ARTICLE

EZETIMIBE-SIMVASTATIN SPC INVALID IN FRANCE FOR NON-COMPLIANCE WITH BOTH ARTICLES 3A) AND 3C) OF REGULATION NO 469/2009

Patent Law | 01/10/20 | François Pochart

PROPRIÉTÉ INTELLECTUELLE

The Court of appeal of Paris, in a decision on the merits, has ruled that the supplementary protection certificate ("SPC") covering the combination of ezetimibe and simvastatine is invalidl. The decision was rendered on September 25, 2020, in a case opposing Merck and Teva (free translation available here). This is the first decision in Europe on the merits to be rendered by an appellate court.

Facts of the case

The basic patent

The basic patent protects novel compounds useful in the treatment and prevention of atherosclerosis, and mentions combinations with other active principles. It specifically claims ezetimibe (claim 8) as well as the combination ezetimibe-simvastatine (claim 17).

The SPC

Merck filed multiple SPCs on the ezetimibe basic patent. The first granted SPC covered ezetimibe alone, and the second the combination of ezetimibe and simvastatine. Merck filed two other SPCs for other combinations with statins (not granted).

Court reasoning

Although the Court was presented with various CJEU decisions, it focuses on Sanofi (C-443/12)[1], Georgetown (C-484/12)[2], Gilead (C121/17)[3] and Royalty Pharma (C650/17)[4], and especially Sanofi.

The Court considers the situation to be very close to the Sanofi one. It also considers Gilead and Royalty Pharma refer to situations in which (i) one of the active principles was not named by its chemical name, and (ii) the SPC granted for the combination product was the first one on that basic patent – and the only one, too. The Court therefore considers that the notion of "distinct product" in recitals 29 + 30 of Georgetown, and in Sanofi, is not applicable to Gilead / Royalty Pharma.

In Georgetown and Sanofi, where -as in the present case- the same basic patent could serve as a basis for multiple SPCs, there is a requirement that the basic patent protects distinct products.

The question to be answered, according to the Court, is whether for the skilled person the combination product is a distinct product over the single active ingredient product. To that end the skilled person reads the specification and claims of the basic patent, using if necessary Art 69 EPC and its interpretation protocol[5], and can use his general knowledge.

The Court reads the patent and emphasises that the specification

- uses the singular when designating the invention,
- presents the combinations as "another aspect of the invention",
- makes no distinction in therapeutic effect between the monotherapy and the combination therapies.

The Court mentions that at the relevant date, the skilled person was well aware of the combination of anticholesterolemic drugs having different modes of action, and also was aware of statins.

The skilled person will therefore not consider that the ezetimibe simvastatine combination is a distinct product protected as such in the basic patent.

The Court further refers to Sanofi and recital 40, and mentions that in Sanofi and in the present case, (i) the basic patent had already served as a basis for the mono product, and (ii) the mono SPC could have been used against combination products having a similar indication.

The Court rules the SPC is invalid based on 3a) and 3c)[6].

The decision can be appealed to the Supreme Court. Of note, the Supreme Court is already considering three ezetimibe-simvastatine SPC cases, involving Biogaran, Mylan and Sandoz, on appeal of PI cases (not on the merits as in the Teva case).

Originally published in Kluwer : http://patentblog.kluweriplaw.com/2020/09/29/ezetimibe-simvastatin-spc-invalid-in-france-for-non-compliance-with-both-3a-and-3c/

[1] CJEU, December 12, 2013, case C-443/12, Actavis Group PTC EHF and Actavis UK Ltd v Sanofi, available here: http://curia.europa.eu/juris/liste.jsf?language=en&jur=C,T,F&num=C-443/12&td=ALL

[2] CJEU, December 12, 2013, case C-484/12, Georgetown University v Octrooicentrum Nederland, available here: http://curia.europa.eu/juris/liste.jsf?language=en&jur=C,T,F&num=c-484/12&td=ALL

[3] CJEU, July 25, 2018, case C-121/17, Teva UK Ltd and Others v Gilead Sciences Inc., available here : http://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=C-121/17

[4] CJEU, April 30, 2020, case C-650/17, Royalty Pharma Collection Trust v Deutsches Patent- und Markenamt, available here : http://curia.europa.eu/juris/liste.jsf?num=C-650/17&language=en

[5] https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar69.html

[6] Regulation No 469/2009 available here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009R0469