WIDER BACKGROUND NOTE | 6/2020

Making a COVID-19 vaccine globally available once developed

Decoupling production of the vaccine from its development

Arnab Acharya*

June 2020

wider.unu.edu

Abstract: To speed up the development of a vaccine to fight COVID-19, a large amount of public investments has been made available to undertake multiple number of vaccine research projects. An issue receiving scant planning effort is how to make available globally the vaccine once developed. The assignment of intellectual property (IP) rights to a vaccine would delay ramping up of its production and furthermore the enforcement of IP rights may make the vaccine unaffordable for the poorer counties. Due to the large public investment in the development of the vaccine, there is little reason to allow for cost recovery of the development of the vaccine to its developer through assignment of IP rights, allowing the developer to set the price of the vaccine. A buy-out of IP rights would allow multiple investors to build up manufacturing capacity or make available where possible current excess capacity toward the production of the vaccine.

Key words: COVID-19 vaccine, intellectual property rights, vaccine price, developing countries, advanced market commitment

JEL classification: I10

Acknowledgements: I would like to thank Tony Addison, Kunal Sen, Steven Forsythe, and Catharine Taylor for their insights. For editorial assistance, including much aid in writing style, I would like to thank Timothy Shipp, Annett Victorero, Lorraine Telfer-Taivainen, Steven Hahn, and Sally James.

*Independent researcher, arnabacharya@yahoo.com

This note has been prepared within the UNU-WIDER project on Academic Excellence.

Information and requests: publications@wider.unu.edu

https://doi.org/10.35188/UNU-WIDER/WBN/2020-6

United Nations University World Institute for Development Economics Research

Katajanokanlaituri 6 B, 00160 Helsinki, Finland

The United Nations University World Institute for Development Economics Research provides economic analysis and policy advice with the aim of promoting sustainable and equitable development. The Institute began operations in 1985 in Helsinki, Finland, as the first research and training centre of the United Nations University. Today it is a unique blend of think tank, research institute, and UN agency—providing a range of services from policy advice to governments as well as freely available original research.

The Institute is funded through income from an endowment fund with additional contributions to its work programme from Finland, Sweden, and the United Kingdom as well as earmarked contributions for specific projects from a variety of donors.

Development and production of a COVID-19 vaccine

There is a high risk that the intellectual property (IP) rights of a COVID-19 vaccine will effectively block people in many poorer countries from accessing it. To avoid this situation, I propose that a practical solution would be to separate out the manufacturing of the vaccine from its development, which would allow the vaccine to be sold at a price near the cost of its production. Although a strong public–private partnership is necessary for the development and distribution of a vaccine, the requirements for the availability of the vaccine at a massive scale will be best facilitated if no firm owns exclusive rights to producing this vaccine.

Developing countries and their donor partners are already experiencing serious problems in dealing with the pandemic. In early April 2020, *The New York Times* reported that UNICEF could only procure 28 million masks, while it was seeking to buy 240 million masks. The report stated that brokers had tried to sell expired masks at five to ten times the pre-COVID-19 price to developing countries. Testing for the virus has been low in developing countries because the required chemical reagents are not being made available to them, and there is a dearth of laboratories to process the tests.

Meanwhile, leaders of richer countries have made personal contacts with executives of suppliers and provided their own transport to procure supplies. A normally coherent set of supply chain rules has 'devolved into arm-twisting exercises', according to an expert and stakeholder.

Given the current experience with buying masks and chemical reagents, developing countries could be priced out from acquiring pharmaceutical products required to manage COVID-19. Pricing problems from IP rights will loom particularly large for developing countries when a vaccine is developed.

Why are intellectual property rights anathema to achieving broad vaccination cover?

IP rights, which play an outsize role in driving up pharmaceutical prices in normal times, have yet to play a role during this pandemic. Testing reagents have been modified in India to develop a US$14.00 test kit (IN₹R1,000), requiring lower machine time and thereby increasing the number of tests. Rapid diagnostic testing methods or screening tests such as ELISA would be welcome for developing countries; pooled testing as a screening method is making testing cheaper. A proposed treatment method through the use of remdesivir, produced by Gilead Sciences Inc. for treating Ebola, may be sold for a low price.

As long as a vaccine for COVID-19 has not been found, both rich and poor countries have a great deal to fear from the virus. Once a vaccine is developed, most likely in the richer countries, the incentives to eliminate this illness in the poorer countries diminish for those living in the rich countries once herd immunity levels are reached. The incentives diminish further if the price of the vaccine is high. Under present laws, a vaccine developed to manage COVID-19 most likely will have IP rights—in this scenario the price for such a vaccine will be high while the volume of production will be low. This is a problem that will need solving now, before the vaccine is developed.

What would be the cost of vaccinating the population of the entire world?

Michael Kremer, a 2019 Nobel Laureate, and others noted that during the initial years of the HIV/AIDS crisis that there may be market failure in the development of a vaccine to prevent HIV infection. An important reason was that in richer countries there were large differentials in the risk of contracting HIV—only a few were at high risk, and although such people worldwide were many, they lacked much market power. In such a situation it was argued that vaccine development could be catalyzed through the guaranteed purchase of large amounts of vaccine once developed under IP rights. The guaranteed purchase or advanced market commitment (AMC) would induce market power on an ongoing basis to meet the needs of developing countries, and was a suitable solution when demand is relatively small.

In the case of COVID-19 the demand for purchasing the vaccine will be as high as the entire human population, or very near it, say, around 80–90 per cent will need to be vaccinated. Centers for Disease Control (CDC) price list reports that, depending on who buys the vaccine, prices range from US$10 to US$225; UNICEF procures vaccines at lower costs. If the cost for a COVID-19 vaccine would be at the upper bound of the CDC price list, the cost for the entire US population would be just shy of US$100 billion, and for India it would be US$300 billion—five times the public sector budget for health. Slightly short of US$2 trillion would be needed to vaccinate the entire world.

The role governments play in the vaccine development is not negligible

Research shows the cost of developing a vaccine to licensure on average takes more than 10 years to complete and costs billions of dollars.

Governments have not played a large role in the development of drugs since the US efforts to develop a polio vaccine in the late 1940s and 1950s. Governments, however, still play an important role—most pharmaceutical developments in past decades have received some government research funding. Now governments are investing heavily in a COVID-19 vaccine as hopes to return from the 'new normal' pandemic world to a post-COVID reality are likely to hinge on this.

For example, the US Congress has already made available US$3 billion for COVID-19 vaccine development so far in 2020.

Another initiative supporting all COVID-19-related medical activities globally, including a vaccine, is the Access to COVID-19 Tools (ACT) Accelerator. ACT is a consortium organized through WHO, though without the participation of the US and China, which has raised US$8 billion. This effort is supported by the Coalition for Epidemic Preparedness Innovations (CEPI) which explicitly supports vaccine development and distribution. An optimal strategy, research from Athey et al. (2020) suggest, is that the ACT Accelerator support 15-20 candidate vaccine to increase the probability of success. There are 115 vaccines being explored as of April 2020, including those being repurposed to combat similar viruses. COVID-19 vaccine development will be expensive, but a fraction of the economic and human costs it has induced.

Financial grants up to US$1.2 billion have been awarded by the US government to AstraZeneca to develop a vaccine working with Oxford University's Jenner Institute, which has received funding from CEPI, with the aim of supplying 300 million dosage to the US. The US government is following the AMC strategy whilst keeping the IP rights intact. Separate to the US agreement,

AstraZeneca has been working with other firms such as The Serum Institute of India to manufacture an additional 1 billion of the same vaccines. This is a plausible solution to cover a large population, such as that of India, and the capital build-up for large-scale production is taking place already. But there is uncertainty about the effectiveness of this vaccine and furthermore there is no clarity as to what sort of pricing structure we can expect. At a high price, many countries will be left out.

There is as much uncertainty about how the vaccine will be manufactured and distributed at mass scale worldwide as there is about whether and when a vaccine will be developed. The problem could become acute if the development of a vaccine occurs through an exclusive relationship with either China or the US, away from an organization such as CEPI. Even aside from that possibility, Lurie et al. (2020), authors with CEPI affiliation, noted that there is no global entity responsible for financing or organizing vaccine manufacture. CEPI involvement has not resulted in clarifying the role of intellectual property rights.

Given the need to vaccinate so many people, many of whom are poor, it is important to ensure now that this vaccine will be priced at a value close to the cost of its production.

Ensuring generic manufacturing of any COVID-19 vaccine is key

Supposing a viable vaccine is developed by early 2021, what are the steps that would ensure vaccine availability to billions in the following months?

Mobilizing public funds for pharmaceutical development has not yielded clear pricing guidelines even when the patent has been essentially owned by the government, as evidenced in the case of selling of pre-exposure HIV prophylaxis by Gilead Sciences which was accused in 2019 of exaggerating its role in the development of the product. Gilead charged US$20,000 for yearly usage of the product while the similar generic product could not be sold in the US at the price of US$60 due to legal efforts taken by Gilead.

In the case of a COVID-19 vaccine unleashing global generic manufacturing capacity is much needed, as has been noted elsewhere.

Generic manufacturing of drugs can decouple the production process from the development of the drug. Given the involvement of the governments around the world in developing a COVID-19 vaccine perhaps the quickest way to make it available would be simply to buy out the patent rights by awarding a prize, or prizes, for undertaking the effort toward the development of the vaccine. Such buyouts can occur in the form of awarding a prize to the successful development vaccine at a cost-plus prize. International collaborations will allow for cost recovery schemes that are mindful of rent-seeking behaviour as there is considerable asymmetric information advantages to the developer. With allowance for cost recovery of development there would be no granting of IP rights.

Some manufacturers fear that even minimal governmental involvement can end up in loss of future IP rights. But the involvement of governments is not minor during this pandemic. Pharmaceutical firms may see an extraordinary avenue for profit during this time, thus they have the incentive to try and present as enormous the specific cancellation of IP rights in this pandemic as setting an adverse precedent for future development of pharmaceuticals. But, as COVID-19 defies all normalcy, I would strongly argue it cannot set precedence. Government involvement, it has been suggested, should be immense, at the level observed for the Manhattan Project.

Decoupling of development and production of the vaccine will solve issues ranging from quick production to access

Without IP rights, manufacturing can take place independent of the research and development process. Manufacturing capacity can be built now before we know which vaccine development effort will succeed, as the developer of the vaccine will not have to be the sole producer.

This decoupling of manufacturing from development allows: (1) competition in making the production process more resource efficient; (2) any existing excess capacity in the production process of drugs worldwide can be utilized; and (3) multiple firms can more easily make a vast amount of the vaccine.

Bill Gates's proposal for the building of seven factories stems from the last observation. A fourth factor centers on the fact that some of the manufacturing potential that needs to be built up now may become redundant depending on the vaccines that are finally effective. This is too much risk for a firm to absorb. Decoupling production from manufacturing along with public funding allows unused capacity to be used for some other purpose or even simply not used.

Under any IP arrangement, as under the award system proposed here, the richer countries would have had to pay for the development cost for their own citizens as its administration is rolled out. With the development costs already borne out in patent buy-out, production of vaccines can occur in many places around the world and at a lower price. Most likely, overseeing the production process in developing countries will require international co-operation; many developing countries will not have the regulatory capacity to monitor the production process. This is a role for organizations such as CEPI.

Noting a common argument against patent buy-out put forth by many pharmaceuticals, under IP rights the holder would donate the vaccine free or sell at a low price to developing countries. This is not a solution, as the price of the vaccine in richer countries will still be high even if the marginal cost of manufacturing is low. When high price drugs are heavily discounted for developing countries, the process allows for tax breaks for the IP holder. The tax breaks can be expensive and open to opportunism.

Conclusion

COVID-19 has induced a unique situation where richer governments can offer incentives for research and development in return for doing away with IP rights. Suspension of IP rights will help lower selling prices, and with international co-operation vaccine manufacturing can take place cheaply without burdening richer nations excessively. Co-operation will limit the exclusion of the poorest populations in the world.

Much advanced preparation is needed, regardless of whether an effective vaccine is indeed developed, as manufacturing to scale will be a daunting task. CEPI and the ACT Accelerator working with the existing infrastructures of WHO, along with other UN organizations and the World Bank, can co-ordinate the preparation at various levels, including at the country level. Decoupling manufacturing from development will unleash rapid scaling up as well as ensure a lower price. This approach, requiring much international co-operation, opens up a clear path toward ensuring the availability of the much-needed vaccine once developed.

References

Alluri, A., and K. Pathi (2020). 'India coronavirus: Should people pay for their own COVID-19 tests?', *BBC News*, 20 April.

AstraZeneca (2020). 'AstraZeneca advances response to global COVID-19 challenge as it receives first commitments for Oxford's potential new vaccine', AstraZeneca Press Release, 21 May.

Athey, S., K. Hoyt, and M. Kremer (2020). 'Everyone Wins from Vaccine Cooperation', 14 May, Project Syndicate.

Bradley, J. (2020). 'In Scramble for Coronavirus Supplies, Rich Countries Push Poor Aside', *The New York Times,* 9 May.

Feuerstein, A., and M. Herper (2020). 'Early peek at data on Gilead coronavirus drug suggests patients are responding to treatment'. *STAT News*, 16 April.

Gale J. (2020). 'Potential Coronavirus Drugs May Cost as Little as $1, Study Says', *Bloomberg Prognosis*, 10 April.

Gates, B. (2020). 'Here's how to make up for lost time on COVID-19', *The Washington Post*, 1 April.

Gates, B. (2020). 'What you need to know about the COVID-19 vaccine', *Gates Notes* (blog), 20 April.

Gouglas, D. et al. (2018) 'Estimating the cost of vaccine development against epidemic infectious diseases: a cost minimisation study', *The Lancet*, 6: e1386–96. https://doi.org/10.1016/S2214-109X(18)30346-2

Kremer, M., C. Snyder, and N. Drozdoff (2016). 'Vaccines, drugs, and Zipf distributions', 29 January, *VOX CEPR Policy Portal*.

Lurie, N., M. Saville, R. Hatchett, and J. Halton (2020). 'Developing COVID-19 Vaccines at Pandemic Speed', *The New England Journal of Medicine: Perspective*, 21 May. https://doi.org/10.1056/NEJMp2005630

Maxmen, A. (2020). 'How poorer countries are scrambling to prevent a coronavirus disaster', *Nature*, 2 April. https://doi.org/10.1038/d41586-020-00983-9

Mazzucato, M., and A. Momenghalibaf (2020) 'Drug Companies Will Make a Killing From Coronavirus', *The New York Times*, 18 March.

William Davidson Institute (2020). *Pooled Procurement in the Vaccine Market: UNICEF's Experience*, Ann Arbor: William Davidson Institute at the University of Michigan.