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Round and round and round we go: Another Article 3 SPC Reference

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SPCs are often valuable and therefore important to their proprietors. Indeed, such is the potential value of an additional period of exclusivity, that in the last decade or so, we have seen SPCs challenged where only a few weeks or even a few days of the SPC term remain. It is therefore hardly surprising, especially in light of the often Delphic language used by the CJEU in its rulings, that parties will fight hard to argue each and every point of possible ambiguity.

In the past few weeks, in ongoing proceedings relating to Merck's SPC for the combination of ezetimibe and simvastatin, the Supreme Court of Ireland has referred a series of questions to the CJEU on the interpretation of Articles 3(a) and 3(c) of the SPC Regulation. This is despite the two lower Irish Courts having found the SPC to be invalid. The patent on which the SPC was based was directed to hydroxysubstituted azetidinones used to lower cholesterol (including ezetimibe) but also contained claims to combinations of such agents in combination with other compounds known to lower cholesterol (including statins such as simvastatin).

In relation to Article 3(a) and whether the combination was protected by a basic patent in force, Merck argued that there were three possible interpretations: (i) that the product should simply fall within the scope of the claims of the basic patent; (ii) a so-called "identificatory" approach in which the product needed to be identified in the wording of the claims either expressly or to the requisite degree of precision and (iii) that the product represented an inventive advance within the patent. Merck contended that the lower Irish Courts had adopted the third, qualitative test but that this approach had been expressly rejected in the Teva and Royalty Pharma cases[1]. As the Supreme Court put it, "*In [Merck's] view, only where the active ingredients are not expressly identified in the claims must the description and drawings relating to the ingredient be taken into account*". Merck's view stems from an arguably acontextual reading of the ruling of the Grand Chamber of the CJEU in Teva:

"Article 3(a) of [the SPC Regulation] must be interpreted as meaning that a product composed of several active ingredients with a combined effect is 'protected by a basic patent in force' within the meaning of that provision where, ***even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent****, those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:*

– *the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and*

– *each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent."*

Clonmel's arguments were based more on policy and context. They contended that an express reference to a combination in the claims of a patent could not be conclusive of the Article 3(a) issue. This policy argument had appeared to find favour with at least the first instance court in Ireland which had opined that if Merck were right and that naming the combination in the claims was the be-all and the end-all: "*it would have the bizarre consequence that the concerns expressed by the CJEU [about the granting of an SPC for a product not covered by the patent] could easily be side-stepped by those patentees who taken the course of assiduously listing expressly in the claims of the relevant patent a large range of products or combinations of products where those claims went beyond the limits of the underlying invention*." Clonmel thus contended that the CJEU in Teva had not proposed a triumph of form over substance and that the description and drawings of the patent should be taken into account when ascertaining the limits of the invention in that basic patent, relying on among others, paragraph 40 of the ruling of the CJEU in Teva:"*However, it is not the purpose of the SPC to extend the protection conferred by that patent beyond the invention which the patent covers. It would be contrary to the objective of Regulation No 469/2009 … to grant an SPC for a product which does not fall under the invention covered by the basic patent, inasmuch as such an SPC would not relate to the results of the research claimed under that patent.*"

As regards the 3(c) issue, this provision has been largely left undisturbed since the rulings of the court in Sanofi v Actavis[2] and Boehringer Ingelheim v Actavis[3] which held that even if Article 3(a) was satisfied, in circumstances where a basic patent included a claim to a product comprising an active ingredient which constituted the sole subject matter of the invention and for which the holder of that patent had already obtained an SPC as well as a subsequent claim to a product comprising a combination of that active ingredient and another substance, Article 3(c) would preclude the holder from obtaining a second SPC for the combination. In the face of this comparatively clear ruling, Merck sought to differentiate between the situation in Boehringer where the patent was amended to introduce claims to the combination which was the subject of a second SPC and the present situation where the claims of the basic patent covered the combination from the outset. At least to the author, this seems an odd distinction since the claims, once amended, are deemed to have existed in that form *ab initio*. Also the CJEU did not consider it relevant whether the subsequent claim was introduced before or after grant. Merck also argued that the lower Courts in Ireland's misapplication of the law of Article 3(a) had led them to fall into error on 3(c) too and that the product which was protected for 3(a) and which should be considered for 3(c) was the combination of ezetimibe and simvastatin. For its part, Clonmel pointed to the fact that the Boehringer case had been referred to expressly in the Teva ruling at paragraphs 41 and 42 of the decision and had not been overruled or doubted. Therefore Article 3(c) serves to prevent the situation whereby a patent holder could obtain a new SPC each time it placed on the market a medicinal product containing the active ingredient protected as such by the holder's basic patent and another substance which does not constitute the subject matter of the invention.

Ultimately, the Irish Supreme Court decided that it was appropriate for them to make a reference. The following questions were referred:

1. (a) For the purpose of the grant of a supplementary protection certificate, and for the validity of that SPC in law, under Article 3(a) of Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L152/1, does it suffice that the product for which the SPC is granted is expressly identified in the patent claims, and covered by it; or is it necessary for the grant of an SPC that the patent holder, who has been granted a marketing authorisation, also demonstrate novelty or inventiveness or that the product falls within a narrower concept described as the invention covered by the patent?

1. (b) If the latter, the invention covered by the patent, what must be established by the patent holder and marketing authorisation holder to obtain a valid SPC?

2. Where, as in this case, the patent is for a particular drug, ezetimibe, and the claims in the patent teach that the application in human medicine may be for the use of that drug alone or in combination with another drug, here, simvastatin, a drug in the public domain, can an SPC be granted under Article 3(a) of the Regulation only for a product comprising ezetimibe, a monotherapy, or can an SPC also be granted for any or all of the combination products identified in the claims in the patent?

3. Where a monotherapy, drug A, in this case ezetimibe, is granted an SPC, or any combination therapy is first granted an SPC for drugs A and B as a combination therapy, which are part of the claims in the patent, though only drug A is itself novel and thus patented, with other drugs being already known or in the public domain; is the grant of an SPC limited to the first marketing of either that monotherapy of drug A or that first combination therapy granted an SPC, A+B, so that, following that first grant, there cannot be a second or third grant of an SPC for the monotherapy or any combination therapy apart from that first combination granted an SPC?

4. If the claims of a patent cover both a single novel molecule and a combination of that molecule with an existing and known drug, perhaps in the public domain, or several such claims for a combination, does Article 3(c) of the Regulation limit the grant of an SPC;

(a) only to the single molecule if marketed as a product ;

(b) the first marketing of a product covered by the patent whether this is the monotherapy of the drug covered by the basic patent in force or the first combination therapy, or

(c) either (a) or (b) at the election of the patentee irrespective of the date of market authorisation?

And if any of the above, why?

The case has now appeared on the CJEU docket as C-149/22. It is to be hoped that any ruling from the CJEU in this reference will bring clarity, particularly with regards to the law on Article 3(a) where the CJEU's ruling in Teva appears not to have brought an end to the uncertainty. As regards Article 3(c), there is no indication that the CJEU has intended to depart from the position it adopted in the two Actavis references, which were decided on highly similar facts, and the policy objectives appear to remain the same – it will therefore be interesting to see how the CJEU respond both to this reference and to the reference on Article 3(c) from the Finnish Market Court (C-119/22) in proceedings concerning Merck's SPC for sitagliptin and metformin.

[1] Cases C-121/17 and combined cases C-650/17 and C-114/18 respectively

[2] C-443/12

[3] C-577/13

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