Discussion of compulsory licenses in the COVID-19 pandemic

With the Epidemic Protection Act of March 27, 2020, Germany declared an "emergency of national dimension" in view of the COVID-19 pandemic. At the same time, tensions and international pressure to "abrogate certain IP rights" increased. In addition to the Federal Republic of Germany, there are numerous other countries around the world that, in principle, can make use of emergency decrees to fundamentally restrict patent rights, such as in the United Kingdom, France, the United States, Canada, Israel, Australia, China, Japan and Korea. However, up to now, in the summer of 2021, neither an order for use (Section 13 PatG) nor - according to current knowledge - an action for a compulsory license (Section 24 PatG) has been brought before the courts responsible for this. The demand to be met is enormous, especially for vaccine developments that have been described as "game changers". The following points summarize why this is so - despite numerous and strongly debated demands.

The temporal aspect:
Involuntary restrictions on the rights of the patent holder are only possible once a patent is granted. A significant increase in patent applications specifically directed to COVID-19 therapies is to be expected. However, due to the standard 18-month window until publication, therapies could remain hidden for an extended period of time, and the length of time until a patent is granted means that compulsory licenses will not be available for this reason alone.

The territorial restriction:
Despite an internationally common basis in the TRIPS Agreement among WTO countries, the exercise of compulsory licenses is internationally fragmented. For exports to countries with parallel patents, compulsory licenses would have to be obtained separately in each country. COVID-19 therapies, however, need unrestricted international application.

Public interest, alternatives, know-how, and manufacturing capacity:
Any restriction of the patent holder's property rights must be well justified. A governmental use order (§13 PatG) would have to be justified by a guarantee of supply and production of active substances or vaccines. In the case of a compulsory license under private law (Sec. 24 PatG), the license seeker must be able to work the invention also in technical terms - a problem probably not in the case of classical active substances, but certainly in the case of vaccines with their complex technical manufacturing steps.

Moreover, in the case of the all-important vaccines, numerous alternative therapeutic options are now available (for example, the mRNA vaccines from BioNTech/Pfizer and Moderna, and the adenovirus vector vaccines from AstraZeneca, Sputnik V, and Johnson&Johnson/Janssen). So there is no lack of existing as well as potential new candidates here, and certainly no lack of "will" on the part of the original manufacturers; more critical are issues beyond considerations of compulsory patent licensing: Regulatory approval, manufacturing and supply capacity, and commercialization. For the provision of sufficient vaccine doses, government support of the original developers and their partners is certainly of greater help than compulsory licenses to third parties, especially if the third party lacks the corresponding know-how. For the area of substance therapeutics, i.e., small-molecule active substances, the situation would presumably be different. Here, production and supply are much less critical. In the case of classical active ingredients, the originator and patent holder will want to retain the sole right of use. If he and, if applicable, his cooperation partners or licensees can cover the demand, a compulsory license is probably not grantable.

The problem of "patent stacking":
Vaccine technologies build on a large number of previously filed and granted patents. A large number of platform technologies are used, which are themselves patented by different owners. Such situations of patent stacking are generally considered difficult to license, and interdependencies of patent rights to Covid-19 vaccines are to be expected. More important than the mere existence of patents is the question of whether sufficient know-how is available to develop and manufacture a vaccine against COVID-19. It can be assumed that in the case of involuntary threats, the patent holder would have neither the obligation nor the interest to disclose its know-how. Valuable time would be lost.

This situation description shows: it is not possible against, but only with the will of the patent holder to cooperate. The current situation makes it clear that the originators want to enter into such cooperation.

The situation would be different for the hypothetical case that the very specific and effective SARS-CoV-2 active is found in the sense of a small molecule substance. There, patent stacking would not be expected; third parties would probably themselves be effective in meeting a large demand for sufficient active ingredients in the absence of the will and ability of the patent holder.

Lack of consistency with data and market exclusivity:
Regardless of compulsory licensing issues, the eligible third party would need a marketing authorization for an affected COVID-19 drug. Approval procedures are not governed by the Patent Act, but by a *lex specialis* specifically provided for this purpose - in Germany, the German Medicines Act (AMG). If, as in the case of the corresponding vaccines, a COVID-19 drug is approved, it could nevertheless be in the public interest to use the clinical data already available by means of a more rapid generic approval. However, the first applicant has 10 years of data and market exclusivity as a reward for its regulatory efforts. In the absence of a link between a compulsory license under patent law and data protection, the protection of documents under pharmaceutical law therefore constitutes a legal barrier to compulsory use by third parties. Data and market exclusivity should not be restricted by law, at least not on the current law and not without the consent of the marketing authorization holder, even if there were a right to a compulsory license.

For the reasons stated above, compulsory patent licenses – whether by government order or private law claim – do not currently provide an effective means of addressing the need in the COVID-19 pandemic, at least as the law currently stands. Meeting the need also currently presents more of a problem of manufacturing capacity as well as complex supply chains – at least for the only therapies currently available approved vaccines.

The bottom line is that while many countries have national legislation on governmental or private compulsory licensing, there are numerous legal and factual barriers to exercise and use in the current situation. Accordingly, it is doubtful that patent law compulsory remedies can contribute to solving the need for comprehensive COVID-19 control. In contrast, it is practical factors rather than legal provisions – such as production capacity, supply chain complexity, and economic conditions – that may provide a way out of the crisis. Action plans agreed with vaccine developers, as well as accompanying support measures beyond compulsory measures, appear much more effective.

Examples of this are provided by "Operation Warp Speed" in the USA or the EU's "Hera Incubator" initiative.

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A detailed discussion on the topic is published at *GRUR Int* as well as in the *Journal of Intellectual Property Law & Practice* (Oxford University Press), accessible via the link 10.1093/grurint/ikab091

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