

# 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:<sup>1</sup>

*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 469/2009<sup>2</sup> and Regulation EC No 1610/96<sup>3</sup>), 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,<sup>4</sup> 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

**LAURA ORLANDO AND RACHEL MONTAGNON**

Herbert Smith Freehills LLP, Milan and London

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](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.<sup>5</sup>

*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-44/21<sup>1</sup> 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,<sup>2</sup> we reported that the Munich Regional Court had turned to the CJEU with a corresponding request for a preliminary ruling.<sup>3</sup> 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](https://ec.europa.eu/info/consultations/public-consultation-supplementary-protection-certificates-spcs-and-patent-research-exemptions_en).

## PATENTS: NEW PRINCIPLES IN PRELIMINARY INJUNCTION PROCEEDINGS

**HEIKE RÖDER-HITSCHKE**

Maiwald Patentanwalts- und Rechtsanwalts-GmbH,  
Munich

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).