# 1AC Harvard-Westlake CR

#### Contention 1: Vaccine Inequality

#### 1. Global health inequality threatens progress in fight vs COVID-19 encouraging vaccine resistant mutations

Fink 7-30-21

(Jenni, https://www.newsweek.com/who-warns-world-blind-understanding-covid-spread-hurting-ability-end-pandemic-1614722)

A lack of testing for COVID-19 in parts of the world is preventing countries from having a clear picture of how the virus is spreading and therefore hurting the world's chances at fighting the virus and ending the pandemic, according to the World Health Organization. Health inequities throughout the world have plagued the global response to COVID-19 from the outset and WHO has pushed higher income countries to help lower income countries in the interest of ending the pandemic. Along with restricted access to vaccines, lower income countries have struggled to have sufficient testing, meaning the virus is likely going undetected in certain areas, further enabling its ability to spread. Low testing rates is "leaving the world blind to understanding where the disease is and how it's changing," Dr. Tedros Adhanom Ghebreyesus, director general of the WHO said on Friday during a press briefing. Without improving global testing rates, Ghebreyesus said the world can't "fight the disease" or mitigate the risk it poses to people around the globe. who blind covid spread cases On Friday, the World Health Organization warned the world is "blind" to how COVID-19 is spreading because of a lack of testing in certain places. WHO Director-General Tedros Adhanom Ghebreyesus attends a daily press briefing on the new coronavirus dubbed COVID-19, at the WHO headquaters on March 2, 2020, in Geneva. FABRICE COFFRINI//AFP/GETTY IMAGES NEWSWEEK NEWSLETTER SIGN-UP > One of Ghebreyesus' biggest frustrations with the pandemic response is the failure to evenly distribute the vaccine around the world. In some countries, like the United States and other higher-income nations, significant portions of the population have been vaccinated. While those large vaccinated populations help reduce the spread of the virus in some areas, other countries, especially those in Africa, haven't been able to vaccinate even 10 percent of their population. This puts the entire world at risk because when the virus is able to spread throughout communities it has the ability to mutate, thereby increasing the possibility that a mutation could evade the vaccines. It's a scenario public health officials have been warning about for months and Ghebreyesus said on Friday that "hard won gains are in jeopardy" or have already been lost because the virus has been able to spread. Nearly 30 countries have high or rising oxygen needs and the shortage of life-saving oxygen could lead to increased deaths. More than 196 million cases of COVID-19 have been reported around the world, according to a Johns Hopkins University tracker, and more than 4.2 million people have died. Ghebreyesus suspected the number of cases would top 200 million within the next two weeks and warned that health systems in many countries are being overwhelmed. Preventing hospitals from exceeding capacity was a massive concern when the pandemic first broke out and a year later, parts of the U.S. are having their health systems strained as the more transmissible Delta variant spreads. On Thursday, Arkansas Governor Asa Hutchinson declared a public health emergency that allows the state to bring in health care workers from outside Arkansas and makes it easier for retired health care workers and medical students to become licensed. The goal is to help alleviate stress on health care systems and Hutchinson said they've had people waiting in ambulances because there wasn't an open spot in a hospital. That strain will only become more exacerbated if a mutation occurs that evades the vaccine, as inoculations have proven effective at helping to keep people out of the hospital. Ghebreyesus warned that more variants will emerge if global access to vaccines and testing doesn't improve. "The pandemic will end when the world chooses to end it. It is in our hands. We have all the tools we need. We can prevent this disease. We can test for it and we can treat it," Ghebreyesus said.

#### 2. IP protections are the vital internal link to reduce vaccine inequality. Empirics disprove all pro patent arguments

Kumar, PhD, 7-12-21

(Rajeesh, Associate Fellow Manohar Parrikar Institute for Defence Studies and Analysis, https://www.idsa.in/issuebrief/wto-trips-waiver-covid-vaccine-rkumar-120721)

In October 2020, India and South Africa had submitted a proposal to the World Trade Organization (WTO), suggesting a waiver of certain provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement for the “prevention, containment and treatment of COVID-19”. The proposal seeks the waiver of “the implementation, application, and enforcement of sections 1, 4, 5 and 7 of part II of the TRIPS agreement”, which are stipulations referring to copyright, industrial design, patents, and undisclosed information (trade secrets).1 The proponents of the proposal argue that a waiver will enable timely and equitable access to affordable health products and technologies, including vaccines. Though many member countries had supported and co-sponsored the proposal, a small but influential group of countries, mainly Australia, Canada, the European Union (EU), Japan, the United Kingdom (UK) and the United States (US), opposed it. They argued that existing exceptions under the TRIPS Agreement are sufficient to address the concerns mentioned in the proposal. This resulted in sidelining of the waiver proposal for months. However, on 5 May 2021, the Joseph Biden administration announced its support for waiving intellectual property protections for COVID-19 vaccines.2 It was a significant step towards breaking the seven-month gridlock, and led to many more countries modifying their position on the waiver proposal. On 25 May 2021, the co-sponsors of the waiver proposal submitted a revised proposal that specified the scope of the waiver as applying to “health products and technologies” and also added a section on the proposed duration of the waiver, i.e., three years.3 At present, more than 100 countries, including the US and China support this proposal. The principal opponent of the waiver is the EU and in June 2021, it submitted an alternative proposal to the TRIPS Council, which requested to keep TRIPS’ provisions intact and focused on compulsory licensing and removing vaccine export restrictions to address the concerns raised by India and South Africa.4 The EU proposal also stated that the TRIPS Agreement does not prevent countries from taking measures to protect public health.5 At the meeting of the TRIPS Council on 8–9 June 2021, the member states agreed to text-based negotiations focusing on two proposals tabled by members. The members also decided to hold a series of meetings till the end of July 2021 to take stock of the text-based negotiations. However, the latest developments show that the waiver discussions hit a hurdle due to a split between the developed and developing countries over the negotiation text. This brief discusses how TRIPS becomes a barrier to the equitable access of COVID-19 vaccines. It also examines how a waiver will help India in its fight against COVID-19 at home and abroad. TRIPS and its Exceptions TRIPS, a comprehensive multilateral agreement on Intellectual Property (IP), was an outcome of the Uruguay Round (1986–94) of negotiations of the General Agreement on Tariffs and Trade (GATT). The Agreement came into force on 1 January 1995 and offers a minimum standard of protection for Intellectual Property Rights (IPR).6 In WTO, IPR are divided into two main categories. First, copyright and related rights (Articles 9 to 14, Part II of the TRIPS Agreement). Second, industrial property that includes trademarks, geographical indications, industrial designs, patents, integrated circuit layout designs, and undisclosed information (Articles 15 to 38, Part II of the TRIPS Agreement).7 Article IX.3 and IX.4 of the Marrakesh Agreement Establishing the WTO deals with TRIPS waivers. Article IX.3 says that in “exceptional circumstances” the Ministerial Conference may waive off an obligation imposed on WTO member countries.8 Such a decision requires the support of three-fourths of the WTO membership. According to Article IX.4, any waiver granted for more than one year will be reviewed by the Ministerial Conference. Based on the annual review, the Conference may extend, modify, or terminate the waiver. The TRIPS Agreement provides some flexibility primarily in the form of compulsory licensing and research exceptions through Articles 30 and 31. While Article 30 permits WTO members to make limited exceptions to patent rights, Article 31 provides a detailed exception, provided certain conditions are met. Compulsory licensing is the process of granting a license by a government to use a patent without the patent holder's consent. Article 31 permits granting compulsory license under circumstances such as “national emergencies”, “other circumstances of extreme urgency”, “public noncommercial use”, or against “anti-competitive” practices.9 In addition to these original waivers, the Declaration on the TRIPS Agreement and Public Health, adopted at the 2001 Doha Ministerial Meeting, also recognises some exceptions, for instance, in situations of a public health emergency, member countries have the freedom to determine the grounds upon which compulsory licenses are granted. Similarly, under Article 66.1, the least developed countries (LDCs) are given waivers for implementing TRIPS on pharmaceuticals till 1 January 2033. COVID-19 and TRIPS Waiver Two significant factors rekindled the debate on TRIPS waiver for essential medical products—first, vaccine inequity, and second, the insufficiency of existing waiver provisions in fighting the COVID-19 pandemic. COVID-19 is an exceptional circumstance, and equitable global access to the vaccine is necessary to bring the pandemic under control. However, the world is witnessing quite the reverse, i.e., vaccine nationalism. Vaccine nationalism is “my nation first” approach to securing and stockpiling vaccines before making them available in other countries. A TRIPS waiver would be instrumental in addressing the growing inequality in the production, distribution, and pricing of the COVID-19 vaccines. Vaccine Inequity According to Duke Global Health Innovation Center, which monitors COVID-19 vaccine purchases, rich nations representing just 14 per cent of the world population have bought up to 53 per cent of the most promising vaccines so far. As of 4 July 2021, the high-income countries (HICs) purchased more than half (6.16 billion) vaccine doses sold globally. At the same time, the low-income countries (LICs) received only 0.3 per cent of the vaccines produced. The low and middle-income countries (LMICs), which account for 81 per cent of the global adult population, purchased 33 per cent, and COVAX (COVID-19 Vaccines Global Access) has received 13 per cent.10 Many HICs bought enough doses to vaccinate their populations several times over. For instance, Canada procured 10.45 doses per person, while the UK, EU and the US procured 8.18, 6.89, and 4.60 doses per inhabitant, respectively.11 Source:“Tracking COVID-19 Vaccine Purchases Across the Globe”, Duke Global Health Innovation Center, Updated 9 July 2021. Consequently, there is a significant disparity between HICs and LICs in vaccine administration as well. As of 8 July 2021, 3.32 billion vaccine doses had been administered globally.12 Nonetheless, only one per cent of people in LICs have been given at least one dose. While in HICs almost one in four people have received the vaccine, in LICs, it is one in more than 500. The World Health Organization (WHO) notes that about 90 per cent of African countries will miss the September target to vaccinate at least 10 per cent of their populations as a third wave looms on the continent.13 South Africa, the most affected African country, for instance, has vaccinated less than two per cent of its population of about 59 million. This is in contrast with the US where almost 47.5 per cent of the population of more than 330 million has been fully vaccinated. In Sub-Saharan Africa, vaccine rollout remains the slowest in the world. According to the International Monetary Fund (IMF), at current rates, by the end of 2021, a massive global inequity will continue to exist, with Africa still experiencing meagre vaccination rates while other parts of the world move much closer to complete vaccination.14 This vaccine inequity is not only morally indefensible but also clinically counter-productive. If this situation prevails, LICs could be waiting until 2025 for vaccinating half of their people. AllSpowing most of the world’s population to go unvaccinated will also spawn new virus mutations, more contagious viruses leading to a steep rise in COVID-19 cases. Such a scenario could cause twice as many deaths as against distributing them globally, on a priority basis. Preventing this humanitarian catastrophe requires removing all barriers to the production and distribution of vaccines. TRIPS is one such barrier that prevents vaccine production in LMICs and hence its equitable distribution. TRIPS: Barrier to Equitable Health Care Access The opponents of the waiver proposal argue that IPR are not a significant barrier to equitable access to health care, and existing TRIPS flexibilities are sufficient to address the COVID-19 pandemic. However, history suggests the contrary. For instance, when South Africa passed the Medicines and Related Substances Act of 1997 to address the HIV/AIDS public health crisis, nearly 40 of world’s largest and influential pharma companies took the South African government to court over the violation of TRIPS. The Act, which invoked the compulsory licensing provision, allowed South Africa to produce affordable generic drugs.15 The Big Pharma also lobbied developed countries, particularly the US, to put bilateral trade sanctions against South Africa.16 Similarly, when Indian company Cipla decided to provide generic antiretrovirals (ARVs) to the African market at a lower cost, Big Pharma retaliated through patent litigations in Indian and international trade courts and branded Indian drug companies as thieves.17 Another instance was when Swiss company Roche initiated patent infringement proceedings against Cipla’s decision to launch a generic version of cancer drug, “erlotinib”. Though the Delhi High Court initially dismissed Roche's appeal by citing “public interest” and “affordability of medicines,” the continued to pressure the generic pharma companies over IPR. 18 Likewise, Pfizer’s aggressive patenting strategy prevented South Korea in developing pneumonia vaccines for children.19 A recent document by Médecins Sans Frontières (MSF), or Doctors Without Borders, highlights various instances of how IP hinders manufacturing and supply of diagnostics, medical equipment, treatments and vaccines during the COVID-19 pandemic. For instance, during the peak of the COVID-19 first wave in Europe, Roche rejected a request from the Netherlands to release the recipe of key chemical reagents needed to increase the production of diagnostic kits. Another example was patent holders threatening producers of 3D printing ventilators with patent infringement lawsuits in Italy.20 The MSF also found that patents pose a severe threat to access to affordable versions of newer vaccines.21 Source:“COVID-19 Vaccine R&D Investments”, Global Health Centre, Graduate Institute, Geneva, Updated 9 July 2021. The opponents of the TRIPS waiver also argue that IP is the incentive for innovation and if it is undermined, future innovation will suffer. However, most of the COVID-19 medical innovations, particularly vaccines, are developed with public financing assistance. Governments spent billions of dollars for COVID-19 vaccine research. Notably, out of $6.1 billion in investment tracked up to July 2021, 98.12 per cent was public funding.22 The US and Germany are the largest investors in vaccine R&D with $2.2 billion and $1.5 billion funding. Source:“COVID-19 Vaccine R&D Investments”, Global Health Centre, Graduate Institute, Geneva, Updated 9 July 2021. Private companies received 94.6 per cent of this funding; Moderna received the highest $956.3 million and Janssen $910.6 million. Moreover, governments also invested $50.9 billion for advance purchase agreements (APAs) as an incentive for vaccine development. A recent IMF working paper also notes that public research institutions were a key driver of the COVID-19 R&D effort—accounting for 70 per cent of all COVID-19 clinical trials globally.23 The argument is that vaccines are developed with the support of substantial public financing, hence there is a public right to the scientific achievements. Moreover, private companies reaped billions in profits from COVID-19 vaccines. Source: Katharina Buchholz, “COVID-19 Vaccines Lift Pharma Company Profits”, Statista, 17 May 2021. One could argue that since the US, Germany and other HICs are spending money, their citizens are entitled to get vaccines first, hence vaccine nationalism is morally defensible. Nonetheless, it is not the case. The TRIPS Agreement includes several provisions which mandates promotion of technology transfer from developed countries to LDCs. For instance, Article 7 states that "the protection and enforcement of IP rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technical knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."24 Similarly, Article 66.2 also mandates the developed countries to transfer technologies to LDCs to enable them to create a sound and viable technological base. The LMICs opened their markets and amended domestic patent laws favouring developing countries’ products against this promise of technology transfer. Another argument against the proposed TRIPS waiver is that a waiver would not increase the manufacturing of COVID-19 vaccines. Indeed, one of the significant factors contributing to vaccine inequity is the lack of manufacturing capacity in the global south. Further, a TRIPS waiver will not automatically translate into improved manufacturing capacity. However, a waiver would be the first but essential step to increase manufacturing capacity worldwide. For instance, to export COVID-19 vaccine-related products, countries need to ensure that there are no IP restrictions at both ends – exporting and importing. The market for vaccine materials includes consumables, single-use reactors bags, filters, culture media, and vaccine ingredients. Export blockages on raw materials, equipment and finished products harm the overall output of the vaccine supply chain. If there is no TRIPS restriction, more governments and companies will invest in repurposing their facilities. Similarly, the arguments such as that no other manufacturers can carry out the complex manufacturing process of COVID-19 vaccines and generic manufacturing as that would jeopardise quality, have also been proven wrong in the past. For instance, in the early 1990s, when Indian company Shantha Biotechnics approached a Western firm for a technology transfer of Hepatitis B vaccine, the firm responded that “India cannot afford such high technology vaccines… And even if you can afford to buy the technology, your scientists cannot understand recombinant technology in the least.”25 Later, Shantha Biotechnics developed its own vaccine at $1 per dose, and the UNICEF (United Nations Children’s Emergency Fund) mass inoculation programme uses this vaccine against Hepatitis B. In 2009, Shantha sold over 120 million doses of vaccines globally. India also produces high-quality generic drugs for HIV/AIDS and cancer treatment and markets them across the globe. Now, a couple of Indian companies are in the last stage of producing mRNA (Messenger RNA) vaccines.26 Similarly, Bangladesh and Indonesia claimed that they could manufacture millions of COVID-19 vaccine doses a year if pharmaceutical companies share the know-how.27 Recently, Vietnam also said that the country could satisfy COVID-19 vaccine production requirements once it obtains vaccine patents.28 Countries like the United Arab Emirates (UAE), Turkey, Cuba, Brazil, Argentina and South Korea have the capacity to produce high-quality vaccines but lack technologies and know-how. However, Africa, Egypt, Morocco, Senegal, South Africa and Tunisia have limited manufacturing capacities, which could also produce COVID-19 vaccines after repurposing. Moreover, COVID-19 vaccine IPR runs across the entire value chain – vaccine development, production, use, etc. A mere patent waiver may not be enough to address the issues related to its production and distribution. What is more important here is to share the technical know-how and information such as trade secrets. Therefore, the existing TRIPS flexibilities, such as compulsory and voluntary licensing, are insufficient to address this crisis. Further, compulsory licensing and the domestic legal procedures it requires is cumbersome and not expedient in a public health crisis like the COVID-19 pandemic.

#### 3. Failure to contain COVID-19 causes extinction

Guy R. **McPherson, PhD, 20** [PhD Range Science, Professor Emeritus, University of Arizona School of Natural Resources and Department of Ecology & Evolutionary Biology], “Will COVID-19 Trigger Extinction of All Life on Earth?” Eart & Envi Scie Res & Rev, Volume 3 Issue 2, 4-8-2020, <https://opastonline.com/wp-content/uploads/2020/04/will-covid-19-trigger-extinction-of-all-life-on-earth-eesrr-20-.pdf>

Small lives matter. Indeed, the “human body contains about 100 trillion cells, but only maybe one in 10 of those cells is actually — human” [1]. We are comprised of bacteria and other tiny living organisms, as well as non-living entities such as viruses. One such virus has captured the attention of the world, and with good reason. **The novel coronavirus could trigger extinction of humans, and therefore the extinction of all life on Earth**. I frequently hear and read that COVID-19 is a nefarious attempt by the so-called “elite” among us to depopulate the burgeoning human population on Earth. Other conspiracy theories abound, including COVID-19 as an attempt to further reduce human rights, promote expensive medical therapies, and otherwise enrich the wealthy at the expense of the bamboozled masses. I do not doubt the ability of the informed wealthy to fleece the ignorant masses. Nor do I doubt the ability of the informed wealthy to turn virtually any situation into an opportunity for monetary gain. A quick glance at the past two centuries provides plenty of examples. However, I doubt the monetarily wealthy among us are interested in accelerating human extinction, even for financial gain. As I explain below, **the ongoing reduction in industrial activity as a result of COVID-19 almost certainly leads to loss of habitat for human animals, hence putting us on the fast track to human extinction**. I doubt the knowledgeable “elite” are interested in altering the sweet deal they are experiencing with the current set of living arrangements. The aerosol masking effect, or global dimming, has been described in the peer-reviewed literature since at least 1929 [2, 3]. **Coincident with industrial activity adding to greenhouse gases that warm the planet, industrial activity simultaneously cools the planet by adding aerosols to the atmosphere. These aerosols block incoming sunlight, thereby keeping cool our pale blue dot. Reducing industrial activity by as little as 35 percent is expected to cause a global-average temperature rise of 1 degree Celsius within a few weeks**, according to research on the aerosol masking effect [4]. Such research was deemed collectively too conservative by a paper in the 17 January 2019 issue of Science [5]. As pointed out by the lead author of the latter paper on 22 January 2019 “Global efforts to improve air quality by developing cleaner fuels and burning less coal could end up harming our planet by reducing the number of aerosols in the atmosphere, and by doing so, diminishing aerosols’ cooling ability to offset global warming” [6].

The cooling effect is “nearly twice what scientists previously thought,” and the paper by Rosenfeld et al. [5] cites the conclusion by Levy et al. [4], indicating as little as 35% reduction in industrial activity drives a 1 C global-average rise in temperature, thereby suggesting that as little as a 20% reduction in industrial activity will drive a 1 C spike in temperature within a few weeks [7]. Additional, recent support for the importance of the aerosol masking effect comes from [8, 9]. Furthermore, loss of aerosols exacerbates heat waves [10]. Human extinction might have been triggered several years ago when the global-average temperature of Earth exceeded 1.5 C above the 1750 baseline. According to a comprehensive overview published by European Strategy and Policy Analysis System in April, an “increase of 1.5 degrees is the maximum the planet can tolerate; … at worst, [such a rise in temperature above the 1750 baseline will cause] the extinction of humankind altogether” [11, 12]. Earth’s global-average temperature hit 1.73 C above the 1750 baseline by April, 2018 the highest global-average temperature experienced by Homo sapiens on Earth [13, 14].

By 13 March 2020, 2 C above the 1750 baseline was crossed [11]. In other words, human extinction via the death-by-a-thousandcuts route might be locked in with no further heating of Earth. In light of the ongoing pandemic, the ongoing Mass Extinction Event, and abrupt, irreversible climate change, it is pleasantly surprising that humans still occupy Earth. The pandemic-induced reduction in industrial activity may have already reduced the aerosol masking effect sufficiently to trigger a 1 C temperature spike. The outcome is not yet obvious because the timing of the outbreak of the novel coronavirus was favorable for human habitat. Trees produced leaves in the Northern Hemisphere spring of 2020 as a result of carbohydrates stored the previous year and grain crops were harvested before the novel coronavirus emerged. Results of the recent and ongoing rise in temperature, which have already been reported in China and India, will become obvious to most humans when many more trees die. Large-scale die-off of trees likely will approximately correspond with catastrophic crop failure. This might occur by the end of this year, although I would rather it not. **Every civilization requires bread and circuses**. There is little doubt **the circuses attendant to industrial civilization will continue until the end of the planetary show for Homo sapiens. Bread, however, requires wheat. Wheat production requires a delicate balance of growing conditions that, like habitat for humans, teeters on the brink** [15]. **The path to near-term human extinction thus runs from a tiny virus underlying a pandemic through a reduction of industrial activity that overheats a planet already running a fever**.

**The outbreak of COVID-19 could very well be the event that accelerates human extinction via reduction of industrial activity, hence loss of habitat for Homo sapiens. As a result of the rapid environmental change likely to follow, we are almost certain to lose all life on Earth** [16]. History is replete with examples of human hubris. We thought we were mighty, and we certainly have left our mark on Earth. **How embarrassing for the big-brained human species that a microscopic virus could pull the trigger on our extinction** [15].

#### Plan: Member nations of the World Trade Organization ought to reduce intellectual property protections for medicines for COVID-19

#### Communication from India and South Africa to the WTO 20

(WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION,

CONTAINMENT AND TREATMENT OF COVID-19 <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>, 10-2)

5. An effective response to COVID-19 pandemic requires rapid access to affordable medical products

including diagnostic kits, medical masks, other personal protective equipment and ventilators, as

well as vaccines and medicines for the prevention and treatment of patients in dire need.

6. The outbreak has led to a swift increase in global demand with many countries facing acute

shortages, constraining the ability to effectively respond to the outbreak. Shortages of these

products has put the lives of health and other essential workers at risk and led to many avoidable

deaths. It is also threatening to prolong the COVID-19 pandemic. The longer the current global crisis

persist, the greater the socio-economic fallout, making it imperative and urgent to collaborate

internationally to rapidly contain the outbreak.

7. As new diagnostics, therapeutics and vaccines for COVID-19 are developed, there are significant

concerns, how these will be made available promptly, in sufficient quantities and at affordable price

to meet global demand. Critical shortages in medical products have also put at grave risk patients

suffering from other communicable and non-communicable diseases.

8. To meet the growing supply-demand gap, several countries have initiated domestic production

of medical products and/or are modifying existing medical products for the treatment of COVID-19

patients. The rapid scaling up of manufacturing globally is an obvious crucial solution to address the

timely availability and affordability of medical products to all countries in need.

9. There are several reports about intellectual property rights hindering or potentially hindering

timely provisioning of affordable medical products to the patients.3

It is also reported that some

WTO Members have carried out urgent legal amendments to their national patent laws to expedite

the process of issuing compulsory/government use licenses.

10. Beyond patents, other intellectual property rights may also pose a barrier, with limited options

to overcome those barriers. In addition, many countries especially developing countries may face

institutional and legal difficulties when using flexibilities available in the Agreement on Trade-Related

Aspects of Intellectual Property Rights (TRIPS Agreement). A particular concern for countries with

insufficient or no manufacturing capacity are the requirements of Article 31bis and consequently the

cumbersome and lengthy process for the import and export of pharmaceutical products.

11. Internationally, there is an urgent call for global solidarity, and the unhindered global sharing

of technology and know-how in order that rapid responses for the handling of COVID-19 can be put

in place on a real time basis.

12. In these exceptional circumstances, we request that the Council for TRIPS recommends, as

early as possible, to the General Council a waiver from the implementation, application and

enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement in relation to prevention,

containment or treatment of COVID-19.

13. The waiver should continue until widespread vaccination is in place globally, and the majority

of the world's population has developed immunity hence we propose an initial duration of [x] years

from the date of the adoption of the waiver.

14. We request that the Council for TRIPS urgently recommends to the General Council adoption of

the annexed decision text.

#### Contention 2: Solvency

#### 1. Critics of the IP waiver are wrong- it’s the most effective way to combat covid inequality, alternatives fail

Erfani et al, 21

(Parsa Erfani, Fogarty global health scholar1 2, Agnes Binagwaho, vice chancellor2, Mohamed Juldeh Jalloh, vice president3, Muhammad Yunus, chair4, Paul Farmer, professor57, Vanessa Kerry, associate professor810 Harvard Medical School, Boston, USA 2University of Global Health Equity, Rwanda 3Sierra Leone 4Yunus Centre, Bangladesh 5Global Health and Social Medicine, Harvard Medical School, Boston, USA 6Division of Global Health Equity, Brigham and Women’s Hospital, USA 7Partners In Health, USA 8Seed Global Health, USA 9Program in Global Public Policy and Social Change, Harvard Medical School, Boston, USA 10Division of Pulmonary and Critical Care Medicine, Massachusetts General Hospital, USA Intellectual property waiver for covid-19 vaccines will advance global health equity BMJ 2021; 374 doi: https://doi.org/10.1136/bmj.n1837 (Published 03 August 2021) Cite this as: BMJ 2021;374:n1837 https://www.bmj.com/content/374/bmj.n1837.full) The barrier to adequate vaccine supply today is not lack of vaccine options, nor even theoretical production capacity; the problem is the intellectual property (IP) protection governing production and access to vaccines—and ultimately, the political and moral will to waive these protections in a time of global crisis. Without such liberty, there will not be enough vaccine fast enough to prevent the spread of variants, the avoidable deaths, and the continued choking of low and middle income countries (LMICs) through poor health. Beyond donor based models of global vaccine equity As covid-19 became a pandemic, global efforts emerged to help ensure vaccines would be delivered across the globe to the highest risk populations. One of the first was Covax, a risk sharing mechanism in which countries, tiered by means, contribute to collectively source and equitably distribute vaccines globally. The effort, however laudable in intent, has been undercut by vaccine scarcity and underfunding. Covax aims to vaccinate 20% of the population in 92 low and middle income countries by the end of 2021. At the end of April, however, it had shipped only one fifth of its projected estimates and lacked critical resources for distribution.3 LMICs are wary about participating in well worn dynamics of global health aid. Instead, they are mobilising to overcome the fundamental paucity of available vaccines by challenging established global IP rules. At issue is the 1995 Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which established minimum protection standards for IP—including patents, industrial designs, trade secrets, and copyright—that all 164 members of the World Trade Organization (WTO) must respect.5 Subsequent rulings (such as the Doha declaration) have strived to clarify safeguards on patents, including compulsory licensing, which allows governments to license patents to a third party without consent (table 1).6 Today, these rules provide strong IP protection for vaccine technologies and affect the quantity and location of vaccine production and availability. Table 1 Licensing of intellectual property View popupView inline In October 2020, South Africa and India submitted a proposal to the WTO to temporarily waive certain provisions of the TRIPS agreement for covid-19 health products and technologies. The waiver would prevent companies that hold the IP for covid-19 vaccines from blocking vaccine production elsewhere on the grounds of IP and allow countries to produce covid-19 medical goods locally and import or export them expeditiously (table 1). Although the proposed IP waiver is supported by over 100 countries, WTO has not reached a consensus on the proposal because of opposition and filibustering by several high income countries, including the UK, Germany, and Japan.7 Waiver opponents argue that the limited capacity of LMICs to produce complex covid-19 vaccines safely is the true barrier to global production, not IP. They suggest that the TRIPS waiver would penalise drug companies, stifle biomedical innovation, and deter future investments in research and development—in sum, that it would reduce returns on investment and dismantle an IP system that provided the goods needed to end the pandemic. Others are concerned that an IP waiver would fuel supply chain bottlenecks for raw materials and undermine ongoing production. Moreover, policy makers argue that a waiver is unnecessary as company driven voluntary licensing—in which companies decide when and how to license their technologies—and existing TRIPS flexibilities (such as country determined compulsory licensing) should suffice in establishing production in LMICs (table 1). They suggest that waiving IP for covid-19 vaccines would provide no meaningful progress, but the data do not support this. What effect would a waiver have? Contrary to detractors’ concerns about the possible effect of a temporary TRIPS waiver, global health analyses suggest that it will be vital to equitable and effective action against covid-19. LMIC’s manufacturing capabilities have been underestimated, even though several LMICs have the scientific and manufacturing capacity to produce complex covid-19 vaccines. India, Egypt, and Thailand are already manufacturing viral vector or mRNA-based covid-19 vaccines,8910 and vaccine production lines could be established within months in some other LMICs,11 offering substantial benefit in a pandemic that will last years.11 Companies in India and China have already developed complex pneumococcal and hepatitis B recombinant vaccines, challenging existing vaccine monopolies.12 The World Health Organization launched an mRNA technology transfer hub in April 2021 to provide the logistical, training, and know-how support needed for manufacturers in LMICs to repurpose or expand existing manufacturing capacity to produce covid-19 vaccines and to help navigate accessing IP rights for the technology.13 Twenty five respondents from LMICs expressed interest, and South Africa was selected as the first hub, with plans to start producing the vaccine through the Biovac Institute in the coming months.14 Removing IP barriers through the waiver will facilitate these efforts, more rapidly enable future hubs, engage a greater number of manufacturers, and ultimately yield more doses faster. Moreover, as the waiver facilitates vaccine production, demand for raw materials and active ingredients will increase. Coupled with pre-emptive planning to anticipate and expand raw material production, the waiver—which encompasses the IP of all covid-19 vaccine-related technology— can offer a path to overcome bottlenecks and expand production of necessary vaccine materials. Current licensing mechanisms inadequate Voluntary licences have not and will not keep pace with public health demand. Since companies determine the terms of voluntary licences, they are often granted to LMICs that can afford them, leaving out poorer regions.10 For example, in South Asia, AstraZeneca has voluntarily licensed its vaccine to the Serum Institute of India, even though the region has multiple capable vaccine manufacturers.9 Many covid-19 vaccine developers have not taken steps towards licensing their technologies, simply because there is limited financial incentive to do so.11 To date, none have shared IP protected vaccine information with the WHO Covid-19 Technology Access Pool (C-TAP) established last year.15 Relying on the moral compass of companies that answer to shareholders to voluntarily license their technologies will have limited effect on vaccine equity. Their market is driven by profit margins, not public health. Compulsory licensing by LMICs will also be insufficient in rapidly expanding vaccine production, as each patent licence must be negotiated separately by each country and for each product based on its own merit. From 1995 to 2016, 108 compulsory licences were attempted and only 53 were approved.6 The case-by-case approach is slow and not suitable for a global crisis that requires swift action. In addition, TRIPS requires compulsory licences to be used predominantly for domestic supply, limiting exports of the licensed goods to nearby low income countries without production capacity.5 Although a “special” compulsory licence system was agreed in the Doha declaration to allow for expeditious exportation and importation (formalised as the article 31bis amendment to TRIPS in 2017), the provision is limited by cumbersome logistical procedures and has been rarely used.16 Governments may also be hesitant to pursue compulsory licences as high income countries have previously bullied them for doing so. Since India first used compulsory licensing for sorafenib tosylate in 2012 (reducing the cancer drug’s price by 97%), the US has consistently pressured the country not to use further compulsory licences.17 During this pandemic, Gilead sued the Russian government for issuing a compulsory licence for remdesivir.18 Furthermore, while compulsory licences are primarily for patents, covid-19 vaccines often have other types of IP, including trade secrets, that are integral for production.19 The emergency TRIPS waiver removes all IP as a barrier to starting production (not just patents) and negates the prolonged time, inconsistency, frequent failure, and political pressure that accompany voluntary licensing and compulsory licensing efforts. It also provides an expeditious path for new suppliers to import and export vaccines to countries in need without bureaucratic limitations. Finally, there is no compelling evidence that the proposed TRIPS waiver would dismantle the IP system and its innovation incentives. The waiver is restricted to covid-19 related goods and is time limited, helping to protect future innovation. It would, however, reduce profit margins on current covid-19 vaccines. With substantial earnings in the first quarter of 2021, many drug companies have already recouped their research and development costs for covid-19 vaccines.20 However, they have not been the sole investors in vaccine development, and they should not be the only ones to profit. Most vaccines received a substantial portion of their direct funding from governments and not-for-profit organisations—and for some, such as Moderna and Novavax, nearly all.21 Decades of publicly funded research have laid the groundwork for current innovations in the background technologies used for vaccines.22 Given that companies were granted upfront risk protection for covid-19 vaccine research and development, a waiver that advances global public health but reduces vaccine profits in a global crisis is reasonable. Knowledge transfer An IP waiver for covid-19 vaccines is integral to boosting vaccine supply, breaking vaccine monopolies, and making vaccines more affordable in LMICs.

It is, however, only a first, but necessary, step. Originator companies must transfer vaccine technology and share know-how with C-TAP, transfer hubs, or individual manufacturers to help suppliers begin production.23 In addition, governments must leverage domestic law, private sector incentives, and contract terms with pharmaceutical companies to compel companies to cooperate with such transfers.24 If necessary, governments can require technology transfers in exchange for continuing enterprise in a country or avoiding penalties. Politicians and leaders are at a critical juncture: they will either take the necessary steps to make vaccine technology available to scale production, stimulate global collaboration, and create a path to equity or they will protect a hierarchical system based on an economic bottom line. The former will not only build a vaccination trajectory that puts equal value on the lives of the rich and the poor, but will also help stem the pandemic’s relentless momentum and quell the emergence of variants. We are in the middle of one of the largest vaccination efforts in human history. We cannot rely on companies to thread the needle of corporate social and moral responsibility with shareholder and stock value returns nor expect impacted governments to endure lengthy bureaucratic licensing processes in this time of crisis. It will be a legacy of apathy and unnecessary death. As the human impact of the proposed IP waiver becomes clear, consensus behind it is growing. Countries that previously opposed the waiver—such as the US and Brazil—now support written text based negotiations.7 Opposing countries must stop blocking the waiver, engage in transparent text negotiations, and commit to reaching consensus swiftly. The longer states stall, the more people die needlessly. Covid-19 has repeatedly shown that people without access to resources such as strong health systems, health workers, medicines, and vaccines will preferentially fall ill and die. For too long, this cycle has been “other people’s” problem. It is not. It is our problem.