

Why are compulsory licences not an effective solution to the COVID-19 pandemic?



07 June 2021

Intellectual Property, Brazil

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COVID-19 and fake news

In addition to the COVID-19 pandemic – the biggest health crisis since the Spanish flu – the public is living with access to large amounts of information on complex topics without having the necessary knowledge to discern whether such information is true, 'fake news' or half-true (ie, constituting false statements which contain elements of truth). Half-truths are arguably the worst type of information conveyed by the media as they can result in real harm to the public.

In 2020 the discussion regarding compulsory licences gained traction in Brazil and abroad. Now, the urgent need for vaccines has turned this discussion into a hot topic. Industrial property has become a relevant subject in politics and political advocates are imparting biases even where political spin should not be the focus.

Recently, reports which indicate a supposed direct link between compulsory licences and the acceleration of global vaccination have been circulating in the media. Rich countries, big pharmaceutical companies and the patent system in general have been blamed for the delay in vaccinations.

However, such a relationship between compulsory licences and vaccination rates does not yet exist. This discourse not only confuses society, but also weakens the discussion around two important topics in Brazil:

- the extremely low quantity of COVID-19 vaccines; and
- the influence of the patent system on public health.

Vaccines in Brazil

Brazil has one of the most well-respected public health systems in the world. Since Brazil became a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Rights in 1994 (a necessary condition to be part of the World Trade Organisation), Brazilian patent law has changed to allow the patenting of pharmaceutical processes and products, among other things. Since then, discussion about how this temporary commercial exclusivity affects the public health system has been rife.

It is not the vaccine patents (which have been claimed to cause a phenomenon known as 'vaccine apartheid') that limit vaccination. In Brazil, the biggest obstacles are:

- the shortage of doses;
- the shortage of raw materials; and
- the low capacity for production of vaccines.

Complexities of compulsory licensing

Although 'production capacity' refers to the quantity of doses produced, the ability to produce vaccines must also be considered since the technology involved in such production can be extremely complex.

It is sometimes thought that once a compulsory licence has been granted for a patent, any pharmaceutical company would have what it takes in terms of knowledge and structure to produce large amounts of safe and effective doses. People also often think that vaccine developers do not receive any royalties in return.

However, it is not that simple. The production of a vaccine involves several complex steps and advanced and specific technical knowledge. Thus, there must be a good technology transfer process between the company that developed the vaccine and the company or institution that is to carry out its production. The more complex and innovative the vaccine, the more complicated the transfer of technology.

Expert opinions

In this regard, it is important to highlight the opinions of those involved in the production of the only two vaccines which are currently produced in Brazil:

- Dimas Covas, director of the Butantan Institute, which is responsible for the Coronavac vaccine; and
- Mario Moreira, vice president of management and institutional development at Fiocruz, which is responsible for the AstraZeneca vaccine.

On 8 April 2021 both representatives attended a meeting of the COVID-19 Commission in the Senate to debate the transfer of technology in the production of vaccines in Brazil. Both Covas and Moreira categorically affirmed that compulsory licensing will not solve the issue of the shortage of vaccines in Brazil. According to Covas, it may represent an even greater obstacle.

Further, Moreira explained that both agencies are at their production limit. He emphasised the lack of availability of the active pharmaceutical ingredient (API). Moreira also mentioned the importance of diplomacy, especially regarding the possibility of increasing the volume of API purchases.

Both Covas and Moreira highlighted that the collaboration of the company which developed the technology is essential for the production of a vaccine by other companies to be carried out safely and effectively.

For example, in the case of Fiocruz – even with a bilateral agreement with AstraZeneca through which access to all of the necessary documents was available – the time it would take to internalise the technology was between approximately six and eight months. This is because the patent is just one aspect of the complex technology, which is also protected by know-how and industrial secrecy.

However, despite Covas's and Moreira's opinions, on 29 April 2021 the Senate approved the proposal of Bill 12/2021, which authorises the government to decree compulsory licences for vaccine patents, diagnostic tests and medicines for COVID-19 on the grounds that such measures would speed up the immunisation process.

Compulsory licensing in Brazil

Compulsory licensing is an exceptional and extreme measure and has therefore been applied in Brazil only once since 1996. However, the current vaccine situation has been compared with the situation in 2007 regarding the drug Efavirenz (used for the treatment of the human immunodeficiency virus), despite the two situations having unique challenges and peculiarities. Such comparisons tend to reduce all complexities of the system to the mere suspension of patents.

Articles 61 to 63 of the Patent Law already provide for the grant of compulsory licences in specific situations (eg, national emergencies or where it is in the public interest). However, compulsory licences may be decreed only after discussions between the government and the patent holder have taken place and attempts to adjust the price have

been made. The payment of royalties inevitably continues.

Comment

Even though the process of decreeing a compulsory licence for a patent is quite simple, this does not mean that the technology will be easily available for any interested company to produce and commercialise it, or that such technology will be free of charge (as has been falsely claimed by the media). While compulsory licences must be considered for future occasions, they are not the solution to the current obstacles faced in Brazil. Further, considering that the Patent Law already provides for the grant of compulsory licences, Congress and the Senate need not work to create a new law that is already present in the legal structure.

Innovation and technological development – driven largely by the patent system – have played important roles in the fast development of COVID-19 vaccines. Having a good patent system in place should be seen as a great incentive to such innovation. It is this system that guarantees temporary exclusivity to its patentees and enables the exchange and dissemination of technical knowledge. Without it, many companies would choose to keep their technology confidential, which would greatly affect the general population.

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