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#### Existential risks outweigh

Ord 20. Toby Ord, Senior Research Fellow in Philosophy at Oxford University & world-renowned risk-assessment expert who’s advised the World Health Organization, the World Bank, the World Economic Forum, the US National Intelligence Council and the UK Prime Minister’s Office. (3-3-2020, “The Precipice: Existential Risk and the Future of Humanity,” Hachette Book Group & Bloomsbury Publishing, <https://www.google.com/books/edition/The_Precipice/3aSiDwAAQBAJ?hl=en&gbpv=0>, Google Books)//pacc + AM \*bracketed for clarity\*

UNDERSTANDING EXISTENTIAL RISK

Humanity’s future is ripe with possibility. We have achieved a rich understanding of the world we inhabit and a level of health and prosperity of which our ancestors could only dream. We have begun to explore the other worlds in the heavens above us, and to create virtual worlds completely beyond our ancestors’ comprehension. We know of almost no limits to what we might ultimately achieve. Human extinction would foreclose our future. It would destroy our potential. It would eliminate all possibilities but one: a world ~~bereft~~ [lacking] of human flourishing. Extinction would bring about this failed world and lock it in forever—there would be no coming back. The philosopher Nick Bostrom showed that extinction is not the only way this could happen: there are other catastrophic outcomes in which we lose not just the present, but all our potential for the future. Consider a world in ruins: an immense catastrophe has triggered a global collapse of civilization, reducing humanity to a pre-agricultural state. During this catastrophe, the Earth’s environment was damaged so severely that it has become impossible for the survivors to ever reestablish civilization. Even if such a catastrophe did not cause our extinction, it would have a similar effect on our future. The vast realm of futures currently open to us would have collapsed to a narrow range of meager options. We would have a failed world with no way back. Or consider a world in chains: in a future reminiscent of George Orwell’s Nineteen Eighty-Four, the entire world has become locked under the rule of an oppressive totalitarian regime, determined to perpetuate itself. Through powerful, technologically enabled indoctrination, surveillance and enforcement, it has become impossible for even a handful of dissidents to find each other, let alone stage an uprising. With everyone on Earth living under such rule, the regime is stable from threats, internal and external. If such a regime could be maintained indefinitely, then descent into this totalitarian future would also have much in common with extinction: just a narrow range of terrible futures remaining, and no way out. [FIGURE 2.1 Omitted] Following Bostrom, I shall call these “existential catastrophes,” defining them as follows: 3 An existential catastrophe is the destruction of humanity’s longterm potential. An existential risk is a risk that threatens the destruction of humanity’s longterm potential. These definitions capture the idea that the outcome of an existential catastrophe is both dismal and irrevocable. We will not just fail to fulfill our potential, but this very potential itself will be permanently lost. While I want to keep the official definitions succinct, there are several areas that warrant clarification. First, I am understanding humanity’s longterm potential in terms of the set of all possible futures that remain open to us. 4 This is an expansive idea of possibility, including everything that humanity could eventually achieve, even if we have yet to invent the means of achieving it. 5 But it follows that while our choices can lock things in, closing off possibilities, they can’t open up new ones. So any reduction in humanity’s potential should be understood as permanent. The challenge of our time is to preserve our vast potential, and to protect it against the risk of future destruction. The ultimate purpose is to allow our descendants to fulfill our potential, realizing one of the best possible futures open to us. While it may seem abstract at this scale, this is really a familiar idea that we encounter every day. Consider a child with high longterm potential: with futures open to her in which she leads a great life. It is important that her potential is preserved: that her best futures aren’t cut off due to accident, trauma or lack of education. It is important that her potential is protected: that we build in safeguards to make such a loss of potential extremely unlikely. And it is important that she ultimately fulfills her potential: that she ends up taking one of the best paths open to her. So too for humanity. Existential risks threaten the destruction of humanity’s potential. This includes cases where this destruction is complete (such as extinction) and where it is nearly complete, such as a permanent collapse of civilization in which the possibility for some very minor types of flourishing remain, or where there remains some remote chance of recovery. 6 I leave the thresholds vague, but it should be understood that in any existential catastrophe the greater part of our potential is gone and very little remains. Second, my focus on humanity in the definitions is not supposed to exclude considerations of the value of the environment, other animals, successors to Homo sapiens, or creatures elsewhere in the cosmos. It is not that I think only humans count. Instead, it is that humans are the only beings we know of that are responsive to moral reasons and moral argument—the beings who can examine the world and decide to do what is best. If we fail, that upward force, that capacity to push toward what is best or what is just, will vanish from the world. Our potential is a matter of what humanity can achieve through the combined actions of each and every human. The value of our actions will stem in part from what we do to and for humans, but it will depend on the effects of our actions on non-humans too. If we somehow give rise to new kinds of moral agents in the future, the term “humanity” in my definition should be taken to include them. My focus on humanity prevents threats to a single country or culture from counting as existential risks. There is a similar term that gets used this way—when people say that something is “an existential threat to this country.” Setting aside the fact that these claims are usually hyperbole, they are expressing a similar idea: that something threatens to permanently destroy the longterm potential of a country or culture. Third, any notion of risk must involve some kind of probability. What kind is involved in existential risk? Understanding the probability in terms of objective long-run frequencies won’t work, as the existential catastrophes we are concerned with can only ever happen once, and will always be unprecedented until the moment it is too late. We can’t say the probability of an existential catastrophe is precisely zero just because it hasn’t happened yet. Situations like these require an evidential sense of probability, which describes the appropriate degree of belief we should have on the basis of the available information. This is the familiar type of probability used in courtrooms, banks and betting shops. When I speak of the probability of an existential catastrophe, I will mean the credence humanity should have that it will occur, in light of our best evidence.9 There are many utterly terrible outcomes that do not count as existential catastrophes. One way this could happen is if there were no single precipitous event, but a multitude of smaller failures. This is because I take on the usual sense of catastrophe as a single, decisive event, rather than any combination of events that is bad in sum. If we were to squander our future simply by continually treating each other badly, or by never getting around to doing anything great, this could be just as bad an outcome but wouldn’t have come about via a catastrophe. Alternatively, there might be a single catastrophe, but one that leaves open some way for humanity to eventually recover. From our own vantage, looking out to the next few generations, this may appear equally bleak. But a thousand years hence it may be considered just one of several dark episodes in the human story. A true existential catastrophe must by its very nature be the decisive moment of human history—the point where we failed. Even catastrophes large enough to bring about the global collapse of civilization may fall short of being existential catastrophes. While colloquially referred to as “the end of the world,” a global collapse of civilization need not be the end of the human story. It has the required severity, but may not be permanent or irrevocable. In this book, I shall use the term civilization collapse quite literally, to refer to an outcome where humanity across the globe loses civilization (at least temporarily), being reduced to a pre-agricultural way of life. The term is often used loosely to refer merely to a massive breakdown of order, the loss of modern technology, or an end to our culture. But I am talking about a world without writing, cities, law, or any of the other trappings of civilization. This would be a very severe disaster and extremely hard to trigger. For all the historical pressures on civilizations, never once has this happened— not even on the scale of a continent.10 The fact that Europe survived losing 25 to 50 percent of its population in the Black Death, while keeping civilization firmly intact, suggests that triggering the collapse of civilization would require more than 50 percent fatality in every region of the world.11 Even if civilization did collapse, it is likely that it could be reestablished. As we have seen, civilization has already been independently established at least seven times by isolated peoples.12 While one might think resource depletion could make this harder, it is more likely that it has become substantially easier. Most disasters short of human extinction would leave our domesticated animals and plants, as well as copious material resources in the ruins of our cities—it is much easier to re-forge iron from old railings than to smelt it from ore. Even expendable resources such as coal would be much easier to access, via abandoned reserves and mines, than they ever were in the eighteenth century. 13 Moreover, evidence that civilization is possible, and the tools and knowledge to help rebuild, would be scattered across the world. There are, however, two close connections between the collapse of civilization and existential risk. First, a collapse would count as an existential catastrophe if it were unrecoverable. For example, it is conceivable that some form of extreme climate change or engineered plague might make the planet so inhospitable that humanity would be irrevocably reduced to scattered foragers.14 And second, a global collapse of civilization could increase the chance of extinction, by leaving us more vulnerable to subsequent catastrophe. One way a collapse could lead to extinction is if the population of the largest remaining group fell below the minimum viable population—the level needed for a population to survive. There is no precise figure for this, as it is usually defined probabilistically and depends on many details of the situation: where the population is, what technology they have access to, the sort of catastrophe they have suffered. Estimates range from hundreds of people up to tens of thousands.15 If a catastrophe directly reduces human population to below these levels, it will be more useful to classify it as a direct extinction event, rather than an unrecoverable collapse. And I expect that this will be one of the more common pathways to extinction. We rarely think seriously about risks to humanity’s entire potential. We encounter them mostly in action films, where our emotional reactions are dulled by their overuse as an easy way to heighten the drama.16 Or we see them in online lists of “ten ways the world could end,” aimed primarily to thrill and entertain. Since the end of the Cold War, we rarely encounter sober discussions by our leading thinkers on what extinction would mean for us, our cultures or humanity. 17 And so in casual contexts people are sometimes flippant about the prospect of human extinction. But when a risk is made vivid and credible—when it is clear that billions of lives and all future generations are actually on the line—the importance of protecting humanity’s longterm potential is not, for most people, controversial. If we learned that a large asteroid was heading toward Earth, posing a greater than 10 percent chance of human extinction later this century, there would be little debate about whether to make serious efforts to build a deflection system, or to ignore the issue and run the risk. To the contrary, responding to the threat would immediately become one of the world’s top priorities. Thus our lack of concern about these threats is much more to do with not yet believing that there are such threats, than it is about seriously doubting the immensity of the stakes. Yet it is important to spend a little while trying to understand more clearly the different sources of this importance. Such an understanding can buttress feeling and inspire action; it can bring to light new considerations; and it can aid in decisions about how to set our priorities.

## 1

#### A. Interpretation: medicine refers to treatments and cures only. Affirmatives must not reduce other medical IP protections.

**B. Violation: vaccines are medical interventions, not medicines**

Elbe 10 [Stefan Elbe, director of the Centre for Global Health Policy and a professor of international relations at the University of Sussex. "Security and Global Health," ISBN 0745643744, accessed 8-10-2021, https://www.wiley.com/en-ee/Security+and+Global+Health-p-9780745643731] HWIC

Yet here too we must be careful not to overlook other types of medical intervention simultaneously pursued by the 'social' arm of modern medicine at the population level. Vaccines in particular continue to be particularly important medical interventions that repeatedly surface in a variety of different health security delib- erations. Strictly speaking, vaccines are not medicines because they consist of small concentrations of disease-causing microbes (or their derivatives) used to enhance a person's immuno-response to a future infection. As a public health measure, vaccines have therefore also been largely sidelined in the existing medicalization literature. Yet, generally speaking, vaccines too can be considered as medical inter- ventions. That is certainly how the World Health Organization views them, pointing out that 'vaccines are among the most important medical interventions for reducing illness and deaths' available today (WHO 2009a). Whereas pills and other therapies mark the tools of clinical medicine, vaccines play a crucial part in the arsenal of 'social' medicine and public health. Developing and rolling out of new vaccines against a range of current (and future) diseases therefore represents further evidence of how the rise of health security is also encouraging security to be practised through the introduction of new medical interventions in society.

**Vaccines are different from medicines in the context of intellectual property**

Garrison 04 [Christopher Garrison, Consultant Legal Advisor to WHO. "Intellectual Property Rights and Vaccines in Developing countries," 04-13-2004, accessed 9-2-2021, https://www.who.int/intellectualproperty/events/en/Background\_paper.pdf?ua=1] HWIC

In the last few years, there has been a substantial debate about how intellectual property impacts medicines and in particular how the TRIPS Agreement impacts access to medicines in the developing world. Vaccines are different from medicines in a number of important respects however (at least from the small molecule ‘pill’ medicines if not the newer ‘biotech’ medicines). The issues raised in the access to medicines debate may therefore apply to a greater or lesser extent for vaccines, depending on these differences. This section examines a few of the different forms of intellectual property rights that are relevant in the context of vaccines and outlines the impact of some of the differences between vaccines and medicines.

#### C. Reasons to prefer

#### 1. Limits -- allowing any patented medical intervention includes testing and screening methods, surgery, contact tracing software etc. which takes away generics like innovation bc that applies to pharmaceutical development not distribution of preventative measures which explodes neg prep burden

#### 2. Precision -- we cite the WHO which proves common usage -- they add a whole new caselist based on social medicine which kills predictability -- that's k2 pre-tournament prep and deep clash around the core topic controversy. Reject counter-interps without a positive vision of the topic -- otherwise they can always shift the goalposts

## 2

#### Biopharma R&D is surging, but it’s shaky because of productivity levels – now is not a time to let up

Adams 5/19 [Ben Adams, Ben Adams is a business, science and healthcare journalist, 5-19-2021, "Biopharma R&D 'surged' in 2020, but trial productivity levels a mixed bag: report," FierceBiotech, <https://www.fiercebiotech.com/biotech/biopharma-r-d-surged-2020-but-trial-productivity-levels-a-mixed-bag-report>] // WW LD

A major global pandemic was not enough to stop surging rates of biopharma research and development, but trial productivity still remains below the long-term average. That is according to a new report out by CRO analytics firm IQVIA, which found that funding for early- and late-stage R&D, as well as deals, jumped last year regardless of the pandemic, while aggregate R&D spend for the top 15 companies “reached a record high.” It also found that, overall, clinical trial activity recovered from midyear 2020 to levels above 2019–even without factoring in COVID-19 trials, which clearly didn’t exist the year before. Total trials reached 4,686, more than 300 extra than 2019 and an 8% rise, with 985 in phase 3, 1,880 in midstage testing and 1,821 in phase 1. But there is more complexity here: There was an increase in the clinical trial productivity index, i.e., the way IQVIA measures how these trials are doing, but in 2020 it found this was mostly due to an improvement in phase 3 trials, widening the gap with phase 1 trials, “which score significantly lower with this index.” When it comes to midstage tests, trials “have consistently been above the overall index” as success rates have been trending up and durations have been trending down, “even as complexity has been rising in phase 2 as rising numbers of endpoints and eligibility criteria are attributes of these trials.” Overall, however, productivity “remains below historic levels,” the report found, as success rates are below the long-term average. This is because the complexity of trials is generally increasing, as are study durations in many diseases, IQVIA’s authors note. Looking at the pipeline of pharma, IQVIA saw that growth in the late-stage pipeline continued in 2020, bringing total expansion to 43% since 2015, as cancer drugs reached record-high numbers. Growth in the early-stage pipeline, including next-generation biotherapeutics, paused in 2020, however. RELATED: The top 10 pharma R&D budgets in 2020 The dismal lack of diversity in clinical trials also continued: African Americans or races identified as Black account for 13.4% of the U.S. population, while the clinical trials used to approve new medicines had a median participation of only 3% in the past six years and “were under-representative 79% of the time from 2015 to 2020,” IQVIA said. Persons of Asian descent are also estimated to comprise 6.5% of the U.S. population, but again, only in 2015 was the median above this threshold, and 52% of trials in the past six years that were used by the FDA to approve medicines had under-representative participation. “The growth in research and development driven by new oncology drugs, new funding and strategic investments is a testament to the resilience and strength of the innovative, global biopharmaceutical industry,” said Murray Aitken, executive director of the IQVIA Institute for Human Data Science, in an accompanying release. “Faced with significant disruptions and the need to reprioritize research and development, the global life sciences industry has demonstrated its ability to meet and even exceed expectations for new and better lifesaving therapies and vaccines.”

#### Patents foster innovation

Grabowski et al 15 [Henry G. Grabowski, Joseph A. DiMasi, and Genia Long, February 2015, "The Roles Of Patents And Research And Development Incentives In Biopharmaceutical Innovation," https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047] // WW DL

The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term. Several economic characteristics make patents and intellectual property protection particularly important to innovation incentives for the biopharmaceutical industry. 5 The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a billion dollars in out-of-pocket costs. 6 Only approximately one in eight drug candidates survive clinical testing. 6 As a result of the high risks of failure and the high costs, research and development must be funded by the few successful, on-market products (the top quintile of marketed products provide the dominant share of R&D returns). 7,8 Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market. Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents. New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment. Patents play an essential role in the economic “ecosystem” of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. 11 The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms. Universities also play a key role in the R&D ecosystem because they conduct basic biomedical research supported by sponsored research grants from the National Institutes of Health (NIH) and the National Science Foundation (NSF). The Patent and Trademark Law Amendments Act of 1980 (commonly known as the Bayh-Dole Act) gave universities the right to retain title to patents and discoveries made through federally funded research. This change was designed to encourage technology transfer through industry licensing and the creation of start-up companies. Universities received only 390 patents for their discoveries in 1980, 12 compared to 4,296 in 2011, with biotechnology and pharmaceuticals being the top two technology areas (accounting for 36 percent of all university patent awards in 2012). 13 University licensing trends have generated debate. For instance, there have been recent proposals to encourage the federal government to “march in” and require a university to license a patent or enforce reduced pricing or other terms. 14 The percentage of approved drugs with public-sector patents is relatively small. 15 Nevertheless, if the government exercised its march-in rights in this way, that action could have adverse effects on technology transfer activities and early-stage company investment, particularly if it were to disrupt existing expectations of grantees, licensees, and investors. 12 There have been four petitions to the NIH requesting it to exercise march-in rights on behalf of the federal government; none has been granted. 16

#### Biotech relies on innovation from pharma

Cooper 6 [Garth JS Cooper, independent medical scientist at the University of Auckland, “Fates Intertwined,” March 2006, <https://library.wur.nl/WebQuery/file/cogem/cogem_t4505194e_001.pdf>] //recut WW LD

Biotechnology and pharmaceuticals are inextricably intertwined. Although biotech companies often rely upon the resources of larger pharma companies, the converse is also true. Among other things, biotechs require funding, validation, and access to expertise and markets. Big pharma continues to need ideas and products, and places to outsource risk. The pharmaceutical industry faces uncertainties driven by falling innovation 1,2, its relevance to reducing the global burden of disease , and the equity of access to its products3. If biotechs are not embraced by pharma—they cannot be copied —then as competitors they will increasingly come to dominate the industrial nexus. The issues of both industries need to be addressed together. Apart, biotech and pharma will continue to struggle with the self-determining issues that they currently confront. Working together, the fabric of these industries will be transformed and the world of human therapeutics will flourish.

#### Biotech is key to solving food insecurity

Doyle 08 [Alister Doyle, Environment Correspondent, 6-3-2008, "Biotechnology seen as a key to solving food crisis," U.S., <https://www.reuters.com/article/us-food-summit-biotech/biotechnology-seen-as-a-key-to-solving-food-crisis-idUSL0356693120080603>] // WW LD

“Biotechnology is one of the most promising tools for improving the productivity of agriculture and increasing the incomes of the rural poor,” U.S. Agriculture Secretary Ed Schafer said. “We are convinced of the benefits it offers to developing countries and small farmers,” he told a U.S.-led briefing on the sidelines of the June 3-5 summit seeking ways to combat high food prices when climate change may aggravate shortages. Some green groups say genetically-engineered crops threaten biodiversity while many European consumers are wary of eating products dubbed by critics as “Frankenfoods”. Schafer said biotechnology, including genetically-modified organisms (GMOs), could help produce more food by raising yields and producing crops in developing nations that are resistant to disease and pests. “Genetic engineering offers long-term solutions to some of our major crop production problems,” said Philippine Agriculture Minister Arthur Yap. But he said that it was not a panacea for all of his country’s agricultural problems. ADVERTISEMENT Progress being made in the Philippines included research into rice and coconuts resistant to disease, he said. “We’re also working on virus-resistant papaya, papaya hybrids with a longer shelf life that should be ready for market in 2009,” he said. Climate change could aggravate production around the world with more droughts, floods, disruptions to monsoons and rising sea levels, says the U.N. Climate Panel. In Africa alone, 250 million people could face extra stress on water supplies by 2020. COTTON Burkina Faso Agriculture Minister Laurent Sedogo said the African country had worked with U.S. agriculture group Monsanto to battle pests that blighted the cotton crop. ADVERTISEMENT “We are about to plant 15,000 hectares” of a new crop that was resistant to pests, he said. That would also cut down on the use of pesticides that could damage the health of farmers. The World Bank and aid agencies estimate that soaring food prices could push as many as 100 million more people into hunger. About 850 million are already hungry. Bangladesh said that it was going ahead with efforts to make crops able to survive floods and more salinity in the soil. A cyclone last year “is a wake-up call for all of us”, said C.S. Karim, an adviser to Bangladesh’s agriculture ministry. “It shows the vulnerability of Bangladesh. “

#### Food wars go nuclear—multiple studies

FDI 12 (Future Directions International - a Research institute providing strategic analysis of Australia’s global interests; citing Lindsay Falvery - PhD in Agricultural Science and former Professor at the University of Melbourne’s Institute of Land and Environment, “Food and Water Insecurity: International Conflict Triggers & Potential Conflict Points,” 5/25/12, <http://www.futuredirections.org.au/publication/international-conflict-triggers-and-potential-conflict-points-resulting-from-food-and-water-insecurity/>) // recut WW DL

There is a growing appreciation that the conflicts in the next century will most likely be fought over a lack of resources. Yet, in a sense, this is not new. Researchers point to the French and Russian revolutions as conflicts induced by a lack of food. More recently, Germany’s World War Two efforts are said to have been inspired, at least in part, by its perceived need to gain access to more food. Yet the general sense among those that attended FDI’s recent workshops, was that the scale of the problem in the future could be significantly greater as a result of population pressures, changing weather, urbanisation, migration, loss of arable land and other farm inputs, and increased affluence in the developing world. In his book, Small Farmers Secure Food, Lindsay Falvey, a participant in FDI’s March 2012 workshop on the issue of food and conflict, clearly expresses the problem and why countries across the globe are starting to take note. . He writes (p.36), “…if people are hungry, especially in cities, the state is not stable – riots, violence, breakdown of law and order and migration result.” “Hunger feeds anarchy.” This view is also shared by Julian Cribb, who in his book, The Coming Famine, writes that if “large regions of the world run short of food, land or water in the decades that lie ahead, then wholesale, bloody wars are liable to follow.” He continues: “An increasingly credible scenario for World War 3 is not so much a confrontation of super powers and their allies, as a festering, self-perpetuating chain of resource conflicts.” He also says: “The wars of the 21st Century are less likely to be global conflicts with sharply defined sides and huge armies, than a scrappy mass of failed states, rebellions, civil strife, insurgencies, terrorism and genocides, sparked by bloody competition over dwindling resources.” As another workshop participant put it, people do not go to war to kill; they go to war over resources, either to protect or to gain the resources for themselves. Another observed that hunger results in passivity not conflict. Conflict is over resources, not because people are going hungry. A study by the International Peace Research Institute indicates that where food security is an issue, it is more likely to result in some form of conflict. Darfur, Rwanda, Eritrea and the Balkans experienced such wars. Governments, especially in developed countries, are increasingly aware of this phenomenon. The UK Ministry of Defence, the CIA, the US Center for Strategic and International Studies and the Oslo Peace Research Institute, all identify famine as a potential trigger for conflicts and possibly even nuclear war.

#### Food insecurity cause extinction

Cribb ‘10 [Julian, principal of JCA, fellow of the Australian Academy of Technological Sciences, “The Coming Famine: The¶ Global Food Crisis and What We Can Do to Avoid It”, pg 10] // recut WW LD/WWVL

The character of human conflict has also changed: since the early 1990S, more wars have been triggered by disputes over food, land, and water than over mere political or ethnic differences. This should not surprise US: people have fought over the means of survival for most of history. But in the abbreviated reports on the nightly media, and even in the rarefied realms of government policy, the focus is almost invariably on the players—the warring national, ethnic, or religious factions—rather than on the play, the deeper subplots building the tensions that ignite conflict. Caught up in these are groups of ordinary, desperate people fearful that there is no longer sufficient food, land, and water to feed their children—and believing that they must fight ‘the others” to secure them. At the same time, the number of refugees in the world doubled, many of them escaping from conflicts and famines precipitated by food and resource shortages. Governments in troubled regions tottered and fell. The coming famine is planetary because it involves both the immediate effects of hunger on directly affected populations in heavily populated regions of the world in the next forty years—and also the impacts of war, government failure, refugee crises, shortages, and food price spikes that will affect all human beings, no matter who they are or where they live. It is an emergency because unless it is solved, billions will experience great hardship, and not only in the poorer regions. Mike Murphy, one of the world’s most progressive dairy farmers, with operations in Ireland, New Zealand, and North and South America, succinctly summed it all up: “Global warming gets all the publicity but the real imminent threat to the human race is starvation on a massive scale. Taking a 10—30 year view, I believe that food shortages, famine and huge social unrest are probably the greatest threat the human race has ever faced. I believe future food shortages are a far bigger world threat than global warming.”2° The coming famine is also complex, because it is driven not by one or two, or even a half dozen, factors but rather by the confluence of many large and profoundly intractable causes that tend to amplify one another. This means that it cannot easily be remedied by “silver bullets” in the form of technology, subsidies, or single-country policy changes, because of the synergetic character of the things that power it.

## 3

#### Climate Patents and Innovation high now and solving Warming but patent waivers set a dangerous precedent for appropriations - the mere threat is sufficient is enough to kill investment.

Brand 5-26, Melissa. “Trips Ip Waiver Could Establish Dangerous Precedent for Climate Change and Other Biotech Sectors.” IPWatchdog.com | Patents & Patent Law, 26 May 2021, www.ipwatchdog.com/2021/05/26/trips-ip-waiver-establish-dangerous-precedent-climate-change-biotech-sectors/id=133964/. //sid

The biotech industry is making remarkable advancestowards climate change solutions, and it is precisely for this reason that it can expect to be in the crosshairs of potential IP waiver discussions. President Biden is correct to refer to climate change as an existential crisis. Yet it does not take too much effort to connect the dots between President Biden’s focus on climate change and his Administration’s recent commitment to waive global IP rights for Covid vaccines (TRIPS IP Waiver). “This is a global health crisis, and the extraordinary circumstances of the COVID-19 pandemic call for extraordinary measures.” If an IP waiver is purportedly necessary to solve the COVID-19 global health crisis (and of course [we dispute this notion](https://www.ipwatchdog.com/2021/04/19/waiving-ip-rights-during-times-of-covid-a-false-good-idea/id=132399/)), can we really feel confident that this or some future Administration will not apply the same logic to the climate crisis? And, without the confidence in the underlying IP for such solutions, what does this mean for U.S. innovation and economic growth? United States Trade Representative (USTR) [Katherine Tai](https://www.ipwatchdog.com/2021/05/05/tai-says-united-states-will-back-india-southafrica-proposal-waive-ip-rights-trips/id=133224/) was subject to questioning along this very line during a recent Senate Finance Committee hearing. And while Ambassador Tai did not affirmatively state that an IP waiver would be in the future for climate change technology, she surely did not assuage the concerns of interested parties. 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 compensationand 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 proprietaryknow-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 internationalcollaborations. Even if one could assume that the United States could not implement forced tech transfer on its own soil, what about the governments of our international development partners? It is not hard to understand that a U.S.-based company developing climate change technologies would be unenthusiastic about partnering with a company abroad knowing that the foreign country’s government is on track – with the assent of the U.S. government – to change its laws and seize proprietary materials and know-how that had been voluntarily transferred to the local company. Necessary Investment Could Diminish Developing climate change solutions is not an easy endeavor and bad policy positions threaten the likelihood that they will materialize. These products have long lead times from research and development to market introduction, owing not only to a high rate of failure but also rigorous regulatory oversight. Significant investment is required to sustain and drive these challenging and long-enduring endeavors. For example, synthetic biology companies critical to this area of innovation [raised over $1 billion in investment in the second quarter of 2019 alone](https://www.bio.org/sites/default/files/2021-04/Climate%20Report_FINAL.pdf). If investors cannot be confident that IP will be in place to protect important climate change technologies after their long road from bench to market, it is unlikely they will continue to investat the current and required levels**.**

#### Climate change destroys the world.

Specktor 19 [Brandon writes about the science of everyday life for Live Science, and previously for Reader's Digest magazine, where he served as an editor for five years] 6-4-2019, "Human Civilization Will Crumble by 2050 If We Don't Stop Climate Change Now, New Paper Claims," livescience, <https://www.livescience.com/65633-climate-change-dooms-humans-by-2050.html> Justin

The current climate crisis, they say, is larger and more complex than any humans have ever dealt with before. General climate models — like the one that the [United Nations' Panel on Climate Change](https://www.ipcc.ch/sr15/) (IPCC) used in 2018 to predict that a global temperature increase of 3.6 degrees Fahrenheit (2 degrees Celsius) could put hundreds of millions of people at risk — fail to account for the **sheer complexity of Earth's many interlinked geological processes**; as such, they fail to adequately predict the scale of the potential consequences. The truth, the authors wrote, is probably far worse than any models can fathom. How the world ends What might an accurate worst-case picture of the planet's climate-addled future actually look like, then? The authors provide one particularly grim scenario that begins with world governments "politely ignoring" the advice of scientists and the will of the public to decarbonize the economy (finding alternative energy sources), resulting in a global temperature increase 5.4 F (3 C) by the year 2050. At this point, the world's ice sheets vanish; brutal droughts kill many of the trees in the [Amazon rainforest](https://www.livescience.com/57266-amazon-river.html) (removing one of the world's largest carbon offsets); and the planet plunges into a feedback loop of ever-hotter, ever-deadlier conditions. "Thirty-five percent of the global land area, and **55 percent of the global population, are subject to more than 20 days a year of** [**lethal heat conditions**](https://www.livescience.com/55129-how-heat-waves-kill-so-quickly.html), beyond the threshold of human survivability," the authors hypothesized. Meanwhile, droughts, floods and wildfires regularly ravage the land. Nearly **one-third of the world's land surface turns to desert**. Entire **ecosystems collapse**, beginning with the **planet's coral reefs**, the **rainforest and the Arctic ice sheets.** The world's tropics are hit hardest by these new climate extremes, destroying the region's agriculture and turning more than 1 billion people into refugees. This mass movement of refugees — coupled with [shrinking coastlines](https://www.livescience.com/51990-sea-level-rise-unknowns.html) and severe drops in food and water availability — begin to **stress the fabric of the world's largest nations**, including the United States. Armed conflicts over resources, perhaps culminating in **nuclear war, are likely**. The result, according to the new paper, is "outright chaos" and perhaps "the end of human global civilization as we know it."

## Case

#### **Vote neg on presumption – the aff can’t solve any of their impacts ow on recency**

Garde et al 5-6 [Damian Garde , Helen Branswell , and Matthew Herper May 6, 2021, 5-6-2021, "Waiver of patent rights on Covid vaccines may be mostly symbolic, for now," STAT, <https://www.statnews.com/2021/05/06/waiver-of-patent-rights-on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/>] // WW LD

The U.S.’s stunning endorsement of a proposal to waive Covid-19 vaccine patents has won plaudits for President Biden and roiled the global pharmaceutical industry. But, at least in the short term, it’s likely to be more of a symbolic milestone than a turning point in the pandemic. For months, proponents of the proposal have argued that the need to waive intellectual property protections was urgent given the growth of Covid cases in low- and middle-income countries, which have been largely left without the huge shipments of vaccine already purchased by wealthy countries. But patents alone don’t magically produce vaccines. Experts suggested the earliest the world could expect to see additional capacity flowing from the waiver — if it’s approved at the World Trade Organization — would be in 2022. Prashant Yadav, a supply chain expert and senior fellow at the Center for Global Development, said the biggest barrier to increasing the global vaccine supply is a lack of raw materials and facilities that manufacture the billions of doses the world needs. Temporarily suspending some intellectual property, as the U.S. proposes to do, would have little effect on those problems, he said. “My take is: By itself, it will not get us much benefit in increased manufacturing capacity,” Yadav said. “But as part of a larger package, it can.” That larger package would include wealthy nations like the U.S. mounting an Operation Warp Speed-style effort to invest in manufacturing in low-income countries, he said, using their vast financial resources to actually produce vaccine doses rather than solely targeting patents. Lawrence Gostin, director of the O’Neill Institute for National and Global Health Law at Georgetown Law, said the waiver is necessary but hardly sufficient. It will likely take months of international infighting before the proposal would take effect, he said, months during which would-be manufacturers would not have the right to start producing vaccines. “We’re not talking about any immediate help for India or Latin America or other countries going through an enormous spread of the virus,” Gostin said. “While they’re going to be negotiating the text, the virus will be mutating.” Even James Love, director of the nonprofit Knowledge Ecology International and a longtime advocate of intellectual property reform, acknowledges a patent waiver would be a valuable first step, not a panacea. The fairly narrow proposal would mostly allow countries to issue compulsory licenses, essentially allowing third-party manufacturers to make and sell other companies’ patented products, while also helping free up some information about how that manufacturing is done. But that, at least, could provide a financial incentive for those third parties to invest in vaccine production. “In our experience, when the legal barriers disappear and there’s a market, capacity increases faster than you would think,” he said. In October, Moderna vowed not to enforce its Covid-19-related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses. That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines. “There are currently no generic vaccines primarily because there are hundreds of process steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, but the transfer of skills is not that simple,” said Norman Baylor, who formerly headed the Food and Drug Administration’s Office of Vaccines Research and Review, and who is now president of Biologics Consulting. While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — using messenger RNA technology — require skilled expertise that even existing manufacturers are having trouble sourcing. “In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said. There are already huge constraints on some of the raw materials and equipment used to make vaccines. Pfizer, for instance, had to appeal to the Biden administration to use the Defense Production Act to help it cut the line for in-demand materials necessary for manufacturing. Rajeev Venkayya, head of Takeda Vaccines — which is not producing its own Covid vaccine but is helping to make vaccine for Novavax — said supply shortages are impacting not just Covid vaccine production but the manufacture of other vaccines and biological products as well. “This is an industry-wide … looming crisis that will not at all be solved by more tech transfers,” Venkayya said. He suggested many of the people advocating for this move are viewing the issue through the prism of drug development, where lifting intellectual property restrictions can lead to an influx of successful generic manufacturing. “I think in this area there is an unrecognized gap in understanding of the complexities of vaccine manufacturing by many of the ‘experts’ that are discussing it,” said Venkayya, who stressed that while he believes they have good intentions, “nearly all of the people who are providing views on the value of removing patent protections have zero experience in vaccine development and manufacturing.” As Michelle McMurry-Heath, CEO of the trade group BIO, put it in a statement, “handing needy countries a recipe book without the ingredients, safeguards, and sizable workforce needed will not help people waiting for the vaccine.” Conversely, the drug industry claims that waiving patents, even temporarily, risks irreparable damage to the system of incentives that made the rapid development of Covid-19 vaccines possible. Stephen Ubl, CEO of the powerful lobbying group PhRMA, said in a statement that the idea “flies in the face of President Biden’s stated policy of building up American infrastructure and creating jobs by handing over American innovations to countries looking to undermine our leadership in biomedical discovery.” Umer Raffat, an equities analyst who tracks pharmaceuticals at Evercore ISI, thinks the risks to the drug industry might be overstated. It’s highly doubtful a patent waiver would set a precedent beyond vaccines, Raffat wrote in a note to investors, and the scarcity of raw materials combined with complexity of modern pharmaceutical manufacturing makes it unlikely that any third party could meaningfully compete with a multinational drug company. But the decision could nonetheless be a sea change for the way governments think about intellectual property — a hole in the IP dam that unleashes a tidal wave. Love, of Knowledge Ecology, said that the decision shifts the discussion around pandemic vaccines from countries believing there is nothing that can be done to a new position: “What do we need to do?” Said Love: “If you really think this is a big emergency, ‘what do we need to do’ should be the question, not just saying we can’t do anything.” That could, in turn, have long-term impacts on how countries view pharmaceutical intellectual property — and how much protection drug makers are provided on their own patents.

#### WTO creates monopolies through hyperglobalization; doesn’t prioritize climate change policies, continuing to cede authority to the WTO doesn’t solve under their own fwk

Lori Wallach, 11-28-2019, "Opinion," No Publication, <https://www.nytimes.com/2019/11/28/opinion/seattle-world-trade-organization.html/ww> ap

Twenty years ago this weekend, 50,000 people converged on Seattle to protest the World Trade Organization, which was holding a ministerial-level meeting in the city, and a plan championed by the world’s largest corporations to increase the organization’s authority over even more facets of people’s lives. The epic protests, televised worldwide, revealed that Americans were united with millions of people protesting the organization in other countries, who demanded new rules for the global economy to make it benefit more people. Those protests, and subsequent protests and activism around the world, bolstered developing-country negotiators who derailed the W.T.O.’s plans for expansion. But the W.T.O.’s underlying principles still shape the global economy. And the stubborn refusal to alter that model of globalization has fostered a global backlash against “trade” and, in recent years, brought the organization to near collapse. The [dirty little secret](https://www.citizen.org/wp-content/uploads/introforweb.pdf) is that the World Trade Organization is not mainly about trade. Rather the organization has the primary task of carrying out what the Harvard economist [Dani Rodrik calls hyperglobalization](https://www.nytimes.com/2016/09/18/opinion/sunday/put-globalization-to-work-for-democracies.html?auth=login-email&login=email) — the worldwide imposition of one-size-fits-all rules, favored by global financial markets, which constrain democratic governments’ ability to address their societies’ needs. The W.T.O. asserts expansive power to set binding rules over a wide range of non-trade issues; countries are required to “[ensure the conformity](https://www.wto.org/english/docs_e/legal_e/04-wto_e.htm) of its laws, regulations and administrative procedures” with W.T.O. rules — and, in turn, corporate financial interests. This includes limits on energy policy, financial regulation and food and product safety, as well as new monopoly protections for pharmaceutical firms to charge consumers more. If countries do not comply, they are subject to millions of dollars in trade penalties. Of the [242 completed W.T.O. cases, in only 22](https://www.citizen.org/wp-content/uploads/wto_disputes_summary_-_march_2019_final.pdf) did the domestic policies, many unrelated to trade, survive challenged. Thus, the country-of-origin labels on meat that we relied on in American grocery stores were [eliminated](https://www.citizen.org/wp-content/uploads/cool-repeal-december-2015.pdf) after the W.T.O. classified them as “illegal trade barriers” and authorized $1 billion in sanctions. The United States was also forced to weaken regulations under the [Clean Air Act](https://www.washingtonpost.com/archive/politics/1999/11/29/gasoline-dispute-highlights-environmental-concerns/62dea60b-d37f-41f3-9433-5202296041a4/), [dolphin protection](https://www.citizen.org/wp-content/uploads/migration/case_documents/trump_factor_in_wto_dolphin-safe_tuna_ruling.pdf) laws and Endangered Species Act rules. Given the role played by the United States in pushing the W.T.O., there is a certain irony that more than a third of challenges decided by the organization have targeted American policies — which have been found to violate W.T.O. rules 90 percent of the time. Developing countries have fared yet worse, losing 95 percent of 87 challenges. The United States has filed 49 challenges against other countries, with rulings against Indian policies promoting access to seeds for poor farmers and European limits on genetically modified foods and a ban on artificial growth hormones in meat. The United States has used threats to pressure Thailand, Brazil and South Africa to reverse policies on access to AIDS medication and other lifesaving drugs. Recently the W.T.O. has facilitated a [circular firing squad](https://www.piie.com/commentary/op-eds/cooling-planet-without-chilling-trade) over climate-change efforts. The European Union and Japan challenged Canadian incentives on renewable energy. The United States won a case against a solar-power program in India. Then India attacked renewable energy programs in several American states. Then China filed a case in 2018 against additional American renewable energy measures. But the W.T.O.’s overreach could prove to be its undoing. Its ability to decide such cases will effectively end on Dec. 11, when its appellate review board will no longer have a quorum. After a series of W.T.O. decisions in which tribunals cooked up new standards — never agreed to by member nations — related to anti-dumping and subsidy issues, the Obama administration initiated a protest. Last year, the Trump administration doubled down, blocking the appointment of new appellate adjudicators. The Seattle protesters who raised concerns about giving too much power to the W.T.O. were dismissed as anti-trade. But it was W.T.O. proponents, those who branded the organization and similar deals as “trade agreements,” who have given trade a bad name. Since the W.T.O.’s formation in 1995, its proponents have oversold it with grandiose promises of dazzling economic gains. [President Bill Clinton said](https://www.c-span.org/video/?61809-1/general-agreement-tariffs-trade.) the organization would deliver the average American family $1,700 a year of additional income. It would facilitate open market access that would, in turn, reduce our trade deficit, create new high-paying jobs and bring new riches to farm country. But the organization’s rules were not designed for those outcomes, which never materialized. Instead, trade negotiations have been [dominated by corporate interests](https://www.washingtonpost.com/business/economy/trade-deals-a-closely-held-secret-shared-by-more-than-500-advisers/2014/02/28/7daa65ec-9d99-11e3-a050-dc3322a94fa7_story.html), while labor, consumer, and environmental groups are largely shut out. It’s no shock, then, that the W.T.O. has no labor or environmental requirements to raise wages or limit pollution, or that it sets ceilings but no floors on consumer safety standards. Nor are there rules disciplining monopolistic mega-corporations that now distort global markets or combating currency manipulations that create unfair trade advantages. No doubt some American workers are bitterly angry and moved by Donald Trump’s trade rhetoric after having repeatedly been promised great gains from “trade” agreements. During the W.T.O. era, developed countries have lost millions of high-paying manufacturing jobs, especially after China joined in 2001. Income inequality between rich and poor countries, and within countries, has increased greatly. Of course, the W.T.O. isn’t dead yet; the question is, will it see the looming crisis and undertake the reforms necessary to save itself? Unlikely: Its current priority is to set new limits on regulations regarding e-commerce and data privacy at a time when most people are clamoring for some check on the industry. This is especially perverse, given that the original global trade body, the 1948 International Trade Organization, provides a ready foundation for creating better global trade rules. With a focus on full employment and fair competition coming out of the horrors of World War II, the I.T.O. included labor standards, anti-monopoly provisions and currency-cheating rules to ensure the benefits of trade accrued to more people. But the Senate blocked American participation in the organization, effectively killing it. That very different vision for a rules-based global trading system remains attainable, once we agree that the system is supposed to work for people around the world, not the world’s largest corporations. Twenty years after Seattle, we still have work to do.

#### A vaccine waiver greenlights counterfeit medicine – independently turns Case.

Conrad 5-18 John Conrad 5-18-2021 "Waiving intellectual property rights is not in the best interests of patients" <https://archive.is/vsNXv#selection-5353.0-5364.0> (president and CEO of the Illinois Biotechnology Innovation Organization in Chicago.)//Elmer

The Biden's administration's support for India and South Africa's proposal before the World Trade Organization to temporarily waive anti-COVID vaccine patents to boost its supply will fuel the **development of counterfeit vaccines and weaken the already strained global supply chain**. The proposal will not increase the effective number of COVID-19 vaccines in India and other countries. The manufacturing standards to produce COVID-19 vaccines are **exceptionally complicated**; it is unlike any other manufacturing process. To ensure patient safety and efficacy, only manufacturers with the **proper facilities and training should produce the vaccine, and they are**. Allowing a temporary waiver that permits compulsory licensing to allow a manufacturer to export counterfeit vaccines will **cause confusion and endanger public health**. For example, between 60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit vaccine containing incorrect active pharmaceutical ingredients, resulting in more than **100 fatal infections.** Beyond the patients impacted, counterfeit drugs erode public confidence in health care systems and the pharmaceutical industry. Vaccine hesitancy is a rampant threat that feeds off of the distribution of misinformation. Allowing the production of vaccines from improper manufacturing facilities further opens the door for antivaccine hacks to stoke the fear fueling **vaccine hesitance**.

#### Counterfeit drugs lead to drug resistant diseases - turns the aff

**Jahnke, 19** (Art Jahnke, Art Jahnke began his career at the Real Paper, a Boston area alternative weekly. He has worked as a writer and editor at Boston Magazine, web editorial director at CXO Media, and executive editor in Marketing & Communications at Boston University, where his work was honored with many awards., 1-14-2019, accessed on 8-17-2021, Boston University, "How Substandard and Counterfeit Drugs Drive Drug-Resistant Infections", https://www.bu.edu/articles/2019/how-bad-drugs-turn-treatable-diseases-deadly/)

Muhammad Zaman learned at an early age that one did not shop for medicine at the convenient neighborhood pharmacy. In Pakistan, where he grew up, the safer thing to do was walk the extra mile to a pharmacy whose drugs were known to be high quality. Four decades later as a Boston University professor of biomedical engineering and materials science and engineering, Zaman was reminded of the dangers of low-quality drugs in his native country when he learned that more than 200 people in the city of Lahore died after being treated with an adulterated version of a hypertension drug. That event, in 2012, altered the course of Zaman’s research. Now, he focuses on the global problem of “substandard drugs,” poorly made medicines containing ingredients that are either ineffective or toxic. His most recent discovery has startling implications for our understanding of drug resistance: a low-quality version of rifampin, a broad spectrum antibiotic typically used as the first line of defense to treat tuberculosis, can greatly contribute to the development of drug-resistant infections. The findings, published in Antimicrobial Agents and Chemotherapy, are particularly pressing because drug-resistant TB is an increasing problem worldwide. Of the 10 million new cases of tuberculosis in 2016, about 600,000 were rifampin resistant, requiring second-line treatments which come with increased toxicity. “There had not been a definitive study showing that lack of [antibiotic] quality leads to resistance,” says Zaman, who is also a Howard Hughes Medical Institute Professor of Biomedical Engineering and International Health. “Now we are sure that it does, and it does with TB, a global problem that has become stubbornly hard to resolve.” “We had always thought of this a scientific issue, but now it is also an ethical issue.”Muhammad Zaman Zaman says substandard drugs, as well as drugs that are deliberate counterfeits, are all too common in developing nations. A recent survey by the World Health Organization found that in low- and middle-income countries, one in ten medicines is substandard or falsified. One contributing factor could be that government enforcement of safe manufacturing practices is feeble or nonexistent. In Pakistan, for example, a country of nearly 200 million people, only a handful of federal inspectors monitor the quality of drug manufacturing. Across sub-Saharan Africa, things are no better. A recent World Health Organization (WHO) study written in part by Paul Newton, an adjunct professor at BU School of Public Health, found that substandard antimalarials killed more than 120,000 children under the age of five in 2013. Another WHO study, conducted in 2008, found that 64 percent of antimalarial drugs tested in Nigeria were substandard. When the same study looked at antimalarials in Cameroon, Ethiopia, Ghana, Kenya, Nigeria, and Tanzania, it found that 28 percent of 267 samples were substandard. Zaman says it’s impossible to know how many deaths globally are caused by substandard drugs because people don’t usually die immediately. They could die, as the Lahore victims did, from a toxic reaction, or they could die from the disease that the drug was supposed to cure. Or, says Zaman, he and other scientists have long speculated that they could die for a third reason: adulterated medicines could encourage the development of drug resistance, rendering the disease incurable with standard treatments. Although that possibility had been considered for years, Zaman and Zohar Weinstein teamed up to finally put the hunch to the test. In the lab, Zaman and Weinstein, a postdoctoral researcher in biomolecular pharmacology who’s nearly finished with her medical degree as well, conducted several tests with rifampin to learn if a degraded form of the TB drug could build drug resistance in bacteria. They first ran a series of in vitro tests pitting rifampin against E. coli, sometimes referred to as the workhorse bacteria of laboratories because its rapid doubling time makes it ideal for such studies. The researchers exposed the bacteria to gradually increasing doses of rifampin, which suppresses RNA transcription in bacteria, leading to cell death. They then ran the same tests with rifampin quinone, the most commonly found form of degraded rifampin. Within a week, they observed that the bacteria became significantly more resistant to the drug. Next, the researchers repeated the experiment, swapping out E. coli for a strain of tuberculosis called M. smegmatis, selected because it has a conveniently short doubling time of two hours, while the more common strain of tuberculosis has a doubling time of about one day. After two weeks, the M. smegmatis also began to show signs of resistance. “We found that over five days, E. coli exposed to [rifampin quinone] became up to 64 times more resistant to rifampin,” says Weinstein. “And over 22 days, M. smegmatis became up to 100 [times] more resistant to rifampin.” “You could be a good patient and still acquire drug-resistant bacteria, because the drugs you were taking were leading you to resistance.”Muhammad Zaman Zaman and Weinstein had expected such responses, but they didn’t expect to find such a powerful resistance. In fact, once the bacteria gained resistance, no amount of standard rifampin would kill them. The researchers also looked for another indicator of rifampin resistance: a genetic mutation in a gene called rpoB. What they discovered was alarming. “We found that the majority of bacteria exposed to [rifampin quinone] also had mutations in this gene, even though they had never been exposed to the standard drug,” says Weinstein. In other words, the degraded drug wasn’t just failing to cure the disease, it was cultivating cross-resistance to the high-quality, standard product. In that sense, says Zaman, bad drugs can become doubly dangerous. “That [observation] was very revealing,” says Zaman. “It changed the equation, because we had always thought of this a scientific issue, but now it is also an ethical issue. We usually think of the spread of resistant TB in two ways. We say you got it because you were exposed to resistant TB, maybe you were living with someone with resistant TB. The second way is you got it because you were supposed to take drugs and you didn’t adhere to the program. But what this study reveals is that you could be a good patient and still acquire drug-resistant bacteria, because the drugs you were taking were leading you to [treatment] resistance.” “While it is well established that subtherapeutic doses of medicines play a role in antimicrobial resistance, this is, as far as I know, the first demonstration of how substandard medicines directly drive the emergence of resistance genes in pathogens,” says Michael Levy, vice president of USP’s Quality Institute, which researches the influence of substandard drugs on health outcomes. USP is a nonprofit organization that sets drug quality standards that are legally recognized in the US and are also used in more than 140 other countries. Zaman’s next steps will be threefold. First, he plans to test the quality of drugs that are available in the community hospitals of several low-income countries, looking specifically for the presence of rifampin quinone, the degraded form of rifampin. Second, he plans to work with researchers at the National Emerging Infectious Diseases Laboratories (NEIDL) on a mouse model to study the resistance mechanism in vivo. Third, he says he hopes to expand his work to investigate adulterated forms of other commonly used, high-impact antibiotics. Meanwhile, patients around the world are still being prescribed substandard antibiotics every day. “The patient may be doing everything he or she is supposed to do and still become resistant [to treatment],” Zaman says. This work was supported by National Institute of General Medical Sciences and USP.

#### Reducing IP protections isn’t the silver bullet to vaccine distribution – lack of technical knowledge and expertise and export restrictions constrain the process

de Bolle and Obstfeld 5/12, Monica, senior fellow at the Peterson Institute for International Economics, Maurice, nonresident senior fellow at the Peterson Institute, Peterson Institute for International Economics, “Waiving patent and intellectual property protections is not a panacea for global vaccine distribution”, <https://www.piie.com/blogs/realtime-economic-issues-watch/waiving-patent-and-intellectual-property-protections-not>, Accessed 6/27/21 VD

The second, and arguably more intractable, challenge is technical: Even if they overcome IP obstacles and get permission to produce vaccines, less prosperous countries lack the know-how, facilities, and trained personnel to produce them. Despite the abysmal decades-long record of vaccine distribution in those countries, existing TRIPS flexibilities have done nothing to improve the situation. A smoother IP waiver process might help, but only as a component of a broader effort. True, patent protection is the main obstacle to creation of generic small-molecule drugs, which chemists can synthesize. But other major obstacles exist for vaccines, which are biologics. For the latter category of drugs, an identical product requires an identical production technology, with most steps categorized as hard-to-replicate trade secrets rather than patentable innovations. Thus, Moderna announced in October 2020 that it would not enforce its COVID-19-related patents during the pandemic. But this step, however laudable, is of limited immediate help to would-be producers of a "generic" version of the Moderna vaccine. Without precisely replicating all steps of Moderna's production process, including the many quality controls, a generic version would have untested immunogenicity (the ability to induce the body to generate an immune response) and thus would require extensive clinical trials before release. Production glitches—such as those that afflicted the Janssen/Johnson & Johnson vaccine in the United States—could prompt widespread vaccine skepticism, damaging pandemic control efforts. The replication hurdle is especially high for the new and more sophisticated messenger ribonucleic acid (mRNA) vaccines, which have proven most effective against SARS-CoV-2 (the virus that causes COVID-19) and which are likely to provide the most adaptable platforms for the vaccines of the future. The genetic vaccines produced by Pfizer-BioNTech and Moderna require considerable technical knowledge and sophisticated techniques to generate a version of the viral spike protein that elicits a strong immune response.1 Therefore, from a biological standpoint, patent and IP waivers alone cannot resolve the existing lack of capacity in most countries to produce genetic vaccines at scale locally. A final challenge is that vaccine supply chains are intricate and global in scope. Different stages of vaccine manufacturing are spread across different parts of the globe, with various countries supplying key inputs and equipment. Patent and IP waivers cannot resolve export restrictions that these countries may decide to impose—and in fact have imposed—throughout the pandemic. Nor can poor countries with production waivers easily integrate into global supply chains. At the moment, current production capacity and quality standards continue to constrain global supply.

#### Multiple alt causes to high drug prices and limited access

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The Panel Is Poised To Ignore Real Access Problems The Panel’s misguided focus on patents has led the U.S. State Department to encourage the Panel to abandon its “narrow mandate” and instead focus on actual obstacles that stand in the way of persons obtaining life-saving drugs. Echoing the WHO, the State Department has pointed to four main reasons that the developing world lacks access to healthcare: (1) an inability to select and use medicines rationally; (2) unaffordable drug prices; (3) unreliable health and supply systems; and (4) inadequate financing. **None of these barriers are directly related to patents**. First, irrational drug use is a serious barrier to access. The WHO defines “irrational use” as any use that is not “appropriate to [patients’] clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.” Two recent studies conducted in Africa illustrate this problem. One study conducted at Kapiri Mposhi District Hospital in Central province, Zambia found a high prevalence of irrational drug use. Fifty percent of 680 patient records surveyed showed some form of inappropriate drug use. And a study in Sudan found that 73% of participants reported to have acquired and used medication without a prescription at least a month prior to the study. Second, there is no doubt that affordability is a barrier to access. But patent protections are not to blame. In fact, patents do not protect the vast majority of essential medicines, which the WHO defines as “those drugs that satisfy the health care needs of the majority of the population.” 350 of these 375 “essential medicines” are available in generic versions and are thus sold at a much lower price point. Moreover, data shows that patent-holding companies do not frequently make use of patent laws in developing countries, even where they could. Moreover, **patent rights do not explain the high cost of drugs in the developing world.** The WHO itself points out that **taxes, tariffs** and other government policies play a significant role in keeping drug prices high in emerging markets. And, in fact, reports have concluded that excessive tariffs and taxes on imported medicines **may inflate the cost of medicines by up to one-third.** When combined with taxes on medicines, government-imposed levies account for an additional 55% in India; 40% in Sierra Leone; 34% in Nigeria; and 29% in Bangladesh. In any event, contrary to the Panel’s suggestion, patent protections ultimately help keep the costs of drugs low. To be sure, patented drug prices will often decline only after a patent expires. But the decline in price after patent expiration is not evidence that the drug manufacturer charged too much for the product. To the contrary, the decline in price of a formerly patented medicine is consistent with an efficient market. Patents expire after a certain period of time fixed by law. As economists have explained, during this period, prices will reflect both the costs of production and the company’s research and development costs. The exclusivity period that the patent creates attracts investment, which enables the innovator company to recoup its research and development costs. Once the patent expires, other companies may create generics that are priced lower. But these lower costs reflect the fact that copycat companies only need to recoup production costs, not research and development. In other words, a patent’s provision of an opportunity for an innovator company to recover costs enables it to produce the medicine in the first place. And the patent’s eventual expiration allows for robust competition that drives prices down. Third, as many experts point out, structural and economic barriers are a significant barrier to access to medicine in the developing world. Poor infrastructure and weak healthcare systems plague third-world countries. Several countries’ medical centers are located in remote areas that may only be reached through impassable roads. Also, many drugs and vaccines must be stored at certain temperatures. But many developing countries lack reliable electricity and sanitary facilities to enable proper storage. In India, for example, a quality-control study followed a series of vaccine vials through the supply-chain delivery process. The study found that 76 percent of the vaccines could not be used because they were stored in substandard storage facilities. Fourth, experts also acknowledge that developing countries tend to underinvest in health. In 2001, for example, African leaders met in Abuja, Nigeria, and pledged to allocate 15 percent of their national budgets to health. The 2015 DATA Report found, however, that between 2011 and 2013, just eight of the 47 countries for which there was data available spent 15 percent or more on health: Uganda, Rwanda, Malawi, Swaziland, Nigeria, Ethiopia, Liberia, and Togo. Twenty countries did not reach even the 10 percent level. If anything, patent protections could incentivize further investment in health in these countries. \* \* \* The UN has a real opportunity to address the critical issue of healthcare access. As it stands now, however, it seems poised to do more damage than good.

#### IP protection is needed to increase vaccine production.

Silverman ND, Rachel Silverman. [Policy Fellow, CGD.] “Would Exempting COVID-19 Vaccines from Intellectual Property Rights Improve Global Access and Equity?”, Center for Global Development, No Date. //recut WW DL

I agree that the current imperative is to scale existing vaccines as quickly as possible while maintaining strict safety and quality standards. But for the premise of this debate to be true, there would need to be additional manufacturers who could and would stand ready to manufacture additional vaccines if not thwarted by IP restrictions. I see no evidence that is currently the case—and, to the contrary, believe taking an antagonistic posture toward IP may actually slow or **compromise** **production**. Innovator companies are under enormous commercial and geopolitical pressure to scale as quickly as possible to meet enormous, immediate demand. Their profit-driven interest, in this case, is aligned with the **global imperative** to **increase production**. To do so, they are already cooperating widely with competitors and generic manufacturers, including via voluntary licenses, contracted production, and proactive technology transfer. Diluting that **commercial incentive** may reduce their interest in pursuing the **voluntary horizontal collaborations** that are already **driving scale**. It is also not clear that any additional generic manufacturers are “standing by” ready to produce. Under existing TRIPS flexibilities, countries can already issue compulsory licenses to produce vaccines without permission from the patent-holder. None have done so. Voluntary licensing and technology transfer from originator companies can help increase long-term manufacturing capacity, especially if paired with public investment; originators also have an interest in enforcing safety and quality control standards while doing so, which is especially important in the context of widespread vaccine hesitancy. Their cooperation is important for both speed and quality, and so far they seem willing to play ball. To be clear, I am not arguing that IP protections always serve the public good; nor am I necessarily ruling out a future scenario in which IP becomes a major challenge for global access. But all evidence suggests the current constraint to global access is capacity, not legal strictures.