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THE SEARCH IS OVER

INNsight article by Duncan Curley, February 2012

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Court of Justice SPC Rulings

On 24 November 2011, the Court of Justice of the European Union (the "CJEU") issued two decisions on the interpretation of Articles 3(a) and 3(b) of Regulation (EC) No 469/2009, concerning the grant criteria for supplementary protection certificates ("SPCs"): Case C-322/10 ("Medeva") and Case C-422/10 ("Georgetown"). A day later, the CJEU issued further decisions in the related SPC case C-6/11 ("Daiichi") and in a further case, C-630/10 ("Queensland"). These rulings will have consequences for future applicants for supplementary protection, as well as potentially impacting on the validity of some SPCs that have already been granted. However, the recent rulings by the CJEU also leave open certain key questions that will no doubt have to be the subject of further references to the court in the future.

In brief, the applicant for a SPC must show that it has a valid patent that contains at least a claim that covers an active moiety in an authorised medicinal product. This requirement is set out in Article 3(a) of Regulation (EC) No 469/2009. The precise wording of Article 3(a) is that the product (meaning the active ingredient) is protected by a basic patent that is in force. The applicant must also cite in its application for a SPC a marketing authorisation for the medicinal product containing the active ingredient that has been granted by a competent authority (e.g. the European Medicines Agency). This requirement is set out in Article 3(b) of Regulation (EC) No 469/2009.

The Medeva and Georgetown referrals

Medeva and Georgetown University each applied for SPCs. In each case, the medicinal products that were the subject of the marketing authorisations relied upon in the SPC applications were vaccines. The vaccines were 'multicomponent' products, containing a number (8, 9 or 10) of active components. In the Medeva case, the basic patent contained a claim only to two of these active components, but SPCs were applied for multicomponent products. In a sense, the protection sought by Medeva by means of their applications for their SPCs was broader than the monopoly conferred by the underlying patent claims. In the Georgetown case, the basic patents contained a claim only to one active component. The SPCs applied for were restricted only to single components patented by Georgetown University, even though the

marketing authorisation relied upon was for a multicomponent vaccine.

The Daiichi referral

In the Daiichi case, the English Patents Court asked the CJEU to clarify whether Article 3(a) would be satisfied where the claim relied upon in a patent in support of an application for an SPC for a combination product was not to an explicitly claimed combination of specific active ingredients, but where the claim instead:
(a) was to a single active ingredient in combination with another, unspecified active ingredient, e.g. one described to be a member of a class of compounds; or
(b) was to an active ingredient in combination with another, unspecified active ingredient, where the claim language used would ordinarily extend to protect the combination (in an infringement context).

The judgments

In relation to Article 3(a), the CJEU decided in all three of these cases that in order to get a SPC for a combination product, it was necessary to have a claim in a patent which specified the active ingredients for which supplementary protection was being sought. It was not enough to get an SPC on a combination product to have just a patent claim to only one component of the combination. In addressing this question, the CJEU decided that Article 3(a) was to be interpreted as precluding the grant of a SPC, where the active ingredients specified in the SPC application included active ingredients not identified in the wording of the claims of the basic patent. The CJEU thus ruled out the so-called "infringement"-type test, for the determination of whether a product was protected by a basic patent, within the meaning of Article 3(a).

In relation to Article 3(b), the CJEU decided that there did not have to be a precise match between a patented active ingredient and a sole active component in an authorised medicinal product. An SPC could still be granted for a particular active ingredient, even if it was only authorised for use in a medicine as merely one component of a medicinal product. Unfortunately, the CJEU did not address directly either of the two scenarios posited by the English Patents Court in the Daiichi referral (as set out above). It repeated its conclusion in the Medeva and Georgetown cases, i.e. that Article 3(a) was to be interpreted as precluding the grant of a SPC for a combination product, when an active ingredient specified in the SPC application is not identified in the wording of the claims of the basic patent.

Finally, in the Queensland decision, the CJEU stated that where a process patent is chosen for extension under the SPC regime, Article 3(a) precludes an SPC from being granted for a product other than one identified in the wording of the claims of the patent as the product deriving from the relevant process.

Implications of the decisions

The ramifications of these decisions are still being considered, but already the English Patents Court has stated that the

test put forward by the CJEU in the Medeva, Georgetown and Daiichi cases is unclear (see the comments of Mr Justice Arnold in the case of Novartis v MedImmune, judgment of 10 February 2012). Although the words 'specified' and 'identified' in the claims appear on first impression to suggest a rigid test for compliance with Article 3(a) - in relation to combination products at least - questions arise as to what degree of specificity is actually required in order to get a SPC. It seems that there will need to be further references to the CJEU in order to obtain yet further clarification of the criteria for the grant of a SPC in Article 3(a).

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