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Waiving COVID-19 Vaccine Patents: A Bad Idea and a Dangerous Precedent

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ABSTRACT

The Biden Administration believes that suspending COVID-19 vaccine patents will expedite the swift development of high quality “cheap” versions of existing vaccines and hasten the pandemic’s end. This view is dangerously wrong. Vaccinating the world is essential, but temporarily waiving patent rights for COVID-19 vaccines (also known as “compulsory licensing”) will actually slow their availability to the developing world.

While providing no gain, compulsory licensing promises lots of pain. Waiving patent protection discourages cutting-edge research investments, which in turn produce breakthrough treatments not just for COVID-19, but for other diseases, like cancer. Weakening these protections would be anti-patient and counterproductive.

The reality is that, in order to save the world, we must all work together as partners. The remarkable speed with which we developed diagnostics, therapeutics, and vaccines to combat COVID-19 points to the need for more collaboration, not less. Patents are a foundational principle upon which that success rests.

While the policy of temporarily waiving patents seems fair and humanitarian, the devil is in the details. Such a policy will not result in a single citizen of the developing world getting vaccinated one minute sooner. In fact, the unintended consequences are the reverse. More confusion, lower quality, less transnational cooperation. A triple play of disastrous global proportions.

We cannot negotiate with people who say “What’s mine is mine and what’s yours is negotiable.” – John F. Kennedy

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INTRODUCTION

“TEMPORARILY” WAIVING BIOPHARMACEUTICAL patent rights (also known as “compulsory licensing”¹) for COVID-19 vaccines is a bad idea – and a dangerous precedent.

When it comes to broadening the availability of vaccines, dispensing with patent protection will actually slow their availability to the developing world — and what does “temporary” really mean? Shunting aside patent and intellectual property rights sends a very

dangerous signal to innovator biopharmaceutical companies (and their investors) that the government may not be such a good partner after all.

The claim, by India, South Africa and some high-profile members of civil society (such as Knowledge Ecology International²), is that suspending COVID-19 vaccine patents would allow developing countries to manufacture their own “cheap” versions, hastening the end to the pandemic. They’re wrong. Dangerously wrong – and entirely unnecessary.

Innovator vaccine developers have been ramping up production for months.³ It has taken time, industry officials said, because the shots currently available rely on newer technologies like messenger RNA. With the extra output, Pfizer had begun shipping U.S.-produced doses to countries including Mexico and Canada, while Moderna agreed to deliver the COVAXX Initiative doses to supply shots to poor nations.⁴

The companies were also in discussions with the Biden administration about how to get more supplies to the developing world. The industry proposed providing more doses to developing countries at cost or not for profit, said Jeremy Levin, chairman of the Biotechnology Innovation Organization (BIO) and chief executive of Ovid Therapeutics Inc. “These proposals appear to not even have been looked at.”⁵

Gutting IP protections won’t make COVID-19 vaccines more readily available but it will set a terrible precedent that will chill future medical innovation and hurt those they are most vociferously claiming to assist. *Cui bono?*

Biopharmaceutical research is risky and expensive. For every 5000 molecules developed in the lab, only one successfully advances through lab, animal, and clinical testing and receives regulatory approval.⁶ After accounting for all these failures, it costs almost \$3 billion, on average, to bring a single medicine to pharmacy shelves.⁷

Biotech investors only take these risks because of strong patent protections.⁸ When a startup receives its first patent, the firm’s chances of attracting funding from institutional investors—such as venture capitalists—increases 53%, according to a National Bureau of Economic Research working paper.⁹ Patents save lives and enhance the value of medicines. As Abraham Lincoln (the only President to ever hold a patent) said, “Patents add the fuel of interest to the passion of genius.”¹⁰

Not surprisingly, nations with strong patent laws (and specifically the United States and the European Union) produce higher volumes of new treatments. The United States has the most robust IP protections, which explains why American scientists develop over half of the new drugs invented globally.¹¹ Waiving patent protection discourages research and development here in America and around the globe.

Patent protections incentivize firms to make big research investments, which in turn produce breakthrough treatments not just for COVID-19, but for other diseases, like cancer. Weakening these protections would be anti-patient and counterproductive. It wouldn’t speed the rollout of existing vaccines, but it would ensure we’re less prepared to fight the next phase of the COVID-19 pandemic – not to mention future global public health emergencies. This was precisely the strategy behind the Orphan Drug Act of 1983.¹² This major piece of

legislation was the first-of-its-kind for rare diseases and its success has helped to encourage similar legislation in other parts of the world. In the late 1970s and early 1980s, there was growing awareness that very few medical treatments were being developed for people who had diseases affecting small patient populations. The problem was that pharmaceutical companies couldn’t expect to recover the investment required to develop treatments for diseases affecting a small number of people. Hence, these diseases came to be known as “orphan” diseases.

The Orphan Drug Act provided pharmaceutical manufacturers with three primary incentives: Federal grants for orphan drug research; a 50% tax credit to defray the cost of clinical trials and; seven years of marketing exclusivity for products approved as orphans. The result? Currently, more than 400 orphan designated drugs are commercially available and close to 1000 drugs are undergoing clinical trials.¹³ Incentives work, threats do not and actions have consequences. Incentives drive behavior as do disincentives. One day after President Biden announced his support for a temporary waiver of COVID-19 patent rights, stock prices for innovative biopharmaceutical companies plummeted.

When the power of the healthcare ecosystem (government, biopharmaceutical companies, academia, healthcare providers, logicians and patients) work together as partners, we accomplish miracles at Warp Speed. “Waiving” patents isn’t good partnership behavior.

HISTORICALLY, COMPULSORY LICENSING HAS NOT WORKED

Compulsory licensing is legal under international law, but only in limited instances. It allows local companies to produce generic versions of patented medicines in desperate times — such as an infectious disease outbreak. However, India, Brazil, and other nations abuse this policy and allow drug-makers to produce just about any generic without any urgent reason at all, and without the patent owners’ permission.¹⁴ “Temporary?” *Caveat emptor.*

Developing countries obviously need COVID-19 vaccines as quickly as possible. But removing IP protections won’t accelerate vaccine distribution in these nations. In fact, it could slow it down. In the past, when developing countries have issued compulsory licenses—which effectively allow domestic manufacturers to create knockoff treatments even before drug patents expire—it has taken years for generic manufacturers to receive the drug formulas, work out logistical and payment challenges, and scale up production. In one case, it took

over four years to bring a generic AIDS drug to Rwanda with half that time spent settling a contract between the domestic manufacturer and the patent holder.¹⁵ A valuable lesson learned with direct and immediate application for the COVID-19 patent debate is that patents do not hinder availability, but lack of patent production eviscerates incentives for innovation.

As the late Senator Daniel Patrick Moynihan quipped, “People are entitled to their own opinions, but not to their own facts.” Hopefully this reality will result in an open and honest negotiation at the World Trade Organization (WTO) over the next several months, leading up to their Ministerial meeting on November 30th. At the May 6th 2021 WTO General Council meeting, Director General Ngozi Okojo Iweala urged members to begin text-based negotiations of the proposed COVID-19 vaccine waiver.¹⁶

AREN'T COVID-19 VACCINES “ESSENTIAL?”

Vaccinating the world against COVID-19 is essential. But how has the world fared in addressing the accessibility of other “essential medicines?” Considering its the World Health Organization (WHO) that is driving the policy of pausing COVID-19 vaccine patents, it’s worthwhile to examine the impact of that institution’s Essential Drug List. The WHO’s Model List of Essential Medicines contains the medications considered to be most effective and safe to meet the most important needs in a health system.¹⁷

Very few of the 400 or so drugs deemed essential are new, or patented (or ever patented) in the world’s poorest countries. In category after category, from aspirin to Zithromax, in almost every case and in almost every country, these medicines have always been (or have been for many years) in the public domain. That is, the medicines are fully open to legal and legitimate generic manufacture. Their availability remains spotty and their quality questionable. Just as the coronavirus mutates to survive and thrive, so to do the purveyors of counterfeit medicines. There is no value at all in vaccines that are not manufactured to the highest standards. Poorer nations must receive the same high-quality vaccines that are available in the West. According to a recent report from the Center for Medicine in the Public Interest, “Not surprisingly, the COVID-19 pandemic has increased the public’s exposure to counterfeit medical products.”¹⁸ Allowing manufacturers with questionable safety records to produce vaccines that require sophisticated processes, procedures, material and manufacturing is a recipe for disaster.

According to Dr. Michelle McMurry-Heath, the President of BIO, “Handing needy countries a recipe book without the ingredients, safeguards, and sizable workforce needed will not help people waiting for the vaccine. Handing them the blueprint to construct a kitchen that—in optimal conditions—can take a year to build will not help us stop the emergence of dangerous new COVID-19 variants.”¹⁹

Dr. Jeremy Levin reinforces the proposition that, “This is not just a matter of forcibly transferring IP and know-how from America to other nations. There was and is no need to rebuild factories around the world where not only will it take a long time to do so but also the standards and capabilities that exist in America cannot be easily replicated or guaranteed. In the future, this decision will act as a disincentive to companies to respond to the next pandemic.”²⁰

WHERE DO MEDICINES COME FROM?

Many politicians and pundits mistakenly believe that biopharmaceutical innovation is primarily driven by the National Institutes of Health (NIH). The reality is that the primary engine of drug innovation is private industry. The members of the Pharmaceutical Research and Manufacturers Association (PhRMA) spend in excess of \$136 billion on research and development — and these are only some of the larger companies.²¹

Both the NIH and private firms provide research financing to academic institutions. But it is industry that employs most of the scientists that conduct the hands-on development work. Unfortunately, some lawmakers have bought the myth that the NIH is primarily responsible for new medicines.

A study by Bhaven N. Sampat and Frank R. Lichtenberg entitled “What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?”²² provides a data-driven analysis that gives the National Institutes of Health (NIH) its due—but in the proper frame of reference. Sampat and Lichtenberg studied 478 drugs that were associated with \$132.7 billion in prescription drug sales in 2006. Less than 10 percent of these drugs had a public-sector patent. Drugs with public-sector patents accounted for just 2.5 percent of sales, although the indirect impact was higher for drugs granted priority review by the FDA. (Priority Review is given to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists.²³) Drugs whose applications cited federally funded research and development or government publications accounted for 27 percent of sales.

Another study in the British Medical Journal also analyzed the topic. Comparable to prior research, the investigators found that the majority of biopharmaceutical research was conducted and funded by the private sector. Despite having excluded vaccines, biologic medicines and gene therapies from their final analysis, a study limitation noted by the authors, the researchers found that 75% of all Food and Drug Administration (FDA) approved drugs between January 2008 and December 2017 were funded and researched by private companies. Only 19% of the approved drugs had origins in publicly supported research and development, and 6% originated in companies that were spun from publicly supported research programs. Thus, 25% of approved medicines benefited from “some” public support. The results were impressive, and indicative of how central private-sector research is to biopharmaceutical innovation.²⁴

THE DEBATE OVER REMDESIVIR

Consider remdesivir and the related debate over Bayh/Dole March-in Rights.²⁵ The recently released Government Accountability Office (GAO) report, *Information on Federal Contributions to Remdesivir*,²⁶ considered whether federal patent rights were appropriate, given the federal government’s contributions in researching and developing the drug.

The GAO report came in response to stiff political headwinds. In August 2020, citing concerns over pricing and availability of remdesivir, 34 state attorneys general (including present Health and U.S. Human Services Secretary Xavier Becerra) asked federal officials to exercise the government’s march-in rights over the COVID-19 treatment.²⁷ The attorneys general said Gilead has been “unable to assure a “supply of remdesivir sufficient to alleviate the health and safety needs of the country” amid the COVID-19 pandemic.

The straightforward, unambiguous, and politically inconvenient conclusion of the independent GAO report found that “Federally supported remdesivir research conducted by CDC, DOD, NIH, and NIH-funded universities has not resulted in government patent rights, because, according to agency and university officials, federal contributions to the research did not generate new inventions.” The principal investigators at the NIH, who were working on coronavirus research projects, told the GAO they did not consider filing invention disclosures because their work did not involve modifying remdesivir or its parent compound.²⁸

It was President Franklin Roosevelt who recognized the vital role of the federal government partnering with “Good old American know-how” to win the Second

World War and propel the American Century forward. Decades before Operation Warp Speed forged a partnership to defeat a natural foe, an earlier public/private partnership of industry, academia, and government, the Manhattan Project, proved the value of collaboration in the face of a deadly human enemy.

When it comes to regulated health care technologies specifically, and the anti-COVID-19 armamentarium explicitly, collaboration is a *sine qua non*. One of the most important lessons of the pandemic is that when the health care ecosystem works together, we can achieve amazing things. We are all in this together. Politics is a distraction. Science must be collegial, intramural, and transnational.

BAD POLICY IDEAS HAVE REAL-WORLD CONSEQUENCES

The COVID-19 vaccine debate is not America’s first joust with pharmaceutical patents. Senator Bernie Sanders has previously introduced a bill that would replace our current patent system for pharmaceuticals with a “Medical Innovation Prize Fund.”²⁹

It’s not a new idea. The prize model has been used in the past by the old Soviet Union — and it didn’t work.³⁰ The Soviet experience was characterized by low levels of monetary compensation and poor innovative performance. The US experience isn’t much better. The federal government paid Robert Goddard (the father of American rocketry) \$1,000,000 as compensation for his basic liquid rocket patents.³¹ A fair price? Not when you consider that during the remaining life of those patents, US expenditures on liquid-propelled rockets amounted to around \$10 billion. This is certainly not what Schumpeter had in mind when he wrote about a “spectacular prize thrown to a small minority of winners.” There’s a difference between “Creative destruction” and destroying medical innovation.³²

“Prizes over Patents” legislation would replace a patent system that has allowed the average American lifespan to increase by almost a full decade over the last 50 years³³ with a prize program that has a solid record of complete failure. To borrow an over-used adjective from the world of global climate change – we must protect “sustainable” innovation.

It’s important to put the “temporary” COVID-19 vaccine patent waiver in the context of the on-going battle by the global “anti-pharmaceutical patent” lobby. There is a small but vocal and influential public health policy cohort that believes patents are the most significant cause of healthcare disparities worldwide. Their philosophies repeat and reinforce many misunderstandings

relative to the impediments to broader access to medicines. Their ill-considered policy schemes (such as a prize system and a more regular and aggressive use of compulsory licensing practices) reinforce the false narrative of a “Good Guys/Bad Guys” *weltanschauung* that pits the innovative biopharmaceutical industry against the needs of the developing world. This is untrue, unfortunate and counter-productive. There are rarely simple answers to complex questions. The reality is that, in order to save the world, we must all work together as partners. A free-market healthcare paradigm for drug development, although far from perfect, works. A well-appointed armamentarium of COVID-19 diagnostic tools, therapeutics and vaccines – all invented in under one year, speaks to the power of ecosystem teamwork and fair incentives – most importantly patent protection for innovation.

According to a recent article in Health Affairs, “The remarkable speed with which we developed diagnostics, therapeutics, and vaccines to combat COVID-19 points to the need for more collaboration, not less. One of the most important lessons of the pandemic is that when the health care ecosystem works together, we can achieve amazing things.”³⁴ And patents are a foundational principle upon which that success rests.

The Biden Administration has empowered a resurgence in the anti-biopharmaceutical industry, anti-patent, anti-intellectual property debate. Shortly after President Biden signaled his support for waiving COVID-19 vaccine patents, Representative Alexandria Ocasio-Cortez tweeted, “Let’s do insulin next”³⁵ and Senator Sanders commented, “This is exactly the kind of leadership the world needs right now ... I also recognize the dedicated work done by activists in communities around the world to put this issue on the global agenda. We are all in this together.”³⁶

President Biden’s support of “temporary” waivers may not end up being so temporary at all if elected officials such as Ocasio-Cortez and Sanders have their way.

Despite this constant negativity from the anti-patent lobby, global production capacity is expanding and accelerating global access is possible. Strengthening the current system that created vaccines and treatments at a record-setting pace is the best way to achieve this important global public health goal. It’s time to ask some tough questions: are poorer nations engaged with global manufacturers in negotiating a fair price for vaccines? If not, why not? Have these same developing nations countries thought about partnering with the biopharmaceutical companies to build manufacturing facilities that can legally and safely produce the vaccines — facilities can then be used to manufacture other essential medicines? If we shy away from asking the tough questions, we are unlikely to find the right answers.

While, *prima facie*, the policy to temporarily waive patent rights seems fair and humanitarian (two words regularly used to describe President Biden), the reality is quite different. Such a policy will not result in a single citizen of the developing world getting vaccinated one minute sooner. The anti-patent consortium is, unfortunately, willing to sacrifice the developing world on its own infallible Altar of Altruism, fueled by their dogmatic adversity to free-market principles.

The most empowering relationships are those in which each partner lifts the other to a higher possession of their own being. — Pierre Teilhard de Chardin.

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