# COVID-19 and Patent Law

## FAQ on Compulsory Licences and Governmental Orders of Use

**1. I am working on a vaccine against COVID-19. How can I protect my sizeable investment in its research and development?**

For new active pharmaceutical ingredients which involve an innovative step or for new and innovative uses of an active pharmaceutical ingredient which is already known, a patent may be obtained, giving their owner the sole right to use the patented invention and to prohibit third parties from using it (Sec. 9 German Patent Act). This applies to drugs and vaccines which may be used to combat the COVID-19 pandemic as well.

In the exceptional case of an overriding public interest, it is possible that two restrictions to the exclusive right may apply: On the one hand, a competitor may obtain a compulsory licence for the patent (Sec. 24 German Patent Act). On the other hand, the state may issue a governmental order of use (Sec. 13 German Patent Act in conjunction with Sec. 5 para. 2 no. 5 German Infection Protection Act). In both cases, the patent proprietor must tolerate the use of their invention by third parties and thus loses the economically lucrative exclusive right.

**2. A competitor wants to produce a drug against COVID-19 for which I own a patent and has therefore asked me for a licence. However, I do not want to grant him a right of use. Can I be obliged to do so?**

Yes, under certain conditions the competitor may obtain a compulsory licence through judicial proceedings at the Federal Patent Court. To do so, they must meet two requirements:

- The competitor must have previously made unsuccessful efforts within a reasonable period of time to obtain a licence from the patent proprietor on reasonable commercial terms (Sec. 24 para. 1 no. 1 German Patent Act). In their request, the competitor must have indicated that they are prepared to adequately compensate the patent proprietor. The proprietor must either have refused their request or not have answered within a reasonable period of time. How quickly they must react to it depends on the circumstances of the individual case. If the competitor requests the licence to solve a supply shortage with regard to a COVID-19 drug, it is advisable for the patent proprietor to react quickly.

- Additionally, public interest must require the granting of a compulsory licence (Sec. 24 para. 1 no. 2 German Patent Act). In principle, the protection of the population's health constitutes such a public interest. However, it must also *require* the granting of a licence. A compulsory licence can thus only be considered if the protection cannot be provided otherwise. This could be the case, for example, if the patent proprietor does not have the necessary production capacities to ensure a nationwide supply of the COVID-19 drug.

**3. The Federal Patent Court has granted my competitor a compulsory licence to my patented COVID-19 drug. What does this mean for me and my licensees?**

A compulsory licence is always a non-exclusive license (Sec. 24 para. 1 German Patent Act). It follows that both the patent proprietor and their licensees may continue to use the patented invention as they did before the compulsory licence was granted. They can thus continue to produce and sell their COVID-19 drug.

In addition, however, the holder of the compulsory licence may now use the patented invention commercially as well. The extent of the permitted use is not prescribed by statute. Instead it is the task of the court to limit the scope of the compulsory licence to the purpose for which it was granted in each specific case (Sec. 24 para. 6 sentence 3 German Patent Act). It may also restrict the compulsory licence further or make it subject to conditions (Sec. 24 para. 6 sentence 2 German Patent Act). If, for example, only the principal claim of a patent ought to be used for the production of an urgently needed COVID-19 drug, but not the independent claims, the compulsory license will likely be granted with corresponding restrictions. It is also conceivable, although not yet decided by the highest courts, that a compulsory licence could be restricted under aspects of proportionality to the use of a drug by specific groups of patients, provided that a public interest exists only to that extent and there are practical criteria allowing to distinguish these groups from others.

**4. Is my competitor required to pay a licence fee for the use allowed under the compulsory licence?**

Yes. Where the Federal Patent Court grants a compulsory license, the patent proprietor has a claim for remuneration against the licensee. The amount of the licence fee to be fixed by the court must be appropriate to the circumstances of the case and must take into account the economic value of the compulsory licence (Sec. 24 para. 6 sentence 4 German Patent Act). It is based on what the patent proprietor and the licensee would reasonably have agreed upon in the event of a contractual settlement.

**5. I would like to obtain a compulsory license to produce a COVID-19 vaccine on which my competitor holds a patent. When can I start manufacturing the vaccine?**

If the license seeker can credibly demonstrate that on the one hand the requirements for a compulsory license contained in Sec. 24 para. 1 German Patent Act are met and on the other hand the immediate granting of a compulsory license is urgently required in the public interest, they may be allowed to use the invention by interim injunction while the court proceedings are still ongoing (Sec. 85 para. 1 German Patent Act).

This presupposes that an immediate permission to use the invention is so urgently required to avoid substantial disadvantages that a longer waiting period cannot be justified. This may be the case, for example, if the patent proprietor is unable to produce a vital COVID-19 drug in an adquate quantity sufficiently quickly. In the past, the courts have been quite generous in assessing the urgency – a stark contrast to their assessment in interim injunction proceedings under Sec. 935, 940 German Code of Civil Procedure. In particular, it does not preclude the urgency if the licence seeker does not file their application at the earliest conceivable date, but waits for some time.

However, the licence seeker should take into account that they are obliged to pay damages to the patent proprietor if it is later determined that there was no basis for the interim injunction and, thus, for the use of the invention (Sec. 85 para. 5 German Patent Act).

The first-instance judgment of the Federal Patent Court may be declared provisionally enforceable against the provision of a security if such enforceability is in the public interest (Sec. 85 para. 6 sentence 1 German Patent Act). If the Federal Patent Court has found a public interest in granting a compulsory license, such interest in the provisional enforceability is usually affirmed as well. However, the license seeker who starts production immediately also runs the risk of having to pay damages to the patent proprietor in case of a successful appeal (Sec. 85 para. 6 sentence 2 German Patent Act).

**6. I have obtained a patent for a drug against COVID-19. Can the state revoke this patent in order to supply the population with my drug?**

No, even patents on drugs to combat the COVID-19 pandemic cannot simply be withdrawn from their proprietors. It is possible under certain circumstances, however, that the Federal Ministry of Health or an authority subordinate to it may issue a governmental order of use according to Sec. 13 German Patent Act in conjunction with Sec. 5 para. 2 no. 5 German Infection Protection Act. This new legal basis was introduced in the Act on the Protection of the Population in Case of an Epidemic Situation of National Significance. A governmental order of use specifies certain acts of use which the patent proprietor must tolerate – for example, the production of their COVID-19 vaccine. It such an order is made, the authorities can for example commission a private company to produce

the vaccine for them without the patent proprietor being able to prevent this. The governmental order of use does not, however, affect the validity of the patent in any way.

**7. What are the circumstances under which I should expect the authorities to issue a governmental order of use for a COVID-19 drug for which I hold a patent?**

The newly introduced Sec. 5 para. 2 no. 5 German Infection Protection Act only applies to certain patents: It affects patents on pharmaceuticals and active ingredients, starting materials and auxiliary materials for these, medical devices, laboratory diagnostics, auxiliary materials, objects of personal protective equipment and disinfection products (Sec. 5 para. 2 no. 4 German Infection Protection Act). This affects product patents as well as process patents. The proprietor of a patent on the manufacturing process for protective clothing, for example, may be subject to a governmental order of use based on the new provision.

In addition, the Federal Ministry of Health or the authorities subordinate to it may only issue the governmental order of use if it safeguards one of two alternative interests: the interest of public welfare or the interest of federal security. In its explanatory memorandum to the Act on the Protection of the Population in the Event of an Epidemic Situation of National Significance, the legislator specified when these interests may come into play during the COVID-19 pandemic: It should only be possible to issue a governmental order of use in the event of a supply shortage concerning essential active ingredients or drugs. The requirements for issuing a governmental order of use are therefore high.

**8. The Federal Ministry of Health has issued a governmental order of use with regard to my COVID-19 vaccine. Does this mean that my licensees and I will now have to stop its production?**

No. The purpose of a governmental order of use based on Sec. 13 German Patent Act in conjunction with Sec. 5 para. 2 no. 5 German Infection Protection Act is to eliminate supply shortages for essential active ingredients and drugs necessary to fight the COVID-19 pandemic. If the patent proprietor and their licensees were prohibited from manufacturing such drugs, this would contradict the objective of providing them to the population in a comprehensive manner. The governmental order of use is therefore likely only to have the scope of a non-exclusive licence, thus allowing third companies in addition to the patent proprietor to produce COVID-19 drugs on behalf of the state.

**9. Will I receive a licence fee if a private company produces a COVID-19 drug on which I have a patent based on a governmental order of use?**

Yes. If the Federal Ministry of Health or a subordinate authority issues a governmental order of use, the patent proprietor is entitled to an appropriate remuneration according to Sec. 13 para. 3 sentence 1 German Patent Act.

However, the debtor is not the company which produces the COVID-19 drug, but the federal government which commissioned its production.

The level of remuneration is determined by striking a fair balance between the interests of the general public and those of the patent proprietor. There is no established case law on this balancing exercise, so that from today's perspective it is unclear which level of payment the patent proprietor may expect. It is to be expected that the level of remuneration may be calculated by means of a licence analogy. If a dispute arises between the federal government and the patent proprietor concerning the remuneration, they may bring the matter before the civil courts which will then fix the amount of the remuneration claim with binding effect (Sec. 13 para. 3 sentence 2 German Patent Act).

**10. I have received a governmental order of use in respect of my patented COVID-19 vaccine. Which steps can I take to fight it?**

The governmental order of use according to Sec. 13 German Patent Act in conjunction with Sec. 5 para. 2 no. 5 German Infection Protection Act is an administrative act. Where the Federal Ministry of Health has issued the order, an action for annulment may be brought against it (Sec. 42 para. 1 German Law on Administrative Court Proceedings). Note: Pursuant to Sec. 13 para. 2 German Patent Law, said action must be filed with the Federal Administrative Court.

Where a subordinate authority has issued the order on behalf of the Ministry, it may be necessary under the respective state law to go through opposition proceedings before filing an action with the court (Sec. 68 et seq. German Law on Administrative Court Proceedings). The action for annulment must in this case be filed with the locally competent administrative court.

It should be noted that legal remedies against a governmental order of use under Sec. 13 German Patent Act in conjunction with Sec. 5 para. 2 no. 5 German Infection Protection Act do not have a suspensive effect (Sec. 5 para 4 sentence 4 German Infection Protection Act). In addition to the admissible legal remedy against the order itself, the patent proprietor should therefore file an urgent motion to establish the suspensive effect of said remedy if they wish to prevent the immediate enforcement of the order (Sec. 80 para. 5 sentence 1 German Law on Administrative Court Proceedings).

## 11. Do a compulsory licence or a governmental order of use concerning my COVID-19 drug mean that I must accept that third parties may use the invention for the remaining term of my patent?

No, neither the compulsory licence nor the governmental order of use allows the use for an unlimited period of time.

Where a compulsory licence is granted, the court has to determine the period of time during which the use of the patented invention is permitted at the time of the granting. The compulsory licence may only exist as long as its purpose requires it (Sec. 24 para. 6 sentence 3 German Patent Act). Thus, if it is granted to remedy a shortage of COVID-19 drugs, it may only cover the period during which such a shortage actually exists. As this is difficult to predict, it is conceivable that the protection of the population's health can be ensured before the expiry of the period specified in the judgment. In this case, the patent proprietor is entitled to a withdrawal of the compulsory licence pursuant to Sec. 24 para. 6 sentence 6 German Patent Act. For this purpose, they may file a petition to modify the judgment with the Federal Patent Court pursuant to Sec. 323 German Code of Civil Procedure.

A governmental order of use must also be limited in time to the period during which a shortage of supply exists at the time of its issuing. This ensures its proportionality. The patent proprietor is additionally entitled to a revocation of the order as soon as its conditions are no longer met. If the supply of COVID-19 drugs to the population is ensured, the patent proprietor may therefore seek to have the governmental order of use revoked – if necessary by way of an action for performance (Sec. 42 para. 1 German Law on Administrative Court Proceedings).

A specific feature of the governmental order of use is that Sec. 5 German Infection Protection Act in its current version is only valid until 31 March 2021. An order issued on its basis is therefore deemed to be revoked at the end of this day at the latest. If the determination of the epidemic situation, which the Federal Parliament has made on 27 March 2020, is repealed before that date, the governmental order of use is deemed to be revoked at the end of the earlier day (Sec. 5 para. 4 sentence 3 German Infection Protection Act).

## 12. What can I do to prevent the use of my patented COVID-19 vaccine under a compulsory license or governmental order of use?

Those patent proprietors that do not want to run the risk of being forced to allow third parties to use their COVID-19 drug can take certain proactive steps in order to eliminate the need for coercive measures:

- When applying for a patent for their invention as well as after this point in time, the patent proprietor can make a declaration of willingness to license. For this purpose, they must declare to the Patent Office in writing that they are prepared to allow anyone to use their invention in exchange for an appropriate license fee (Sec. 23 para. 1 sentence 1 German Patent Act).

  If a competitor wishes to produce the patented COVID-19 vaccine, they merely have to notify its patent proprietor of their intention to use it (Sec. 23 para. 3 sentence 1 German Patent Act). Subsequently, they may start the production of the vaccine (Sec. 23 para. 3 sentence 4 German Patent Act).

  A declaration has the additional advantage that the annual patent fees are reduced by half (Sec. 23 para. 1 sentence 1 German Patent Act).

- The patent proprietor may join forces with the proprietors of other patents on drugs which combat the COVID-19 pandemic by combining their patents in a patent pool, which can be licensed as a bundle under predefined conditions. This greatly simplifies the licensing process, compared to the otherwise necessary, often lengthy negotiations between the individual parties involved.

- Other bilateral or multilateral collaboration between the patent proprietor and their competitors is also conceivable. The patent proprietor could, for example, grant local pharmaceutical companies non-exclusive rights to produce their COVID-19 vaccine in order to ensure supply in areas where they are not active themselves.

Such cooperation always carries the risk of being classified as a concerted practice within the meaning of Art. 101 para. 1 TFEU. Additionally, the European Commission has recently indicated

in a “Comfort Letter”[1] that a cooperation of pharmaceutical companies intended to counter logistical shortages in the supply of COVID-19 drugs should in principle be possible. At the same time, however, the Commission has also pointed out that competition law sets narrow limits for such a cooperation. Patent proprietors should therefore always check in each case whether and to what extent a specific planned collaboration is permitted.


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[1] https://ec.europa.eu/competition/antitrust/medicines_for_europe_comfort_letter.pdf