# Round 2 1NC v. Marlborough Adler

## UHC CP

#### The member nations of the World Trade Organization ought to implement a universal single-payer healthcare system

#### UHC will solve COVID inequalities + more

Walcott MD PhD 4/21

David Alexander Walcott, (MD., Ph.D. MSc. Entrepreneur and Rhodes Scholar), 4-1-2021, "COVID-19 vaccine success can enable universal healthcare – here's how," World Economic Forum, <https://www.weforum.org/agenda/2021/04/covid-19-vaccine-success-enable-universal-healthcare/> // AW

For more than 200 years, human beings managed to avert widespread pestilence with vaccines. While not a silver bullet, vaccines provide us with the freedom to engage with the world without the fear of debilitating disease. As we reflect on the global relevance of vaccines during World Immunization Week, we quickly acknowledge that persistent societal disparities have affected our ability to equitably vaccinate, a phenomenon that has been illuminated by COVID-19. As we pursue systems designed to equal the playing field in the spirit of collective global welfare, we must consider whether immunizations are simply products of universal access, or are themselves are enablers of this global target. Global value of immunization diminished by health inequalities Despite the target for global equitable access to immunization by organizations such as GAVI and the World Health Organization, there remains a [huge gap](https://pubmed.ncbi.nlm.nih.gov/30646979/) in levels of vaccine accessibility at both national and global levels. Low and middle-Income CountrieS have notably reduced access to vaccines, and within countries, social factors such as like conflict and [destitution](https://pubmed.ncbi.nlm.nih.gov/19884162/) have detrimental effects on immunization. Despite the global successes we have achieved with elimination of smallpox and near-elimination of polio, inadequate access remains a challenge in many regions in the world. Up to [15% of the world’s children](http://www.who.int/news-room/fact-sheets/detail/immunization-coverage) have no access to immunization, and [millions of children](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4024226/) still die from infections, including pneumonia and diarrhoea, many cases of which could be prevented by vaccination. Data showing that COVID-19 mortality rates are higher among BIPOC communities. Global vaccine inequity has been seen even more starkly in the pandemic where low-income countries have struggled to get access to vaccines. As of 4 March 2020, [many such countries](https://www.sciencenews.org/article/covid-19-global-inequity-vaccines-deaths-economy-pandemic) had yet to administer a single dose while many of their larger contemporaries had enough doses to inoculate their populations several times over. Our pleasant illusions of equitable access were quickly supplanted by the harsh reality of the perennial global economic disparities, and their tangible effects on global health were impossible to ignore. Vaccines are not a simply a product of UHC, they also drive UHC Regarding global health inequities, it is clear that universal health care (UHC) is an enabler of widespread immunization given its inclusive mandate of bringing all under the net of healthcare access. Greater access to healthcare services inevitably translates into greater opportunities for immunization. Interestingly, one may argue that this relationship also exists in the reverse, where the pursuit of routine and universal immunization itself can serve as a potent platform towards enabling coverage for all. Immunization is one of the few platforms that bring most households into contact with healthcare systems [five or more times](https://www.gavi.org/sites/default/files/publications/Immunisation%20-%20a%20platform%20for%20universal%20health%20coverage.pdf) during the first year of a child’s life. This offers a clear opportunity for providing additional primary healthcare services at these touchpoints, and we must consider whether it can serve as a platform upon which additional healthcare outcomes can be built. Furthermore, vaccines have indirect effects on driving access to healthcare resources through influencing the distribution of healthcare services. Through averting preventable diseases which consume copious health resources, vaccines permit the deployment of capabilities towards those who need them most. Immunization programmes take pressure off healthcare systems, enabling allocation of resources to the underserved, particularly around non-communicable diseases which are now responsible for [over 70%](https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases) of global mortality. This phenomenon is shown in the pandemic, where greater levels of vaccine uptake have finally allowed for the allocation of resources towards other socially valuable initiatives. Graph showing how vaccines have reduced the burden (and therefore spending) of certain infectious diseases (measles, mumps, rubella). Finally, considering that poverty is a key factor standing in the way of UHC, it is clear that immunization permits the maximization of our economic potential and drives poverty reduction. It has been projected that vaccines administered between 2016 and 2030 will [prevent 24 million](https://www.gavi.org/sites/default/files/publications/Immunisation%20-%20a%20platform%20for%20universal%20health%20coverage.pdf) people in 41 of the world’s low and middle-income countries from falling into poverty, and has been shown to drive [significant value-creation](https://www.gavi.org/sites/default/files/publications/Immunisation%20-%20a%20platform%20for%20universal%20health%20coverage.pdf) – with every $1 invested in immunization driving a return of $54 in social and economic value. Speed of vaccine development brings hope for UHC COVID-19 has been our most pressing challenge, and our world has managed the mammoth task of condensing several years of vaccine development into a single year. The global health community has never been more connected, engaged and collaborative, and levels of interest in supporting immunization services, vaccine development and effective procurement systems have never been higher. True to the theme of World Immunization Week, vaccines have indeed “brought us closer” to economic, social and psychological normality. Necessity has been the mother of invention and several of the assets developed through this pandemic – immunization programmes, embracing health technology, and greater public health awareness – will serve us well in the days to come. The spirit of collaboration demonstrated between competing companies such as Pfizer and BioNTech illustrate the potential unlocked through collaboration and the power of resolve. With the second wind of hope promised by our experience with vaccines, it is hoped that we will be able to solve the problems in vaccine development against more complex infections, such as malaria and HIV, which have seen substantial but modest success in recent times. Significant progress has also been made in vaccine development against many non-infectious diseases such as Alzheimers and diabetes, and [therapeutic cancer vaccines](https://clincancerres.aacrjournals.org/content/27/3/689) remain promising. Greater levels of prevention, treatment and access to care are expected in the days to come and vaccines will continue to offer opportunities for expanding our ability to influence global health. No arm left behind Though we face an uncertain future, the pandemic has reminded us that we now live in a global village and that no one is safe until there is safety for all. It is hoped that we are able to take our immunizations, our learnings and our resolve and maintain commitment to the Immunization Agenda 2030 and SDG3. True to the words of Tedros Adhanom Ghebreyesus, Director-General of the [World Health Organization](https://www.devex.com/organizations/world-health-organization-who-30562), “There is no health for all without vaccines for all…” As we move beyond the pandemic and reflect on the idea that vaccines have indeed “brought us closer” let us ensure that in the days to come there is no man, woman or arm left behind.

## Innovation DA

#### A. Uniqueness- Pharma profits are up from COVID vaccines, patent waivers threaten this

Buchholz 5-17-21

(Katharina, https://www.statista.com/chart/24829/net-income-profit-pharma-companies/)

The profitability of coronavirus vaccines has been in the spotlight since U.S. President Joe Biden come out in support of temporarily lifting vaccine patents to make the production of the life-saving inoculations more financially feasible for poorer countries. EU leaders meanwhile remain divided over such a move. Company financial reports show that COVID-19 vaccine makers and developers like Johnson & Johnson, Pfizer, Moderna, AstraZeneca and BioNTech have seen their profits increase since the vaccine rollout, at times majorly. In early May, stocks of several companies that benefit from COVID-19 vaccine sales took a nosedive on the news of Biden’s reversal. Moderna stocks, for example, were still down more than 6 percent at close on May 5, the day of the announcement. Stocks recovered somewhat as German chancellor Angela Merkel came out against patent waivers the following day. While fluctuations in the stock market price have hurt drug makers in the short term, patent waivers would diminish the bottom line of companies involved with the development and production of COVID-19 vaccines in the long term. Pharma giants like Johnson & Johnson and Pfizer bring in billions of dollars of income every quarter from diverse sources, so the COVID bump was smaller for them. In the case of Pfizer, which has been a bigger producer than J&J, the year-over-year profit increase was a handsome 44 percent, however. For smaller AstraZeneca, the COVID year meant that its profits doubled. In the case of Moderna, the past year has turned a Q1 loss into a profit. The case is similar for German company BioNTech, which collaborated with Pfizer on its COVID vaccine. While Q1 2021 brought in a profit of $1.1 billion, the company ran a deficit since its founding in 2008 up until Q4 2020, when it posted a profit for the first time. The $446 million earned stood in contrast to losses of almost $428 million accrued in the first nine months of the year.

#### B. Link- IP Protections are vital to innovation and economic growth-reject myopic moralizing about human rights

Bacchus, JD, 20

(James, adjunct scholar at the Cato Institute, a professor of global affairs at the University of Central Florida, An Unnecessary Proposal A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines <https://www.cato.org/sites/cato.org/files/2020-12/FTB_78.pdf>, 12-16)

At the heart of this emerging trade debate is a belief by many people worldwide that all medicines should be “global public goods.” There is little room in such a belief for consideration of any rights to IP. As one group of United Nations human rights experts expressed: “There is no room for . . . profitability in decision-making about access to vaccines, essential tests and treatments, and all other medical goods, services and supplies that are at the heart of the right to the highest attainable standard of health for all.”16 This view is myopic. Subordinating IP rights temporarily to pressing public needs during a pandemic or other global health emergency is one thing. Eliminating any consideration of “profitability” in all policymaking relating to “access to vaccines, essential tests and treatments, and all other medical goods, services and supplies” is quite another.17 To be sure, there is a superficial moral appeal in such a view. But does this moral appeal hold up if such a “human rights” approach does not result in meeting those urgent public needs? With the belief that medicines should be “public goods,” there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in such goods is viewed as a violation of human rights and of the overall public interest. This view, though, does not reflect the practical reality of a world in which many medicines would simply not exist if it were not for the existence of IP rights and the protections they are afforded. Technically, IP rights are exceptions to free trade. A long-standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion. The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long-term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”18 The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know-how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth in the 21st century is increasingly ideas-based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation. In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.19 As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, “A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights.”20 This fault line is much on display in the WTO rules on IP rights. These rules recognize that “intellectual property rights are private rights” and that rules and disciplines are necessary for “the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights.”21 Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

#### C. Impact- Pharmaceutical profits are key to innovation against emerging disease threats

Engelhardt 8 – PhD, MD, Professor of Philosophy @ Rice

(Hugo, “Innovation and the Pharmaceutical Industry: Critical Reflections on the Virtues of Profit,” EBrary)

Many are suspicious of, or indeed jealous of, the good fortune of oth-ers. Even when profit is gained in the market without fraud and with the consent of all buying and selling goods and services, there is a sense on the part of some that something is wrong if considerable profit is secured. There is even a sense that good fortune in the market, especially if it is very good fortune, is unfair. One might think of such rhetorically disparaging terms as "wind-fall profits". There is also a suspicion of the pursuit of profit because it is often embraced not just because of the material benefits it sought, but because of the hierarchical satisfaction of being more affluent than others. The pursuit of profit in the pharmaceu-tical and medical-device industries is tor many in particular morally dubious because it is acquired from those who have the bad fortune to be diseased or disabled. Although the suspicion of profit is not well-founded, this suspicion is a major moral and public-policy challenge.¶ Profit in the market for the pharmaceutical and medical-device¶ industries is to be celebrated. This is the case, in that if one is of the view (1) that the presence of additional resources for research and development spurs innovation in the development of pharmaceuticals and med-ical devices (i.e., if one is of the view that the allure of profit is one of the most effective ways not only to acquire resources but productively to direct human energies in their use), (2) that given the limits of altruism and of the willingness of persons to be taxed, the possibility of profits is necessary to secure such resources, (3) that the allure of profits also tends to enhance the creative use of available resources in the pursuit of phar-maceutical and medical-device innovation, and (4) if one judges it to be the case that such innovation is both necessary to maintain the human species in an ever-changing and always dangerous environment in which new microbial and other threats may at any time emerge to threaten human well-being, if not survival (i.e., that such innovation is necessary to prevent increases in morbidity and mortality risks), as well as (5) in order generally to decrease morbidity and mortality risks in the future, it then follows (6) that one should be concerned regarding any policies that decrease the amount of resources and energies available to encourage such innovation. One should indeed be of the view that the possibilities for profit, all things being equal, should be highest in the pharmaceutical and medical-device industries. Yet, there is a suspicion regarding the pursuit of profit in medicine and especially in the pharmaceutical and medical-device industries.

#### D. Emerging diseases and bioterrorism are comparatively the largest impact – pharmaceutical industry key

Milne 4 – Formerly a practicing veterinarian in New Jersey and Maryland, Dr. Milne attended Johns Hopkins University in 1987-88 where he earned a master's degree in public health with a concentration in epidemiology. For six years, he worked for the New Jersey Department of Health in risk assessment as well as legislative and regulatory review, and finally served as Emergency Response Coordinator. Dr. Milne joined Tufts University's Center for the Study of Drug Development in 1998 as a Senior Research Fellow, after graduation from law school. His research interests include the evaluation of regulatory initiatives affecting the pharmaceutical and biotechnology industries, and incentive programs for the development of new medicines for neglected diseases of the developing world. Dr. Milne is currently Assistant Director at the Center and a member of the bar in New Hampshire

(Christopher, “Racing the Globalization of Infectious Diseases: Lessons from the Tortoise and the Hare,” 11 New Eng. J. Int'l & Comp. L. 1)

Although we have faced planet-killing events such as nuclear brinkmanship during the Cold War and mega-meteors colliding with earth in pre-history, the most imminent threat is one we face everyday from the globalization of infectious diseases. Leading authorities in government, medical institutions, and schools of public health have been ringing the warning bell for over a decade about the major threats to global public health. 2Link to the text of the note Threats such as infectious diseases in the developing world, drug resistant bacteria, and the problem of multiple HIV strains, remain unaddressed. The public health community lacks answers to key scientific questions for an AIDS vaccine, and needs to press harder on research for a tuberculosis (TB) vaccine, a process which could take twenty to fifty years. 3Link to the text of the note Experts believe that the threat warning level has risen from orange to red, comparing the circumstances favoring a pandemic today to the "Perfect Storm," due to the continuing increase of worldwide antimicrobial resistance, diminished U.S. capacity to recognize and respond to microbial threats, and the likelihood of intentional releases of biological agents.¶ The sources of this public health challenge derive from a panoply of emerging and re-emerging natural plagues, thirty of which have been recognized just in the last few decades with thirteen occurring in North America. 4Link to the text of the note According to Anthony Fauci, Director of the National Institutes [3] of Allergies and Infectious Diseases (NIAID), emerging diseases are defined as ones that have not been previously recognized, such as acquired immunodeficiency syndrome (AIDS) or severe acute respiratory syndrome (SARS). Comparatively, re-emerging disease has usually been in existence for a long time but has changed location, as did the West Nile Virus. Dr. Fauci considers bioterrorism to be a part of the continuum of emerging and re-emerging diseases, and points out that when it comes to bioterror: "The Worst Bioterrorist May be Nature Itself." 5Link to the text of the note¶ Infectious diseases with the potential to be global killers come in two basic forms: the "slow epidemic," taking months or years to reach pandemic status, with an insidious onset and long latency, that resists treatment - the archetypical example being AIDS, 6Link to the text of the note and the "fast epidemic," rapidly spreading from country to country, typically aerosol-borne, with fairly quick onset, and high mortality and morbidity - most recently manifested in pandemic SARS. 7Link to the text of the note Both forms have potential uses as bioweapons, although most of the counter-terror attention focuses on the SARS-like diseases.¶ Part II of this article will discuss the scenarios for a global pandemic presented by SARS, AIDS, or bioweaponized incarnations - what they have done, what they could do, and why it is so hard to stop them. Part III will describe the scope of the public health problem, particularly the globalization factors that serve as enablers of the pandemic potential of these diseases, as well as a host of ill-defined "x" factors that have served to further complicate the dynamics of dealing with these global killers. Part IV will consider solutions to the problem by discussing what we have versus what we need. Part V will present recommendations for how government, pharmaceutical and biotechnology industries, as well as international non-governmental organizations can be part of the solution. Lastly, Part VI provides a conclusion.¶ "Ring around the rosie, pocket full of posies,¶ Ashes, ashes - we all fall down!" - According to legend, a children's rhyme dating from the time of the plague in medieval Europe.¶ II. Scenes from a Plague¶ SARS has been compared to the bubonic plague of the Middle Ages, but the Black Death was not a "fast epidemic" due to the limitations of its [4] mode of transmission, as well as the modes of medieval transportation. While SARS is somewhat comparable to flu epidemics of the last century and to the putative bioterror agents of today, AIDS has the dubious distinction of being closer to the experience of the Black Death. However, unlike that ancient pandemic, which was more limited temporally and geographically, AIDS is embarking upon what, Dr. Peter Piot, executive director of UNAIDS, refers to as a "true globalization phase." 8Link to the text of the note¶ A. Black Death Redux¶ The superlatives used to describe the public health impact of AIDS never seem to be exhausted. One commentator noted that AIDS will soon exceed the death toll of the Bubonic Plague, making it the most "numerically lethal pandemic" the world has ever known. 9Link to the text of the note The World Health Organization (WHO) refers to it more prosaically, but with similar notoriety, as the "toughest health assignment the world has ever faced." 10Link to the text of the note Even after twenty years, AIDS is still something of a medical and scientific conundrum. Diversity of the virus increases with duration of infection, further complicating drug treatment. 11Link to the text of the note Vaccine development is similarly complicated due to existence of ten major genetic types or clades of HIV-1, each with a distinct geographical spread. 12Link to the text of the note¶ What we do know is that AIDS is caused by an infection with the human immunodeficiency virus (HIV), transmitted through unprotected sex, sharing hypodermic needles, transfusions of contaminated blood, or from mother to child during pregnancy, labor, delivery, or breast-feeding. The virus attacks the immune system by infecting white blood cells, known as CD4+ cells, making it difficult for the body to fight off infections. AIDS itself is considered the final stage of HIV disease. 13Link to the text of the note Without treatment, HIV will progress to full-blown AIDS within nine to eleven years, and is usually fatal within two years after that point. 14Link to the text of the note The AIDS/HIV toll is [5] approaching forty million infected, with fourteen thousand new infections daily and ninety-five percent of new infections occurring in the developing world. 15Link to the text of the note¶ What we do not know is just how soon and how much of an impact AIDS will have. In sub-Saharan Africa, only an estimated ten percent of the predicted illness and death has occurred; the full impact on people, communities, and economies is still to come. 16Link to the text of the note Nonetheless, one forecast is that seventy million will die of AIDS by 2020, mostly in Africa and Asia. 17Link to the text of the note Besides its own death-dealing impact, AIDS exacerbates the morbidity and mortality of other "slow epidemics" like malaria and tuberculosis, and drains resources that would otherwise be dedicated to their treatment. 18Link to the text of the note By 2010, a report by the Central Intelligence Agency (CIA) states that five countries - Nigeria, Ethiopia, Russia, India, and China - will suffer a total of fifty to seventy-five million cases of HIV/AIDS. 19Link to the text of the note¶ For a preview of the AIDS wasteland that faces us without a serious course change, consider the devastation wrought by AIDS on Botswana. Before the AIDS epidemic reached Botswana in the early 1990s, per-capita income had risen tenfold over the previous thirty years, primary school enrollment had doubled, and infant mortality had decreased almost threefold. A decade after AIDS swept over the land, thirty percent of the country's economic growth was erased and the number of years each citizen is expected to contribute to the economy has been reduced from fifteen-to-thirty productive years to just five. Moreover, one-fifth of Botswana's children will soon be AIDS orphans. 20Link to the text of the note Botswana now has the lowest life expectancy of any country in the world at 30.8 years of age, which is about three times less than the highest life expectancy of 83.5 years in the European nation of Andorra. 21Link to the text of the note At the current pace, close to [6] fifty percent of the world's population could live in countries gripped by the AIDS pandemic by the end of the decade.¶ B. Cold Virus on Steroids¶ The official acronym for severe acute respiratory syndrome is SARS-CoV, which derives from the fact that it is a coronavirus, the same family of viruses that cause the common cold. However, SARS acts more like a cold virus pumped up on anabolic steroids. According to statistics, the recent outbreak of SARS was both debilitating and deadly: eleven percent of its victims died; sixty percent required hospitalization; twenty to thirty percent needed treatment in intensive care units with intubations; six to twenty percent suffered respiratory sequelae; and thirty to sixty percent experienced post-traumatic stress. 22Link to the text of the note Ultimately, the SARS pandemic led to ten billion dollars in economic losses. 23Link to the text of the note¶ The SARS incubation period is typically six days, but can range anywhere from two to twenty days. SARS is more environmentally stable than other respiratory viruses. However, unlike most respiratory viruses the role of seasonality is unknown, noting that most respiratory viruses are winter creatures. SARS is primarily transmitted by respiratory droplets or fomites (i.e., inanimate objects or substances that transfer an infectious agent), in health care and hospital settings, but also by contaminated sewage. Old age and co-existing illness are contributory factors to SARS, but children tend to contract a more mild form of the illness. SARS is believed to be of an animal origin, but unlike most other species jumpers, SARS has also become efficient at human-to-human transmission. 24Link to the text of the note¶ Although we are still learning from the SARS pandemic, some lessons are clear: animal pathogens pose major risks; a problem in a remote area can become a world problem within weeks; molecular virology can identify and sequence genetic structures of new pathogens within weeks; the epidemiological tracks of a disease can be followed even in remote areas; basic infection control measures work well; and the phenomena of the superspreader (i.e., an infected person responsible for a disproportionate number of transmissions), airborne transmission, and heightened risk to health care workers (i.e., twenty-one percent of SARS infections were in health care workers 25Link to the text of the note) complicate control efforts. 26Link to the text of the note Another lesson is that [7] humans can be the worst enemy regarding transmission. Four SARS outbreaks occurred within one year in Singapore, Taipei, and Beijing from laboratory accidents. 27Link to the text of the note The loose ends that dangle perilously from the tail of the SARS epidemic caused one SARS researcher to remark ominously: "this is not the end of the story… ." 28Link to the text of the note¶ C. Black Wind of Death¶ A warning on a radical Islamic fundamentalist website stated that a "Black Wind of Death" would soon be visited upon the enemies of Islam. Some believe that this statement refers to the use of a bioweapon. A conservative estimate of the number of naturally occurring potential bioterror agents is about seventy to eighty, but the possibilities for genetically engineered pathogens are practically limitless. In fact, the pioneers of the Soviet bioweapons program were able to refine the "binary inoculary," in which treatment of the first microbe would set off infection with a more deadly second microbe. The combinations were limitless, but the results were always the same - the ultimate nightmare. For example, if a person contracts a dreaded disease, such as the plague, and is treated with tetracycline, the treatment may unleash a second disease lying dormant, such as Ebola, for which there is no cure.¶ The question remains: How much lethal know-how is out there? In the 1980s, the Soviets' bioweapons industry employed about sixty thousand people, half of whom were scientists. In the past thirty years, critical masses of two to three thousand new pathogens have appeared; some developing from nature and some designed in the lab, but not always as bioweapons. Fully mapping and understanding the complex interactions of hosts and pathogens for the known biological entities that could be weaponized would take decades. 29Link to the text of the note D.A. Henderson, senior advisor for the Center for Biosecurity at the University of Pittsburgh, framed this problem: "Like it or not, I'm afraid the threat is with us forever." 30Link to the text of the note¶ [8] "Globalization, after all, is fundamentally about market expansion, the rise of new political, social, and cultural movements, and changes in the state and institutions." - Hitchner, Tufts University¶ III. Scope¶ For better or worse, globalization is also about public health. The scope of the public health challenge faced today must now be considered within the context of other globalization factors. Just as addressing the problems of globalization, public health must also be taken into account. This is especially true for infectious diseases, as West Nile virus, monkey pox, SARS, avian flu, and antibiotic-resistant bugs are only the beginning. According to one expert, "the new normal" has become a public health problem uniquely created by globalization. 31Link to the text of the note¶ A. The Global Village: A Good Place to Raise Deadly Offspring¶ 1. The Urbanization Triplets: Crowding, Poverty, and Destruction of Habitat¶ Certain sequelae of globalization have been identified as facilitating the spread of global infectious diseases. Urbanization, which is defined as rapid population growth in the cities, especially in tropical and subtropical areas in less developed countries, results in large populations coming into closer contact with one another, increasing the probability of infectious diseases. Urbanization is also characterized by poverty and poor sanitation. 32Link to the text of the note Poverty is considered both a cause and an effect of widespread disease. For instance, poverty often results in malnutrition, which in turn weakens the population's ability to fight off diseases, such as malaria. Malaria can cause the deaths of up to half of a million children per year in sub-Saharan Africa alone, resulting in a loss of one percent of the region's GNP. 33Link to the text of the note Urbanization and poverty also contribute to overcrowding in hospitals and health care facilities, which then leads to a struggle with sterilization and isolation procedures. Cross-contamination through blood and instruments occurs more readily. Due to the favorable environment, microbes increase in number and become more diverse through mutations. If a virulent "bug" pops up, it has a good chance of becoming established quickly.¶ Urbanized areas are often large population centers and are served by [9] modern transportation routes. Once an individual becomes infected, they are only a plane ride away from anywhere in the world. 34Link to the text of the note Urbanization also causes destruction of natural habitats, resulting in the release of previously unknown infectious diseases. Many such diseases have been unleashed by the increased human contact with animal reservoirs, due to altered land-use patterns and changing movement of animal and human populations. 35Link to the text of the note In fact, many of the thirty or so new pathogens recognized in the past three decades originated in animals. 36Link to the text of the note¶ 2. The "T-way" of Global Plague¶ Through the pathways provided by the "3Ts" of globalization - travel, trade, and tourism - humans have inadvertently paved the way for pandemics. Two million people travel internationally everyday, 37Link to the text of the note with approximately five hundred million traveling by commercial airlines every year, 38Link to the text of the note and millions of tons of food, hazardous materials, and waste in transport daily. 39Link to the text of the note With international travel increasing by fifty percent each decade, the prospects of containing new outbreaks of disease are diminishing. 40Link to the text of the note We are no longer protected by formerly formidable natural barriers like oceans, and even less so by artificial barriers, such as political borders.¶ B. The "X" Factors: The Known, the Unknown, and the Unknowable¶ The factors discussed are complex and their impacts are still under study, but to some degree, they are "known" factors that are quantifiable in the calculus of planning for the future. There are also a number of biological, environmental, socioeconomic, cultural, legal, and political factors that continue to crop up in unpredictable manners. Some were previously unknown but have been factored into the problem equation. Others seem to be so random in occurrence and incalculable as to outcomes [10] that the ultimate impacts remain "unknowable."¶ 1. Microbial Resistance¶ Resistant strains to antibiotics developed within a few years of the discovery of antibiotics some fifty years ago. However, according to the United States Food and Drug Administration (FDA), the difference now is that resistance is no longer an isolated problem, especially in hospitals. 41Link to the text of the note For example, in the United States, about seventy percent of bacteria causing infections in hospitals are resistant to at least one of the most common drugs used to treat them. 42Link to the text of the note In the United Kingdom, the infection rate for methicillin-resistant Staphylococcus aureus, a common hospital contaminant, has risen six-hundred percent over the last ten years. 43Link to the text of the note The WHO warned that due to the overuse of antibiotics in rich countries and the under use in poor countries, drug resistance is a worldwide problem. The result is wasting of billions of dollars that could have been better spent on research and development (R&D) for infectious disease treatments over the last few years. 44Link to the text of the note¶ Antibiotics are not the only medicines with resistance problems. The main drugs used to combat AIDS, the so-called anti-retrovirals (ARVs), are also a source of concern. A recent study showed that ten percent of all newly infected patients in Europe 45Link to the text of the note are infected with drug-resistant strains. In San Francisco, the rate is twenty-seven percent. 46Link to the text of the note According to a recent survey of infectious disease specialists in the U.S., only forty-one percent of patients are able to be treated with the most commonly used ARV regimen, while another forty-five percent are on back-up regimens. For fourteen percent of infected patients, treatment with ARVs has all but failed. 47Link to the text of the note¶ [11] Experts agree that resistance is also a problem in the developing world, 48Link to the text of the note further complicated by factors such as counterfeit drugs, irregular access to treatments, environmental degradation, inconsistent compliance, and diversion of drugs to the black market. 49Link to the text of the note¶ 2. Sociocultural¶ None of the problems associated with the globalization of infectious diseases seem to be confined to one part of the world. For instance, half of reported polio cases worldwide occurred in Nigeria, due to disruption of vaccination efforts. This interruption stemmed from a rumor that the United States government was clandestinely implementing population control by adding contraceptives to the vaccine. 50Link to the text of the note In the U.S., a surgeon recently reported that a several-year-long effort to convince a hospital staff to regularly use a sixty percent alcohol gel for hand disinfection was almost thwarted by a rumor that the gel would reduce fertility. 51Link to the text of the note¶ Actions taken by the general public are often at cross-purposes with actions taken to protect the public health. One of the most crucial problems involved with tackling AIDS in the developing world is the extreme fear and social stigma associated with the disease. These sentiments are exemplified by violence and abuse against woman in Africa 52Link to the text of the note and discrimination against HIV patients by their own families and hospitals in India. 53Link to the text of the note In the U.S., the population is so risk-averse that the construction of three Biosafety Level Four labs in California, Texas, and Massachusetts are being vigorously disputed by residents. 54Link to the text of the note¶ [12] ¶ 3. Legal¶ The criminal element always seems to find a way to further complicate an already complicated situation, which is not dissimilar to opportunistic infections. Up to ten percent of the world's drug supply is counterfeit, and may be perhaps as high as fifty percent in many developing countries. 55Link to the text of the note Diversion of medicines to the black market is most common in certain parts of the developing world, but occurs universally. Serostim, a growth hormone prescribed to fight wasting syndrome in AIDS patients, has found an underground recreational use as a bodybuilding drug in the United States. The drug costs about eighty thousand dollars for a year's supply, often paid for by Medicaid, but on the black market, it can fetch two thousand dollars for a week's supply. 56Link to the text of the note Even a new disease, such as SARS, did not take long to develop a criminal element. In May 2002, the FDA issued a special alert regarding internet marketing of bogus SARS prevention products. 57Link to the text of the note¶ In addition to violations of the law, tensions exist within the law as well. The needs of bioscience and the concerns for biosecurity are often adverse. The regulations for "select agents" are so confusing that one researcher was reportedly arrested simply because he traversed a room where a select agent was stored. 58Link to the text of the note Such incidents are one reason why an international group of scientists seeks to keep SARS off the select agents list, arguing [13] that restrictions would stifle research and hurt public health efforts. 59Link to the text of the note However, other experts acknowledge that the transfer of knowledge among scientists is often a leaky process, and scientists may become unwitting accomplices to global bioterror. 60ALink to the text of the note careful balance must be struck between freedom in research endeavors and controls designed to prevent the misuse of material and knowledge. 61Link to the text of the note¶ Conflicts of law also exist between public health and privacy. Due to the evolving nature of the newly implemented medical privacy regulations under the Health Insurance Portability and Accountability Act (HIPAA), 62Link to the text of the note state health officials believe themselves to be limited in releasing information regarding deaths from the flu or other reportable diseases, due to new legal protections afforded to patients. However, HIPAA contains a public health exception, and most officials argue that releasing certain information is required by state public health laws to provide information about risk factors that the public should be aware of. 63Link to the text of the note¶ The United States Security and Exchange Commission (SEC) has become embroiled in this problem as well. SEC regulations are an issue, not only due to antitrust laws prohibiting collaboration on countermeasures by "competing" companies, 64Link to the text of the note but also due to accounting regulations that determine when a company can recognize revenue from a stockpile. Under the current scheme, the United States Department of Health and Human Services (HHS) plans to purchase vaccines, but have companies store them until needed to avoid additional cost and logistical problems for HHS. Problems then arise under current SEC regulations, as entities may not declare revenue from undelivered products. 65Link to the text of the note¶ [14] ¶ 4. The Ultimate "X" Factor¶ Global infectious disease, bioterror, and national security are becoming strange bedfellows. The HHS Secretary announced in the fall of 2003 that grants totaling 350 million dollars over five years would be made available for the establishment of eight Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases Research (RCEs), stating: "These new grants add to this effort and will not only better prepare us for a bioterrorism attack, but will also enhance our ability to deal with any public health crisis, such as SARS… ." 66Link to the text of the note Concern regarding the public health crisis precipitated by SARS was believed to have caused some "holdouts" waffling on support of Bioshield to come on board. 67Link to the text of the note The President of the Association of State and Territorial Health Officials believes that the infusion of dollars into bioterrorism awareness has helped to improve the public health system capacity to deal with health emergencies in general. 68Link to the text of the note¶ Internationally, the Security Council of the United Nations (UN) discussed a health issue for the first time as a threat to world stability: HIV/AIDS in Africa. 69Link to the text of the note The African, Caribbean, and Pacific Ocean sectors of the World Trade Organization (WTO) petitioned the WTO's Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) to find a solution to the deadlock over access to affordable drugs, as the outbreak of diseases such as SARS had made it "a matter of urgency." 70Link to the text of the note The deadlock was broken. In a report by the United States National Intelligence Council, experts emphasized the worldwide threat presented by infectious disease to military capacity, socioeconomic development, international trade and travel, and global stability. 71Link to the text of the note¶ [15] However, common goals can sometimes result in competition instead of cooperation when time, money, and resources are limited. The media reported that National Institute of Health (NIH) studies on AIDS, TB, malaria, and other infectious diseases would be shortened in length due to a White House mandate shifting funding to development of an anthrax vaccine. 72Link to the text of the note While the NIAID budget grew twenty-fold from 1980 to 2004, the increase was mainly due to efforts to combat changing priorities of life-threatening infectious diseases, such as AIDS in the 1990s and bioterror in the 2000s. 73Link to the text of the note In fact, the NIAID budget allotment for AIDS R&D has flat lined for 2002 through 2005, while the biodefense budget went up from $ 200 million in 2002 to $ 1.6 billion slated for 2005. 74Link to the text of the note In a survey of nearly four hundred scientists, forty-six percent felt that government spending on bioterror R&D diverts monies from more important investigative work. 75Link to the text of the note Internationally, in January 2002, the WHO's Executive Board stated that it was focusing attention on the health effects of poverty, but also needed to devote attention to preparations for "newer threats such as the deliberate use of anthrax and smallpox agents." 76Link to the text of the note¶ C. The World as a Marketplace, Health Care as a Business¶ Due to the globalization of infectious diseases, the distinction between national and international public health programs have as little relevance as political borders. 77Link to the text of the note However, this also implies that public health counter-measures must be considered within the context of market realities driving globalization. There is a strengthening current within the international public health community to consider access to health care as a universal human right shared by rich and poor alike. 78Link to the text of the note However, one must inquire: Where does the money for health research come from? Independent [16] foundations and charities contribute only about four percent of the billions spent globally each year on health research. 79Link to the text of the note Regarding medicine, a sizeable amount of the funding for basic research comes from governments, but the lion's share of the funding for applied research that turns concepts brewing in test-tubes on lab benches into bottles for injection on clinic shelves comes from private industry. In particular, these are the major pharmaceutical companies, also known as "big pharma." 80Link to the text of the note¶ They don't call it big pharma for nothing! The industry's financial might and resources are impressive. When the list of the world's one hundred largest public companies by market value is released each year, close to one-fifth are pharmaceutical companies. Monsanto, a life-science multinational corporation, has a R&D budget more than twice the R&D budget of the entire worldwide network of public sector tropical medicines research institutes. 81Link to the text of the note¶ These resources must be brought to bear if the global community is to make any headway against the globalization of infectious diseases. However, this is where the economic and political realities of globalization are actualized. According to previous work on providing incentives to industry to conduct R&D for neglected parasitic and infectious diseases in the developing world, five disincentives must be addressed: lack of interest on the part of big pharma; an unfavorable cost/risk ratio for big pharma; the fact that only impoverished markets exist for the products of such R&D; the difficulty of directing capacity in the Northern hemisphere to address the needs of the South; and the realities of the vaccine market. 82Link to the text of the note

## Safety DA

#### Vaccines produced by trusted manufacturers work – 96% efficacy in trials and empirically 99% of cases are unvaccinated

#### Removing IP would cause ineffective and unsafe vaccines

Brougher MPH 3/30/21

Joanna T. Brougher, Esq., Mph &amp; Andrew Kingsbury, 3-30-2021, "Calls for Compulsory Licensing and IP Waivers of COVID-19 Vaccines Ignore Technical Complexities," IPWatchdog, <https://www.ipwatchdog.com/2021/03/30/calls-compulsory-licensing-ip-waivers-covid-19-vaccines-ignore-technical-complexities/id=131617/> // AW

While seeking compulsory licensing or IP waivers may seem an attractive solution to address technological disparities across human populations, these mechanisms ignore some of the more technical hurdles to increasing accessibility to vaccination. This post will first briefly explain what compulsory licensing and IP waivers are and then examine three possible causes for why compulsory licenses and IP waiver are not a feasible solution to the current COVID-19 pandemic. Compulsory Licensing One of the agreements that countries must ratify upon joining the World Trade Organization (WTO) is the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement was negotiated in 1994 to harmonize intellectual property laws across different countries and to establish minimum standards for protecting and enforcing intellectual property rights for all WTO member countries. There are several provisions under TRIPS that allow governments to provide for limitations to intellectual property rights. In [Article 31](https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_oth.pdf), for instance, TRIPS allows governments to order domestic manufacturers to make a patented product without permission from the patent holder. This practice is known as compulsory licensing. Article 31 permits countries to engage in compulsory licensing if there is a “case of a national emergency or other circumstances of extreme urgency,” or in cases of “public non-commercial use.” Under these circumstances, the country is first required to negotiate with, or seek approval from, the patent holder of the drug, but if the negotiations fail, is ultimately just permitted to manufacture patented products, such as essential medicines, for its domestic market. For countries that cannot manufacture drugs themselves, and who would thus not be able to issue compulsory licenses under Article 31, Article 31bis was created to permit a developed country to export a generic drug under a compulsory license to a less developed country. IP Waivers Contrary to compulsory licensing, IP waivers simply ask that countries be exempt from the provisions of TRIPS that require countries to protect and enforce patent rights to COVID-19 treatments and vaccines. In October 2020, [India and South Africa petitioned the WTO](https://www.ipwatchdog.com/2021/01/02/india-south-africas-covid-vaccine-proposal-wto-patent-waiver-must-considered-compulsory-licensing/id=128652/) for a temporary waiver from specific provisions of the TRIPS Agreement that could essentially put entire realms of existing intellectual property law on hold at the international level until widespread vaccination has become globally implemented. Perhaps unsurprisingly, this proposal was met with strong resistance from developed nations while developing and less developed nations were more welcoming towards it. In March 2021, the proposal failed to pass resolution at the WTO. Covid-19 Vaccines are New What these proposals fail to take into account is the nature of the Pfizer and Moderna vaccines. The efficacy of both of these proposals turns on a country’s internal technological capabilities to recreate and administer the vaccine. The Pfizer and Moderna vaccines, however, are not typical vaccines. Whereas traditional vaccines functioned by introducing parts of a virus — or a weakened form of a virus — Pfizer’s and Moderna’s vaccines use messenger RNA to cause host cells to produce the protein themselves. These are the [first vaccines to utilize this type of technology](https://www.abc27.com/news/health/coronavirus/vaccination-frustration/digital-original-how-do-covid-19-vaccines-compare-to-other-vaccinations/). The novelty of these vaccines potentially degrades the utility of a compulsory license or IP waiver. For instance, remdesivir received a great deal of focus early in the pandemic. Bangladesh managed to recreate the drug without Gilead Science’s approval because it is exempt from Article 31 of TRIPS, and Bangladesh [was able to produce a sufficient supply for the country by the summer of 2020](https://patentlyo.com/patent/2021/01/shortages-compulsory-licensing.html) because information about the drug was available. Given the fact that Pfizer’s and Moderna’s vaccines represent a new form of vaccine, lacking technical information on how to make this new form of vaccine could lead the countries to create entirely ineffective vaccine replicas. These issues may be compounded by the fact that many vaccine manufactures [rely on trade secret protection more heavily](https://www.jdsupra.com/legalnews/trade-secret-protection-the-covid-19-37383/) following the [Ass’n for Molecular Pathology v. Myriad Genetics, Inc](https://www.leagle.com/decision/insco20130613e08). decision. These trade secrets can withhold critical scientific know-how that might be necessary for replicating a vaccine. Thus, the new technology behind these messenger RNA vaccines and the lack of accessibility to the related know-how might deter countries from attempting to manufacture them. Lack of Information Yet another more fundamental problem exists for replicating these vaccines. Not only do these vaccines represent a new form of vaccine, but information about these particular vaccines is simply unavailable. Even if the Pfizer and Moderna vaccines do not utilize any trade secrets, the discovery of these vaccines is fundamentally different than remdesivir’s timeline, which resulted in Bangladesh’s recreation of the drug. [A patent for remdesivir was filed as early as 2015](https://patents.google.com/patent/US20170071964A1/en), and thus the information had been publicly available for years. While the technology underlying mRNA vaccines has been in development for decades, there are likely specific technological hurdles associated with, for instance, the coronavirus, mass production and scale up, and delivery mechanisms that needed to be developed for this specific application of the legacy technology. This additional information will not be found in scientific journals or magazine articles, nor can it be found in any patent application, yet. Patents, moreover, can take up to 18 months from filing to be published. BioNTech made an [F-1 filing with the SEC](https://www.sec.gov/Archives/edgar/data/1776985/000119312520195911/d939702df1.htm) on July 21, 2020, in which it acknowledged its partnership with Pfizer to develop the vaccine. If this filling is at all indicative of when a patent could have been filed, then this would mean the patent may not be available to the public until late-2021–mid-2022. With Novelty Comes Difficulty The newness of these vaccines also creates problems due to the complexity in how these types of vaccines function and how to produce them. According to a [Wall Street Journal report](https://www.wsj.com/articles/mrna-covid-19-vaccines-are-fast-to-make-but-hard-to-scale-11614776401), manufactures say that vaccine production is difficult both “because some steps are difficult to scale up quickly or because they simply haven’t been done before.” Even Pfizer is [having difficulty obtaining](https://www.wsj.com/articles/pfizer-slashed-its-covid-19-vaccine-rollout-target-after-facing-supply-chain-obstacles-11607027787) the necessary materials for vaccine production. Here, the complexity of these vaccines demonstrates the potential futility of a compulsory license or IP waivers. Even if other countries could compel manufactures to license the underlying intellectual property and provided them with the information about how to do so, the complexity of manufacturing these types of vaccines could be a particularly high barrier to overcome. It’s Complicated Countries face roadblocks for producing a viable vaccine candidate based on Pfizer’s and Moderna’s vaccines. The new technology that utilizes messenger RNA vaccines, coupled with the lack of public information about these vaccines and the vaccines’ complicated nature, present significant hurdles to seeking compulsory licenses or IP waivers.

#### The only producers who move quickly enough to solve don’t do it safely

Winegarden PhD et al 21

WAYNE WINEGARDEN (PhD in Medical Economics and Innovation, ROBERT POPOVIAN, PETER PITTS, June 21, 2021, “Waiving Covid-19 Vaccine Patents Is a Bad Idea and Sets a Dangerous Precedent”, Pacific Research Institute, https://medecon.org/waiving-covid-19-vaccine-patents-is-a-bad-idea-and-sets-a-dangerous-precedent/ // AW

It all sounds so simple: to hasten the end of the pandemic globally, suspend intellectual property protections on Covid-19 vaccines to allow swift production of low-cost copies the world over. The Biden administration has bought into exactly that strategy at the World Trade Organization. But some simple ideas are also simplistic, and this one is dangerously so. Waiving patent rights for Covid-19 vaccines will actually slow their availability in the developing world, thereby prolonging the pandemic. The production of these breakthrough Covid-19 vaccines requires sophisticated processes, procedures, staff training, material, and manufacturing. Under typical patent-protected arrangements for new global production facilities, patent-holders voluntarily license their product information to qualified third party-manufacturers. The patent-owners work closely with the licensees to stand up facilities that meet rigorous technological specifications and standards for safety. Even under ideal conditions, it can take a year or longer to build out this infrastructure the right way. The WTO waiver blows up this careful process by allowing pretty much anyone to go into the business of producing Covid-19 vaccines. Suddenly, **it’s the wild west out there**, with legitimate producers trying to compete with aggressive cost and corner-cutters, to say nothing of the outright fraud that has long driven the lucrative counterfeit drug trade. All the research demonstrating the safety and efficacy of the Covid-19 vaccines goes out the window under such conditions. Nor is such a process going to produce faster results. Historically, under compulsory rather than voluntary licensing arrangements, it has taken even legitimate generic manufacturers years to receive the formulas, work out logistical challenges, and scale up production. In one case of compulsory licensing, it [took over four years](https://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?article=1184&context=jipl) to bring a generic AIDS drug to Rwanda. The World Health Organization regularly publishes a list of “essential” medications, the vast majority of which patent protections have long expired. Any generic manufacturer can therefore set itself up producing them. Yet the WHO reports that availability of these medicines in many parts of the developing world remains spotty, at best. The quality of many of these essential medicines is also questionable. Yet none of the drugs on the WHO list are in the same universe of complexity as the Covid-19 vaccines. The patent system is not the problem here. But, some ask, why should private companies enjoy the property rights to innovation driven by government funding? This question likewise misses the mark. In a study of 478 drugs less than [10 percent had a public-sector patent](https://www.researchgate.net/publication/49805993_What_Are_The_Respective_Roles_Of_The_Public_And_Private_Sectors_In_Pharmaceutical_Innovation) associated with it. While providing no gain, compulsory licensing promises lots of pain. Shunting aside patent and intellectual property rights sends a dangerous signal to innovative biopharmaceutical companies and their investors. Biopharmaceutical research is risky. It [costs almost $3 billion](https://pubmed.ncbi.nlm.nih.gov/26928437/), on average, to bring a single medicine to pharmacy shelves. Biotech investors take these risks because of [strong patent protection](https://pubs.aeaweb.org/doi/pdf/10.1257/jep.27.1.23) like those in the United States. Scientists in America now [develop over half of all new drugs worldwide](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2866602/). It’s important to understand the current advocacy for a “temporary” IP waiver. A small but vocal and influential public health policy cohort believes that IP protections are the most significant cause of global healthcare disparities. Their philosophies repeat and reinforce many misconceptions about the problem of improving global access to medicines. The reality is that, in order to save the world, we must all work together as partners. A free-market healthcare paradigm for drug development, although far from perfect, works. A well-appointed armamentarium of Covid-19 diagnostic tools, therapeutics, and vaccines – all invented in under one year, speaks to the power of today’s innovation ecosystem. That ecosystem is built on IP protections. Right now, under voluntary licensing, global production capacity for Covid vaccines and treatments is expanding and accelerating. **A move to nullify IP will not result in a single resident of the developing world getting vaccinated one minute sooner.**

## Case

### AT: Vaccine Apartheid

#### Corporate innovation is key to easy access to cheap and accessible treatment in LICs

**Access to Medicine Foundation 16** (The Access to Medicine Index is published by the Access to Medicine Foundation, a non-profit organisation based in the Netherlands that aims to advance access to medicine in developing countries by encouraging the pharmaceutical industry to accept a greater role in improving access to medicine in less developed countries. The Index methodology was developed, and is continually refined, in consultation with multiple expert stakeholders including the World Health Organization, NGOs, governments and universities, as well as institutional investors. The Index is funded by the Bill & Melinda Gates Foundation, the Dutch Ministry of Foreign Affairs and the UK Department for International Development. “Pharmaceutical Companies' Strategies for Reaching the Poor Are Maturing. but Expansion Is Gradual.” Access to Medicine Foundation, accesstomedicinefoundation.org/newsroom/pharmaceutical-companies-strategies-for-reaching-the-poor-are-maturing-but-expansion-is-gradual. // $)

The 2016 Access to Medicine Index, published Monday, ranks the top 20 pharmaceutical companies on their efforts to improve access to medicine in low- and middle-income countries. It found that GSK, which leads the Index for the fifth time, performs best when it comes to matching its access activities with particular needs within the access to medicine agenda. GSK is joined at the top of the Index by a closely packed group comprising Johnson & Johnson, Novartis and Merck KGaA. The pharmaceutical industry is extremely diverse, and this is reflected in the way each company approaches access to medicine. However, the four companies in this leadership group share some distinguishing characteristics. They have the most mature access programmes, with well-organised access strategies that support business development in emerging markets, where the need for access to medicine is high. They also show the most evidence of addressing independently identified high-priority needs. The 2016 Index has assessed the extent to which a company’s access operations are needs-oriented: where actions match specific priorities identified by, for instance, countries, the global health community or the Index. In this regard, the Index analysis reveals uneven performance. The companies have 850 products on the market for the 51 most burdensome diseases in low- and middle-income countries, and are developing another 420. This includes more than 100 products that have entered the pipeline since 2014 and 151 with low commercial incentive but which are urgently needed, mainly by the poor. The majority (67%) of the research projects that companies have for high-priority, low-incentive products are being conducted in partnerships, the Index finds. “We see evidence that collaborative R&D models are engaging the industry in developing urgently needed medicines they would not otherwise be considering because there is not enough of a commercial market for them,” said Jayasree K. Iyer, Executive Director of the Access to Medicine Foundation. “The partnership approach is working.” Progress in making more medicines more available is also seen in the way companies are handling their patents and in the extent to which they are allowing other manufacturers to make generic versions of their products. Since 2014, seven companies have published new or expanded pledges to waive or abandon patent rights for certain products in certain regions. More HIV/AIDS products are covered by voluntary licenses and these apply in more countries than they did before. And for the first time, they are being used to expand access to medicines for a disease other than HIV/AIDS – hepatitis C. Globally, between 130–150 million people have chronic hepatitis C infection. However, a product can only be made available in a country once it has been registered there. The Index finds that, for their newest products, companies apply for registration in only 25% of countries the Index identifies as the highest priority. Making products more affordable is another cornerstone of increasing access to medicine. The Index finds that pricing schemes that take account of the ability to pay are being applied to one-third of relevant products. This has not changed since the last Index two years ago. Only 5 % of products (44 out of 850) have such pricing strategies applied in countries the Index identifies as the highest-priority, with at least one socio-economic factor being taken into account. Around half of these products are from GSK and AstraZeneca. Other findings include: A quarter of companies (5) are piloting new business models that aim to reach low-income populations. The diseases getting the most attention from company access activities are heart disease, lower respiratory infections and HIV/AIDS. R&D is still concentrated on five diseases, with lower respiratory infections getting the most focus, followed by diabetes, malaria, viral hepatitis and HIV/AIDS. Most companies are working to strengthen healthcare systems in low- and middle-income countries. Six consistently match these activities to priorities identified by local parties, including governments. The companies that rose most significantly up the Index were AstraZeneca and Takeda, which both extensively expanded and updated their access strategies. AstraZeneca climbed eight positions into the top 10 to take 7th position, while Takeda moved up five places to rank 15th. Meanwhile, Novo Nordisk, Roche and Gilead have experienced the most significant drops in ranking, after being outperformed by peers. “We have been assessing these 20 companies for 10 years now. We know what works, where. There is good practice and where there are mechanisms to incentivise industry engagement, such as patent pooling, collaborative R&D models, multi-stakeholder initiatives and international commitments to certain diseases, we see the industry responding,” Iyer said. “Access to medicine is a collective responsibility and all stakeholders –from the industry to governments and the global health community– need to challenge themselves to support the ramping up of these efforts to ensure they are expanded to more products in more countries so that pharmaceutical products reach the people who need them.”

### AT: Solvency

#### No solvency, own cards say Tech transfer is key -- not included under IP!

Smith 05/05

(Laura Smith-Spark; Newsdesk Editor, CNN Digital; (05-05-21) Rich nations urged to share vaccine knowledge while WTO debates waiving patents; CNN; <https://www.cnn.com/2021/05/05/world/covid-19-vaccine-patents-wto-intl/index.html>; CKD)

Thomas Bollyky, director of the Global Health Program at the Council on Foreign Relations, told CNN on Friday that what's really needed to scale up global manufacturing of vaccines is technology transfer. "It's not just a matter of intellectual property. It's also the transfer of know-how," he said. "I don't think there's clear evidence that a waiver of an intellectual property is going to be the best way for that technology transfer to occur." Waiving patents will not work in the same way for vaccines as it has for drugs, Bollyky said. For HIV drugs, for example, manufacturers were more or less able to reverse engineer them without much help from the original developer. "It's very different for vaccines, where it's really a biological process as much as a product. It's hard to scale up manufacturing in this process for the original company, let alone another manufacturer trying to figure this out without assistance," he said. "It requires a lot of knowledge that's not part of the IP." The deal between AstraZeneca and the Serum Institute of India is a successful example of such technology transfer, Bollyky said, where the licensing of IP happened voluntarily. "The question is what can we do to facilitate more deals like the one between AstraZeneca and the Serum Institute of India to have this transfer," he said. Michael Head, senior research fellow in global health at the University of Southampton, in England, told CNN that increasing regional manufacturing capacity, particularly in the global south, was key -- and should be a focus between pandemics. "Sharing intellectual property during the pandemic is something that should happen but that doesn't resolve the issues," he said. "Manufacturing vaccines is hard. It's hard to rapidly set up a new site with all the equipment, infrastructure, all the vaccine ingredients, with suitable staff to produce a large number of high quality vaccine products." Philanthropist Bill Gates, a major supporter of [global Covid-19 vaccine equity](https://www.cnn.com/2021/02/05/world/covax-explainer-intl/index.html) through the Bill & Melinda Gates Foundation, also [told Sky News](https://news.sky.com/story/covid-19-bill-gates-hopeful-world-completely-back-to-normal-by-end-of-2022-and-vaccine-sharing-to-ramp-up-12285840) last month that he did not believe overriding IP rules was the answer. "There's only so many vaccine factories in the world and people are very serious about the safety of vaccines," he said. "The thing that's holding things back in this case is not intellectual property. There's not, like, some idle vaccine factory with regulatory approval that makes magically safe vaccines. You've got to do the trials on these things and every manufacturing process has to be looked at in a very careful way."

#### No capacity for production -- MRNA expert shortages.

Garde et al 21 [Damian Garde (National Biotech Reporter), Helen Branswell (Senior Writer, Infectious Disease)Matthew Herper (Senior Writer, Medicine, Editorial Director of Events), 5/6/21, Waiver of patent rights on Covid-19 vaccines, in near term, may be more symbolic than substantive, <https://www.statnews.com/2021/05/06/waiver-of-patent-rights-on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/>] Justin

In October, Moderna vowed not to enforce its Covid-19-related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses.

That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines.

“There are currently no generic vaccines primarily because there are hundreds of process steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, but the transfer of skills is not that simple,” said Norman Baylor, who formerly headed the Food and Drug Administration’s Office of Vaccines Research and Review, and who is now president of Biologics Consulting.

While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — using messenger RNA technology — require skilled expertise that even existing manufacturers are having trouble sourcing.

“In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said.

### AT: Framing

#### Concede to the 1AC framing.

### AT: Underview 2 Disads

#### AT A: Impacts of the DAs make worse the conditions of the world’s most vulnerable people – not just a defense of WTO countries.

#### AT B,C,E: Criticism relies on weak link chains and low probability – doesn’t apply to our DAs. Probabilities are high

#### AT D: Removing IP there is no going back – can’t change course on eroding pharma profits & vaccine safety because the only solution is to put IP back, which means DA is true.