

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 benefiting society by spurring innovation and protecting rightful ownership. It sets forth positive ethical arguments for a temporary waiver that appeal to standing in solidarity and holding companies accountable. After examining built-in exceptions to existing agreements and finding them inadequate, the paper replies to objections to a temporary waiver and concludes, in section III, that the ethical argument for temporarily waiving IP protection for COVID-19 vaccines is strong.

In April 2021, over 100 Nobel laureates and 75 former heads of state called on United States (US) President Biden to waive intellectual property (IP) protections for coronavirus 2019 (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 making vaccines available to low-income and middle-income countries (LMICs), the signatories stated, ‘these actions would expand global manufacturing capacity unhindered by industry monopolies that are driving the dire supply shortages blocking vaccine access.’ On 5 May, facing mounting pressure, Biden spoke out in support of a waiver. This remarkable turn of events came in the wake of two proposals before the World Trade Organization (WTO). The first petitioned the WTO for a temporary waiver of IP rights for COVID-19-related products.² The second proposed licensing vaccine manufacturing to increase supply.³ While the letter to Biden alluded to solidarity and saving lives, it did not present a full ethical argument. This paper fills the gap, offering ethical arguments for temporarily waiving IP protections for COVID-19 vaccines. Section I gives background leading up to the WTO debate. Section II presents ethical arguments. Section III proposes next steps.

Throughout, the paper focuses on vaccines, which represent the most urgent need. The paper acknowledges that a temporary waiver is one of many steps needed to get shots in arms. While controversy exists about the most expedient method to increase global vaccine access, the paper makes the plausible assumption that the current approach will continue falling short. It further assumes that a temporary

waiver can help speed access and prepare the world for future pandemics. Based on these assumptions, we argue that a temporary waiver is ethically imperative and represents the world’s best bet.

BACKGROUND

Just months after the WHO determined COVID-19 was a pandemic, it issued a ‘solidarity call to action,’ imploring the global community to pool knowledge, IP, and data to benefit humanity.⁴ 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. In 2021, Pfizer/BioNTech will score 15–30 billion US dollars for COVID-19 vaccine sales, while Moderna could rake in 18–20 billion US dollars and Johnson & Johnson 10 billion US dollars.⁵ In contracts with companies, government purchasers poured billions into procuring raw materials, financing clinical trials, and retrofitting factories for drug companies, without requiring them to share know-how or make vaccines accessible to LMICs. In pursuit of their own self-interest, governments simply paid for their own spot at the front of the vaccine line. This has led to unequal access between rich and poor nations. As of June 2021, 85% of shots that have gone into arms worldwide were administered in high and upper-middle-income countries, and only 0.3% in low-income countries.⁶

Is there any ethical defence 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 labour. They have a right, protected by IP, to control pricing and supply of products they own. They can give their goods away, or 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 recognisable brands); and trade secrets. Prior to 1995, IP was protected internationally by flexible rules, tailored to a country’s socio-economic conditions. Under the Paris Convention, for example, rules protecting industrial property allowed states to exclude whole sectors and to determine the length of IP protection.⁷

The WTO’s 1995 Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement changed the landscape. It dictated stricter protocols, mandating compulsory protection of IP rights and requiring WTO members to enforce them within their territories. Importantly, the TRIPS agreement required countries to treat pharmaceuticals as an area protected by patents.



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

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 essential role in encouraging innovation. The view is summarised by Suzman, Chief Executive Officer 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...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 ability to make COVID-19 vaccines and they are at capacity.¹⁰ WTO members who urge staying the course, including the European Union, Switzerland, Norway, and Australia, assert there is ‘no concrete indication’ IP rights are ‘a genuine barrier’ to accessing COVID-19 vaccines and IP is 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-19.² The waiver would apply to all WTO members and lift restrictions in four TRIPS sections: copyright and related rights, industrial designs, patents and protection of undisclosed information. It would be annually reviewed and last for a set length, determined by the WTO Council. Proponents of the proposal argue that IP protections have ‘hindered urgent scale-up of vaccine production’ and that ‘many countries—especially LMICs countries—may face institutional and legal difficulties when using TRIPS flexibilities’.¹² To break the divide, WTO Director General, Okonjo-Iweala, proposed ‘a third way’ in which ‘we... license manufacturing to countries so that we can have adequate supplies while still making sure that IP issues are taken care of’.¹³ This approach permits companies to retain ownership while licensing other companies to manufacture their vaccines.

ETHICAL ARGUMENTS

Ethical arguments for temporarily waiving IP protections for COVID-19 vaccines begin by showing why arguments to the contrary fall short. Ethical defences of IP protections include both utilitarian and deontological arguments.

Utilitarian arguments

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, advance society’s interests. Absent such profits, discoveries would languish, and progress would slow.

In reply, even if the final translation of science into marketable products would not occur absent financial incentives, how much money does it take? As noted, in 2021, Pfizer/BioNTech will make 15–30 billion US dollars from COVID-19 vaccine sales, Moderna 18–20 billion US dollars, and Johnson & Johnson 10 billion US dollars. Could these companies earn less 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 that, consider a study comparing the profits of 35 large pharmaceutical companies with 357 companies in the S&P 500 index between 2000 to 2018.¹⁴ It found large pharmaceutical companies had significantly higher profits than other large companies. This suggests 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 it would sustain innovation.

Since consequentialist justifications treat the value of IP as purely instrumental, they are also vulnerable to counterarguments showing that a sought-after goal is not the sole or most important end. During the COVID-19 pandemic, we submit that the vaccinating the world is an overriding goal. With existing IP protections intact, the world has fallen well short of this goal. Current forecasts show that at the current pace, there will not be enough vaccines to cover the world’s population until 2023 or 2024.¹⁵ IP protections further frustrate the goal of universal access to vaccines by limiting who can manufacture them. The WHO reports that 80% of global sales for COVID-19 vaccines come from five large multinational corporations.¹⁶ Increasing the number of manufacturers globally would not only increase supply, but reduce prices, making vaccines more affordable to LMICs. It would stabilise supply, minimising disruptions of the kind that occurred when India halted vaccine exports amidst a surge of COVID-19 cases.

It might be objected that waiving IP protections will not increase supply, because it takes years to establish manufacturing capacity. However, since the pandemic began, we have learnt it takes less time. Repurposing facilities and vetting them for safety and quality can often happen in 6 or 7 months, about half the time previously thought.¹⁷ Since COVID-19 will not be the last pandemic humanity faces, expanding manufacturing capacity is also necessary 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?’¹⁸

Deontological arguments

Deontological arguments for retaining IP protections maintain that patent holders are the rightful owners of their inventions and are thus entitled to existing protections. With respect to COVID-19 vaccines, the claim is that pharmaceutical companies own these vaccines, which are the products of their labour; no one can rightfully take what is theirs.

In reply, the public has invested heavily, and these products are theirs’ too. Even when the translational part of product development is carried out by for-profit companies, this would be impossible without enormous upstream public investment. 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.¹⁹

Beyond government contributions to developing COVID-19 vaccines, there are immeasurable, yet crucial, contributions from others whose shoulders vaccine developers stand on. As Hettlinger notes, deontological arguments often give short shrift to the fact that discoveries do not occur in a vacuum but are ‘fundamentally social products.’²⁰ As one grateful physician, who received the Pfizer COVID-19 vaccine, put 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.²¹

The physician also thanked people who volunteered for and conducted Pfizer’s trials, 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...and the people who fed them and clothed them and housed them so that they could do this life saving work.’

In sum, the deontological claim that pharmaceutical companies wholly own COVID-19 vaccines do not withstand scrutiny. What they own is limited to the additional value their efforts impart.

Additional arguments

We turn next to positive ethical arguments for temporarily waiving IP protections, which appeal to the values of globally solidarity and corporate responsibility.

Global solidarity underscores that during the COVID-19 pandemic, each nation’s interests are entwined with the interests of every other.²² Just as it is impossible for any nation standing alone to address the threat to human health climate change raises, it is impossible for any single nation to meet the challenge that COVID-19 and future pandemics present. Instead, humanity must stand together. In the past, nations have 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, even though Africa was the hardest hit region and antiretroviral drugs provided 90% mortality reduction. Although the US government was an early investor in research that produced antiviral drugs for HIV, distribution was controlled by big pharmaceutical companies driven by profit. The USA 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 LMICs). Ethically, the task ahead is fixing a problem of human making.

A second argument, based on corporate social responsibility, stresses expectations for and benefits of socially responsible behaviour by for-profit companies. Increasingly, companies appreciate the potential impact that socially responsible behaviour has on competitive advantage, reputation, retention of workers and customers, employee morale and relationships with stakeholders.²³ IP protections shield pharmaceutical companies from competition, enabling them to monopolise markets and generate above-normal profits. During a pandemic, social responsibility requires temporarily limiting profits and requiring companies to

give back, rather than allowing above-normal profits to accrue unchecked. 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.²⁴

Building on this analysis, we submit that displays of social responsibility fall along a continuum. During the COVID-19 pandemic, a high degree of responsibility would be shown by temporarily sharing patents for products aimed at preventing, containing, or treating COVID-19, which is India and South Africa’s proposal; moderate responsibility would be demonstrated by temporarily sharing licenses to manufacture COVID-19 vaccines, as the WTO Director General proposes; and minimal responsibility would be shown by sending vaccines directly to nations in response to pleas for help, which Pfizer did when it pledged up to 40 million doses of its vaccine to COVAX (which represents under 2% of the 2.5 billion doses Pfizer will produce in 2021).²⁵

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 show the high degree of social responsibility the moment calls for. Governments, especially in wealthy nations, should stand up to influence peddling by pharmaceutical companies,²⁶ and should do their part, beginning with WTO members voting for a temporary waiver to IP protections for COVID-19 vaccines.

Against our proposal it might be claimed a temporary waiver is not enough. Manufacturing COVID-19 vaccines requires technical know-how, technology, raw materials and equipment, which are lacking in many LMICs. Pfizer, for example, says its vaccine requires 280 components from 86 suppliers in 19 countries, along with specialised equipment and trained personnel.²⁷ Since it takes more than simply waiving IP to vaccinate the world, what good is a temporary waiver?

In response, we agree temporarily losing the right to exclude companies from manufacturing vaccines is not enough. However, it can help break the logjam, creating a climate favourable to investment, since it removes the threat of being sued or prosecuted. Expedient investment strategies should focus on developing and repurposing existing capacities; Guzman notes 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 to contribute to the fill-and-finish stage of vaccine production.²⁸

A proponent of IP protections may insist TRIPS already includes built-in exceptions adequate to the task. Article 31 grants governments rights to issue licenses for using a patent during the patent term without a patent holder’s consent. This exception was used 144 times between 2001 and 2016 to create flexibilities for 89 countries.²⁹ In 2017, it was extended to allow licensed countries to export products to countries that lack production capacity. Isn’t that enough?

In reply, Article 31 will not take us very far. While useful for some applications, it is cumbersome. For example, for pharmaceutical products, after applying for an exception, exporting countries must prove products go only to destination nations, are readily identifiable based on variations of colour or shape, and include only product necessary to meet requirements of an eligible country; importing nations must notify the TRIPS

council of receipt. Fulfilling these requirements would needlessly delay the vital task of vaccinating the world.

Finally, critics might point to the case of Moderna, which voluntarily pledged (in October 2020) not to enforce its patents during the pandemic. Since companies have not lined up to produce Moderna's vaccine, doesn't that show the ineptitude of temporary waivers? In reply, a single pledge by a single company is a start, but insufficient to catalyse the global changes needed.

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 filled a gap in current debates about IP protections for COVID-19 vaccines by focusing on ethics. In the final analysis, a temporary waiver of IP protections is the world's best bet.

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