

Covid: “Removing vaccine patents would not solve the challenge of mass production, but would threaten future innovation”

Calls to make these products a global common good are getting louder, but such a decision would have the opposite effect to the desired outcomes, says Frédéric Collet, Chairman of Leem, the French Association of Pharmaceutical Companies, in an opinion piece in *Le Monde*.

Opinion piece

We absolutely understand the impatience caused by phased deliveries of Covid-19 vaccines. And just like everyone else, we want to see an end to this pandemic. We also believe that the response must be global and mutually supportive, and delivered as quickly as possible. But we should not overlook the exceptional achievement of having developed effective vaccines in just one year.

However, removing vaccine patents would not have the effect of accelerating and expanding their production to make them available to everyone in the world more quickly. To assume this is the case would be to ignore the complexity of vaccine development; worse, it would be to undermine the essential nature of the regulatory framework around intellectual property.

It is true that the French Intellectual Property Code provides for the lawful existence of an *ex-officio* licence. The relevant article is worded as follows: “*If the public interest so requires and in the absence of an amicable agreement with the owner of the patent, the Minister responsible for industrial property may (...) by means of ministerial order subject (...) any patent to the ex-officio licensing regime*”. However, France has yet to use this provision. That is because, quite rightly, solutions have always been found. In the case of Covid vaccines, this situation could occur only where pharmaceutical companies refused to make their vaccines available. Quite clearly, this is not the case.

The pharmaceutical companies, which have been working alongside everyone else over the past year in the race against the virus, are collaborating on an unprecedented scale (as evidenced by the large increase in voluntary licences) to meet the demand for research and production facilities, but also access to vaccines for the public vaccination campaigns.

Technologies that are simply too innovative

In February this year, there were more than 230 manufacturing and production agreements in place worldwide. Pharmaceutical companies are also involved in the Covax initiative launched by the World Health Organization (WHO) to ensure fair access to vaccines for the poorest countries.

But that is not really the point of this debate. Making billions of doses available for people around the world without ever compromising on vaccine quality or safety is a challenge on the scale we have never seen before. These biological products are complex to develop and all currently available production resources are already at full stretch.

These technologies are simply too innovative to be easily transferred from one facility to another, and the real limiting factors - which are technology and logistics - would neither be addressed nor overcome by *ex-officio* licensing. Each vaccination site requires highly qualified technicians and state-of-the-art equipment (bioreactors, centrifuges, cold rooms, etc.) that meet demanding regulatory standards of safety and performance.

So in terms of practicality, removing the patents from Covid vaccines would do nothing to solve the mass production challenge we now face. Furthermore, the SARS-Cov2 and messenger RNA genetic codes are already in the public domain; it is the encapsulation technology and expertise that are owned by pharmaceutical companies.

Vaccines are not commodities

The truth is quite the opposite, because removing patents would threaten future innovation. Let us remind that it would never have been possible to develop Covid vaccines so quickly and so safely without the existence of a legal intellectual property framework to recognise the successes. The driving force that impels pharmaceutical companies to leverage innovation, sometimes at a financial loss, is the possibility of gaining exclusive access to a secure market for a limited period of time, thanks to patents.

Compulsory licensing would remove any incentive for these companies to invest their own funds, without which it would be regrettably very challenging to develop the new technologies to carry forward the fight against this virus, its variants and future threats to public health. To say nothing of the potential future benefits of the innovative technologies developed during the Covid crisis for the treatment of many other diseases.

As manufacturing companies, but also as good citizens, our pharmaceutical companies will continue - as they have since the beginning of the crisis - to do everything in their power to put an end to this pandemic which has already persisted far too long. Today's situation reminds us that pharmaceutical products are a very long way from being commodities like any other, that research is uncertain and that the business of pharmaceuticals companies is by its nature a high-risk venture.

Governments and companies must continue to work together to facilitate the rapid development, testing and distribution of Covid-19 vaccines and treatments.

We can achieve this only by working together. We will never achieve it through ineffective decisions that take no account of the industrial realities of therapeutic innovation.