

EUROPEAN REPORTS

The European Commission has announced a proposal for a regulation on supplementary protection certificates ('SPCs') to create a unitary SPC right across participating states and/or a single 'unified' procedure for granting national SPCs.

The Commission's webpage states:¹

Supplementary protection certificates (SPCs) are intellectual property rights extending patent protection for specific medicinal and plant protection products. While this regime is fit for purpose, differences between EU countries in its administration and enforcement create inefficiencies. This initiative will put in place a unitary SPC and/or a single ('unified') procedure for granting national SPCs. This will make SPCs more accessible and efficient, and benefit the health sector.

The Commission will 'invite evidence' in relation to this initiative in due course.

Laura Orlando, an IP partner in Herbert Smith Freehills' Milan office, and EMEA co-lead partner for the Life Sciences sector, commented:

The variations in approach to grant seen across the EU mean that a centralised, and thus harmonised, application procedure would be likely to be welcomed by industry. A unitary SPC for unitary patents could be a good solution to the issue of SPC protection for this new unitary right. Failing this, unitary patent holders might apply for separate national SPCs for the designations covered by the particular unitary patent. In either case a centralised application procedure would be helpful.

Background

There is currently no centralised procedure for the granting of SPCs which are separate national rights, as European patents ('EPs') are, once granted. SPCs are granted on a national basis by national patent offices by reference to the SPC Regulations (Regulation EC No 469/2009² and Regulation EC No 1610/96³), but with differing approaches to grant (some jurisdictions require substantive examination whereas in others it is a mainly administrative process).

With the advent of the UPC,⁴ which is likely to commence towards the end of 2022 or the start of 2023, the EPO will be able to offer unitary effect for EPs at grant (a 'unitary patent'). No provision has so far been made for the terms of unitary patents to be extended by unitary SPCs but there has been speculation that this would be needed in due course. These proposals may provide the means by which such a unitary patent SPC is created. Otherwise, the holder of a unitary patent would need to apply to national patent offices for separate SPCs based on its unitary patent, as happens currently with EPs.

EU NEWS

THE CREATION OF UNITARY SPCs AND A 'UNIFIED' PROCEDURE FOR GRANTING SPCs: THE EUROPEAN COMMISSION ANNOUNCES PROPOSALS

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1) https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13353-Medicinal-&-plant-protection-products-single-procedure-for-the-granting-of-SPCs_en.

2) <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02009Ro469-20190701>.

3) <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01996R1610-20130701>.

4) See: <https://www.herbertsmithfreehills.com/latest-thinking/hubs/upc>.

Proposals

Whilst no further details have yet been released, the outline given by the Commission, as set out above, suggests that a centralised procedure could be used to grant both SPCs for current EPs, and ‘unitary’ SPCs. There is no indication as yet what body might be used for any centralised SPC application procedure, but the EPO or indeed the EUIPO could be an option, or even an independent body. The Commission conducted a consultation in 2018, in which an independent body of experts from individual national patent offices operating virtually was a popular option.⁵

The authors will discuss the details of the Commission’s proposals in a subsequent issue of BSLR once these are published.

On 28 April 2022, the CJEU delivered its decision in the preliminary ruling case C-44/21¹ and held that the case law of the German higher regional courts in proceedings for interim relief in patent matters, according to which the grant of interim measures for infringement of a patent is *in principle* to be refused if the patent has not yet survived opposition or revocation proceedings at first instance confirming its validity, is not compatible with Article 9(1) of Directive 2004/48/EC (‘the Enforcement Directive’).

In our article of 25 January 2021,² we reported that the Munich Regional Court had turned to the CJEU with a corresponding request for a preliminary ruling.³ In the underlying preliminary injunction proceedings, the court had come to the conclusion that the applicant’s patent was legally valid and infringed but saw itself prevented from issuing a preliminary injunction due to the above-mentioned binding case law of the Munich Higher Regional Court.

In its judgment, the CJEU emphasises that:

- granted patents are, in principle, presumed to be valid and enjoy, from the date of publication of the grant, the full protection afforded, *inter alia*, by Directive 2004/48;
- Member States must ensure that, under Article 9(1), national courts have the power to order provisional measures and, after examining the particular circumstances of the case, to grant them;
- Directive 2004/48 lays down a minimum standard and the remedies prescribed therein are intended to prevent, remedy, or put an end to any infringement of an existing intellectual property right.

The court states, with reference to the German case law leading to the reference:

It must be stated that such case law imposes a requirement which deprives Article 9(1)(a) of Directive 2004/48 of any practical effect in so far as it does not allow the national court to adopt, in accordance with that provision, an interlocutory injunction in order to terminate immediately the infringement of the

5) See the Commission’s summary of the replies to the consultation at: https://ec.europa.eu/info/consultations/public-consultation-supplementary-protection-certificates-spcs-and-patent-research-exemptions_en.

PATENTS: NEW PRINCIPLES IN PRELIMINARY INJUNCTION PROCEEDINGS

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1) ECLI:EU:C:2022:309.

2) <https://www.maiwald.eu/en/maiwald-blog/cjeu-referral-no-preliminary-injunctions-based-on-newly-granted-patents/>.

3) For the request for preliminary ruling of 19 January 2021 and discussion status see: GRUR 2021, 466 – Validity of a patent in preliminary injunction proceedings (with comment by Kühnen, presiding judge at the Düsseldorf Higher Regional Court); and GRUR 2021, 557 – The significance of the grant of the patent for the prognosis of its validity in preliminary injunction proceedings (reply by Pichlmaier, judge at Munich Regional Court).

patent in question even though that patent, according to the national court, is valid and is being infringed. (para. 34)

...

A national procedure aimed at the immediate termination of any infringement of an existing intellectual property right would be ineffective and, consequently, would disregard the objective of a high level of protection of intellectual property, if the application of that procedure were subject to a requirement such as that laid down by the national case law referred to in paragraph 33 of the present judgment. (para. 40)

Further, both Directive 2004/48 and the Member States bound by it provided sufficient safeguards to prevent provisional measures and proceedings from being misused.

Accordingly, the German courts of first instance are now required, if necessary, to disregard the previous case law of the higher regional courts that is incompatible with Article 9(1) of the Enforcement Directive. The CJEU judgment contains an unambiguous instruction in this respect (para. 53) and a clear request to change established case law that is contrary to Union law (para. 52).

This highly anticipated ruling is likely to have a significant impact on future practice in preliminary injunction proceedings. It is true that courts have already developed and implemented extensive exceptions to the above-mentioned principle. However, the mere argument that a patent for an injunction has not yet survived proceedings on the validity of the patent in the first instance should no longer lead to the rejection of a request for interim injunction. Rather, and more than ever, it will be up to the alleged infringer to make the doubtful validity of the patent credible and, on this basis, the courts will subject the respective patent to a thorough summary examination. It will be a challenge for all concerned to manage this with the speed that is customary for preliminary injunction proceedings in Germany.

In the same decision, the CJEU also reiterates its views on the requirements for the implementation of the expedited procedure under Article 105 of the Rules of Procedure (see also Case C-590/20 of 3 March 2022,⁴ with further references). The Munich Regional Court had requested that the case be dealt with on an expedited basis, as the *nature of the case* required a speedy decision. The court confirmed its previous case law according to which the mere – albeit legitimate – interest of the applicant in having her rights clarified as quickly as possible in the context of preliminary injunction proceedings was not suitable to prove the existence of the exceptional circumstances required for Article 105. A reference for a preliminary ruling in the context of domestic interlocutory proceedings is not in itself capable of establishing that the nature of the case requires its speedy disposal. The request was dismissed.

4) ECLI:EU:C:2022:150.