

***I affirm the resolution- The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.***

**Frame work:**

The criterion is Utilitarianism, defined as achieving the greatest good for most people

This is the best criterion for 4 reasons:

1. Actor specificity: States can't interpret intentions. Every government action entails trade offs because every action benefits some and harms others. They have to deliberate over multiple choices to determine which one has the best effect.
2. No Act-Omission distinction: Omissions are actions, if you see a baby drowning in a pool and you could save it, then choosing not to save it is still a choice that confers moral responsibility. This means we must use util because governments have to actively consider what policies to implement and what policies to omit.
3. Only consequentialism explains degrees of wrongness—if I break a promise to meet up for lunch, that is not as bad as breaking a promise to take a dying person to the hospital. Only the consequences of breaking the promise explain why the second one is much worse than the first. Intuitions outweigh—they're the foundational basis for any argument and theories that contradict our intuitions are most likely false even if we can't deductively determine why.
4. Lexical pre-requisite: If people are suffering and in conditions where they can't properly act, they can't act on other moral theories. Death and unnecessary suffering always comes first otherwise they can't act. You have to be alive to perform moral actions

# Contention 1- COVID

**COVID is a serious problem, and third world countries aren't getting access to vaccines because first world countries bought excess doses from companies. Banerjee et. al 21 discuss,**

The World Bank, 08/03/21,

<https://www.worldbank.org/en/news/podcast/2021/07/30/-absolutely-unacceptable-vaccination-rates-in-developing-countries-the-development-podcast>

Raka Banerjee: Hello, and welcome to The Development Podcast coming to you from the World Bank Group in the United States and around the world. I'm Raka Banerjee alongside Paul Blake. Paul Blake: Today, the race to vaccinate the world against COVID-19. We're examining why many **low-income countries** are **struggling to vaccinate their populations** and what's being done to help. Mamta Murthi (Clip): The situation that we see right now is absolutely unacceptable because **a large part of the world remains unvaccinated, and this is a danger** for all of us. Paul Blake: And from Addis Ababa, the steps being taken to accelerate vaccination rates across the African continent. Ahmed Ogwel (Clip): What we **want** are **vaccines now. We don't want vaccines in 2022, 2023.** And those vaccines that would be made available now have already been bought up. **It means that even though we have the money, we can't be able to buy because there's nothing to buy.** Paul Blake: All that and more over the next few minutes, but first let's take a look at some data. Paul Blake: All right, Raka. So you've been digging into the data and when it comes to COVID-19 vaccination rates around the world, what are you finding? Raka Banerjee: So I was looking at data that's available from the Our World in Data website, which is updated daily based on the latest official statistics from governments and health ministries around the world. And what has become painfully clear is that the main story when it comes to vaccines is inequality. Paul Blake: And what are some of those sort of major discrepancies? Raka Banerjee: So worldwide, almost 4 billion vaccine doses have been administered globally. And 27.6% of the world's population has received at least one dose of a vaccine at this point. So that sounds pretty good. But then if you break it down by country income groups, **1.1% Of people living in low income countries have received even one dose of a vaccine.** Paul Blake: And 1.1% is a very low number. Can you break it down and further? Raka Banerjee: So that's in terms of percentage of population, but then if you look at the breakdown when it comes to the percentage of doses to date, and this is as of July 28th, 84% of all doses that have been administered so far have all gone to people in high and upper middle-income countries. And in comparison, looking at the percentage of doses that have been administered in low-income countries, it's a shockingly low 0.3%. Paul Blake: I mean, that's a huge difference. Do things look any better if you start to compare across regions? Raka Banerjee: Honestly, not really. So in terms of doses administered per every 100 people, Europe and North America come in at 84 and 82 doses respectively, and keep in mind that most of the vaccines are two dose regimens, right? Paul Blake: Right. Raka Banerjee: And then right from there, it drops really starkly. So South America has administered only 59 doses per 100 people, Asia 54, and then across Africa the rate is fewer than five doses for every 100 people. Paul Blake: And is it a question of problems with production or with making the vaccines? Or is this an issue with doses being sort of held in surplus and not being made available to people who need them in other locations? And I guess if it's about that second point, like excess doses, where are they and why aren't they being released? Raka Banerjee: So a big part of the problem is that many **wealthy countries** actually

pre-ordered far more vaccine doses than they even needed to vaccinate their populations. Looking at data coming from Duke University, just for example, the US paid for enough vaccines for twice its

## Global vaccine inequality threatens progress in overcoming Covid 19. 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 headquarters 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.

## Arguments against the TRIPS waiver are short sighted, and slow down incentives to improve the situation of the pandemic

**Lindsey 21** (Brink Lindsey is Vice President and Director of the Open Society Project at the Niskanen Center. Previously he was the Cato Institute's vice president for research. "Why intellectual property and pandemics don't mix"  
<https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/> )

Although focusing on these immediate constraints is vital, we cannot confine our attention to the short term. First of all, the COVID-19 pandemic is far from over. Although Americans can now see the light at the end of the tunnel thanks to the rapid rollout of vaccines, most of the world isn't so lucky. The virus is currently raging in India and throughout South America, overwhelming health care systems and inflicting suffering and loss on a horrific scale. And consider the fact that Australia, which has been successful in suppressing the virus, recently announced it was sticking to plans to keep its borders closed until mid-2022. Criticisms of the TRIPS waiver that focus only on the next few months are therefore short-sighted: this pandemic could well drag on long enough for elimination of patent restrictions to enable new vaccine producers to make a positive difference. Furthermore, and probably even more important, this is almost certainly not the last pandemic we will face. Urbanization, the spread of factory-farming methods, and globalization all combine to increase the odds that a new virus will make the jump from animals to humans and then spread rapidly around the world. Prior to the current pandemic, the 21st century already saw outbreaks of SARS, H1N1, MERS, and Ebola. Everything we do and learn in the current crisis should be viewed from the perspective of getting ready for next time. When we take the longer view, we can see a fundamental mismatch between the policy design of intellectual property protection and the policy requirements of effective pandemic response. Although patent law, properly restrained, constitutes one important element of a well-designed national innovation system, the way it goes about encouraging technological progress is singularly ill-suited to the emergency conditions of a pandemic or other public health crisis. Securing a TRIPS waiver for COVID-19 vaccines and treatments would thus establish a salutary precedent that, in emergencies of this kind, governments should employ other, more direct means to incentivize the development of new drugs. Here is the basic bargain offered by patent law: encourage the creation of useful new ideas for the long run by slowing the diffusion of useful new ideas in the short run. The second half of the bargain, the half that imposes costs on society, comes from the temporary exclusive rights, or monopoly privileges, that a patent holder enjoys. Under U.S. patent law, for a period of 20 years nobody else can manufacture or sell the patented product without the permission of the patent holder. This allows the patent holder to block competitors from the market, or extract licensing fees before allowing them to enter, and consequently charge above-market prices to its customers. Patent rights thus slow the diffusion of a new invention by restricting output and raising prices. The imposition of these short-run costs, however, can bring net long-term benefits by sharpening the incentives to invent new products. In the absence of patent protection, the prospect of easy imitation by later market entrants can deter would-be innovators from incurring the up-front fixed costs of research and development. But with a guaranteed period of market exclusivity, inventors can proceed with greater confidence that they will be able to recoup their investment. For the tradeoff between costs and benefits to come out positive on net, patent law must strike the right balance. Exclusive rights should be valuable enough to encourage greater innovation, but not so easily granted or extensive in scope or term that this encouragement is outweighed by output restrictions on the patented product and discouragement of downstream innovations dependent on access to the patented technology.

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

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).<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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 focus[s] on compulsory licensing and removing vaccine export restrictions to address the concerns raised by India and South Africa.<sup>4</sup> The EU proposal also stated that the TRIPS Agreement does not prevent countries from taking measures to protect public health.<sup>5</sup> 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).<sup>6</sup> 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).<sup>7</sup> 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.<sup>8</sup> 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.<sup>9</sup> 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.<sup>10</sup> 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.<sup>11</sup>

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.<sup>12</sup> 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.<sup>13</sup> 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.<sup>14</sup> 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.<sup>15</sup> The Big Pharma also lobbied developed countries, particularly the US, to put bilateral trade sanctions against South Africa.<sup>16</sup> 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.<sup>17</sup> 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. <sup>18</sup> Likewise, Pfizer's aggressive patenting strategy prevented South Korea in developing pneumonia vaccines for children.<sup>19</sup> 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.<sup>20</sup> The MSF also found that patents pose a severe threat to access to affordable versions of newer vaccines.<sup>21</sup> 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.<sup>22</sup>

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.<sup>23</sup> 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."<sup>24</sup> Similarly, Article 66.2 also mandates the developed countries to transfer technologies to LDCs to enable them to create a sound and viable technological base. The LMICs opened their markets and amended domestic patent laws favouring developing countries' products against this promise of technology transfer. Another argument against the proposed TRIPS waiver is that a waiver would not increase the manufacturing of COVID-19 vaccines. Indeed, one of the significant factors contributing to vaccine inequity is the lack of manufacturing capacity in the global south. Further, a TRIPS waiver will not automatically translate into improved manufacturing capacity. *However, a waiver would be the first but essential step to increase manufacturing capacity worldwide*. For instance, to export COVID-19 vaccine-related products, countries need to ensure that there are no IP restrictions at both ends – exporting and importing. The market for vaccine materials includes consumables, single-use reactors bags, filters, culture media, and vaccine ingredients. Export blockages on raw materials, equipment and finished products harm the overall output of the vaccine supply chain. If there is no TRIPS restriction, more governments and companies will invest in repurposing their facilities. Similarly, the arguments such as that no other manufacturers can carry out the complex manufacturing process of COVID-19 vaccines and generic manufacturing as that *would jeopardise quality*, have also been *proven wrong in the past*. For instance, in the early 1990s, when Indian company Shantha Biotechnics approached a Western firm for a technology transfer of Hepatitis B vaccine, the firm responded that "India cannot afford such high technology vaccines... And even if you can afford to buy the technology, your scientists cannot understand recombinant technology in the least."<sup>25</sup> 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.<sup>26</sup> Similarly, Bangladesh and Indonesia claimed that they could manufacture millions of COVID-19 vaccine doses a year if pharmaceutical companies share the know-how.<sup>27</sup> Recently, Vietnam also said that the country could satisfy COVID-19 vaccine production requirements once it obtains vaccine patents.<sup>28</sup> 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.

## **Contention 2- pharmaceutical industries**

**Patent law facilitates the abuse of the pharmaceutical industry.**

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<https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/> )

Unfortunately, **the U.S. patent system at present is out of balance.** Over the past few decades, **the expansion of patentability** to include software and business methods as well as a general relaxation of patenting requirements **have led to wildly excessive growth in these temporary monopolies**: the number of patents granted annually has skyrocketed roughly fivefold since the early 1980s. One unfortunate result has been the rise of "non-practicing entities," better known as patent trolls: firms that make nothing themselves but buy up patent portfolios and monetize them through aggressive litigation. **As a result, a law that is supposed to encourage innovation has turned into a legal minefield for many would-be innovators.** In the pharmaceutical industry, firms have abused the law by piling up patents for trivial, therapeutically irrelevant "innovations" **that allow them to extend their monopolies and keep raising prices** long beyond the statutorily contemplated 20 years. Patent law is creating these unintended consequences because policymakers have been caught in an ideological fog that conflates "intellectual property" with actual property rights over physical objects. Enveloped in that fog, **they regard any attempts to put limits on patent monopolies as attacks on private property** and view ongoing expansions of patent privileges as necessary to keep innovation from grinding to a halt. In fact, patent law is a tool of regulatory policy with the usual tradeoffs between costs and benefits; like all tools, it can be misused, and as with all tools there are some jobs for which other tools are better suited. **A well-designed patent system, in which benefits are maximized and costs kept to a minimum, is just one of various policy options that governments can employ to stimulate technological advance—including tax credits for R&D, prizes for targeted inventions, and direct government support.** PUBLIC HEALTH EMERGENCIES AND DIRECT GOVERNMENT SUPPORT For pandemics and other public health emergencies, patents' mix of costs and benefits is misaligned with what is needed for an effective policy response. **The basic patent bargain, even when well struck, is to pay for more innovation down the road with slower diffusion of innovation today. In the context of a pandemic, that bargain is a bad one and should be rejected entirely.** Here **the imperative is to accelerate the diffusion of vaccines and other treatments, not slow it down.** Giving drug companies the power to hold things up by blocking competitors and raising prices pushes in the completely wrong direction. What approach to encouraging innovation should we take instead? How do we incentivize drug makers to undertake the hefty R&D costs to develop new vaccines without giving them exclusive rights over their production and sale? The most effective approach during a public health crisis is direct government support: public funding of R&D, advance purchase commitments by the government to buy large numbers of doses at set prices, and other, related payouts. And when we pay drug makers, we should not hesitate to pay generously, even extravagantly: we want to offer drug companies big profits so that they prioritize this work above everything else, and so that they are ready and eager to come to the rescue again the next time there's a crisis. It was direct support via Operation Warp Speed that made possible the astonishingly rapid development of COVID-19 vaccines and then facilitated a relatively rapid rollout of vaccine distribution (relative, that is, to most of the rest of the world). And it's worth noting that a major reason for the faster rollout here and in the United Kingdom compared to the European Union was the latter's misguided penny-pinching. The EU bargained hard with firms to keep vaccine prices low, and as a result their citizens ended up in the back of the queue as various supply line kinks were being ironed out. This is particularly ironic since the Pfizer-BioNTech vaccine was developed in Germany. As this fact underscores, the chief advantage of direct support isn't to "get tough" with drug firms and keep a lid on their profits. Instead, it is to accelerate the end of the public health emergency by making sure drug makers profit handsomely from doing the right thing. Patent law and direct support should be seen not as either-or alternatives but as complements that apply different incentives to different circumstances and time horizons. Patent law provides a decentralized system for encouraging innovation. The government doesn't presume to tell the industry which new drugs are needed; it simply incentivizes the development of whatever new drugs that pharmaceutical firms can come up with by offering them a temporary monopoly. It is important to note that patent law's incentives offer no commercial guarantees. Yes, you can block other competitors for a number of years, but that still doesn't ensure enough consumer demand for the new product to make it profitable. DIRECT SUPPORT MAKES PATENTS REDUNDANT **The situation is different in a pandemic. Here the government knows exactly what it wants to incentivize: the creation of vaccines to prevent the spread of a specific virus and other drugs to treat that virus.** Under these circumstances, the decentralized approach isn't good enough. **There is no time to sit back and let drug makers take the initiative on their own timeline.** Instead, the government needs to be more involved to incentivize specific innovations now. As recompense for letting it call the shots (pardon the pun), the government sweetens the deal for drug companies by insulating them from commercial risk. If pharmaceutical firms develop effective vaccines and therapies, the government will buy large, predetermined quantities at prices set high enough to guarantee a healthy return. For the pharmaceutical industry, it is useful to conceive of patent law as the default regime for innovation promotion. It improves pharmaceutical companies' incentives to develop new drugs while leaving them free to decide which new drugs to pursue – and also leaving them to bear all commercial risk. **In a pandemic or other emergency, however, it is appropriate to shift to the direct support regime, in which the government focuses efforts on one disease.** In this regime, it is important to note, the government provides qualitatively superior incentives to those offered under patent law. Not only does it offer public funding to cover the up-front costs of drug development, but it also provides advance purchase commitments that guarantee a healthy return. **It**

should therefore be clear that the pharmaceutical industry has no legitimate basis for objecting to a TRIPS waiver. Since, because of the public health crisis, drug makers now qualify for the superior benefits of direct government support, they no longer need the default benefits of patent support. Arguments that a TRIPS waiver would deprive drug makers of the incentives they need to keep developing new drugs, when they are presently receiving the most favorable incentives available, can be dismissed as the worst sort of special pleading. That said, it is a serious mistake to try to cast the current crisis as a morality play in which drug makers wear the black hats and the choice at hand is between private profits and public health. We would have no chance of beating this virus without the formidable organizational capabilities of the pharmaceutical industry, and providing the appropriate incentives is essential to ensure that the industry plays its necessary and vital role. It is misguided to lament that private companies are profiting in the current crisis: those profits are a drop in the bucket compared to the staggering cost of this pandemic in lives and economic damage.