PATENT LAW: APPROPRIATE BALANCE BETWEEN PRIVATE AND PUBLIC HEALTH INTERESTS IN TIMES OF CORONAVIRUS CRISIS

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Patent protection in pharma and healthcare has always been a matter of intense debate. In the context of coronavirus (Covid-19), the debate about the right balance between justified exclusivity and the public interest in any progress in scientific (pharmaceutical) research becomes even more urgent. Here, patent law must reconcile different interests: On the one hand, it must reward inventors in order to encourage them to make new innovations, while ensuring on the other hand that the general public and not only a few privileged individuals benefit from the inventions. Outside times of crisis, the patent system has proved its worth and has always provided for an appropriate balance between the various interests. However, will this assessment also hold true for the coronavirus crisis or will adjustments be required?

Key issues

- In principle, patent protection grants the owner of an invention an exclusive right for its use and commercialisation.
- However, the coronavirus crisis could lead to restrictions of patent rights.
- Last week, the Bundestag passed an amendment to the Protection against Infection Act which empowers the Federal Health Minister to oblige research institutes and pharmaceutical companies to make patented drugs available to the general public in return for appropriate compensation.
- Besides, the German Patent Act ("**GPA**") provides for a compulsory licence regime under which access to a specific patent may exceptionally be granted under certain conditions.

INTRODUCTION

Due to the massive spread of *COVID-19* and the daily increasing number of new infections, many pharmaceutical companies intensified their researches to develop and market a vaccine as soon as possible. For the individual governments the protection of public health is a top priority. Along with the *Coalition for Epidemic Preparedness Innovations* (*CEPI*), an international foundation in public-private partnership, they invest large sums of money in the development of a vaccine.

Generally, the company can expect to realize an appropriate return on invest with the development of a vaccine or any potent anti-viral drug, given that patent protection grants the owner of an invention an exclusive right for its use and commercialisation.

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However, provided that – as is currently the case – the protection of public health is at issue and that there is a significant public interest in access to and the affordability of drugs, exceptions to the exclusive protection of the patent holder might be necessary. In such cases, the German Patent Act ("**GPA**") provides for a compulsory licence regime under which access to a specific patent may exceptionally be granted in accordance with the requirements of section 24 GPA.

In addition, section 13 GPA provides for the possibility to suspend the exclusive right in so far as the Federal Government orders that the invention shall be used in the interest of public welfare or federal security. In this case, the patent holder must tolerate the usage of the patent but receives a certain remuneration in turn.

Based on this regulation, on 28 March the Bundestag passed an amendment to the Protection against Infection Act (*Infektionsschutzgesetz*), which gives the Federal Minister of Health far-reaching powers in the fight against the coronavirus. To ensure that the population has access to medicines against the coronavirus, the Federal Health Minister is from now on authorized to oblige research institutes and pharmaceutical companies to make patented vaccines or medicines available to the general public in return for an appropriate compensation. Prerequisite is that the Bundestag has previously identified an epidemic situation of national importance. Therewith, the German government ensures that in the event of a crisis the population is provided with the necessary vaccines and medicines.

This article intends to provide an overview of the interplay and the implications between the patent as an exclusive right and the compulsory licence and further access rights according to the Protection against Infection Act as restriction for the patent holder. Moreover, it raises the question of whether the current patent system can sufficiently satisfy the different interests against the background of the current coronavirus crisis.

PATENT AS AN EXCLUSIVE RIGHT

Patent law rewards the respective inventor with an exclusive right to his invention for a maximum of 20 years. On the one hand, such an exclusive right provides an incentive for private companies to create further innovations. On the other hand, it causes a monopoly on the invention which – as critics of the patent system usually argue – can limit competition and the free use of innovations.

Patent law has succeeded in striking an appropriate balance between those private and public interests by granting an exclusive right to the patent holder, but at the same time imposing on him an obligation to disclose his invention and limiting the protection in terms of time, scope and territory. This mechanism has so far ensured an appropriate balance between the multiple interests, which in turn encourages inventors to do research and invest.

EXCEPTION OF EXCLUSIVITY: COMPULSORY LICENCES

Since absolute protection of the patent, however limited in the aforementioned sense, may not prove to be in the interest of the public in any and all situations, the German legislator created the compulsory licensing regime in section 24 GPA.

At international level, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS-Agreement), which applies to all member states of the

World Trade Organisation (*WTO*), provides for the possibility of granting a compulsory licence in Article 31.

Character of compulsory licences

Compulsory licences are non-exclusive licences that allow third parties to use the patent against the will of the patent holder. They can be requested at the Federal Patent Court, but only under strict conditions in very limited exceptional cases, as they substantially encroach on the property right of the patent holder. In the past, there seems to be only one single case[2] in the pharmaceutical sector in which both the Federal Patent Court[3] and the Federal Court of Justice[4] have so far granted a compulsory license for reasons of public health protection.

A pandemic such as the coronavirus could give cause to examine the conditions and consequences of compulsory licences.

When is a compulsory licence granted and what are the consequences?

According to section 24(1) GPA a compulsory license may be granted if (i) the patent applicant has tried without success for a reasonable period of time to obtain a permission from the patent holder to use his invention under reasonable conditions and (ii) there is a special public interest for the grant of the licence.

The first condition for a compulsory licence is thus that the patent holder refuses to grant a licence to the licence applicant although the latter has previously offered him an adequate compensation. The offer made by the applicant must be reasonable. In this respect, the Federal Court of Justice stated that the perspective of the licence applicant is decisive.[5] He is required to make efforts to obtain a licence on terms which a reasonable and economically acting third party would be prepared to bear in his place.

Secondly, a public interest must require the grant of a compulsory licence. The Federal Supreme Court emphasised that this requirement cannot be generally defined. Rather, all circumstances of the individual case have to be taken into account. When weighing up the different interests, however, it must be considered that the legal system in principle grants the patent holder an exclusive right. Therefore, the Federal Court of Justice held that a compulsory licence can only be granted if there are special circumstances in which the public interest prevails. In the specific case, the Court of Justice affirmed a public interest for the grounds that – without the licence – a drug with a comparable therapeutic effect would no longer be available for the treatment of the serious illness HIV.[6]

If the requirements for the grant of a compulsory licence are met, the Federal Patent Court grants the applicant a non-exclusive licence. At the same time, it determines a license fee of an appropriate amount. Thus, in addition to the

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2 The Federal Patent Court had granted a compulsory licence also in another case, but its decision was reversed by the Federal Court of Justice in the second instance on the reason that there was a lack of public interest [see Federal Court of Justice, decision of 5 December 1995 – X ZR 26/92 (*Polyferon*)].
3 Federal Patent Court, Decision of 31 August 2016 – 3 LiQ 1/16 (EP).
4 Federal Court of Justice, Decision of 11 July 2017 – X ZB 2/17 (*Isentress/Raltegravir*).
5 Ibid, recital 29 ff.
6 Ibid. recital 38 ff.

patent holder, a third party can use the patent for a fee that is usually lower than the fee requested by the patent holder.

IMMEDIATE BUT TEMPORARILY SUSPENSION OF PATENT RIGHTS ACCORDING TO PROTECTION AGAINST INFECTION ACT

However, even in the field of medical and vaccine research, where the health of the population as a particularly sensitive asset is at stake, compulsory licences have so far been the absolute exception. This indicates that exclusive protection of the patent holder has in principle proven to be appropriate in this area as well, whereas the compulsory licence has only the function of a last means in licence negotiations which – as we have seen – has only been used under very narrow circumstances.

This applies at least outside times of crisis. The actual significance of the compulsory license regime might now be tested in the context of the current coronavirus crisis. With the Amendment to the Protection against Infection Act, the parliament declared the coronavirus crisis as an epidemic situation of national importance. Regarding patents, as said, the amendment empowers the Ministry of Health to issue that an invention can be used in the interest of public welfare or in the interest of federal security[7].

Although section 13 GPA does not affect the validity of the patent, it is one of the provisions that set limits to the exclusive right of the patent holder in the interest of the public. It remains to be seen whether this means will be used. However, the current legislative clearly highlight that the government is more than willing to make use of its powers.

Contrary to what might be assumed at first sight, the Protection against Infection Act is not aimed at vaccines that are currently being developed and are not yet patented, but rather at known and already patented active substances that were developed in the past for other diseases and are now being tested for their effect on coronaviruses.

Why became this additional Protection against Infection Act necessary? A court procedure according to section 24 GPA is likely to take longer than an order by the Federal Minister of Health in accordance with the Protection against Infection Act. In case of a threat to the public health, time is of outmost importance and thus the preliminary suspension of patent rights may be justified under the narrow prerequisites: pandemic situation, temporarily and compensation for the patent holder.

CLOSING REMARKS

In principle, the interests of the patent holder are comprehensively protected by an exclusive right to the patent and are brought into an appropriate balance with public interests – at least in 'regular times'.

Yet, in the context of the current coronavirus crisis, patent holders must be aware of the outlined restrictions, such as compulsory licenses, if they do not agree to market a vaccine or medicine at reasonable prices or grant a respective licence.

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[7] See Article 1 section 5 para 2 no 5 of the Act for the protection of the population in the event of an epidemic situation of national importance, 27 March 2020, see BGBl. 2020 I Nr. 14, p. 587 ff.

It is essential that the involved stakeholders try to achieve an appropriate balance in order to ensure the affordability of adequate health care for the general public and allow the development of urgently needed drugs and, at the same time, uphold an adequate patent protection level.

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