Shall we fear a Covid-19 Patent Waiver?[1]

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Abstract

Shall vaccine patents be temporarily suspended? In a simple model, we reflect the essence of the debate on the Covid-19 patent waiver. The central message is that if the probability of imitating innovative vaccines is low, then a patent waiver would be harmless to future R&D. Conversely, a patent waiver would be undesirable if it is too easy to imitate future innovations.

This paper also derives a simple policy rule for R&D subsidies that governments can use to correct the adverse effects of the waiver on the incentives to innovate. The government can use R&D subsidies to neutralize the harmful effects of an expected patent waiver on the incentives to invest in R&D.We will compute the R&D subsidy increase able to keep innovation as it would be without a patent waiver. The optimal R&D subsidy turns out to be no larger than the probability of successful imitation by competitors following a suspension. This result holds for any R&D technology. Moreover, it is valid in general, even beyond the Covid-19 case.

The vaccine industry is highly concentrated. While the social gains from successful imitation are huge, it is usually challenging to transfer vaccine know-how from the handful of patent holders to potential imitators. In this environment, loosening intellectual property rights (IPRs) protection in a pandemic has significant macroeconomic advantages. Still, it may harm future innovation because it would create an expectation of future IPRs waivers. This paper allows an upbeat assessment of the conditions that make a patent waiver desirable, even considering the future R&D implications. Moreover, it shows how reasonable rises in R&D subsidies can overcome the IPRs' uncertainty and restore innovation to the same level that would prevail without a patent waiver. However, mRNA technology vaccines require more protection, given their easier replicability.

Keywords: Covid-19, Research and Development, Vaccines, Intellectual Property Rights.
JEL Classification: I18, O30.

"*Some commentators contend that all feasible capacity is being brought to bear on COVID-19 vaccines; further expansion will be prohibitively expensive, if not impossible, in a reasonable time frame. The need for additional capacity is too urgent to take these contentions for granted.*" Castillo et.al., (2021).

1 Introduction

The Covid-19 pandemic has provided a lot of food for thought for those interested in innovation and intellectual property rights. The most striking was the speed at which effective and innovative vaccines emerged.

Vaccines capitalized on more than a decade of basic research in genetics and biotechnology. In Pfizer/BioNTech's case, most notably the University of Mainz, the German public sector supported research on mRNA vaccines, potentially crucial against cancer. Indeed, BioNTech used to work in this area, which prepared it for the new Covid-19 challenge. Moderna capitalized on three decades of basic research in the United States to get to its path-breaking mRNA vaccine. Basic research, with its broad focus and strong public sector support (Gersbach et al., 2013, 2015, 2019, and 2021), prepared the ground for successful applied research. This example confirms Mazzuccato's (2013)[1] about the importance of active public involvement in shaping a national innovation system capable of creating world champion firms. Laplane and Mazzuccato (2020) have documented the importance of public sector capacity in the Covid-19 pandemics.

Another historical surprise happened in 2021. The United States proposed a temporary patent waiver for all Covid-19 vaccines to help developing countries ramp up production capacity and soon end the Covid-19 pandemic. This proposal is at odds with the traditional U.S. stand, which takes a solid defensive approach for all its intellectual property rights (IPRs), often in start conflict with the more liberal requests of developing countries. The European Union, taken by surprise by the Biden Administration's proposal, eventually opposed it in the WTO negotiations of July 2021. Given the relevance of the United States and the more than 100 countries supporting worldwide the Covid-19 patent waiver, Europe decided to target a somehow similar alternative: compulsory licensing. Hence, the spectrum of IPRs loosening is haunting the world, which triggered intense debate among experts in the media.

Meanwhile, other important proposals contributing to Covid-19 vaccine affordability have been followed. Most notably, the advance market commitments (AMC) proposed by Kremer and Glennerster (2004) is currently in use in developing countries via the GAVI and COVAX platforms.[2] Forslide and Herzing (2021) analyze a complete epidemiological model with vaccination and different age groups to best assess who should be vaccinated first. If the target is to reduce mortality, old age should be given priority. If instead, the target is to eradicate the virus, the young, the

[1] Also see Deleidi and Mazzucato (2021) and Mazzucato and Li (2021)

[2] Following Kremer, Levin, and Snyder (2020) recommendation to focus on productive capacity rather than on the sheer number of doses would boost the success.

highest spreaders, should be given priority. Alternatively, the middle-aged should have precedence if economic productivity is the main target.

The recent debate on the Covid-19 vaccines patent waiver has been only verbal, without any attempt at modelling it. A rare exception is Forslid and Herzing's (2015) paper on classical influenza, which modelled a vaccine monopolist producing fewer jabs than socially optimal. The reason is that the monopolist has less incentive to slow down the pandemics than society. They highlight a critical market failure complementary to this paper.[3]

Therefore, it is time to write a first economic model about Covid-19, which would be especially useful to discipline the discussion. Consequently, here we propose a simple, transparent model, which captures in reduced form the following elements raised in the informal debate so far:

1. A patent waiver is unlikely to generate entry by additional producers because Covid-19 patents rely on highly specialized technologies and complex manufacturing processes;

2. Regardless of its current effects, a patent waiver now will discourage future R&D because innovative firms will fear another patent waiver in the future;

3. Government will have to spend too much to compensate future innovators for the expected loss of a future patent waiver.

The stylized paper model takes these points into account in evaluating the desirability of a patent waiver on Covid-19 vaccines. We will assume that:

- The probability of successful imitation is low.
- Innovators will expect a future patent waiver when taking their R&D decision.
- The government will strive to subsidize R&D to successfully mitigate the disincentive effect of an expected future patent waiver.

The rest of the paper proceeds as follows. Section 2 describes our model and characterizes it analytically. Section 3 obtained the central policy rule of this paper: the R&D subsidy level that guarantees the same R&D investment under a patent waiver as without it. In particular, Section 3.1 shows that the previously obtained policy rule is valid for general R&D technologies. Section 4 offers some numerical results and illustrates an assessment of the proposed policy rule. Section 5 argues that mRNA technologies may need more protection because of their higher replicability. Section 6 concludes.

2 IPR Waiver or Not?

Abolishing Covid-19 vaccine patents, including their ingredients, may trigger a wave of competitive entry by imitating firms with probability $p \in (0,1)$. With probability $1-p$ no firm other than the patent holders will enter and produce the former protected products. Let $V_E \geq 0$ be the

[3] In a seminal paper, Michael Kremer (1998) proposed a mechanism for patent buy-out by governments.

representative patent holder's profit in case of entry; and let $V_{NE} > V_E \geq 0$ be the profit in case of no entry.

Let Q_{NE} be the aggregate quantity of jabs produced in case of no entry, while $Q_E > Q_{NE} > 0$ be the aggregate quantity of vaccine produced in case of successful entry. Hence, without patent waiver, total production will be equal to Q_{NE}.

From a social viewpoint, the expected production level, Q^e_{PW}, associated with the patent waiver is

$$Q^e_{PW} = pQ_E + (1-p)Q_{NE} > Q_{NE}.$$

Consequently, we can state:

Proposition 1. *An unexpected patent waiver will increase the expected amount of vaccine production.*

The results we have obtained in Proposition 1 is contingent on vaccines existing. However, what if a future patent waiver is expected before R&D expenditure is paid? An analysis of this case is crucial to establish the potentially harmful effects of patent suspension for developing vaccines against future variants or for equally destructive future pandemics.

Let R_{NE} the amount of R&D investment (in laboratory, specialized labour time, etc.) undertaken by the existing producers under the assumption that patents will be protected. Let us assume that R&D has decreasing returns at the social level and constant returns at the individual firm level. Denoting r_i generic firm i R&D expenditure, its probability of innovation is assumed equal to $(R_{NE})^{-\frac{1}{2}} r_i$, where the negative exponent of aggregate R&D reflects a "stepping on toes" congestion externality (Romer, 1990, and Jones and Williams, 1998).

Summing up over the firms, the aggregate probability of innovation, denoted I_{NE}, be increasing in $R_{NE} \equiv \sum_i r_i$ at decreasing marginal products, that is

$$I_{NE} = (R_{NE})^{\frac{1}{2}}.$$

We have chosen a quadratic cost function consistently with Jones and Williams (1998) and Bloom et al (2020) congestion externality calibrations. We assume that only one firm can win the patent race (as in Cozzi and Galli, 2018), and that its probability of winning the innovation race, conditional on innovation being found, be $\frac{r_i}{R_{NE}}$. Hence, the expected profit, π^e_i, of R&D firm i is

$$\pi^e_i = \frac{r_i}{R_{NE}} I_{NE} V_{NE} - r_i,$$

where V_{NE} denotes the value of the innovation.[4]. We assume free entry of innovative firms, and more and more innovators will join the patent race until the R&D expected profits are zero. This means

$$\frac{r_i}{R_{NE}} I_{NE} V_{NE} = r_i,$$

[4] As in Scotchmer (1996), Denicolo (2000), and Forslid and Herzing (2015), V_{NE} is the expected and present discounted value of all future profits from the innovation.

which implies

$$R_{NE} = (V_{NE})^2 .$$

Conversely, let us now assume that the R&D firms expect the patent waiver conditional on innovation. The waiver does not necessarily imply successful entry by imitators because this happens with probability p. If the waiver generates successful entry by generic firms, the private value of the innovation drops to $V_E < V_{NE}$. With slight abuse of notation, let R_E be the aggregate R&D investment in case of expected patent waiver - and possible entry. Since successful generic entry only happens with probability p, R&D firm i's expected profit is

$$\pi_i^e = \frac{r_i}{R_E} I_E \left(pV_E + (1-p)\, V_{NE}\right) - r_i,$$

which is zero if

$$R_E = \left[pV_E + (1-p)\, V_{NE}\right]^2 .$$

Since $I_E = (R_E)^{\frac{1}{2}}$, the equilibrium R&D investment, R_E, will be

$$R_E = \left[pV_E + (1-p)\, V_{NE}\right]^2 < (V_{NE})^2 = R_{NE}. \tag{1}$$

Consequently, $I_E < I_{NE}$, and we can state:

Proposition 2. *An expected patent waiver will decrease R&D and the probability of vaccine development.*

Is it better to waive or not to waive the patent? To answer, we must compare the expected patent production under each scenario. A patent waiver will imply more expected vaccine doses if and only if:

$$(R_{NE})^{\frac{1}{2}}\, Q_{NE} < (R_E)^{\frac{1}{2}}\, Q_{PW}^e$$

that is:

$$(R_{NE})^{\frac{1}{2}}\, Q_{NE} < (R_E)^{\frac{1}{2}} \left[pQ_E + (1-p)Q_{NE}\right]. \tag{2}$$

Since $(R_{NE})^{\frac{1}{2}} = V_{NE}$ and $(R_E)^{\frac{1}{2}} = pV_E + (1-p)\, V_{NE}$, condition (2) becomes:

$$V_{NE}Q_{NE} < \left[pV_E + (1-p)\, V_{NE}\right] \left[pQ_E + (1-p)Q_{NE}\right]. \tag{3}$$

which we can simplify to:

$$p\left(\frac{Q_E}{Q_{NE}} - 1\right) + 1 > \frac{1}{p\left(\frac{V_E}{V_{NE}} - 1\right) + 1}. \tag{4}$$

Therefore:

Proposition 3. *An expected patent waiver will increase the expected available vaccines if and only if (4) holds.*

Inequality (4) is a simple policy rule helpful in discerning whether a patent waiver is desirable. When it holds, the expected number of vaccine doses obtained under an expected patent waver would be higher than in the case of no patent waver.

For example, suppose a successful patent waiver, by allowing entry, doubles jabs production by 100% and halves the patent holder firm's profits. In that case, any positive probability of successful competitive imitation makes an expected waiver desirable.

In this case, $Q_E = 2Q_{NE}$ and $V_E = 0.5V_{NE}$. Then condition (4) becomes:

$$p\,(2-1)+1 > \frac{1}{p\,(0.5-1)+1}.$$

that is:

$$0.5\,(1-p)\,p > 0$$

which is satisfied for all $p < 1$.

More in general, let us assume: $\frac{Q_E}{Q_{NE}} > 2 - \frac{V_E}{V_{NE}}$. Then condition (4) holds for

$$p \in \left(0, \frac{\left(\frac{Q_E}{Q_{NE}} - 1\right) + \left(\frac{V_E}{V_{NE}} - 1\right)}{-\left(\frac{V_E}{V_{NE}} - 1\right)\left(\frac{Q_E}{Q_{NE}} - 1\right)} \right] \tag{5}$$

Quite interestingly, eq. (5) implies that the probability of imitators succeeding in copying the vaccine know-how cannot be high for the patent waiver to be beneficial.

3 Corrective Policy

Even when the waiver is beneficial according to our policy rule (4), R&D is discouraged by an expected patent waiver. So then, a question comes naturally: how much would it cost for governments to compensate the innovators not to reduce R&D investment at all? The answer follows eq. (1). Let governments subsidize R&D by a share $s \in [0, 1)$. The R&D expected profit, $(R_E)^{\frac{1}{2}}\,(pV_E + (1-p)\,V_{NE}) - R_E(1-s)$, is zero for

$$R_E = \left(\frac{pV_E + (1-p)\,V_{NE}}{1-s} \right)^2$$

Then to determine the patent waiver neutralizing subsidy rate s^* - i.e. such that $I_E = I_{NE}$ - rewrite eq. (1) as

$$R_E = \left(\frac{pV_E + (1-p)\,V_{NE}}{1-s^*} \right)^2 = (V_{NE})^2 = R_{NE}, \tag{6}$$

which implies

$$s^* = \frac{V_{NE} - V_E}{V_{NE}} p. \tag{7}$$

Hence, the optimal vaccine R&D subsidy rate equals a share of the percentage of the lost profit due to copying, equivalent to the probability of successful imitation.

In the case of a previously positive no-entry R&D subsidy, s_{NE}, the optimal expected entry R&D subsidy equation becomes

$$R_E = \left(\frac{pV_E + (1-p)\, V_{NE}}{1-s^*} \right)^2 = \left(\frac{V_{NE}}{s_{NE}} \right)^2 = R_{NE}, \tag{8}$$

leading to our R&D subsidy rule:

$$s^* = s_{NE} + \frac{V_{NE} - V_E}{V_{NE}} p\,(1 - s_{NE})\,. \tag{9}$$

Therefore we can state:

Proposition 4. *An expected patent waiver will not decrease the equilibrium R&D investment if and only if the R&D subsidy rate is given by (9).*

Policy rule (9) is elementary to apply once given an estimate of the relative profit loss of entry and the entry probability. Interestingly, the lower the likelihood of successful imitation and the lower the optimal R&D subsidy increase.

3.1 Corrective Policy: General Case

Let us generalize the results of the previous section by assuming that the aggregate probability of innovation is any function of R&D expenditure: $f(R_E)$. Function f is postulated to take on values between 0 and 1, to be increasing in R_E, continuous and strictly concave. Strict concavity reflects the decreasing returns to R&D. The government is assumed to subsidize R&D by a share $s \in [0, 1)$. The R&D expected profit becomes:

$$f\,(R_E)\,(pV_E + (1-p)\, V_{NE}) - R_E(1-s)$$

which is zero for

$$\frac{R_E}{f\,(R_E)} = \left(\frac{pV_E + (1-p)\, V_{NE}}{1-s} \right).$$

Let us define

$$g\,(R_E) \equiv \frac{R_E}{f\,(R_E)}.$$

The strict concavity of function $f(R_E)$ implies that $g\,(R_E)$ is strictly increasing in R_E.

In the case of no patent waiver expected, the R&D expected profit becomes the following simpler expression:

$$f\,(R_{NE})\,(V_{NE}) - R_{NE}$$

which is zero for

$$g\,(R_{NE}) \equiv \frac{R_{NE}}{f\,(R_{NE})} = V_{NE}.$$

Then to determine the patent waiver neutralizing subsidy rate s^* - i.e. such that $R_E = R_{NE}$, it suffices to write

$$g\left(R_{NE}\right) = g\left(R_E\right), \tag{10}$$

that is

$$\frac{pV_E + (1-p)\,V_{NE}}{1-s} = V_{NE}, \tag{11}$$

which implies

$$\begin{aligned} s^* &= \frac{V_{NE} - V_E}{V_{NE}} p = & (12)\\ &= .\left(1 - \frac{V_E}{V_{NE}}\right) p = & (13)\\ &= p - \frac{V_E}{V_{NE}} p < p & (14) \end{aligned}$$

As before, the optimal vaccine R&D subsidy rate equals a share of the percentage of the lost profit due to copying, equivalent to the probability of successful imitation.

Straightforward is the case of a previously positive no-entry R&D subsidy, s_{NE}, because only the no patent waiver R&D expected profit changes, becoming:

$$f\left(R_{NE}\right)\left(V_{NE}\right) - R_{NE}(1-_{NE})$$

and eq. (11) becomes

$$\frac{pV_E + (1-p)\,V_{NE}}{1-s^*} = \frac{V_{NE}}{s_{NE}}, \tag{15}$$

leading to the same R&D subsidy rule as before our generalization:

$$s^* = s_{NE} + \frac{V_{NE} - V_E}{V_{NE}} p\left(1 - s_{NE}\right). \tag{16}$$

Therefore, we can state:

Proposition 5. *For general R&D technologies expressed by function f,* a*n expected patent waiver will not decrease the equilibrium R&D investment if and only if the R&D subsidy rate is given by (9).*

It follows that the increase in the R&D subsidy rate needed to correct the adverse incentive effects of an expected patent waiver is

$$\begin{aligned} s_{Waiver} - s &= \frac{V_{NE} - V_E}{V_{NE}} (1-s)\, p\\ &= \left(1 - \frac{V_E}{V_{NE}}\right)(1-s)\, p\\ &< p \end{aligned}$$

The lower the probability of successful imitation, p, the lower the corrective R&D subsidy rate.

4 Simple Numerical Examples of Covid-19 Patent Waver

Based on the debates on this issue, at least nine out of ten commentators seem to believe that abolishing the Covid-19 vaccine patents will generate no entry by imitating firms able to produce and obtain authorization for vaccines equivalent to those currently used. Therefore, we will here assume that the probability of successful entry of generic vaccine producers is relatively low, that is

$$p = 0.10.$$

Let us assume that, in the unlikely case of successful entry, the generic producers will lead world vaccine production to become twice as much as its not-entry level, that is,

$$\frac{Q_E}{Q_{NE}} = 2.$$

We will also make the extreme assumption that monopolistic profits will drop to zero following entry, that is:

$$\frac{V_E}{V_{NE}} = 0.$$

Plugging these numbers, we can say that condition (4) does not hold.

$$2 = \frac{Q_E}{Q_{NPW}} > \frac{1}{1-p} = \frac{10}{9}. \tag{17}$$

Hence, a Covid-19 vaccine patent waiver would not spontaneously increase the expected amount of jabs available in the future because of the too high drop in R&D investment. Governments will have to intervene to correct the R&D disincentives of the expected potentially devastating future competition.

Let us use eq. (9) to estimate the increase in the subsidy rate that guarantees that R&D will not decrease following the expectation of a patent waiver. This condition becomes

$$s^* = s_{NE} + \frac{1}{10}\left(1 - s_{NE}\right). \tag{18}$$

Given the massive amount of public resources spent to support the development of the Covid-19 vaccines, we can realistically assume $s_{NE} = 0.5$. Therefore, the optimal subsidy rate becomes:

$$s^* = 0.5 + \frac{1}{10}0.5 = 0.55. \tag{19}$$

Governments can correct the adverse effects of expected patent wavers on R&D by increasing the current R&D subsidy rate by an additional 5%.

If instead $p = 10\%$, $V_C = 0.5V_M$, and $s = 50\%$, then R&D subsidies will have to increase by an additional 2.5%.

In both cases, the public expenditure costs of an expected waiver are minor.

Notice that, since the total amount of R&D investment stays constant by construction, the percentage change in the R&D subsidy rate also coincides with the percentage change in the aggregate public support to private R&D.

5 The Emerging mRNA Technologies may need more Protection

So far, this paper has followed the general view of hard-to-imitate vaccines. However, the mRNA technology vaccines need a qualification of this assumption. They are novel, but mounting medical evidence shows that they are also relatively easy to reproduce once the basic know-how spreads.

Since the early 1990s, several new primary vaccine technologies have been actively researched and introduced. Among these, mRNA vaccines currently hold a tremendous promise to increase manufacturing productivity and better serve public health in future emergencies. Messenger RNA technologies fall into two broad categories: messenger RNA (mRNA) and self-amplifying RNA (saRNA) vaccines. The two approved anti-COVID mRNA vaccines are based on the former mRNA, while a newly validated (to be soon approved probably) RNA vaccine is based on saRNA (Arcturus). The technologically feasible and economically viable production scales have been previously determined for BNT162b2 and mRNA- 1273 (developed by Pfizer-BioNTech and Moderna, respectively) by assuming a 30 Liters optimal scale for the working volume of bioreactors (see Pardi, Hogan, and Porte, 2018). The same study highlights how the mRNA production process offers the flexibility of producing a wide range of different vaccines and vaccine candidates. In addition, high-volume and rapid production can be achieved using small scale production lines in small facilities. For example, in 30 litres of in vitro transcription, there is enough mRNA for 5 million vaccine doses (using 30 micrograms per dose as in the BioNTech/Pfizer vaccine). Most importantly, when a public health emergency is binding, these production lines can also operate based on single-use equipment, allowing fast switching to produce a different vaccine against a different viral target (or variant).

Pascolo (2004) found that mRNA molecules generated by in vitro transcription are easy to produce in large amounts and at very high purity. This feature facilitates the good manufacturing process (GMP) and guarantees batch-to-batch reproducibility (Pascolo, 2017).

All this implies that, while in the first wave of patent suspension, the imitation of mRNA vaccines by competitors not yet acquainted with the new mRNA technology could be very hard, imitation difficulty could sharply drop in the future. Indeed, after the initial imitative effort is successful, all the imitators will have learned all the needed basic knowledge. This learning-by-doing knowledge transfer will massively increase the probability of future imitation, conditional on current imitation happening. To study this critical point, we shall modify the numerical results of the previous section accordingly. Let us assume that after the first waiver is successfully implemented, the probability p jumps to 90%. Then, by eq. (9), the new level of R&D subsidy needed to neutralize the disincentive effect of the patent waiver will become

$$s^* = 0.5 + 0.9 * 0.5 = 0.95, \tag{20}$$

where we have assumed a 50% initial R&D subsidy and zero profits for the patent hold in case of competitive entry (i.e. $V_E = 0$). The required R&D subsidy would have to increase to 95%, meaning that the public finances should bear almost all of the R&D costs of the new vaccine.

If the profits of the patent holder are not assumed to disappear following competitive entry but just to halve (i.e. $V_E = 0.5V_{EN}$), the required R&D subsidy would become:

$$s^* = 0.5 + 0.5 * 0.9 * 0.5 = 0.725. \tag{21}$$

So the R&D subsidy should increase from 50% to 72.5%. That is, public support for R&D should rise by 45%.

6 Conclusions

This paper has set up a stylized model to instruct policy on the desirability of temporarily suspending vaccine patents. Depending on the crucial parameters of our model, it may or may not be desirable to waive vaccine patents temporarily. In addition, our user-friendly policy rule can readily estimate the extra vaccine R&D public funding needed to compensate innovators for future patent suspensions.

If the Covid-19 vaccine industry likely has a low probability of competitive firms successfully imitating the existing innovative patents, as many commentators claim, the advantages of a patent waiver are prevailing. On the other hand, the disadvantage of additional public spending on R&D subsidies needed to compensate for the likely R&D disincentive effect of an expected future patent waiver is approximately 10%. Hence, they will likely be minimal compared to the faster vaccination benefits on public finances.

In the case of mRNA technologies, a growing body of medical evidence finds that imitation and rescaling could be more accessible after the basic know-how spreads. Then, as shown in Section 5, the patent waiver could be more difficult to neutralize and guarantee a well-functioning innovative ecosystem.

As Section 3.1 shows, our results are pretty general because they do not depend on the specific R&D technology adopted.

Moreover, while motivated by Covid-19 vaccines, our results generalize to any patent waiver. Therefore, pharmaceutical treatments, vaccines for different diseases, and even non-pharmaceutical patents are subject to the same logic as this paper.

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