Weighing Government Intervention During the Global Covid Health Crisis

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Introduction

Inequitable access to vaccines has been cited as the most significant failure in the global fight against Covid-19, exacerbating the damage it has inflicted in low- and middle-income countries and contributing to the risk that new coronavirus strains would emerge to threaten all countries (Coggi & Regazzoni, 2022). Thus, a key question is whether governments should waive drug patent laws and require pharmaceutical companies to transfer their technologies to help deliver vaccines in a timely fashion globally, especially to low- and middle-income countries. This debate was highlighted in the *New York Times* article "What Would It Take to Vaccinate the World Against Covid?" (Goodman et al., 2021), with the *Times* strongly arguing for such intervention in an accompanying editorial entitled "America Is Failing Its Moral Test on Vaccines" (*New York Times* Editorial Board). This specific debate is the latest in an ongoing debate about whether governments should – and, if so, to what extent – actively intervene in the economy during a public health crisis like Covid-19 or AIDS/HIV. Noted Stanford University economist John McMillan's book *Reinventing the Bazaar: A Natural History of Markets*, which puts forth a view of markets as tools that address societal needs without ideological perspective, provides helpful insights into this debate. As discussed later, simply waiving patents represents an imperfect solution, one potentially resulting in curtailment of technological innovation – due to loss of economic market incentives that emanate from patents – that may be critically needed to address future variants. Instead, a balanced approach is called for whereby government intervention focuses on increasing manufacturing infrastructure both domestically and abroad. Furthermore, the justification for opening up patents to allow for this additional manufacturing should emphasize national self-interest in preventing future outbreaks and new variants rather than framing it in purely ethical terms.

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Case Example: "Pharmaceutical Catch-up" during the Covid-19 Global Crisis

The distribution of Covid vaccines fundamentally involves supply and demand: The high demand for vaccines can be resolved by expanding the global supply correspondingly. However, slow vaccine production and the resultant low supply may lead to the rise of new and potentially more dangerous variants, further increasing demand in a vicious cycle referred to as "pharmaceutical catch-up" (Okan et al., 2022). A simple solution appears to be increasing vaccine production through the government waiving enforcement of vaccine patents held by major pharmaceutical companies like Pfizer, Moderna, and Johnson & Johnson. This action would allow other manufacturers to step in and provide the needed extra vaccine doses. However, simply voiding patents would not necessarily suffice to meet the end goal of providing the necessary resources (i.e., vaccines) in the most timely and efficient manner. In particular, technology transfer and availability (in terms of machinery, software, etc.) and access to necessary raw materials must also be addressed.

Due to the global risk of new variants emerging, global leaders and countries must function on a unified front to safeguard against both present and future threats (Goodman et al., 2021). To that end, the *New York Times* editorial board asserts the need for high-income countries such as the United States to intervene by helping low- and middle-income nations build manufacturing facilities and offer technical expertise, which in turn aids the collective global effort to overcome the Covid health crisis. The dilemma emerges in that the waiving of vaccine patents may hinder future innovation needed to address potential variants, but at the same time, the waiver can lessen the possibility of variants emerging in the first place by addressing the crisis in a timely global manner. Consequently, the economic and social/ethical stakes involve whether to prioritize intellectual property and future innovation or to waive patent protections to immediately aid low- and middle-income countries and potentially avert a prolonged global health crisis.

The Problem at Stake: Protecting or Waiving Patents

By examining the ideological conflict of protecting or waiving patents through the lens of McMillan, who views markets as tools that address societal needs without an ideological perspective, it becomes clear that the government should seek to provide incentives and design the market around self-interest. As McMillan emphasizes, no one is in control of a market, but rather, everyone is in charge, thereby granting participants autonomy in decision-making. The only limits to this freedom, according to McMillan, are the extent of the resources available and the rules of the marketplace.

By applying this framework to the case of pharmaceutical companies in a global health crisis, it appears that, in attempting to protect their patents, these companies are simply responding to the "incentives" present in the government-designed marketplace, namely those where investments are optimal. However, as the cost of research and development to create new drugs and vaccines is expensive and uncertain, balancing incentives with patents alongside advancing innovation should become an essential aim of government intervention.

One could argue that the weakening of intellectual property hinders innovation for the future, including the development of new treatments to prevent more pandemics, since pharmaceutical companies follow the market to ensure optimizing their profit. This pro-patent argument relies on

the assumption that innovation is a high-stakes dice roll. According to an Massachusetts Institute of Technology (MIT) study, only approximately 14% of all drugs in clinical trials eventually win approval from the Food and Drug Administration (FDA), with approval rates for specific illnesses ranging from a high of 33.4% for infectious-disease vaccines to a low of 3.4% for cancer (Wong et al., 2019). Nonetheless, the companies are not the primary source of the low success rate of the global drug market. Companies will do what it takes to maximize their profits for future innovations to cover their research costs, as such efforts are expensive and uncertain. Thus, although it may appear that successful drugs are priced unnecessarily above their manufacturing cost, such a high cost is a direct result of patent laws, enabling the grant of monopoly rights to the innovator. Thus, the challenge for those who believe patent law is flawed is to devise an alternative market design that would induce better outcomes for long-term innovation.

On the other hand, one can contend that the weakening of intellectual property is necessary to address a health crisis in a timely and ethical manner by sharing essential information and associated technology. This anti-patent argument was seen, for example, when European institutions challenged the American company Myriad Genetics' patent monopoly on the genetic work associated with the *BRCA1* gene of breast cancer (Lecrubier, 2002). In particular, the European institutions contended that Myriad's monopoly would have the unintended consequence of posing another barrier to breast cancer healthcare, namely the high cost of screening for the *BRCA1* gene. Moreover, they contended that such a monopoly would also have a long-term effect in that Myriad's collection of DNA samples of the BRCA1 gene – the only such sample bank in the world – would give them ultimate control over the raw material for future research. In this way, a snowball effect could occur, whereby Myriad's gain of a monopoly would enable it to secure even more patents and thus build a larger barrier against future *BRCA1* gene research. Hence, one could argue, like the European institutions did, that the weakening of such intellectual property is necessary to propel and expand current and future research on said treatments on both a national and an international level.

Potential Solution: Government Intervention in the Name of National Self-Interest

As the *New York Times* editorial board and McMillan both point out, simply waiving patents in the designed market of pharmaceuticals yields a solution that, in the words of McMillan, "admits no ideal solution" (McMillan, 2002). In recognition of such shortcomings, the *Times* editorial board proposes a two-prong effort focused on ramping up vaccine production: both internationally – with the U.S. joining together with other high-income nations to help low- and medium-income countries build and operate their own manufacturing plants, following a playbook established by the President's Emergency Plan for AIDS Relief (PEPFAR) back in 2003 – and domestically via the creation of publicly owned manufacturing plants run by private entities akin to the "Government-Owned, Contractor-Operated" (GOCO) facilities that both the Departments of Defense and Energy utilize (*New York Times* Editorial Board). The *Times* justifies its proposal based mainly on ethical considerations, calling it a "moral test." In contrast, McMillan, who views markets as non-ideological entities, would evaluate the proposal from an economic perspective, with market participants motivated by both profit and self-interest, including government self-interest.

Considering first the international side of the *Times* proposal, their argument for high-income nations agreeing to open up and aid vaccine manufacturing in low- and middle-income countries is one that McMillan would approve. Since there is uncertainty toward the future regarding the potential need for rapid and extensive responses for supplying booster shots and addressing localized outbreaks and variants, efforts to produce and deliver vaccines domestically must coexist with steps to do so elsewhere due to the global nature of the crisis. In doing so, the designed international market for vaccines should account for the self-interest of high-income countries, wherein helping low- and middle-income countries would, in turn, benefit them in the long term by ending the pandemic. Moreover, high-income countries assisting low- and middle-income countries would enable the necessary global distribution to be regionally concentrated. This approach would allow for better adaptation to changing and uncertain circumstances, such as the possible need for booster shots and addressing sudden outbreaks and variants.

Likewise, on the domestic side of the *Times* proposal, agreement from McMillan can be seen. Here, U.S. government support in the form of building GOCO-type vaccine production facilities for private entities to operate serves to satisfy both private and public (both government and the general public) interests. By balancing private economic autonomy and government intervention in this way, the designed market would simultaneously account for the self-interest of the United States to protect itself from future health crises and the profit motivation of the private pharmaceutical companies.

In doing so, the private market for pharmaceutical companies would contain and promote both positive freedom – the capacity to act upon one's free will – and negative freedom, or freedom from external constraints from the government. At the same time, government intervention in increasing both manufacturing infrastructure and the accessibility of raw materials would address the current health crisis and safeguard its changing and unpredictable nature in the future. For instance, similar to how Goodman et al. (2021) argue that the root issue with the Covid vaccine is that "many raw materials and key equipment remain in short supply," McMillan asserts in his example of the AIDS health crisis in Africa that the roots of the shortcomings in the global pharmaceutical market lie not in companies' policies but instead in countries' poverty (McMillan). Without basic healthcare and infrastructure in place, McMillan argues that the effects of more accessible and cheaper drugs would still be limited in fighting AIDS, thereby leading him to contend that economic growth from governmental intervention is the only reliable source for addressing AIDS (McMillan, 2002). Similarly, Hoen et al. (2011) cite addressing regulatory issues, strengthening supply chains, and establishing current pharmacovigilance systems as additional actions that were needed beyond waiving the AIDS patent for success. In this way, the private pharmaceutical companies' successes are correlated with governmental intervention to ensure the necessary resources for said success are available during global health crises.

However, in contradiction to the title of the *New York Times* opinion piece "America Is Failing Its Moral Test on Vaccines," framing the argument as a moral imperative is counterproductive when viewed through McMillan's lens: it is unwise to criticize companies for seeking maximum profit as such profits are a necessary evil for fueling innovation. As a result, as McMillan contends, pharmaceutical companies are simply following market incentives, ensured by patents that, in turn, allow for future innovation. Consequently, McMillan would agree with the editorial board in championing government intervention, but he would propound that it should emphasize national self-interest rather than framing it as an ethical matter.

As McMillan argues, ethical matters are unproductive without the economic infrastructure to support them, while economic matters are ineffective if participants do not have their healthcare needs met (McMillan, 2002). In this way, it becomes clear that not only is the economy a necessary pipeline to taking morally "correct" actions, but the reverse is true as well: taking morally correct actions requires that a sufficient economic pipeline exists. Hence, government actions must not overly discourage private company participation in the marketplace, lest the economic pipeline runs dry.

Conclusion

The global Covid-19 health crisis has brought upon the world an unprecedented public health challenge, one that has thus far resulted in over 750 million confirmed cases of Covid-19, including over 6.8 million deaths reported to the World Health Organization (WHO) as of January 2023 (WHO Coronavirus Dashboard). This challenge necessitates a thoughtful and coordinated response to meet it effectively, one that seeks to also not produce unintended consequences, such as limiting future innovations that may be critically needed to address variants and new outbreaks. In that regard, the *New York Times* proposal represents a balanced approach using select government intervention focused on increasing vaccine manufacturing infrastructure both domestically and abroad. This proposal is not only justifiable under ethical conditions, as strongly argued by the *Times*, but seen to be justifiable under economic and self-interest – especially national self-interest – reasoning when viewed through the lens of the noted Stanford economist John McMillan. Thus, it is highly worthy of immediate implementation by not just the United States but other high-income nations as well.

Appendix A

Passage from "What Would It Take to Vaccinate the World Against Covid?":

The problem is that many raw materials and key equipment remain in short supply. And the global need for vaccines might prove far greater than currently estimated, given that the coronavirus presents a moving target: If dangerous new variants emerge, requiring booster shots and reformulated vaccines, demand could dramatically increase, intensifying the imperative for every country to lock up supply for its own people. The only way around the zero-sum competition for doses is to greatly expand the global supply of vaccines. On that point, nearly everyone agrees. But what is the fastest way to make that happen? On that question, divisions remain stark, undermining collective efforts to end the pandemic.

Some health experts argue that the only way to avert catastrophe is to force drug giants to relax their grip on their secrets and enlist many more manufacturers in making vaccines. In place of the existing arrangement – in which drug companies set up partnerships on their terms, while setting the prices of their vaccines – world leaders could compel or persuade the industry to cooperate with more companies to yield additional doses at rates affordable to poor countries.

Those advocating such intervention have focused on two primary approaches: waiving patents to allow many more manufacturers to copy existing vaccines and requiring the pharmaceutical companies to transfer their technology – that is, help other manufacturers learn to replicate their products.

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Some experts warn that revoking intellectual property rules could disrupt the industry, slowing its efforts to deliver vaccines – like reorganizing the fire department amid an inferno.

"We need them to scale up and deliver," said Simon J. Evenett, an expert on trade and economic development at the University of St. Gallen in Switzerland. "We have this huge production ramp up. Nothing should get in the way to threaten it."

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Many public health experts say that patent waivers will have no meaningful effect unless vaccine makers also share their manufacturing methods. Waivers are akin to publishing a complex recipe; tech transfer is like sending a master chef to someone's kitchen to teach them how to cook the dish.

"If you're to manufacture vaccines, you need several things to work at the same time," the W.T.O. director-general, Ngozi Okonjo-Iweala, told journalists recently. "If there is no transfer of technology, it won't work."

Even with waivers, technology transfers and expanded access to raw materials, experts say it would take about six months for more drug makers to start churning out vaccines.

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Changing that calculus may depend on persuading wealthy countries that allowing the pandemic to rage on in much of the world poses universal risks by allowing variants to take hold, forcing the world into an endless cycle of pharmaceutical catch-up.

"It needs to be global leaders functioning as a unit, to say that vaccine is a form of global security," said Dr. Rebecca Weintraub, a global health expert at Harvard Medical School. She suggested that the G7, the group of leading economies, could lead such a campaign and finance it when the members convene in England next month.

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But other health experts accuse major pharmaceutical companies of exaggerating the manufacturing challenges to protect their monopoly power, and implying that developing countries lack the acumen to master sophisticated techniques is "an offensive and a racist notion," said Matthew Kavanagh, director of the Global Health Policy and Politics Initiative at Georgetown University.

With no clear path forward, Ms. Okonjo-Iweala, the W.T.O. director-general, expressed hope that the Indian and South African patent-waiver proposal can be a starting point for dialogue. "I believe we can come to a pragmatic outcome," she said. "The disparity is just too much."

Appendix B

Passage from "America Is Failing Its Moral Test on Vaccines":

The United States is well on its way to protecting Americans from the coronavirus. It's time to help the rest of the world. By marshaling this nation's vast resources to produce and distribute enough vaccines to meet global demand, the United States would act in keeping with the nation's best traditions and highest aspirations while advancing its geopolitical and economic interests. It is a moment of both obligation and opportunity.

Unfortunately, instead of a bold, comprehensive strategy to vaccinate the world as quickly as possible, the Biden administration has thus far made a string of tactical decisions: donating millions of doses to countries in need, signaling its support for patent waivers that might expedite vaccine production efforts and nudging two companies – Merck and Johnson & Johnson – to collaborate on increasing supply. These are good steps, but they are not nearly sufficient to meet the moment. The United States and the rest of the world's wealthiest nations are facing a great moral challenge.

Increasing manufacturing capacity has proved tricky. The global demand for vaccines may be high now, but once the coronavirus pandemic recedes, it will plummet back to normal levels. Increased public ownership, for its part, would ensure that vaccine-production capacity is ready for future pandemics, which are inevitable – potentially including new coronavirus variants for which routine boosters may be required.

To this end, the administration should consider taking a page from the Department of Energy playbook: Create publicly owned manufacturing facilities and contract with private companies to run them. (Several of the D.O.E.'s federally owned laboratories are run by private companies like General Electric and Bechtel.)

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Efforts to dramatically increase domestic production should be paired with efforts to do the same elsewhere. The coronavirus is here to stay for the foreseeable future. If new variants require different boosters and localized outbreaks require rapid response, it will be far easier to manage those eventualities with regionally concentrated supplies. That kind of distributed capacity will also leave the world much better prepared for future pandemics.

Low- and middle-income countries have been clamoring for the chance to manufacture their own doses – many of them have infrastructure that could be repurposed, and expertise making other complicated pharmaceuticals that could be built upon. If wealthier nations are concerned about those countries' ability to manage this challenge safely or quickly, they should step in to help. This worked before. The 2004 BARDA initiative to increase flu vaccine production in low-income countries achieved a fivefold increase since the program began. While the work was hard, the strategy was simple: Invest in companies in low-income countries, help them build facilities and support them as they cultivate expertise.

Vaccinating the globe will require leadership and a level of international cooperation that many people may consider impossible. But if the United States provides that leadership and demands that cooperation, millions of lives will be saved, and the world will have a new template for solving some of the many challenges that transcend our borders.

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