# 1NC

#### I negate the resolution resolved that: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

### C1: Disease Innovation

#### Studies currently show that IPR has been effective in pharmaceutical innovations that help with diseases. The only incentive for companies to researches new drugs is reduced competition which the affirmative destroys. The huge risk that goes into developing a drug would otherwise not make its innovation worthwhile.

Will Rinehart, Director of Technology and Innovation Policy at the American Action Forum 14, Director of Technology and Innovation Policy at the American Action Forum, 7-29-2014, "Intellectual Property Underpinnings of Pharmaceutical Innovation: A Primer," https://www.americanactionforum.org/research/intellectual-property-underpinnings-of-pharmaceutical-innovation-a-primer/

Being that it is an exclusive right to a piece of knowledge, patents are often considered to be a kind of monopoly. Criticism has been heaped upon patents in exactly the way one would expect given this definition. The creation of intellectual property rights creates an allowable exclusivity. Yet, it should be immediately apparent that patents do not automatically confer a monopoly over an industry. For example, a pharmaceutical company that invents a new and improved cancer medicine is still in competition with alternatives from other companies, which ultimately acts as a constraint on their ability to charge prices above a competitive level. Commercial success is tied to more than just an innovative idea; superior marketing, management, positioning, and other factors are likely to be more important than the patent itself. Moreover, individuals and companies will seek multiple solutions to the same problem, whether that might be in new commercial arrangements or products. By limiting a particular avenue for competitors, patents have the potential effect of promoting further innovation by encouraging others to develop new products. PATENTS IN PHARMACEUTICALS The medical field presents a strong case for patents, and because of its unique features, allows for a better understanding of the current tensions in other areas of patent policy. The medical field has a lone inventor myth, which is exemplified in the belief of the cure for cancer. The truth is that there is unlikely to be any sole cure, but rather through research and applied innovation, effective methods and treatments for dealing with these diseases will be found. Of course, this means that the entire endeavor will be expensive. As with any piece of property, the bounds of intellectual property must be set, which is where we first encounter the variance that can exist between industries under patent protection. Compared to software patents where there is far less clarity in breadth of patents, medical patents tend to be more discreet in their delineation. It is relatively clear what constitutes a new drug and what does not. Pharmaceutical companies also differ from other industries in their cost structure, including the time and resources needed to bring an innovation to market. Both the research phase and the regulatory approval process are costly and time intensive. Biopharmaceutical discovery has benefited from a remarkable shift in research and technology. Even in the last 10 years, the methods to innovation have been revolutionized, spurred on by better understandings of genetic relationships. Take for example, Gleevec, a treatment for chronic myeloid leukemia. Before the drug was introduced, less than a third of those diagnosed with chronic myeloid leukemia were alive five years later, but after it became available that figure jumped to 90 percent. The method of research responsible for its development was extremely innovative and as such the total development was costly. Gleevec and the drugs that followed it are part of a new breed of drugs that are far more complex than their predecessors. Even with biopharmaceutical innovations, estimates place the average cost of bringing a successful new drug to market at around $1.2 billion. After compounds are screened for use to treat a condition, only about 1 out of the 6 that make it to clinical trials will eventually obtain FDA approval. The table below shows that total industry research and development (R&D) has increased in recent years. The marginal cost of another pill is often miniscule compared to the initial investment cost. Prices for generic drugs are substantially lower than the original brand because these new firms don’t have to amortize the initial R&D costs over a drugs patent life. Additionally, pharmaceutical firms face high risks in their ventures as well as high costs of entry compared to other industries. Clinical trials provide an example of the costs to develop a market ready drug. As the Tufts Group has shown, the average length of a clinical trial increased by 70 percent from 1999 to 2005. In that same time period, the average number of routine procedures per trial increased by 65 percent. To add to that, the average clinical trial staff work burden increased by 67 percent. To top it all off, enrollment criteria and trial protocols resulted in 21 percent fewer volunteers being admitted into trials and 30 percent more enrollees dropping out before completion of the tests. Overall, the regulatory process of drug approval levies a heavy risk for manufacturers and innovators. For every one drug that passes through the regulatory approval process, manufacturers usually assess 5,000-10,000 substances. This is a time consuming and expensive process where innovators hope to see a return on their investment over the long-term. The FDA aims to strike a balance between access to life-saving treatments and assuring the public with standards of safety in all pharmaceuticals. The final step in pending drug approval usually involves hundreds to thousands of participants in a blind study of the drug. This part of the process now represents about 40 percent of pharmaceutical companies’ R&D expenditures. However, this often-cited statistic actually understates the amount spent. R&D expenditures include all pharmaceutical candidates that a company tests—including hundreds that never reach this trial stage. An analysis conducted by the Manhattan Institute found that for the drugs that are actually approved, these clinical trials typically represent 90 percent or more of the cost of developing an individual drug all the way from laboratory to pharmacy. CONCLUSION Medical treatments are among the best cases where intellectual property law has gotten things right. Patents are an important way to ensure that the benefits of research are captured by the creator. Solving the 21st Century’s problems will require complex solutions that will only come about because of intense research and development. Patents ensure that this research takes place. Even though some have criticized aspects of the patent regime, the system itself still serves as a testament to and an enabler of American innovation.

#### **Innovating new drugs that deal with disease is crucial to humanity’s well being – history shows that pandemics, from smallpox to influenza to COVID, we should always be finding new drugs**

Dennis Pamlin & Stuart Armstrong, Executive Project Managers of Global Risks 15, Dennis Pamlin, Executive Project Manager Global Risks, Global Challenges Foundation, and Stuart Armstrong, James Martin Research Fellow, Future of Humanity Institute, Oxford Martin School, University of Oxford, February 2015, “Global Challenges: 12 Risks that threaten human civilization: The case for a new risk category,” Global Challenges Foundation, p.30-93, https://api.globalchallenges.org/static/wp-content/uploads/12-Risks-with-infinite-impact.pdf

4 Global A pandemic (from Greek πᾶν, pan, “all”, and δῆμος demos, “people”) is an epidemic of infectious disease that has spread through human populations across a large region; for instance several continents, or even worldwide. Here only worldwide events are included. A widespread endemic disease that is stable in terms of how many people become sick from it is not a pandemic. 260 84 Global Challenges – Twelve risks that threaten human civilisation – The case for a new category of risks 3.1 Current risks 3.1.4.1 Expected impact disaggregation 3.1.4.2 Probability Influenza subtypes266 Infectious diseases have been one of the greatest causes of mortality in history. Unlike many other global challenges pandemics have happened recently, as we can see where reasonably good data exist. Plotting historic epidemic fatalities on a log scale reveals that these tend to follow a power law with a small exponent: many plagues have been found to follow a power law with exponent 0.26.261 These kinds of power laws are heavy-tailed262 to a significant degree.263 In consequence most of the fatalities are accounted for by the top few events.264 If this law holds for future pandemics as well,265 then the majority of people who will die from epidemics will likely die from the single largest pandemic. Most epidemic fatalities follow a power law, with some extreme events – such as the Black Death and Spanish Flu – being even more deadly.267 There are other grounds for suspecting that such a highimpact epidemic will have a greater probability than usually assumed. All the features of an extremely devastating disease already exist in nature: essentially incurable (Ebola268), nearly always fatal (rabies269), extremely infectious (common cold270), and long incubation periods (HIV271). If a pathogen were to emerge that somehow combined these features (and influenza has demonstrated antigenic shift, the ability to combine features from different viruses272), its death toll would be extreme. Many relevant features of the world have changed considerably, making past comparisons problematic. The modern world has better sanitation and medical research, as well as national and supra-national institutions dedicated to combating diseases. Private insurers are also interested in modelling pandemic risks.273 Set against this is the fact that modern transport and dense human population allow infections to spread much more rapidly274, and there is the potential for urban slums to serve as breeding grounds for disease.275 Unlike events such as nuclear wars, pandemics would not damage the world’s infrastructure, and initial survivors would likely be resistant to the infection. And there would probably be survivors, if only in isolated locations. Hence the risk of a civilisation collapse would come from the ripple effect of the fatalities and the policy responses. These would include political and agricultural disruption as well as economic dislocation and damage to the world’s trade network (including the food trade). Extinction risk is only possible if the aftermath of the epidemic fragments and diminishes human society to the extent that recovery becomes impossible277 before humanity succumbs to other risks (such as climate change or further pandemics). Five important factors in estimating the probabilities and impacts of the challenge: 1. What the true probability distribution for pandemics is, especially at the tail. 2. The capacity of modern international health systems to deal with an extreme pandemic. 3. How fast medical research can proceed in an emergency. 4. How mobility of goods and people, as well as population density, will affect pandemic transmission. 5. Whether humans can develop novel and effective anti-pandemic solutions.

### C2: Safety

#### While it may sound like a good idea to reduce ITP in a vaccum, the alternative is actually much worse. Because people can build off of previous innovated drugs without patents, they can make counterfeit drugs that aren’t safe. However, because they offer them at a cheaper price, many are willing to buy them.

Tavares, an experience patent attorney focused on medical drugs 9/28 [Inês D. Tavares (Trademark and Patent Attorney at Inventa International focusing on the African continent. “Worldwide: Counterfeiting Of Fake Drugs In Africa: Current Situation, Causes And Countermeasures”. Mondaq. 28 September 2020. Accessed 8/8/21. <https://www.mondaq.com/nigeria/trademark/988968/counterfeiting-of-fake-drugs-in-africa-current-situation-causes-and-countermeasures> //Xu]

Although stopping counterfeiting is proven to be an extremely difficult challenge in Africa, several countries, along with the help of World Health Organization and other Institutions have been joining the fight. The WHO is assisting countries in developing the expertise needed to regulate drugs. One of the most important measures is the effective drug registration. Drug registration, also known as marketing authorization and product licensing, allows a country to evaluate if a specific pharmaceutical is safe for consumers to use. Through marketing licensing authorities can also assure that the manufacturing, the storage as well as the distribution of a pharmaceutical was righteously made and cared for without putting at risk the product efficiency and most importantly safety. The incursion of Anti-Counterfeiting Acts in the jurisdictions is of extreme importance to give Authorities the necessary mandate to combat counterfeiting by means of carrying out the adequate and necessary actions that will address the issue directly. A strategy that has been put in place in Tanzania and Ghana, for instance, is to instead of shutting out illegal vendors, invest in training, regulating and licensing them. Furthermore, different countries are investing in awareness campaigns to educate locals to the dangers of consuming fake pharmaceuticals. By educating the consumers they are making people more alert to the signs. Pharmaceutical red flags include, but are not limited to the following: they almost always have a cheaper price tag, they can have a different packaging or the packaging can be altered from the original, the location where the drugs are being sold is usually not reliable and trustworthy. Of course, it can be difficult, at times, to set the original product from the fake product apart. The best indicatory is usually the price point of the fake drug, being set much lower than the first generation good and the problem aggravates when the underground markets take advantage of the loopholes existing in the pharmaceutical distributing systems to channel their counterfeited drugs into the hospital, pharmacies and other distributors, which is one big reason for the education and training of consumers and health workers who are often unable to detected fake products from first generation goods. Countries like Kenya, Ghana and Nigeria have also implemented mobile telephone based consumer verification into their regulations. This system allows consumers to be protected, empowering them against fraudulent products. African countries working together is crucial, regional coordination can help control the problem at customs and at safeguarding borders. Nigeria and Cameroon had signed a cooperation agreement and compromise to sharing experiences and technical expertise to combat the problem. More recently, the Presidents of the Democratic Republic of Congo, Niger, Senegal, Togo, Uganda, Ghana and Gambia signed the Lomé initiative, dated of January 2020, a binding agreement to criminalize trafficking of falsified medicines. The Lomé initiative tackles soft spots such as the lack of regulation and weak healthcare systems. Several African countries are now trying to implement a set of measures at customs such as enabling the interception of contraband (illegal drugs as well as weapons), conduct baggage, cargo and mail inspections to travellers, protect businesses against illegal trade malpractice and enforce import and export restrictions and even prohibitions. However, and although countries are making more efforts into fighting the pharmaceutical counterfeiting problematic, the matter is extremely complex. It involves dangerous lobbies and the work of organized crime, corruption and bribery. All of these are not easy to dismantle. Several previously mentioned factors such as extreme poverty, the uneducated level of the people and lack of an effective and responsive Healthcare System aggravates the predicament. More often than not, consumers have no other alternative than to resort to drug outlets. We have to join efforts worldwide to combat fake medicine markets to thrive in Africa and other areas and Intellectual Property has an enormous role in the fight. More and more regulations are being put in place and a larger number of officials are being trained at customs to be able to detect and identify counterfeited goods, either pharmaceutical or not. Counterfeiting is a global pandemic with tragic consequences and it is crucial for countries and other institutions governmental and non-governmental to join forces and keep fighting to end the problem thus save millions of lives and jobs each year.

### Case [COVID]

#### T/L: Even if they are able to deal with covid, you still vote neg, because our innovation contention means we deal with every future pandemic. Covid probably wont be the last pandemic we have to deal with, the only way to ensure we have a stable plan against future pandemics is by fostering innovation

#### 1] The Affirmative ruins our progress against covid because reducing IP protections would lead to counterfeit vaccines

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[ing] 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**.

#### 2] IP has been successful to even creating covid vaccines in the first place, so it makes no sense to destroy what has worked

**Value Ingenuity, 20** [Value Ingenuity, (The Value Ingenuity project is telling the story of innovation, its roots, its impact, its social and moral imperatives, and the public policy prescriptions that will assure a continued upward trajectory for the generations to follow.

Our objective is to advance globally a shared purpose of mutual investment in sustainable innovation.)]. "WTO IP Waiver Would Undermine Covid Innovation." 10-2-2020, Accessed 8-5-2021. https://www.valueingenuity.com/2021/05/18/wto-ip-waiver-would-undermine-covid-innovation/ // duongie

A TRIPS waiver for vaccines would do nothing to help — and could in fact hurt — the effort to produce billions of vaccine doses and get them in arms. Supply of these high-tech products is ramping up quickly, with about 10 billion doses projected to be produced by the end of 2021 — we shouldn’t distract attention away from that all-important goal. IP is not a barrier to vaccine access. It already enabled the creation of three vaccines, in record-breaking time, that have received FDA authorization. IP is also safely facilitating international partnerships (275+ to date) to share technology and information more easily with trusted partners across borders. An IP waiver could lead to untested and unregulated copycats. Some nations are looking to manufacture sophisticated vaccines without permission, exacerbating the shortage of the critical materials (raw materials, tubing, vials etc.) and increasing vaccine hesitancy due to the development of unsafe products and medicines. The proposal jeopardizes U.S. manufacturing & jobs. Allowing other countries to take and commercialize American-made technologies conflicts with President Biden’s goal to build up American infrastructure and create manufacturing jobs. In the U.S. alone, biopharmaceutical companies support 4 million jobs across all 50 states, with many more across innovation ecosystems in labs, finance, and SMEs. Waiving IP undermines America’s leadership in the life sciences. We should not be forfeiting IP to countries looking to undermine America’s global leadership in biomedical technology and innovation. IP protections enabled decades of R&D by biopharmaceutical research companies, allowing them to move quickly and effectively against COVID-19. Business welcomes the Biden Administration’s support for the global vaccine program, COVAX. This type of program can have a significant positive, practical impact on global rollout of vaccines and therapies without disrupting the incredible IP-enabled progress that has been made to date to defeat the pandemic. Its effects will be even more effective as trade barriers are removed and all countries allow vaccines to be exported internationally. GOOD TO KNOW: Today 57% of all new medicines globally come from the United States with its world-class IP ecosystem, and private companies in the life sciences community make up more than 80% of the investment in the research and development of those new drugs. The U.S. biopharmaceutical industry directly and indirectly supports over 4 million American jobs. SCIENTISTS, ACADEMICS, ADVOCATES AND POLITICAL LEADERS SKEPTICAL OF WAIVING IP RIGHTS “The goal is noble, but the demand [for an IP waiver] is more slogan than solution … patents on vaccines are not the central bottleneck, and even if turned over to other nations, would not quickly result in more shots. This is because vaccine manufacturing is exacting and time-consuming. Look at the production difficulties encountered by Emergent BioSolutions, a vaccine manufacturer in Baltimore, where 15 million doses were contaminated. That was caught before the shots were distributed, but one can imagine the horrific consequences of a failure to maintain quality control elsewhere in the world.” WASHINGTON POST EDITORIAL BOARD, May 4, 2021 “The goal is noble, but the demand [for an IP waiver] is more slogan than solution … patents on vaccines are not the central bottleneck, and even if turned over to other nations, would not quickly result in more shots. This is because vaccine manufacturing is exacting and time-consuming. Look at the production difficulties encountered by Emergent BioSolutions, a vaccine manufacturer in Baltimore, where 15 million doses were contaminated. That was caught before the shots were distributed, but one can imagine the horrific consequences of a failure to maintain quality control elsewhere in the world.” WALL STREET JOURNAL EDITORIAL BOARD, May 6, 2021 “The U.S. decision to support a temporary waiver of intellectual-property protections for Covid-19 vaccines won’t end debate on the issue, much less end the pandemic. Reaching a formal agreement could take months and even then may not accelerate vaccine production; opposition from countries such as Germany could yet doom any compromise.” BLOOMBERG EDITORIAL BOARD, May 12, 2021 “The collaboration that’s happened in the midst of this pandemic I think points to the ways in which IP has actually not been a barrier, but a facilitator of critical, cutting-edge innovation […] I don’t think that waiving IP rights will suddenly enable other countries to ramp up the manufacturing of complex vaccines.” SEN. CHRIS COONS (D-DE), CSIS: April 22, 2021 “There are only so many vaccine manufacturers in the world […] people are very careful about the safety of vaccines […] The thing that is holding us back is not IP. There is no idle factory with regulatory approval that makes magically safe vaccines […] we have all the rights from the vaccine companies and the work is going at full speed” BILL GATES, Sky News: April 25, 2021 “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.” ADAR POONAWALLA, CEO SERUM INSTITUTE OF INDIA, February 14, 2021 “These [vaccines] are complex to make so just waiving IP and patents isn’t going to help […] you can only get trade secrets and knowhow with the cooperation of the originator companies, and they don’t have the bandwidth to do this in every part of the world … the only immediate solution is for rich countries to donate or sell their surplus vaccine to COVAX or other countries.” JAYASHREE WATAL, GEORGETOWN LAW PROFESSOR & FORMER WTO IP COUNSELOR, April 22, 2021 “It is also unclear whether a waiver of IP rights will make a difference […] Furthermore, as others have pointed out, IP rights are only a piece of what is needed to produce vaccines. There is currently a global shortage of raw materials and proper manufacturing facilities.” SAPAN KUMAR, LAW FOUNDATION PROFESSOR OF LAW AT THE UNIVERSITY OF HOUSTON LAW CENTER, May 9, 2021 “This is technology that’s every bit as critical as munitions and encryption codes […] It’s a platform technology that can be used to make all manner of treatments going forward, including vaccines.” DAVID KAPPOS, FORMER U.S. PATENT AND TRADEMARK OFFICE FOR PRESIDENT OBAMA, April 22, 2021 “The notion that we would then turn around and go to the World Trade Organization and basically endorse a policy of DARPA-funded technology transfer to China is just inconceivable. You’re basically aiding and abetting China’s ‘Made in China 2025’ plans for technological dominance.” CLETE WILLEMS, FORMER SPECIAL ASSISTANT TO THE PRESIDENT FOR INTERNATIONAL TRADE, INVESTMENT, AND DEVELOPMENT, April 22, 2021.

#### 3] Reducing IP wont work because countries don’t have the technology to make covid vaccines in the first place

Carla **Delgado, 5/25** [Carla Delgado, (Carla is a Filipino writer whose work has been published in Insider, Business Insider, Architectural Digest, Elemental, Observer, and more. She writes about a wide range of topics, but her interests lie in health & wellness, culture, and sustainability. Outside of writing, she is a theatre practitioner with several theatre credits under her belt.)]. "Experts Say Patent Waivers Aren't Enough To Increase Global Vaccination." Verywell Health, 5-25-2021, Accessed 8-5-2021. https://www.verywellhealth.com/covid-vaccine-patent-waivers-global-supply-5185669 // duongie

Why Waiving Patents Isn’t Enough to Speed Up Production Countries looking to produce COVID-19 vaccines face many logistical hurdles even if vaccine patents are waived. “Waiving intellectual property rights for COVID-19 vaccines is likely to only have a modest impact on global vaccine supply,” William Moss, MD, executive director of the International Vaccine Access Center at the Johns Hopkins Bloomberg School of Public Health, tells Verywell. “A vaccine IP waiver is not in itself likely to lead to increased vaccine production in less developed countries because much more needs to be in place to increase the global vaccine supply.” Lack of Manufacturing Capacity For several countries outside of the U.S. that have the necessary equipment to produce mRNA vaccines effectively and safely, the IP waiver can be of great help. However, many more countries lack this capacity, and this move still leaves them behind. “The majority of the world’s countries lack the capacity to produce and distribute COVID-19 vaccines, and especially at the scale required to get this pandemic under control,” Richard Marlink, MD, director of the Rutgers Global Health Institute, tells Verywell. “They need funding, manufacturing facilities, raw materials, and laboratory staff with the technological expertise required.” We've already seen what can go wrong with substandard vaccine manufacturing. In April, the Food and Drug Administration (FDA) inspected the Emergent BioSolutions factory in Baltimore and consequently shut down their production after concerning observations, which include:3 The factory was not maintained in a clean and sanitary condition. Waste handling was found to be inadequate because generated waste was transported through the warehouse before disposal, which can potentially contaminate other areas. Employees were seen dragging unsealed bags of medical waste from the manufacturing area across the warehouse. Peeling paint, paint flecks, loose particles/debris were observed. There were also damaged floors and rough surfaces that cannot be properly cleaned and sanitized. Employees were seen removing their protective garments where raw materials were staged for manufacturing. They reportedly spoiled about 15 million doses of the Johnson and Johnson COVID-19 vaccine, and more than 100 million doses are on hold as regulators inspect them for possible contamination.4 “Vaccines are complex biological products, much more complex than drugs, and need to be produced by manufacturers and in facilities with the highest quality control standards,” Moss says. “Adverse events associated with a poorly made or contaminated batch of vaccines would have a devastating impact on vaccine confidence.” Lack of Technology, Skills, and Raw Materials In a statement last October, Moderna announced that they will not enforce their COVID-19-related patents against those who will make vaccines during this pandemic.5 While waiving some vaccine patents may allow third-party manufacturers to make and sell COVID-19 vaccines, the transfer of skills and technology that will allow them to manage production isn't very simple. For instance, a spokesperson for Pfizer said that the Pfizer-BioNTech vaccine required 280 different components sourced from 86 suppliers across various countries. Manufacturing the vaccine would require highly specialized equipment and complex technology transfers.6 “Technology transfer also would need to be a critical component to expand vaccine manufacturing by other companies as an IP waiver is insufficient to provide the ‘know how’ needed to manufacture mRNA or adenovirus-vectored COVID-19 vaccines,” Moss says. “And supply chains for the reagents, supplies, and equipment would be needed.” Interested manufacturers would need to have the proper equipment to test the quality and consistency of their manufacturing. At present, the World Health Organization (WHO) has plans to facilitate the establishment of technology hubs to transfer "a comprehensive technology package and provide appropriate training" to manufacturers from lower- and middle-income countries.7 While waiving vaccine patents is necessary, it's likely not enough. Additionally, negotiations about it are still ongoing. Even though the U.S. supports the waiver of COVID-19 vaccine patents, other countries like the United Kingdom, Japan, and Germany oppose it.8 It's also important to remember that manufacturing vaccines is only one step of the process of vaccinating the global population—distributing it is yet another hurdle.

4] COVAX, the EU made a deal with the entirety of Africa

5] their second contention is about how developing countries and corporations from the entire world

#### Even if you get better vaccines, its not enough

#### IP reductions are insufficient vaccines are too difficult to reproduce Moderna proves

Silverman 3-15 Rachel Silverman 3-15-2021 "Waiving vaccine patents won’t help inoculate poorer nations" <https://www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity/> (Rachel Silverman is a policy fellow at the Center for Global Development)//Duong

Reality is more complicated, however. Because of the technical complexity of manufacturing coronavirus vaccines, waiving intellectual-property rights, by itself, would have little effect. It could even backfire, with companies using the move as an excuse to disengage from global access efforts. There are more effective ways to entice — and to pressure — companies to license and share their intellectual property and the associated know-how, without broadly nullifying patents. The Moderna vaccine illustrates the limits of freeing up intellectual property. Moderna announced in October that it would not enforce IP rights on its coronavirus vaccine — and yet it has taken no steps to share information about the vaccine’s design or manufacture, citing commercial interests in the underlying technology. Five months later, production of the Moderna vaccine remains entirely under the company’s direct control within its owned and contracted facilities. Notably, Moderna is also the only manufacturer of a U.S.- or British-approved vaccine not yet participating in Covax, a global-aid-funded effort (including a pledged $4 billion from the United States) to purchase vaccines for use in low- and middle-income countries. It is true, however, that activist pressure — including threats to infringe upon IP rights — can encourage originators to enter into voluntary licensing arrangements. So the global movement to liberate the vaccine patents may be useful, even if some advocates make exaggerated claims about the effects of waivers on their own. We focused on covid. Now our other patients are suffering. 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.

#### 1-due to worldwide concerns about the vaccine

Andrea **Taylor, 2/6** [Andrea Taylor, (Andrea leads a portfolio of global innovation programs focused on evaluation, scaling, and adaptation of healthcare innovations to address critical access and quality challenges. Her work with the Duke Global Health Innovation Center and Innovations in Healthcare drive evidence-based recommendations for scaling transformative models of care, adapting models into new contexts, and facilitating system change. She is the research lead for the Launch and Scale project’s COVID-19 workstream, analyzing global data on vaccines, partnerships, and therapeutics to combat the pandemic. She led design and research for the USAID-funded Social Entrepreneurship Accelerator at Duke (SEAD) and the development of several publications for the recent evaluation of the Saving Lives at Birth program, with USAID and GCC.)]. "VACCINE HESITANCY WILL SOON BECOME THE PRIMARY OBSTACLE TO GLOBAL IMMUNITY – Global Health Innovation Center." 2-16-2021, Accessed 8-5-2021. https://dukeghic.org/2021/02/16/vaccine-hesitancy-will-soon-become-the-primary-obstacle-to-global-immunity/ // duongie

Vaccine hesitancy will soon become the primary obstacle to global immunity Global manufacturing capacity has been the primary rate limiter for Covid-19 vaccinations. Our vaccine manufacturing infrastructure was not designed to produce enough doses to cover 70% of the world’s population within a year (in addition to regular and routine vaccines) and, as expected, demand is outstripping supply. There has been good news on the manufacturing front, however, with several large pharma companies recently joining with rivals to ramp up production. At the same time, data on vaccine hesitancy suggest that it may soon overtake manufacturing capacity as the primary obstacle to global coverage and reaching herd immunity. If this is the case, we will soon find that producing enough vaccines does not translate to enough vaccinations. Covid-19 vaccine hesitancy is growing around the world. A survey of 15 countries found that willingness to get a Covid-19 vaccine dropped in nearly all of the countries between October and December 2020. France and Russia had the lowest rates of vaccine intent in the survey, below 50%. Another survey of 32 countries found that fewer than half of the population in Lebanon, France, Croatia, and Serbia intend to get vaccinated. In Peru, vaccine hesitancy grew by 26 percentage points (from 22% to 48%) between August and December and the population is now evenly split between those willing and those not willing to receive the vaccine. Other data indicate some countries fall much lower: in the Philippines, fewer than a third are willing to have a Covid-19 vaccine. Even in China, a country with historically high rates of vaccine take-up, intent to get a Covid-19 vaccine dropped in late 2020 (though at 80% China was still at the top of the chart). Negative coverage of western-developed vaccines in Chinese state media appears to be fueling mistrust of even Chinese-developed Covid-19 vaccines and slowing vaccination rates. In both the US and UK, recent studies found that hesitancy rates are highest among younger adults, racial minorities, and people with lower education and income. A similar trend was noted this week in Israel, where vaccine take-up has slowed and is particularly low among minority communities and younger populations. There was improvement in vaccine intent among Black and LatinX populations in the US between December and January; however, these groups are still most likely to say that they will “wait and see” rather than get the vaccine as soon as possible. Experts suggest that supply may outstrip demand in the US as early as April. Public health leaders in countries around the world have pulled every lever they can to secure vaccine doses to protect their populations. Each dose is the result of unprecedented scientific and industry cooperation, complex negotiations, and a flat-out global effort. But the race to develop, manufacture, and distribute vaccines must result in vaccinations. We need to get ahead of vaccine hesitancy now, with strong outreach campaigns, before it becomes the rate limiter.

#### 2-Covid mutates too fast such that the vaccine wont solve-South Africa and UK prove

David **Ho 3/8** [David Ho, (David Da-i Ho is a Taiwanese-American AIDS researcher, physician, and virologist who has made a number of scientific contributions to the understanding and treatment of HIV infection.)]. "New Study of Coronavirus Variants Predicts Virus Evolving to Escape Current Vaccines, Treatments." Columbia University Irving Medical Center, 3-8-2021, Accessed 8-5-2021. https://www.cuimc.columbia.edu/news/new-study-coronavirus-variants-predicts-virus-evolving-escape-current-vaccines-treatments // duongie

A new study of the U.K. and South Africa variants of SARS-CoV-2 predicts that current vaccines and certain monoclonal antibodies may be less effective at neutralizing these variants and that the new variants raise the specter that reinfections could be more likely. The study was published in Nature(link is external and opens in a new window) on March 8, 2021. A preprint of the study was first posted to BioRxiv(link is external and opens in a new window) on January 26, 2021. The study’s predictions are now being borne out with the first reported results of the Novavax vaccine, says the study's lead author David Ho, MD. The company reported(link is external and opens in a new window) on Jan. 28 that the vaccine was nearly 90% effective in the company’s U.K. trial, but only 49.4% effective in its South Africa trial, where most cases of COVID-19 are caused by the B.1.351 variant. "Our study and the new clinical trial data show that the virus is traveling in a direction that is causing it to escape from our current vaccines and therapies that are directed against the viral spike,” says Ho, the director of the Aaron Diamond AIDS Research Center and the Clyde’56 and Helen Wu Professor of Medicine at Columbia University Vagelos College of Physicians and Surgeons. “If the rampant spread of the virus continues and more critical mutations accumulate, then we may be condemned to chasing after the evolving SARS-CoV-2 continually, as we have long done for influenza virus,” Ho says. “Such considerations require that we stop virus transmission as quickly as is feasible, by redoubling our mitigation measures and by expediting vaccine rollout.” After vaccination, the immune system responds and makes antibodies that can neutralize the virus. Ho and his team found that antibodies in blood samples taken from people inoculated with the Moderna or Pfizer vaccine were less effective at neutralizing the two variants, B.1.1.7, which emerged last September in England, and B.1.351, which emerged from South Africa in late 2020. Against the U.K. variant, neutralization dropped by roughly 2-fold, but against the South Africa variant, neutralization dropped by 6.5- to 8.5-fold. “The approximately 2-fold loss of neutralizing activity against the U.K. variant is unlikely to have an adverse impact due to the large 'cushion' of residual neutralizing antibody activity,” Ho says, “and we see that reflected in the Novavax results where the vaccine was 85.6% effective against the U.K. variant.” Data from Ho’s study about the loss in neutralizing activity against the South Africa variant are more worrisome. “The drop in neutralizing activity against the South Africa variant is appreciable, and we’re now seeing, based on the Novavax results, that this is causing a reduction in protective efficacy,” Ho says. The new study did not examine the more recent variant found in Brazil (B.1.1.28) but given the similar spike mutations between the Brazil and South Africa variants, Ho says the Brazil variant should behave similarly to the South Africa variant. “We have to stop the virus from replicating and that means rolling out vaccine faster and sticking to our mitigation measures like masking and physical distancing. Stopping the spread of the virus will stop the development of further mutations,” Ho says. The study also found that certain monoclonal antibodies used now to treat COVID patients may not work against the South Africa variant. And based on results with plasma from COVID patients who were infected earlier in the pandemic, the B.1.351 variant from South Africa has the potential to cause reinfection. New study contains comprehensive analysis of variants The new study conducted an extensive analysis of mutations in the two SARS-CoV-2 variants compared to other recent studies, which have reported similar findings. The new study examined all mutations in the spike protein of the two variants. (Vaccines and monoclonal antibody treatments work by recognizing the SARS-CoV-2 spike protein.) The researchers created SARS-CoV-2 pseudoviruses (viruses that produce the coronavirus spike protein but cannot cause infection) with the eight mutations found in the U.K. variant and the nine mutations found in the South African variant. They then measured the sensitivity of these pseudoviruses to monoclonal antibodies developed to treat COVID patients, convalescent serum from patients who were infected earlier in the pandemic, and serum from patients who have been vaccinated with the Moderna or Pfizer vaccine. Implications for monoclonal antibody treatments The study measured the neutralizing activity of 18 different monoclonal antibodies—including the antibodies in two products authorized for use in the United States. Against the U.K. variant, most antibodies were still potent, although the neutralizing activity of two antibodies in development was modestly impaired. Against the South Africa variant, however, the neutralizing activity of four antibodies was completely or markedly abolished. Those antibodies include bamlanivimab (LY-CoV555, approved for use in the United States) that was completely inactive against the South Africa variant, and casirivimab, one of the two antibodies in an approved antibody cocktail (REGN-COV) that was 58-fold less effective at neutralizing the South Africa variant compared to the original virus. The second antibody in the cocktail, imdevimab, retained its neutralizing ability, as did the complete cocktail. “Decisions of the use of these treatments will depend heavily on the local prevalence of the South Africa and Brazil variants,” Ho says, “highlighting the importance of viral genomic surveillance and proactive development of next-generation antibody therapeutics.” Reinfection implications Serum from most patients who had recovered from COVID earlier in the pandemic had 11-fold less neutralizing activity against the South Africa variant and 4-fold less neutralizing activity against the U.K. variant. “The concern here is that reinfection might be more likely if one is confronted with these variants, particularly the South Africa one,” Ho says.