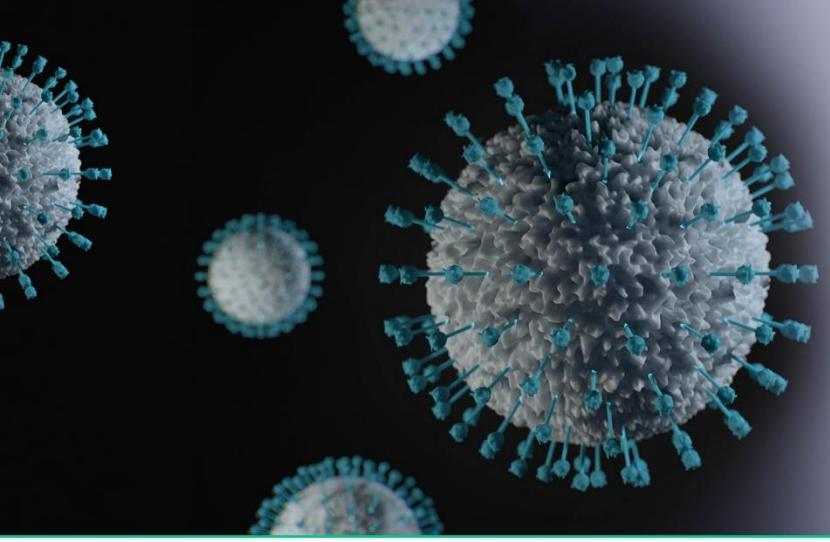

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# Restrictions for patents owners to preserve the public interest in the sufficient availability of necessary medicinal products

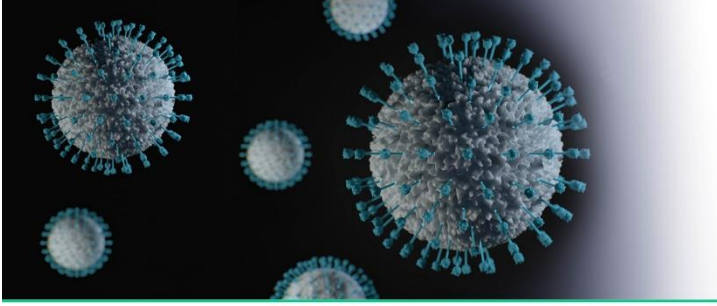
## Governmental Order of Use of a Patent in Germany and Compulsory Licensing

### Principle: The patent owner has the exclusive right to use patents and to exclude others

The search for effective medicines against SARS-CoV 2 / Corona and the urgent necessity for effective treatment leads to considerations about restrictions for patent owners. Usually, and in particular in the pharmaceutical market, inventions are patent protected and protection could even be prolonged by supplementary protection certificates in order to allow the patent owner amortization of its usually significant costs for research and development. Hence, the patent owner can prohibit any other party from manufacturing or selling the patented medicine. The patent owner does not even have a legal obligation to make use of its patent and to manufacture and distribute the patented medicine on his own.

### Restrictions provided by the Patent Act

However, the German Patent Act knows two important restrictions: First, the Government could by of **administrative order** restrict the effects of a patent in the way that the invention shall be used in the interest of public welfare only. Second, the Federal Patent Court could grant a **compulsory license** upon the request of a competing pharmaceutical company in the event public interest requires it. These restrictions will likely come into play if an active ingredient turns out to be effective against SARS-CoV 2, be it a vaccine or a medical treatment of the disease and if the patent owner cannot provide it in a sufficient and efficient way to all people who would need it.





## Governmental Order of Use according to Sec. 13 German Patent Act, Sec. 5 Infection Protection Act

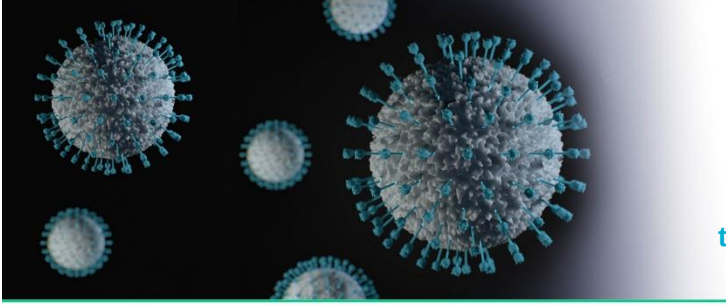
The recently enacted Act on the Protection of the Population in Case of an Epidemic Situation of National Significance (Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite) of March 27, 2020 which entered into force on March 28, 2020, amending Sec. 5 of the German Infection Protection Act (Infektionsschutzgesetz) serves as legal basis for the Government to order limitations of patents generally allowed by Sec. 13 German Patent Act.

With the entry into force of such order of use, the Government itself or any third party authorized by the competent Government entity is able to use the patented technology lawfully without the authorization of the patent proprietor. Such use includes the manufacturing, offering and marketing of products normally falling under the scope of protection of the patent. However, the third party may not use the invention for his own commercial purposes, but must limit himself to the promotion of public welfare.

The indefinite legal term of public welfare in Sec. 13 German Patent Act covers all cases in which state care appears to be necessary, in particular the cases of emergency such as epidemic plagues. It has now been specified by the Sec. 5 para. 2 no. 5 German Infection Protection Act.

The patent proprietor is also entitled to receive an appropriate remuneration from the Federal Government.

The measures are only lawful as long as the state of emergency lasts as provided by Sec. 13 German Patent Act. In accordance with the Patent Act, the newest version of the German Infection Protection Act provides that the order of use are deemed to be revoked upon the repeal of the finding of an epidemic situation of national significance, and otherwise upon expiry of March 31, 2021 (Sec. 5 para 4 German Infection Protection Act)





## Compulsory License under Sec. 24 of the German Patent Act

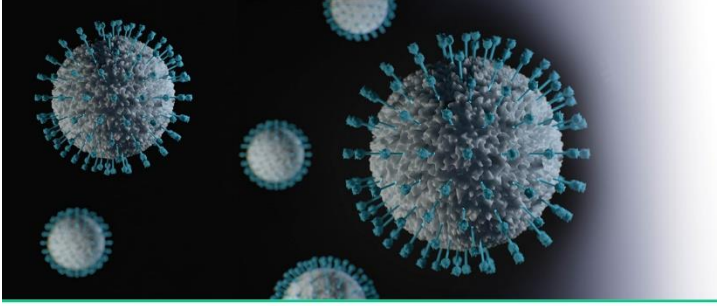
A compulsory license is a way for private companies on a civil law basis and can be granted by the Federal Patent Court or on appeal by the Federal Supreme Court. It does not suspend the entire effect of the patent, but the license seeker receives a non-exclusive right to use the patented innovation within the limitations and conditions attached to it. Moreover, the patent holder is entitled to receive an appropriate remuneration from the compulsory license holder, which is measured inter alia by the economic value of the patent. Until so far, an effective compulsory license claim was usually raised as a reaction to a patent infringement litigation in order to avoid the patentee to enforce injunctions.

The grant of a compulsory license requires that the license seeker has unsuccessfully tried to obtain a license under reasonable conditions and that the use of the patented innovation is in public interest.

First, the license seeker has to enquire the authorization of the patent holder at first. For this purpose the law provides for a "reasonable" period of time. After his unsuccessful licensing efforts, the license seeker must then apply to the Federal Patent Court for a compulsory license. The license seeker can in addition ask for a preliminary grant of a compulsory license according to Sec. 85 German Patent Act. Such preliminary proceedings in the past took 2 – 3 months in first instance. In case of SARS-CoV 2 it might perhaps be speeded up by the Federal Patent Court.

There are various other circumstances like technical, economic, social, environmental and medical aspects that could create public interest according to Sec. 24 German Patent Act. With regard to the medicinal aspects, the main aim is to provide medical care and promote the health of the general population. Recently, the German Federal Supreme Court (FSC) found that there was a public interest in case of an HIV drug (*Raltegravir* FSC docket number X ZB 2/17 - GRUR 2017, 1017) while in case of a cholesterol lowering drug having the same mode of action as the patent owner's product but allegedly less side effects, it was denied (*Alirocumab*, FSC docket number X ZB 2/19 = GRUR 2019, 1038 see our annotation).

It is quite likely that the compulsory license will also become an issue in the current SARS-SoV 2 crisis provided that an effective active ingredient will be technically available and not (sufficiently) provided to the German public by the patent owner.





In contrast to authorized third parties under Sec. 13, the compulsory license holder according to Sec. 24 German Patent Act may also use the patented technology for commercial purposes, if he himself is economically, technically and legally capable of commercial use. However, the compulsory license will be limited by the Court in its scope and duration to fulfil its purpose to preserve the public interest.

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