

Vaccine

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Patents in times of COVID-19 pandemic: What are patents on vaccines worth in times of a pandemic?

Immediately after the novel COVID-19 virus SARS-CoV-2 had been reported for the first time, vaccines, treatments, and technologies were searched in a rush in order to get the disease under control and save lives. German biotechnology company BioNTech developed the COVID-19 vaccine in collaboration with US pharmaceutical company Pfizer, which was approved by the European Union at the end of 2020. Shortly after, vaccination started in Germany and in several EU countries. In the meantime, the Corona vaccine from the US company Moderna and from the British-Swedish manufacturer AstraZeneca have also received EU-wide approval. Vaccines from other manufacturers are also currently being tested and could soon be approved in the EU. The exact time and the quantity cannot be predicted exactly

at the moment. It has already become apparent that the demand for the vaccine is so enormous that the vaccines in the final phase of approval would not supply the European Union much less the whole world sufficiently. Facing the expected shortage of vaccine, disinfectant, treatments, face masks and others, the German Bundestag has put in place amendments for protective measures into the already existing German Infection Protection Act (IfSG). According to Sec 5 Para 2 No 5 IfSG, the government is authorized to determine

13 PatG and subjected to compulsory licensing Sec 24 PatG in the interest of public welfare existed before. It remains to be seen if patented COVID-19 vaccines and treatments will be subjected to compulsory licensing and governmental restrictions in order to prevent the pandemic. In the following, we will provide you with an overview about the involving

consequences for a patent owner's rights due to these compulsory measures.

In general, patent protection for inventions in all fields of technology is available, also

for vaccines, antivirals, diagnostic methods, hygiene products, etc. The patent owner has the exclusive right for use and exploitation (monopoly rights) for 20 years Art 33

Principle

TRIPS, Sec 16 PatG).

Limitations of patent protection The monopoly right of the patent owner may exceptionally be restricted by: compulsory license, Sec 24 Para 1 PatG order for exploitation, Sec 13 PatG in connection with Sec 5 Para 2 No 5 IfSG

The barriers for obtaining a compulsory license or an exploitation order for use of products relating to the COVID-19 pandemic are extremely high and can only be

applied in special circumstances. It would only be justified in case of supply shortage

Does a patent owner need to fear compulsory measures?

in order to ensure the supply of essential products.

remuneration is supposed to continue and patents will be maintained, i.e. the patent owner is entitled to use and exploit the patent for his/her own purposes. The compulsory measures are likely to be limited by the end of the pandemic and the

in this sector will remain important in the future.

For more information click

Compulsory license

Fighting coronavirus with data sets on the following topics

regard to German patents, a so-called declaration of willingness to license can be issued. This means, that the patent owner's renewal fees will be reduced by 50%. Besides, patent pools can be established, constituting relevant patents of several competitors with reasonable license conditions. Patents are important and valuable instruments to save innovations, particularly in times of a pandemic. We strongly recommend you to have your inventions protected sufficiently.

The patent owner can be obliged by the German Federal Patent Court to transfer a

requirements: the licensee has unsuccessfully attempted to obtain permission

public interest calls for grant of a compulsory license, for instance, in the field of

time and content-limited license to a third party (usually a private company), see Sec 24 Para 1, No 6 PatG. A compulsory license may be considered under the following

(unwillingness of patent owner to transfer license or excessive financial demands) or

health protection (fight against the pandemic). Alternatively, it has to be ensured that

no weaker or identical treatment already exists. This might be the case if the patent

owner does not have sufficient production capacity. A compulsory license may be

The patent owner is entitled to receive a reasonable remuneration from the license

appropriate and the economic value of the compulsory license has to be taken into account. Fixing the remuneration is based on the agreements of the parties under

In Germany, the barriers for obtaining compulsory licenses are huge. Only once, the

German Federal Court of Justice confirmed a compulsory license justified due to

public interest (BGH-decision X ZB 2/17 of 11.07.2017 "Raltegravir").

granted if there is an urgent need in public interest for immediate permission.

seeker (Sec 24 para 6 p 4 PatG) set by court. The remuneration has to be

consideration of the circumstances in the individual case.

the German Federal Court of Justice. The license seeker was not able to demonstrate that the medical product had therapeutic advantages over others. Order for exploitation The order for exploitation of an invention according to Sec. 13 PatG constitutes an authorized, time and content limited partial limitation of rights of a patent owner which will be issued only in exceptional cases.

The above-mentioned provision of Sec 5 Para 2 No 5 IfSG authorizes the Federal

Ministry of Health to issue exploitation orders according to Sec 13 PatG in the case that the German Bundestag declares an epidemic situation of national importance,

responsibility from the Federal Government to the Federal Ministry of Health should

An order for exploitation constitutes the strongest interference in the patent owner's

rights and is only authorized to be issued in case the exploitation of the invention is

subject to public welfare or national security. Since the current COVID-19 pandemic

constitutes an epidemic situation of national importance (Sec 5 Para 2 No 5 IfSG),

these conditions would be justified. Patents relating to medical products, laboratory diagnostics, auxiliary materials, items of personal protective equipment and products

for disinfection (Sec 5 Para 2 No 4 IfSG) are limited by Infection Protection Act. The

The patent owner is entitled to receive a reasonable remuneration from the Federal

There has been only one case in history where an exploitation order was issued,

shortly after the end of World War II (OLG Frankfurt PMZ 49, 330).

Republic of Germany (Sec 13 Para 3 PatG). The impact of the patent and the loss of

principle of proportionality applies also here. It has to be ensured that no weaker

as it happened on 25 March 2020 due to the COVID-19 pandemic. The shift of

serve to accelerate the procedure.

treatment already exists

INFORMATICS

storage

technology transitions.

as wind and solar power.

Further information:

EPA NEWS

FULL STUDY

EXECUTIVE SUMMARY

the patent owner have to be taken into account.

VACCINES AND THERAPEUTICS

• DIAGNOSTICS AND ANALYTICS

Dr Marco Findeisen, partner **VIEW PROFILE BACK TO TOP**

evidence of intellectual assets The new online tool WIPO PROOF enables to generate tamper-proof and globally valid evidence proving the existence of a digital file at a certain point in time. A WIPO PROOF Token is generated by means of secure technology. It constitutes

an encrypted record of the content and the existence of a digital file. The token will

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WIPO PROOF can be used to prevent misuse and misappropriation. The

documentation provided by WIPO PROOF can be used to certify evidence in legal

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WIPO PROOF uses the newest encryption technology with the highest security

WIPO PROOF the new online tool to safeguard

be timestamped in the second it is created.

intellectual assets at a specific point in time.

Benefits of WIPO PROOF

Settlement of legal disputes

Evidence

disputes.

Security

story?

lead to further setbacks once again.

German ratification process with obstacles

Confidentiality

For more information click <u>here</u>. **BACK TO TOP**

The EU Unified Patent Court (UPC): A never ending

After a long warm-up, there is light at the end of the tunnel and the prospects are

At the end of 2020, the German legislation approved the act of approval on the EU

Unified Patent Court in a second run. However, two constitutional complaints might

promising that the EU Unified Patent Court might be operating in 2021.

We strongly recommend our clients to carefully secure and safe data that contain

intellectual assets, regardless of whether a patent application is planned. In this

context, WIPO PROOF provides further opportunities to safe intellectual assets.

that an invention relating to medical products, laboratory diagnostics, auxiliary materials, items of personal protective equipment and products for disinfection are to be used in the interest of public welfare or in the interest of Germany's security. Regulations relating to patents to be restricted according to German patent law Sec

In case of a supply shortage, it might be equally possible that an exploitation order or a compulsory license will be imposed on the patent owner in terms of the pandemic. In view of the high standards mentioned above and the risk of permanent damage to the patent system, it is rather unlikely that exploitation orders or compulsory licenses will become effective in Germany in connection with the COVID-19 pandemic. This might be based on the fact that supply shortage is rather caused by limited production capacities, development and authorization processes and not by patent owners not willing to license. Several companies have already announced to hold back pandemic-related inventions and patent applications.

Even if an exploitation order, or a compulsory license, will be issued within the next

months, the effects on patent owners are moderate. The possibility to claim

patent owner will be able to freely dispose about the monopoly rights. Since,

according to experts, the COVID-19 virus is likely to occur locally restricted, IP rights

Patent owners in the field of COVID-19 vaccines, treatments or similar COVID-19

related products could protect themselves of an exploitation order or a compulsory

license by indicating their willingness to license or by issuing patent pledges. With

In a following decision "Alirocumab" (BGH-decision X ZB 2/19 of 04.06.2019), however, public interest required for granting a compulsory license was denied by

EPO-IEA study on innovation in batteries and electricity

Improving electricity-storage capacity is playing a key role in clean energy

The European Patent Office (EPO) and the International Energy Agency (IEA)

The report reveals that global patenting activity in the field of batteries and electricity

storage increased at an annual growth rate of 14% between 2005 and 2018, four

According to the study, battery technology accounts for almost 90% of all patenting

activity in the field of electricity storage. The rise in innovation can be particularly

attributed to the progress in the field of rechargeable lithium-ion battery cells for

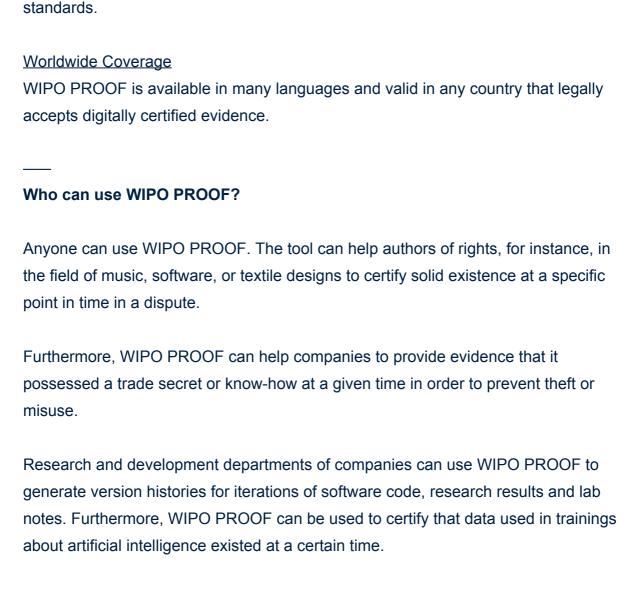
consumer electronic devices and electric vehicles. Technological progress is also

encouraged by the increasing need for power supply from renewable sources such

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recently published a study on battery and electricity storage innovations.

times faster than in any other technical sector.



What is happening next? In the next step, the Federal Constitutional Court has to decide whether the constitutional complaints will be approved for decision. In case of rejection, the Unified Patent Court would likely be able to act in 2021, which means, the Unified Patent Court will become effective. However, should the Federal Constitutional Court, again decide in the long term run about the constitutional complaints on the agreement, it will likely be remembered as a never ending story.

Deutschlands Witte, Weller & Partner Gewerblicher Rechtsschutz Handelsblatt • 26.06.2020 Best Lawyers Multiple awards for WITTEWELLER in 2020 In 2020, WITTEWELLER was once again awarded multiple times for outstanding achievements in the field of patent law and IP rights. WITTEWELLER as <u>Germany's Best Lawyers</u> in the category IP rights. Handelsblatt particularly recognizes the expertise and work of patent attorneys Dr. Volker Heuckeroth, Stephan Keck and Mark Wegener. The German business magazine WirtschaftsWoche lists WITTEWELLER as one of the top ranked law firms in patent law. We are proud to announce that our partner, Dr. Gabriele Laufer, is mentioned as highly recommended patent attorney amongst few. Furthermore, WITTEWELLER was again awarded by JUVE as one of the leading patent law firms in the category Patent Filing - Germany 2020.

The act of approval to the agreement on the Unified Patent Court had reached the same procedural state in 2017, and has then been declared null and void by the Constitutional Court in March 2020 due to lack of a two-thirds majority of all members of the German Bundestag. We reported about this decision in one of our past newsletters WITTEWELLER News I/2020. In November and December 2020, the German Bundestag and the German Bundesrat approved the UPC legislation in the second attempt and with identical wording achieving the two-thirds majority. The same day it was passed, however, two constitutional complaints were filed against it once again. It is currently not known which grounds of appeal are cited and who the complainants are. It seems, however, that the Dusseldorf lawyer, who had filed the

It is also not clear yet whether the German Federal Constitutional Court will accept

the constitutional complaints and whether the ratification will be exposed again by

the Federal President. In the course of the last constitutional complaint, the Federal

President complied with the informal request from Karlsruhe to sign the ratification.

The Unified Patent Court is supposed to consist of two judicial divisions. In the first

instance, a central division will be located in Paris and local divisions in London and

After Brexit, the UK location with seat in London will have to be moved. A temporary

solution could be to move responsibility to the central division in Paris and the

Munich. It is expected that four regional chambers will be established in Germany,

complaint in 2017, filed a further constitutional complaint.

Organization and locations of the Unified Patent Court

namely Mannheim, Munich, Hamburg, and Dusseldorf.

division in Munich until an adequate alternative is found.

For more information click here.

According to the JUVE ranking, WITTEWELLER provides special expertise in the field of electronics, mechanics, process and mechanical engineering, medical technology as well as pharma and biotechnology. Patent attorneys Dr. Volker Heuckeroth, Stephan Keck and Christian Steil are especially recommended in this context. We highly appreciate these awards and consider them as confirmation and motivation to provide our clients with our expertise, knowledge and commitment. **BACK TO TOP**

BACK TO TOP We are pleased to report that the German business magazine Handelsblatt awarded

Responsible according to German press law: Mark Wegener, Patentanwalt Picture credits from top to bottom: No. 2 Daniel Schludi, No. 3 Tyler Lastovich, No. 4 Erik Aquino, No. 5 Christian Lue, No. 6 Giammarco Boscaro, No. 7 Mitia Arzensek WITTEWELLER PATENTANWÄLTE Witte, Weller & Partner Patentanwälte mbB Königstr. 5 (Phoenixbau) 70173 Stuttgart (Germany)

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