Kluwer Patent Blog

SPC cases are back and there are more to come: will the CJEU definitively heal the Medeva wounds on 12 march, or will it rub salt into them?

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The Supplementary Protection Certificate ("SPC") seas have been relatively calm after the turmoil caused by "Super Thursday" (i.e. 12 December 2013), when shortly before packing for Christmas the Court of Justice of the European Union ("CJEU") published three judgments on SPCs in a row. However, over the last few months there have been recent developments, some of which we would like to pick-up on in this blog.

The first development relates to what the relevant date is for calculating the term of the SPC: the date when the marketing authorization was "granted" or the date when the applicant was notified of the decision granting the authorization. So far, patent offices in the United Kingdom ("UK"), Slovenia and Portugal appear to have embraced the "grant" date. In contrast, their counterparts in Denmark, Sweden and the Netherlands seem to be defending the "notification" date. The final say will lie with the CJEU, which has been called to resolve this debate by a referral for a preliminary ruling sent on 15 October 2014 by the Oberlandesgericht Wien (Case C-471/14 *Seattle Genetics Inc v. Österreichisches Patentamt*).

The second development raises the debate as to whether limited uses made in the context of emergency epidemic situations or compassionate use, for example, could prevent the grant of an SPC based on a subsequent marketing authorization according to article 3(b) of Regulation (EC) 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the Supplementary Protection Certificate for Medicinal Products (the "SPC Regulation"). In this case, it will be for the EFTA Court to decide (Case E 16/*14 Pharmaq v. Intervet*). The case deals with an SPC granted in Norway in relation to a vaccine used in the prevention of an epidemic disease in salmon. It is hoped that the EFTA Court, following the Commission and the UK Government, will conclude that, normally, early emergency uses of a medicinal product should not prevent the grant of an SPC based upon a subsequent marketing authorization. Otherwise, there would be a clear disincentive for practices such as compassionate use, which would ultimately be to the detriment of potential patients. Taking into account that the hearing before the EFTA Court took place on 27 January 2015, the decision is expected to come out at any time now. The case has sparked a high level of expectation, as it raises other very interesting issues related to supplementary protection for biological products. However, as readers are well aware, the decisions from the EFTA Court have a much more limited effect than decisions from the CJEU.

The third development that we would like to briefly discuss in this blog relates to the Judgment of

12 February 2015 handed down by the CJEU in Case C-539/13 *Merck Canada Inc, MSD v. Sigma Pharmaceuticals*, where the CJEU has revisited a topic already addressed in its Judgment of 27 October 1992 (Case C-191/90 *Generics (UK) and Harris Pharmaceuticals v. Smithkline & French Laboratories, Ltd*). The case addressed some interpretative questions raised by the so-called "Specific Mechanism" which, as readers will know, is a derogation of the principle of free movement of goods included in the Act of Accession of Eastern European countries. The defendant had conducted "parallel" imports of Singulair®, a pharmaceutical product owned by MSD, from Poland to the United Kingdom. The parallel importer had sent some letters to the UK subsidiary of MSD seeking to comply with the formalities required by the Specific Mechanism, which were never answered. To cut a long story short, the preliminary questions addressed to the CJEU were aimed at clarifying who should send these letters to whom, and in which circumstances the importation can be opposed. The CJEU's answer may be summarised as follows: (i) if the holder or beneficiary of a patent or SPC does not indicate an intention to oppose a proposed importation within one month of receiving notification, the person proposing to import the pharmaceutical product in question may legitimately apply to the competent authorities for authorization to import the product and, where appropriate, import and market it; (ii) the notification must be given to the holder, or beneficiary, of the patent or the SPC, the latter term designating any person enjoying the rights conferred by law on the holder of the patent or the SPC; (iii) the Specific Mechanism does not require the person intending to import or market the pharmaceutical product in question to give notification himself, provided that it is possible from the notification to identify that person clearly.

There have been a few other judgments, such as the Judgment of 19 June 2014 (Case C-11/13 *Bayer CropScience AG v. Deutsches Patent – und Markenamt*), where the CJEU held that the term "product" in Article 1.8 and Article 3(1) of Regulation (EC) 1610/96 concerning the creation of a SPC for plant protection products, must be interpreted as meaning that those terms may cover a substance intended to be used as a "safener", where the substance has a toxic, phytotoxic or plant protection action of its own. Or the Judgment of 15 January 2015 (Case C-631/13 *Arne Forsgren v. Österrichisches Patentamt*), which considered whether an SPC is allowable for a product alone when the marketing authorization related to a medicine where such product was covalently bonded to other ingredients, and whether the applicant could rely on a marketing authorization where the product was only described as a carrier protein, without providing any information on the therapeutic effect described in the basic patent.

And there is yet more to come, as on 12 March 2015 the CJEU is due to publish its judgment in response to the questions referred by the Patents Court of England & Wales (Justice Birss) in Case C-577/13 *Actavis Group PTC EHF, Actavis UK Limited and Boehringer Ingelheim Pharma GMBH & Co, KG.*, where the CJEU will have the opportunity to definitively heal the wounds open by the Medeva accident, or rub salt into them…

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