# SO IPR IP Protections Aff

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### Definitions:

Reduce: Make smaller or less in amount, degree, or size.

“Definitions, Meanings, Synonyms, and Grammar by Oxford Dictionary on Lexico.com.” *Lexico Dictionaries | English*, Lexico Dictionaries, www.lexico.com/en/definition/reduce%E2%80%AF.

Medicines: A compound or preparation used for the treatment or prevention of disease, especially a drug or drugs taken by mouth.

 “Medicine English Definition and Meaning.” *Lexico Dictionaries | English*, Lexico Dictionaries, www.lexico.com/en/definition/medicine.

Ought: Used to indicate duty or correctness, typically when criticizing someone's actions.

“Ought English Definition and Meaning.” *Lexico Dictionaries | English*, Lexico Dictionaries, www.lexico.com/en/definition/ought.

### Framework AT DA/CP Debate

#### Lincoln Douglass is a debate about morality; therefore, the judge ought to first and foremost prioritize a moral framework

Ought in the resolution implies a moral framework

Roberts , **Josh.** “Lincoln Douglass Debate: An Introduction .” *National Speech and Debate Association*, **National Speech and Debate Association , 2012**, www.speechanddebate.org/wp-content/uploads/Intro\_to\_LD.J.Roberts.7.5.27.pdf.

Lincoln-Douglas debate (more commonly referred to as LD) is a competitive speaking activity that involves two debaters arguing for and against a resolution that is selected by the NFL (National Forensics League) and voted on by coaches. Today, somewhat like the old debates, LD focuses on the conflicting values of social and philosophical issues, for example, by examining questions of morality, justice, democracy, etc. Typically, LD debates concern themselves with deciding whether or not certain actions, or states of affairs, are good or bad, right or wrong, moral or immoral

**In order to weigh what is the most moral action, the Affirmative offers the value criterion of structural violence: Prioritize structural violence**

#### Structural outweighs on probability and magnitude – risk assessment is not neutral but is epistemologically biased towards privileged white male elites who discount the severity of everyday violence in destroying marginalized populations.

**Verchick 96** [Robert, Assistant Professor, University of Missouri -- Kansas City School of Law. J.D., Harvard Law School, 1989, “IN A GREENER VOICE: FEMINIST THEORY AND ENVIRONMENTAL JUSTICE” 19 Harv. Women's L.J. 23]

Because risk assessment is based on statistical measures of risk, policymakers view it as an accurate and objective tool in establishing environmental standards. n275 The scientific process used to assess risk purports to focus single-mindedly on only one feature of a potential injury: the objective probability of its occurrence. n276 Risk assessors, who consider most value judgments irrelevant in determining statistical risk, seek to banish them at every stage. n277 As a result, the language of risk assessment -- and of related environmental safety standards -- often carry an air of irrebuttable precision and certainty. The EPA, for example, defines the standard acceptable level of risk under Superfund as "10<-6>" -- that is, the probability that one person in a million would develop cancer due to exposure to site contamination. n278 [\*76] Feminism challenges this model of scientific risk assessment on at least three levels. First, feminism questions the assumption that scientific inquiry is value-neutral, that is, free of societal bias or prejudice. n279 Indeed, as many have pointed out, one's perspective unavoidably influences the practice of science. n280 Western science may be infused with its own ideology, perpetuating, in the view of the ecofeminists, cycles of discrimination, domination, and exploitation. n281 Second, even if scientific inquiry by itself were value-neutral, environmental regulation based on such inquiry would still contain subjective elements. Environmental regulation, like any other product of democracy, inevitably reflects elements of subjectivity, compromise, and self-interest. The technocratic language of regulation serves only to "mask, not eliminate, political and social considerations." n282 We have already seen how the subjective decision to prefer white men as subjects for epidemiological study can skew risk assessments against the interests of women and people of color. The focus of many assessments on the risk of cancer deaths, but not, say, the risks of birth defects or miscarriages, is yet another example of how a policymaker's subjective decision of what to look for can influence what is ultimately seen. n283 Once risk data are collected and placed in a statistical form, the ultimate translation of that information into rules and standards of conduct once again reflects value judgments. A safety threshold of one in a million or a preference for "best conventional technology" does not spring from the periodic table, but rather evolves from the application [\*77] of human experience and judgment to scientific information. Whose experience? Whose judgment? Which information? These are the questions that feminism prompts, and they will be discussed shortly. Finally, feminists would argue that questions involving the risk of death and disease should not even aspire to value neutrality. Such decisions -- which affect not only today's generations, but those of the future -- should be made with all related political and moral considerations plainly on the table. n284 In addition, policymakers should look to all perspectives, especially those of society's most vulnerable members, to develop as complete a picture of the moral issues as possible. Debates about scientific risk assessment and public values often appear as a tug of war between the "technicians," who would apply only value-neutral criteria to set regulatory standards, and the "public," who demand that psychological perceptions and contextual factors also be considered. n285 Environmental justice advocates, strongly concerned with the practical experiences of threatened communities, argue convincingly for the latter position. n286 A feminist critique of the issue, however, suggests that the debate is much richer and more complicated than a bipolar view allows. For feminists, the notion of value neutrality simply does not exist. The debate between technicians and the public, according to feminists, is not merely a contest between science and feelings, but a broader discussion about the sets of methods, values, and attitudes to which each group subscribes. Furthermore, feminists might argue, the parties to this discussion divide into more than two categories. Because one's world view is premised on many things, including personal experience, one might expect that subgroups within either category might differ in significant ways from other subgroups. Therefore, feminists would anticipate a broad spectrum of views concerning scientific risk assessment and public values. Intuitively, this makes sense. Certainly scientists disagree among themselves about the hazards of nuclear waste, ozone depletion, and global warming. n287 Many critics have argued that scientists, despite their allegiance [\*78] to rational method, are nonetheless influenced by personal and political views. n288 Similarly, members of the public are a widely divergent group. One would not be surprised to see politicians, land developers, and blue-collar workers disagreeing about environmental standards for essentially non-scientific reasons. Politicians and bureaucrats are two sets of the non-scientific community that affect environmental standards in fundamental ways. Their adherence to vocal, though not always broadly representative, constituencies may lead them to disfavor less advantaged socioeconomic groups when addressing environmental concerns. n289 In order to understand a diversity of risk perception and to see how attitudes and social status affect the risk assessment process, we must return to the feminist inquiry that explores the relationship between attitudes and identity. 1. The Diversity of Risk Perception A recent national survey, conducted by James Flynn, Paul Slovic, and C.K. Mertz, measured the risk perceptions of a group of 1512 people that included numbers of men, women, whites, and non-whites proportional to their ratios in society. n290 Respondents answered questions about the health risks of twenty-five environmental, technological, and "life-style" hazards, including such hazards as ozone depletion, chemical waste, and cigarette smoking. n291 The researchers asked them to rate each hazard as posing "almost no health risk," a "slight health risk," a "moderate health risk," or a "high health risk." The researchers then analyzed [\*79] the responses to determine whether the randomly selected groups of white men, white women, non-white men, and non-white women differed in any way. The researchers found that perceptions of risk generally differed on the lines of gender and race. Women, for instance, perceived greater risk from most hazards than did men. n292 Furthermore, non-whites as a group perceived greater risk from most hazards than did whites. n293 Yet the most striking results appeared when the researchers considered differences in gender and race together. They found that "white males tended to differ from everyone else in their attitudes and perceptions -- on average, they perceived risks as much smaller and much more acceptable than did other people." n294 Indeed, without exception, the pool of white men perceived each of the twenty-five hazards as less risky than did non-white men, white women, or non-white women. n295 Wary that other factors associated with gender or race could be influencing their findings, the researchers later conducted several multiple regression analyses to correct for differences in income, education, political orientation, the presence of children in the home, and age, among others. Yet even after all corrections, "gender, race, and 'white male' [status] remained highly significant predictors" of perceptions of risk. n296 2. Explaining the Diversity From a feminist perspective, these findings are important because they suggest that risk assessors, politicians, and bureaucrats -- the large majority of whom are white men n297 -- may be acting on attitudes about security and risk that women and people of color do not widely share. If this is so, white men, as the "measurers of all things," have crafted a system of environmental protection that is biased toward their subjective understandings of the world. n298 [\*80] Flynn, Slovic, and Mertz speculate that white men's perceptions of risk may differ from those of others because in many ways women and people of color are "more vulnerable, because they benefit less from many of [society's] technologies and institutions, and because they have less power and control." n299 Although Flynn, Slovic, and Mertz are careful to acknowledge that they have not yet tested this hypothesis empirically, their explanation appears consistent with the life experiences of less empowered groups and comports with previous understandings about the roles of control and risk perception. n300 Women and people of color, for instance, are more vulnerable to environmental threat in several ways. Such groups are sometimes more biologically vulnerable than are white men. n301 People of color are more likely to live near hazardous waste sites, to breathe dirty air in urban communities, and to be otherwise exposed to environmental harm. n302 Women, because of their traditional role as primary caretakers, are more likely to be aware of the vulnerabilities of their children. n303 It makes sense that such vulnerabilities would give rise to increased fear about risk. It is also very likely that women and people of color believe they benefit less from the technical institutions that create toxic byproducts. n304 Further, people may be more likely to discount risk if they feel somehow compensated for the activity. n305 For this reason, Americans worry relatively little about driving automobiles, an activity with enormous advantages in our large country but one that claims tens of thousands of lives per year. The researchers' final hypothesis -- that differences in perception can be explained by the lack of "power and control" exercised by women and people of color -- suggests the importance that such factors as voluntariness and control over risk play in shaping perceptions. [\*81] Risk perception research frequently emphasizes the significance of voluntariness in evaluating risk. Thus, a person may view water-skiing as less risky than breathing polluted air because the former is accepted voluntarily. n306 Voluntary risks are viewed as more acceptable in part because they are products of autonomous choice. n307 A risk accepted voluntarily is also one from which a person is more likely to derive an individual benefit and one over which a person is more likely to retain some kind of control. n308 Some studies have found that people prefer voluntary risks to involuntary risks by a factor of 1000 to 1. n309 Although environmental risks are generally viewed as involuntary risks to a certain degree, choice plays a role in assuming risks. White men are still more likely to exercise some degree of choice in assuming environmental risks than other groups. Communities of color face greater difficulty in avoiding the placement of hazardous facilities in their neighborhoods and are more likely to live in areas with polluted air and lead contamination. n310 Families of color wishing to buy their way out of such polluted neighborhoods often find their mobility limited by housing discrimination, redlining by banks, and residential segregation. n311 The workplace similarly presents workers exposed to toxic hazards (a disproportionate number of whom are minorities) n312 with impossible choices between health and work, or between sterilization and demotion. n313 Just as marginalized groups have less choice in determining the degree of risk they will assume, they may feel less control over the risks they face. "Whether or not the risk is assumed voluntarily, people have greater [\*82] fear of activities with risks that appear to be outside their individual control." n314 For this reason, people often fear flying in an airplane more than driving a car, even though flying is statistically safer. n315 If white men are more complacent about public risks, it is perhaps because they are more likely to have their hands on the steering wheel when such risks are imposed. White men still control the major political and business institutions in this country. n316 They also dominate the sciences n317 and make up the vast majority of management staff at environmental agencies. n318 Women and people of color see this disparity and often lament their back-seat role in shaping environmental policy. n319 Thus, many people of color in the environmental justice movement believe that environmental laws work to their disadvantage by design. n320 [\*83] The toxic rivers of Mississippi's "Cancer Alley," n321 the extensive poisoning of rural Indian land, n322 and the mismanaged cleanup of the weapons manufacturing site in Hanford, Washington n323 only promote the feeling that environmental policy in the United States sacrifices the weak for the benefit of the strong. In addition, the catastrophic potential that groups other than white men associate with a risk may explain the perception gap between those groups and white males. Studies of risk perception show that, in general, individuals harbor particularly great fears of catastrophe. n324 For this reason, earthquakes, terrorist bombings, and other disasters in which high concentrations of people are killed or injured prove particularly disturbing to the lay public. Local environmental threats involving toxic dumps, aging smelters, or poisoned wells also produce high concentrations of localized harm that can appear catastrophic to those involved. n325 Some commentators contend that the catastrophic potential of a risk should influence risk assessment in only minimal ways. n326 Considering public fear of catastrophes, they argue, will irrationally lead policymakers to battle more dramatic but statistically less threatening hazards, while accepting more harmful but more mundane hazards. n327 [\*84] At least two reasons explain why the catastrophic potential of environmental hazards must be given weight in risk assessment. First, concentrated and localized environmental hazards do not simply harm individuals, they erode family ties and community relationships. An onslaught of miscarriages or birth defects in a neighborhood, for instance, will create community-wide stress that will debilitate the neighborhood in emotional, sociological, and economic ways. n328 To ignore this communal harm is to underestimate severely the true risk involved. n329 Second, because concentrated and localized environmental hazards tend to be unevenly distributed on the basis of race and income level, any resulting mass injury to a threatened population takes on profound moral character. For this reason, Native Americans often characterize the military's poisoning of Indian land as genocide. n330 [\*85] 3. Understanding Through Diversity Flynn, Slovic, and Mertz challenge the traditional, static view of statistical risk with a richer, more vibrant image involving relationships of power, status, and trust. n331 "In short, 'riskiness' means more to people than 'expected number of fatalities.'" n332 These findings affirm the feminist claim that public policy must consider both logic and local experience in addressing a problem**.** n333 Current attempts to "re-educate" fearful communities with only risk assessments and scientific seminars are, therefore, destined to fail. n334 By the same token, even dual approaches that combine science and experience will fall short if the appeal to experience does not track local priorities and values. Cynthia Hamilton illustrates these points in her inspiring account of how a South Central Los Angeles community group, consisting mainly of working-class women, battled a proposed solid waste incinerator. n335 At one point, the state sent out consultants and environmental experts to put the community's fears into perspective. The consultants first appealed to the community's practical, experience-based side, by explaining how the new incinerator would bring needed employment to the area and by offering $ 2 million in community development. n336 But the community group found the promise of "real development" unrealistic and the cash gift insulting. n337 When experts then turned to quantifying the risks "scientifically" their attempts backfired again. Hamilton reports that "expert assurance that health risks associated with dioxin exposure were less than those associated with 'eating peanut butter' unleashed a flurry of dissent. All of the women, young and old, working-class and professional, had made peanut butter sandwiches for years." n338 The sandwich analogy, even assuming its statistical validity, could not convince the women because it did not consider other valid risk factors (voluntariness, dread, and so on) and because it did not appear plausible in the group members' experience. In the end, Hamilton explains that the superficial explanations and sarcastic responses of the male "experts" left the women even more united and convinced that "working-class women's [\*86] concerns cannot be dismissed." n339 Thus even the "science" of risk assessment, if it is to serve effectively, must include the voices of those typically excluded from its practice.

### Adv 1: Vaccines

#### Inherency

**Baschuk ’21** -- mulitmedia journalist based in Geneva, Switzerland (Bryce Baschuk, 7-26-2021, "WTO Holiday From Vaccine Equity Talks Draws Calls for Action," Bloomberg, <https://www.bloomberg.com/news/articles/2021-07-26/wto-s-holiday-from-vaccine-equity-talks-draws-calls-for-action>, accessed 8-29-2021) //nikki

An urgent global effort to rebalance the inequity between rich, vaccinated nations and poor nations sliding further into pandemic misery is colliding with an immovable calendar conflict: the European summer holiday. Next week World Trade Organization delegates are planning to depart Geneva for their August break and, in doing so, pause their fractious debate over a proposal to waive intellectual-property protections for Covid-19 shots until the second week of September. Before they leave, members will adopt a report that acknowledges they’ve made scant headway on the proposal aimed at making doses more widely available, which the world’s top health expert says is critical to ending a “moral failure.” “With so many lives on the line, profits and patents must come second,” World Health Organization Director-General Tedros Adhanom Ghebreyesus said during a virtual summit last week. WTO Director-General Ngozi Okonjo-Iweala previously urged ambassadors to shorten their usual six-week summer holiday to focus on pressing issues like the waiver. Nevertheless, members aren’t planning to reconsider the matter until the week of Sept. 6, according to officials familiar with the planning. “August doesn’t matter in Geneva; it doesn’t matter if people are dying around the world,” said Shailly Gupta, a spokesperson at Médecins Sans Frontières. “We hope members will move at a faster pace.” Disagreement persists on the fundamental question of whether a waiver is the “appropriate and most effective way” to address the shortage of vaccines, according to a draft status report produced by Dagfinn Sørli, the chairman of WTO council on Trade-Related Aspects of Intellectual Property Rights, or TRIPS. That split could sink prospects for an ambitious vaccine waiver because WTO decisions must be taken on the basis of consensus -- which means any of the 164 members can veto a final agreement for any reason. ”The WTO’s response to Covid is the most critical issue before our organization right now,” WTO spokesman Keith Rockwell said a phone interview. “Millions have died and lives are at stake. Finding a pragmatic outcome by December is essential.” Proponents of the waiver had hoped to conclude their negotiations by the end of July and are now criticizing the European Union and other developed nations for sandbagging the talks. EU ‘Not Interested’ The European Commission, which opposes a WTO TRIPS waiver, has proposed a series of measures that it argues will create greater legal certainty for nations to leverage existing trade tools in order to expand their production capacities. “The EU is not interested,” Gupta said. “Switzerland, Norway and the United Kingdom are not engaging. They’re saying: ‘This or that won’t work; the waiver won’t work.’ There is no intention of engaging.” A spokesman for the EU mission in Geneva declined to comment. Critics counter that the proposal from Brussels is a distraction to redirect focus from India and South Africa’s earlier waiver proposal and to prevent members from engaging in more detailed negotiations. “The EU’s actions are incredibly cynical and dangerous,” said Lori Wallach, the founder of Public Citizen’s Global Trade Watch. “They have submitted a paper that basically conflicts with the text-based negotiations by saying ‘We don’t want a waiver.’” The U.S., meanwhile, has taken a back seat in the process and enthusiasm about Washington’s engagement on the issue has begun to wane in the three months since Trade Representative Katherine Tai announced American support for a waiver. Though Tai’s surprise announcement briefly knocked shares of Moderna Inc., Pfizer Inc., and BioNTech SE, the stocks quickly rebounded and all are now trading at or near their highest levels of the year. “People feel that message from Ambassador Tai is not playing out on the ground or being implemented in a meaningful way,” said Thiru Balasubramaniam a managing director at Knowledge Ecology International in Europe. “U.S. support for waiving intellectual property protections for Covid-19 vaccines provided important momentum for the WTO process,” U.S. Trade Representative spokesman Adam Hodge said via email. “We remain deeply engaged in discussions towards finding consensus while the Biden-Harris Administration continues to ramp up our efforts to donate doses and expand the manufacturing and equitable distribution of vaccines around the world.” Waiver Drawbacks Most nations producing the vaccines oppose a blanket waiver to the WTO’s intellectual property rules because they say it would harm innovation, do little to expand access to vaccines and may even backfire. Specifically, opponents to the waiver say it would create a chaotic patchwork of laws, unravel existing industry partnerships, lead to a supply crunch for scarce vaccine inputs and inject even more uncertainty into already complex arrangements. There’s also the possibility that an IP waiver could result in the production of counterfeit and substandard medicines, which could increase vaccine hesitancy that’s already pervasive in even the world’s wealthiest nations. “Everybody knows IP isn’t the problem and there is no quick fix to vaccinating the world with the latest technology,” said Robert Grant, a senior director at the U.S. Chamber of Commerce. “Most governments know this but due to the political sensitivities they won’t say it publicly.” Uneven Distribution Indeed, the waiver debate is a politically explosive issue for nations with high vaccination rates because they don’t want to be seen as standing in the way of getting life-saving drugs to poor nations whose citizens are suffering at disproportionate rates. To date, 75% of vaccines have been administered in just 10 countries and only 1% of people in low-income countries have received at least one dose, according to WHO statistics. Drug manufacturers say they are working every day to address the real bottlenecks and are on track to deliver 11 billion vaccines by year-end -- enough to inoculate the world’s entire adult population. While diplomats go on holiday, the process of getting the vaccines out there hasn’t stopped, said a spokeswoman for the International Federation of Pharmaceutical Manufacturers and Associations.

#### 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.

#### IP protections are the vital internal link to resolve vaccine deficiencies. 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. 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.

#### 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.

#### Neocolonial dynamics limit COVID vaccines to the Global North---that results in debt imperialism and undermines the right to health.

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The current global distribution of COVID-19 vaccines is largely dictated by **power disparities** and inequities in financial and other resources, with predominantly high-income countries contracting bilaterally with individual pharmaceutical companies (many in their own countries) for specific vaccines, leaving countries from the Global South facing **inequitable vaccine access**. Bilateral deals between states and pharmaceutical companies, whether completed by Global North or Global South states, significantly compromise the effectiveness and equity of the **COVAX initiative**, limited as it already is by the **coercive influence**, **vested interests** and **participation of pharma**ceutical **companies** and their host nations. The African Union, for example, endorsed the TRIPS waiver to relax WTO rules so that LMICs could create their own COVID-19 vaccines, but this collective effort across African countries **faced resistance** from Global North countries and pharmaceutical companies.

The IP system appears to have pushed countries in the Global South that may prefer not to be dependent on the charitable model of the COVAX scheme to join **high-income countries** in engaging directly with manufacturers to purchase COVID-19 vaccines. This has included African countries, despite the African Union’s criticism of the inequities resulting from IP law protections. This process has **reproduced colonially entrenched power dynamics**, in which poorer countries lack the bargaining power to obtain competitive rates and, consequently, typically end up paying **far more** than the wealthier, developed countries. More broadly, countries in the Global South are pressured into participating in global systems of trade that result in the exploitation of their own populations by unjust global economic systems and IP laws.39 The high cost of vaccines for countries from the Global South constitutes a large proportion of their health expenditure, and this comes at the expense of **other health priorities**.

In many cases, the only way in which Global South countries can purchase vaccines is to move themselves **further into debt**. Given the **detrimental neocolonial implications** of **debt**, with a **long history** of loan conditionalities through structural adjustment programmes, **increasing debt to service health** needs contributes to the **worsening** of **inequalities** between the Global North and Global South.40 These programmes may increase debt and **undermine development** in ways that limit the realisation of the **right to health**.41 The World Bank has set aside US$12 billion and has already disbursed **loans** of US$500 million for vaccines in low-income and middle-income nations;42 **poorer nations**, instead of servicing already depleted health systems, are forced to divert additional funds to **servicing debt.**

**Anti-capitalist sentiment is at the heart of the plan. The status quo accedes to intellectual monopoly capitalism.**

**Sell 20** (Susan K. Sell, School of Regulation and Global Governance, Australian National University, Acton, ACT Australia. “What COVID-19 Reveals About Twenty-First Century Capitalism: Adversity and Opportunity”. Nov 2020)

In the late 1970s and early 1980s, US-based IP owners lobbied for regulatory and legislative reform to expand IP protection. Pharmaceutical, software, publishing and entertainment producers argued that their industries provided America with competitive advantages in global markets. They sought **the incorporation of IP into the trade regime** to ensure that their IP would be remunerated in global markets and that trading partners would respect and enforce their ‘rights’. By 1994 IP owners had succeed in globalizing their preferences **through** the Agreement on Trade-Related Intellectual Property Rights (**TRIPs**) **in the W**orld **T**rade **O**rganization (Sell 2003). TRIPs is hard law; it is binding and enforceable. It mandates 20 years of patent protection for pharmaceutical products. Violations result in trade sanctions. The institutionalization of intellectual property protection in the global trade regime **cemented** the shift from Reagan/Thatcher neoliberalism to **intellectual monopoly capitalism**. When we talk about ‘trade’ these days, we are really discussing the role of intangibles such as IP and financial services. The main beneficiaries of contemporary trade agreements are those who control global value chains (GVCs), including international banks, Big Tech, Big Pharma, Big Food and Transnational Corporations. Lead firms in GVCs promote stricter IP requirements in trade agreements to ‘contain the risk of IP appropriation resulting from the international fragmentation of production’ (Durand and Milberg 2018: 21–22). Most of the post-TRIPs trade agreements in which IP-rich nations are involved feature IP provisions that extend well beyond the TRIPs obligations in the WTO. Today, ‘profitability is a function of a firm’s ability to extract monopoly rents from complex value chains using their control over IPRs’ (Schwartz 2017: 197). For example, Apple extracts the lion’s share of value from every iPad sold whereas the manufacturers in China receive only pennies on the dollar. Big Pharma routinely blocks pro-health initiatives aimed at promoting the use of TRIPs’ flexibilities, such as compulsory licensing and parallel importation, that would make essential medicines affordable and accessible; these would threaten their profits and reduce shareholder value (Correa 2006). **The profit imperative of financialized capitalism has meant that Big Pharma has invested far more in lifestyle diseases such as e**rectile **d**ysfunction and baldness **than in diseases of the Global South.** As Feldman argues, ‘our incentive structure is badly misaligned with societal goals’ (Feldman 2018). **Patent protection increases prices and reduces access to medicines**, diagnostics, vaccines, medical devices and PPE. Strategic behaviour aimed at blocking generic competition contributes to rising drug prices. **Pharma firms routinely engage in ‘evergreening’ to extend patent protection terms.** A firm may have a popular drug with an about-to-expire patent, and then offer a ‘new’ formulation—from a tablet to a gel cap—of the same drug and obtain another 20 years of protection. This strategic behaviour does not affect everyone equally. For example, during the HIV/AIDS pandemic of the late 1990s/early 2000s as deaths plummeted in affluent countries an estimated 12 million infected Africans were left to die, ‘waiting for enough life-saving drugs to reach the continent’ (Nkengasong et al. 2020: 198). **India and South Africa have both asked the World Trade Organization to waive TRIPs provisions** to allow them to engage in compulsory licensing and parallel importation of COVID-19 therapies (Reuters 2020). **Their past experiences with HIV/AIDs and the** s`````````````````````````````````````wine and avian in**flu**enzas **have bred understandable suspicion about the barriers to access that IP can create.** As COVID-19 tests, therapies and vaccines are developed there is legitimate concern that ‘intellectual property rights and reluctance to share related know-how may act as barriers to the rapid scale up for timely supply at affordable prices in all countries’ (Tellez 2020).

#### Imperial hegemony is actualized through intellectual property restrictions that enable the use of vaccines as a mode of postcolonial hostage taking – Latin American countries have been coerced by American pharmaceutical companies into relinquishing sovereign assets in exchange for medical necessities.

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Pfizer has been accused of “bullying” Latin American governments in Covid vaccine negotiations and has asked some countries to put up sovereign assets, such as embassy buildings and military bases, as a guarantee against the cost of any future legal cases, the Bureau of Investigative Journalism can reveal. In the case of one country, demands made by the pharmaceutical giant led to a three-month delay in a vaccine deal being agreed. For Argentina and Brazil, no national deals were agreed at all. Any hold-up in countries receiving vaccines means more people contracting Covid-19 and potentially dying. Officials from Argentina and the other Latin American country, which cannot be named as it has signed a confidentiality agreement with Pfizer, said the company’s negotiators demanded additional indemnity against any civil claims citizens might file if they experienced adverse effects after being inoculated. In Argentina and Brazil, Pfizer asked for sovereign assets to be put up as collateral for any future legal costs. One official who was present in the unnamed country’s negotiations described Pfizer’s demands as “high-level bullying” and said the government felt like it was being “held to ransom” in order to access life-saving vaccines. Campaigners are already warning of a “vaccine apartheid” in which rich Western countries may be inoculated years before poorer regions. Now, legal experts have raised concerns that Pfizer’s demands amount to an abuse of power. “Pharmaceutical companies shouldn't be using their power to limit life-saving vaccines in low- and middle-income countries,” said Professor Lawrence Gostin, director of the World Health Organization’s Collaborating Center on National and Global Health Law. “[This] seems to be exactly what they're doing.” Protection against liability shouldn’t be used as “the sword of Damocles hanging over the heads of desperate countries with a desperate population,” he added. Pfizer has been in talks with more than 100 countries and supranational organisations, and has supply agreements with nine countries in Latin America and the Caribbean: Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, Mexico, Panama, Peru, and Uruguay. The terms of those deals are unknown. Pfizer told the Bureau: “Globally, we have also allocated doses to low- and lower-middle-income countries at a not-for-profit price, including an advance purchase agreement with Covax to provide up to 40 million doses in 2021. We are committed to supporting efforts aimed at providing developing countries with the same access to vaccines as the rest of the world.” It declined to comment on ongoing private negotiations. Most governments are offering indemnity – exemption from legal liability – to the vaccine manufacturers they are buying from. This means that a citizen who suffers an adverse effect after being vaccinated can file a claim against the manufacturer and, if successful, the government would pay the compensation. In some countries people can also apply for compensation through specific structures without going to court. This is fairly typical for vaccines administered in a pandemic. In many cases adverse effects are so rare that they do not show up in clinical trials and only become apparent once hundreds of thousands of people have received the vaccine (a 2009 H1N1 flu vaccine, for example, was eventually linked to narcolepsy). Because manufacturers have developed vaccines quickly and because they protect everyone in society, governments often agree to cover the cost of compensation. However, the government officials from Argentina and the unnamed country who spoke to the Bureau felt Pfizer's demands went beyond those of other vaccine companies, and beyond those of Covax, an organisation created to ensure low-income countries can access vaccines, which is also requiring its members to indemnify manufacturers. This presents an additional burden for some countries because it means having to hire specialist lawyers and sometimes pass complex new legislation, so manufacturers’ liabilities can be waived. ‘An extreme demand’ Pfizer asked for additional indemnity from civil cases, meaning that the company would not be held liable for rare adverse effects or for its own acts of negligence, fraud or malice. This includes those linked to company practices – say, if Pfizer sent the wrong vaccine or made errors during manufacturing. “Some liability protection is warranted, but certainly not for fraud, gross negligence, mismanagement, failure to follow good manufacturing practices,” said Gostin. “Companies have no right to ask for indemnity for these things.” Dr Mark Eccleston-Turner, a lecturer in global health law at Keele University, said Pfizer and other manufacturers have received government funding to research and develop the vaccines and are now pushing the potential costs of adverse effects back on to governments, including those in low- and middle-income countries. (Pfizer’s partner BioNTech was given $445m by the German government to develop a vaccine and the US government agreed a deal in July to pre-order 100m doses for nearly $2bn, before the vaccine had even entered phase three trials. Pfizer expects to make sales of $15bn worth of vaccines in 2021.) “Pfizer misbehaved with Argentina. Its intolerance with us was tremendous” – Ginés González Garcia, former minister of health In Eccleston-Turner’s opinion, it looks like Pfizer “is trying to eke out as much profit and minimise its risk at every juncture with this vaccine development then this vaccine rollout. Now, the vaccine development has been heavily subsidised already. So there's very minimal risk for the manufacturer involved there.” The Bureau spoke to officials from two countries, who all described how meetings with Pfizer began promisingly but quickly turned sour, and reviewed a report by the Brazilian Ministry of Health. The Argentinian Ministry of Health began negotiating with the company in June and President Alberto Fernández held a meeting with Pfizer Argentina’s CEO the following month. During subsequent meetings Pfizer asked to be indemnified against the cost of any future civil claims. Although this had never been done before, Congress passed a new law in October allowing for it. However, Pfizer was not happy with the phrasing of the legislation, according to an official from the president’s office. The government believed Pfizer should be liable for any acts of negligence or malice. Pfizer, said the official, disagreed. The government did offer to amend the existing law to make it clear “negligence” meant problems in the distribution and delivery of the vaccines. But Pfizer was still not satisfied. It asked the government to amend the legislation through a new decree; Fernández refused. “Argentina could compensate for the vaccine’s adverse effects, but not if Pfizer makes a mistake,” said the official, who has detailed knowledge of the negotiations. “For example, what would happen if Pfizer unintentionally interrupted the vaccine’s cold chain [of -70C transport and storage] … and a citizen wants to sue them? It would not be fair for Argentina to pay for a Pfizer error.” The official said talks soon became tense and complicated: “Instead of giving in on some points, Pfizer demanded more and more.” In addition to the changes in the new law, it asked Argentina to take out international insurance to pay for potential future cases against the company (countries were also asked to do this during the H1N1 outbreak). In late December, Pfizer made another unexpected request: that the government put up sovereign assets – which might include federal bank reserves, embassy buildings or military bases – as collateral. “We offered to pay for millions of doses in advance, we accepted this international insurance, but the last request was unusual: Pfizer demanded that the sovereign assets of Argentina also be part of the legal support,” the official said. “It was an extreme demand that I had only heard when the foreign debt had to be negotiated, but both in that case and in this one, we rejected it immediately.” An illustration of a medicine bottle where the cap is a padlock ‘Good cop, bad cop’ The failed negotiations mean Argentinian citizens, unlike those in neighbouring countries, do not have access to Pfizer’s vaccine, leaving them with Russia’s Sputnik V vaccine, AstraZeneca’s vaccine and those delivered through Covax. The government is also negotiating to acquire vaccines from Moderna, Sinopharm and CanSino. “Pfizer misbehaved with Argentina,” said Ginés González Garcia, Argentina’s former minister of health. “Its intolerance with us was tremendous.” (González Garcia resigned at the weekend after allegations that VIPs had been allowed to jump the queue for vaccines.) The same demands were made of Brazil’s Ministry of Health. Pfizer asked to be indemnified and asked the ministry to put up sovereign assets as collateral, as well as create a guarantee fund with money deposited in a foreign bank account. In January, the ministry refused these terms, describing the clauses as “abusive”. An official from another Latin American country, which cannot be named, described talks unfolding similarly. They said the government began negotiating with Pfizer in July, before the vaccine was approved. There was a perception that Pfizer’s negotiators had a “good cop, bad cop” routine, with the “bad cop” pressing the government to buy more doses. “[At that time] there was not a single drug or vaccine in the world with this kind of technology that had been shown to be safe and effective … You had this lady putting pressure saying: ‘Buy more, you’re going to kill people, people are going to die because of you,’” the offi

### Solvency & Impact:

#### : The plan solves because it would facilitate increased production and enable others to build vaccines thus increase access preventing neoclonial imperialism, people dying

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What is the TRIPS COVID-19 waiver? This narrow waiver, proposed initially by South Africa and India, would temporarily waive patent rights over these products to facilitate increased production volume and more widespread manufacturing worldwide. Nevertheless, while the US and the EU push for more discussion about the facts of the current situation, South Africa, India, and others are seeking to negotiate the text of the proposed waiver. At the moment, the talks are at an impasse. But evidence is mounting that signing the TRIPS waiver would not only be good for the current supporters of the initiative, but for the whole world, and maybe especially for the developed countries who are currently opposed to it. The financial costs to all countries during the pandemic goes far beyond paying for the research and development, treatments and vaccines to manage COVID-19 cases. Economic impacts will be felt across the global economy through supply chain disruptions rooted in growing inequality within and between countries, likely costing around $9.2 trillion dollars, half of which would be borne by a handful of developed economies. The projected timeline for vaccinations exacerbates the financial costs. Initial predictions for vaccine rollout all over the world have proven optimistic at best and current projections suggest that many will have to wait at least three, and up to seven, years for substantial global immunity through vaccines, leaving low-income countries hopelessly behind. The lack of manufacturing capacity by drugmakers One of the main reasons the vaccines have not become as widely available as initially hoped is the lack of production capacity by key firms. For obvious reasons, a small handful of corporations cannot produce enough vaccines for the whole world population. Producing enough will depend heavily on licensing and transferring technology to more manufacturers. This reality is highlighted by a recent case in which a vaccine innovator company (Inovio) sued its own contracted biologics manufacturer (VGXI) because they refused to release their own trade secrets to other potential producers in order to ramp up capacity. These same supply capacity issues afflict other more well-known companies as well – including Novavax and Moderna. Pharmaceutical companies would prefer to rely on voluntary licensing agreements (VLAs) to increase production. These VLAs allow the patent holder to control who is producing their patented good and where they are able to sell the product. Gilead’s VLA to produce remdesivir is the most widely known example of such a process. While initially applauded for increasing access and to a potentially life-saving treatment for COVID-19 at affordable prices, further research showed that the agreement excluded 70 countries who would have to purchase the drug at the monopoly price. Given that cautionary tale, it is unlikely that VLAs would be enough to ensure widespread access. The rigid reality of the TRIPS Agreement Many countries who push back against a TRIPS waiver suggest that the TRIPS Agreement is already flexible in its allowance of compulsory licensing to facilitate generic manufacture of patented vaccines. The agreement allows member states to authorise compulsory licenses (CLs) under their own domestic law in cases of extreme urgency, as long as the scope and duration of the license is narrowly circumscribed. In ordinary circumstances, countries can impose a CL if they are unable to negotiate a voluntary license within a reasonable period of time. In both cases, the innovator is due “adequate remuneration” (Art. 31). Certainly, there has never been a case of extreme urgency like this one, and WTO members theoretically may have recourse to this provision. However, previous CLs issued by member states have met with both public and private opposition. The United States has repeatedly put pressure on India for its CL on an expensive cancer drug, claiming that India is “diluting” intellectual property rights and violating the TRIPS Agreement. Private pharmaceutical companies and U.S. lawmakers have even taken action to threaten sanctions against India through its Special 301 Report, a trade watch-list of sorts. Colombia faced similar backlash when they took the first steps toward issuing a CL for a leukemia treatment – Glivec. Both the Swiss government and Novartis, the patent holder, argued forcefully that CLs are “tantamount to expropriation” – code for exercising a sort of eminent domain through regulation. More recently, Malaysia attempted to use a CL to increase affordability of a Hepatitis C medication and once more the United States, together with its pharmaceutical industry, threatened to wield the power of sanctions through a Special 301 Report. As a result of these and other instances, countries have, understandably, been reluctant to develop more flexible domestic CL policies and are certainly out of practice in using them. A TRIPS COVID-19 waiver opens up global production Given the challenges of imposing compulsory licenses and the limits of voluntary ones, the TRIPS waiver offers another way for vaccine producers around the world to ramp up global production without the risks of contending with domestic and international IP disputes.

Additionally, the countries opposing the TRIPS waiver make two other key and yet contradictory, arguments. In the first place, they argue, intellectual property protection is what made these vaccines possible to begin with – undermining those rights, then could undercut the potential for future lifesaving products. The protection of intellectual property is certainly aimed at increasing innovation, and some studies have shown that innovation does increase with greater protection. At the same time, other research suggests that strong IP protection could actually discourage subsequent innovation. Even without disregarding the valuable role of intellectual property protection, however, the TRIPS waiver would not dismantle our current system of innovation incentives. Rather it is a narrow, time-limited waiver aimed only at facilitating global access to COVID-19 related products. Most of the vaccine developers have already received ample government support for the research and development stage – diminishing the need for patent monopolies (which are supposed to make up for large up-front capital expenditure). The second argument put forward by opponents of the TRIPS waiver points out that intellectual property rights are not the real bottleneck preventing more rapid global production, at least in the case of vaccines. Rather, the manufacturing capacity of most of the world’s countries is simply not advanced enough to make these types of vaccines. But this argument seems to run up against the vein of the previous contention – if intellectual property rights are not the issue, if no vaccine manufacturers are going to be able to ramp up production to make any kind of real difference in distribution, then there’s no point in being concerned about temporarily waiving those rights. The current producers will still effectively benefit from their patent monopolies. The current producers will still effectively benefit from their patent monopolies. On the other hand, there is growing evidence that perhaps qualified producers around the world stand ready to contribute to the production of more vaccines. Despite an unknown timeline, there is a real possibility that the TRIPS waiver may make it possible for a huge increase in vaccine production, not to mention the production of other COVID-19 treatments and equipment. When could the TRIPS COVID-19 waiver happen? Looking toward the next scheduled meeting of the TRIPS Council on February 25, the rationale behind protecting the profits of large pharmaceutical companies seems to be weakening. Signing the TRIPS waiver for COVID-19-related products, treatments and vaccines is the right thing to do, and everyone will benefit from it.

#### Waiver boosts vaccine production it helped with N-95 mask

**Siripurapu ’21** -- Anshu Siripurapu covers economics, energy, and geopolitics, and helps edit the Daily News Brief. He holds a BA in political economy from the University of Southern California. (Anshu Siripurapu, 5-26-2021, "The Debate Over a Patent Waiver for COVID-19 Vaccines: What to Know," Council on Foreign Relations, <https://www.cfr.org/in-brief/debate-over-patent-waiver-covid-19-vaccines-what-know>, accessed 8-29-2021) //nikki

Proponents say the waiver could boost the production of vaccines and other live-saving products. The WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) commits members to guaranteeing a minimum level of IP protection, including twenty-year patents and safeguards for copyrights, trade secrets, and industrial designs. Those rules, advocates of the waiver say, are preventing companies other than the inventors from manufacturing critical medical products. In their initial proposal, India and South Africa cited an example of such a bottleneck: early in the pandemic, the United States suffered N95 respirator shortages which led Kentucky Governor Andy Beshear to call on the manufacturer to lift its patents. Waiver proponents also point to the generous government funding that pharmaceutical companies received to support their development of COVID-19 vaccines and argue that the public is entitled to greater access even if that means fewer profits. Without a waiver, governments still have the authority to allow companies to produce a patented product without the rights-holder’s consent during public health emergencies—known as compulsory licensing. But those in support of a waiver say the process is too complicated and piecemeal. In addition, the United States and other wealthy countries have looked unfavorably on, and often pressured, countries that grant compulsory licenses.

#### A Waiver is not outrageous, it solves, and its been funded by the public

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The World Trade Organization (WTO) General Council gathered virtually on Monday for the first of two days of talks amid increasing calls from civil society, states and nongovernmental actors to temporarily waive patents for COVID-19 vaccines and other coronavirus-related medical products. Endorsing a waiver on Friday, World Health Organization (WHO) Director-General Tedros Adhanom Ghebreyesus said: “If not now, when?” At the core of the discussion stands a proposal (PDF) submitted in October by South Africa and India to suspend the WTO’s agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for the duration of the coronavirus pandemic. The goal is to facilitate the transfer of technology and scientific knowledge to developing countries to ramp up the global production of vaccines and other necessary equipment. “The biggest evidence [to endorse the waiver] is people that continue to die,” said Yuanqiong Hu, legal adviser for the Access Campaign for Doctors Without Borders (Medecins Sans Frontieres, or MSF). Several high-income countries and companies that have developed coronavirus vaccines have rejected the idea of a waiver for the duration of the pandemic. On her first day in office on Monday, WTO Director-General Ngozi Okonjo-Iweala did not endorse either side, saying that dialogue on the proposal was “intensifying”. Tedros Adhanom Ghebreyesus has endorsed a waiver [World Health Organization/Handout via Reuters] Growing calls for waiver Nearly one year into the pandemic, three-quarters of the current vaccine supply has been secured and administered by 10 countries that account for 60 percent of global economic growth, the WHO said in early February. By contrast, about 130 countries – home to 2.5 billion people – had not received a single dose, the United Nations health agency said. The UN-backed COVID-19 Vaccines Global Access Facility (COVAX), a scheme designed to boost the distribution of vaccines to low-income nations, has since begun sending shipments to some countries. Ghana and the Ivory Coast each received hundreds of thousands of doses last week and dozens of other African countries are expected to receive shipments this week, but the disparity between high- and low-income countries remains vast. The strikingly unequal distribution of vaccines has boosted support for India and South Africa’s proposal, which now counts 100 supporters among WTO members, including 58 official sponsors. Last week more than 400 organisations in the United States joined forces, calling on US President Joe Biden to endorse the waiver, while 115 members of the European Commission issued a declaration (PDF) urging the European Union to drop its opposition to the temporary suspension. The African Union on Thursday backed the relaxing of rules on intellectual property (IP), calling it a “win-win for everybody”. What are the arguments? Several high-income countries – including the US, the United Kingdom and members of the European Union – pushed back at the WTO, arguing that waiving patents would hamper scientific innovation by deterring private investment and that existing regulations, which allow drugmakers to voluntarily engage in bilateral agreements with generic manufacturers, are already flexible enough when it comes to tackling a public health emergency. Supporters of the plan disagree that a waiver would hamper scientific development, ­­­­­­­­and point out that vaccine developers received about $10bn in public and non-profit funding for their vaccine candidates, with five top companies securing between $950m and $2.1bn in funding commitments, mostly from the Coalition for Epidemic Preparedness Innovations (CEPI) and the US government, as reported by The Lancet medical journal. In terms of developing countries’ production capacity, proponents of the waiver pointed to already existing networks, such as the Developing Countries Vaccine Manufacturers Network (DCVMN). Comprised of 41 members – including the Serum Institute of India, the world’s largest vaccine maker – the DCVMN has supplied some 3.5 billion vaccines to the globe annually. “There is definitely capability out there but it won’t happen overnight,” said Tahir Amin, cofounder and co-executive director of I-MAK, a global non-profit organisation advocating for equitable access to medicines. “Companies might have to do some restructuring and get funds. But by removing IP, then governments might make investments and within a year we could have a new setup,” said Amin. “Considering mutations, more outbreaks – the fact that we need more manufacturers and not to rely on a few is imperative now,” he added. A waiver would not just enable the establishment of a practical framework to scale up production amid a pandemic, but would send a strong public health message, according to Fatima Hassan, founder and director of the Health Justice Initiative. “It is also a moral victory to say that we have a new order where IP cannot trump patients’ and public health’s needs – this is at the heart of it,” said Hassan, who has conducted public interest litigation against the South African government, private employers and pharmaceutical companies on behalf of people with HIV/AIDS in South Africa. Age-old argument The debate over intellectual property rights, while gaining traction in recent months, is not new. At the peak of the global HIV/AIDS crisis in the 1990s, millions of people in the developing world died without access to necessary drugs that were available on the market but were prohibitively expensive due to patents’ rules. It took a three-year fight before South Africa managed to import cheap antiretroviral drugs by removing some patent barriers after drug makers dropped a lawsuit accusing the country of infringing on international trade agreements. In 2001, WTO countries reached a landmark agreement by passing the Doha Declaration, which allowed member states to seek compulsory licensing when faced with extreme emergencies. It meant that governments were allowed to waive IP rights without the licence owner’s consent. Opponents to the waiver argue that compulsory licensing means that WTO members have sufficient flexibility regarding IP protections and that a temporary waiver is unnecessary. But experts warn the procedure is lengthy and complicated and its use would likely be met with fierce political resistance. When dealing with the production of complex drugs, such as mRNA vaccines, a manufacturer could seek a compulsory licence to overcome any patent barriers to producing the vaccine, but this will not give access to other elements needed to produce vaccines such as know-how, cell lines, and regulatory filings. “For that to happen, direct technology transfer is necessary,” said Ellen ‘t Hoen, director of Medicines Law & Policy. And for that purpose, the WHO has established the COVID-19 Technology Access Pool (C-TAP), where companies can share their know-how. “However, so far the C-TAP is empty,” said Hoen. “COVID-19 development has been largely funded with public money, so the request to share the know-how developed with this public financing is not only necessary but also reasonable.” Compromise? Supporters and opponents to the waiver plan have been engaging in a circular discussion without reaching a breakthrough, but “there is an understanding that something has to be done”, said South Africa’s WTO representative Mustaqeem De Gama. While it may still take some time before finding a convergence between the two sides, De Gama said, there is hope that countries will show at the council “at least a willingness to address the text of the proposal to see if we can find a landing zone”. The issue will likely be discussed again at the WTO TRIPS Council meeting on March 10. But despite the growing public support for the India-South Africa plan, Amin believes it is more likely that governments could strike a compromise by pressuring drug companies to grant more voluntary licences to manufacturers located in the Global South. So far, the existing arrangements between drugmakers and manufacturers in the developing world include Johnson & Johnson with Aspen Pharmacare in South Africa, while AstraZeneca and Novavax have made deals with the Serum Institute of India. After Monday’s meeting, Okonjo-Iweala urged WTO members to work with drugmakers to license more vaccine manufacturing in developing countries. “I propose that we ‘walk and chew gum’ by also focusing on the immediate needs of dozens of poor countries that have yet to vaccinate a single person. People are dying in poor countries,” she said in a speech. “The world has a normal capacity of production of 3.5 billion doses of vaccines and we now seek to manufacture 10 billion doses.”

#### Just because of a few concerns, you cannot deny the right to give people life saving drugs – its immoral and it solves

**Nature ’21** -- (Nature, 5-25-2021, "A patent waiver on COVID vaccines is right and fair," Nature, <https://www.nature.com/articles/d41586-021-01242-1>, accessed 8-29-2021) //nikki

Every country should have the right to make its own vaccines during a pandemic. That’s the principle underpinning the campaign to temporarily waive intellectual property (IP) protection on coronavirus vaccines. The campaign was initiated by India and South Africa, and is being backed by more than 100 countries, along with international organizations including the World Health Organization and the United Nations AIDS charity, UNAIDS. The goal is to reduce the barriers to countries producing their own vaccines — particularly for the lowest-income nations. At present, the proposal does not have the support of the pharmaceutical industry, nor that of most high-income nations. Instead, these countries are pledging to share more of their own vaccines with low-income nations and to provide more funding to charitable vaccine-provision schemes such as COVAX. However, in a surprising and welcome move earlier this month, the United States, Russia and China came out in support of an IP waiver on vaccines. The significance of the US decision in particular cannot be overstated, because the country is the world’s largest market for pharmaceuticals. For decades, US governments have worked with industry, universities and other research-intensive nations in setting — and enforcing — IP rules, most recently through the World Trade Organization (WTO), where the IP waiver proposal is being discussed. Even a few months ago, the mere idea of the United States taking this position would have been unthinkable. Now that it has done so, those countries still holding out — notably Japan, South Korea, the United Kingdom and European Union member states — need to follow suit. How COVID spurred Africa to plot a vaccines revolution One of the biggest concerns about IP waivers is that they provide a short-cut to competitors looking to acquire expensive technology. Companies also say that IP relief will not accelerate vaccine manufacturing, because materials are in short supply and it can take several years to build up capacity from scratch. Moreover, the governments opposing the waiver argue that current WTO rules already allow countries to apply for ‘compulsory licensing’ to override IP during emergencies. Right now, for example, Bolivia is applying to the WTO to use this process to allow it to manufacture Johnson & Johnson’s COVID vaccine. However, a group of researchers in the United Kingdom who study patent law point out in a draft paper on the waiver proposal that compulsory licences are extremely complex and time-consuming to apply for (S. Thambisetty et al. Preprint at https://ssrn.com/abstract=3851737; 2021). The EU has also pointed out that the United States has been blocking exports of COVID-19 vaccines and their components. It is right that this be called out. The easing of such restrictions is essential in a pandemic. These are important arguments, and need to be addressed. But they are not, in themselves, reasons for denying IP relief. If anything, as the pandemic wears on, the reasons to allow a waiver grow stronger. The core problem is that vaccine manufacturing, research and development is too heavily concentrated in a small group of high- and middle-income countries. Companies in these countries, which are also the main IP holders, have sold the majority of available vaccine doses to their own governments, and to governments of other high-income nations. Some 6 billion doses out of the 8.6 billion confirmed purchases so far have been pre-ordered by governments in high- and middle-income countries. It’s time to consider a patent reprieve for COVID vaccines According to pharmaceutical-industry data, the industry expects to have made a total of about ten billion vaccine doses by the end of 2021. But on the basis of current trends, this is unlikely to happen, according to researchers at the International Monetary Fund in Washington DC. In a paper published on 19 May, they report that the industry is likely to have produced around six billion doses by the end of 2021 (see go.nature.com/2tchn13). This potential shortfall increases the risk that people in low-income countries will need to wait even longer for their first doses. As Nature went to press, the number of vaccines given so far in Africa amounted to little more than one dose per person for some 2% of Africa’s 1.2 billion people. This is, among other factors, because the continent currently imports 99% of its vaccines, and because African countries lack the pre-order purchasing capacity of richer nations. It is why the African Union has announced a plan for 60% of Africa’s vaccines to be manufactured on the continent by 2040. At the Global Health Summit in Rome last week, ahead of this week’s World Health Assembly in Geneva, Switzerland, European nations promised to share more vaccine doses with low- and middle-income countries. European Commission president Ursula von der Leyen is also proposing to ‘clarify and simplify’ the existing ways in which countries can implement compulsory licensing. And there is a strong possibility that the G7 group of the world’s biggest economies will pledge more funding for vaccination when member countries meet in the United Kingdom next month. These commitments are crucial in the race to end the pandemic. But they do not deal with the systemic issue — countries backing the IP waiver are not asking for charity, but for the right to develop and make their own vaccines, free from the worry that they will be sued by patent holders. Those backing the COVID IP waiver understand this core principle. The leaders of countries that are not currently in favour of the patent waiver must recognize it, too. As John Nkengasong, director of the Africa Centres for Disease Control and Prevention, says: they need to be on the right side when the history of the pandemic comes to be written.