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What does Article 3(a) of the SPC regulation* mean by "protected by a basic patent"?

Laura Reynolds (Bristows) · Thursday, April 26th, 2018

Yesterday, 25 April 2018, AG Wathelet has handed down his opinion in the **Teva v Gilead** reference (Case C-121/17) suggesting that the question should be answered as follows:

"*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 … A product is protected by a patent … 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.*" (emphasis added).

This case concerned an SPC Gilead had obtained for the combination of tenofovir and emtricitabine based upon Gilead's patent, which claimed "*A pharmaceutical composition comprising a compound according to any one of claims 1 to 25 together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients*". It was clear that the patent protected tenofovir, which was claimed in claim 25, but emtricitabine was not disclosed in the patent and there was no evidence that it was known to be efficacious at the priority date of the patent. Gilead had relied upon the fact that "*optionally other therapeutic ingredients*" would encompass emtricitabine to obtain the SPC.

The AG agreed with Arnold J, who made the reference, that it is necessary but not sufficient that the product falls within at least one of the claims of the basic patent under the Extent of Protection Rules**. However he did not agree with Arnold J that it is necessary to determine whether the product embodies the inventive advance of the patent, which is referred to in the CJEU's decision in **Actavis v Sanofi** (C-443/12), noting that the Actavis case was only concerned with Article 3(c), not 3(a) and commenting that he had difficulty in understanding the difference between the "core inventive advance" and the invention disclosed by the claims. Instead he found it clear from CJEU case law that the only means for determining whether the product is protected by the basic patent "*is to be found only in the wording, or interpretation of the wording, of the claims of the patent … and nowhere else*". The issue is with what degree of specificity or abstraction a product needs to be "specified" in the claims.

It is clear that the AG is of the opinion that the patent did not "specifically and precisely" identify

emtricitabine for the purposes of Article 3(a) although, as the AG acknowledges, this is a matter for the national court to decide. What is not clear is the extent (if any) to which the AG had in mind the two other pending references***: **Royalty Pharma's application** (C-650/17), which concerns an SPC for sitagliptin based upon a patent which did not individually disclose sitagliptin (indeed sitagliptin was developed after the priority date of the patent) and **Sandoz v GD Searle** ([2018] EWCA Civ 49) which concerns an SPC for darunavir based upon a patent which did not individually disclose darunavir but had claims in the form of a Markush formula, which covered darunavir.

The AG for the first time, suggests that the CJEU should take account of what would have been obvious to a person skilled in the art as having been identifiable in the claims of the patent at the priority date. It is difficult to see how such a test would be a simple test that can be easily applied by national patent offices without, in some cases, needing evidence as to what the skilled person would have known at the priority date. It will be interesting to see if the CJEU follows this opinion.

*Regulation No 469/2009
**As set out in Article 69 of the European Patent Convention
***The AG refers to the existence of the two other references at the start of the opinion, but they are not referred to expressly anywhere else.

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