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#### Vaccine nationalism and profit driven incentives runs IP laws – covid and AIDS proves

Miriam Berger, 2-23-2021, Berger attended Wesleyan University, BA in College Social Studies; Oxford University, MPhil in Modern Middle Eastern Studies, "Global vaccine inequality runs deep. Some countries say intellectual property rights are part of the problem.," Washington Post, <https://www.washingtonpost.com/world/2021/02/20/poor-countries-arent-getting-vaccines-waiving-intellectual-property-rights-could-help/> //Eagan AE

As the coronavirus pandemic rages, World Trade Organization representatives have periodically gathered around a virtual table and clashed over how to more equitably increase global access to vaccines. On one side are the United States and other mainly wealthy Western democracies, where the major pharmaceutical companies developing key vaccines and related medical technologies are based. They want to maintain the status quo, in which the trade secrets of their vaccines — i.e., intellectual property — remain in their hands to preserve profits and the incentive for future development. On the other side are South Africa and India, leading the charge on behalf of the vast number of countries without any — or a limited supply of — vaccine doses and other equipment for fighting the virus. They argue that the rest of the world cannot keep waiting for the lifesaving shots, which Western countries have monopolized by buying up existing supplies and pre-purchasing future rounds.

The zero-sum vaccine game: How a dose in the U.S. takes a dose away from a poorer country

Given the gravity of the global public health crisis, the latter camp wants to resort to an emergency waiver mechanism, whereby the intellectual property rights for making vaccines and related medical supplies would be temporarily suspended, which in theory would lead to production and distribution ramping up more equitably in factories worldwide. It’s a hyper-technical issue — turning on interpretation of TRIPS, the WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights — and it’s heavy in symbolism for developing countries increasingly alarmed by a race to vaccinate that is stacked against them. In the immediate term, waiving intellectual property rights alone cannot fix the problem of vaccine inequities and shortages. But, drawing on lessons learned during the HIV/AIDS crisis, experts said it could have far-reaching implications by preventing subsequent scarcities and sending a signal now about the imperative of collective action. “Developing countries are already fed up with what they perceive as the selfishness of the West buying up all of the demand and [that] they’ve got to get to the back to the queue,” said David Fidler, adjunct senior fellow for cybersecurity and global health at the Council on Foreign Relations. Now, he said, “they are having these sort of ridiculous conversations at the WTO about how to deal with this debacle for humanity.” Meanwhile, he added, “inequitable vaccine access is just going to get worse.” Moderna agreed to ‘equitable access’ for its coronavirus vaccine, but most of its doses are going to wealthy countries Anthony S. Fauci, President Biden’s chief medical adviser on the coronavirus, told a virtual World Health Organization briefing Monday that the impasse is “a very sensitive issue but an issue that I think really does need to be addressed.” Citing compromises that countries and companies reached during the AIDS epidemic, he expressed support for similar action but not for any specific proposal. “I’m not sure exactly what the model will be, but I think at least we do have some precedent that you can make arrangements with companies that would allow them both to maintain a considerable amount of profit at the same time that areas of the world that don’t have resources can share in a way that would be lifesaving to literally millions of people,” he said.

Lessons from the AIDS epidemic

When the WTO was formed in 1995, public health experts worried that many of the global agency’s agreements would empower private companies and ultimately harm public health. Over time, various sides largely worked out their differences, Fidler said, except when it came to intellectual property, which he called a “a festering sore.” That sore proved lethal during the HIV/AIDS crisis. By the 1990s, antiviral drugs were available to combat infections, but restrictions on production because of patent rules kept them far too expensive for most infected people in sub-Saharan Africa to access. In 2001, a deal was finally reached. Called the Doha Declaration, it clarified “that the TRIPS Agreement does not and should not prevent member governments from acting to protect public health,” according to the WTO. The amendments specified that countries could seek compulsory licensing — a way for a government to waive intellectual property rights without the patent owner’s consent — in cases of national or other extreme emergencies. It also laid out mechanisms for the companies to still receive compensation. The Doha Declaration helped lower the cost of lifesaving HIV/AIDS medications for the hardest-hit victims. Along with the President’s Emergency Plan for AIDS Relief (PEPFAR), a U.S. program that was passed in 2003, these collective actions started to turn the tide on a treatable disease upending the lives of millions of people in less wealthy countries. The WTO’s action set a precedent, said Yuan Qiong Hu, legal adviser for the Doctors Without Borders Access Campaign, which is advocating for the WTO coronavirus waiver. But countries with the power to enact change acted too late for too many, dragging their feet on lowering prices. “If they took action earlier, it could have been even better. We could have maybe saved more lives,” she said. “It’s purely a matter of political will to recognize the challenges.”

Vaccine poverty

The coronavirus pandemic, unlike the AIDS epidemic, is not centered in low-income countries. Rather, it’s affecting all countries simultaneously scrambling for the same resources. That’s why Mustaqeem De Gama, an intellectual property expert and South Africa’s WTO representative, said it’s time for the global trade agency to act to ensure that “inappropriate use of intellectual property” doesn’t lead to “an artificial scarcity of supply.” TRIPS, he said, recognizes that every country has the right “to ensure that its citizens have access to necessary medicines, equipment and technology that will address covid-19.” He said a WTO waiver would reinforce that principle and allow countries to prepare to start their own production rather than having to wait until richer countries fill their vaccine orders first. “The ability to pay shouldn’t be the determinant for access,” Hu said. WTO action instead could “allow countries to prepare to produce and share resources.” A spokesperson for U.S. Trade Representative Adam Hodge said in an email that the Biden administration “is exploring every avenue to coordinate with our global partners and are evaluating the efficacy of this specific proposal by its true potential to save lives.” Vaccines have never been distributed equally. A coronavirus vaccine would be no different, history suggests. In terms of official tallies of coronavirus infections and deaths, Africa overall has not been as hard hit as Europe and North America, although South Africa has been the exception as the continent’s epicenter. But De Gama said that fact alone presents an incomplete picture of the pandemic’s effect on people in countries without adequate medical resources or government relief during the pandemic. Now added to the list: unattainable coronavirus vaccine doses. From a public health standpoint, De Gama said, this also poses a global danger. “It’s not the case where rich countries could insulate themselves by vaccinating the entire population and not care about what happens with the rest of the world,” he said. The global threat is even greater, he added, given that “we now have variants, and these variants come about because of the transmission of the virus among millions of people.” Fidler, however, disagreed that intellectual property rights represent an immediate impediment to vaccine access. In the short term, he said, the issue is not simply that production is constrained because only certain companies, and under certain restrictions, can make vaccines. Rather, it’s that Western countries have monopolized current and future supplies by buying up and pre-purchasing doses at rates other countries cannot afford. But he said the WTO impasse remains worrying because it could push developing countries closer to the brink while further eroding U.S. standing. If the United States takes “a big and bold stand” — as it did with PEPFAR — “that could get us focused on the capabilities we need now and for the next crisis and restore some credibility” to U.S. pledges to help. Instead, he said, Washington appears to be hemmed in by domestic pressures and sticking to an us-against-them stance in the WTO as the world faces “a colossal debacle for human health.” “It’s like 1995 again,” Fidler said, referring to the HIV/AIDS epidemic. “What is going on here?”

#### Covid proves countries can produce their own vaccine – ending IP laws solves

Public Citizen, 3-29-2021, Public Citizen is a nonprofit consumer advocacy organization that champions the public interest in the halls of power, "Waiver of the WTO's Intellectual Property Rules: Facts vs. Common Myths," <https://www.citizen.org/article/waiver-of-the-wtos-intellectual-property-rules-myths-vs-facts/> //Eagan AE

In the press and on Capitol Hill, Big Pharma is pushing a Big Lie. The claim is that a lack of manufacturing capacity, not pharmaceutical corporation’s monopoly intellectual property (IP) protections, are thwarting greater production of COVID-19 vaccines. A related argument, with decidedly racist overtones, is that COVID-19 vaccines are too complicated for producers in developing countries to make successfully. The reality is that in every region of the world, there are multiple producers that could be greatly increasing global vaccine supplies if the technology and know-how were shared. Just in Africa, “Biovac and Aspen in South Africa, Institute Pasteur in Senegal, and Vacsera in Egypt could rapidly retool factories to make mRNA vaccines,” notes a group of medicine-production experts in a recent Foreign Policy article. Indeed, a former Moderna director of chemistry revealed that with enough technology transfer and know- how-sharing, a modern factory should be able to get mRNA vaccine production online in, at most, three to four months. The Serum Institute in India already is slated to produce the AstraZeneca and Novavax vaccines, while Moderna declined to partner with a qualified Bangladeshi vaccine maker, claiming its engineers were too busy to focus beyond U.S. and EU production. In Latin America, existing facilities in Brazil, Argentina and Mexico under contract to monopoly holders are already pumping out vials, and in countries like Chile and Colombia, the pharmaceutical industry has expressed willingness to kickstart vaccine production. Existing and planned contract manufacturing arrangements prove facilities in developing countries certainly can produce COVID-19 vaccines. But unless technology and know-how are shared more openly, the monopoly holders maintain absolute control over how much can be produced, what the price is and where it will be sold. So, 91% of the Johnson & Johnson vaccine that South African firm Aspen will manufacture must be shipped for sale outside South Africa, according to South Africa’s WTO Counselor. And the Serum Institute is barred from supplying upper- middle-income and high-income countries with the AstraZeneca vaccines it makes, meaning AstraZeneca can artificially segment the global market and ensure that it is the only supplier of the Oxford vaccine in the most profitable national markets, according to Doctors Without Borders. Most critically, there simply is not enough supply to go around now or for every year in the future during which the whole world will need regular COVID vaccination to keep the virus under control. Thankfully, scores of countries are ready to invest in building new or repurposing existing production capacity. That is why more than 100 countries support a waiver of the WTO’s Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). These countries seek certainty that if they adjust their domestic laws and practices to support that investment by providing access to the necessary technology, they will not get dragged into expansive WTO litigation or face retaliatory sanctions from countries claiming WTO violations. The waiver will also serve as a worldwide buffer against the political pressure and legal harassment to which Big Pharma subjects countries that seek to promote affordable access to medicines. In many countries, the regulatory authorities that had to approve domestic use of various vaccines and other COVID-related medical products have significant information from the firms that they could share with skilled teams from local universities, government agencies and pharmaceutical manufacturers — if they were not obliged by WTO rules to guarantee monopoly control of it. And world-class pharmaceutical firms already are making generic versions of new cutting-edge HIV-AIDS medicines and pumping out vaccines based on the platform that, for instance, the Johnson & Johnson vaccine uses.

#### **Waiving for COVID spills up and creates precedent**

Brink Lindsey, 6-3-2021, Brink Lindsey is the VP of the Niskanen Center a nonpartisan think tank, "Why intellectual property and pandemics don’t mix," Brookings, <https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/> // Eagan AE

Furthermore, and probably even more important, this is almost certainly not the last pandemic we will face. Urbanization, the spread of factory-farming methods, and globalization all combine to increase the odds that a new virus will make the jump from animals to humans and then spread rapidly around the world. Prior to the current pandemic, the 21st century already saw outbreaks of SARS, H1N1, MERS, and Ebola. Everything we do and learn in the current crisis should be viewed from the perspective of getting ready for next time. THE NATURE OF THE PATENT BARGAIN When we take the longer view, we can see a fundamental mismatch between the policy design of intellectual property protection and the policy requirements of effective pandemic response. Although patent law, properly restrained, constitutes one important element of a well-designed national innovation system, the way it goes about encouraging technological progress is singularly ill-suited to the emergency conditions of a pandemic or other public health crisis. Securing a TRIPS waiver for COVID-19 vaccines and treatments would thus establish a salutary precedent that, in emergencies of this kind, governments should employ other, more direct means to incentivize the development of new drugs. Here is the basic bargain offered by patent law: encourage the creation of useful new ideas for the long run by slowing the diffusion of useful new ideas in the short run. The second half of the bargain, the half that imposes costs on society, comes from the temporary exclusive rights, or monopoly privileges, that a patent holder enjoys. Under U.S. patent law, for a period of 20 years nobody else can manufacture or sell the patented product without the permission of the patent holder. This allows the patent holder to block competitors from the market, or extract licensing fees before allowing them to enter, and consequently charge above-market prices to its customers. Patent rights thus slow the diffusion of a new invention by restricting output and raising prices.

1. **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, IDSA, “WTO TRIPS Waiver and COVID-19 Vaccine Equity”, <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. Allowing 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 worldwid**e. 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.

#### Pandemics are only increasing – and getting more deadly – ending IP laws is necessary

Robert Roy **Britt 1/19** [Independent health and science journalist, former editor-in-chief of LiveScience, writing about how we age and how to optimize your mind and body through time. "This Pandemic Is Not Even the ‘Big One’" Elemental, January 19, 2021 https://elemental.medium.com/this-pandemic-is-not-even-the-big-one-df8660da2564]

As bad as Covid-19 seems, the world has grown increasingly vulnerable to an even deadlier global outbreak that experts expect is inevitable.  It’s unclear when and where a more aggressive pathogen will emerge, but scientists say it will almost surely threaten an even worse pandemic than Covid-19. “This pandemic has been very severe, has spread around the world extremely quickly, it has affected every corner of this planet. But this is not necessarily the big one,” says Mike Ryan, MD, an expert on emerging epidemics and executive director of the Emergencies Program at the World Health Organization (WHO). “This virus is very transmissible,” Ryan says. “But its current case fatality rate is reasonably low in comparison to other emerging diseases. This is a wake-up call.” Other infectious disease experts agree. “While Covid-19 has been terrible, what is more concerning is a virus that would be both highly transmissible and more virulent than SARS-CoV-2 has been to date,” says Tara C. Smith, PhD, a professor of infectious disease epidemiology at Kent State University. Importantly, the global community — and particularly the United States — won’t be prepared to battle the “big one” unless more is invested in research and preparedness and, critically, if we don’t collectively learn from the history we’re currently living through. think the United States’ response to SARS-CoV-2 shows that pretty dramatically,” Smith tells Elemental. “Other places have done better — such as South Korea, Australia, New Zealand — but globally, response overall has been dire.” A spectrum of virulence There are some 1.6 million known viruses circulating in animals. At least 600,000 of them have the potential to cross the species barrier and infect humans. Concern is fueled by outdoor markets in parts of Asia — though these are increasingly being banned — and also by burgeoning populations near areas of dense wildlife. . “The sharing of space between wildlife and humans, and their domesticated animals, has dramatically increased in recent decades and is a key driver of pathogen spillover,” researchers write in a December study in One Health. Air travel to and from cities in or near animal-human interfaces makes global spread all but inevitable, they say. “Increasing animal-human interface has also occurred in concert with both increasing globalization and failing health systems, resulting in a trifecta with dire implications for human and animal health.” The fear is not far-fetched. “A new pathogen with substantial potential for human harm is discovered every year, on average,” says Tom Frieden, MD, former director of the U.S. Centers for Disease Control and Prevention. “Covid-19 is the latest but far from the last health emergency the world will face.” Coronaviruses exemplify the range of threats from just one type of pathogen. At one end of the virulence spectrum, some common colds are caused by coronaviruses yet rarely bring severe symptoms or death. Covid-19 is thought to kill around 2% of those known to be infected, but this “case fatality rate” is grossly misleading. A large yet unknown number of people have had the disease with mild or no symptoms and were never diagnosed, so the actual “death rate,” when calculated using the true total case count, is lower; the case fatality rate varies dramatically by age — around 0.01% at age 25 and 15% at age 85, according to one study. Mortality for two other coronaviruses was much worse and more mathematically definitive, because both caused mostly symptomatic cases, so the case fatality rate was roughly in line with the actual death rate. A 2003 outbreak of a coronavirus (named SARS-CoV) killed about 10% of all those who contracted it and did not discriminate much between young and old. Emerging in 2012, a coronavirus causing a disease dubbed MERS kills around 35% of its victims.

#### Pandemics exacerbate racial disparities -- COVID proves

**Wen and Sadeghi 20** [Wen, Leana, and Nakisa Sadeghi. "Addressing racial health disparities in the COVID-19 pandemic: immediate and long-term policy solutions." Health Affairs (July 20, 2020). https://www.healthaffairs.org/do/10.1377/hblog20200716.620294/full/]

The devastating impact of COVID-19 is apparent, with nearly three million confirmed cases and more than 131,000 deaths in the US. Among those affected, communities of color bear the brunt of the pandemic. Health disparities in the COVID-19 crisis call attention to long-standing inequities that pervade the health care system and society at large. This post will present a framework for understanding health disparities during the COVID-19 pandemic, as well as provide short-term and long-term solutions to reduce these disparities. Acute On Chronic The pattern of disparities during the COVID-19 crisis is analogous to the medical concept of “acute on chronic.” This refers to a long-standing medical condition that is exacerbated by an acute illness, often leading to worse outcomes than would have resulted from the acute illness alone. This is the case for COVID-19: It is a novel disease and global pandemic that has unmasked long-standing underlying health disparities. New federal data reveals that African Americans and Latinos in the US have been three times more likely to contract COVID-19 than white residents and nearly twice as likely to die from it. Some counties with a majority of African American residents have almost six times the death rate compared to counties that are predominantly white. In some states such as Illinois, Latinos have nearly seven times the rate of COVID-19 cases compared to white people, while African Americans have the highest death rate. In California, Pacific Islanders face a death rate from COVID-19 that is 2.6 times higher than the rest of the state, while in South Dakota, the rate of COVID-19 among Asian Americans is six times what would be predicted based on their share of the population. Other minority communities are also disproportionately affected, including in New Mexico, where Native American people comprise about 11 percent of the population yet account for more than half of COVID-19 cases. Health disparities during COVID-19 reflect two important patterns of inequity. First, minority communities have a high likelihood of contracting the virus by living in urban areas and disproportionately working in higher-risk environments. According to data from the Bureau of Labor Statistics, a greater number of African American workers are unable to work from home, compared to white workers. A study of the “Mission District” community in California showed that Latinos accounted for more than 95 percent of positive COVID-19 cases and 90 percent of individuals with positive tests were unable to work from home. Certain industries that have workers that are predominantly minorities face higher rates of COVID-19: At meatpacking plants, where the rate of COVID-19 infections is higher than the rate in 75 percent of US counties, nearly half of workers are Hispanic and a quarter are African American. Second, racial minorities also experience higher rates of chronic medical conditions, including obesity, diabetes, and kidney disease, which are risk factors for severe illness from COVID-19. These statistics occur on a backdrop of existing disparities in outcomes: For example, African Americans have higher rates of maternal mortality and death from cancer and heart disease than any other racial and ethnic group. Individuals from underserved communities are also more likely to have undiagnosed chronic disease, compounding the acute impact of COVID-19. These inequities are tied to long-standing barriers to accessing essential resources such as food, transportation, and housing, as well as a long history of unequal treatment, discriminatory policies, and systemic racism.

#### Pandemics are an existential threat

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In 2003 a doctor with SARS unknowingly infected several guests while staying at a Hong Kong hotel, and overnight the virus reached across the globe. China is currently battling a bird flu that kills nearly half of the people infected. If Ebola, which transmits through fluids, were spread by air, or if Zika, which has reached over 50 countries, were as deadly as Ebola, we would be facing an unprecedented catastrophe. An uncontrolled outbreak or bioterror attack could result in a contagion that kills over 30 million people. We fear it is only a matter of time before we face a deadlier and more contagious pathogen, yet the threat of a deadly pandemic remains dangerously overlooked. Pandemics now occur with greater frequency, due to factors such as climate change, urbanization, and international travel. Other factors, such as a weak World Health Organization and potentially massive cuts to funding for U.S. scientific research and foreign aid, including funding for the United Nations, stand to deepen our vulnerability. We also face the specter of novel and mutated pathogens that could spread and kill faster than diseases we have seen before. With the advent of genome-editing technologies, bioterrorists could artificially engineer new plagues, a threat that Ashton Carter, the former U.S. secretary of defense, thinks could rival nuclear weapons in deadliness. The two of us have advised the president of Guinea on stopping Ebola. In addition, we have worked on ways to contain the spread of Zika and have informally advised U.S. and international organizations on the matter. Our experiences tell us that the world is unprepared for these threats. We urgently need to change this trajectory. We can start by learning four lessons from the gaps exposed by the Ebola and Zika pandemics. Faster Vaccine Development The most effective way to stop pandemics is with vaccines. However, with Ebola there was no vaccine, and only now, years later, has one proven effective. This has been the case with Zika, too. Though there has been rapid progress in developing and getting a vaccine to market, it is not fast enough, and Zika has already spread worldwide. Many other diseases do not have vaccines, and developing them takes too long when a pandemic is already under way. We need faster pipelines, such as the one that the Coalition for Epidemic Preparedness Innovations is trying to create, to preemptively develop vaccines for diseases predicted to cause outbreaks in the near future. Point-of-Care Diagnostics Even with such efforts, vaccines will not be ready for many diseases and would not even be an option for novel or artificially engineered pathogens. With no vaccine for Ebola, our next best strategy was to identify who was infected as quickly as possible and isolate them before they infected others. Because Ebola’s symptoms were identical to common illnesses like malaria, diagnosis required laboratory testing that could not be easily scaled. As a result, many patients were only tested after several days of being contagious and infecting others. Some were never tested at all, and about 40% of patients in Ebola treatment centers did not actually have Ebola. Many dangerous pathogens similarly require laboratory testing that is difficult to scale. Florida, for example, has not been able to expand testing for Zika, so pregnant women wait weeks to know if their babies might be affected. What’s needed are point-of-care diagnostics that, like pregnancy tests, can be used by frontline responders or patients themselves to detect infection right away, where they live. These tests already exist for many diseases, and the technology behind them is well-established. However, the process for their validation is slow and messy. Point-of-care diagnostics for Ebola, for example, were available but never used because of such bottlenecks. Greater Global Coordination We need stronger global coordination. The responsibility for controlling pandemics is fragmented, spread across too many players with no unifying authority. In Guinea we forged a response out of an amalgam of over 30 organizations, each of which had its own priorities. In Ebola’s aftermath, there have been calls for a mechanism for responding to pandemics similar to the advance planning and training that NATO has in place for its numerous members to respond to military threats in a quick, coordinated fashion. This is the right thinking, but we are far from seeing it happen. The errors that allowed Ebola to become a crisis replayed with Zika, and the WHO, which should anchor global action, continues to suffer from a lack of credibility. Stronger Local Health System International actors are essential but cannot parachute into countries and navigate local dynamics quickly enough to contain outbreaks. In Guinea it took months to establish the ground game needed to stop the pandemic, with Ebola continuing to spread in the meantime. We need to help developing countries establish health systems that can provide routine care and, when needed, coordinate with international responders to contain new outbreaks. Local health systems could be established for about half of the $3.6 billion ultimately spent on creating an Ebola response from scratch. Access to routine care is also essential for knowing when an outbreak is taking root and establishing trust. For months, Ebola spread before anyone knew it was happening, and then lingered because communities who had never had basic health care doubted the intentions of foreigners flooding into their villages. The turning point in the pandemic came when they began to trust what they were hearing about Ebola and understood what they needed to do to halt its spread: identify those exposed and safely bury the dead. With Ebola and Zika, we lacked these four things — vaccines, diagnostics, global coordination, and local health systems — which are still urgently needed. However, prevailing political headwinds in the United States, which has played a key role in combatting pandemics around the world, threaten to make things worse. The Trump administration is seeking drastic budget cuts in funding for foreign aid and scientific research. The U.S. State Department and U.S. Agency for International Development may lose over one-third of their budgets, including half of the funding the U.S. usually provides to the UN. The National Institutes of Health, which has been on the vanguard of vaccines and diagnostics research, may also face cuts. The Centers for Disease Control and Prevention, which has been at the forefront of responding to outbreaks, remains without a director, and, if the Affordable Care Act is repealed, would lose $891 million, 12% of its overall budget, provided to it for immunization programs, monitoring and responding to outbreaks, and other public health initiatives. Investing in our ability to prevent and contain pandemics through revitalized national and international institutions should be our shared goal. However, if U.S. agencies become less able to respond to pandemics, leading institutions from other nations, such as Institut Pasteur and the National Institute of Health and Medical Research in France, the Wellcome Trust and London School of Hygiene and Tropical Medicine in the UK, and nongovernmental organizations (NGOs have done instrumental research and response work in previous pandemics), would need to step in to fill the void. There is no border wall against disease. Pandemics are an existential threat on par with climate change and nuclear conflict. We are at a critical crossroads, where we must either take the steps needed to prepare for this threat or become even more vulnerable. It is only a matter of time before we are hit by a deadlier, more contagious pandemic. Will we be ready?

#### WTO flexibilities aren’t enough – nor are they designed for pandemics like covid

Public Citizen, 3-29-2021, Public Citizen is a nonprofit consumer advocacy organization that champions the public interest in the halls of power, "Waiver of the WTO's Intellectual Property Rules: Facts vs. Common Myths," <https://www.citizen.org/article/waiver-of-the-wtos-intellectual-property-rules-myths-vs-facts/> //Eagan AE

In the late 1990s, millions of people in developing countries were dying from AIDS because pharmaceutical firms refused to provide affordable access to the medicines that were saving those who could afford them. After needless millions died, a global campaign targeting the WTO finally forced the 2001 “Doha Declaration” that clarified flexibilities for governments to mitigate some negative impacts that intellectual property rules may have on public health. The flexibilities are largely premised on countries experiencing a public health emergency issuing compulsory licenses to override patents so that domestic companies can produce equivalent medicines. The flexibilities were not designed for – nor do they function effectively in – a global pandemic where vaccines and other critical technologies are protected by multiple forms of IP and where production relies on complex global supply chains. Indeed, pharmaceutical firms have made it harder to effectively use compulsory licensing by creating broader intellectual property “thickets” of numerous patents, copyrights, industrial design, undisclosed data and trade secrets protections for COVID-19 technologies – each of which would require a license. For instance, mRNA vaccines include 100-plus key components manufactured in over a dozen countries that may be subject to patents, in addition to copyright protections on software, algorithms and training material used to make the drugs and on storage and use guidelines as well as undisclosed data protections covering some trade secrets plus perhaps industrial design protections for key machinery used to mix lipids and genetic materials for mRNA vaccines. Non- mRNA vaccines that rely on biologic technologies to produce the active vaccine ingredient rely on secret, proprietary cell-lines. To develop markets attractive to new producers, multiple countries would have to try to coordinate national compulsory licensing strategies that would allow prospective producers to import the needed components, machinery and more. In contrast, a TRIPS waiver would simply clear the thorny IP thickets and related investment-chilling liabilities. But even then, the existing WTO flexibilities may not encompass elements of IP critical to COVID-19 vaccines and biologic medicines. Neither the TRIPS Agreement nor the “Doha Declaration” describes explicit mechanisms for easily overcoming trade secrets and undisclosed confidential information with respect to complex manufacturing processes, formulas, bespoke equipment, and biologic resources. Similarly, TRIPS copyright protections, which apply to software embedded in instrument-based diagnostics and other medical devices, in e- health technologies, and in production manuals and industrial blueprints, do not allow for easy override, nor are there such provisions for industrial designs. The compulsory licensing process for patents is cumbersome and slow under any circumstance, but the “product- by-product” and “country-by-country” compulsory licensing at the heart of the current TRIPS flexibilities are not suited to products relying on complex supply chains. In order to manufacture a “generic” COVID-19 mRNA vaccine using TRIPS flexibilities, the relevant producer would have to seek compulsory licenses for each IP-protected commodity in its country of manufacturer and export, which would require the compulsory licensing cooperation of the exporting country. It would likewise have to seek a compulsory license allowing for import of each such component and allowing for production of the vaccine. Restrictive WTO production-for-export rules make compulsory licensing in a global pandemic context even more complex and unworkable. Under WTO rules, compulsory licenses are to be issued predominately for the supply of the domestic market. WTO rules covering export of compulsory-licensed products to a country lacking its own production capacity are so complex that this flexibility has only been used once in the past 20 years. Finally, countries attempting to invoke the existing TRIPS flexibilities in the past have been subject to criticisms and trade pressures from the United States and the European Union in efforts to discourage them from doing so. The U.S. government 2020 Special 301 List explicitly targets countries seeking compulsory licenses with possible investigations and sanctions. The 2021 Special 301 submissions from industry include explicit attacks on compulsory licensing in the context of the COVID-19 pandemic.

#### And it doesn’t hurt innovation – in the case of PHE governments cover costs

Brink Lindsey, 6-3-2021, Brink Lindsey is the VP of the Niskanen Center a nonpartisan think tank, "Why intellectual property and pandemics don’t mix," Brookings, <https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/> //Eagan AE

The situation is different in a pandemic. Here the government knows exactly what it wants to incentivize: the creation of vaccines to prevent the spread of a specific virus and other drugs to treat that virus. Under these circumstances, the decentralized approach isn’t good enough. There is no time to sit back and let drug makers take the initiative on their own timeline. Instead, the government needs to be more involved to incentivize specific innovations now. As recompense for letting it call the shots (pardon the pun), the government sweetens the deal for drug companies by insulating them from commercial risk. If pharmaceutical firms develop effective vaccines and therapies, the government will buy large, predetermined quantities at prices set high enough to guarantee a healthy return. For the pharmaceutical industry, it is useful to conceive of patent law as the default regime for innovation promotion. It improves pharmaceutical companies’ incentives to develop new drugs while leaving them free to decide which new drugs to pursue – and also leaving them to bear all commercial risk. In a pandemic or other emergency, however, it is appropriate to shift to the direct support regime, in which the government focuses efforts on one disease. In this regime, it is important to note, the government provides qualitatively superior incentives to those offered under patent law. Not only does it offer public funding to cover the up-front costs of drug development, but it also provides advance purchase commitments that guarantee a healthy return. It should therefore be clear that the pharmaceutical industry has no legitimate basis for objecting to a TRIPS waiver. Since, because of the public health crisis, drug makers now qualify for the superior benefits of direct government support, they no longer need the default benefits of patent support. Arguments that a TRIPS waiver would deprive drug makers of the incentives they need to keep developing new drugs, when they are presently receiving the most favorable incentives available, can be dismissed as the worst sort of special pleading.

#### It directly questions liberal institutions and increases political will

Meyer, 6/18**/21,** Meyer, David [the Editor of CEO Daily and a senior writer on Fortune’s European team. Author of the digital rights primer, Control Shift: How Technology Affects You and Your Rights.] “The WTO’s survival hinges on the COVID-19 vaccine patent debate, waiver advocates warn,”, https://fortune.com/2021/06/18/wto-covid-vaccines-patents-waiver-south-africa-trips/ *Fortune,* June 18, 2021. AA

The World Trade Organization knows all about crises. Former U.S. President Donald Trump threw a wrench into its core function of resolving trade disputes—a blocker that President Joe Biden has not yet removed—**and there is widespread dissatisfaction over the fairness of the global trade rulebook. The** 164-country **organization**, under the fresh leadership of Nigeria's Ngozi Okonjo-Iweala, **has a lot to** fix. However, **one crisis is more pressing than** the **others**: the battle over COVID-19 vaccines, and whether the protection of their patents and other intellectual property should be temporarily lifted to boost production and end the pandemic sooner rather than later. According to some of those pushing for the waiver—which was originally proposed last year by India and South Africa—**the WTO's future rests on what happens next.** **"The credibility of the WTO will depend on its ability to find a meaningful outcome on this issue** that truly ramps-up and diversifies production," says Xolelwa Mlumbi-Peter, South Africa's ambassador to the WTO. "Final nail in the coffin" The Geneva-based **WTO isn't an organization with power**, as such—it's a framework within which countries make big decisions about trade, generally by consensus. **It's supposed to be** the forum **where disputes get settled,** because all its members have signed up to the same rules. And one of its most important rulebooks is the Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPS, which sprang to life alongside the WTO in 1995. The WTO's **founding agreement allows for rules to be waived in exceptional circumstances,** and indeed this has happened before: its members agreed in 2003 to waive TRIPS obligations that were blocking the importation of cheap, generic drugs into developing countries that lack manufacturing capacity. (That waiver was effectively made permanent in 2017.) **Consensus is the key here**. Although the failure to reach consensus on a waiver could be overcome with a 75% supermajority vote by the WTO's membership, this would be an unprecedented and seismic event. **In the case of the COVID-19 vaccine IP waiver, it would mean standing up to the European Union,** and Germany in particular, as well as countries such as Canada and the U.K.—the U.S. recently flipped from opposing the idea of a waiver to supporting it, as did France. **It's a dispute between countries, but the result will be on the WTO as a whole**, say waiver advocates. "**If, in the face of one of humanity's greatest challenges** in a century, **the WTO functionally becomes an** obstacle as in contrast to part of the solution, **I think it could be the final nail in the coffin"** **for the organization**, says Lori Wallach, the founder of Public Citizen's Global Trade Watch, a U.S. campaigning group that focuses on the WTO and trade agreements. **"If the** TRIPS **waiver is successful, and people see the WTO as being part of the solution**—saving lives and livelihoods—**it could create goodwill and momentum to address what are still daunting structural problems."** Those problems are legion. Reform needs Top of the list is the WTO's Appellate Body, which hears appeals in members' trade disputes. It's a pivotal part of the international trade system, but Trump—incensed at decisions taken against the U.S. —blocked appointments to its seven-strong panel as judges retired. The body became completely paralyzed at the end of 2019, when two judges' terms ended and the panel no longer had the three-judge quorum it needs to rule on appeals. Anyone who hoped the advent of the Biden administration would change matters was disappointed earlier this year when the U.S. rejected a European proposal to fill the vacancies. "The United States continues to have systemic concerns with the appellate body," it said. "As members know, the United States has raised and explained its systemic concerns for more than 16 years and across multiple U.S. administrations." At her confirmation hearing in February, current U.S. Trade Representative Katherine Tai reiterated those concerns—she said the appellate body had "overstepped its authority and erred in interpreting WTO agreements in a number of cases, to the detriment of the United States and other WTO members," and accused it of dragging its heels in settling disputes. "Reforms are needed to ensure that the underlying causes of such problems do not resurface," Tai said. "While the U.S. [has] been engaging [with the WTO] it hasn't indicated it would move quickly on allowing appointments to the Appellate Body," says Bryan Mercurio, an economic-law professor at the Chinese University of Hong Kong, who opposes the vaccine waiver. "This is not a good sign. In terms of WTO governance, it's a much more important step than supporting negotiations on an [intellectual property] waiver." It's not just the U.S. that wants to see reform at the WTO. In a major policy document published in February, the EU said negotiations had failed to modernize the organization's rules, the dispute-resolution system was broken, the monitoring of countries' trade policies was ineffective, and—crucially—"the trade relationship between the U.S. and China, two of the three largest WTO members, is currently largely managed outside WTO disciplines." China is one of the key problems here. It became a WTO member in 2001 but, although this entailed significant liberalization of the Chinese economy, it did not become a full market economy. As the European Commission put it in February: "The level at which China has opened its markets does not correspond to its weight in the global economy, and the state continues to exert a decisive influence on China's economic environment with consequent competitive distortions that cannot be sufficiently addressed by current WTO rules." "China is operating from what it sees as a position of strength, so it will not be bullied into agreeing to changes which it sees as not in its interests," says Mercurio. China is at loggerheads with the U.S., the EU and others over numerous trade-related issues. Its rivals don't like its policy of demanding that Chinese citizens' data is stored on Chinese soil, nor do they approve of how foreign investors often have to partner with Chinese firms to access the country's market, in a way that leads to the transfer of technological knowhow. They also oppose China's industrial subsidies. Mercurio thinks China may agree to reforms on some of these issues, particularly regarding subsidies, but "only if it is offered something in return." **All these problems won't go away if the WTO manages to come up with a TRIPS waiver** for COVID-19 vaccines and medical supplies, Wallach concedes. "**But**," she adds, "**the will and the good faith to tackle these challenges is increased enormously if the WTO has the experience of being part of the solution, not just an obstacle."** Wallach points to a statement released earlier this month by Asia Pacific Economic Cooperation (APEC) trade ministers, which called for urgent discussions on the waiver. "**The WTO must demonstrate that global trade rules can help address the human catastrophe** of the COVID-19 pandemic and facilitate the recovery," the statement read in its section about WTO reform. Okonjo-Iweala's role The **WTO's new director general**, whose route to the top was unblocked in early 2021 with the demise of the Trump administration, i**s certainly keen to fix the problems** that contributed to the early departure of her predecessor, Brazil's Robert Azevedo. "**We must act now** to get all our ambassadors to the table to negotiate a text" on the issue of an IP waiver for COVID vaccines, Ngozi Okonjo-Iweala, director general of the World Trade Organization, has said. Dursun Aydemir—Anadolu/Bloomberg/Getty Images Earlier this week, when the U.S. and EU agreed a five-year ceasefire in a long-running dispute over Boeing and Airbus aircraft subsidies, Okonjo-Iweala tweeted: **"With political will, we can solve even the most intractable problems."** However, Mercurio is skeptical about her stewardship having much of an effect on the WTO's reform process. "Upon taking [over she] stated it was time for delegations to speak to each other and not simply past each other, but at the recent General Counsel meeting delegations simply read prepared statements in what some have described as the worst meeting ever," he says. "On the other hand, **Ngozi is very much someone who will actively seek solutions to problems,** and in this way different to her predecessor. If the role of mediator is welcomed, **she could have an impact not in starting discussions but in getting deals over the finish line."**

### 1ac - plan

#### **Thus the plan – The Member Nations of the World Trade Organization ought to reduce intellectual property protections for medicines by eliminating them in the case of Global Public Health Emergencies.**

#### The plan would model India and South Africa’s proposal

Dhar, Biswajit and KM Gopakumar (2020). Dhar is a Professor of Economics, Jawaharlal Nehru University, New Delhi, India and adviser to ARTNeT and Gopakumar is a Legal Advisor, Third World Network, Penang, Malaysia, “Towards more affordable medicine: A proposal to waive certain obligations from the Agreement on TRIPS”, ARTNeT Working Paper Series No. 200, November 2020, Bangkok: ESCAP, <https://www.unescap.org/sites/default/d8files/knowledge-products/AWP200_Dhar.pdf>

The COVID-19 pandemic has once again brought a similar response from India and South Africa. The two countries have tabled a joint proposal, which was discussed by the TRIPS Council, seeking waiver from certain obligations under the TRIPS Agreement for the “prevention, containment, and treatment of COVID-19” (World Trade Organization 2020a). Kenya and Eswatini have also supported this Proposal. Using the provisions of Article IX of the Marrakesh Agreement Establishing the WTO, the proposal makes a request to the General Council of the WTO, to waive the implementation, application, and enforcement of four forms of IPRs covered by the TRIPS Agreement for some years for the prevention, containment, and treatment of COVID-19. The scope of waiver includes the following: copyright and related rights, industrial designs, patents, and trade secrets. It should be noted here that the waiver of legal obligations under WTO agreement is not new. Since 1995, of the waivers that were granted, three were from TRIPS obligations (World Trade Organization 2016).3

#### Intellectual property includes patents, industrial designs, trademarks, copyright laws, and geographical indications

Chandra Nath Saha and Sanjib Bhattacharya, Apr/Jun 2011, Chandra is a Quality Assurance Department, Claris Lifesciences Ltd., Ahmedabad, Gujarat, India, Bhattacharya is a Pharmacognosy Division, Bengal School of Technology (A College of Pharmacy), Sugandha, Hooghly, West Bengal, India, “Intellectual property rights: An overview and implications in pharmaceutical industry”, NCBI, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/

Originally, only patent, trademarks, and industrial designs were protected as ‘Industrial Property’, but now the term ‘Intellectual Property’ has a much wider meaning. IPR enhances technology advancement in the following ways:[1–4]

1. it provides a mechanism of handling infringement, piracy, and unauthorized use
2. it provides a pool of information to the general public since all forms of IP are published except in case of trade secrets.

IP protection can be sought for a variety of intellectual efforts including

(i) Patents

(ii) Industrial designs relates to features of any shape, configuration, surface pattern, composition of lines and colors applied to an article whether 2-D, e.g., textile, or 3-D, e.g., toothbrush[5]

(iii) Trademarks relate to any mark, name, or logo under which trade is conducted for any product or service and by which the manufacturer or the service provider is identified. Trademarks can be bought, sold, and licensed. Trademark has no existence apart from the goodwill of the product or service it symbolizes[6]

(iv) Copyright relates to expression of ideas in material form and includes literary, musical, dramatic, artistic, cinematography work, audio tapes, and computer software[7]

(v) Geographical indications are indications, which identify as good as originating in the territory of a country or a region or locality in that territory where a given quality, reputation, or other characteristic of the goods is essentially attributable to its geographical origin[8]

#### Reduce means to reduce in size, amount, or intensity

Walker ‘4

“Reduce” means to reduce in size, amount, or intensity. Allen Walker Read, (Prof., English, Columbia U.), THE NEW INTERNATIONAL WEBSTER’S COMPREHENSIVE DICTIONARY OF THE ENGLISH LANGUAGE, 2004, 1058.

Reduce: To make less in size, amount, number, intensity, etc.; diminish.

#### Medicines includes articles – things put into you

NY Code 21, 8-25-2021, "Section 528.4," No Publication, <https://casetext.com/regulation/new-york-codes-rules-and-regulations/title-20-department-of-taxation-and-finance/chapter-iv-sales-and-use-and-other-miscellaneous-taxes/subchapter-a-sales-and-use-taxes/part-528-exemptions/section-5284-drugs-and-medicines-medical-equipment-and-supplies> //ArchanSen + //Eagan AE

(b) Drugs and medicines.

(1) Drugs and medicines mean:

(i) articles, whether or not a prescription is required for purchase, which are recognized as drugs or medicines in the United States Pharmacopeia, Homeopathic Pharmacopeia of the United States, or National Formulary, and intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans;

(ii) articles (other than food) intended to affect the structure or any function of the human body.

(2) The base or vehicle used (oil, ointment, talc, etc.) and the medium used for delivery (disposable wipe, syringe, saturated pad, etc.) of a drug or medicine will not affect its exempt status. (3) Products consumed by humans for the preservation of health include other substances used internally or externally, which are not ordinarily considered drugs or medicines. Example 1:Analgesics, antiseptics, antacids, cough and cold remedies, laxatives, aspirin, boric acid ointment, cod liver oil and castor oil are exempt. Example 2:Antibiotics, sulfa drugs, and birth control pills are exempt. Example 3:Insulin that is packaged with disposable syringes is exempt. Example 4:Acne preparations, including acne soaps, are exempt provided they contain a recognized drug or medicine. Example 5:All dandruff preparations, including dandruff shampoos, are exempt provided they contain a recognized drug or medicine. Example 6:Any diagnostic drug, chemical or other substance which is used internally or externally on a human, such as a barium product for gastric X-rays, is exempt. Example 7:Vaginal creams, foams, ointments, douches, jellies, powder, and sprays provided they function as treatments for specific conditions are exempt, but products that only deodorize are taxable. Example 8:Foot powders that eliminate excessive perspiration and prevent athletes foot or other fungus infections are exempt, but foot powders which act only as deodorants are taxable. Example 9:Lip ice that treats or prevents chapped lips is exempt, but products that color the lips are taxable. Example 10:Products used to kill lice which infest humans are exempt. Similar products which prevent or treat mange or ringworm in humans are also exempt. Example 11:Products used for treatment of burns and products used to relieve pain from burns are exempt. Example 12:Gelatin capsules, blood and its derivatives are exempt. Example 13:Medical oxygen and nitrous oxide are exempt. (c) Cosmetics. Articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles are subject to tax. Example:Cold creams, suntan lotions and makeup are taxable cosmetics. (d) Toilet articles. Any article advertised or held out for grooming purposes and those articles which are customarily used for grooming purposes, regardless of the name by which they may be known are subject to tax. Example:Soap, toothpaste and hair spray are taxable toilet articles.

#### **Global public health Emergencies means the international spread of disease**

Wendy Parmet, 09/15/14, Wendy Parmet is the Director of the Northeastern Program on Health Policy & Law and a Matthews Distinguished professor of Law at Northeastern University, “Defining Public Health Emergencies”, <https://blog.petrieflom.law.harvard.edu/2014/09/15/defining-public-health-emergencies/>, Bill of Health – Harvard Law Petrie-Flom Center //Eagan AE

Some laws attempt to offer a bit more guidance. The 2005 International Health Regulations define a “public emergency of international concerns” as “an extraordinary event which is determined… (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response.” The 2001 Model State Emergency Public Health Powers Act, stated that a “public health emergency” is “an occurrence or imminent threat of an illness or health condition” caused by one of several factors, including bioterrorism or a novel or previously eradicated pathogen, that “poses a high probability of the following harms: (1) a large number of deaths in the affected populations; (ii) a large number of serious or long-term disabilities in the affected population; or (iii) widespread exposure to an infectious or toxic agent that poses a significant risk of substantial future harm to a large number of people in the affected population.” Interestingly, this definition varied from the one appearing in an earlier version of the Model Act., which didn’t require that an infectious illness be novel or previously eradicated, allowing for the possibility that HIV/AIDS or hepatitis would be declared a public health emergency. But even narrowed, the Model Act’s definition remains purposefully broad. Although HIV could not qualify today, because the virus is well established, it could have been declared a public health emergency in 1981, when it first appeared. Of course, in many ways HIV was an emergency, and should have been met with more attention and resources than was given. That doesn’t mean, however, that the rule of law should have been suspended; or that such suspension would have been helpful. To the contrary, it is easy to imagine that if emergency powers had been used in the 1980s, they would have been used, at least in some jurisdictions in harsh and punitive ways that targeted vulnerable populations, thereby impeding efforts to encourage people to be tested for the virus.

### 1ac - Framework

#### Evaluate the debate through the lens of probability – weighing impossibly long internal link chains distorts policy analysis by promoting selectivity and the ignoring of realism

Conetta and Knight 98 (Carl Conetta and Charles Knight, writers for the Project on Defense Alternatives of the Commonwealth Institute, Cambridge, Massachusetts, USA Project on Defense Alternatives, February 1998, <http://www.comw.org/pda/bullyweb.html>) cliv

7. Playing with Wild Cards Without doubt, simulations -- including nonstandard ones -- can aid planning. The question is: To what end? And to what effect? Exploring "wild cards" in order to identify warning signs or to define limits is one thing; using them to establish force structure or modernization requirements, quite another. Especially suspect would be using scenarios that are detached from declared US interests to define current requirements; this would put the military "cart" before the political "horse." Another, broader concern is how the effusion of improbable conflict scenarios affects public policy discourse overall. Conflict scenarios, both wild and tame, can gain more credibility in the telling than they deserve. Cognitive researcher Massimo Piattelli-Palmarini calls this the "Othello effect," referring to the trail of plausible but false suppositions that led Othello to murder his wife, Desdemona. Even the most farfetched scenarios comprise a number of steps or links each of which may seem plausible or even probable given the one that came before. Although the likelihood of the scenario dwindles with each step, the residual impression is one of plausibility. Omitted are the many branches at each step that would lead to a neutral or even positive outcome. The resulting snapshots, although numerous, offer a highly-selective view of what the future may hold.

#### Prefer probability first –

Kessler 08 (Oliver; April 2008; PhD in IR, professor of sociology at the University of Bielefeld, and professor of history and theory of IR at the Faculty of Arts; Alternatives, Vol. 33, “From Insecurity to Uncertainty: Risk and the Paradox of Security Politics” p. 211-232)

The problem of the second method is that it is very difficult to "calculate" politically unacceptable losses. If the risk of terrorism is defined in traditional terms by probability and potential loss, then the focus on dramatic terror attacks leads to the marginalization of probabilities. The reason is that even the highest degree of improbability becomes irrelevant as the measure of loss goes to infinity.^o The mathematical calculation of the risk of terrorism thus tends to overestimate and to dramatize the danger. This has consequences beyond the actual risk assessment for the formulation and execution of "risk policies": If one factor of the risk calculation approaches infinity (e.g., if a case of nuclear terrorism is envisaged), then there is no balanced measure for antiterrorist efforts, and risk management as a rational endeavor breaks down. Under the historical condition of bipolarity, the "ultimate" threat with nuclear weapons could be balanced by a similar counterthreat, and new equilibria could be achieved, albeit on higher levels of nuclear overkill. Under the new condition of uncertainty, no such rational balancing is possible since knowledge about actors, their motives and capabilities, is largely absent. The second form of security policy that emerges when the deterrence model collapses mirrors the "social probability" approach. It represents a logic of catastrophe. In contrast to risk management framed in line with logical probability theory, the logic of catastrophe does not attempt to provide means of absorbing uncertainty. Rather, it takes uncertainty as constitutive for the logic itself; uncertainty is a crucial precondition for catastrophes. In particular, catastrophes happen at once, without a warning, but with major implications for the world polity. In this category, we find the impact of meteorites. Mars attacks, the tsunami in South East Asia, and 9/11. To conceive of terrorism as catastrophe has consequences for the formulation of an adequate security policy. Since catastrophes hap-pen irrespectively of human activity or inactivity, no political action could possibly prevent them. Of course, there are precautions that can be taken, but the framing of terrorist attack as a catastrophe points to spatial and temporal characteristics that are beyond "rationality." Thus, political decision makers are exempted from the responsibility to provide security—as long as they at least try to preempt an attack. Interestingly enough, 9/11 was framed as catastrophe in various commissions dealing with the question of who was responsible and whether it could have been prevented. This makes clear that under the condition of uncertainty, there are no objective criteria that could serve as an anchor for measuring dangers and assessing the quality of political responses. For ex- ample, as much as one might object to certain measures by the US administration, it is almost impossible to "measure" the success of countermeasures. Of course, there might be a subjective assessment of specific shortcomings or failures, but there is no "common" currency to evaluate them. As a consequence, the framework of the security dilemma fails to capture the basic uncertainties. Pushing the door open for the security paradox, the main problem of security analysis then becomes the question how to integrate dangers in risk assessments and security policies about which simply nothing is known. In the mid 1990s, a Rand study entitled "New Challenges for Defense Planning" addressed this issue arguing that "most striking is the fact that we do not even know who or what will constitute the most serious future threat, "^i In order to cope with this challenge it would be essential, another Rand researcher wrote, to break free from the "tyranny" of plausible scenario planning. The decisive step would be to create "discontinuous scenarios ... in which there is no plausible audit trail or storyline from current events"52 These nonstandard scenarios were later called "wild cards" and became important in the current US strategic discourse. They justified the transformation from a threat-based toward a capability- based defense planning strategy.53 The problem with this kind of risk assessment is, however, that even the most absurd scenarios can gain plausibility. By constructing a chain of potentialities, improbable events are linked and brought into the realm of the possible, if not even the probable. "Although the likelihood of the scenario dwindles with each step, the residual impression is one of plausibility. "54 This so-called Othello effect has been effective in the dawn of the recent war in Iraq. The connection between Saddam Hussein and Al Qaeda that the US government tried to prove was disputed from the very beginning. False evidence was again and again presented and refuted, but this did not prevent the administration from presenting as the main rationale for war the improbable yet possible connection between Iraq and the terrorist network and the improbable yet possible proliferation of an improbable yet possible nuclear weapon into the hands of Bin Laden. As Donald Rumsfeld famously said: "Absence of evidence is not evidence of absence." This sentence indicates that under the condition of genuine uncertainty, different evidence criteria prevail than in situations where security problems can be assessed with relative certainty.

#### In order to have the most accurate evaluation of consequences we must listen to the oppressed

**Lawrence Hinman, professor of philosophy, writes in Ethics: A Pluralistic Approach to Moral Theory, 2012:** [Lawrence Hinman, prof. emeritus of philosophy @ San Diego, Ethics: A Pluralistic Approach to Moral Theory, 5th ed. 2012 p. 152]

One of the attractions of utilitarianism is that it promises impartiality and objectivity grounded in quantiﬁcation. If everything can be translated into units of utility, then there is an objective basis for deciding between competing courses of action. Ultimately, the numbers decide for us. Yet as the inhabitants of India well knew when the Empire applied its utilitarian logic to them, it makes a difference who is doing the calculating. When one group in society does the calculations for another group, it is all too easy for those calculations to become miscalculations. What mattered to the native inhabitants of India was very different from what the British thought mattered to them, as Gandhi was to prove. Similar considerations have certainly applied in the United States, where we have seen time and again that one group (usually white, upper middle class,[men have] and male) has made decisions for other groups (including ethnic minorities). Even when it has done so with good will

, it has often been wrong. This is, at least in part, an epistemological point. Many would argue that those most directly affected by consequences are in the best position to estimate the importance of those consequences for themselves. There is also a moral and a psychological point here. The moral one is that those who will bear consequences should have a voice in determining those consequences. The psychological point is that people are more likely to bear onerous consequences when they themselves have had a voice in choosing them. Thus, considerations of race, ethnicity, and culture have an important place in a utilitarian framework in regard to the calculator. All other things being equal, it is better that identiﬁable racial and ethnic groups be represented among the calculators of utility and that one group not assume the role of calculator for all other groups.