# Advocate General delivers opinion in the first of three CJEU referrals concerning Article 3(a) of the SPC Regulation

The Advocate General (Wathelet) has handed down his opinion in *Teva v Gilead* (Case C-121/17) on the interpretation of Article 3(a) of the SPC Regulation.

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In the first of three referrals pending before the CJEU on the interpretation of Article 3(a) of the SPC Regulation - seeking to clarify what it means for a product to be "protected" by a basic patent - the Advocate General (Wathelet) has just handed down his opinion in *Teva v Gilead* (Case C-121/17). The opinion is available here.

The referral from the UK Patent's Court had repeated the question of simply: "what are the criteria" under Article 3(a)? The AG has offered the following answer (emphasis added):

> "Article 3(a) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products precludes the grant of a supplementary protection certificate relating to active ingredients which are not specified in the wording of the claims of the basic patent. **The fact that a substance or combination of substances falls within the scope of protection of the basic patent is a necessary, but not sufficient, requirement** for it to constitute a product protected by a patent within the meaning of Article 3(a) of Regulation No 469/2009. A product is protected by a patent within the meaning of Article 3(a) of that regulation if, **on the priority date of the patent, it would have been obvious to a person skilled in the art that the active ingredient in question was specifically and precisely identifiable in the wording of the claims of the basic patent**. In the case of a combination of active ingredients, each active ingredient in that combination must be specifically, precisely and individually identifiable in the wording of the claims of the basic patent."

The AG considers the term "protected" at length and finds that the fulfilment of Article 3(a) is founded "only in the wording, or interpretation of the wording, of the claims of the patent granted, and nowhere else". In this way, the AG dismisses the "core inventive advance" test (as advocated by the Member States who made submissions), noting that it "runs the risk, in [his] view, of giving rise to confusion with the criteria for determining whether an invention is patentable". Nonetheless, the AG opines that scope of protection under the EPC and national Member State law is a "necessary but not sufficient condition" for Article 3(a). The additional requirement that the AG has devised in respect of being "specifically and precisely identifiable" concocts a yet further formulation which does not appear to have been

advanced by any of the parties (or non-parties) to the case. The opinion also seems to advocate a separate and specific test for combination SPCs, adding that each active ingredient must not only be specifically and precisely identifiable, but also “individually” identifiable.

It remains to be seen whether the CJEU will follow this opinion when it delivers its decision - expected in the summer. In any event, were the CJEU to follow this opinion, the UK Patents Court will need to consider the proposed test/criteria and apply it to the facts of the case. As noted by the AG, despite proffering an answer that the proposed test would not be satisfied by the SPC in question, this remains subject to the assessment of the referring court.

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