# Jack Howe Round 1 NC

### 1NC – OFF

#### Interpretation – the affirmative may not specify a subset of medicines

#### 1] Grammar – Medicines is a generic bare plural

Nebel 20 [Jake Nebel is an assistant professor of philosophy at the University of Southern California and executive director of Victory Briefs. He writes a lot of this stuff lol – duh.] “Indefinite Singular Generics in Debate” Victory Briefs, 19 August 2020. no url AG

I agree that if “a democracy” in the resolution just meant “one or more democracy,” then a country-specific affirmative could be topical. But, as I will explain in this topic analysis, that isn’t what “a democracy” means in the resolution. To see why, we first need to back up a bit and review (or learn) the idea of generic generalizations.

The most common way of expressing a generic in English is through a *bare plural*. A bare plural is a plural noun phrase, like “dogs” and “cats,” that lacks an overt determiner. (A determiner is a word that tells us which or how many: determiners include quantifier words like “all,” “some,” and “most,” demonstratives like “this” and “those,” posses- sives like “mine” and “its,” and so on.) LD resolutions often contain bare plurals, and that is the most common clue to their genericity.

We have already seen some examples of generics that are not bare plurals: “A whale is a mammal,” “A beaver builds dams,” and “The woolly mammoth is extinct.” The first two examples use indefinite singulars—singular nouns preceded by the indefinite article “a”—and the third is a definite singular since it is preceded by the definite article “the.” Generics can also be expressed with bare singulars (“Syrup is viscous”) and even verbs (as we’ll see later on). The resolution’s “a democracy” is an indefinite singular, and so it very well might be—and, as we’ll soon see, is—generic.

But it is also important to keep in mind that, just as not all generics are bare plurals, not all bare plurals are generic. “Dogs are barking” is true as long as some dogs are barking. Bare plurals can be used in particular ways to express existential statements. The key question for any given debate resolution that contains a bare plural is whether that occurrence of the bare plural is generic or existential.

The same is true of indefinite singulars. As debaters will be quick to point out, some uses of the indefinite singular really do mean “some” or “one or more”: “A cat is on the mat” is clearly not a generic generalization about cats; it’s true as long as some cat is on the mat. The question is whether the indefinite singular “a democracy” is existential or generic in the resolution.

Now, my own view is that, if we understand the difference between existential and generic statements, and if we approach the question impartially, without any invest- ment in one side of the debate, we can almost always just tell which reading is correct just by thinking about it. It is clear that “In a democracy, voting ought to be compul- sory” doesn’t mean “There is one or more democracy in which voting ought to be com- pulsory.” I don’t think a fancy argument should be required to show this any more than a fancy argument should be required to show that “A duck doesn’t lay eggs” is a generic—a false one because ducks do lay eggs, even though some ducks (namely males) don’t. And if a debater contests this by insisting that “a democracy” is existen- tial, the judge should be willing to resolve competing claims by, well, judging—that is, by using her judgment. Contesting a claim by insisting on its negation or demanding justification doesn’t put any obligation on the judge to be neutral about it. (Otherwise the negative could make every debate irresolvable by just insisting on the negation of every statement in the affirmative speeches.) Even if the insistence is backed by some sort of argument, we can reasonably reject an argument if we know its conclusion to be false, even if we are not in a position to know exactly where the argument goes wrong. Particularly in matters of logic and language, speakers have more direct knowledge of particular cases (e.g., that some specific inference is invalid or some specific sentence is infelicitious) than of the underlying explanations.

But that is just my view, and not every judge agrees with me, so it will be helpful to consider some arguments for the conclusion that we already know to be true: that, even if the United States is a democracy and ought to have compulsory voting, that doesn’t suffice to show that, in a democracy, voting ought to be compulsory—in other words, that “a democracy” in the resolution is generic, not existential.

Second, existential uses of the indefinite, such as “A cat is on the mat,” are upward- entailing.3 This means that if you replace the noun with a more general one, such as “An animal is on the mat,” the sentence will still be true. So let’s do that with “a democracy.” Does the resolution entail “In a society, voting ought to be compulsory”? Intuitively not, because you could think that voting ought to be compulsory in democracies but not in other sorts of societies. This suggests that “a democracy” in the resolution is not existential.

#### It applies to this topic – a] the noun “medicines” in the topic has no determiner preceding it to justify speccing a subset of medicines. that means medicines is an existential bare plural b] it fails the upward entailment test bc “member nations ought to reduce ip protections for medicines” does not entail that “member nations ought to reduce ip protections for pharmaceuticals” even though all medicines are pharmaceuticals.

#### Violation – they only defend the COVID vaccine

#### Standards:

#### 1] Limits: There’s an infinite number of medicines – hundreds of vaccines (Influenza, Coronavirus, Diptheria, Yellow Fever, etc.) and thousands of pharmaceutical drugs (Metformin, Lisinopril, Atorvastatin, and many more) – the negative could spec AND choose combinations – that’s supercharged by the fact that they can also spec countries. Kills neg burdens – it’s impossible for me to research every possible combination of medicines. Functional limits don’t check – each individual weapon has implications and articles as to why it is bad

#### 2] Prep hazard – there are an infinite number of medicines they could possibly spec exploding neg prep – generics and functional limits don’t apply because each medicine has different effects, capabilities, and implications which makes there infinite arguments for each weapon being bad

#### 3] TVA Solves – just read your aff as an advantage to a whole rez aff. We aren’t stopping them from reading new FWs, mechanisms, or advantages. PICs don’t solve – it’s ridiculous to say that neg potential abuse justifies the aff making it impossible for me to win

#### Fairness and education are voters – debate’s a game that needs rules to evaluate it and education gives us portable skills for life like research and thinking.

#### 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.

#### Drop the debater – a) they have a 7-6 rebuttal advantage and the 2ar to make args I can’t respond to, b) it deters future abuse and sets a positive norm.

#### Use competing interps – a) reasonability invites arbitrary judge intervention since we don’t know your bs meter

#### No RVIs – a) illogical – you shouldn’t win for being fair – it’s a litmus test for engaging in substance, b) norming – I can’t concede the counterinterp if I realize I’m wrong which forces me to argue for bad norms

### 1NC – OFF

#### Interpretation: reduce means to diminish

Idao State Court of Appeals 03

(State v. Knutsen, 71 P. 3d 1065 - Idaho: Court of Appeals 2003) EE

By its plain language, Rule 35 grants a district court the authority within a limited period of time to reduce or modify a defendant's sentence after relinquishing jurisdiction. To "reduce" means to diminish in size, amount, extent or number, or to make smaller, lessen or shrink. WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1905 (1993). To "modify" means to make more temperate and less extreme, or to lessen the severity of something. Id. at 1452. Thus, under the plain meaning of its language, Rule 35 authorizes a district court to diminish, lessen the severity of, or make more temperate a defendant's sentence. An order placing a defendant on probation lessens the severity of a defendant's sentence and thus falls within the district court's authority granted by Rule 35. Other state jurisdictions have held likewise in interpreting similar rules for reduction of sentence. See [State v. Knapp, 739 P.2d 1229, 1231-32 (Wy.1987)](https://scholar.google.com/scholar_case?case=1318610396541051353&q=%22the+term+reduce%22+OR+%22the+word+reduce%22+OR+%22the+phrase+reduce%22+OR+%22reduce+means%22&hl=en&as_sdt=2006) (similar rule of criminal procedure authorizes reduction of a sentence of incarceration to probation); [People v. Santana, 961 P.2d 498, 499 (Co.Ct.App.1997)](https://scholar.google.com/scholar_case?case=17890892396701062585&q=%22the+term+reduce%22+OR+%22the+word+reduce%22+OR+%22the+phrase+reduce%22+OR+%22reduce+means%22&hl=en&as_sdt=2006) (grant of probation is a "reduction" under Colorado Cr. R. 35(b)).

#### It has to be permanent

New York Supreme Court 3rd Appellate Division

(MATTER OF MONTESANI v. Levitt, 9 AD 2d 51 - NY: Appellate Div., 3rd Dept. 1959) EE

Section 83's counterpart with regard to nondisability pensioners, section 84, prescribes a reduction only if the pensioner should again take a public job. The disability pensioner is penalized if he takes any type of employment. The reason for the difference, of course, is that in one case the only reason pension benefits are available is because the pensioner is considered incapable of gainful employment, while in the other he has fully completed his "tour" and is considered as having earned his reward with almost no strings attached. It would be manifestly unfair to the ordinary retiree to accord the disability retiree the benefits of the System to which they both belong when the latter is otherwise capable of earning a living and had not fulfilled his service obligation. If it were to be held that withholdings under section 83 were payable whenever the pensioner died or stopped his other employment the whole purpose of the provision would be defeated, i.e., the System might just as well have continued payments during the other employment since it must later pay it anyway. The section says "reduced", does not say that monthly payments shall be temporarily suspended; it says that the pension itself shall be reduced. The plain dictionary meaning of the word is to diminish, lower or degrade. The word "reduce" seems adequately to indicate permanency.

#### Violation: their aff is temporary

#### Vote neg for limits and ground – nonpermanent affs open the floodgates to delay and conditions affs that could hypothetically result in future reductions. These affs don’t materially change the status quo which destroys neg link uniqueness and avoids core topic questions of medical IP good/bad in favor of burner condition-of-the-week affs that gain advantages from the most extreme of crises.

#### Cross apply paradigm issues from first shell.

### 1NC – OFF

#### CP Text: The member nations of the World Trade Organization ought to enforce compulsory licensing measures regarding the COVID-19 vaccine

#### Compulsory license continues innovation AND checks back manufacturing capacity and scarcity of materials which a waiver doesn’t solve

**Ezell, 21,** “TRIPS Waiver on COVID-19 IP Rights Wouldn’t Help Vaccine Access; It Would Just Harm Innovation”, ITIF, Stephen Ezell is vice president, global innovation policy, at the Information Technology and Innovation Foundation (ITIF), Ezell holds a B.S. from the School of Foreign Service at Georgetown University, with an honors certificate from Georgetown’s Landegger International Business Diplomacy program, URL; <https://itif.org/publications/2021/03/09/trips-waiver-covid-19-ip-rights-wouldnt-help-vaccine-access>, KR

And while petitioners made this call on the alleged grounds of ensuring sufficient access to needed vaccines and therapeutics, their call for the suspension of every facet of IP rights on every conceivable COVID-19 related technology—even such as for copyrights and industrial designs—betrays the reality that the petitioners’ core goal isn’t really about access, but about undermining the global intellectual property rights system.

To be sure, the developed world needs to be fully committed to ensuring that the world’s citizens receive the COVID-19 vaccines and therapeutics they need. But this can be accomplished through structures such as licensing and product development partnerships, without requiring an abrogation of intellectual property rights. For instance, in February 2021, the Biden administration announced it would contribute up to $4 billion to COVAX, a vaccine alliance seeking to distribute COVID-19 vaccines to 92 low- and middle-income countries. COVAX aims to deliver at least 2 billion vaccine doses by the end of 2021, covering at least 20 percent of the most vulnerable citizens in poor- and middle-income countries.

Innovative life-sciences companies have entered into a number of licensing agreements to facilitate dramatically expanded manufacturing of COVID-19 vaccines and therapeutics. For instance, Gilead Sciences has licensed its therapeutic remdesivir royalty-free to nine generic drug manufacturers, in Egypt, India, and Pakistan. AstraZeneca reached a licensing and technology transfer agreement enabling India’s Serum Institute to manufacture one billion vaccine doses for low- and middle-income countries. The Serum Institute has further entered into manufacturing licenses with a number of developers of yet to be approved COVID-19 vaccines, as have several other Indian vaccine manufacturers. Johnson and Johnson has announced plans to allocate up to 500 million vaccine doses to lower-income countries, with delivery starting by mid-2021. Companies like Johnson & Johnson are making the vast majority of these vaccine doses available on a not-for-profit basis.

Thus, the fundamental problem isn’t high prices due to IP rights; it’s dramatically scaling up manufacturing capacity. It takes 60 to 110 days to produce one batch of COVID-19 vaccine. When Serum Institute CEO Adam Poonawalla was asked if vaccine rollout was slowed because vaccine patentholders were licensing too few manufacturers to make them, he responded, “No. There are enough manufacturers, it just takes time to scale up. And by the way, I have been blown away by the cooperation between the public and private sectors in the last year, in developing these vaccines.” Poonawalla actually cited the lack of global regulatory harmonization as a far greater cause of delays in the vaccine rollout. Even Médecins Sans Frontières’ Rose Scourze acknowledged (in a January 20, 2021 BBC interview) that suspending patent rights “wouldn’t produce millions of more vaccines.”

Instead of forcing the disclosure of IP, policymakers should encourage the use of voluntary licensing agreements to expand production of the needed COVID-19 vaccines and therapeutics. One reason this critically matters is to ensure consistency and safety in the production of these treatments. The mRNA-based vaccines developed by Moderna and Pfizer are incredibly complex biologic products that require specialized experience, expertise, and equipment to manufacture. For example, mRNA vaccines require a complicated technique known as “bioprocess” that requires specialty bioreactors to first manufacture DNA that codes for the desired mRNA sequence, and then uses a second bioprocess to create billions of identical mRNA segments. These are then wrapped in a nanolipid wrapper using yet another very specialized fluidics and mixing process, and for which there are only three facilities in the world that can execute the step of creating the liquid capsule around the RNA.

Instead of simply being forced to divulge their IP or see it be compulsorily licensed to other manufacturers, in light of the extreme complexity of manufacturing COVID-19 vaccines and therapeutics, companies should have the right to evaluate potential license partners and ensure that they can meet the production standards required to safely and reliably produce COVID-19 vaccines or treatments before entering into license arrangements with them. Indeed, this is critical for it would be disastrous if defective vaccines or therapeutics were produced at facilities not properly equipped to produce such complex treatments. As Phil Stevens and Mark Schultz have written, there’s simply no evidence that invalidating IP rights would achieve more than the licensing agreements currently being forged between innovators and reputable vaccine manufacturers in countries such as India and Brazil.

Instead of rolling back intellectual property rights, policymakers in developed and developing nations alike should focus on mechanisms to scale up production of vaccines and make them affordably available to citizens in developing countries. But to achieve that, there is simply no compelling reason for a blanket suspension of the intellectual property rights associated with COVID-19 products and technologies. For this reason, the Biden administration should continue the previous administration’s stance of opposing the waiver at the WTO TRIPS council, where deliberations resume on March 10, and reject calls from some in Congress to endorse the proposed TRIPS waiver.

### 1NC – OFF

#### Current WTO legislation on IP rights promotes innovation

Ezell et al 4/29 Jaci McDole, Stephen Ezell [Stephen Ezell is vice president, global innovation policy, at the Information Technology and Innovation Foundation (ITIF). He focuses on science and technology policy, international competitiveness, trade, manufacturing, and services issues.] 4/29/21, “Ten Ways IP Has Enabled Innovations That Have Helped Sustain the World Through the Pandemic” Information Technology and Innovation Foundation, <https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through> DD AG

Although anti-IP proponents have attacked biopharmaceutical manufacturers particularly hard, the reality is all IP-protected innovations are at risk if these rights are ignored, or vitiated. Certain arguments have shown a desire for the term “COVID-19 innovations” to include everything from vaccines, therapeutics, diagnostics, and PPE to biotechnology, AI-related data, and educational materials.14 This could potentially open the floodgates to invalidate IP protection on many of the innovations highlighted in this report.

However, much of the current discussion concerning IP focuses almost entirely on litigation fears or R&D incentives. Although R&D is an important aspect of IP, as previously mentioned, these discussions ignore the fact that IP protection can be—and often is—used for other purposes, including generating initial capital to create a company and begin manufacturing and, more importantly, using licensing agreements and IP to track the supply chain and ensure quality control of products.

In 2018, Forbes identified counterfeiting as the largest criminal enterprise in the world.15 The global struggle against counterfeit and non-regulated products, which has hit Latin America particularly hard during the pandemic, proves the need for safety and quality assurance in supply chains.16 Some communities already ravaged by COVID-19 are seeing higher mortality rates related to counterfeit vaccines, therapeutics, PPE, and cleaning and sanitizing products.17

Polish authorities discovered vials of antiwrinkle treatment labeled as COVID-19 vaccines. 18 In Mexico, fake vaccines sold for approximately $1,000 per dose.19 Chinese and South African police seized thousands of counterfeit vaccine doses from warehouses and manufacturing plants.20 Meanwhile, dozens of websites worldwide claiming to sell vaccines or be affiliated with vaccine manufacturers have been taken down.21 But the problem is not limited to biopharmaceuticals. The National Intellectual Property Rights Coordination Center has recovered $48 million worth of counterfeit PPE and other products.22

Collaborative efforts between law enforcement and manufacturers have kept numerous counterfeits from reaching the population. In countries with strong IP protection, the chances of counterfeit products reaching the market are significantly lower. This is largely because counterfeiting tends to be an IP-related issue, and these countries generally provide superior means of tracking the supply chain through trademarks, trade secrets, and licensing agreements. This enables greater quality control and helps manufacturers maintain a level of public confidence in their products.

By controlling the flow of knowledge associated with IP, voluntary licensing agreements provide innovators with opportunities to collaborate, while ensuring their partners are properly equipped and capable of producing quality products. Throughout this difficult time, the world has seen unexpected collaborations, especially between biopharmaceutical companies worldwide such as Gilead and Eva Pharma or Bharat Biotech and Ocugen, Inc.

Throughout history, and most significantly in the nineteenth century through the widespread development of patent systems and the ensuing Industrial Revolution, IP has contributed toward greater economic growth.23 This is promising news as the world struggles for economic recovery. A 2021 joint study by the EU Intellectual Property Office (EUIPO) and European Patent Office (EPO) shows a strong, positive correlation between IP rights and economic performance.24 It states that “IP-owning firms represent a significantly larger proportion of economic activity and employment across Europe,” with IP-intensive industries contributing to 45 percent of gross domestic product (GDP) (€6.6 trillion; US$7.9 trillion).25 The study also shows 38.9 percent of employment is directly or indirectly attributed to IP-intensive industries, and IP generates higher wages and greater revenue per employee, especially for small-to-medium-sized enterprises.26 That concords with the United States, where the Department of Commerce estimated that IP-intensive industries support at least 45 million jobs and contribute more than $6 trillion dollars to, or 38.2 percent of, GDP.27

In 2020, global patent filings through the World Intellectual Property Organization’s (WIPO) Patent Cooperation Treaty (PCT) system reached a record 275,900 filings amidst the pandemic, growing 4 percent from 2019.28 The top-four nations, which accounted for 180,530 of the patent applications, were China, the United States, Japan, and Korea, respectively.29 While several countries saw an increase in patent filings, Saudi Arabia and Malaysia both saw significant increases in the number of annual applications, with the top two filing growths of 73 percent and 26 percent, respectively.30

#### Reductions in protections kill medical innovation, economic growth, and knowledge building for the future

McDole and Ezell 04/29 – Jaci McDole is a senior policy analyst covering intellectual property (IP) and innovation policy at ITIF. She focuses on IP and its correlations to global innovation and trade. Her work includes ITIF’s Innovate4Health Initiatives (2017–2019) and A Covid-19 TRIPS Waiver Makes No More Sense for Copyrights Than It Does for Patents (2021). McDole comes to ITIF from the Institute for Intellectual Property Research, an organization she cofounded to study and further robust global IP policies. Stephen J. Ezell is ITIF vice president for Global Innovation Policy. He focuses on science, technology, and innovation policy as well as international competitiveness and trade policy issues. He is the coauthor of Innovating in a Service Driven Economy: Insights Application, and Practice (Palgrave McMillan, 2015) and Innovation Economics: The Race for Global Advantage (Yale 2012). The Information Technology and Innovation Foundation (ITIF) is an independent, nonprofit, nonpartisan research and educational institute focusing on the intersection of technological innovation and public policy. Recognized by its peers in the think tank community as the global center of excellence for science and technology policy, ITIF’s mission is to formulate and promote policy solutions that accelerate innovation and boost productivity to spur growth, opportunity, and progress; April 29, 2021; “Ten Ways IP Has Enabled Innovations That Have Helped Sustain the World Through the Pandemic”; <https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through> //advay

Innovation can—and does—happen anywhere and at any time. As society ground to a halt in 2020, innovators around the world worked tirelessly to develop treatments, vaccines, and solutions to COVID-19 pandemic-related challenges. From personal protective equipment (PPE) to treatments and vaccines to autonomous delivery robots to remote and social distancing solutions for the workplace, intellectual property (IP) played an indispensable role in enabling research, development, and commercialization of many of the innovations meeting the challenges of the pandemic. IP enables start-ups to gain access to much-needed capital. IP gives innovators the confidence to invest in research and development (R&D) and provides incentives for commercialization. Indeed, it is difficult to innovate without the protection of ideas.

Despite this, some—particularly anti-business IP opponents—have blamed IP rights for a host of problems, including limited access to therapeutics, vaccines, and biotechnology. They offer seemingly simple solutions—weaken or eliminate IP rights—and innovation will flow like manna from heaven. Eliminating IP rights might accelerate the diffusion of some pre-existing innovations, but it would absolutely limit future innovations. Innovators, a bit like Charlie Brown kicking the football held by Lucy, would be wary of trusting governments who might say, “Well, this time we won’t take away your IP rights, so go ahead and invest large amounts of time and money.” Given the nature of COVID-19, nations around the world cannot afford to take this risk. Future pandemics and other challenges for which we will need to rely on IP-protected innovations to overcome are near certain to arise.

Moreover, the blame game usually ignores the real, underlying problems. For access to innovations to fight COVID-19, especially biotechnology, vaccines, and therapeutics, the underlying problems are regulatory delays and a lack of adequate and appropriate manufacturing infrastructure.1 The lack of infrastructure has resulted in supply chain bottlenecks in places where few are currently equipped to handle the manufacturing requirements.2 Meanwhile, regulatory delays have prevented vaccines, therapeutics, and diagnostics from entering certain markets.3

To better understand the role of IP in enabling solutions related to COVID-19 challenges, this report relies on 10 case studies drawn from a variety of nations, technical fields, and firm sizes. This is but a handful of the thousands of IP-enabled innovations that have sprung forth over the past year in an effort to meet the tremendous challenges brought on by COVID-19 globally. From a paramedic in Mexico to a veteran vaccine manufacturing company in India and a tech start-up in Estonia to a U.S.-based company offering workplace Internet of Things (IoT) services, small and large organizations alike are working to combat the pandemic. Some have adapted existing innovations, while others have developed novel solutions. All are working to take the world out of the pandemic and into the future.

The case studies are:

Bharat Biotech: Covaxin

Gilead: Remdesivir

LumiraDX: SARS-COV-2 Antigen POC Test

Teal Bio: Teal Bio Respirator

XE Ingeniería Médica: CápsulaXE

Surgical Theater: Precision VR

Tombot: Jennie

Starship Technologies: Autonomous Delivery Robots

Triax Technologies: Proximity Trace

Zoom: Video Conferencing

As the case studies show, IP is critical to enabling innovation. Policymakers around the world need to ensure robust IP protections are—and remain—in place if they wish their citizens to have safe and innovative solutions to health care, workplace, and societal challenges in the future.

THE ROLE OF INTELLECTUAL PROPERTY IN R&D-INTENSIVE INDUSTRIES

Intangible assets, such as IP rights, comprised approximately 84 percent of the corporate value of S&P 500 companies in 2018.4 For start-ups, this means much of the capital needed to operate is directly related to IP (see Teal Bio case study for more on this). IP also plays an especially important role for R&D-intensive industries.5

To take the example of the biopharmaceutical industry, it is characterized by high-risk, time-consuming, and expensive processes including basic research, drug discovery, pre-clinical trials, three stages of human clinical trials, regulatory review, and post-approval research and safety monitoring. The drug development process spans an average of 11.5 to 15 years.6 For every 5,000 to 10,000 compounds screened on average during the basic research and drug discovery phases, approximately 250 molecular compounds, or 2.5 to 5 percent, make it to preclinical testing. Out of those 250 molecular compounds, approximately 5 make it to clinical testing. That is, 0.05 to 0.1 percent of drugs make it from basic research into clinical trials. Of those rare few which make it to clinical testing, less than 12 percent are ultimately approved for use by the U.S. Food and Drug Administration (FDA).7

In addition to high risks, drug development is costly, and the expenses associated with it are increasing. A 2019 report by the Deloitte Center for Health Solutions concluded that since 2010 the average cost of bringing a new drug to market increased by 67 percent.8 Numerous studies have examined the substantial cost of biopharmaceutical R&D, and most confirm investing in new drug development requires $1.7 billion to $3.2 billion up front on average.9 A 2018 study by the Coalition for Epidemic Preparedness found similar risks and figures for vaccines, stating, “In general, vaccine development from discovery to licensure can cost billions of dollars, can take over 10 years to complete, and has an average 94 percent chance of failure.”10 Yet, a 2010 study found that 80 percent of new drugs—that is, the less than 12 percent ultimately approved by the FDA—made less than their capitalized R&D costs.11 Another study found that only 1 percent (maybe three new drugs each year) of the most successful 10 percent of FDA approved drugs generate half of the profits of the entire drug industry.12

To say the least, biopharmaceutical R&D represents a high-stakes, long-term endeavor with precarious returns. Without IP protection, biopharmaceutical manufacturers have little incentive to take the risks necessary to engage in the R&D process because they would be unable to recoup even a fraction of the costs incurred. Diminished revenues also result in reduced investments in R&D which means less research into cancer drugs, Alzheimer cures, vaccines, and more. IP rights give life-sciences enterprises the confidence needed to undertake the difficult, risky, and expensive process of life-sciences innovation secure in the knowledge they can capture a share of the gains from their innovations, which is indispensable not only to recouping the up-front R&D costs of a given drug, but which can generate sufficient profits to enable investment in future generations of biomedical innovation and thus perpetuate the enterprises into the future.13

#### Two Impacts –

#### 1] Turns their disease impact – future pandemics are more likely and more deadly which makes innovation key to stop extinction

Ceballos 5/27 Gerardo Ceballos [PhD, Dr Gerardo Ceballos is an ecologist and conservationist at the Universidad Nacional Autonoma de Mexico. He is particularly recognized for his influential work on global patterns of distribution of diversity, endemism, and extinction risk in vertebrates. He is also well-known for his contribution to understanding the magnitude and impacts of the sixth mass extinction.], 5/27/21, “THE SIXTH MASS EXTINCTION AND THE FUTURE OF HUMANITY”, Population Matters, <https://populationmatters.org/news/2021/05/sixth-mass-extinction-and-future-humanity> DD AG

Somewhere, sometime in late 2019, a coronavirus from a wild species, perhaps a bat or a pangolin, infected a human in China. This could have been an obscure event, lost without trace in the annals of history, as it is very likely this has occurred many times in the last centuries. But this particular event was somehow different. The coronavirus became an epidemic first and a pandemic later. Covid-19 became the worst pandemic since the Spanish flu in 1918. The horrific human suffering it has caused, and its economic, social and political impacts, are still unraveling.

The reason Covid-19 and more than forty other very dangerous viruses, such as Lassa fever, HIV and Ebola, have jumped from wild animals to humans in the last four decades is the destruction of natural environments and the trafficking and consumption of wild animals.

The wildlife trade is to satisfy the insatiable and extravagant demand for these species in the Asian market, in countries such as China, Vietnam and Indonesia. The illegal wildlife trade is a gigantic business. It is as lucrative as the drug trade, but without the legal implications. The immense appetite of China and other Asian societies for exotic animals has promoted exponential growth in trade and profits. Wild and domestic animals sold in “wet markets” are kept in unsanitary and unethical conditions. There, feces, urine and food waste from cages at the top spill into cages at the bottom, creating the perfect conditions for viruses to leap from wild animals to domestic animals and humans. Thousands of wildlife species or their products are traded annually.

Wildlife trade is one of several human impacts, including habitat loss and fragmentation, pollution, toxification and invasive species, that have caused the extinction of thousands of species and threaten many more. Indeed, most people are unaware that the current extinction crisis is unprecedented in human history. Extinction occurs when the last individual of a species dies. The UN recently estimated that one million species, such as the panda, the orangutan and the Sumatran rhino, are at risk of extinction.

The second finding is that population extinctions, which are the prelude to species extinctions, are occurring at very fast rates (Ceballos et al., 2017). Around 32 percent of a sample of 27,000 species have declining populations and have experienced massive geographic range contractions. Population extinctions are a very severe and widespread environmental problem which we have called “Biological Annihilation”.

Finally, our third finding indicates that the magnitude of the extinction crisis is underestimated because there are thousands of species on the brink of extinction (Ceballos et al., 2020). Those species will likely become extinct in the near future unless a massive conservation effort is launched soon.

Many times, people have asked me why we should care about the loss of a species. There are ethical, moral, philosophical, religious and other reasons to be concerned. But perhaps the one that is most tangible for most people is the loss of ecosystem services, which are the benefits that humans derive from the proper function of nature. Ecosystem services include the proper mix of gases in the atmosphere that support life on Earth, the quantity and quality of water, pollination of wild crops and plants, fertilization of the soil, and protection against emerging pests and diseases, among many others. Every time a species is lost, ecosystem services are likely to erode and human well-being is reduced.

The loss of so many ecosystems and species is pushing us towards the point of collapse of civilization. The good news is that there is still time to reduce the current extinction crisis. The species and ecosystems that we manage to save in the next 10 – 15 years will define the future of biodiversity and civilization. What it is at stake is the future of mankind.

#### 2] Anticipated economic results in nuclear war – especially for a post-pandemic world

Tønnesson 15 [Tønnesson is a research professor at the Peace Research Institute Oslo (PRIO) in Norway and the leader of the East Asia Peace program at Uppsala University in Sweden.] “Deterrence, interdependence and Sino–US peace.” International Area Studies Review, volume 18, number 3, pgs. 297-311. 2015 // recut advay

Several recent works on China and Sino–US relations have made substantial contributions to the current understanding of how and under what circumstances a combination of nuclear deterrence and economic interdependence may reduce the risk of war between major powers. At least four conclusions can be drawn from the review above: first, those who say that interdependence may both inhibit and drive conflict are right. Interdependence raises the cost of conflict for all sides but asymmetrical or unbalanced dependencies and negative trade expectations may generate tensions leading to trade wars among inter-dependent states that in turn increase the risk of military conflict (Copeland, 2015: 1, 14, 437; Roach, 2014). The risk may increase if one of the interdependent countries is governed by an inward-looking socio-economic coalition (Solingen, 2015); second, the risk of war between China and the US should not just be analysed bilaterally but include their allies and partners. Third party countries could drag China or the US into confrontation; third, in this context it is of some comfort that the three main economic powers in Northeast Asia (China, Japan and South Korea) are all deeply integrated economically through production networks within a global system of trade and finance (Ravenhill, 2014; Yoshimatsu, 2014: 576); and fourth, decisions for war and peace are taken by very few people, who act on the basis of their future expectations. International relations theory must be supplemented by foreign policy analysis in order to assess the value attributed by national decision-makers to economic development and their assessments of risks and opportunities. If leaders on either side of the Atlantic begin to seriously fear or anticipate their own nation’s decline then they may blame this on external dependence, appeal to anti-foreign sentiments, contemplate the use of force to gain respect or credibility, adopt protectionist policies, and ultimately refuse to be deterred by either nuclear arms or prospects of socioeconomic calamities. Such a dangerous shift could happen abruptly, i.e. under the instigation of actions by a third party – or against a third party. Yet as long as there is both nuclear deterrence and interdependence, the tensions in East Asia are unlikely to escalate to war. As Chan (2013) says, all states in the region are aware that they cannot count on support from either China or the US if they make provocative moves. The greatest risk is not that a territorial dispute leads to war under present circumstances but that changes in the world economy alter those circumstances in ways that render inter-state peace more precarious. If China and the US fail to rebalance their financial and trading relations (Roach, 2014) then a trade war could result, interrupting transnational production networks, provoking social distress, and exacerbating nationalist emotions. This could have unforeseen consequences in the field of security, with nuclear deterrence remaining the only factor to protect the world from Armageddon, and unreliably so. Deterrence could lose its credibility: one of the two great powers might gamble that the other yield in a cyber-war or conventional limited war, or third party countries might engage in conflict with each other, with a view to obliging Washington or Beijing to intervene.

## CASE

**Conceeded extinction first in cross – stop ultimate form of suffering – but still That threatens the ontological conditions of life itself**

**Burke et al.**, Associate Professor of International and Political Studies @ UNSW, Australia, **‘16**

(Anthony, Stefanie Fishel is Assistant Professor, Department of Gender and Race Studies at the University of Alabama, Audra Mitchell is CIGI Chair in Global Governance and Ethics at the Balsillie School of International Affairs, Simon Dalby is CIGI Chair in the Political Economy of Climate Change at the Balsillie School of International Affairs, and, Daniel J. Levine is Assistant Professor of Political Science at the University of Alabama, “Planet Politics: Manifesto from the End of IR,” Millennium: Journal of International Studies 1–25)

8. Global ethics must respond to mass extinction. In late 2014, the Worldwide Fund for Nature reported a startling statistic: according to their global study, 52% of species had gone extinct between 1970 and 2010.60 This is not news: for three decades, conservation biologists have been warning of a ‘sixth mass extinction’, which, by definition, could eliminate more than three quarters of currently existing life forms in just a few centuries.61 In other words, it could threaten the practical possibility of the survival of earthly life. Mass extinction is not simply extinction (or death) writ large: **it is a qualitatively different phenomena that demands its own ethical categories.** It cannot be grasped by aggregating species extinctions, let alone the deaths of individual organisms. Not only does it erase diverse, irreplaceable life forms, their **unique histories** and **open-ended possibilities**, but it **threatens the ontological conditions of Earthly life**.

IR is one of few disciplines that is explicitly devoted to the pursuit of survival, yet it has almost nothing to say in the face of a possible mass extinction event.62 It utterly lacks the conceptual and ethical frameworks necessary to foster diverse, meaningful responses to this phenomenon. As mentioned above, Cold-War era concepts such as ‘nuclear winter’ and ‘omnicide’ gesture towards harms massive in their scale and moral horror. However, they are asymptotic: they imagine nightmares of a severely denuded planet, yet they do not contemplate the **comprehensive negation** that a mass extinction event entails. In contemporary IR discourses, where it appears at all, extinction is treated as a problem of scientific management and biopolitical control aimed at securing existing human lifestyles.63 Once again, this approach fails to recognise the reality of extinction, which is a **matter of being and nonbeing**, not one of life and death processes.

Confronting the enormity of a possible mass extinction event requires a total overhaul of human perceptions of what is at stake in the disruption of the conditions of Earthly life. The question of what is ‘lost’ in extinction has, since the inception of the concept of ‘conservation’, been addressed in terms of financial cost and economic liabilities.64 Beyond reducing life to forms to capital, currencies and financial instruments, the dominant neoliberal political economy of conservation imposes a homogenising, Western secular worldview on a planetary phenomenon. Yet the **enormity, complexity, and scale** of mass extinction is so huge that humans need to **draw on every possible resource in order to find ways of responding**. This means that they need to mobilise multiple worldviews and lifeways – including those emerging from indigenous and marginalised cosmologies. Above all, it is crucial and urgent to realise that extinction is a **matter of global ethics**. It is not simply an issue of management or security, or even of particular visions of the good life. Instead, it is about staking a claim as to the goodness of life itself. If it does not fit within the existing parameters of global ethics, then it is these boundaries that need to change.

9. An Earth-worldly politics. Humans are worldly – that is, we are fundamentally worldforming and embedded in multiple worlds that traverse the Earth. However, the Earth is not ‘our’ world, as the grand theories of IR, and some accounts of the Anthropocene have it – an object and possession to be appropriated, circumnavigated, instrumentalised and englobed.65 Rather, it is a complex of worlds that we share, co-constitute, create, destroy and inhabit with countless other life forms and beings.

The formation of the Anthropocene reflects a particular type of worlding, one in which the Earth is treated as raw material for the creation of a world tailored to human needs. Heidegger famously framed ‘earth’ and ‘world’ as two countervailing, conflicting forces that constrain and shape one another. We contend that existing political, economic and social conditions have pushed human worlding so far to one extreme that it has become almost entirely detached from the conditions of the Earth. Planet Politics calls, instead, for a mode of worlding that is responsive to, and grounded in, the Earth. One of these ways of being Earth-worldly is to embrace the condition of being entangled. We can interpret this term in the way that Heidegger66 did, as the condition of being mired in everyday human concerns, worries, and anxiety, to prolong existence. But, in contrast, we can and should reframe it as authors like Karen Barad67 and Donna Haraway68 have done. To them and many others, ‘entanglement’ is a radical, indeed fundamental condition of being-with, or, as Jean-Luc Nancy puts it, ‘being singular plural’.69 This means that no being is truly autonomous or separate, whether at the scale of international politics or of quantum physics. World itself is singular plural: what humans tend to refer to as ‘the’ world is actually a multiplicity of worlds at various scales that intersect, overlap, conflict, emerge as they surge across the Earth. World emerges from the poetics of existence, the collision of energy and matter, the tumult of agencies, the fusion and diffusion of bonds.

Worlds erupt from, and consist in, the intersection of **diverse forms of being** – material and intangible, organic and inorganic, ‘living’ and ‘nonliving’. Because of the tumultuousness of the Earth with which they are entangled, ‘**worlds’ are not static, rigid or permanent. They are permeable and fluid**. They can be **created**, **modified** – and, of course, destroyed. Concepts of violence, harm and (in)security that focus only on humans ignore at their peril the destruction and severance of worlds,70 **which undermines the conditions of plurality that enables life on Earth to thrive.**

#### Removing patents fails – knowledge is key but patents don’t force it, and manufacturing disparities exist which the plan DOESN’T SOLVE

**Rutschman, Barnes-Weise, 21,** Harvard Law: Bill of Health, “The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal”, Ana Santos Rutschman is an Assistant Professor of Law at Saint Louis University School of Law. Julia Barnes-Weise is Executive Director of the Global Healthcare Innovation Alliance Accelerator.URL: <https://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver/>, KR

In order to understand the practical limitations of a waiver of intellectual property rights when a vaccine is involved, it may be useful to think of patents as informational mechanisms akin to the information and tools needed to turn a recipe into an edible product. One or more patents will provide a recipe for a process or a component needed to produce a vaccine. But, just as with a culinary recipe, the informational power of a patent does not cover any tips or instructions that have not been memorialized in writing, nor does it provide any access to the raw materials needed to put a vaccine together. Waivers, therefore, temporarily remove exclusionary rights, but do not address two fundamental sources of the current vaccine scarcity problem.

First, we are still left with a significant informational problem: as many commentators have remarked, knowledge disclosed through patents alone is often insufficient for a third party to actually be able to replicate a vaccine.

From a scientific perspective, vaccines are biological products, and, as such, their relative complexity makes them highly dependent on specific manufacturing processes and practices, many of which are not disclosed in a patent — think of it as the unwritten tips or instructions for a particular recipe. Some of this information may be kept secret by a company for competitive reasons; in these cases, lifting patent rights will not result in increased informational disclosure, unless the patent holders themselves are willing to collaborate. A waiver thus solves the exclusivity problem, but not the information problem that undergirds competition in vaccine manufacturing. To revisit the analogy introduced above, a waiver allows third parties to freely use the recipe. It does not, however, provide all the information that may be needed to manufacture the desired good, nor does it provide manufacturers with the tacit knowledge that only the original manufacturer possesses and is not disclosed elsewhere.

Second, even if all types of legal restrictions on the use of vaccine technology were lifted — or had never existed in the first place — there is simply not enough infrastructure (manufacturing facilities and equipment) nor raw materials (the components needed to manufacture and deliver vaccines) to produce and distribute COVID-19 vaccines as predicted under current waiver proposals. We have long faced a global vaccine manufacturing problem that will not be fully resolved during the current pandemic. In the case of vaccines that need to be kept at ultra-cold temperatures, these problems intensify.

One of us (Barnes-Weise) has been involved in the contractual negotiations for the development, manufacturing and transfer of technology related to COVID-19 vaccines. In addition to the informational gaps described above, COVID-19 vaccine manufacturers are most concerned about how well the recipients of the technology transfer will understand and be able to implement such knowledge in making vaccines of the necessary quality. Shortages do not merely affect materials necessary to manufacture vaccines and facilities adequate to manufacture the vaccines; they also affect the availability of personnel qualified to instruct the licensee and recipient of this information. Sending an employee of this caliber out of the original manufacturing site to a partner site risks reducing the capacity of the first site. And remote instruction, necessitated by the pandemic, has its own shortcomings.

In relation to the patents on the vaccines themselves, most of the concerns that the vaccine manufacturers express are around the protection of their vaccine platforms for the purposes of making future or non-COVID-19 vaccines. Moderna shared information about its patents in summer 2020. The manufacturers, as evidenced by the number of licenses to manufacture granted to date, are eager to find partners with the capabilities to expand production. It is not to their benefit to produce an inadequate supply of a highly sought-after vaccine. However, even willingness to transfer patented vaccine technology has faced numerous practical hurdles to date: 1) infrastructural limitations; 2) scarcity of raw materials; 3) concerns about licensees having the ability to actually manufacture effective vaccines in light of the infrastructural and product scarcity, even in situations in which there might be no informational gaps.

A patent waiver would not address any of the practical concerns currently at the root of tech transfer negotiations involving COVID-19 vaccine technology. Compounding these problems is the fact that, should a waiver be issued, there is no legal mechanism that can compel the transfer of certain types of know-how or trade secrets should a company be unwilling to license its intellectual property — which, again, at this point in the pandemic, is not a problem we have observed.

#### Turn – Reductions in IP protections decks innovation

Pipes 3/5 Sally Pipes [Sally C. Pipes is President, CEO, and Thomas W. Smith Fellow in Health Care Policy at the Pacific Research Institute, a California-based think tank founded in 1979.], 3-5-2021, "Intellectual Property Rights Are Key To Fighting Covid-19 And Protecting Public Health," Forbes, <https://www.forbes.com/sites/sallypipes/2021/03/05/intellectual-property-rights-are-key-to-fighting-covid-19-and-protecting-public-health/> DD AG

The record-setting development of multiple Covid-19 vaccines will go down in history as some of medical science's greatest achievements. In less than a year, the competing vaccines went from the drawing board to saving lives around the world. Unfortunately, many liberal policymakers are attacking the system of strong intellectual property rights that underpinned the work of these heroic scientists. If their attacks are successful, then there could be many fewer medical miracles in our future. Later this month, the World Trade Organization is expected to rule on a petition championed by the governments of India and South Africa to suspend patents related to Covid-19 vaccines and treatments. Supporters of this scheme claim it would boost the availability of vaccines in poorer countries. They also argue that governments have helped fund the research that led to the Covid-19 vaccines—so the public has a claim on the fruits of that work. There's no evidence that suspending intellectual property rights will speed up the manufacturing or distribution of Covid vaccines. The process of making these vaccines is hard. The machines that make the particles that go into the shots are highly complex, and their supply is limited. As pharmaceutical researcher Derek Lowe has explained, "There are definitely not dozens of companies who can make enough RNA," the genetic material in the Moderna and Pfizer/BioNTech vaccines that instructs our cells in how to fight the coronavirus. Lowe continues: "And you can count on one hand the number of facilities who can make the critical lipid nanoparticles" that carry the mRNA to our cells. There's a wealth of evidence, on the other hand, that revoking patents will cause drugmakers to put their research and development efforts on hold. Pharmaceutical companies spend an average of 15 years and nearly $3 billion to bring a new medicine to market. Just one-tenth of one percent of potential pharmaceutical compounds ever enter clinical trials in humans. And just 0.02% of those compounds ends up garnering approval and being dispensed to patients. Clearly, developing life-saving medicines is a risky, expensive, and time-consuming endeavor. Few investors would ever consider funding drug research if there were a threat that governments could seize the fruits of that research and prevent them from having a chance to recoup their money. India and South Africa aren't the only countries looking to launch a broadside on the global intellectual property system. The idea has a following here in the United States, too. Last year, attorneys general from 31 states, as well as American Samoa, Guam, and the District of Columbia, called on the federal government to revoke the patent for remdesivir, the antiviral developed by Gilead Sciences that shortened stays in the hospital for patients with Covid-19. The attorneys general argued that the government had a claim on the intellectual property behind the drug, since it had funded early-stage research. Nevermind that the federal government's own experts determined that it didn't "qualify. . . as a joint inventor of the compound." The public's investment in research broadly related to remdesivir totaled about $70 million; Gilead, with no guarantee of any success, risked more than $1 billion developing the drug. Drugmakers have come up with the vaccines that will ultimately save millions of lives and allow the world to return to life as usual. They've also developed ways to get those vaccines to as many people quickly and cheaply—often to the detriment of their bottom line. AstraZeneca, for example, has volunteered not to take any profits during the pandemic and pledged to direct more than 64% of its vaccine doses to developing nations. Johnson & Johnson has promised to allocate up to half a billion vaccines to lower-income countries. All four major vaccine developers—Pfizer, Moderna, AstraZeneca, and Johnson & Johnson—are allowing manufacturers to license their patents for free in order to make more vaccines available as quickly as possible. Suspending patents won't increase the number of vaccines available. It will only prevent the development of new innovative and life-saving drugs—and leave us less prepared for future pandemics. It's an idea that tomorrow's patients will pay for.

#### Tons of thumpers, the aff makes vaccines more expensive, and current production is sufficient

McMurry-Heath 21 [Michelle McMurry-Heath assumed the leadership of the Biotechnology Innovation Organization (BIO) as President and CEO on June 1, 2020. A medical doctor and molecular immunologist by training, Dr. McMurry-Heath becomes just the third chief executive to steward the world’s largest biotechnology advocacy group since BIO’s founding in 1993.] “Waiving intellectual property rights would compromise global vaccination efforts,” August 18th, 2021, <https://www.statnews.com/2021/08/18/waiving-intellectual-property-rights-compromise-global-vaccination-efforts/>, STAT, VM

“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 of various vaccines every year. Now the world needs an additional 11 billion doses — 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 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, 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.”

#### Waiving IP rights won’t solve vaccine distribution

Hilty et al. 21 [Dr. Reto M. Hilty is Director at the Max Planck Institute for Innovation and Competition in Munich and a professor at Univ. Zurich, with a PhD from Univ. Zurich; Pedro Henrique D. Batista is Doctoral Student and Junior Research Fellow, Legal Manager GRUR Int. in the department Intellectual Property and Competition Law; Dr. Suelen Carls is Senior Research Fellow in the department Intellectual Property and Competition Law at the Max Planck Institute for Innovation and Competition; Dr. Daria Kim is Senior Research Fellow in the department Intellectual Property and Competition Law at the Max Planck Institute; Dr. Matthias Lamping is Senior Research Fellow in the department Intellectual Property and Competition Law at the Max Planck Institute; Peter R. Slowinski, J.S.M. is Doctoral Student and Junior Research Fellow in the department Intellectual Property and Competition Law at the Max Planck Institute, “Covid-19 and the Role of Intellectual Property,” Max Planck Institute for Innovation and Competition, 5/7/21, <https://ipradiodigital.com.ng/wp-content/uploads/2021/05/2021_05_07_Position_statement_Covid_IP_waiver.pdf>) EG Recut VM

The holdups in vaccine manufacturing and distribution have been caused mainly by the shortage in raw materials, insufficient production capacity and highly complex manufacturing process (in the case of mRNA and vector vaccines).6 It is unlikely that a waiver of IP protection could solve these factual problems. The problems of insufficient production capacity and access to raw materials were already witnessed in the earlier days of the pandemic, e.g. with regard to masks and breathing equipment. Overall, IP holders have been rather actively entering into partnerships and granting manufacturing licences to capable licensees. One of the main manufacturers of mRNA vaccines, Moderna, pledged not to enforce their Covid-19-related patents against other manufacturers of vaccines to combat the pandemic.9 So far, cases where a patent holder (reportedly) refused to license IP appear to be a rare exception.10 If a refusal cannot be justified on the objective grounds (e.g. by quality and safety considerations), such cases should be resolved by means of the existing remedies (see below at 5) instead of burdening all right holders for the wrongdoings of a few. In any case, the pursuits to scale up manufacturing should not prioritise quantity at the expense of quality and safety of medicinal products.

#### Vaccine waivers don’t solve due to operational challenges

Silverman 21

Rachel Silverman [Rachel Silverman is a policy fellow at the Center for Global Development, where she leads policy-oriented research on global health financing and incentive structures][, 15 March 2021, https://www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity //](file:///Users/virenmehta/,%2015%20March%202021,%20https:/www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity%20) AK

One reason patent waivers are unlikely to help much in this case is that vaccines are harder to make than ordinary drugs. Because most drugs are simple chemical compounds, and because the composition of the compounds is easily analyzable, competent chemists can usually reverse-engineer a production process with relative ease. When a drug patent expires, therefore — or is waived — generic companies can readily enter the market and produce competitive products, lowering prices dramatically. Vaccines, in contrast, are complex biological products. Observing their contents is insufficient to allow for imitation. Instead, to produce the vaccine, manufacturers need access to the developer’s “soft” IP — the proprietary recipe, cell lines, manufacturing processes and so forth. While some of this information is confidentially submitted to regulators and might theoretically be released in an extraordinary situation (though not without legal challenge), manufacturers are at an enormous disadvantage without the originator’s cooperation to help them set up their process and kick-start production. Even with the nonconsensual release of the soft IP held by the regulator, the process of trial and error would cause long delays in a best-case scenario. Most likely, the effort would end in expensive failure. Manufacturers also need certain raw ingredients and other materials, like glass vials and filtration equipment; overwhelming demand, paired with disruptive export restrictions, has constricted the global availability of some of these items.