## 1

#### Interpretation: The aff must defend that member nations reduce intellectual property protections for all medicines

#### Violation:

#### The upward entailment test and adverb test determine the genericity of a bare plural

Leslie and Lerner 16 [Sarah-Jane Leslie, Ph.D., Princeton, 2007. Dean of the Graduate School and Class of 1943 Professor of Philosophy. Served as the vice dean for faculty development in the Office of the Dean of the Faculty, director of the Program in Linguistics, and founding director of the Program in Cognitive Science at Princeton University. Adam Lerner, PhD Philosophy, Postgraduate Research Associate, Princeton 2018. From 2018, Assistant Professor/Faculty Fellow in the Center for Bioethics at New York University. Member of the [Princeton Social Neuroscience Lab](http://psnlab.princeton.edu/).] “Generic Generalizations.” Stanford Encyclopedia of Philosophy. April 24, 2016. <https://plato.stanford.edu/entries/generics/> TG

1. Generics and Logical Form

In English, generics can be expressed using a variety of syntactic forms: bare plurals (e.g., “tigers are striped”), indefinite singulars (e.g., “a tiger is striped”), and definite singulars (“the tiger is striped”). However, none of these syntactic forms is dedicated to expressing generic claims; each can also be used to express existential and/or specific claims. Further, some generics express what appear to be generalizations over individuals (e.g., “tigers are striped”), while others appear to predicate properties directly of the kind (e.g., “dodos are extinct”). These facts and others give rise to a number of questions concerning the logical forms of generic statements.

1.1 Isolating the Generic Interpretation

Consider the following pairs of sentences:

(1)a.Tigers are striped.

b.Tigers are on the front lawn.

(2)a.A tiger is striped.

b.A tiger is on the front lawn.

(3)a.The tiger is striped.

b.The tiger is on the front lawn.

The sentence pairs above are prima facie syntactically parallel—both are subject-predicate sentences whose subjects consist of the same common noun coupled with the same, or no, article. However, the interpretation of first sentence of each pair is intuitively quite different from the interpretation of the second sentence in the pair. In the second sentences, we are talking about some particular tigers: a group of tigers in ([1b](https://plato.stanford.edu/entries/generics/#ex1b)), some individual tiger in ([2b](https://plato.stanford.edu/entries/generics/#ex2b)), and some unique salient or familiar tiger in ([3b](https://plato.stanford.edu/entries/generics/#ex3b))—a beloved pet, perhaps. In the first sentences, however, we are saying something general. There is/are no particular tiger or tigers that we are talking about.

The second sentences of the pairs receive what is called an existential interpretation. The hallmark of the existential interpretation of a sentence containing a bare plural or an indefinite singular is that it may be paraphrased with “some” with little or no change in meaning; hence the terminology “existential reading”. The application of the term “existential interpretation” is perhaps less appropriate when applied to the definite singular, but it is intended there to cover interpretation of the definite singular as referring to a unique contextually salient/familiar particular individual, not to a kind.

There are some tests that are helpful in distinguishing these two readings. For example, the existential interpretation is upward entailing, meaning that the statement will always remain true if we replace the subject term with a more inclusive term. Consider our examples above. In ([1b](https://plato.stanford.edu/entries/generics/#ex1b)), we can replace “tiger” with “animal” salva veritate, but in ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) we cannot. If “tigers are on the lawn” is true, then “animals are on the lawn” must be true. However, “tigers are striped” is true, yet “animals are striped” is false. ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) does not entail that animals are striped, but ([1b](https://plato.stanford.edu/entries/generics/#ex1b)) entails that animals are on the front lawn (Lawler 1973; Laca 1990; Krifka et al. 1995).

Another test concerns whether we can insert an adverb of quantification with minimal change of meaning (Krifka et al. 1995). For example, inserting “usually” in the sentences in ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) (e.g., “tigers are usually striped”) produces only a small change in meaning, while inserting “usually” in ([1b](https://plato.stanford.edu/entries/generics/#ex1b)) dramatically alters the meaning of the sentence (e.g., “tigers are usually on the front lawn”). (For generics such as “mosquitoes carry malaria”, the adverb “sometimes” is perhaps better used than “usually” to mark off the generic reading.)

#### It applies to “Medicines” –

#### 1] upward entailment- “member nations of the wto ought to reduce IPP on medicines” does not entail that member nations ought to reduce intellectual property protections for medicines because it doesn’t prove that we should reduce intellectual property protections for vaccines.

#### 2] adverb quantification -- adding “generally” to the res doesn’t substantially change its meaning because the res never specified further

#### Vote negative:

#### 1] Limits – There are over 20,000 affs.

FDA 11/18 [(U.S. Food and Drug Administration, federal agency of the Department of Health and Human Service) “Fact Sheet: FDA at a Glance,” 11/18/2020] JL

There are over 20,000 prescription drug products approved for marketing.

FDA oversees over 6,500 different medical device product categories.

There are over 1,600 FDA-approved animal drug products.

There are about 300 FDA-licensed biologics products.

#### You can pick anything from vaccines to marijuana to HIV medicine to something that treats rare diseases like daraprim and there’s no universal DA since each one treats a different disease, has different patents and IP protections, and has a different function – it explodes neg prep and leads to random medicine of the week affs making stable neg links impossible. PICs don’t solve – it’s absurd to say neg potential abuse justifies the aff being flat out not T, which leads to a race towards abuse. Limits key to reciprocal engagement since they create a caselist for neg prep.

#### 2] TVA: read the aff as an advantage to a whole rez aff.

#### Voters:

#### Precision o/w – anything else justifies the aff arbitrarily jettisoning words in the resolution at their whim which decks negative ground and preparation because the aff is no longer bounded by the resolution.

#### Use competing interps – a) reasonability invites arbitrary judge intervention since we don’t know your bs meter, b) collapses to competing interps – we justify 2 brightlines under an offense defense paradigm just like 2 interps.

#### Evaluate T before 1AR theory – norms – we only have a couple months to set T norms but can set 1AR theory norms anytime

## 2

#### Text: Member nations of the World Trade organization should revise TRIPS by

#### Extending patent protection of medicine by 3 weeks

#### Replacing the compulsory licensing provision with a requirement that patent protection is contingent upon drug donation, using previous qualification standards

* Revising the parallel import article to prohibit the flow of donated medicine into wealthy markets

#### Solves equitable medicine access

**Andreassen 14** Tom Andreassen [Tom Andreassen is Ph.D-candidate at the Programme for Applied Ethics at the Norwegian University of Science and Technology, Trondheim]. (2014). Patent Funded Access to Medicines. Developing World Bioethics Volume 15 Number 3 2015 pp 152–161, 15(3). [https://onlinelibrary.wiley.com/doi/10.1111/dewb.12058 //](https://onlinelibrary.wiley.com/doi/10.1111/dewb.12058%20//) ash

Irrespective of the extent to which the TRIPS induced IP protection makes essential drugs unattainable to the poorest, solutions could be sought that utilize the patent system in creating such incentives to promote access, even in the short term. The opportunity to be explored is how an extension of the patent period in certain cases, beyond the time sufficient to recover the inventor company’s expenses and to make for a decent profit, could create funding for free supplies of essential drugs to developing countries according to need and capacity. If such a step, which should be both technically and politically feasible, were to be taken, the developing countries themselves would have an incentive to look for solutions as to how the medicines and treatments could be distributed and delivered.

For reasons thoroughly discussed by others,41 the flexibility provisions in TRIPS have not resulted in any significant improvement of access to drugs among poor populations. Parallel imports, one of the provisions, show no sign of taking on the proportions needed to accommodate the severely poor.42 One other flexibility provision in TRIPS, that of compulsory licensing has proven not to be effective despite the fact that it was reiterated by the WTO ministers at the Doha meeting.43 The voluntary donations made by the pharmaceutical industry are selective instead of comprehensive, thus these cannot secure the human right to basic health for the poor.44 If the donations could be systematized, however, they might come closer to filling that function. Systematic donation of medicines, financed through time-extended patents, could be included in TRIPS, since the Agreement is so closely associated with the current situation of lack of access due to high prices.

As noted above, the recuperation of the investments in a new medicine is largely realized in high cost markets. It is estimated that between 80 and 90 per cent of the sales of patented medicine occur in the OECD countries.45 This is where the recovery of costs in research and development takes place, and not in the developing countries. Jean O. Lanjouw and William Jack have pointed out that the developed countries already offered patents on pharmaceuticals before TRIPS, and that ‘the main result of the harmonization of standards required by TRIPS is to strengthen pharmaceutical patent rights in a group of poorer countries.’46

Lanjouw and Jack comments on the effect of extending the patent period: ‘Lengthening patent protection for a couple of weeks in rich countries, for example, could provide returns equivalent to the introduction of 20-year patents in the developing world.’47 This concerns then the compensation for lost sales in developing countries. Another matter is the cost of producing the needed drugs for free supply. Here it is significant that the patent holder will already have its own, or they have out-licensed, ongoing production. The cost of R&D, marketing and testing for approval, as well as setting up production, will be covered by the ordinary patent period and should therefore be kept outside the calculation of cost for the added production. Details need to be worked out regarding the calculation of the cost and the length of the extended patent period, and the companies will most likely need to accept an authorized auditing instrument verifying the data necessary for the calculations.

The average effective sales protection is, as shown above, ten years. It is safe to assume that the extension needed for added production is a small fraction of that. Indeed it has been said by Harvey Bale, then the director general of the International Federation of Pharmaceutical Manufacturers Associations, that ‘Companies are able, through sales they make in developed countries, to offset the cost of donating drugs to poor countries.’48

Here we see a strong reason to keep the patent institute in place instead of weakening it. If surplus values generated by extended patent protection could be used to make the donations programs comprehensive, then the patent system, instead of cutting people off from access to essential medicines, actually would be the arrangement that made them accessible to people that could not even afford generic medicines. Lanjouw and Jack in fact concludes that certain medicines should be made available to the very poorest countries free of charge.49

An extended patent period would imply that the introduction of generic drugs and the price competition that follows from it would be slightly postponed. The cost for this, in that the price reduction is delayed in wealthier countries, would come as a result of expanded market protection through TRIPS and not from any new demands from patients in developing countries. They are cut off from generic medicines by the Agreement, a trait that needs to be addressed more actively by the Agreement itself.

The criteria for triggering donations of drugs would, taken together, look similar to the rational justification for a compulsory license. They would be i. public noncommercial use or ii. The widespread outbreak of a disease in a WTO country. iii. The country itself has no production capacity or purchasing capacity to meet the need. iv. The country can show plans for distributing the medicines and treatment of patients. v. The first four criteria are confirmed by an independent body like the WTO itself, or more suitably the WHO. Regarding the fourth point, an auditing instrument might be necessary at this end also, assuring the accuracy of the receiving capacity.

In TRIPS the compulsory licensing provision, which has not proven to be effective, should then be replaced by a requirement that patent protection is available in the WTO countries only under the condition that when the criteria are confirmed by WHO to prevail in any (WTO) country, the patentee is obliged to make the necessary drug donations.50 To compensate for the cost, an extension of the patent period is offered.

The receiving country could not ask for more drugs than it can distribute and make effective use of. Focus would therefore shift to local conditions in the event that essential medicines do not reach where they are critically needed. Conditions that would need attention could be the host country’s distributive capacity, its allocation of resources to meet an emergency and so forth.51 This access of free medicines would serve as an incentive for governments to provide infrastructure like electricity and clean water as argued by Novak, citing Ellen ‘t Hoen from Doctors Without Borders: ‘We have seen that in countries like Cameroon, Mozambique and Kenya that as the cost of drugs comes down, governments start to talk about infrastructure, and patient access to the drugs goes up.’52

The donated medicine would still be patented and adaptive measures should be built into the agreement to secure that such medicine will not flow into the wealthier markets. This would imply a revision of the parallel import article.53

In the event that the country where the emergency occurs is not capable or for other reasons is unready to receive donated medicine and distribute it, NGOs operating within its borders can act on behalf of national or regional athorities. The NGOs could hand in documentation on the quantity of medicine they are able to deliver to patients and function as the partner of the donation authority (WHO for example) in cases where national health authorities fail their obligation.

The revised TRIPS would serve the interest of not only one party, i.e. society, but also the pharmaceutical industry, which would see a key reason for its poor reputation disappear. The main advantage for this industry would be the abolition of the threat of compulsory licenses and thereby the security and predictability of uninfringeable patents.

The concern for intellectual property rights to essential medicines and the concern for the human right to access such medicine would be better balanced through a revision of TRIPS implying systematized and patent funded drug donations. The biggest gain that would result from the revision, however, might be the shift of focus mentioned above. The attention which has up until now been given to the pharmaceutical industry and the patent law in the WTO would give way to renewed attention to all those other factors that are making medicines inaccessible to the poor, thus providing incentives to their governments, their neighbors and the international institutions to build competence, health institutions and distribution capacity.

## 3

#### Biotech industry strong now

Cancherini et al. 4/30 [(Laura, Engagement Manager @ McKinsey & Company, Joseph Lydon, Associate Partner @ McKinsey & Company, Jorge Santos Da Silva, Senior Partner at McKinsey & Company, and Alexandra Zemp, Partner at McKinsey & Company), “What’s ahead for biotech: Another wave or low tide?“, McKinsey & Company, 4-30-2021, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide] TDI

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6

What about SPACs?

The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story.

Fundamentals continue strong

When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances.

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have more than 250 vaccine candidates in their pipelines, along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries.

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the top dozen pharma companies having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic.

More innovation on the horizon

The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science.

#### Lack of IP protection makes medical innovation prohibitively risky and expensive

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

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.

#### IP enables critical information sharing

Simon 6/25 [(Brenda, professor at California Western School of Law, research interests focus on how technological developments affect intellectual property and information law, former teaching fellow for the Law, Science and Technology LL.M. Program at Stanford Law School, and a research fellow in the Stanford Center for Law and the Biosciences, JD from UC Berkeley School of Law) “Patents, Information, and Innovation,” Brooklyn Law Review, 6/25/2020] JL

Patents play numerous roles in encouraging the exchange of information during the investment-seeking process in the medical device industry. One role is reducing the likelihood that the medical device will be expropriated. The risks of expropriation at this stage vary depending on the circumstances, which were set forth from a theoretical perspective in Part I and will be contextualized with examples from the medical device industry in this Part. Some of the variables in assessing expropriation risks, and consequently the function of patents in enabling information exchange, include whether the medical device is self-disclosing and easily reverse engineered, the importance of reputational and industry norms, and whether staging disclosure over time is an option.222 Time and resource constraints may limit the efficacy of some of these alternative mechanisms to patents in mitigating the risks of expropriation.223

Apart from their ability to ensure exclusivity, patents have an independent function of providing a useful signal to investors about information distinct from the medical device invention, such as resource allocation and the experience of the executive team, similar to their role in the biotechnology industry.224 An issued patent can also provide an indication about the viability of the invention, such as the ability to limit competition, extend the first mover advantage, and provide an independent source of value to the company through licensing or sale.225

One survey of twenty venture capital fund managers looked at the importance of intellectual property protection in assessing the risk-return ratio of portfolio companies .226 For medical device companies, respondents ranked intellectual property protection third, after reimbursement and regulatory concerns at the FDA.227 The authors of the survey reasoned that intellectual property protection was a concern of venture fund managers, given the high patenting rates among venture-backed companies and that the size of medical device companies necessitated "their reliance on patent protection to maintain barriers to market entry by competitors ."228 Additionally, court decisions that cast doubt on whether patent protection would be available for some medical devices have also raised concerns.229

#### MRNA solves a litany of diseases, but continued innovation is key

Gupta 5/7 [(Swati, vice president and head of emerging infectious diseases and scientific strategy at IAVI, a nonprofit scientific research organization that develops vaccines and antibodies for HIV, tuberculosis, emerging infectious diseases (including COVID-19) and neglected diseases, PhD and MPH from Yale University) “The Application and Future Potential of mRNA Vaccines,” Yale School of Public Health, 5/7/2021] JL

The implications of mRNA technology are staggering. Several vaccine developers are studying this technology for deployment against rabies, influenza, Zika, HIV and cancer, as well as for veterinary purposes. Its potential utility is based upon its being a “platform technology” that can be developed and scaled rapidly. Given that only the genetic code for a protein of interest is needed, synthetically produced mRNA vaccines can be made rapidly, in days. Other vaccine approaches involve growing and/or producing proteins in cells, a process that can take months. Messenger RNA vaccines are generally regarded as safe, since they do not integrate into our cells’ DNA and naturally degrade in the body after injection. They also can be safely administered repeatedly, as we are seeing with the two-dose regimen for both the Pfizer-BioNTech and Moderna vaccines.

Despite the current success of mRNA vaccines for COVID-19, scientists continue to work on making the technology better. A number of laboratories are testing more thermostable formulations of mRNA vaccines, which currently must be kept at freezing or ultra-cold temperatures. Others are investigating second-generation vaccines that will only require a single shot, and “universal” coronavirus vaccines that could protect against future emerging coronaviruses. Messenger RNA vaccines that target a broad range of different diseases, all in one shot, are also in development; this approach has the potential to greatly simplify current vaccination schedules.

Taken together, these advantages and potential future developments position mRNA vaccines as an increasingly important technology in our arsenal of tools against infectious disease outbreaks, and are likely to be critical to fighting future epidemics and pandemics. Global partnerships like the Coalition for Epidemic Preparedness and Innovation (CEPI), tasked with facilitating the development of vaccines to stop future epidemics, have called for vaccines to be able to be tested in the clinic within months after a new pathogen is identified. With the latest discoveries in mRNA technology, we are well on our way to this goal; the ability of this platform technology to be transformative is no longer a hope, but more likely to be a reality in the very near future.

#### Disease causes extinction – defense is wrong

Piers Millett 17, Consultant for the World Health Organization, PhD in International Relations and Affairs, University of Bradford, Andrew Snyder-Beattie, “Existential Risk and Cost-Effective Biosecurity”, Health Security, Vol 15(4), http://online.liebertpub.com/doi/pdfplus/10.1089/hs.2017.0028

Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world’s population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization.

A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity’s favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6

While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and theWestern Abenaki (which suffered a staggering 98% loss of population).

In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-2

## Case

#### High magnitude, low probability first

Bostrom 13 ---- Nick, Philosopher and professor (Oxford), Ph.D. (LSOE), director of The Future of Humanity Institute and the Programme on the Impacts of Future Technology, “Existential Risk Prevention as Global Priority,” Global Policy, Vol 4, Issue 1, <http://www.existential-risk.org/concept.html>

The maxipok rule 1.1. Existential risk and uncertainty An existential risk is one that threatens the premature extinction of Earth-originating intelligent life or the permanent and drastic destruction of its potential for desirable future development (Bostrom 2002). Although it is often difficult to assess the probability of existential risks, there are many reasons to suppose that the total such risk confronting humanity over the next few centuries is significant. Estimates of 10-20% total existential risk in this century are fairly typical among those who have examined the issue, though inevitably such estimates rely heavily on subjective judgment.1 The most reasonable estimate might be substantially higher or lower. But perhaps the strongest reason for judging the total existential risk within the next few centuries to be significant is the extreme magnitude of the values at stake. Even a small probability of existential catastrophe could be highly practically significant (Bostrom 2003; Matheny 2007; Posner 2004; Weitzman 2009). Humanity has survived what we might call natural existential risks for hundreds of thousands of years; thus it is prima facie unlikely that any of them will do us in within the next hundred.2 This conclusion is buttressed when we analyze specific risks from nature, such as asteroid impacts, supervolcanic eruptions, earthquakes, gamma-ray bursts, and so forth: Empirical impact distributions and scientific models suggest that the likelihood of extinction because of these kinds of risk is extremely small on a time scale of a century or so.3 In contrast, our species is introducing entirely new kinds of existential risk — threats we have no track record of surviving. Our longevity as a species therefore offers no strong prior grounds for confident optimism. Consideration of specific existential-risk scenarios bears out the suspicion that the great bulk of existential risk in the foreseeable future consists of anthropogenic existential risks — that is, those arising from human activity. In particular, most of the biggest existential risks seem to be linked to potential future technological breakthroughs that may radically expand our ability to manipulate the external world or our own biology. As our powers expand, so will the scale of their potential consequences — intended and unintended, positive and negative. For example, there appear to be significant existential risks in some of the advanced forms of biotechnology, molecular nanotechnology, and machine intelligence that might be developed in the decades ahead. The bulk of existential risk over the next century may thus reside in rather speculative scenarios to which we cannot assign precise probabilities through any rigorous statistical or scientific method. But the fact that the probability of some risk is difficult to quantify does not imply that the risk is negligible. Probability can be understood in different senses. Most relevant here is the epistemic sense in which probability is construed as (something like) the credence that an ideally reasonable observer should assign to the risk's materializing based on currently available evidence.4 If something cannot presently be known to be objectively safe, it is risky at least in the subjective sense relevant to decision making. An empty cave is unsafe in just this sense if you cannot tell whether or not it is home to a hungry lion. It would be rational for you to avoid the cave if you reasonably judge that the expected harm of entry outweighs the expected benefit. The uncertainty and error-proneness of our first-order assessments of risk is itself something we must factor into our all-things-considered probability assignments. This factor often dominates in low-probability, high-consequence risks — especially those involving poorly understood natural phenomena, complex social dynamics, or new technology, or that are difficult to assess for other reasons. Suppose that some scientific analysis A indicates that some catastrophe X has an extremely small probability P(X) of occurring. Then the probability that A has some hidden crucial flaw may easily be much greater than P(X).5 Furthermore, the conditional probability of X given that A is crucially flawed, P(X|¬A), may be fairly high. We may then find that most of the risk of X resides in the uncertainty of our scientific assessment that P(X) was small (figure 1) (Ord, Hillerbrand and Sandberg 2010).

#### Probability is contextual, not an impact filter – they need to beat back the specifics of our disad.

#### Extinction is the only coherent and egalitarian framework – prefer it

Khan 18 (Risalat, activist and entrepreneur from Bangladesh passionate about addressing climate change, biodiversity loss, and other existential challenges. He was featured by The Guardian as one of the “young climate campaigners to watch” (2015). As a campaigner with the global civic movement Avaaz (2014-17), Risalat was part of a small core team that spearheaded the largest climate marches in history with a turnout of over 800,000 across 2,000 cities. After fighting for the Paris Agreement, Risalat led a campaign joined by over a million people to stop the Rampal coal plant in Bangladesh to protect the Sundarbans World Heritage forest, and elicited criticism of the plant from Crédit Agricolé through targeted advocacy. Currently, Risalat is pursuing an MPA in Environmental Science and Policy at Columbia University as a SIPA Environmental Fellow, “5 reasons why we need to start talking about existential risks,” https://www.weforum.org/agenda/2018/01/5-reasons-start-talking-existential-risks-extinction-moriori/)

Infinite future possibilities I find the story of the Moriori profound. It teaches me two lessons. Firstly, that human culture is far from immutable. That we can struggle against our baser instincts. That we can master them and rise to unprecedented challenges. Secondly, that even this does not make us masters of our own destiny. We can make visionary choices, but the future can still surprise us. This is a humbling realization. Because faced with an uncertain future, the only wise thing we can do is prepare for possibilities. Standing at the launch pad of the Fourth Industrial Revolution, the possibilities seem endless. They range from an era of abundance to the end of humanity, and everything in between. How do we navigate such a wide and divergent spectrum? I am an optimist. From my bubble of privilege, life feels like a rollercoaster ride full of ever more impressive wonders, even as I try to fight the many social injustices that still blight us. However, the accelerating pace of change amid uncertainty elicits one fundamental observation. Among the infinite future possibilities, only one outcome is truly irreversible: extinction. Concerns about extinction are often dismissed as apocalyptic alarmism. Sometimes, they are. But repeating that mankind is still here after 70 years of existential warning about nuclear warfare is a straw man argument. The fact that a 1000-year flood has not happened does not negate its possibility. And there have been far too many nuclear near-misses to rest easy. As the World Economic Forum’s Annual Meeting in Davos discusses how to create a shared future in a fractured world, here are five reasons why the possibility of existential risks should raise the stakes of conversation: 1. Extinction is the rule, not the exception More than 99.9% of all the species that ever existed are gone. Deep time is unfathomable to the human brain. But if one cares to take a tour of the billions of years of life’s history, we find a litany of forgotten species. And we have only discovered a mere fraction of the extinct species that once roamed the planet. In the speck of time since the first humans evolved, more than 99.9% of all the distinct human cultures that have ever existed are extinct. Each hunter-gatherer tribe had its own mythologies, traditions and norms. They wiped each other out, or coalesced into larger formations following the agricultural revolution. However, as major civilizations emerged, even those that reached incredible heights, such as the Egyptians and the Romans, eventually collapsed. It is only in the very recent past that we became a truly global civilization. Our interconnectedness continues to grow rapidly. “Stand or fall, we are the last civilization”, as Ricken Patel, the founder of the global civic movement Avaaz, put it. 2. Environmental pressures can drive extinction More than 15,000 scientists just issued a ‘warning to humanity’. They called on us to reduce our impact on the biosphere, 25 years after their first such appeal. The warning notes that we are far outstripping the capacity of our planet in all but one measure of ozone depletion, including emissions, biodiversity, freshwater availability and more. The scientists, not a crowd known to overstate facts, conclude: “soon it will be too late to shift course away from our failing trajectory, and time is running out”. In his 2005 book Collapse, Jared Diamond charts the history of past societies. He makes the case that overpopulation and resource use beyond the carrying capacity have often been important, if not the only, drivers of collapse. Even though we are making important incremental progress in battles such as climate change, we must still achieve tremendous step changes in our response to several major environmental crises. We must do this even while the world’s population continues to grow. These pressures are bound to exert great stress on our global civilization. 3. Superintelligence: unplanned obsolescence? Imagine a monkey society that foresaw the ascendance of humans. Fearing a loss of status and power, it decided to kill the proverbial Adam and Eve. It crafted the most ingenious plan it could: starve the humans by taking away all their bananas. Foolproof plan, right? This story describes the fundamental difficulty with superintelligence. A superintelligent being may always do something entirely different from what we, with our mere mortal intelligence, can foresee. In his 2014 book Superintelligence, Swedish philosopher Nick Bostrom presents the challenge in thought-provoking detail, and advises caution. Bostrom cites a survey of industry experts that projected a 50% chance of the development of artificial superintelligence by 2050, and a 90% chance by 2075. The latter date is within the life expectancy of many alive today. Visionaries like Stephen Hawking and Elon Musk have warned of the existential risks from artificial superintelligence. Their opposite camp includes Larry Page and Mark Zuckerberg. But on an issue that concerns the future of humanity, is it really wise to ignore the guy who explained the nature of space to us and another guy who just put a reusable rocket in it? 4. Technology: known knowns and unknown unknowns Many fundamentally disruptive technologies are coming of age, from bioengineering to quantum computing, 3-D printing, robotics, nanotechnology and more. Lord Martin Rees describes potential existential challenges from some of these technologies, such as a bioengineered pandemic, in his book Our Final Century. Imagine if North Korea, feeling secure in its isolation, could release a virulent strain of Ebola, engineered to be airborne. Would it do it? Would ISIS? Projecting decades forward, we will likely develop capabilities that are unthinkable even now. The unknown unknowns of our technological path are profoundly humbling. 5. 'The Trump Factor' Despite our scientific ingenuity, we are still a confused and confusing species. Think back to two years ago, and how you thought the world worked then. Has that not been upended by the election of Donald Trump as US President, and everything that has happened since? The mix of billions of messy humans will forever be unpredictable. When the combustible forces described above are added to this melee, we find ourselves on a tightrope. What choices must we now make now to create a shared future, in which we are not at perpetual risk of destroying ourselves? Common enemy to common cause Throughout history, we have rallied against the ‘other’. Tribes have overpowered tribes, empires have conquered rivals. Even today, our fiercest displays of unity typically happen at wartime. We give our lives for our motherland and defend nationalistic pride like a wounded lion. But like the early Morioris, we 21st-century citizens find ourselves on an increasingly unstable island. We may have a violent past, but we have no more dangerous enemy than ourselves. Our task is to find our own Nunuku’s Law. Our own shared contract, based on equity, would help us navigate safely. It would ensure a future that unleashes the full potential of our still-budding human civilization, in all its diversity. We cannot do this unless we are humbly grounded in the possibility of our own destruction. Survival is life’s primal instinct. In the absence of a common enemy, we must find common cause in survival. Our future may depend on whether we realize this.

#### 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**.

The problem is resources not IP  
Garde et al 21 Damian Garde [national biotech reporter for STAT], Helen Branswell [writer at STAT covering infectious diseases and global health], Matter Herper [senior writer at STAT covering medicine], May 6, 2021, “Waiver of patent rights on Covid-19 vaccines, in near term, may be more symbolic than substantive " <https://www.statnews.com/2021/05/06/waiver-of-patent-rights-on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/> //kangu

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](https://www.statnews.com/2020/10/26/mrna-vaccines-face-their-first-test-in-the-fight-against-covid-19-how-do-they-work/) — 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.

#### plan increases price of scarce materials and results in costly, ineffective facilities

Mcmurry-Heath 8/18 (Michelle Mcmurry-Heath, [physician-scientist and president and CEO of the Biotechnology Innovation Organization.], 8-18-2021, “Waiving intellectual property rights would harm global vaccination“, STAT, accessed: 8-19-2021, https://www.statnews.com/2021/08/18/waiving-intellectual-property-rights-compromise-global-vaccination-efforts/) ajs

Covid-19 vaccines are already remarkably cheap, and companies are offering them at low or no cost to low-income countries. Poor access to clinics and transportation are barriers in some countries, but the expense of the shot itself is not. In fact, if the World Trade Organization grants the IP waiver, it could make these vaccines more expensive.

Here’s why. Before Covid-19 emerged, the world produced at most [5.5 billion doses](https://www.barrons.com/articles/a-plan-to-break-the-vaccine-manufacturing-bottleneck-51621952245) of various vaccines every year. Now the world needs an additional [11 billion doses](https://www.who.int/director-general/speeches/detail/director-general-s-opening-remarks-at-the-g7-summit---12-june-2021) — including billions of doses of mRNA vaccines that no one had ever mass-manufactured before — to fully vaccinate every eligible person on the planet against the new disease.

Even as Covid-19 vaccines were still being developed, pharmaceutical companies began retrofitting and upgrading existing facilities to produce Covid-19 vaccines, at a cost of $40 to $100 million each. Vaccine developers also licensed their technologies to well-established manufacturers, like the Serum Institute of India, to further increase production. As a result, almost every facility in the world that can quickly and safely make Covid-19 vaccines is already doing so, or will be in the next few months.

The cutting-edge mRNA vaccines from Moderna and Pfizer-BioNTech face an even bigger capacity issue. Since the underlying technology is new, there are no mRNA manufacturing facilities sitting idle with operators just waiting for licensing agreements to turn on the machines. Nor are there trained personnel to run them or ensure safety and quality control. Embedding delicate mRNA vaccine molecules inside lipid nanoparticle shells at temperatures colder than Antarctica isn’t as easy as following a recipe from Bon Appetit.

Another big barrier to producing more shots is a shortage of raw materials. Suspending intellectual property protections and allowing any manufacturer to try to produce these vaccines, regardless of preparedness or experience, would increase the demand for scarce raw materials, driving up prices and impeding production.

Nor could all companies that suddenly get a green light due to suspended intellectual property rights produce vaccines as cheaply or quickly as existing manufacturers. Building a new vaccine manufacturing facility costs about $700 million, takes many months — if not years — to build and, once opened, requires another [four to six months](https://www.americanprogress.org/issues/healthcare/reports/2020/07/28/488196/comprehensive-covid-19-vaccine-plan/) to start producing vaccine doses. And because negotiations surrounding the WTO waiver, which began this summer, could take until December before they are completed, it wouldn’t be until well into 2023 or later that any additional doses would become available.

That’s slower than our current production rate. According to a report from Duke University’s [Global Health Innovation Center](https://launchandscalefaster.org/covid-19/vaccinemanufacturing), companies are on track to manufacture enough shots in 2021 to fully vaccinate at least 70% of the global population against Covid-19 — the level required to achieve herd immunity.

Covid-19 vaccines are saving millions of lives and protecting trillions of dollars of economic activity for an exceptionally low cost. Israel, for example, which has one of the world’s highest vaccination rates, paid [$23.50 per dose](https://www.timesofisrael.com/israel-said-to-be-paying-average-of-47-per-person-for-pfizer-moderna-vaccines/) for early shipments, for a total of about $315 million. That’s approximately equal to the gross domestic productivity losses incurred during [just two days of shutdowns](https://www.bmj.com/content/372/bmj.n281) in the country.

Many countries are buying shots for under $10 per dose. India and South Africa — the two countries leading the petition to gut IP rights — are paying just $8 and $5.25 per dose, respectively. For reference, a regular flu shot costs about $14 in the United States, and pediatric vaccines average about $55 per dose.

Meanwhile, low-income countries that can’t afford even modest prices are getting their vaccines at no charge. [COVAX](https://www.who.int/initiatives/act-accelerator/covax), the international nonprofit vaccine distributor, aims to deliver 2 billion doses to developing nations by the end of the year.

President Biden vowed to make America the world’s [“arsenal of vaccines.”](https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/05/17/remarks-by-president-biden-on-the-covid-19-response-and-the-vaccination-program-4/) The U.S. has already committed $4 billion to COVAX, has donated more than 100 million vaccine doses abroad, and is on track to donate [500 million more](https://www.npr.org/sections/goatsandsoda/2021/08/03/1023822839/biden-is-sending-110-million-vaccines-to-nations-in-need-thats-just-a-first-step) by the end of summer. Other countries are following the administration’s leadership and ramping up their donations.

#### IPR hasn’t harmed access – manufacturing capacity alt cause

Mercurio 2/12 (Bryan Mercurio, [Simon F.S. Li Professor of Law at the Chinese University of Hong Kong (CUHK), having served as Associate Dean (Research) from 2010-14 and again from 2017-19. Professor Mercurio specialises in international economic law (IEL), with particular expertise in the intersection between trade law and intellectual property rights, free trade agreements, trade in services, dispute settlement and increasingly international investment law.], 2-12-2021, “WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review“, No Publication, accessed: 8-8-2021, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3789820) ajs

2. Intellectual property rights have not hampered access to COVID-19 vaccines

A WTO waiver is an extreme measure which should only be used when existing WTO obligations prove inadequate. This was the case in relation to the compulsory licencing provisions under Article 31 of the TRIPS Agreement, which essentially precluded Members with no or inadequate manufacturing capabilities from making use of the flexibility granted in the TRIPS Agreement. 25 This was also the case with the Kimberley Process, which attempts to eliminate trade in “conflict diamonds”. 26

Although the IP waiver proposal states that “there are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients”, 27 the sponsors did not provide further elaboration or evidence to support their declaration that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available [under the TRIPS Agreement]”. 28 Instead, many of the examples used by India and South Africa point to problems not with the TRIPS Agreement but rather to failures at the domestic level. As mentioned above, the WTO allowed for the importation of medicines under a compulsory licence in 2003, and yet many developing countries have yet to put in place any framework to allow their country to make use of the flexibility. 29 This is not an institutional problem of the international system but rather a problem at the country level.

Two additional factors which make the proposed waiver unnecessary and potentially harmful. First, pharmaceutical companies are selling the vaccine at extremely reasonable rates and several announced plans for extensive not-for-profit sales.30 Although agreements between the pharmaceutical companies and governments are not publicly disclosed, the Belgian Secretary of State Eva De Bleeker temporarily made publicly available in a tweet the prices the EU is being charged by each manufacturer. The De Bleeker tweet indicated the European Commission negotiated price arrangements with six companies, with the range of spending between €1.78 and €18 per coronavirus vaccine dosage. Specific price per dose listed for each of the six vaccines was as follows: Oxford/AstraZeneca: (€1.78), Johnson & Johnson (€8.50), Sanofi/GSK (€7.56), CureVac (€10), BioNTech/Pfizer (€12) and Moderna (€18).31

While much as been made of the fact that South Africa agreed to purchase 1.5 million doses of the Oxford/AstraZeneca from the Serum Institute of India (SII) at a cost of €4.321 per dose,32 these criticisms are directed at the lack of transparency in pharmaceutical licenses and production contracts – an issue which would be wholly unaddressed by a waiver of IPRs.

Moreover, while the disparity in pricing is concerning the overall per dosage rate South Africa is paying nevertheless represents value for money given the expected health and economic returns on investment. Despite the disparity in pricing between nations, the larger point remains that the industry has not only rapidly produced vaccines for the novel coronavirus but is making them available at unquestionably reasonable prices.

Second, the proposed waiver will do nothing to address the problem of lack of capacity or the transfer of technology and goodwill. Pharmaceutical companies have not applied for patents in the majority of developing countries – in such countries, any manufacturer is free to produce and market the vaccine inside the territory of that country or to export the vaccine to other countries where patents have not been filed.33 Patents cannot be the problem in the countries where no patent applications have been filed, but the lack of production in such countries points to the real problem – these countries lack manufacturing capacity and capability.

While advanced pharmaceutical companies will have the technology, know-how and readiness to manufacture, store and transport complex vaccine formulations, such factories and logistics exist in only a handful of countries.34 Regardless of whether an IP waiver is granted, the remaining countries will be left without enhanced vaccine access and still reliant on imported supplies. With prices for the vaccine already very low, it is doubtful that generic suppliers will be able to provide the vaccine at significantly lower prices. Under such a scenario, the benefit of the waiver would go not to the countries in need but to the generic supplier who would not need to pay the licence fee or royalty to the innovator. Thus, the waiver would simply serve to benefit advanced generic manufacturers, most of which are located in a handful of countries, including China and Brazil as well as (unsurprisingly) India and South Africa. Countries would perhaps be better off obtaining the vaccine from suppliers that have negotiated a voluntary licence from the patent holder, as such licences include provisions for the transfer of technology, know-how and ongoing quality assurance support.

#### Waivers fail – license agreements are key to access and scaling up vaccines

Crosby et al 21 [[Daniel Crosby](https://www.jdsupra.com/authors/daniel-crosby/), [Evan Diamond](https://www.jdsupra.com/authors/evan-diamond/), [Isabel Fernandez de la Cuesta](https://www.jdsupra.com/authors/isabel-fernandez-de-la-cuesta/), [Jamieson Greer](https://www.jdsupra.com/authors/jamieson-greer/), [Jeffrey Telep](https://www.jdsupra.com/authors/jeffrey-telep/), [Brian White](https://www.jdsupra.com/authors/brian-white/)] “Group of Nearly 60 WTO Members Seek Unprecedented Waiver from WTO Intellectual Property Protection for COVID-related Medical Products,” JD Supra, March 5, 2021, <https://www.jdsupra.com/legalnews/group-of-nearly-60-wto-members-seek-2523821/> TG

Waiver risks uncontrolled use of patented technologies, without improving vaccine access. Pharmaceutical companies can provide, and have provided, licenses to distribute or scale-up production of COVID-19 vaccines and therapies at reduced cost. Such license agreements allow for expanded access in low- and middle-income countries, while also setting reasonable parameters so that patents and other IP rights are used to address the specific medical needs of the COVID-19 pandemic at hand, and not for other purposes. License agreements also allow for orderly technology transfer, including of unpatented “trade secret” information and other critical “know-how,” that may be essential to efficiently producing and scaling-up safe and effective versions of technologically complex vaccines and biologic drug products.

Under the present TRIPS waiver proposal, however, member countries could try to exploit an extraordinarily broad scope of IP and copy patented technologies so long as they are “in relation to prevention, containment or treatment of COVID-19.” For example, under an expansive reading of the proposed waiver language, a member country could try to produce patented pharmaceutical compounds that have other indicated uses predating COVID-19, if such compounds had later been studied or experimentally used for potential symptomatic relief or antiviral activity in COVID-19 patients. The same risks may be faced by manufacturers of patented materials or devices that have multiple uses predating COVID-19, but also may be used as “personal protective equipment” or components thereof, or in other measures arguably relating to COVID-19 “prevention” or “containment.”

At the same time, it is unclear how the proposed TRIPS waiver could provide the technology transfer and know-how critical for making the complex molecules and formulations constituting the various COVID-19 vaccines. Vaccine manufacture undertaken by an unauthorized party without the proper processes and controls could result in a different product that is potentially ineffective or results in unwanted health consequences. And even if an unauthorized manufacturer could overcome those substantial hurdles to reverse-engineer and scale up a safe and effective vaccine copy, it would likely take substantial time and a series of failures to do so. Notably, several of the original COVID-19 vaccine developers have recently faced low product yield and other manufacturing challenges during pre-commercial scale-up efforts and the initial months of commercial production.

#### Squo solves – voluntary licensing and other initiatives

Mercurio 2/12 (Bryan Mercurio, [Simon F.S. Li Professor of Law at the Chinese University of Hong Kong (CUHK), having served as Associate Dean (Research) from 2010-14 and again from 2017-19. Professor Mercurio specialises in international economic law (IEL), with particular expertise in the intersection between trade law and intellectual property rights, free trade agreements, trade in services, dispute settlement and increasingly international investment law.], 2-12-2021, “WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review“, No Publication, accessed: 8-8-2021, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3789820) ajs

3. Voluntary licensing and other initiatives are supporting access to COVID-19 vaccines Contrary to assertions the sponsors made at the TRIPS Council, pharmaceutical companies have been actively signing voluntary licensing agreements with various generic drug manufacturers to scale up the production of COVID-19 medication. For instance, Gilead’s antiviral drug named Remdesivir was approved for emergency use for COVID-19 treatment by the US Food and Drug Administration (FDA) and the European Medicines Agency in May 2020.35 As demand surged following the approvals for use in COVID-19, Gilead issued nonexclusive voluntary licences to generic producers based in India, Egypt and Pakistan in order to meet the growing demand for the product. Under the voluntary licensing agreements, these manufacturers receive the technology necessary to manufacture Remdesivir, as well as set their own prices for the generic drugs they produce. The arrangement allows the distribution of the drug in 127 countries, covering nearly all low-income and lower-middle-income countries.36 Another example of industry cooperation is the COVID-19 vaccine co-developed by AstraZeneca and University of Oxford. AstraZeneca has committed to granting voluntary licensing in developing countries and signed sublicence agreements with several generic drugs producers to increase the supply of future vaccine, including with the Serum Institute of India (one of the world’s largest vaccine producers),37 Fiocruz in Brazil,38 BioKangtai in China39 and R-Pharm in Russia,40 enabling the massive production of cheap generic vaccines and supply of over two billion doses to lower-middle-income countries once the vaccine is approved for sale in those countries.

Other initiatives set up in response to IP issues related to COVID-19 treatments and vaccines include the World Health Organization’s (WHO) COVID-19 Technology Access Pool (CTAP), launched to gather COVID-19 technology related patents and other kinds of intellectual properties, such as data, know-how and software.41 This Pool, similar to Medicines Patent Pool (MPP) – established to pool and distribute generic licences for HIV/AIDS-related treatments – aims to accelerate the scale-up of production of medical inventions to fight against COVID-19 and ensure they are available globally and equitably.42 To date, 39 WHO member states and 4 intergovernmental bodies have indicated their support43 and a coalition of 18 generic drugs manufacturers located in India, China, Bangladesh and South Africa have pledged to work together to accelerate access to millions of doses of new interventions for COVID-19 for lowand middle-income countries.

Another effort, the Access to Covid-19 Tools (ACT) Accelerator, has raised $5.8 billion from nearly forty countries and over 40 private and non-governmental sources for the deployment tests, treatments and vaccines. 44 COVAX, convened by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI) and the WHO, is the vaccine pillar of the ACT and acts as a global initiative to pool procurement of safe and effective COVID-19 vaccines. The objective of this accelerator collaboration is to guarantee rapid and fair access to COVID-19 vaccines for every country in the world. As of January 2021, COVAX has agreements in place to access 2 billion doses of promising COVID-19 vaccine candidates, implying that all 190 participating economies are eligible to access effective and approved vaccines in the first half of 2021.45 At least 1.3 billion donor-funded doses will be made available to 92 low- and middle-income economies.46

With the advance of reasonably priced patented treatments and vaccines, as well as the widespread and growing use of non-exclusive voluntary licence agreements and several newly established global initiatives, it is not only unnecessary to waive IPRs to ensure access to affordable medicines for all populations around the world during the pandemic but also unwise as the waiver would stifle cooperative efforts and potentially lead to less availability of needed treatments and vaccines.

#### Existing mechanisms solve – domestic not international policy is the problem

Mercurio 2/12 (Bryan Mercurio, [Simon F.S. Li Professor of Law at the Chinese University of Hong Kong (CUHK), having served as Associate Dean (Research) from 2010-14 and again from 2017-19. Professor Mercurio specialises in international economic law (IEL), with particular expertise in the intersection between trade law and intellectual property rights, free trade agreements, trade in services, dispute settlement and increasingly international investment law.], 2-12-2021, “WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review“, No Publication, accessed: 8-8-2021, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3789820) ajs

4. Existing mechanisms effectively safeguard public health

The international system was designed to deal with all circumstances – including global pandemics like COVID-19 – providing both incentives to industry to spend large amounts of time and money on research and development and tools for developing countries to leverage in their fight against COVID-19.

The rights and protections granted by the TRIPS Agreement must be read in the context of the objectives and principles of the agreement as set out in Article 7 and 8: Article 7 of the TRIPS Agreement provides that the “protection and enforcement of intellectual property rights [shall be] in a manner conducive to social and economic welfare” while Article 8 states that WTO Members “may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health … provided that such measures are consistent with the provisions of this Agreement.” Read together, these two provisions should allow for a wide range of policy choices and health measures taken during a health crisis or emergency, such as the COVID-19 pandemic.47

Moreover, in the wake of the HIV/AIDS crisis, developing countries secured a major victory when WTO Members agreed to adopt the Doha Declaration on TRIPS and Public Health as part of the Doha Ministerial Declaration in November 2001. 48 The Doha Declaration, inter alia, reiterated that every WTO Member “has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.” 49 Members could not agree, however, on how to resolve the issue of how Members with insufficient or no manufacturing capability could make use of the compulsory licensing provision set out in Article 31 of the TRIPS Agreement.50 This issue was resolved in August 2003, when Members adopted a waiver allowing such Members to import generic drugs under a compulsory licence from another country even if the required drugs are protected by patent in that third country. 51 In such a case, licences are required to be issued in both the importing and exporting countries. In 2017, the waiver became the first (and to date only) amendment to any WTO Agreement in the form of Article 31bis of the TRIPS Agreement. 52

Despite repeated assertions by leading non-governmental organizations (NGOs) that the TRIPS flexibilities such as the aforementioned compulsory licence regime are too complicated to use or that threats from developed countries restrict their use, a study by leading public health advocates found that the flexibilities “been used more frequently than commonly assumed and proven effective for procuring generic versions of essential medicines”. 53 More specifically, the study found extensive use of TRIPS flexibilities between 2001 and 2016, with the four leading flexibilities being (i) compulsory licensing (including public non-commercial use licensing); (ii) least-developed countries (LDCs) making use of the pharmaceutical transition measure54; (iii) parallel importation55; and (iv) the research exception.56 In total, the study identified 176 occurrences of possible use of TRIPS flexibilities by 89 countries, of which around 60% engaged in the use of compulsory or government use licences and over one-fifth involved the LDC pharmaceutical transition measure.57

The flexibilities described above have been proven effective in reducing the price of medicines by promoting generic competition and effectively ensuring equitable access to medical products for all. 58 This is especially the case with regards to compulsory licensing. For example, Malaysia’s use of compulsory licences in 2002 reduced the price of antiretrovirals to treat HIV/AIDS by up to 83% while Thailand’s granting of compulsory licences on five medicines (including antiretrovirals and medicines to treat cancer and coronary disease) between 2006 and 2008 contributed to a reduction in prices of up to 98 percent.59

Thus, while the sponsors to the proposal may argue a waiver is urgently needed given that the TRIPS flexibilities are not being fully utilized, the reality is that several developing countries and LDCs have made good use of the flexibilities and those that have not done so lack explicit provisions in their domestic legislation.6

Where available flexibilities have not been utilised, it is often the complicated and unworkable domestic framework which proves to be the stumbling block and not the international system. This point is perhaps illustrated best by reference to compulsory licensing. In Zimbabwe, for example, the institutional framework and capacity to effectively implement and take advantage of the TRIPS flexibility has been severely curtailed since the local regulations establish that a compulsory licence decision requires the approval of two government agencies: the Ministry of Health for medicines procurement and the Patent office for enquiry on the patent status of medicines. The lack of clarity and overlapping in roles and responsibilities leads to delayed access and, worse, a standstill.61 Even the Indian representative to the WTO placed some responsibility on the Members when he admitted that “many smaller countries were not able to fulfil the formalities required” to make use of available flexibilities.62

A final flexibility contained in the TRIPS Agreement is Article 73, which in relevant part allows a Member to take “any action which it considers necessary for the protection of its essential security interests… taken in time of war or other emergency in international relations.” Following precedent established in the Russia–Transit dispute,63 the WTO panel in Saudi Arabia–IPRs found that Article 73 is not self-judging.64 More specifically, the panel held that the mere invocation of Article 73 is justiciable and that it could proceed to assess:

a. whether the existence of a “war or other emergency in international relations” has been established…;

b. whether the relevant actions were “taken in time of” that war or other emergency in international relations; c. whether the invoking member has articulated its relevant “essential security interests” sufficiently to enable an assessment of whether there is any link between those actions and the protection of its essential security interests; and d. whether the relevant actions are so remote from, or unrelated to, the “emergency in international relations” as to make it implausible that the invoking member considers those actions to be necessary for the protection of its essential security interests arising out of the emergency.65

While we cannot say for certain whether the COVID-19 pandemic would constitute an emergency in international relations, whether measures taken by WTO members to override IPRs may be considered necessary to protect their essential security interests, or if the presence of other provisions in the TRIPS Agreement addressing emergencies preclude Members from invoking Article 73, there is scholarly support that the provision could be used to justifiably override IPRs in this time of global health pandemic.66 The debate may indeed be academic as it extremely unlikely that any Member would file a WTO complaint and initiate dispute settlement against a developing country Member invoking Article 73.

What is clear is that instead of calling for an IP waiver a better way to ensure equitable distribution of vaccines during the pandemic and a more lasting sustainable and prodevelopment solution would be for developing countries to revise their domestic laws to allow better use of the flexibilities existing within the TRIPS Agreement.