EIP

EU Commission Announces Major Reforms to Supplementary Protection Certificates

The EU Commission has announced a series of related proposals that will dramatically change the way in which most SPCs are obtained in Europe.

Although SPCs are creatures of EU law, they are currently obtained nationally – once a marketing authorisation for a medicinal or plant protection product has been obtained, a patentee owning a patent covering that product must apply separately to each national patent office in order to obtain a supplementary protection certificate. An SPC can be granted under certain conditions and provides an extension of the coverage of the patent in relation to the authorised product for up to five years following the expiration of the underlying patent.

The substantive rules for when an SPC can be validly obtained will not change, but the procedures by which such SPCs will be granted are proposed to be comprehensively reformed.

Unitary SPC

First, it is proposed to establish a unitary SPC based on the new Unitary Patents which will be available from 1 June 2023.The Unitary Patent represents a single patent right extending over many EU countries (currently 17), and is obtained by requesting unitary effect at the European Patent Office within one month of grant of a European patent.

The EU Commission is proposing two new Regulations – one in respect of medicinal products

and one in respect of plant protection products - which will provide a unitary SPC if the underlying patent is a unitary patent. Thus, analogously to the Unitary Patent, the Unitary
p2 SPC will be a single right covering many EU countries rather than a bundle of national rights.

Examination handed to the EU IPO

The proposal is that the applications for the new Unitary SPC will be handled by the EU IPO, the office in Alicante that currently registers EU trademarks and designs. However, there is provision for the EU IPO to appoint national patent offices to participate in the examination procedure, and examination of the SPC application is to be conducted by a panel including one EU IPO examiner and two examiners from two different national patent offices.

In a dramatic move, the EU Commission is also proposing to hand examination of national SPCs for all EU countries to the EU IPO. While competence of national patent offices to handle SPCs is not removed entirely, using the centralised EU IPO route will be mandatory for SPCs based on European Patents for medicinal products where the marketing authorisation is a centralised EU authorisation and not a national authorisation, which is the case in the majority of situations. To this end, it is proposed to re-write the two Regulations relating to SPCs for medicinal products and plant protection products to introduce the EU IPO competence in this respect and to set out the application and examination procedure to be followed.

The re-cast draft Regulations do not change the substantive requirements for obtaining an SPC. Article 3 is amended to reflect existing caselaw that one owner of multiple patents cannot obtain multiple SPCs for the same product, whereas if two unrelated patentees each have a patent then each may obtain an SPC for the product. However, the other provisions of Article 3 that have resulted in so many referrals to the CJEU and so much uncertainty about substantive SPC law remain untouched.

According to the proposed procedure, in the case of a Unitary Patent, a centralised application to the EU IPO can be made for a unitary SPC covering the countries participating in the Unitary Patent, as well as SPCs having national effect covering any other EU member states in which the European Patent was validated. On the other hand, in the case of a European Patent where unitary effect was not requested, a centralised application to the EU IPO can be made for SPCs having national effect covering the EU member states in which the European Patent was validated.

Following the centralised examination process, there would be published an examination opinion which may be positive or negative, and may be different in respect of different EU

member states. Third party observations on the SPC eligibility of the application may be filed within three months of publication of the SPC application. Also an opposition
p3 procedure is proposed, whereby within 2 months of publication of the examination opinion, any person may oppose on the grounds that any of the requirements to be granted an SPC are not met.

After expiry of the opposition period or once any opposition has concluded, the EU IPO would itself grant a unitary SPC if the underlying patent was a Unitary Patent. In respect of the EU countries outside the unitary patent system, or if the underlying patent was not a Unitary Patent, the EU IPO would not directly grant the SPC, but instead transmit the examination opinion and its translations to the patent office of each EU Member State concerned. Generally, where the opinion is positive, the relevant patent office should grant an SPC but may decide not to so if circumstances have changed, for example if the patent has lapsed before the end of its full term or if the marketing authorisation has been withdrawn.

The institution of a Unitary SPC can be regarded as a necessary corollary to the Unitary Patent system. However, the proposed new competence of the EU IPO over most SPC applications in respect of EU member states irrespective of whether a Unitary Patent is involved is a major development. It should significantly reduce the costs of obtaining SPCs across Europe. The involvement of national patent office examiners in the process is an interesting exercise of shared competence.

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