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ADVOCATE GENERAL PROVIDES OPINION ON THE INTERPRETATION OF ARTICLE 3(A) SPC REGULATION

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Legal Briefings – By **Sebastian Moore, Alex Freelove, Julian Gauld and Grace Pead**

Advocate General Wathelet (the "AG") has provided his opinion to the Court of Justice of the European Union (the "CJEU") on the interpretation of Article 3(a) SPC Regulation (Case C-121/17 *Teva v Gilead*). In doing so, the AG rejected the suggestion of the English referring court that the concept of the "core inventive advance" was a relevant consideration in determining whether a basic patent protects an active ingredient within the meaning of Article 3(a).

In his view, the means of determining whether a basic patent protects an active ingredient within the meaning of Article 3(a) is to be found only in the wording, or interpretation of the wording, of the claims of the granted patent, and nowhere else. A product is protected by a patent in accordance with Article 3(a) of the SPC 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.

1. BUSINESS IMPACT

- This non-binding opinion is of interest to all stakeholders in the pharmaceutical industry. It is the latest in a line of pronouncements from the CJEU in which the interpretation of Article 3(a) of the SPC Regulation has been discussed.

- This opinion is of interest in that it rejects the "core inventive advance" test that has previously been proposed by the English Courts.

- Whilst the opinion is non-binding on the CJEU, if the CJEU were to follow the reasoning of the opinion in its decision, the validity of an SPC in subsequent national proceedings would depend on the facts before the national court as to whether 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.

- The CJEU's decision is expected in the coming months and it will be interesting to see if that decision will be broad enough to dispose of two other pending references on the interpretation of Article 3(a) that have been referred by the English Court of Appeal and German Federal Patent Court.

2. BACKGROUND

Gilead's UK SPC covers pharmaceutical compositions comprising the combination of tenofovir disoproxil and emtricitabine, a preferred "backbone" of active ingredients for the treatment of HIV. Such products include Gilead's blockbuster anti-HIV treatments TRUVADA® and ATRIPLA®.

In 2016, Teva, Generics UK (t/a Mylan), Accord and Lupin commenced proceedings against Gilead in the High Court of England and Wales. They sought to revoke the SPC on the basis that the product the subject of the SPC is not protected by the basic patent.

Mr Justice Arnold delivered his judgment in January 2017. He found he was unable to decide on validity of the SPC on the basis of the existing CJEU case law and he therefore referred a single question to the CJEU: *“What are the criteria for deciding whether ‘the product is protected by a basic patent in force’ in Article 3(a) of the SPC Regulation?”* (Case C-121/17).

The case was heard before 15 judges of the Grand Chamber of the CJEU on 20 February 2018, reflecting the importance of the question.

3. THE AG'S OPINION

Advocate General Wathelet delivered his opinion on 25 April 2018. The AG considered the line of CJEU cases dealing with Article 3(a) SPC Regulation since the key 2011 decision in *Medeva*.

As part of his considerations, the AG rejected the suggestion of the referring court that the concept of the "core inventive advance" was a relevant consideration in determining whether a basic patent protects an active ingredient within the meaning of Article 3(a).

In his view, determining whether a basic patent protects an active ingredient within the meaning of Article 3(a) is to be found only in the wording, or interpretation of the wording, of the claims of the granted patent, and nowhere else. A necessary starting point for determining this is whether a substance or combination of substances falls within the scope of protection of a patent, in particular under Article 69 of the EPC and the Protocol on its interpretation and the provisions of relevant national law.

The AG's conclusion was that a product is protected by a patent in accordance with Article 3(a) of the SPC 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.

The AG's opinion is not binding on the CJEU and it is not certain that the CJEU will follow the same reasoning when it decides the case in the coming months. However, if the CJEU does adopt the AG's opinion, it will be for the national courts to determine the validity of the SPC at issue, based on the facts before them as to whether 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.

It will be interesting to see if the CJEU's decision will be broad enough to dispose of the two other pending references on the interpretation of Article 3(a): one referred by the English Court of Appeal (Case C-650/17 Sandoz v Searle), and the other referred by the German Federal Patent Court (Case C-650/17 Royalty Pharma/Sitagliptin).

KEY CONTACTS

If you have any questions, or would like to know how this might affect your business, phone, or email these key contacts.

SEBASTIAN MOORE
PARTNER AND HEAD OF INTELLECTUAL PROPERTY, UK, LONDON
+39 02 3602 1398
Sebastian.Moore@hsf.com

ALEX FREELOVE
SENIOR ASSOCIATE, LONDON
+44 20 7466 7452
Alex.Freelove@hsf.com

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