Reforming Patent Law: The Case of Covid-19

Michele Boldrin and David Levine

A short time ago the debate over the proposal to temporarily waive intellectual property rights on Covid-19 vaccines was raging worldwide; and the suspension of those rights seemed imminent. Public attention reached its peak in May 2021 when the Biden administration endorsed the idea and committed itself to pursuing it under the World Trade Organization–World Intellectual Property Organization (WTO-WIPO) procedural rules for waiving intellectual property (IP) protection. By suspending IP rights, the administration sought to help low-income countries to start producing vaccines more quickly, reducing the rising and dramatic worldwide vaccine inequality.

It is fair to say that neither the temporary suspension of IP nor the dramatic increase in the supply of vaccines it was supposed to bring about is in the making. In this article, we discuss why this had to be the case; what this teaches us about the economics of vaccine production; and what kinds of changes in IP legislation could increase production and distribution of medical supplies.

Patents and the Global Inequality in Vaccination

While vaccination rates are increasing quickly in wealthier countries, rates in Africa, Latin America, India, and elsewhere are not improving much. So far, the idea of suspending patents has only

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produced lengthy and ineffective discussions, such as the "High-Level Dialogue" on "Expanding COVID-19 Vaccine Manufacture to Promote Equitable Access" on July 21, sponsored by the World Health Organization (WHO) and the WTO. A summary of that meeting follows:

> The event, which was held under the Chatham House Rule, aimed to identify obstacles, and propose solutions for increasing vaccine production and closing the wide gap in vaccination rates between rich and poor countries. Participants described current and projected production volumes as well as plans for new investments in production capacity. They shared experiences about specific supply chain bottlenecks they were encountering, from export restrictions and raw material shortages to onerous regulatory processes and exchanged ideas on how these might be addressed. . . . While there was broad agreement on the importance of keeping supply chains open and predictable, different perspectives were expressed on the proposed waiver of the WTO's Trade-Related Intellectual Property Rights Agreement provisions pertaining to vaccines and other products needed to combat COVID-19 [WTO 2021].

When it comes to vaccine development and distribution, the facts on the ground are easily summarized:

- Only 27.6 percent of the world population has received at least one dose of a Covid-19 vaccine, and only 14.1 percent is fully vaccinated (Our World in Data 2021). The percentage vaccinated in the poorest countries is in the single digits and often as low as 1–2 percent. The international cooperation project known as COVAX (COVID-19 Vaccines Global Access) has managed to ship only 140 million doses in 137 countries.
- About 18 months after the first vaccines were discovered, their profitability is increasing; and global productive capacity remains concentrated in a few countries and in a little more than a handful of firms (Evenett et al. 2021). Almost 90 percent of the key ingredients used in the vaccines' production come from this small group of countries, creating the material conditions for several anti–free trade policies (Toxvaerd and Yates 2021).
- Both China and India are part of this select club, while Russia is not (BBC 2021). China seems to be playing a game of its own

(Mallapaty 2021); and India, the biggest vaccine factory in the world (Frayer 2021), is a major sponsor of the so far unsuccessful proposal to waive patents on vaccines.

We do not claim to provide solutions to global problems of such magnitude. Our goal is modest: we ask whether existing intellectual property regulations played any role in contributing to these inequalities, and suggest possible remedies where we believe a causal nexus exists.

We begin with a brief summary of the reasons why we argued previously (Boldrin, Levine, and Toxvaerd 2021) that the proposal to temporarily suspend patents on vaccines would be futile and divert attention from more relevant issues.

Lessons from the Suspension Debate

At the heart of the idea that by suspending a bunch of patents one could rapidly ramp up worldwide production of highly sophisticated vaccines was and is a myth—the myth of the "secret formulas" covered by a handful of patents. According to this myth (which happens to be the received economic wisdom about innovation), behind every new product, no matter how complex, are several ideas that can be summarized in a simple blueprint. The blueprint must be patented to guarantee exclusivity to its creator; such blueprints are expensive to create; and their cost needs to be recouped.

This mythological view of the economics of technological innovation leads to two incorrect policy conclusions: first, that patents are necessary for innovation, otherwise nobody would incur the expense of creating these blueprints, and, second, that if the patents could be freed, then everyone would be able to manufacture vaccines. These incorrect conclusions lie behind the pointless efforts to bring about a suspension of several patents through WTO rules.

This myth is close to the opposite of the truth. Producing a vaccine, or any new drug, is akin to cooking one of the elaborate dishes of contemporary molecular gastronomy. The recipe written on the mythical blueprint is just the start: one needs also to find the cooks capable of following it, the fresh special ingredients, the sophisticated tools, and, finally, the skills needed to deliver the food to the customers.

Stepping out of the cooking analogy, let us look at what these elements correspond to in the pharmaceutical industry. The "recipe" is

the scientific breakthrough leading to the new drug. Akin to culinary prowess are the set of professional skills and operational know-how that constitute a pharmaceutical company. The "ingredients" are the special inputs to produce vaccines that, as we have learned, faced a real bottleneck for many months, and may still be backlogged (Bollyky and Bown 2021; Pilla 2021). The "serving tools" are the physical plants and sophisticated machinery carrying out the actual production and delivery of the doses.

It is apparent that, apart from the initial breakthrough, patents have relatively little to do with the innovation process. We label the other components of the innovation process "knowledge capital," which is privately owned, rivalrous, and costly. This understanding reverses the implications of the myth. Patenting a formula is not necessary to reward innovation, because its creator has the inherent advantage of owning the knowledge capital needed to make use of it. Second, freeing the patents describing an innovation's formula will have little effect on that innovation's availability unless the corresponding knowledge capital is also equally distributed.

These facts explain both what is happening with regard to the Covid-19 vaccine patents and why Moderna's widely publicized decision to not enforce its Covid-19 vaccine patent licenses against its competitors did not lead, after 16 months, to a mushrooming of plants producing its vaccine. Because of mRNA therapies' novelty, political efforts to either voluntarily pool intellectual property on vaccines or impose compulsory licensing of patents could not lead to much additional output of actual vaccines in the short run. Where the necessary knowledge capital exists (India), vaccines are already being produced at full speed under licensing from one or more innovators. Effectively manufacturing and distributing Covid-19 vaccines requires human capital, technology, raw materials, and equipment—which are lacking in all but a dozen countries in the world (Crager 2018; Plotkin et al. 2017).

Recall that, in the terminology of economics, a good is "nonrivalrous" if it can be profitably used by an increasing number of people without becoming scarce. While ideas may in principle be nonrivalrous (and made excludable to other people only through patents or secrecy), the same is not true of knowledge capital. The latter is scarce, rivalrous, and excludable. That is to say, it is not a public good (i.e., something that is both nonrivalrous and nonexcludable), and it cannot be turned into a public good by a political decision.

This explains why the pure invention (writing the formula) of the vaccines was so rapid and inexpensive: because the new idea behind the formula was the product of preexisting knowledge capital. Decades of investment in biochemical research, mRNA technology, and the machinery and skills for rapidly analyzing the structure of viruses made the easy breakthrough possible. It was no miracle.

Public and Private Financing

While these arguments explain why suspending patents on vaccines cannot suddenly increase their supply, it is also clear that all the knowledge capital of this world would never lead to a new drug without the initial invention. In the next two sections we look again at the experience of the last 18 months with the Covid-19 vaccines to see if there is anything else one can learn about the economics of the pharmaceutical industry.

Consider the four major vaccines used in the United States and European Union (EU): AstraZeneca, J&J, Moderna, and BioNTech-Pfizer. Their formulas came, respectively, from a research university (Oxford), a research company that was a spinoff of a research university (J&J), and two small pharmaceutical research companies. Of these two, the larger (Moderna) had received substantial financing from the public purse even before the pandemic started, while the second (Pfizer) received public funds only after announcing its vaccine. More generally, the inventions were the product of that portion of knowledge capital that is allocated to either basic or industrial research, and that in both the United States and EU is regularly financed by various kinds of government funding. The three major firms involved in the production and distribution of the vaccines provide all the other components of the vaccines' knowledge capital. However, they contributed scarcely, or did not contribute at all, to the invention of the vaccines that they ended up producing. Moderna is the only exception: it is by far the smallest of the four players and has received substantial public resources to support its R&D activity.

During the last three decades or so, the features we have illustrated have progressively come to dominate the way in which the pharmaceutical industry invents and then produces new drugs (Boldrin and Levine 2008; Jung, Engelberg and Kesselheim 2019; Lipton and Nordstedt 2016; Rafols et al. 2014; Reuters 2010). While the experience with the Covid-19 vaccines is extreme along many

dimensions, the overall pattern is general enough to justify policy conclusions that extend beyond the specific case of vaccines.

In recent months, many have argued that the U.S., EU, and UK governments are entitled to the IP benefits of Covid-19 related research, because they helped finance the knowledge capital that produced the inventions; they also invested substantial resources in financing the vaccines' production and manufacturing processes. Tristan Reed (2021), for example, claims that, without the boost provided by the enormous demand coming from various governments, the rapid rise in vaccine supply would never have happened, and pharmaceutical companies would never have invested in the process that led to the reduction in costs. This argument may or may not have merit. However, given that very seldom if ever have governments committed to purchasing billions of doses in advance, or directly supported the development of productive capacity, we will not dwell further on it.

What about the other components of the knowledge capital necessary to produce a new drug? Are they also financed by taxpayer money? As in the case of the Covid-19 vaccines, all of whose Western producers are privately held companies, the knowledge capital of the pharmaceutical industry is almost entirely private. Apart from the industrial productive capacity and the human capital operating it, a major share of such knowledge capital is constituted by the legal and marketing divisions of large pharmaceutical companies. They are essential to navigate the maze of patents and other IP regulations covering the drugs and their production and distribution processes. We break no news in saying that such private capital earns above normal rewards as a result of its position between the invention of new patentable drugs (financed by taxpayers' money), the public regulators authorizing their use, and the customers ultimately purchasing them.[1]

In summary:

- The discovery protected by the patent is relatively cheap to obtain, but is almost always the product of previously accumulated knowledge capital.
- The latter is the product of a complex mixture of both publicly and privately funded research that, because of the Bayh-Dole Act or Patent and Trademark Law Amendments

[1] Ledley, McCoy, and Vaughan (2020) have a fresh look at the data.

Act (December 12, 1980), is eventually owned by the private researchers and institutions being funded, leading to the patentability of anything discovered as a result of this knowledge capital.
- The other components of the knowledge capital needed to produce and distribute the new drug are generally privately financed. The advantage that the innovative firm has over its competitors is mostly due to this factor.
- In financing medical research, taxpayer money does not aid in the production of a public good but funds a mixture of public and private knowledge capital within a legal framework tilted in favor of the second (private capital).

No matter which angle one takes to analyze it, this seems an odd situation. What is the public policy rationale for using taxpayer money to subsidize private firms earning rates of return higher and less risky than the average, and then allowing those firms to monopolize the products of their subsidy?

Where Is the Public Good?

The idea behind patents is that they are a grant of monopoly power: they enable the patent holder to restrict supply and jack up prices by excluding competitors from using the patented invention. The idea behind public financing of private R&D is that it produces a pure public good: scientific information is nonrivalrous—that is, usable by many people or firms simultaneously. Patenting inventions, however, seems the perfect way of defeating the purpose of subsidizing R&D. That is because patenting discoveries financed by the public purse blocks imitation and competition, the main forces that increase and improve productive capacity. Decade after decade this incoherent policy has led to a situation where, in 2021, the productive capacity for vaccines is constrained by a shortage of people possessing the adequate knowledge capital. If the hundreds of scientific discoveries currently used in the production of vaccines had not been patented, more people would have brought further innovations through the use of this knowledge capital. Imitators of Moderna, the Jenner Institute, and BioNTech could have emerged in the meantime; and some of them could be competing by improving upon the original discoveries and providing the world with even more effective treatments.

Is there anything to suggest that forbidding patents for inventions funded through public subsidies would greatly reduce researchers' incentives to make their discoveries in the first place? This cannot have been the case for Moderna, for the reasons discussed earlier. Moderna does not care about its patents as it knows that its competitive advantage comes from its knowledge capital. Most likely, the Jenner Institute would also have developed its vaccine with or without patent availability, as the story of its partnership with AstraZeneca proves (see Garrison 2020). Finally, it may or may not be the case that BioNTech would have not developed its vaccine in the absence of patents. Still, two things are certain: prior to 2020 BioNTech had received almost no public subsidies, and the development of the mRNA technology was the product of a competitive effort in which inventors patented their discoveries mostly to prevent others from doing the same (see Gaviria and Kilic 2021; Shores, Haversack, and Storaska 2021).

Our ability to use the experience of the Covid-19 vaccines in order to understand the way the pharmaceutical industry operates, though, seems to be handicapped by the fact that there are currently almost 20 Covid-19 vaccines available somewhere in the world and more than 100 at various stages of development, according to the London School of Hygiene and Tropical Medicine's online vaccine tracker.[2] This has never been the case for other newly patented drugs: very seldom do more than two firms compete in the same narrowly defined clinical market. While it may be true that the vaccines not yet in use in the United States and the EU are grossly inferior to the leading four, and therefore not real competitors, even the four currently in use in these major countries (soon to become five with the arrival of Novavax) is a large number.

This raises the question of why we do not observe substantial investments taking place around the world to build productive capacity for some form of generic Covid-19 vaccine, producible under compulsory licensing. This brings us to consider the hidden true public good that current IP legislation allows big pharmaceutical companies to monopolize. While the inventions that led to the development of the Covid-19 vaccines happened outside big pharma—and while vaccine production is taking place both within big pharma and

[2] See https://www.lshtm.ac.uk/research/research-action/covid-19.

through licensing to other companies (of which the Serum Institute of India is the best example)—the vaccines' clinical trials were carried out exclusively by their patents' owners. Further, their results are covered by a complex net of various forms of intellectual property rights known on the two sides of the Atlantic as "market exclusivity" and "data exclusivity," respectively.[3]

The fact is that true generic vaccines do not exist, and this is akin to the well-known fact that, when successful drugs come off patent, their generic versions take quite some time to come around. It is not enough to copy a formula and accrue enough knowledge capital to produce and distribute a vaccine or drug. One needs also to be authorized to do so by the likes of the Federal Drug Administration and the European Medicines Agency, which requires supplying those agencies with very costly information about the effects and consequences of the products being commercialized.

Vaccines and new drugs are complex chemical and biological objects, and the equivalence of the original with its generic versions often cannot be demonstrated by simple tests. Regulatory authorities require a complete set of clinical safety and efficacy tests for each imitation therapy before its distribution can be authorized. What is more, the collection of pharmacological and clinical data innovators accumulate during the various stages of their clinical trials—which receives various forms of IP protection outside of patents—is excludable, despite its nonrivalrous nature.

It is our view that, apart from the patenting of the initial formulas, the inability of generic manufacturers to draw from original trial data is where existing IP protection plays an important role in reducing competition in the pharmaceutical industry, thereby damaging the growth of productive capacity and the diffusion of useful drugs. It seems clear that, within the set of inputs leading to the commercialization of a new medicine, if anything is a pure public good, then surely the *results* of the clinical trials are. These results are quite expensive to produce, in particular because of the strong (some would say overly strong) requisites and procedural rules imposed by pharmaceutical regulators. Still, once obtained, the results of clinical

[3] Space constraints prevent an illustration of the way in which this relatively new form of IP protection works, but the interested reader can find abundant material online. See, for instance, WHO (2000) and International Federation of Pharmaceutical Manufacturers and Associations (2011).

trials are much more of a public good than the initial discovery of a drug, because they are necessary for reasons of public safety. To comply with regulatory requirements, clinical trial data can easily be reduced to a set of nonrivalrous pieces of information.

Conclusion

The pharmaceutical industry is subject to a complex array of government regulations, of which patent protections granting monopoly power are only a piece. In a context in which pharmaceutical companies pay for clinical trials and generic manufacturers do not, the removal of patent protection may tilt the current complex equilibrium between regulations and subsidies in the wrong direction. While substantial protection is provided by the first mover advantage—which has played so strong a role in the development of Covid-19 vaccines—simply removing patent protections without reforming the clinical trial system may backfire. We believe that only a careful and thoughtful reform process is likely to succeed, and, to this end, we conclude by proposing two reforms.

First, Congress should start scaling back the powers of the Bayh–Dole Act and subsequent legislation enabling the patenting of government-financed innovations. In fact, given the growing ability of private venture capital to finance even very risky research in the biological and medical fields, the 1950s rationale for providing ample taxpayer support for the R&D of firms operating in these sectors has become groundless.

Second, Congress should shift public resources from research aimed at creating patentable innovations toward research at the other end of the drug-production process. That is, public resources should finance clinical trials for drugs with particularly high societal value, such as vaccines. This can be done on a competitive basis through relatively standard procurement methods.

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