

9 Patent rights in pandemic times

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One of the biggest challenges of the Covid-19 pandemic has been the provision of sufficient quantities of vaccine over months. While rich industrialised countries ordered huge quantities early on, poorer states suffered from a glaring shortage. Against this background, several of them have requested among other things the temporary suspension of patent rights at the World Trade Organization (WTO). Our team has analysed the legal situation.

At first glance, the idea of waiving legal protection in order to speed up the production of patent-protected vaccines may seem plausible. When considered in more detail, however, the focus on patents as the cause of the vaccine shortage during the Covid-19 pandemic proves unhelpful and short-sighted – not least with regard to the fact that innovation will continue to be needed to address health challenges in the future.

Drugs and vaccines are enormously expensive to develop. What is more, both research and market approval require investors to have staying power. Success is never guaranteed. If a market approval is granted, a company needs a certain amount of time to recoup its costs and of course to generate some revenue – even if, in an exceptional situation such as a pandemic, other considerations may play a role. Patents ensure market exclusivity, create legal certainty and are therefore a prerequisite for investments to be made in the first place.

Nonetheless, patents alone are not sufficient: investments are made not to obtain a patent, but to generate profits. So we should not deceive ourselves into thinking that there is any easy substitute for market-based incentives, though patent law is a key factor in terms of the latter's impact. In the case of the Covid-19 vaccines, too, the lion's share of the costs was covered by the private sector. Years before the outbreak of the

pandemic, individual investors were already betting on the potential of mRNA technologies – at a time when no state would have been prepared to spend taxpayers' money without any certain prospect of a concrete benefit.

Complex product facilities

What is more, the idea that it is enough to be allowed to use a protected technology in order to be able to manufacture and distribute the relevant products in sufficient quantity in no way corresponds to reality, especially in the case of mRNA vaccines. These are high-tech products that cannot simply be produced in any chemical factory. Highly complex and specialised production facilities are required, including personnel with specific expertise. In addition, it takes special raw materials with limited availability, which effectively limits the production volume from the outset.

Even having production sites in countries with a high demand would not be enough. Vaccines require regulatory approval where they are to be marketed. Irrespective of whether the original manufacturer has been granted such approval, each independent producer must prove of their own that their products meet the requirements. The only exception here is in the case of

production under licence, i.e. with the consent of the patent holder: in this case, the patent holder's approval extends to the products manufactured this way. Contractual licences usually involve the transfer of knowledge and technical support. All this saves valuable time that would be lost if only patent protection were waived.

Consequently, the most efficient way forward lies in collaborations. The current willingness of the pharmaceutical industry to grant licences even to competitors is unprecedented. However, patents are an indispensable prerequisite for precisely this purpose. Only patents make it possible to determine in a legally secure manner what should be permitted to whom within the framework of a collaboration. If this possibility were to disappear in the event of a suspension of IP rights, the current willingness to cooperate would immediately cease. In the absence of support from the patent holders, the market might even see the launch of inadequate and ineffective vaccines, which would be of no use to anyone.

The proposal to waive patent rights, among other things, is directed against the fundamental obligation of the member states of the World Trade Organization (WTO) to comply with the minimum standards of protection provided for under the so-called TRIPS Agreement within the framework of their national legislation. However, this agreement already allows member states to permit certain uses by third parties under certain conditions, even against the will of the rights holders concerned. In particular, they may grant compulsory licences for patents, whereby each individual country can specify this option in more detail in its national laws.

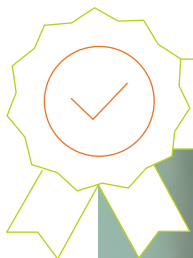
A flexible legal framework

Of course, this is primarily of use if there are at all local companies that are capable of manufacturing the required products – though this is no different when it comes to waiving IP rights. If this requirement is met and a patent holder unjustifiably refuses to grant a licence to a company, that company can sue for permission to use the patent before national courts. This can be costly and time-consuming, however. For this reason, member states are also free to grant rights of use directly to local industries without the need for the latter to litigate. This would allow entire patent groups to be covered, thereby achieving a similar effect to that of the proposed suspension of patent protection.

The international legal framework therefore does not lack flexibility. The problem is more likely to lie in the fact that national law in a number of countries has not been adequately designed to take account of the extraordinary circumstances of a pandemic. If this were to be made swiftly, this alone should motivate patent holders to grant contractual licences so as to avoid compulsory measures and thus a loss of control.

Note: An agreement among WTO member states was in the offing at the time of printing of this article. Under this agreement, the options for the use of vaccine patents as set out in the TRIPS Agreement are to be extended for a limited period of time. In addition, such options are to be permitted under certain conditions, even if national law does not explicitly provide for this. o

Patents create legal certainty and are insofar a prerequisite for any investment to be made in the development of vaccines and medicines.



PATENTED

