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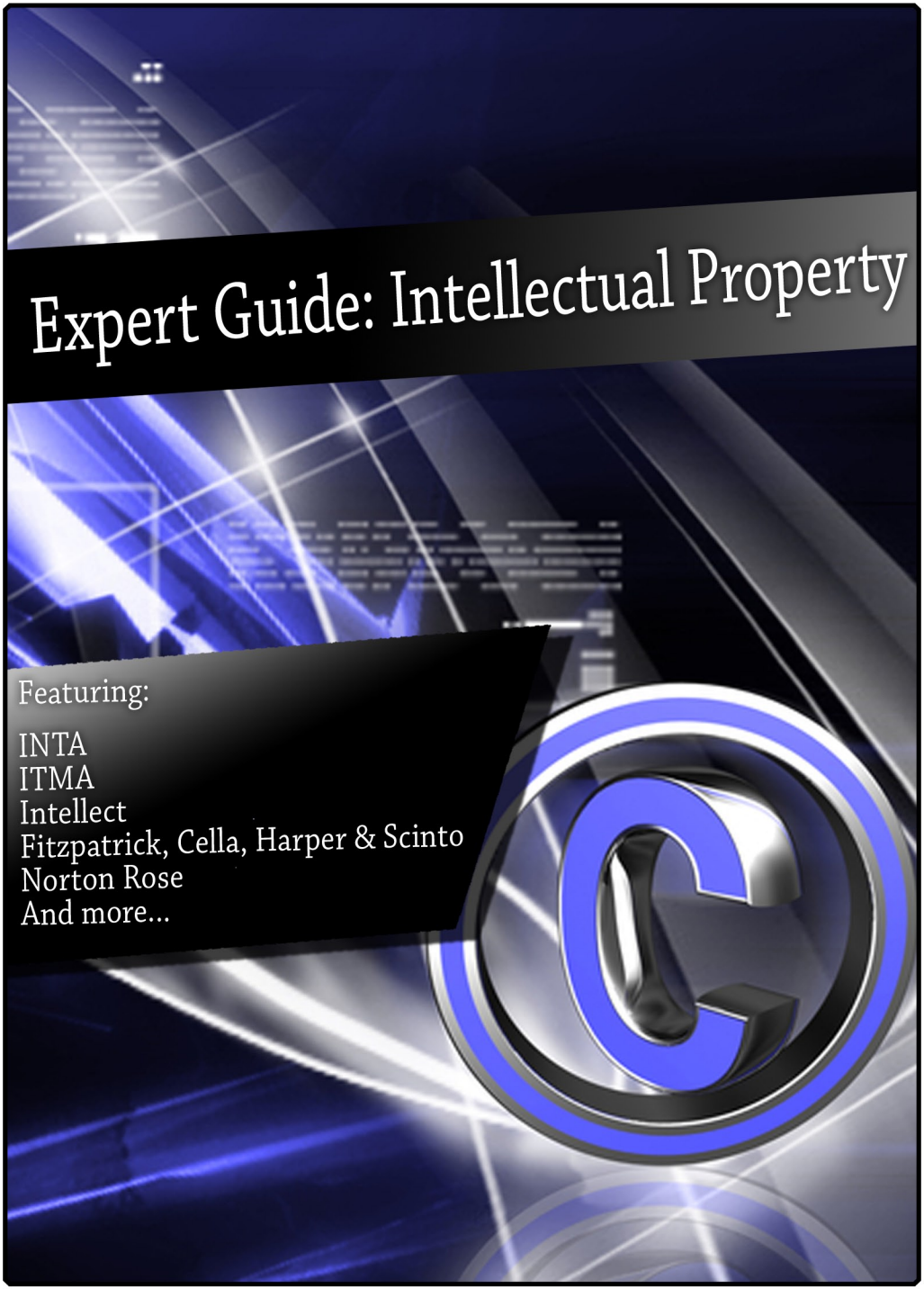

Implications for Business: the Impact of the ECJ's ruling in Medeva and Georgetown

By Sandra Pohlman

In recent years, the issue of supplementary protection certificates (SPCs) for combination products became controversial within the EU, with inconsistent positions taken among the member countries.

The European Court of Justice (ECJ) issued its long awaited decisions in the cases of Medeva BV v. Comptroller-General of Patents, Designs and Trademarks (United Kingdom) (C 322/10) ("Medeva") and Georgetown University, University of Rochester, Loyola University of Chicago v. Comptroller-General of Patents, Designs and Trademarks (United Kingdom) (C 422/10) ("Georgetown") on 24th November 2011. These cases dealt with the requirements for obtaining SPCs for medicinal products containing combinations of active ingredients.

SPCs provide up to five years of additional patent protection with respect to a medicinal product approved in the European Union (EU) and protected by a patent. Thus, SPCs are of great importance and commercial value to pharmaceutical innovator companies.

SPCs are governed by Regulation (EC) No. 469/2009 of the European parliaments and of the Council of 6 May 2009 concerning supplementary protection certificate for medicinal products ("SPC Regulation")1. The purpose of the regulation is to reward innovator companies for the costs associated with bringing a medicinal product to the European market and thus provide incentive for them to research and develop new medicines (see recitals 2 and 3 of the Regulation).

The requirements for obtaining an SPC are set out in Article 3 of the Regulation. Specifically, an SPC shall be granted if:

"(a) the product is protected by a basic patent in force;

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

(c) the product has not already been the subject of a certificate;

(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product."

In the absence of one of these requirements being met, a national patent office that undertakes a substantive review of SPC applications will deny the grant of an SPC. A granted SPC that does not meet any of the above requirements is invalid and may be challenged in national courts (Article 15).

Within the EU, controversy arose as to whether a combination product, for example, a medicinal product containing active ingredient A and active ingredient B, is protected by the basic patent under Article 3(a) if such patent contains a claim for only one of the active ingredients. Furthermore, under Article 3(b), national patent offices and courts had refused SPCs when the approved product did not contain the same combination as the patented product (i.e., the approved product contained active ingredients A, B, C and D and the patent contained a claim to active ingredient A and/or a claim to a combination of active ingredients C and D).

The Medeva and Georgetown cases related to multi-component vaccines containing several antigens, the SPC applications for which were refused in the United Kingdom under Article 3(a) and Article 3(b). The referred questions in each case were essentially the same and the ECJ heard both cases together, handing down the two decisions on the same day. In Medeva, the ECJ decided as follows:

"1. Article 3(a) of Regulation ... 469/2009 ... must be interpreted as precluding the competent industrial property office of a Member State from granting a supplementary protection certificate relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the application for such a certificate.

2. Article 3(b) of Regulation ... 469/2009 must be interpreted as meaning that, provided the other requirements laid down in Article 3 are also met, that provision does not preclude the competent industrial property office of a Member State from granting a supplementary protection certificate for a combination of two active ingredients, corresponding to that specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the marketing authorisation is submitted in support of the application for a special [sic:supplementary] protection certificate contains not only that combination of the two active ingredients but also other active ingredients".

In Georgetown, the ECJ ruled as follows:

"Article 3(b) ... must be interpreted as meaning that, provided the other requirements laid down in Article 3 are also met, that provision does not preclude the competent industrial property office of a Member State from granting a supplementary protection certificate for an active ingredient specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the marketing authorisation is submitted in support of the supplementary protection certificate application contains not only that active ingredient but also other active ingredients".

For Article 3(a) of the SPC Regulation, the ECJ has defined a new test, namely, that an active ingredient must be "specified in the wording of the claims of the basic patent". This test is not found in the regulation itself or in any national provisions or decisions and hence leads to uncertainty. The ECJ test might be broader than the strict "disclosure" test applied by the courts in the Netherlands and the United Kingdom. Yet, it is clearly more restrictive than the infringement test applied by other European courts, including the German courts.

The question of how the new test applies to other claim types such as generic compound claims or claims to antibodies or recombinant proteins remains wide open.

The ECJ's interpretation of Article 3(b) is rather liberal and opens up opportunities for innovator companies. As long as the product (protected by the basic patent) is among the active ingredients of the approved medicinal product, this satisfies Article 3(b). If the patent claims active ingredients A and B, and the approved product contains active ingredients A, B, C and D, then an SPC for the product A + B can be granted.

The decision does not address the scenario where a marketing approval is for a medicine having active ingredient A, but the approved indications state that it is to be administered as part of a combination dosing regimen with a medicine containing active ingredient B. Decisions from the United Kingdom and Germany held that Article 3(b) precluded the granting of an SPC for product A + B under such circumstances2.

Regarding Article 3(a), the ECJ clarified in a third decision on the next day that if a patent claims a combination (for example, active ingredients A and B) and the approved product contains only one of the active ingredients, such as active ingredient A, then the SPC must be denied under Article 3(a) EPC (Yeda Research and Development Company v Aventis Holdings (C 518/10)). Thus, in such a circumstance, only an SPC for product A may be granted and the basic patent must protect product A.

In terms of enforcement of an SPC for product A against those placing a medicinal product containing active ingredient A on the market with instructions to use it with product B, such action would seem to infringe the SPC for product A, since Article 4 of the SPC Regulation states that an SPC confers protection on a "product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate".

In conclusion, the ECJ may have raised the bar for SPC applicants under Article 3(a), and consequently provided new ammunition for attacking already granted SPCs. Fortunately, Article 3(b) has become a lower hurdle.

1 - http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:152:0001:0010:en:PDF

2 - Anti-Helicobacter Preparation (X 2B 1/08, 2008); Yeda, Patents (2010) EWHC 1733 (German Federal Supreme Court)

The views expressed in this article are those of Ms. Pohlman and do not necessarily represent the views of df-mp

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