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Better Solutions to Increasing COVID-19 Vaccine Access: Giving Away Vaccines Rather than Vaccine Formulas

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BETTER SOLUTIONS TO INCREASING COVID-19 VACCINE ACCESS:

GIVING AWAY VACCINES RATHER THAN VACCINE FORMULAS

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Abstract

The debate over giving away the COVID-19 vaccine formulas is a political hot topic. Mention of a Trade-Related Intellectual Property Rights (TRIPS) waiver proposed in early 2021 suggested violating patent law to give away the vaccine formulas. While a tempting option, many problems exist with this solution. Violating patent law to give away the vaccine formulas disincentivizes innovation, undermines confidence in vaccine safety, and harms America's geopolitical objectives. Patent law can be inefficient and is not the only way to incentivize innovation, but it is here to stay. Instead, the United States should give away vaccines rather than vaccine formulas to help the world in the face of the COVID-19 pandemic.

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Better Solutions to Increasing COVID-19 Vaccine Access:

Giving Away Vaccines Rather than Vaccine Formulas

In an unprecedented and devastating situation like the COVID-19 pandemic, the development of vaccines has provided hope. The challenge is how best to reach the rest of the world with the vaccines. One idea to expand vaccine availability is waiving patent law and forcing pharmaceutical companies to give away the vaccine formulas. It is tempting to frame this situation as private profits of Big Pharma versus public health, but the situation is much more complex. Giving away the vaccine formulas may appear to be a panacea to ending a global health crisis. In actuality, giving away the vaccine formulas has many problems, including creating inefficiencies, disincentivizing innovation, undermining confidence in vaccine safety, and harming America's geopolitical objectives. Thus, while the United States can, and certainly should, aid the world in obtaining vaccines, it should not do so by violating patent law and giving away vaccine formulas.

I. Economic Theory

A. Economic Theory Behind Patents

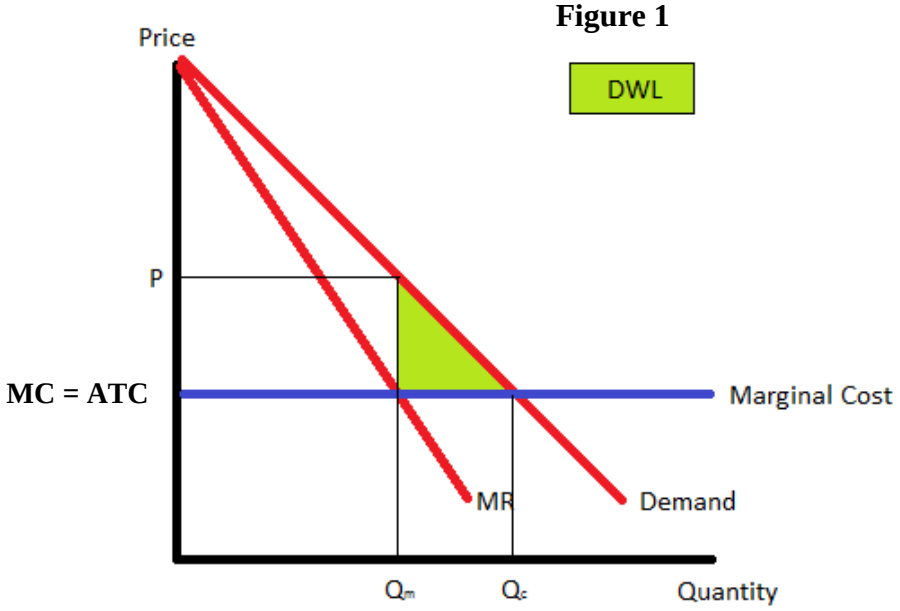
The contention surrounding giving away vaccine formulas is the violation of patent law. In the United States, patents are an exclusive right the government grants for an innovative product or process. (Scherer, 1990, 621). The logic of patent law is to reward innovators for time and money invested into innovative inventions (Scherer, 1990, 621). Modern patents are given to the first inventor of a useful product or process and allow innovators exclusive rights to the use of the invention for a specified period of time (Scherer, 1990, 621). US patent law is structured

to give priority issuance to the "first to invent," for a normal span of 17 years (Scherer, 1990, 621). If contested, criteria are used to determine the patent issuant is (1) the first to conceive the idea, (2) the first to put the concept into practice, and (3) one who "exercised reasonable diligence" when putting the concept into practice (Scherer, 1990, 621). The logic of this criteria allows for original innovators to exclude others from using their rightful invention or selectively license inventions (Scherer, 1990, 621).

Patent laws provide incentives for innovation by securing the rights to inventions (Lindsey 2021). Once the inventors invest time, effort, and money into the development of something those factors become "sunk costs" that inventors are unable to get back (Scherer, 1990, 622). To warrant an investment into inventions, original innovators must expect to be able to make profits that exceed front-end investment (Scherer, 1990, 622). Patents bestow property rights which allow the original inventor to exploit the benefits of exclusively profiting off of an invention (Scherer, 1990, 622). In the case of pharmaceutical drugs, the pharmaceutical industry needs exclusive rights to developed drugs in order to recoup front-end investment into them.

B. Economic Theory Behind Monopolies

Figure 1

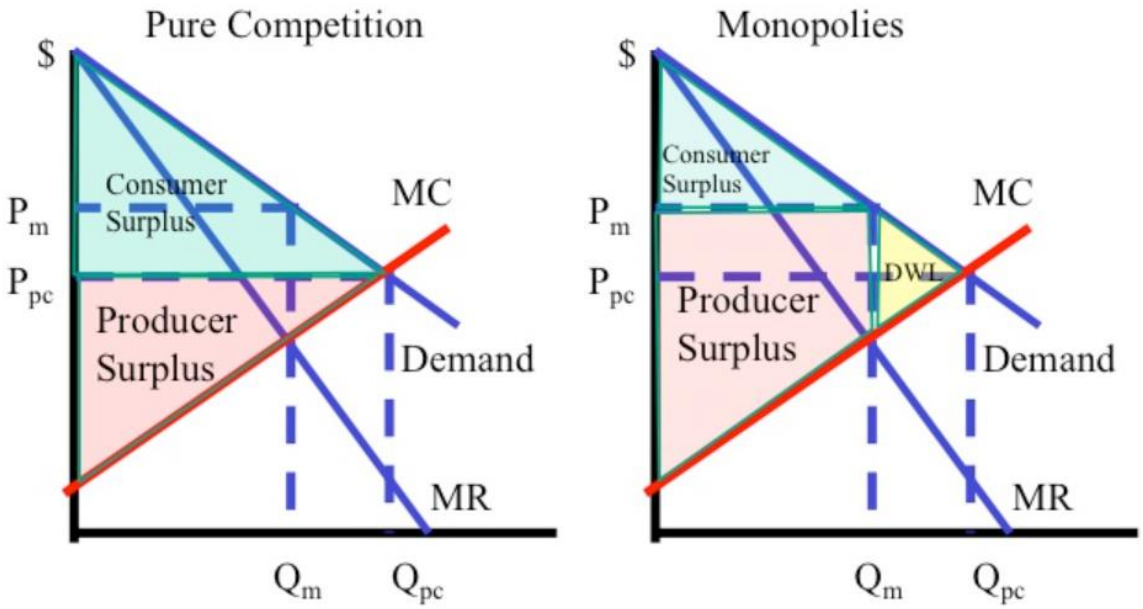


Economic theory shows that giving firms monopoly rights to a product can be inefficient. For an introductory understanding, the Figure 1 graph shows a simplified version of the inefficiencies of monopolies. In a monopoly, the price that customers are willing and able to pay is above where marginal cost (MC) equals average total cost (ATC) (Cooter and Ulen, 2016, 31). MC is defined as additional cost incurred by the production of an additional unit of output. Average total cost refers to total cost divided by the quantity of output produced. Economic activity does not occur, however, in the area between Qc and Qm because monopolies charge a price above MC (Cooter and Ulen, 2016, 31). The deadweight loss (DWL) demonstrates the inefficiency of monopolies (Cooter and Ulen, 2016, 31). In Figure 1, DWL is represented by the green triangle. Deadweight loss is referred to as unmet trades because the graphed triangle represents an area where consumers are willing and able to pay for a good or service (represented

by the demand curve) and yet trade does not occur because monopolies charge a price above where MC meets demand.

Figure 2 illustrates the consumer and producer surplus in perfectly competitive versus monopoly markets. Producer surplus is the difference between what the monopoly is willing to accept for their product (like vaccines in the pharmaceutical industry) versus what the product is worth to consumers in the market. In Figure 2, producer surplus is represented as the area under the monopoly Price (P_M) and above the supply curve in a trapezoidal shape. Consumer surplus occurs when consumers pay less for a product than what they are willing and able to pay. Their willingness to pay is the demand curve. Consumer and producer surplus measure the respective added benefit to each party. In a monopoly, the higher producer surplus, or increased benefits towards the monopoly, create the unmet trades or DWL, as shown in Figure 2. While pricing above where MC meets demand means monopolies recoup higher profits than would be the case in a perfectly competitive market, economists are less concerned with profits and more concerned with reduced output. In Figure 2, the reduced output is shown at $Q_{M,}$ where monopolies produce a quantity below what would be produced in a perfectly competitive market. In Figure 2, the deadweight loss is shown as the yellow triangle.

Figure 2

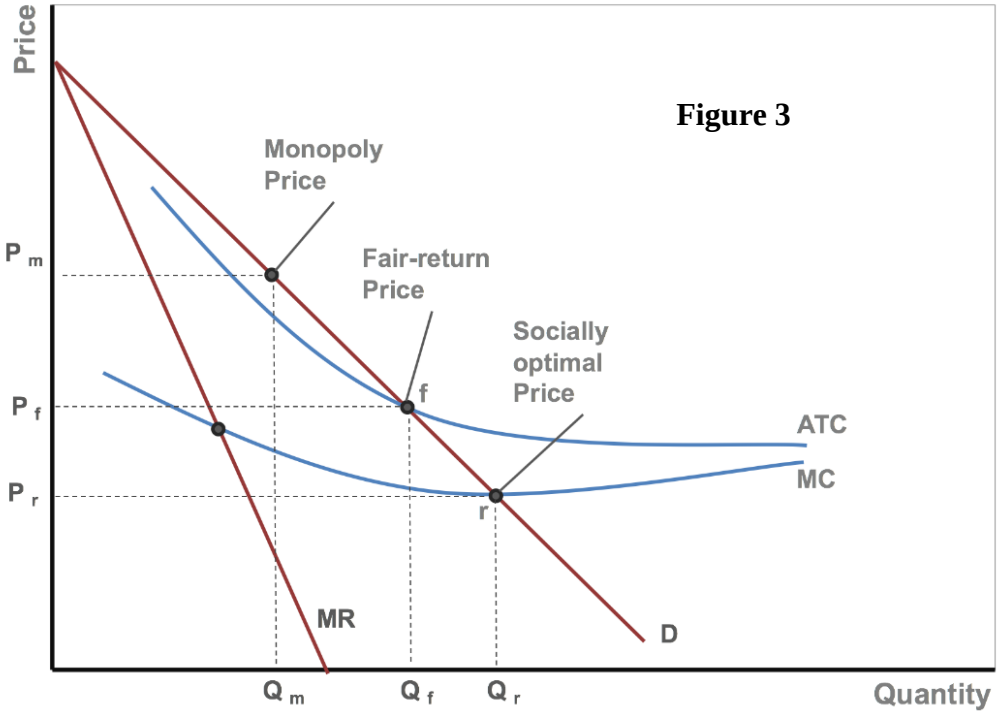


Figures 1 and 2 make simplifying assumptions in depicting marginal cost as a horizontal or upward sloping line. In the pharmaceutical industry, it cannot be assumed that marginal costs are constant or upward sloping due to the high fixed costs. Fixed costs are costs independent of the quantity produced by a firm. Fixed costs are very large in the pharmaceutical industry because pharmaceutical companies do significant research that ends up never generating any revenue. In the pharmaceutical industry, companies have to pay those fixed costs up front before, if ever, realizing any revenues or profit. The pharmaceutical industry better mimics a natural monopoly because of the extraordinarily high fixed costs. Utility companies are examples of natural monopolies because, for example, water providers face high costs to making its infrastructure available to a neighborhood. In the case of water utilities, a fixed cost is building the facility that filters and distributes clean water to houses. Up to a point, say 10,000 houses, the cost of building the plant is the same, whether it filters and pumps water to one house or 10,000

houses. There are barriers to entry in the market for other companies because competing means paying the same fixed costs but a smaller market to access because clients are already being served by one water provider. This is also why natural monopolies better serve the market when there are fewer companies; several water providers running pipes into the same neighborhood would drive up the price of water for each individual household because providers need to recoup investment and are doing so with fewer customers.

It can be argued that research and development costs for the pharmaceutical companies are not entirely fixed costs because costs increase the company performs more research. However, similar to building a water treatment plant, there is still a baseline large sum of money needed to fund equipment, processes, other business structures, and in the case of the pharmaceutical industry, an extensive body of research.

Figure 3 illustrates a downward-sloping marginal cost curve to account for the way the pharmaceutical industry better mimics a natural monopoly. While monopolies charge a higher price than would be the case in a perfectly competitive market, the granting of patents by the government allows for lower prices than without patent law. Government regulation in the form of granting these monopoly rights allows for companies to recoup investment without the threat of other companies competing and putting upward pressure on prices. In the case of pharmaceutical drugs, even in the free-market, the government can improve market outcomes by granting patents.



In Figure 3, the monopoly charges a price above the marginal cost and average total cost curves, which results in the inefficient deadweight loss also referenced in Figures 1 and 2. The socially optimal price (r) occurs where the price is set at marginal cost. This situation would occur in a perfectly competitive market and would maximize producer and consumer surplus while avoiding deadweight loss inefficiencies. The fair-return price (f) occurs where the price is set at average total cost and is a viable alternative for the firm. At the fair-return price, output is restricted below the socially optimal level, but not as inefficient as the output loss occurring at the monopoly price point. Pharmaceutical companies operate as monopolists unless the prices they charge are regulated by the government. Referring back to the water utility example, there is a municipal water board that oversees financial operations and regulates prices. Recently, there has been a push for the government to regulate the price of insulin, which would mean that for that product, the company would be producing more and charging a lower price. This would deplete the resources that company has to invest in future R&D.

II.Reasons to Protect COVID-19 Patents

A. TRIPS Waiver

On May 5, 2021, the Biden Administration announced its support for a Trade-Related Intellectual Property Rights (TRIPS) waiver that would violate patent law to give away the vaccine formulas (Macias et. al 2021). The TRIPS waiver would set a precedent that disincentivizes innovation for pharmaceutical companies, potentially undermining responses to future catastrophic events. Not surprisingly, "stocks of major pharmaceutical companies that have produced vaccines, including Moderna, BioNTech and Pfizer, dropped sharply after news of the potential [TRIPS] waivers first broke" (Macias et al. 2021). Although this policy suggestion gained support in 2021, the TRIPS waiver was never implemented, and the US government did not violate patent laws. Support for the waiver died down over the next several months. Suggestion of the TRIPS waiver was the impetus for the analysis done in this paper.

B. Incentivizes Innovation

Without patent protection, later entrants to the market can achieve a second-mover advantage by avoiding the extensive research and development costs that original innovators suffer from (Lindsey 2021). A famous example is the advantage Apple had in creating the iPhone after Blackberry created the smartphone that dominated the cell phone market in the mid 2000s (Udland 2015). In the case of the COVID-19 pandemic, pharmaceutical companies need to profit from the vaccine formulas to recover the expensive development process that had to be undergone. US pharmaceutical research and development (R&D) costs in 2019 totaled $83 billion dollars, which, adjusted for inflation, is close to 10 times the amount spent per year in the

1980s (Congressional Budget Office 2021). As pharmaceutical research continues to become more expensive, the argument in favor of protecting patents to secure profits is strengthened. Imitating firms who avoid these R&D costs benefit from the original inventor's work and recoup above normal profits (Scherer, 1990, 623). Imitating firms can profit off of similar inventions and receive profits that do not account for R&D costs the original innovators suffer from. With exclusive rights to the market, original innovators have a better chance of recouping investment, especially when it comes to the high costs associated with pharmaceutical research (Lindsey 2021). Out of all drugs entering clinical trials, only about 12 percent get approved by the FDA, which makes a stronger case for pharmaceutical companies needing monopoly rights to their inventions (Congressional Budget Office 2021).

Patent issuance takes into account width and breadth. A broader patent, meaning that one patent encompasses related inventions, will encourage fast, duplicative, pre-patent research (Cooter and Ulen, 2016, 120). A narrow patent, meaning that related inventions will get separate patents, will encourage slower, complementary, pre-patent research (Cooter and Ulen, 2016, 120). To illustrate, suppose one specific type of pizza was invented but the innovator was able to claim all pizza as their invention. Due to the high profits of patenting all pizzas, there would be a race to invent with many innovators duplicating the classic way of making pizza. If the patent were narrowed to that specific type of pizza, innovators would all use the base knowledge of pizza making to perfect individual recipes. When issuing patents, the government must consider the advantages to the speed which the research is developed and disadvantages to duplicative research. For vaccines, how broad or narrow a patent is could depend on the technology used, whether the vaccine is one dose or two, and other factors (Cooter and Ulen, 2016, 120). Ultimately, patent law should strike the right balance in the tradeoff between costs and

benefits. Exclusive rights to inventions should be beneficial enough to incentivize innovation, but not so comprehensive that the restrictions on output outweigh such benefits (Lindsey 2021).

Waiving patent law reduces profits for pharmaceutical companies, but many argue they have already profited from their innovation. In 2021, Pfizer made nearly $37 billion from sales of its COVID-19 vaccine (Kollewe 2021). Pfizer was charging the United States $19.50 per dose of the vaccine, half price for middle-income countries, and at cost for the rest (Sagonowsky 2021, Baker and Silver 2021). Top Pfizer executive Frank D'Amelio called this "pandemic pricing," compared to the $150 or more Pfizer would normally get per dose (Sagonowsky 2021). How deserving pharmaceutical companies might be of their sales does not change the argument that pharmaceutical companies need high revenues and profits to continue to fund future research and development.

C. Maintain Confidence in Vaccine Safety

The complexity of vaccine production is another reason to protect COVID-19 vaccine patents. Experts say that it is highly unlikely for a significant number of manufacturing plants to possess the capabilities to get production up and running immediately (Putterman 2021). Supply chain issues mean that a lack of raw materials and limited production capacity are significant barriers to increasing the global supply of vaccines (Schoen 2021). Furthermore, waiving patent law without teaching manufacturers how to make the vaccine is simply unhelpful (Ott 2021). That approach would be similar to receiving a cake recipe with the ingredients but not the directions (Ott 2021). It is impossible to replicate the cake (vaccine) without knowing how to put the ingredients together (properly manufacture) (Ott 2021).

Even if it were possible for other manufacturers to start producing vaccines, such a decentralized manufacturing process is problematic as well as inefficient. There is a great potential for discrepancies in the manufacturing processes. Vaccines are biologically complex, and changes in manufacturing processes may affect the safety and effectiveness of the vaccines (Putterman 2021). All aspects of vaccine manufacturing are strictly controlled by the Food and Drug Administration's (FDA) Good Manufacturing Practices (GMP) (Putterman 2021). Without stringent conditions surrounding the manufacturing practices of vaccines, the proliferation of sub-standard or counterfeit vaccines could pose a significant health crisis (Ott 2021). This, in turn, could greatly undermine public confidence in vaccine safety (Ott 2021). With vaccine mistrust already concerningly prevalent, it is advisable to avoid any circumstances which further call into question the effectiveness or safety of the vaccine (Putterman 2021). In the end, the efficiency and effectiveness of the original COVID-19 vaccine innovators and manufacturers are in the best interests of society.

D. Advance America's Geopolitical Objectives

With such an unprecedented situation, politics play an important role in the global response to the pandemic. Vaccine diplomacy is key, and the United States has an opportunity to "improve American geopolitical standing abroad… [by making] its vaccines broadly available" (Macias et al. 2021). Therefore, the United States aiding countries with vaccines, rather than the formulas, is the best option. Waiving patent law to give the vaccine formulas effectually leaves other countries on their own, especially because, as discussed earlier, producing vaccines is quite difficult. Giving the vaccine formulas away does nothing to further the United States' agenda.

Former attorney at the Office of the U.S. Trade Representative, Clete Williams, said that giving the vaccine formulas away is a "huge misstep by the Biden Administration that will do nothing to increase vaccine distribution and will endorse China's ability to piggyback on U.S. innovation to further its vaccine diplomacy aims" (Schoen 2021). Another political issue is the increase in jobs for vaccine production and exporting in the United States that is created by domestic production (Macias et al. 2021). Giving away vaccines, instead of the formulas, improves U.S. competitiveness and keeps jobs in America, which is more in line with the Biden Administration's stated objectives (Lindsey 2021). If the Biden Administration's objectives are advancing America's interests, certainly violating patent law is not the way to accomplish such a task.

Many people are concerned about rich countries buying up the vaccine first. Distribution of vaccines to high- and upper-middle-income countries accounts for approximately 77% of the 6.41 billion vaccine doses administered globally by October of 2021 (Green 2021). Across the world, 65.4% people had received at least one dose of a COVID-19 vaccine as of May 2022, compared to 15.7% of individuals in low-income countries (Ritchie et al. 2020). Figures 4, 5 and 6 below show the percent of people who have received at least one dose of a COVID-19 vaccine as of 30 May 2021, 30 October 2021, and 14 May 2022, respectively (Ritchie et al. 2020).

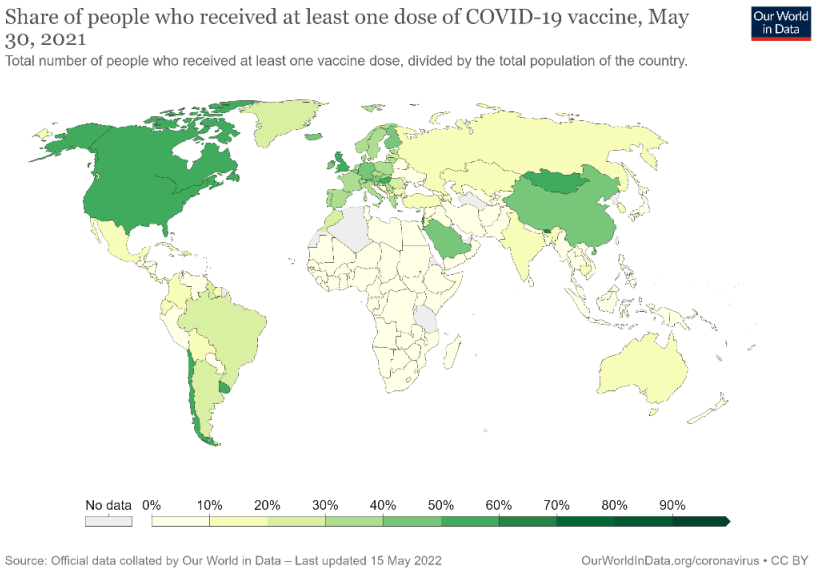


Figure 4

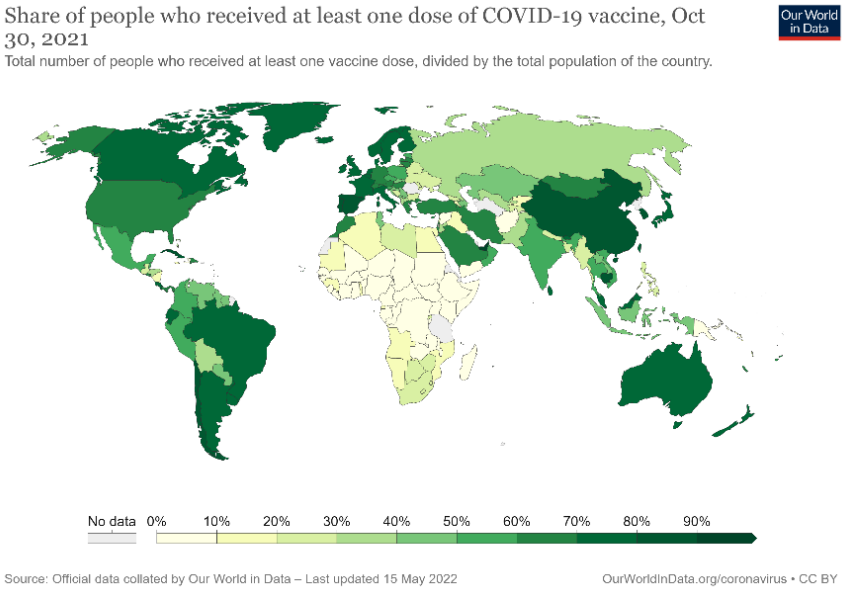


Figure 5

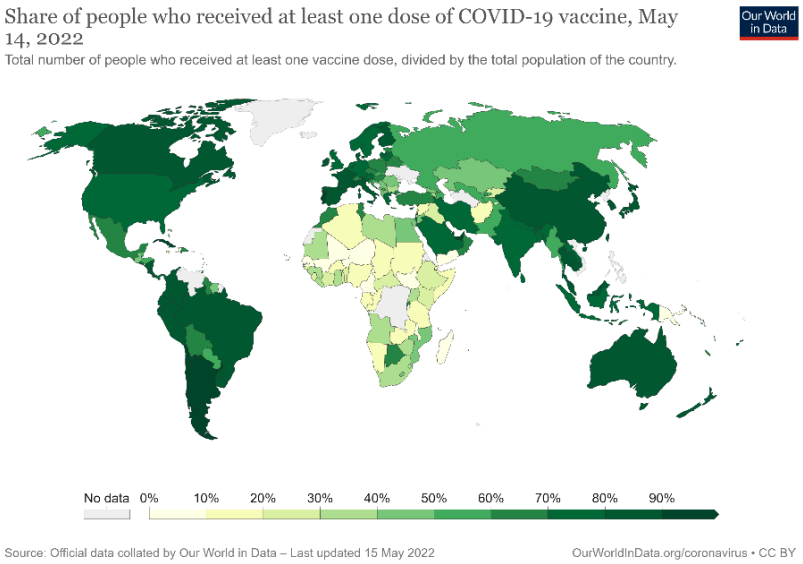


Figure 6

The lack of vaccine distribution to the Global South is a topic of concern, but this is a separate issue and does not mean that violating patent law is the best way to help poorer countries. The United States can and should aid in the distribution of vaccines to the Global South. Access to a vaccine formula is not a panacea to solving the pandemic. Supply chain management, capacity expansion, and innovative technology transfer are necessary for increasing the vaccine supply and reach (Lindsey 2021).

The startling disparity in world vaccine distribution has highlighted the inherent inequality in the pandemic response to the Global South. Low vaccination rates in the Global South have spillover effects on the rest of the world. The COVID-19 variant that originated in South Africa has had adverse effects on Britain, a country with a strong vaccine rollout (Apuzzo and Gebrekidan 2021). Vocal proponents of giving away the patents cite these inequalities but lack robust evidence that such a plan would be more effective than vaccine distribution. There is

no guarantee that waiving patent law will increase distribution and stop variants, due to supply chain and manufacturing issues discussed in this paper.

III. Alternatives to Patent Law

Problems with patents beg the question of whether patent law is the right answer for incentivizing innovation. Incentivizing innovation is not a new idea. The Longitude Prize was awarded in 1737 by the British government to John Harrison for a device that determined a ship's longitude. Napoleonic France award these "prizes" for water turbines, food preservation methods, and the tin can.

There has been a resurgence in interest about replacing patent law with government-funded prizes. This avoids the deadweight problems seen with monopoly rights to products because patents harm short-term allocation efficiency. The efficiency loss is currently seen in the lack of vaccine distribution and access to developing countries. However, patents are critical to dynamic efficiency, in this sense helping to develop vaccines in the first place. Many economists find, however, that "the benefits of dynamic efficiency are vastly larger than the modest allocation efficiency losses" (Stevens 2020).

For now, patent law is here to stay. Patent laws are necessary in the ex-post case of COVID-19 vaccines because waiving patent law today would cause the plethora of problems discussed in this paper. Prizes to create incentives to innovate would have to occur ex-anti, and replace current patent law, at least in relation to pharmaceutical innovation. Taxpayer funds of about $180 billion per year would need to be put towards government-funded medical prizes,

and prizes could still be underfunded because true value of medicines are difficult to measure before creation (Stevens 2020).

IV. Conclusion

While there may be other options for the future, waiving patent law is the incorrect choice in the case of COVID-19. In the end, violating patent law disincentivizes innovation. It is important not to discount the role that innovation incentives play for the development of the vaccines. Pre-pandemic, patent laws have incentivized the foundational pharmaceutical research that has then been used for the development of vaccines, such as the mRNA research that some vaccine formulas used (Baker and Silver 2021). Setting a dangerous precedent of violating patent law could undermine innovative response to future catastrophic events.

Despite the incentives surrounding patent law, some still argue that the United States should force pharmaceutical companies to give away the COVID-19 vaccine formulas. Many argue that Big Pharma has profited off of the pandemic enough, and that protecting patent law is harming vaccine rollout to the developing world. Schoen argues, “the developing world lacks the very manufacturing capabilities needed to accomplish the enormous task of manufacturing the necessary number of doses to vaccinate entire continents” (Schoen 2021). Even if vaccine manufacturing could be outsourced in such a decentralized manner, American manufacturing of vaccines, which is the most advanced and capable in the world, would be greatly stunted (Schoen 2021). Decentralized vaccine production would limit vaccine rollout and distribution to the developing world, not only now but also in the long run, because the United States’ efficiency lends itself to a more successful vaccine production and distribution response (Schoen 21).

Proponents cite large profits earned by Big Pharma do not provide data to show that if developing countries were given the patent formulas, they would quickly be able to produce safe and effective vaccines.

The United States is currently helping other countries with their pandemic responses by giving away the vaccines themselves rather than the formulas. As of February 23rd, 2023, the United States has donated more than 687 million vaccine doses to 116 countries and economies (US Department of State, 2023). While a debate can be had about whether this is too many or too few, it does show that the United States has successful programs in place, such as the COVAX initiative. Recall that Pfizer was charging the United States $19.50 per dose of the vaccine, half price for middle-income countries, and at cost for the rest (Sagonowsky 2021, Baker and Silver 2021). In early 2023, Pfizer announced a price increase to between $110 and $130 per dose, and other pharmaceutical companies are following suit by similarly quadrupling prices (Murphy 2022). Major pharmaceutical company Moderna will raise its price for the US from $15 to $26 a dose to about $130 and will begin selling to the private sector soon (Wingrove 2023). While those insured are unlikely to be affected, Moderna said it is working to offer vaccines to the uninsured for free through financial programs (Wingrove 2023). The announcement was a strongly criticized decision, and Moderna defended its decision by saying they, “landed on a price that is consistent with value” (Wingrove 2023). It is worth pondering if the United States will continue vaccine rollout to the developing world at the same rate now that vaccine prices have drastically increased. Problems with vaccine rollout also include cold storage, which is required for some of the vaccines, and shipping to countries with civil unrest (FedEx 2023).

Some view this debate as one between Big Pharma’s profits and the global public health. Humanitarian efforts, however, are in line with protecting patent law. Violating patent law

disincentivizes innovation and would not necessarily expedite global vaccination rates. Ultimately, the end goal should be that of global safety and mass vaccination. The best way to achieve this goal is not by violating patent law and giving away the vaccine formulas.

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