

What's Yours Is Ours: Waiving Intellectual Property Protections for COVID-19 Vaccines

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ABSTRACT. This paper gives an ethical argument for temporarily waiving intellectual property (IP) protections for COVID-19 vaccines. It examines two proposals under discussion at the World Trade Organization (WTO): the India/South Africa proposal and the WTO Director General proposal. Section I explains the background leading up to the WTO debate. Section II rebuts ethical arguments for retaining current IP protections, which appeal to benefitting society by spurring innovation and protecting rightful ownership. It sets forth positive ethical arguments for temporary waivers that appeal to standing in solidarity and holding companies accountable. After examining built-in TRIPS exceptions and determining they are inadequate, the paper replies to objections to a temporary waiver and concludes, in Section III, that temporarily waiving IP protection for COVID-19 vaccines is a crucial first step to vaccinating the world.

In April 2021, over 100 Nobel laureates and 75 former heads of state called on President Biden to waive intellectual property (IP) protections for COVID-19 vaccines by suspending vaccine patents, urging him to undertake this "vital and necessary step to bringing an end to this pandemic."¹ Gravely concerned by slow progress in scaling up of global COVID-19 vaccine access in low- and middle-income countries, the signatories state that "these actions would expand global manufacturing capacity unhindered by industry monopolies that are driving the dire supply shortages blocking vaccine access." On May 5, 2021, President Biden, facing mounting pressure to do more, spoke out in support of a waiver. This remarkable turn of events came in the wake of two proposals currently before the World Trade Organization (WTO). The first, from India and South Africa, petitions the WTO for a temporary waiver of IP rights FOR COVID-related products.² The second, from the WTO Director General, proposes licensing vaccine manufacturing to countries to enable adequate vaccine supplies.³ While the letter to President Biden alluded to solidarity and saving lives, it does not develop a sustained ethical argument. This paper fills the gap, offering an ethical argument in support of temporarily waiving existing IP protections for COVID-19 vaccines. Section I gives background leading up to the WTO debate. Section II presents the ethical argument. Section III proposes next steps. We acknowledge that a temporary waiver is only one of many steps needed to expand vaccine production and get shots in arms. Since current forecasts suggest it will be 2023 or 2024 before COVID-19 vaccines reach low- and middle-income countries (LMICs), keeping the current IP structure intact is proving inadequate, which adds urgency to our inquiry. We focus on temporarily waiving IP protections for COVID-19 vaccines, rather than for all COVID-19 related products, because vaccines represent the most urgent need and because the protection they afford would make other forms of protection far less urgent than they currently are.

I. Background

Just months after the World Health Organization (WHO) determined COVID-19 was a pandemic, it issued a "solidarity call to action," imploring the global community to "commit to undertaking the...actions which are urgently needed to advance the pooling of knowledge, IP and data that will benefit all of humanity."⁴ Yet, the world has not heeded the call. Instead, for-profit companies have a stranglehold on patents, locking-in profits while simultaneously accepting government subsidies to offset research and development costs. According to Wall Street analysts, in 2021, Pfizer/BioNTech will score between \$15 and \$30 billion USD for COVID-19 vaccine sales, while Moderna could rake in between \$18-20 billion USD and Johnson & Johnson \$10 billion USD.⁵ In contracts with companies, government purchasers poured billions into procuring raw materials, financing clinical trials and retrofitting factories for drug companies, without requiring companies to share know-how or make vaccines accessible to low- and middle-income countries (LMICs). In pursuit of their own self-interest, governments simply paid for their own spot at the front of the vaccine line, leaving others behind. This has led to unequal access for rich and poor nations. As of June 2021, 85% of shots that have gone into arms worldwide have been administered in high and upper-middle income countries, and only 0.3% in low-income countries.⁶

Is there any possible ethical defense of such actions? There is in fact a view that holds vaccines are the brainchild of for-profit companies, who own the products of their labor. They have a right, protected by IP, to control the pricing and supply of products they own. They can give their goods away, or they can make **purchasers** pay through the nose. The law protects IP, both within and between nations, through copyrights (for authors of creative works); patents (for inventors of industrial goods); trademarks (for recognizable brands); and trade secrets. Prior to 1995, IP rights were protected internationally by more flexible rules, tailored to a country's socio-economic conditions. Under the Paris Convention, for example, rules for protecting industrial property allowed states to exclude whole sectors and to determine the length of their IP protection.⁷

The WTO's 1995 Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement changed the landscape for everyone. It dictated stricter protocols, mandating compulsory protection of IP rights by requiring WTO members to ensure minimal protection and enforcement of IP rights within their territories. It also mandated enforcement through a binding dispute settlement mechanism. **Importantly, the TRIPS agreement required countries to treat pharmaceuticals as an area protected by patents.**

The central justification for TRIPS was that stronger IP protections were necessary to incentivize innovation, which benefits everyone. The TRIPS agreement states that

The protections and enforcement of IP rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.⁸

The view underlying TRIPS holds that IP rights must remain in force under virtually all conditions because of their crucial role in encouraging innovation. The view is summarized by Suzman, CEO of the Bill & Melinda

Gates Foundation: "global disparities have sparked important debates about how to achieve more equitable distribution. Some have proposed broadly eliminating drug companies' IP protections for COVID-19 vaccines as a way to increase vaccine supply and reduce prices...this approach misses the mark. At our foundation, we believe that IP fundamentally underpins innovation."⁹ Gates has stated, "At this point, changing the rules wouldn't make any additional vaccines available," since few manufacturers have the capacity to make the vaccines and they are already at capacity.¹⁰ Nations who urge staying the course, which include the European Union, Switzerland, Norway, and Australia, assert there is "no concrete indication" that IP rights are "a genuine barrier to accessing COVID-19 related medicines and technologies," and that IP was only "one aspect of many that affect the manufacture and distribution of the new vaccines."¹¹

This view has come under increasing fire. Two competing positions have emerged. First, India and South Africa petitioned the WTO for a temporary waiver of IP rights for medical products pertaining to preventing, containing, or treating COVID-19.¹² The waiver would apply to all WTO members and lift IP restrictions in four sections of the TRIPS agreement: copyright and related rights, industrial designs, patents, and protection of undisclosed information. It would be reviewed annually and last for a specified number of years, determined by the WTO Council. Proponents of the India-South Africa proposal argue that IP protection has "hindered urgent scale-up of vaccine production" and that "many countries --especially developing countries-- may face institutional and legal difficulties when using TRIPS flexibilities."¹³ To break the divide, WTO Director General, Okonjo-Iweala, proposed a third way: "We can find what I call 'a third way' in which we can license manufacturing to countries so that we can have adequate supplies while still making sure that IP issues are taken care of."¹⁴ This approach allows companies to retain ownership while licensing other companies around the globe to manufacture their vaccines.

II. The Ethical Argument

Ethical arguments for temporarily waiving IP protections begin by showing why ethical arguments to the contrary fall short. Arguments for keeping IP protections intact include utilitarian and deontological types.

1. Consequentialist arguments for maintaining current IP protections fail. Utilitarian arguments set as a goal producing the greatest good to society and hold that IP protections are instrumental to achieving that end. The primary basis for this claim is the belief that the profits IP generates are essential to spur innovation and discovery which in turn, advances society's interests. Absent such profits, scientific discoveries would languish and medical progress would slow.

In reply, even assuming that the final translation of science into marketable products will not occur without financial incentives, how much money does it take? As noted, in 2021, Pfizer/BioNTech is expected to make between \$15 and \$30 billion USD in COVID-19 vaccine sales, Moderna \$18 to \$20 billion USD, and Johnson & Johnson \$10 billion USD. Could these companies earn less revenue and the incentive to innovate remain intact? To determine this, we make an evidence-based distinction between profits *necessary* to drive innovation and profits *exceeding* this. To gauge what is necessary, consider a study comparing the profits of 35 large pharmaceutical companies with 357 companies in the S&P 500 index between 2000 to 2018.¹⁵ It found

that large pharmaceutical companies had significantly higher profits than other large companies. This suggests that curbing pharmaceutical company profits would not necessarily cause innovation to grind to a halt. If profit aligned with comparable large S&P 500 companies, it seems reasonable to think that it would be sufficient to sustain innovation, while making pharmaceutical products more affordable and accessible.

Since consequentialist justifications regard the value of IP as purely instrumental, they are also vulnerable to counterarguments showing that a sought after goal is not the most urgent or important end. During the COVID-19 pandemic, it is easy to see that the goal of ending the pandemic is overriding. The evidence to date shows that IP protections have fallen well short of meeting the goal of vaccinating the world.

Current forecasts are that there will not be enough vaccines to cover the world's population until 2023 or 2024.¹⁶ IP protections have also contributed to a situation in which only a few companies hold the recipes and possess the technologies to make vaccines. The WHO reports that 80% of global COVID-19 vaccine sales come from 5 large multi-national corporations.¹⁷ Increasing the number of vaccine manufacturers around the globe would not only allow vaccines to reach more nations, but reduce prices, making them more affordable for LMICs. Furthermore, increasing vaccine suppliers would minimize disruptions to global vaccine supply, as occurred in March 2021, when India was forced to temporarily halt its vaccine exports. It could be objected that this approach is impractical, because it takes years to establish manufacturing capacity. Yet, since the pandemic began, we have learned that it takes less time than previously thought. Repurposing facilities and vetting them for safety and quality can often happen in six or seven months, about half the time previously thought.¹⁸ Since COVID-19 will not be the last pandemic humanity faces, expanding manufacturing capacity is also much needed preparation for future pandemics. Nkengasong, Director of the African Centres for Disease Control and Prevention, put the point bluntly, "Can a continent of 1.2 billion people --projected to be 2.4 billion in 30 years, where one in four people in the world will be African-- continue to import 99% of its vaccine?"

2. Deontological arguments for maintaining current IP protections fail. Deontological arguments for retaining the existing IP structure focus not on future consequences but rightful ownership. These types of arguments maintain that patent holders are the rightful owners of their inventions and are therefore entitled to have their inventions protected. In the context of COVID-19 vaccines, the claim is that pharmaceutical companies own vaccines, which are the products of their labor; no one can rightfully take what is theirs.

In reply, the public has invested heavily, and these products are *theirs* ' too. Even when the applied, translational part of product development is carried out by for-profit companies, this would be impossible without enormous prior public investment. To illustrate, consider emergency use authorization of remdesivir as a treatment for COVID-19. It came only after a \$6.5 billion National Institutes of Health (NIH) investment in foundational research on the biological target and parent chemical structure of remdesivir that supported its discovery and development for COVID-19.¹⁹ A 2021 review of published research on the technologies used in candidate COVID-19 vaccines, which spanned a range of diverse methodologies, found that these technologies were funded primarily by the public sector, principally governments.²⁰

Beyond the measurable contributions governments make to the development of COVID-19 vaccines, there are immeasurable, yet crucial, contributions made by those whose shoulders vaccine developers stand on. As Hettinger notes, deontological arguments for IP protections often give short shrift to the fact that discoveries do not occur in a vacuum but are "fundamentally social products."²¹ As one grateful physician, who received the Pfizer COVID-19 vaccine, puts it, "there is a whole chain of human toil that makes this possible":

My gratitude starts with scientists who years before this pandemic, perfected the ability to extract DNA from viruses, sequence it and transcribe it to RNA... the scientists who identified the segment of that DNA that codes for the spike proteins that the virus uses to invade our cells; those who made the mRNA that corresponds to that DNA sequence, and those who figured out how to create a lipid womb to protect that precious mRNA payload during its perilous journey from factory floor to the depths of our deltoid musculature.²²

The physician also thanked people who volunteered for Pfizer's trials, ran trials, reviewed and approved the vaccine, produced it, made the equipment producers relied on, and everyone else --"the pilots of planes and drivers of trucks who transported the vaccine ... the workers who made those planes and trucks that carried that precious cargo...and the people who fed them and clothed them and housed them so that they could do this life saving work." ²³

From a deontological standpoint, what patent holders rightfully own is limited to the additional value their efforts imparted to a vaccine. While there might be separate, utilitarian bases for rewarding laborers disproportionately, this is distinct from deontological arguments based on ownership. In sum, the deontological claim that pharmaceutical companies own the COVID-19 vaccines they developed does not withstand careful scrutiny.

2. Positive Arguments for Temporary Waivers. We turn next to positive ethical arguments for temporarily waiving IP protections for COVID-19 vaccines. These reasons supplement the deontological considerations stated above by appealing to globally solidarity and corporate social responsibility.

First, an ethic of global solidarity underscores that during the COVID-19 pandemic, each nation's interests are entwined with the interests of every other nation.²⁴ Just as it is impossible for any single nation, standing alone, to address the threat to human health that climate change raises, it is impossible for any single nation to meet the challenge that the COVID-19 pandemic (and future emerging infectious diseases) presents. Instead, humanity must stand together on the same team, to win the global race against the SARS-CoV-2 virus and its mutant strains. In the past, nations have often failed to do so. The epidemic of HIV/AIDS in Africa illustrates. Shamefully, it took nearly a decade for the first antiretroviral drugs to reach the African continent, despite the fact that Africa was the hardest hit region and antiretroviral drugs provided 90% mortality reduction. Although the U.S. government was an early investor in research that produced antiviral drugs for HIV, distribution of those drugs was controlled by big pharmaceutical companies driven by profit. The U.S. and other wealthy countries repeated this mistake during the COVID-19 pandemic, supporting vaccine developers without requiring technology transfers and donations to COVAX (the multilateral partnership

supplying vaccines to low- and middle-income countries). Ethically, part of the task ahead is fixing a problem of human making.

Second, because IP protections shield pharmaceutical companies from competition, they enabled them to monopolize markets and generate above-normal profits. Rather than allowing above-normal profits to accrue unchecked, society should set reasonable limits by requiring companies to give back to society. Even Locke, who conceived of our modern notion of property rights, held that fundamental rights like property could be justly overridden under certain conditions, namely, when the goods are perishable and would go to waste or when their extraction may intrude on the common good, in which case they extend only to what leaves enough behind for others.²⁵ Companies everywhere are becoming increasingly aware of the need for and benefits of socially responsible behavior, appreciating its impact on competitive advantage, reputation, retention of workers and customers, employee morale, and relationships with stakeholders.²⁶ During the COVID-19 pandemic, Moderna displayed social responsibility by indicating its willingness not to enforce its patents on COVID-19 vaccine technologies during the pandemic and to issue open licenses afterwards.

Building on the above analysis, we submit that displays of corporate social responsibility fall along a continuum. During the COVID-19 pandemic, *a high degree of social responsibility* would be shown by companies sharing recipes for COVID-19 vaccines, as India and South Africa propose; *moderate social responsibility* would be demonstrated by sharing licenses to manufacture COVID-19 vaccines while retaining ownership, as the WTO Director General proposes; and *minimal social responsibility* would be shown by sending vaccines directly to nations in response to pleas for help which was displayed by Pfizer, when it pledged to contribute up to 40 million doses of its COVID-19 vaccine to COVAX, which is less than 2% of the 2.5 billion doses it will produce in 2021.²⁷

III. Next Steps

The extraordinary circumstances of a global pandemic demand more than minimal or even moderate social responsibility. Everyone in a position to help must do what it takes, showing the high degree of social responsibility the moment calls for. Governments, especially governments in wealthy nations, should stand up to influence peddling by pharmaceutical companies,²⁸ which subverts democratic politics, and should do their part, beginning with casting a vote in favor of temporary waivers of IP protections for COVID-19 vaccines at the WTO.

Against our proposal it might be claimed that a temporary IP waiver is not enough. Manufacturing COVID-19 vaccines requires technical knowhow, technology, raw materials and equipment which is lacking in many LMICs. Pfizer, for example, has said that its vaccine requires 280 components from 86 suppliers in 19 countries, along with specialized equipment and trained personnel.²⁹ Since it takes much more than simply handing over recipes to vaccinate the world, what good is a temporary waiver?

In reply, we agree that a temporary waiver is not enough. However, a temporary IP waiver can help break the log jam. It can set in motion the necessary next steps by creating a climate of "legal certainty" that is far more favorable to public and private investment since it removes the threat of being sued or prosecuted.³⁰

Guzman points out that the most expedient strategies to expand vaccine manufacturing in LMICs involve developing and repurposing existing capacities, noting that some middle-income countries are already producing COVID-19 vaccines, and some manufacturers in LMICs are already able to manufacture viral vector vaccines, such as AstraZeneca's, and contribute to the fill-and-finish stage of vaccine production.³¹

A proponent of IP protections may insist that TRIPS already contains built-in exceptions that are adequate to the task. Thus, Article 31 already grants governments the right to issue licenses for the use of a patent during the patent term without the patent holder's consent. This exception was used 144 times between 2001 and 2016 to create flexibilities for 89 countries.³² In 2017, Article 31 was extended to allow licensed countries to export products to countries who lack production capacity. Isn't that enough?

In reply, Article 31 will not take us very far. While useful for some applications, it involves a cumbersome process. For example, for the import and export of pharmaceutical products, after applying for an exception, countries exporting products must prove they go only to the destination nation, are readily identifiable based on variations of colour or shape, and include only the amount necessary to meet requirements of the eligible country; nations receiving products must notify the TRIPS council of the export.³³ Fulfilling such requirements would not only be tedious, it would slow the path to global herd immunity.

Finally a critic of our approach might point to the example of Moderna, which essentially waived its patent rights to COVID-19 vaccines in October 2020, when it voluntarily pledged not to enforce its patents. Since companies have not lined up to produce Moderna's vaccine, doesn't that show the ineptitude of temporary waivers? In reply, a single waiver by a single company is a start, but it is insufficient to catalyze the kind of global changes needed to vaccinate the world.

In conclusion, loosening the grip of IP protections is not a miracle fix, and there are many other barriers to a safer world. This paper has filled a gap in current debates about IP protections for COVID-19 vaccines by focusing on ethics. Arguments based on rights and ownership of COVID-19 vaccines are weak and the ethical case for continuing IP protections therefore turns on consequentialist justifications. The demonstrated failure of the current TRIPS structure to extend Vaccine protection to all the nations of the world gives strong evidence that consequentialist defenses of IP are not holding up. In the final analysis, a temporary waiver of IP protections for vaccines is the world's best bet.

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