers, that level of warming remains something like the scariest scenario it is responsible to consider; just a few years later, with no single industrial nation on track to meet its Paris commitments, two degrees looks more like a best-case outcome, at present hard to credit, with an entire bell curve of more horrific possibilities extending beyond it and yet shrouded, delicately, from public view.28 For those telling stories about climate, such horrific possibilities—and the fact that we had squandered our chance of landing anywhere on the better half of that curve—had become somehow unseemly to consider. The reasons are almost too many to count, and so half-formed they might better be called impulses. We chose not to discuss a world warmed beyond two degrees out of decency, perhaps; or simple fear; or fear of fearmongering; or technocratic faith, which is really market faith; or deference to partisan debates or even partisan priorities; or skepticism about the environmental Left of the kind I’d always had; or disinterest in the fates of distant ecosystems like I’d also always had. We felt confusion about the science and its many technical terms and hard-to-parse numbers, or at least an intuition that others would be easily confused about the science and its many technical terms and hard-to-parse numbers. We suffered from slowness apprehending the speed of change, or semi-conspiratorial confidence in the responsibility of global elites and their institutions, or obeisance toward those elites and their institutions, whatever we thought of them. Perhaps we felt unable to really trust scarier projections because we’d only just heard about warming, we thought, and things couldn’t possibly have gotten that much worse just since the first Inconvenient Truth; or because we liked driving our cars and eating our beef and living as we did in every other way and didn’t want to think too hard about that; or because we felt so “postindustrial” we couldn’t believe we were still drawing material breaths from fossil fuel furnaces. Perhaps it was because we were so sociopathically good at collating bad news into a sickening evolving sense of what constituted “normal,” or because we looked outside and things seemed still okay. Because we were bored with writing, or reading, the same story again and again, because climate was so global and therefore nontribal it suggested only the corniest politics, because we didn’t yet appreciate how fully it would ravage our lives, and because, selfishly, we didn’t mind destroying the planet for others living elsewhere on it or those not yet born who would inherit it from us, outraged. Because we had too much faith in the teleological shape of history and the arrow of human progress to countenance the idea that the arc of history would bend toward anything but environmental justice, too. Because when we were being really honest with ourselves we already thought of the world as a zero-sum resource competition and believed that whatever happened we were probably going to continue to be the victors, relatively speaking anyway, advantages of class being what they are and our own luck in the natalist lottery being what it was. Perhaps we were too panicked about our own jobs and industries to fret about the future of jobs and industry; or perhaps we were also really afraid of robots or were too busy looking at our new phones; or perhaps, however easy we found the apocalypse reflex in our culture and the path of panic in our politics, we truly had a good-news bias when it came to the big picture; or, really, who knows why—there are so many aspects to the climate kaleidoscope that transforms our intuitions about environmental devastation into an uncanny complacency that it can be hard to pull the whole picture of climate distortion into focus. But we simply wouldn’t, or couldn’t, or anyway didn’t look squarely in the face ﻿of the science. This is not a book about the science of warming; it is about what warming means to the way we live on this planet. But what does that science say? It is complicated research, because it is built on two layers of uncertainty: what humans will do, mostly in terms of emitting greenhouse gases, and how the climate will respond, both through straightforward heating and a variety of more complicated, and sometimes contradictory, feedback loops. But even shaded by those uncertainty bars it is also very clear research, in fact terrifyingly clear. The United Nations’ Intergovernmental Panel on Climate Change (IPCC) offers the gold-standard assessments of the state of the planet and the likely trajectory for climate change—gold-standard, in part, because it is conservative, integrating only new research that passes the threshold of inarguability. A new report is expected in 2022, but the most recent one says that if we take action on emissions soon, instituting immediately all of the commitments made in the Paris accords but nowhere yet actually implemented, we are likely to get about 3.2 degrees of warming, or about three times as much warming as the planet has seen since the beginning of industrialization—bringing the unthinkable collapse of the planet’s ice sheets not just into the realm of the real but into the present.29, 30 That would eventually flood not just Miami and Dhaka but Shanghai and Hong Kong and a hundred other cities around the world.31 The tipping point for that collapse is said to be around two degrees; according to several recent studies, even a rapid cessation of carbon emissions could bring us that amount of warming by the end of the century.32 The assaults of climate change do not end at 2100 just because most modeling, by convention, sunsets at that point. This is why some studying global warming call the hundred years to follow the “century of hell.”33 Climate change is fast, much faster than it seems we have the capacity to recognize and acknowledge; but it is also long, almost longer than we can truly imagine. In reading about warming, you will often come across analogies from the planetary record: the last time the planet was this much warmer, the logic runs, sea levels were here. These conditions are not coincidences. The sea level was there largely because the planet was that much warmer, and the geologic record is the best model we have for understanding the very complicated climate system and gauging just how much damage will come from turning up the temperature by two or four or six degrees. Which is why it is especially concerning that recent research into the deep history of the planet suggests that our current climate models may be underestimating the amount of warming we are due for in 2100 by as much as half.34 In other words, temperatures could rise, ultimately, by as much as double what the IPCC predicts. Hit our Paris emissions targets and we may still get four degrees of warming, meaning a green Sahara and the planet’s tropical forests transformed into fire-dominated savanna.35 The authors of one recent paper suggested the warming could be more dramatic still—slashing our emissions could still bring us to four or five degrees Celsius, a scenario they said would pose severe risks to the habitability of the entire planet. “Hothouse Earth,” they called it.36 Because these numbers are so small, we tend to trivialize the differences between them—one, two, four, five. Human experience and memory offer no good analogy for how we should think of those thresholds, but, as with world wars or recurrences of cancer, you don’t want to see even one. At two degrees, the ice sheets will begin their collapse, 400 million more people will suffer from water scarcity, major cities in the equatorial band of the planet will become unlivable, and even in the northern latitudes heat waves will kill thousands each summer.37, 38 There would be thirty-two times as many extreme heat waves in India, and each would last five times as long, exposing ninety-three times more people.39 This is our best-case scenario. At three degrees, southern Europe would be in permanent drought, and the average drought in Central America would last nineteen months longer and in the Caribbean twenty-one months longer. In northern Africa, the figure is sixty months longer—five years. The areas burned each year by wildfires would double in the Mediterranean and sextuple, or more, in the United States. At four degrees, there would be eight million more cases of dengue fever each year in Latin America alone and close to annual global food crises.41 There could be 9 percent more heat-related deaths.40 Damages from river flooding would grow thirtyfold in Bangladesh, twentyfold in India, and as much as sixtyfold in the United Kingdom. In certain places, six climate-driven natural disasters could strike simultaneously, and, globally, damages could pass $600 trillion—more than twice the wealth as exists in the world today. Conflict and warfare could double. Even if we pull the planet up short of two degrees by 2100, we will be left with an atmosphere that contains 500 parts per million of carbon—perhaps more. The last time that was the case, sixteen million years ago, the planet was not two degrees warmer; it was somewhere between five and eight, giving the planet about 130 feet of sea-level rise, enough to draw a new American coastline as far west as I-95.42 Some of these processes take thousands of years to unfold, but they are also irreversible, and therefore effectively permanent. You might hope to simply reverse climate change; you can’t. It will outrun all of us. This is part of what makes climate change what the theorist Timothy Morton calls a “hyperobject”—a conceptual fact so large and complex that, like the internet, it can never be properly comprehended.43 There are many features of climate change—its size, its scope, its brutality—that, alone, satisfy this definition; together they might elevate it into a higher and more incomprehensible conceptual ﻿category yet. But time is perhaps the most mind-bending feature, the worst outcomes arriving so long from now that we reflexively discount their reality. Yet those outcomes promise to mock us and our own sense of the real in return. The ecological dramas we have unleashed through our land use and by burning fossil fuels—slowly for about a century and very rapidly for only a few decades—will play out over many millennia, in fact over a longer span of time than humans have even been around, performed in part by creatures and in environments we do not yet even know, ushered onto the world stage by the force of warming. And so, in a convenient cognitive bargain, we have chosen to consider climate change only as it will present itself this century. By 2100, the United Nations says, we are due for about 4.5 degrees of warming, following the path we are on today.44 That is, farther from the Paris track than the Paris track is from the two-degree threshold of catastrophe, which it more than doubles. As Naomi Oreskes has noted, there are far too many uncertainties in our models to take their predictions as gospel.45 Just running those models many times, as Gernot Wagner and Martin Weitzman do in their book Climate Shock, yields an 11 percent chance we overshoot six degrees.46 Recent work by the Nobel laureate William Nordhaus suggests that better-than-anticipated economic growth means better than one-in-three odds that our emissions will exceed the U.47N.’s worst-case “business as usual” scenario. In other words, a temperature rise of five degrees or possibly more. The upper end of the probability curve put forward by the U.N. to estimate the end-of-the-century, business-as-usual scenario—the worst-case outcome of a worst-case emissions path—puts us at eight degrees. At that temperature, humans at the equator and in the tropics would not be able to move around outside without dying.48 In that world, eight degrees warmer, direct heat effects would be the least of it: the oceans would eventually swell two hundred feet higher, flooding what are now two-thirds of the world’s major cities; hardly any land on the planet would be capable of efficiently producing any of the food we now eat; forests would be roiled by rolling storms of fire, and coasts would be punished by more and more intense hurricanes; the suffocating hood of tropical disease would reach northward to enclose parts of what we now call the Arctic; probably about a third of the planet would be made unlivable by direct heat; and what are today literally unprecedented and intolerable droughts and heat waves would be the quotidian condition of whatever human life was able to endure.49, 50, 51, 52 We will, almost certainly, avoid eight degrees of warming; in fact, several recent papers have suggested the climate is actually less sensitive to emissions than we’d thought, and that even the upper bound of a business-as-usual path would bring us to about five degrees, with a likely destination around four.53 But five degrees is nearly as unthinkable as eight, and four degrees not much better: the world in a permanent food deficit, the Alps as arid as the Atlas Mountains.54 Between that scenario and the world we live in now lies only the open question of human response. Some amount of further warming is already baked in, thanks to the protracted processes by which the planet adapts to greenhouse gas. But all of those paths projected from the present—to two degrees, to three, to four, five, or even eight—will be carved overwhelmingly by what we choose to do now. There is nothing stopping us from four degrees other than our own will to change course, which we have yet to display. Because the planet is as big as it is, and as ecologically diverse; because humans have proven themselves an adaptable species, and will likely continue to adapt to outmaneuver a lethal threat; and because the devastating effects of warming will soon become too extreme to ignore, or deny, if they haven’t already; because of all that, it is unlikely that climate change will render the planet truly uninhabitable. But if we do nothing about carbon emissions, if the next thirty years of industrial activity trace the same arc upward as the last thirty years have, whole regions will become unlivable by any standard we have today as soon as the end of this century. ﻿A few years ago, E. O. Wilson proposed a term, “Half-Earth,” to help us think through how we might adapt to the pressures of a changing climate, letting nature run its rehabilitative course on half the planet and sequestering humanity in the remaining, habitable half of the world.55 The fraction may be smaller than that, possibly considerably, and not by choice; the subtitle of his book was Our Planet’s Fight for Life. On longer timescales, the even-bleaker outcome is possible, too—the livable planet darkening as it approaches a human dusk. It would take a spectacular coincidence of bad choices and bad luck to make that kind of zero earth possible within our lifetime. But the fact that we have brought that nightmare eventuality into play at all is perhaps the overwhelming cultural and historical fact of the modern era—what historians of the future will likely study about us, and what we’d have hoped the generations before ours would have had the foresight to focus on, too. Whatever we do to stop warming, and however aggressively we act to protect ourselves from its ravages, we will have pulled the devastation of human life on Earth into view—close enough that we can see clearly what it would look like and know, with some degree of precision, how it will punish our children and grandchildren. Close enough, in fact, that we are already beginning to feel its effects ourselves, when we do not turn away. ﻿It is almost hard to believe just how much has happened and how quickly. In the late summer of 2017, three major hurricanes arose in the Atlantic at once, proceeding at first along the same route as though they were battalions of an army on the march.56 Hurricane Harvey, when it struck Houston, delivered such epic rainfall it was described in some areas as a “500,000-year event”—meaning that we should expect that amount of rain to hit that area once every five hundred millennia.57 Sophisticated consumers of environmental news have already learned how meaningless climate change has rendered such terms, which were meant to describe storms that had a 1-in-500,000 chance of striking in any given year. But the figures do help in this way: to remind us just how far global warming has already taken us from any natural-disaster benchmark our grandparents would have recognized. To dwell on the more common 500-year figure just for a moment, it would mean a storm that struck once during the entire history of the Roman Empire. Five hundred years ago, there were no English settlements across the Atlantic, so we are talking about a storm that should hit just once as Europeans arrived and established colonies, as colonists fought a revolution and Americans a civil war and two world wars, as their descendants established an empire of cotton on the backs of slaves, freed them, and then brutalized their descendants, industrialized and postindustrialized, triumphed in the Cold War, ushered in the “end of history,” and witnessed, just a decade later, its dramatic return. One storm in all that time, is what the meteorological record has taught us to expect. Just one. Harvey was the third such flood to hit Houston since 2015.58 And the storm struck, in places, with an intensity that was supposed to be a thousand times rarer still. That same season, an Atlantic hurricane hit Ireland, 45 million were flooded from their homes in South Asia, and unprecedented wildfires tilled much of California into ash.59, 60 And then there was the new category of quotidian nightmare, climate change inventing the once-unimaginable category of obscure natural disasters—crises so large they would once have been inscribed in folklore for centuries today passing across our horizons ignored, overlooked, or forgotten. In 2016, a “thousand-year flood” drowned small-town Ellicott City, Maryland, to take but one example almost at random; it was followed, two years later, in the same small town, by another.61 One week that summer of 2018, dozens of places all over the world were hit with record heat waves, from Denver to Burlington to Ottawa; from Glasgow to Shannon to Belfast; from Tbilisi, in Georgia, and Yerevan, in Armenia, to whole swaths of southern Russia.62 The previous month, the daytime temperature of one city in Oman reached above 121 degrees Fahrenheit, and did not drop below 108 all night, and in Quebec, Canada, fifty-four died from the heat.63 That same week, one hundred major wildfires burned in the American West, including one in California that grew 4,000 acres in one day, and another, in Colorado, that produced a volcano-like 300-foot eruption of flames, swallowing an entire subdivision and inventing a new term, “fire tsunami,” along the way.64, 65, 66 On the other side of the planet, biblical rains flooded Japan, where 1.2 million were evacuated from their homes.67 Later that summer, Typhoon Mangkhut forced the evacuation of 2.45 million from mainland China, the same week that Hurricane Florence struck the Carolinas, turning the port city of Wilmington briefly into an island and flooding large parts of the state with hog manure and coal ash.68, 69, 70 Along the way, the winds of Florence produced dozens of tornadoes across the region.71 The previous month, in India, the state of Kerala was hit with its worst floods in almost a hundred years.72 That October, a hurricane in the Pacific wiped Hawaii’s East Island entirely off the map.73 And in November, which has traditionally marked the beginning of the rainy season in California, the state was hit instead with the deadliest fire in its history—the Camp Fire, which scorched several hundred square miles outside of Chico, killing dozens and leaving many more missing in a place called, proverbially, Paradise.74 The devastation was so complete, you could almost forget the Woolsey Fire, closer to Los Angeles, which burned at the same time and forced the sudden evacuation of 170,000. It is tempting to look at these strings of disasters and think, Climate change is here. And one response to seeing things long predicted actually come to pass is to feel that we have settled into a new era, with everything transformed. In fact, that is how California governor Jerry Brown described the state of things in the midst of the state’s wildfire disaster: “a new normal.”75 The truth is actually much scarier. That is, the end of normal; never normal again. We have already exited the state of environmental conditions that allowed the human animal to evolve in the first place, in an unsure and unplanned bet on just what that animal can endure. The climate system that raised us, and raised everything we now know as human culture and civilization, is now, like a parent, dead. And the climate system we have been observing for the last several years, the one that has battered the planet again and again, is not our bleak future in preview. It would be more precise to say that it is a product of our recent climate past, already passing behind us into a dustbin of environmental nostalgia. There is no longer any such thing as a “natural disaster,” but not only will things get worse; technically speaking, they have already gotten worse. Even if, miraculously, humans immediately ceased emitting carbon, we’d still be due for some additional warming from just the stuff we’ve put into the air already. And of course, with global emissions still increasing, we’re very far from zeroing out on carbon, and therefore very far from stalling climate change. The devastation we are now seeing all around us is a beyond-best-case scenario for the future of warming and all the climate disasters it will bring. ﻿What that means is that we have not, at all, arrived at a new equilibrium. It is more like we’ve taken one step out on the plank off a pirate ship. Perhaps because of the exhausting false debate about whether climate change is “real,” too many of us have developed a misleading impression that its effects are binary. But global warming is not “yes” or “no,” nor is it “today’s weather forever” or “doomsday tomorrow.” It is a function that gets worse over time as long as we continue to produce greenhouse gas. And so the experience of life in a climate transformed by human activity is not just a matter of stepping from one stable ecosystem into another, somewhat worse one, no matter how degraded or destructive the transformed climate is. The effects will grow and build as the planet continues to warm: from 1 degree to 1.5 to almost certainly 2 degrees and beyond. The last few years of climate disasters may look like about as much as the planet can take. In fact, we are only just entering our brave new world, one that collapses below us as soon as we set foot on it. Many of these new disasters arrived accompanied by debate about their cause—about how much of what they have done to us comes from what we have done to the planet. For those hoping to better understand precisely how a monstrous hurricane arises out of a placid ocean, these inquiries are worthwhile, but for all practical purposes the debate yields no real meaning or insight. A particular hurricane may owe 40 percent of its force to anthropogenic global warming, the evolving models might suggest, and a particular drought may be half again as bad as it might have been in the seventeenth century. But climate change is not a discrete clue we can find at the scene of a local crime—one hurricane, one heat wave, one famine, one war. Global warming isn’t a perpetrator; it’s a conspiracy. We all live within climate and within all the changes we have produced in it, which enclose us all and everything we do. If hurricanes of a certain force are now five times as likely as in the pre-Columbian Caribbean, it is parsimonious to the point of triviality to argue over whether this one or that one was “climate-caused.” All hurricanes now unfold in the weather systems we have wrecked on their behalf, which is why there are more of them, and why they are stronger. The same is true for wildfires: this one or that one may be “caused” by a cookout or a downed power line, but each is burning faster, bigger, and longer because of global warming, which gives no reprieve to fire season. Climate change isn’t something happening here or there but everywhere, and all at once. And unless we choose to halt it, it will never stop. Over the past few decades, the term “Anthropocene” has climbed out of academic discourse and into the popular imagination—a name given to the geologic era we live in now, and a way to signal that it is a new era, defined on the wall chart of deep history by human intervention. One problem with the term is that it implies a conquest of nature, even echoing the biblical “dominion.” But however sanguine you might be about the proposition that we have already ravaged the natural world, which we surely have, it is another thing entirely to consider the possibility that we have only provoked it, engineering first in ignorance and then in denial a climate system that will now go to war with us for many centuries, perhaps until it destroys us. That is what Wally Broecker, the avuncular oceanographer, means when he calls the planet an “angry beast.”76 You could also go with “war machine.” Each day we arm it more. The assaults will not be discrete—this is another climate delusion. Instead, they will produce a new kind of cascading violence, waterfalls and avalanches of devastation, the planet pummeled again and again, with increasing intensity and in ways that build on each other and undermine our ability to respond, uprooting much of the landscape we have taken for granted, for centuries, as the stable foundation on which we walk, build homes and highways, shepherd our children through schools and into adulthood under the promise of safety—and subverting the promise that the world we have engineered and built for ourselves, out of nature, will also protect us against it, rather than conspiring with disaster against its makers. Consider those California wildfires. In March 2018, Santa Barbara County issued mandatory evacuation orders for those living in Montecito, Goleta, Santa Barbara, Summerland, and Carpinteria—where the previous December’s fires had hit hardest. It was the fourth evacuation order precipitated by a climate event in the county in just three months, but only the first had been for fire.77 The others were for mudslides ushered into possibility by that fire, one of the toniest communities in the most glamorous state of the world’s preeminently powerful country upended by fear that their toy vineyards and hobby stables, their world-class beaches and lavishly funded public schools, would be inundated by rivers of mud, the community as thoroughly ravaged as the sprawling camps of temporary shacks housing Rohingya refugees from Myanmar in the monsoon region of Bangladesh.78 It was. More than a dozen died, including a toddler swept away by mud and carried miles down the mountainslope to the sea; schools closed and highways flooded, foreclosing the routes of emergency vehicles and making the community an inland island, as if behind a blockade, choked off by a mud noose.79 Some climate cascades will unfold at the global level—cascades so large their effects will seem, by the curious legerdemain of environmental change, imperceptible. A warming planet leads to melting Arctic ice, which means less sunlight reflected back to the sun and more absorbed by a planet warming faster still, which means an ocean less able to absorb atmospheric carbon and so a planet warming faster still. A warming planet will also melt Arctic permafrost, which contains 1.8 trillion tons of carbon, more than twice as much as is currently suspended in the earth’s atmosphere, and some of which, when it thaws and is released, may evaporate as methane, which is thirty-four times as powerful a greenhouse-gas warming blanket as carbon dioxide when judged on the timescale of a century; when﻿ judged on the timescale of two decades, it is eighty-six times as powerful.80, 81 A hotter planet is, on net, bad for plant life, which means what is called “forest dieback”—the decline and retreat of jungle basins as big as countries and woods that sprawl for so many miles they used to contain whole folklores—which means a dramatic stripping-back of the planet’s natural ability to absorb carbon and turn it into oxygen, which means still hotter temperatures, which means more dieback, and so on. Higher temperatures means more forest fires means fewer trees means less carbon absorption, means more carbon in the atmosphere, means a hotter planet still—and so on. A warmer planet means more water vapor in the atmosphere, and, water vapor being a greenhouse gas, this brings higher temperatures still—and so on. Warmer oceans can absorb less heat, which means more stays in the air, and contain less oxygen, which is doom for phytoplankton—which does for the ocean what plants do on land, eating carbon and producing oxygen—which leaves us with more carbon, which heats the planet further. And so on. These are the systems climate scientists call “feedbacks”; there are more.82 Some work in the other direction, moderating climate change. But many more point toward an acceleration of warming, should we trigger them. And just how these complicated, countervailing systems will interact—what effects will be exaggerated and what undermined by feedbacks—is unknown, which pulls a dark cloud of uncertainty over any effort to plan ahead for the climate future. We know what a best-case outcome for climate change looks like, however unrealistic, because it quite closely resembles the world as we live on it today. But we have not yet begun to contemplate those cascades that may bring us to the infernal range of the bell curve. Other cascades are regional, collapsing on human communities and buckling them where they fall. These can be literal cascades—human-triggered avalanches are on the rise, with 50,000 people killed by avalanches globally between 2004 and 2016.83 In Switzerland, climate change has unleashed a whole new kind, thanks to what are called “rain-on-snow” events, which also caused the overflow of the Oroville Dam in Northern California and the 2013 flood of Alberta, Canada, with damages approaching $5 billion.84 But there are other kinds of cascade, too. Climate-driven water shortages or crop failures push climate refugees into nearby regions already struggling with resource scarcity. Sea-level rise inundates cropland with more and more saltwater flooding, transforming agricultural areas into brackish sponges no longer able to adequately feed those living off them; flooding power plants, knocking regions offline just as electricity may be needed most; and crippling chemical and nuclear plants, which, malfunctioning, breathe out their toxic plumes. The rains that followed the Camp Fire flooded the tent cities hastily assembled for the first disaster’s refugees. In the case of the Santa Barbara mudslides, drought produced a state full of dry brush ripe for a spark; then a year of anomalously monsoonish rain produced only more growth, and wildfires tore through the landscape, leaving a mountainside without much plant life to hold in place the millions of tons of loose earth that make up the towering coastal range where the clouds tend to gather and the rain first falls. Some of those watching from afar wondered, incredulously, how a mudslide could kill so many. The answer is, the same way as hurricanes or tornadoes—by weaponizing the environment, whether “man-made” or “natural.” Wind disasters do not kill by wind, however brutal it gets, but by tugging trees out of earth and transforming them into clubs, making power lines into loose whips and electrified nooses, collapsing homes on cowering residents, and turning cars into tumbling boulders. And they kill slowly, too, by cutting off food delivery and medical supplies, making roads impassable even to first responders, knocking out phone lines and cell towers so that the ill and elderly must suffer, and hope to endure, in silence and without aid. Most of the world is not Santa Barbara, with its Mission-style impasto of infinite-seeming wealth, and in the coming decades many of the most punishing climate horrors will indeed hit those least able to respond and recover. This is what is often called the problem of environmental justice; a sharper, less gauzy phrase would be “climate caste system.” The problem is acute within countries, even wealthy ones, where the poorest are those who live in the marshes, the swamps, the floodplains, the inadequately irrigated places with the most vulnerable infrastructure—altogether an unwitting environmental apartheid. Just in Texas, 500,000 poor Latinos live in shantytowns called “colonias” with no drainage systems to deal with increased flooding.85 The cleavage is even sharper globally, where the poorest countries will suffer more in our hot new world. In fact, with one exception—Australia—countries with lower GDPs will warm the most.86 That is notwithstanding the fact that much of the global south has not, to this point, defiled the atmosphere of the planet all that much. This is one of the many historical ironies of climate change that would better be called cruelties, so merciless is the suffering they will inflict. But disproportionately as it will fall on the world’s least, the devastation of global warming cannot be easily quarantined in the developing world, as much as those in the Northern Hemisphere would probably, and not to our credit, prefer it. Climate disaster is too indiscriminate for that. In fact, the belief that climate could be plausibly governed, or managed, by any institution or human instrument presently at hand is another wide-eyed climate delusion. The planet survived many millennia without anything approaching a world government, in fact endured nearly the entire span of human civilization that way, organized into competitive tribes and fiefdoms and kingdoms and nation-states, and only began to build something resembling a cooperative blueprint, very piecemeal, after brutal world wars—in the ﻿form of the League of Nations and United Nations and European Union and even the market fabric of globalization, whatever its flaws still a vision of cross-national participation, imbued with the neoliberal ethos that life on Earth was a positive-sum game. If you had to invent a threat grand enough, and global enough, to plausibly conjure into being a system of true international cooperation, climate change would be it—the threat everywhere, and overwhelming, and total. And yet now, just as the need for that kind of cooperation is paramount, indeed necessary for anything like the world we know to survive, we are only unbuilding those alliances—recoiling into nationalistic corners and retreating from collective responsibility and from each other. That collapse of trust is a cascade, too. ﻿Just how completely the world below our feet will become unknown to us is not yet clear, and how we register its transformation remains an open question. One legacy of the environmentalist creed that long prized the natural world as an otherworldly retreat is that we see its degradation as a sequestered story, unfolding separately from our own modern lives—so separately that the degradation acquires the comfortable contours of parable, like pages from Aesop, aestheticized even when we know the losses as tragedy. Climate change could soon mean that, in the fall, trees may simply turn brown, and so we will look differently at entire schools of painting, which stretched for generations, devoted to best capturing the oranges and reds we can no longer see ourselves out the windows of our cars as we drive along our highways.87 The coffee plants of Latin America will no longer produce fruit; beach homes will be built on higher and higher stilts and still be drowned.88 In many cases, it is better to use the present tense. In just the last forty years, according to the World Wildlife Fund, more than half of the world’s vertebrate animals have died; in just the last twenty-five, one study of German nature preserves found, the flying insect population declined by three-quarters.89, 90 The delicate dance of flowers and their pollinators has been disrupted, as have the migration patterns of cod, which have fled up the Eastern Seaboard toward the Arctic, evading the communities of fishermen that fed on them for centuries; as have the hibernation patterns of black bears, many of which now stay awake all winter.91, 92, 93 Species individuated over millions of years of evolution but forced together by climate change have begun to mate with one another for the first time, producing a whole new class of hybrid species: the pizzly bear, the coy-wolf.94 The zoos are already natural history museums, the children’s books already out of date. Older fables, too, will be remade: the story of Atlantis, having endured and enchanted for several millennia, will compete with the real-time sagas of the Marshall Islands and Miami Beach, each sinking over time into snorkelers’ paradises; the strange fantasy of Santa and his polar workshop will grow eerier still in an Arctic of ice-free summers; and there is a terrible poignancy in contemplating how desertification of the entire Mediterranean Basin will change our reading of the Odyssey, or how it will discolor the shine of Greek islands for dust from the Sahara to permanently blanket their skies, or how it will recast the meaning of the Pyramids for the Nile to be dramatically drained.95, 96, 97 We will think of the border with Mexico differently, presumably, when the Rio Grande is a line traced through a dry riverbed—the Rio Sand, it’s already been called.98 The imperious West has spent five centuries looking down its nose at the plight of those living within the pale of tropical disease, and one wonders how that will change when mosquitoes carrying malaria and dengue are flying through the streets of Copenhagen and Chicago, too. But we have for so long understood stories about nature as allegories that we seem unable to recognize that the meaning of climate change is not sequestered in parable. It encompasses us; in a very real way it governs us—our crop yields, our pandemics, our migration patterns and civil wars, crime waves and domestic assaults, hurricanes and heat waves and rain bombs and megadroughts, the shape of our economic growth and everything that flows downstream from it, which today means nearly everything. Eight hundred million in South Asia alone, the World Bank says, would see their living conditions sharply diminish by 2050 on the current emissions track, and perhaps a climate slowdown will even reveal the bounty of what Andreas Malm calls fossil capitalism to be an illusion, sustained over just a few centuries by the arithmetic of adding the energy value of burned fossil fuels to what had been, before wood and coal and oil, an eternal Malthusian trap.99, 100 In which case, we would have to retire the intuition that history will inevitably extract material progress from the planet, at least in any reliable or global pattern, and come to terms, somehow, with just how pervasively that intuition ruled even our inner lives, often tyrannically. Adaptation to climate change is often viewed in terms of market trade-offs, but in the coming decades the trade will work in the opposite direction, with relative prosperity a benefit of more aggressive action. Every degree of warming, it’s been estimated, costs a temperate country like the United States about one percentage point of GDP, and according to one recent paper, at 1.5 degrees the world would be $20 trillion richer than at 2 degrees.101, 102 Turn the dial up another degree or two, and the costs balloon—the compound interest of environmental catastrophe. 3.7 degrees of warming would produce $551 trillion in damages, research suggests; total worldwide wealth is today about $280 trillion.103, 104 Our current emissions trajectory takes us over 4 degrees by 2100; multiply that by that 1 percent of GDP and you have almost entirely wiped out the very possibility of economic growth, which has not topped 5 percent globally in over forty years.105 A fringe group of alarmed academics call this prospect “steady-state economics,” but it ultimately suggests a more ﻿complete retreat from economics as an orienting beacon, and from growth as the lingua franca through which modern life launders all of its aspirations.106 “Steady-state” also gives a name to the creeping panic that history may be less progressive, as we’ve come to believe really only over the last several centuries, than cyclical, as we were sure it was for the many millennia before. More than that: in the vision steady-state economics projects of a state-of-nature competitive scramble, everything from politics to trade and war seems brutally zero-sum. For centuries we have looked to nature as a mirror onto which to first project, then observe, ourselves. But what is the moral? There is nothing to learn from global warming, because we do not have the time, or the distance, to contemplate its lessons; we are after all not merely telling the story but living it. That is, trying to; the threat is immense. How immense? One 2018 paper sketches the math in horrifying detail. In the journal Nature Climate Change, a team led by Drew Shindell tried to quantify the suffering that would be avoided if warming was kept to 1.5 degrees, rather than 2 degrees—in other words, how much additional suffering would result from just that additional half-degree of warming. Their answer: 150 million more people would die from air pollution alone in a 2-degree warmer world than in a 1.1075-degree warmer one. Later that year, the IPCC raised the stakes further: in the gap between 1.1085 degrees and 2, it said, hundreds of millions of lives were at stake. Numbers that large can be hard to grasp, but 150 million is the equivalent of twenty-five Holocausts. It is three times the size of the death toll of the Great Leap Forward—the largest nonmilitary death toll humanity has ever produced. It is more than twice the greatest death toll of any kind, World War II. The numbers don’t begin to climb only when we hit 1.5 degrees, of course. As should not surprise you, they are already accumulating, at a rate of at least seven million deaths, from air pollution alone, each year—an annual Holocaust, pursued and prosecuted by what brand of nihilism? This is what is meant when climate change is called an “existential crisis”—a drama we are now haphazardly improvising between two hellish poles, in which our best-case outcome is death and suffering at the scale of twenty-five Holocausts, and the worst-case outcome puts us on the brink of extinction.109 Rhetoric often fails us on climate because the only factually appropriate language is of a kind we’ve been trained, by a buoyant culture of sunny-side-up optimism, to dismiss, categorically, as hyperbole. Here, the facts are hysterical, and the dimensions of the drama that will play out between those poles incomprehensibly large—large enough to enclose not just all of present-day humanity but all of our possible futures, as well. Global warming has improbably compressed into two generations the entire story of human civilization. First, the project of remaking the planet so that it is undeniably ours, a project whose exhaust, the poison of emissions, now casually works its way through millennia of ice so quickly you can see the melt with a naked eye, destroying the environmental conditions that have held stable and steadily governed for literally all of human history. That has been the work of a single generation. The second generation faces a very different task: the project of preserving our collective future, forestalling that devastation and engineering an alternate path. There is simply no analogy to draw on, outside of mythology and theology—and perhaps the Cold War prospect of mutually assured destruction. Few feel like gods in the face of warming, but that the totality of climate change should make us feel so passive—that is another of its delusions. In folklore and comic books and church pews and movie theaters, stories about the fate of the earth often perversely counsel passivity in their audiences, and perhaps it should not surprise us that the threat of climate change is no different. By the end of the Cold War, the prospect of nuclear winter had clouded every corner of our pop culture and psychology, a pervasive nightmare that the human experiment might be brought to an end by two jousting sets of proud, rivalrous tacticians, just a few sets of twitchy hands hovering over the planet’s self-destruct buttons. The threat of climate change is more dramatic still, and ultimately more democratic, with responsibility shared by each of us even as we shiver in fear of it; and yet we have processed that threat only in parts, typically not concretely or explicitly, displacing certain anxieties and inventing others, choosing to ignore the bleakest features of our possible future and letting our political fatalism and technological faith blur, as though we’d gone cross-eyed, into a remarkably familiar consumer fantasy: that someone else will fix the problem for us, at no cost. Those more panicked are often hardly less complacent, living instead through climate fatalism as though it were climate optimism. Over the last few years, as the planet’s own environmental rhythms have seemed to grow more fatalistic, skeptics have found themselves arguing not that climate change isn’t happening, since extreme weather has made that undeniable, but that its causes are unclear—suggesting that the changes we are seeing are the result of natural cycles rather than human activities and interventions. It is a very strange argument; if the planet is warming at a terrifying pace and on a horrifying scale, it should transparently concern us more, rather than less, that the warming is beyond our control, possibly even our comprehension. That we know global warming is our doing should be a comfort, not a cause for despair, however incomprehensively large and complicated we find the processes that have brought it into being; that we know we are, ourselves, responsible for all of its punishing effects ﻿should be empowering, and not just perversely. Global warming is, after all, a human invention. And the flip side of our real-time guilt is that we remain in command. No matter how out-of-control the climate system seems—with its roiling typhoons, unprecedented famines and heat waves, refugee crises and climate conflicts—we are all its authors. And still writing.

## 2

#### Healthcare counterfeiting is on the rise, but national regulations in the status quo combat the problem for the WTO – IP is the goldilocks enabler for sustained cooperation.

**Author Diana Bentley in 2021**, (“The insidious problem of counterfeiting in healthcare," Raconteur, <https://www.raconteur.net/legal/intellectual-property/counterfeiting-healthcare/>) KD

**Criminal activity in healthcare has also intensified with the coronavirus pandemic**. Under Interpol’s Operation Pangea XIII, conducted last March, police, customs and **health authorities in 90 countries seized counterfeit** face masks, self-testing kits, anti-viral medication and other products worth more than $14 million, leading to 121 arrests and the closure of 2,500 weblinks and websites.

National and regional regulation, and the **work of healthcare producers and law enforcement agencies** including the police and customs officials, all **provide the front-line defence against healthcare counterfeiting**. Healthcare producers use a plethora of measures to combat the problem, notably barcodes, holograms and anti-tampering devices as well as a range of fieldwork.

In addition to mandatory features required by regulators for packaging, including serialisation, **pharmaceuticals giant Novartis uses overt and covert security features so country verifiers can identify falsified products**. Mobile laboratories are used by its forensic teams to analyse suspected samples in the field. A new cloud-based, mobile-enabled solution, which will accelerate the testing, detecting and reporting of false medicines to national authorities and WHO, is now being piloted.

**Technology is a critical enabler in the fight against pharmaceutical crime**, says Stanislas Barro, Novartis global head of anti-counterfeiting. “Detecting falsified medicines requires state-of-the-art technology to test packaging and products in the field. We use online monitoring, like webcrawlers with customised parameters, to monitor the internet 24/7 to detect illicit sales of suspected falsified medicines using our brands,” he says.

The company has also built a data analytics and visualisation dashboard to support its risk-analysis effort, he adds.

**Although counterfeiters are prosecuted by law enforcement agencies, the actions of IP holders remain vital.**

“We file trademarks to clearly identify our products and record our IP rights with customs authorities globally to empower them to identify suspected falsified goods,” says Myrtha Hurtado Rivas, Novartis global head of legal brand protection.

“But companies like ours cannot fully shift responsibility to reduce patient risk to national law enforcers. Taking action based on IP rights is necessary, for instance to ensure rogue online pharmacies are taken down swiftly. In the majority of legal actions, **having an IP right increases the chances of success against counterfeiters**.” Legitimate pharmaceutical companies also have a duty to report confirmed incidents of falsified versions of their products to local health authorities, Novartis points out, and it has voluntarily committed to reporting these to WHO within seven days of discovery following WHO’s recommendations.

#### IP is the key tool to prevent the spread of counterfeit medicines – the 1AC removes insurance measures for companies to have the necessary standards for developing high-quality medications.

**FIFARMA in 2021**, Latin American Federation of Pharma Industry, represent 16 research-based biopharmaceutical companies and 11 local associations dedicated to discovering and developing innovative, quality and safe health products and services that improve the lives of patients in Latin America and the Caribbean and advocate for patient-centric, sustainable health systems characterized by high regulatory standards and ethical principles ("This is how we fight counterfeit medicines with Intellectual Property," https://fifarma.org/en/this-is-how-we-fight-counterfeit-medicines-with-intellectual-property/) KD

**The role of IP**

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.

In the end, with the Intellectual Property associated with the creation of the product, there are also associated standards of transparency and detailed information that every regulatory agency can access. Moreover, the value chains will receive all this information in order to be aware of the appearance of products that are not registered with the standards of a product protected by IP.

Also, **IP helps to combat counterfeit medicines internationally, since there are laws that cover all member countries of the United Nations and punish more severely those who commit this crime.** Likewise, these laws provide countries with the necessary mechanisms to take concrete action once a counterfeit medicine is discovered. This, of course, must go hand in hand with the political will of each country, because only with collaboration between different actors will it be possible to prosecute the entire chain of counterfeit medicines.

#### Counterfeits inflate prices for market introductions and strengthen anti-microbial resistance – that’s the key internal link to pandemics

**Buckley and Gostin 13,** Senior Program Officer at National Academies of Sciences, Engineering, and Medicine; Highest Academic Rank at Georgetown Law, American law professor who specializes in public health law. He was a Fulbright Fellow and is best known as the author of the Model State Emergency Health Powers Act and as a significant contributor to journals on medicine and law ("The Effects of Falsified and Substandard Drugs," <https://www.ncbi.nlm.nih.gov/books/NBK202526/>) KD

**Individual patients have much to lose from substandard and falsified medicines**. These products also **encourage drug resistance** and thereby **threaten population health today and for future generations**. This is a particular concern with substandard products where the dose of active ingredient is low and variable and with **falsified products diluted by criminals in an effort to pass screening assays**. Drug resistance is common in pathogens with short life cycles: viruses, bacteria, and protozoa. Poor-quality antimicrobial medications, taken frequently and, **in poor countries**, generally taken without professional supervision, **contribute to drug resistance.**

Antimicrobial Resistance

Antibiotics should be used only when indicated, in the appropriate dose, and for the correct length of time. Ensuring the proper treatment with the right combination of drugs is the underlying principle of Directly Observed Treatment—Short Course (DOTS), the internationally accepted method of tuberculosis surveillance and treatment ([WHO SEARO, 2006](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). DOTS also depends on a safe and reliable drug supply. **Poor-quality drugs have been cited as a causal factor for the rise of multidrug-resistant tuberculosis** ([Kelland, 2012](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). Over time, the bacteria causing tuberculosis have become increasingly drug resistant. Multidrug-resistant tuberculosis precedes extensively drug-resistant tuberculosis, and finally, sometimes, totally drug-resistant tuberculosis ([Udwadia, 2012](https://www.ncbi.nlm.nih.gov/books/NBK202526/)**). Extensively drug-resistant strains of tuberculosis account for about** **6 percent of incident infections worldwide**, but much more in China, India, and the former Soviet Union ([Jain and Mondal, 2008](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). [Figure 2-1](https://www.ncbi.nlm.nih.gov/books/NBK202526/figure/fig_2_1/?report=objectonly) shows the increasing incidence of multidrug-resistant tuberculosis around the world.

**Drug-resistant bacteria often surface in hospitals, causing infections that are difficult to treat and are an important killer of adults in low-and middle-income countries** ([Okeke et al., 2005b](https://www.ncbi.nlm.nih.gov/books/NBK202526/); [WHO, 2012a](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). It is difficult to estimate the burden of antimicrobial resistance in low- and middle-income countries, in part because of the dearth of data, especially from francophone Africa, the Asian Pacific, and the former Soviet Union ([Okeke et al., 2005a](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). The data that do exist are grim. **Multidrug-resistant staph**ylococcus, an emerging problem in India and sub-Saharan Africa ([Parasa et al., 2010](https://www.ncbi.nlm.nih.gov/books/NBK202526/); [Vincent et al., 2009](https://www.ncbi.nlm.nih.gov/books/NBK202526/)), accounts for more than half of all nosocomial infections in parts of Latin America ([Guzmán-Blanco et al., 2009](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). (See [Figure 2-2](https://www.ncbi.nlm.nih.gov/books/NBK202526/figure/fig_2_2/?report=objectonly).)

In a qualitative study in Orissa, India, **doctors, veterinarians, and pharmacists cited poor-quality antibiotics as a cause of drug resistance,** but mentioned it only in passing, focusing more on patient and provider behaviors([Sahoo et al., 2010](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). This is consistent with most public health literature, which gives great deal of attention to the overuse of antibiotics as contributing to the rise of antimicrobial resistance in general ([Byarugaba, 2010](https://www.ncbi.nlm.nih.gov/books/NBK202526/); [Okeke et al., 2005b](https://www.ncbi.nlm.nih.gov/books/NBK202526/)) and **drug-resistant pneumonia in particular** ([Unicef and WHO, 2006](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). Comparatively little work, however, **discusses the role of drug quality in encouraging bacterial resistance**. Antibiotics that contain low doses of active ingredient cause low circulating levels of the drug in the patient. This contributes to treatment failure and selectively favors the growth of drug-resistant organisms ([Okeke et al., 2005b](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). Resistance is most common among the oldest and least expensive families of antibiotics ([Okeke et al., 2005b](https://www.ncbi.nlm.nih.gov/books/NBK202526/)).

According to a recent Tufts University estimate, it costs more than $1.3 billion to bring a new drug to market ([Kaitin, 2010](https://www.ncbi.nlm.nih.gov/books/NBK202526/)). Antibiotics in particular offer pharmaceutical companies a low return on investment; patients take them for only a week or two, in contrast to lifetime regimes of maintenance drugs. There would be even less monetary incentive to develop antibiotic for only the poorest parts of the world. Preserving antibiotics is imperative and depends on maintaining drug quality as much as on encouraging rational use.

#### ‘AMR is the key internal link to sustained pandemics and causes biowarfare

* AMR -> no herd immunity -> longer-lasting and stronger pandemics

**MacIntyre et al 18,** Principal Research Fellow, School of Public Health and Community Medicine, UNSW Medicine, University of New South Wales, Sydney, NSW 2052 Australia ("Converging and emerging threats to health security," PubMed Central (PMC), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/>) KD

There is growing recognition of the **costs and significance of AMR**. Multi-resistant organisms are emerging at much higher rates than seen previously, with **urgent attention needed to mitigate a risk which is predicted in one report to be the greatest global burden of disease** (Review on Antimicrobial Resistance [2016](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR65)). One recent estimate indicates that **by 2050, infections from resistant bacteria may overtake cancer as the leading cause of death in the world and cost US$100 trillion.** This estimate has been questioned and likely an overestimate, but AMR nonetheless causes a significant burden of disease (De Kraker et al. [2016](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR18)). The world is in urgent need of **new strategies** in the human, animal, agricultural and food industries. This includes **reviewing how we price/value antimicrobials, incentives for new antimicrobial development and judicious use, and restrictions around use across sectors**. In addition, **serious AMR could be engineered and released as an act of bioterrorism**, **given** the availability of **technology such as CRISP Cas9** (MacIntyre and Bui [2017](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR42)). A longer-term model of population risk (versus immediate individual risk of often minor infection) is required to guide everyday use and mitigate this global threat. **Whether a bioterrorist attack, pandemic or infections complicated by AMR**, the risk is increasing as outlined above. Infectious diseases do not respect international borders and can spread rapidly around the world. The continued growth in large urban areas, and megacities in particular, in which high population densities represent optimum conditions for spread of infection merits significant attention in biosecurity. This **risk is** **heightened** for megacities **in developing countries in which serious gaps exist in public health surveillance for early detection of epidemic threats**, together with **inadequate critical infrastructure** and other preparedness resources. Prevention, mitigation and control of these threats, therefore, require efforts at local, national and global levels. Despite the call for a One Health approach (Rabinowitz et al. [2013](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR63)), there is **no suitable system for governing use of antimicrobials across human health, animal health and food production, and often no coordination of efforts across these sectors.** **Global legal and governance frameworks for pandemics and bioterrorism are critical**, but there are **gaps in some relevant regulations**

—the International Health Regulations (IHR) (World Health Organization [2017c](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR95)), the Biological Weapons Convention (BWC) (United Nations Office for Disarmament Affairs [2016](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR85)) and the Cartagena Protocol (Convention on Biological Diversity [2012](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR15)). The IHR provides a framework for epidemic preparedness, **but many countries do not have the resources to comply with them**, and the IHR has not been fully revised since 2005 (World Health Organization [2008](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR90)). The BWC was revised in 2016, but widely regarded as unenforceable and inadequate in **considering new technologies** such as CRISPR Cas9 (Bulletin of the Atomic Scientists [2016](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR9)). The Cartagena protocol was developed to address regulation of movements of living modified organisms (LMOs) resulting from biotechnology from one country to another, but has focused on ecology and biodiversity and has not been utilised for human biosecurity. The TAPIC framework (Trump [2017](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7104605/#CR81)) is a good starting point for considering how existing regulations can be improved and enforced and how new ones could be developed globally.

#### Bioterrorism and future pandemics cause extinction.

Hamish De Bretton-Gordon, CBRN Expert @ British Army, 20 [Director @ DBG Defense, Consultant on CBRN and Biosecurity], “Biosecurity in the Wake of COVID-19: The Urgent Action Needed,” Combatting Terrorism Center Sentinel, November/December 2020, Volume 13, Issue 11, <https://ctc.usma.edu/biosecurity-in-the-wake-of-covid-19-the-urgent-action-needed/>

Policymakers around the world did not grasp just how large the impact of a bio threat could be. Beyond the enormous human and economic impact, the current pandemic has exposed the weakness, lack of preparedness, and poor responsiveness of healthcare systems of even highly developed countries like the United States and the United Kingdom. And the virus has inflicted carnage, even though SARS-CoV-2 (the virus that causes COVID-19) is not especially virulent. The world may be confronted with other viruses in the future whose combination of virulence (the harm a pathogen does to its host), transmissibility, and other characteristics pose much greater danger.

While overwhelming evidence points to SARS-CoV-2 spontaneously spreading to humans, the advances in synthetic biology and the growth in the number of Level 3 and 4 biocontainment facilities around the world storing deadly viruses1 mean there is also the very real possibility that in the future, bad actors will try to engineer or steal/obtain a highly transmissible and highly virulent virus and unleash it onto the world. Another risk is accidental releases from such biocontainment facilities.

COVID-19, a highly transmissible but not very virulent pathogen, has had a devastating global impact, a fact that will not have gone unnoticed by rogue states and terror organizations. Advances in synthetic biology have created tools that could be put to malevolent use. In the last two decades, scientists synthesized the poliovirus from its genetic sequence,2 recreated the 1918 Spanish flu virus,3 and succeeded in **modifying the H5N1 avian flu virus so that it resulted** (in a research laboratory) **in airborne transmission** among mammals.4 In the future, we should think of weaponized biology as no less of an existential threat to the planet than weaponized atomic science. It should also be noted that the fear and panic that even a medium-scale bioterror attack could create could have dangerous implications that may rival or even surpass the immediate loss of life.

The Need to Rethink Likelihood

Given the fact that in late 2019 when, as far as is known, COVID-19 cases first started emerging in China, it had been more than a century since the previous catastrophic outbreak (the 1918-1919 “Spanish flu” pandemic),d it was unsurprising that many thought of such pandemics as a one-in-a-100-year event. Such assumptions should no longer hold. The encroachment of human settlements into areas that had previously been sanctuaries for wildlife5 and the popularity in some parts of the world of markets where people and wild animals are brought into proximity have made it more likely viruses will make the species leap to human beings.e And when they do, as the COVID-19 pandemic illustrated, the interconnectedness of a world in which millions of people fly each day6 means they can spread very rapidly.

There is also growing concern about engineered viruses. Not only have advances in synthetic biology (SynBio) created growing capacity for extremely dangerous viruses to be engineered in a laboratory, but the number of people with access to potentially dangerous ‘dual use’ technology has greatly expanded and continues to expand, making malevolent use of such technology ever more likely.

In the August 2020 issue of this publication, scientists at the U.S. Military Academy at West Point warned that:

The wide availability of the protocols, procedures, and techniques necessary to produce and modify living organisms combined with an exponential increase in the availability of genetic data is leading to a revolution in science affecting the threat landscape that can be rivaled only by the development of the atomic bomb. As the technology improves, the level of education and skills necessary to engineer biological agents decreases. Whereas only state actors historically had the resources to develop and employ biological weapons, SynBio is changing the threat paradigm.

The cost threshold of engineering viruses is also lowering, with the West Point scientists warning that synthetic biology has “placed the ability to recreate some of the deadliest infectious diseases known well within the grasp of the state-sponsored terrorist and the talented non-state actor.”7

As already noted, another source of vulnerability is that deadly viruses could be stolen from or escape from a research laboratory

. There are now around 50 Biosafety Level 4f facilities around the world, where the deadliest pathogens are stored and worked on, and this figure is set to increase in the next few years.g This is a large increase over the last 30 years, creating bigger risk of a breach. Of equal, if not greater concern are the thousands of Biosafety Level 3 labs globally,8 which handle deadly pathogens like COVID-19.9

Given what has been outlined above, the risk of a future destructive biological attack or another devastating global pandemic should no longer be seen as low. From this point forward, there should no higher priority for the international community than biosecurity.

## 3

#### Counterplan Text: The member nations of the World Trade Organization ought to agree on specific conditions under which they could issue a compulsory license.

#### Even the threat of compulsory licensing increases access to essential medicine for developing countries

Ooms and Hanefield 19 (Department of Global Health and Development, Faculty of Public Health and Policy, London School of Hygiene and Tropical Medicine, London, UK. Gorik Ooms is a human rights lawyer and a global health scholar, Honorary Professor of Global Health Law & Governance at the London School of Hygiene & Tropical Medicine, Adjunct Professor at the Law Faculty of Georgetown University, and Visiting Professor at the Faculty of Medicine and Health Sciences of Ghent University. Johanna Hanefield is an Associate Professor in Health Policy and Systems Research at The London School of Hygiene and Tropical Medicine.), “Threat of compulsory licences could increase access to essential medicines”, BMJ 2019;365:l2098, 5-28-19, doi: <https://doi.org/10.1136/bmj.l2098>, <https://www.bmj.com/content/365/bmj.l2098> NT

The power of compulsory licences is most obvious when governments use them effectively. However, compulsory licences also have power when governments warn patent owners that they will use them if necessary. For example, when the US faced the threat of terrorists using anthrax in October 2001, the US secretary of health and social services wanted to stockpile ciprofloxacin, which was the best available treatment for anthrax. Bayer, the patent owner, demanded the usual price for ciprofloxacin, but when the US and Canada declared they might issue a compulsory licence, Bayer reduced the price.22 Neither Canada nor the US needed the Doha declaration to threaten Bayer as there was sufficient manufacturing capacity in both countries (and the Doha declaration came a month later). Thus threatening to use a compulsory licence may be as effective as formally issuing one. The Doha declaration solution is cumbersome to apply effectively, but it does give countries— even those without domestic manufacturing capacity— the power to threaten to use a compulsory licence. This may have an influence on prices. For example, sofosbuvir is a relatively new and highly effective treatment for hepatitis C, but its high price in some countries has proved controversial. Sofosbuvir came to the market in 2007. According to Iyengar and colleagues, the price of sofosbuvir was $64 680 per treatment in the US and $539 in India in 2015.23 In 2015, no country had issued a compulsory licence for sofosbuvir. The first such licence was issued by the Malaysian government in September 2017.24 Why the disparity in the price of sofosbuvir in the US compared with India? The prices were set by the originator, or by generic manufacturers working with a voluntary licence given by the patent owner. Thus, the “discount” for India, given or allowed by the patent owner, was 99% before any compulsory licence was issued. This is similar to the price reduction of the classic combination antiretroviral therapy, attributed to generic competition.25 We cannot be certain that the risk of a compulsory licence was the main reason for the patent owner of sofosbuvir allowing a 99% discount, but there is no other obvious explanation. India has manufacturers that can produce generic equivalents of sofosbuvir, as does Malaysia. Can countries without manufacturing capacity use the same strategy? Before the Doha declaration, patent owners would not have been impressed by a threat to issue a compulsory licence from a country without domestic manufacturing capacity. **Since the declaration, such a threat would be credible**. Although the Doha Declaration solution has been used only once, this was enough to show that it can be done, as long as countries with manufacturing capacity are willing to cooperate. Low and middle income countries would be in a stronger position if they declared their commitment to cooperate to make the Doha Declaration solution work. One option might be for them to agree on specific conditions under which they would issue compulsory licences for export based on the Doha declaration, if required by another member of the alliance.26 This would increase the credibility of threats to issue a compulsory licence by countries without manufacturing capacity. It would also give a signal to generic manufacturers of the potential size of the market, if all countries participating in this alliance would buy from the cheapest provider within the alliance. We should not be naive. As Sell points out, “there is a dizzying array of extra intellectual property protection that is being imposed on developing countries, such as TRIPS Plus agreements, in the form of bilateral agreements, free trade agreements, and plurilateral negotiations such as anti-counterfeiting trade agreements.”27 The political pressure used by rich countries against poorer countries to dissuade them from using their rights under the TRIPS agreement and the Doha declaration has increased. **However, the governments of low and middle income countries with manufacturing capacity are not as powerless as before the Doha declaration. They can issue compulsory licences for all medicines needed to protect public health without violating the TRIPS agreement**. They can declare their intention to help low and middle income countries without manufacturing capacity and, by doing so, empower these other countries. Whether they have the will to confront the likely political pressure is a different matter.

## Case

#### Turn – IP protections reward medical innovation and most essential medicines aren’t under patents, allowing companies to produce inexpensive generic versions

**Kilberg et al 16** (William J. Kilberg is the most senior partner in the Labor and Employment Law Practice Group at Gibson, Dunn & Crutcher LLP. He has served on the firm’s Executive Committee, five-member Management Committee, and as Partner-in-Charge of the Washington office. He has argued many significant matters before eight United States Courts of Appeals and the United States Supreme Court., James A. Paretti, Jr. is an experienced management-side employment and labor relations attorney with in-depth political and policy knowledge of labor, pension, healthcare and employment law, regulations and legislation. Jim is well versed in all aspects of legislative and political processes with demonstrated knowledge in the substance of federal labor and employment policy. He has over two decades of experience working with federal legislators and policymakers, including former Speaker of the U.S. House of Representatives, Chairmen of the U.S. House Committee on Education and the Workforce, and senior level administration officials., Marisa Maleck focuses on litigation, regulatory matters and public policy, with a focus on consumer products. As a former senior counsel at a bio-tech company and in private practice, Marisa has substantial experience with and is skilled in providing creative solutions in the face of uncertainty. Marisa represents clients in a variety of matters with a focus on FDA-regulated products like food, beverages, pharmaceuticals, medical devices, wellness products, cosmetics, tobacco and cannabis. As a former senior counsel at an FDA-regulated biotech company and as a former partner in King & Spalding’s Litigation and Global Disputes practice group, she handled hundreds of suits in a multi-district litigation, multiple agency inquiries, an FTC lawsuit and 10+ state Attorney Generals actions. ), “The United Nations' Misguided Approach to Healthcare Access”, 9-6-16, The Federalist Society, <https://fedsoc.org/commentary/fedsoc-blog/the-united-nations-misguided-approach-to-healthcare-access> NT

Intellectual property (IP) protections promote innovation and spur research and development into life-saving drugs and medical procedures. Indeed, the existence of robust systems of IP rights in Western industrialized nations is one reason the pharmaceutical industry and medical breakthroughs have flourished there. By contrast, drug companies have struggled in the developing world, where IP protections are either nascent or non-existent. One would think, therefore, that global policy advocates would encourage strong, uniform IP protections to help ensure the continued development of innovate treatments and broader access to health care in emerging markets. But instead of pursuing this sensible course, an obscure United Nations (UN) body called the High Level Panel on Access to Medicines is poised to release a report that is likely to recommend scaling back IP rights worldwide. This would be a tragedy for millions of ailing patients around the world. There is no doubt that a substantial need exists to improve access to medicines to the developing world. Approximately one in three patients in the developing world lack access to basic treatments. To solve this problem, the UN must focus on substantial barriers to access such as a lack of infrastructure and training.

Yet the panel appears ready to ignore these barriers by myopically and mistakenly focusing on IP rights. Established last year by UN Secretary General Ban Ki-moon to improve global access to life-saving medications, the Panel was tasked with a mandate “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.” Consistent with this charter, the sixteen-member Panel has reviewed proposals to address what it perceives to be a “misalignment” between inventors’ rights and “access to medicines, vaccines, diagnostics and health technologies.” The Panel is currently finalizing a report to the Secretary-General, which includes an analysis of the proposals and its recommendations. The Secretary-General, in turn, plans to make the report available to the General Assembly, and undertake unspecified further action. Many leaks from the group’s proceedings confirm its plan to emphasize perceived problems with IP rights rather than consider other issues that might hinder access to medicine. The rumors became so pervasive that, in June of this year, the Panel issued an “Official Statement on Speculative Media Reports.” The statement merely avers that the Panel is still working on the report, but it does not in any way deny that the group’s focus is on what it perceives to be a disconnect between access to healthcare and IP rights. The U.S. State Department has encouraged the Panel to shift its narrow focus on IP rights to tackle the real structural and economic problems that prevent access to health care in the developing world. The Panel should heed the State Department’s advice for one simple reason: There is no “policy incoherence” or “misalignment” between IP rights and access to health care. For starters, the vast majority of medicines that have been designated as essential by the World Health Organization (WHO)—350 of 375—are not even under patents. Rather, these medicines are currently available in **relatively inexpensive generic varieties.** In addition, many life-changing breakthroughs in drug research and development are made possible only because of America’s (and other countries’) extensive protections for IP. These protections grant companies a period of market exclusivity for original products, providing an incentive for companies and their investors to invest billions in research and development of the next generation of medications. Indeed, where countries have recently adopted more robust IP protections—such as India and China—pharmaceutical development and partnerships with Western drug companies have flourished and improved access to medicine. Furthermore, strong IP protections reduce the incentives for companies to develop fake or counterfeit drugs, thus helping to **ensure quality control** in the developing world. Ultimately, the Panel’s mandate to root out policy incoherence between IP rights and health care begs the critical question—do IP rights promote or hinder access to drugs and medical treatments in the developing world? The empirical evidence shows that IP rights improve access to health care in poorer countries. Therefore, the Panel should reconsider its marching orders and release a report that focuses on addressing the political, economic, and structural barriers to medicine in the developing world, rather than punishing companies that are responsible for putting life-saving products on the market.

#### Patents and IP protections prevent counterfeit drugs from being on the market while encouraging pharma companies to cooperate internationally

**Kilberg et al 16** (William J. Kilberg is the most senior partner in the Labor and Employment Law Practice Group at Gibson, Dunn & Crutcher LLP. He has served on the firm’s Executive Committee, five-member Management Committee, and as Partner-in-Charge of the Washington office. He has argued many significant matters before eight United States Courts of Appeals and the United States Supreme Court., James A. Paretti, Jr. is an experienced management-side employment and labor relations attorney with in-depth political and policy knowledge of labor, pension, healthcare and employment law, regulations and legislation. Jim is well versed in all aspects of legislative and political processes with demonstrated knowledge in the substance of federal labor and employment policy. He has over two decades of experience working with federal legislators and policymakers, including former Speaker of the U.S. House of Representatives, Chairmen of the U.S. House Committee on Education and the Workforce, and senior level administration officials., Marisa Maleck focuses on litigation, regulatory matters and public policy, with a focus on consumer products. As a former senior counsel at a bio-tech company and in private practice, Marisa has substantial experience with and is skilled in providing creative solutions in the face of uncertainty. Marisa represents clients in a variety of matters with a focus on FDA-regulated products like food, beverages, pharmaceuticals, medical devices, wellness products, cosmetics, tobacco and cannabis. As a former senior counsel at an FDA-regulated biotech company and as a former partner in King & Spalding’s Litigation and Global Disputes practice group, she handled hundreds of suits in a multi-district litigation, multiple agency inquiries, an FTC lawsuit and 10+ state Attorney Generals actions. ), “The United Nations' Misguided Approach to Healthcare Access”, 9-6-16, The Federalist Society, <https://fedsoc.org/commentary/fedsoc-blog/the-united-nations-misguided-approach-to-healthcare-access> NT

Intellectual Property Protections Promote Access to Health Care Far from preventing people from accessing the medicine they need, IP rights promote access to health care in two principal ways. First, IP rights provide scientists and researchers with the necessary incentives to spend time and money to develop life-saving drugs and devices. **Second, patents reduce the incentive to produce counterfeit drugs—a critical barrier to access to safe and effective medicine.** First, IP rights incentivize research and development. For health care companies, choosing whether to invest in developing and selling a particular medical product or treatment is an incredibly costly gamble. On average, an American company must spend over $2 billion and invest in a decade of scientific and legal research before regulators approve its product for the marketplace. The federal Food and Drug Administration as well as state agencies set out complex and demanding standards by which drugs and medical devices must be tested and developed. Companies must also invest time and money in determining whether their product or some part of their product already exists. And even after all that, only one in 12 health care products actually make it to the market—let alone turn a profit. IP rights therefore provide some **legal certainty** that a successful company would be able to protect this profit should it materialize.

Experts confirm that companies tend to invest and develop in countries with strong IP protections. As former U.S. Patent and Trademark Office Director David Kappos explained: “Far from being a roadblock, patents can be the currency of innovation that helps disseminate advanced technology in the developing world. Regardless of global destination, most high-tech goods are manufactured in a handful of countries which have functioning patent systems. Delivering innovative products to Africa, Southeast Asia, South America, or elsewhere thus requires legal rights in the manufacturing centers of the world. Patents enable business relationships that are otherwise difficult or impossible by encapsulating these legal rights into manageable assets.” Recent developments in India, China and Brazil prove Kappos’s observation. Since the mid-1990s, the World Trade Organization’s agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) has governed the international IP system. In 2005, India and China rewrote their domestic laws and became compliant with TRIPS. Prior to this development, Indian and Chinese pharmaceutical companies primarily manufactured generic versions of Western drugs. But since the adoption of TRIPs, with IP protections firmly in place, companies within the two countries have been extremely successful in developing their own products. Indian companies, for example, have developed vaccines for H1N1 influenza and rotavirus. And a Chinese company recently developed a medication for a type of lymph-node cancer. Stronger IP protections have also **fostered business relationships between Chinese and Indian companies and Western pharmaceutical companies.** Global research and development companies, including Bristol-Myers Squibb, Daiichi Sankyo, GlaxoSmithKline, and Sanofi-Aventis now all have partnerships with Indian companies. The same is true in China: Hutchison China MediTech is now working with AstraZeneca and Eli Lilly to research cancer drugs. Brazil has enjoyed similar successes. After it adopted product patent protections in 1996, numerous pharmaceutical companies began operating there. Experts also generally agree that patents promote access to medicine in developing countries, rather than hinder it. Health Issues India, an online joint initiative of various consultancy groups with an interest in Indian policy issues, recently commissioned a series of reports on access to healthcare. Health Issues India interviewed 28 public health officials, academics, and advocates in Brazil, Kenya, and Senegal. Of the 28, only one—a Brazilian AIDS activist—identified patents as part of the problem. By contrast, a number of these experts credited patents as indispensable to promoting access to healthcare. As detailed below, most experts agreed that problems such as a lack of infrastructure and education were the principal factors that created barriers to health-care access. Another study by Margaret Kyle and Yi Qian examined the effect of pharmaceutical patent protection on the speed of drug launch, price, and quantity in 60 countries from 2000 to 2013. The study concluded, among other things, **that stronger IP rights can increase the availability of new treatments to patient populations in developing countries**. In particular, these experts found that IP protections are associated with a **decrease in the price premium** of patented drugs, and that patents are generally associated with an earlier launch of new products and higher sales. In short, far from impeding access to medicine, IP protections have been empirically shown to encourage the development of life-saving drugs, therapies, medical devices, and protocols. Second, as many experts recognize, **strong IP protections inhibit the production and distribution of counterfeit and fake drugs.** The WHO estimates that approximately 10 percent of drugs sold globally are counterfeit, and some reports estimate that 50-70% of drugs sold in developing countries are counterfeit. Fake drugs pose a serious health risk: the WHO has found that as many as 20% of the million annual malaria-related deaths may be attributed to counterfeit medicines. The WHO has also found that it is easier to counterfeit drugs where there is—among other things—a lack of effective IP protections and weak regulatory controls. The threat of government enforcement actions and private suits go a long way in discouraging counterfeiting. Unsurprisingly, experts have criticized the UN Panel for “undermin[ing] the intellectual property rights architecture that . . . protects patients from counterfeit medicines.” As Dr. Kristina Lybecker—an author of a recent Organization for Economic Co-Operation and Development report—recently stated: “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.”