

Kluwer Patent Blog

Update on Patent-Related Measures in Germany in View of Corona Pandemic

Thomas Musmann (Rospatt Osten Pross) · Thursday, April 2nd, 2020

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On March 24, 2020 we reported that the German government planned amendments to the Act on the Prevention and Control of Infectious Diseases in Humans (Gesetz zur Verhütung und Bekämpfung von Infektionskrankheiten beim Menschen – Infektionsschutzgesetz – IfSG), which could also have an impact on patents (see [here](#)). In the meantime these amendments have been enacted by the 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 (see for the legislative process [here](#) and for the IfSG in amended form [here](#)).

Now the IfSG lays down that in case the German Federal Diet (Bundestag), i.e. the lower chamber of parliament, finds that there is an epidemic situation of national significance, the amended IfSG confers upon the Federal Ministry of Health additional powers to control the epidemic situation, including the competence to order limitations on patents. The relevant subsections of the new s. 5 IfSG, which pursuant to Article 3 and Article 7(4) of the Act of March 27, 2020 will expire on March 31, 2021, read as follows:

‘(1) The German Federal Diet may find an epidemic situation of national significance. The German Federal Diet shall repeal the finding of an epidemic situation of national significance if the conditions for its finding no longer exist. The repeal shall be published in the Federal Law Gazette.

(2) The Federal Ministry of Health shall be empowered, within the framework of the epidemic situation of national significance, without prejudice to the powers of the States,

[...]

4. to take measures by statutory instrument, without the consent of the Federal Council, to ensure the supply of medicinal products including narcotics, the active ingredients, starting materials and excipients for these, medical devices, laboratory diagnostics, aids, as well as items of personal protective equipment and products for disinfection and in particular

[...]

5. to order under s. 13(1) of the Patent Act that an invention relating to one of the products mentioned in No. 4 [...] shall be used in the interest of public welfare or in the interest of the security of the Federal Republic of Germany; the Federal Ministry of Health may instruct a subordinate authority to make such an order;

[...]

(4) [...] Orders made pursuant to subsection 2 shall be 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. An action for annulment of orders made pursuant to subsection 2 shall not have suspensory effect.'

On March 25, 2020 the Federal Diet found that due to the spread of the Corona virus in Germany there is an epidemic situation of national significance in accordance with s. 5(1) IfSG. This finding has become effective upon the entering into force of the amendments to the IfSG on March 28, 2020 (see [here](#) and [here](#)).

In consequence, the Federal Ministry of Health or subordinate authorities now have the power under s. 5(2) n. 5 IfSG to issue orders pursuant to s. 13(1) German Patent Act with regard to medicinal products, medical devices, laboratory diagnostics, aids, items of personal protective equipment, and products for disinfection. The provision of s. 13 Patent Act reads as follows:

'(1) The patent shall have no effect in a case where the Federal Government orders that the invention is to be used in the interest of public welfare. Further, it shall not extend to a use of the invention which is ordered in the interest of the security of the Federal Republic of Germany by the competent highest federal authority or by a subordinate authority acting on its instructions.

(2) The Federal Administrative Court shall be competent to hear an appeal from an order made pursuant to subsection (1) if the order was made by the Federal Government or by the competent highest federal authority.

(3) In the cases referred to in subsection (1), the proprietor of the patent shall be entitled to equitable remuneration from the Federal Republic of Germany. In the event of dispute as to its amount, recourse may be taken to the ordinary courts. A Federal Government order pursuant to subsection (1), first sentence, shall be communicated to the person entered in the Register as the proprietor of the patent (section 30 (1)) before the invention is used. Where the highest federal authority which issued an order or instruction in accordance with subsection (1), second sentence, obtains knowledge of a remuneration claim in accordance with the first sentence, this authority shall communicate this to the person registered as the proprietor of the patent.'

Whereas a compulsory license under s. 24 Patent Act is granted by the Federal Patent Court in an individual case in favour of a particular licensee, s. 13(1) Patent Act foresees that the Federal Government, or in case of s. 5(2) n. 5 IfSG the Federal Ministry of Health, can order that a patent has no effect, that means the patent is not revoked but the patentee cannot prohibit uses of the patented invention which are covered by the order. Such uses could be undertaken either by the state itself or by third parties that act on behalf of the state. Any use that exceeds the scope of the order could be regarded as an infringement of the patent. Due to s. 5(4) IfSG, orders taken under s. 13 (1) Patent Act and s. 5(2) n. 5 IfSG will expire on March 31, 2021 at the latest.

An order under s. 13 Patent Act, *inter alia*, requires that it is made in the interest of 'public

welfare'. The concept of 'public welfare' is narrower than the term 'public interest' under s. 24 Patent Act. According to legal scholarship 'public welfare' could be affected in case of a pandemic.

Furthermore, the provisions of s. 13 Patent Act and s. 5(2) n. 5 IfSG are subject to the general principle of proportionality ('Grundsatz der Verhältnismäßigkeit'). That means that an order under s. 13 Patent Act has to be suitable to achieve the desired effect ('geeignet'). Furthermore, from a selection of possible measures it has to be the least interfering one ('erforderlich'). Finally, balancing all interests involved, the order under s. 13 Patent Act has to be an appropriate measure ('angemessen').

One expression of the principle of proportionality is that under s. 13(3) Patent Act the patentee can claim an 'equitable remuneration' from the Federal Republic of Germany. Some scholars suggest that such remuneration should be based on a reasonable royalty.

An order under s. 13 Patent Act as such could be challenged before the administrative courts. Due to s. 5(4) IfSG an action for annulment before the administrative courts would have no suspensory effect. The civil courts would be competent to hear disputes regarding the amount of the 'equitable remuneration'.

The provision of s. 13 Patent Act has not been used for decades and can be regarded as uncharted territory. It remains to be seen whether the Federal Ministry of Health will issue orders under s. 13 Patent Act and s. 5(2) n. 5 IfSG in the course of the Corona pandemic. Such orders require in any event a fair balancing of all interests involved.

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