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Actavis v Boehringer (C-577/13): What is the "sole" subject matter of an invention?

On 12th March 2015, the CJEU handed down its judgment in the *Actavis v Boehringer* referral. This judgment deals with questions referred by the High Court of England and Wales that relate specifically to SPCs for combinations of active ingredients.

The facts of the case underlying the referral follow the fairly common situation where an SPC is granted in respect of an active ingredient A (here telmisartan) and, based on the same basic patent, the patentee subsequently seeks an SPC for a later authorised product comprising a combination of A and a second active ingredient B (here hydrochlorothiazide). The decision is therefore important for many patentees.

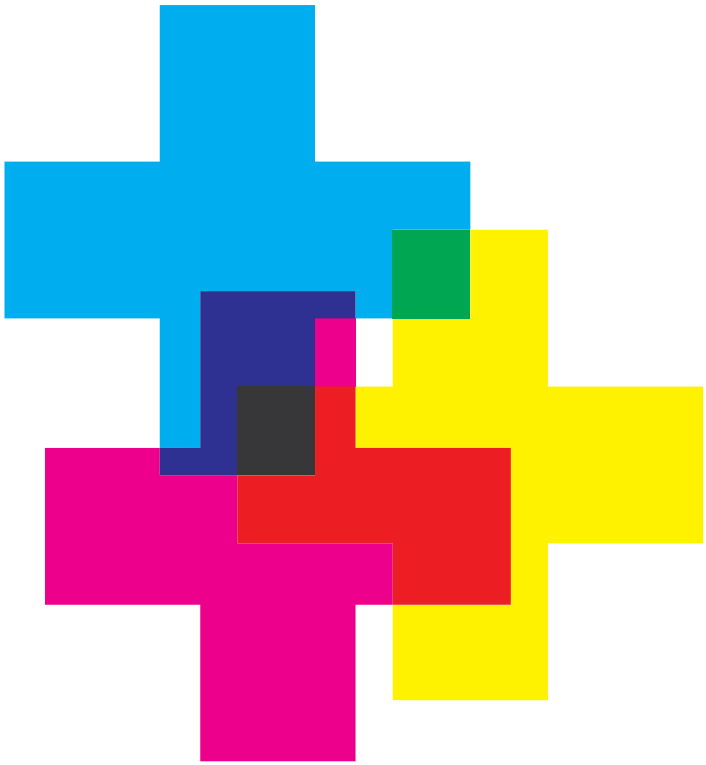
The four questions referred by the High Court to the CJEU can be read in full here. In short, the referral dealt with two general issues.

The first issue is whether the granted SPC for the mono product (the "mono-SPC") precludes the grant of the second SPC to the combination product (the "combo-SPC") and whether it is necessary to consider whether the combo-SPC relates to a distinct and separate invention from the mono-SPC for the purposes of determining whether the conditions of Article 3 of the SPC Regulation are met (see questions 2 and 3). This issue had largely been dealt with by the CJEU before the questions were considered in this case. In *Actavis v Sanofi* (C 443/12), where the facts were similar, the CJEU had held that Article 3(c) precluded the grant of a combo-SPC, where the "core inventive advance" of the patent, i.e. the active ingredient A, had already been the subject of an SPC, particularly when the combo-SPC had a later expiry date.

The second issue is whether it is allowable to amend the basic patent after grant to satisfy Article 3(a) (see questions 1 and 4). Post-grant patent amendment, for example to add a claim which explicitly identifies all active ingredients present in an authorised combination product, is a common way to address earlier CJEU decisions requiring the basic patent to "specify" the active ingredients (e.g *Medeva* (C-322/10) and *Queensland* (C-630/10)). The value of combo-SPCs makes post-grant amendment a useful tool for patentees. The CJEU has not had to consider post-grant amendment before, and so endorsement of that practice would provide much needed certainty to patentees.

In its judgment, the CJEU's view on the first issue was consistent with *Actavis v Sanofi*: the grant of a mono-SPC for an active ingredient which "constitutes the sole subject matter of the invention" precludes the grant of a combo-SPC based on the same patent:

> Article 3(a) and (c) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 16 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that, where a basic patent includes a claim to a product comprising an active ingredient which constitutes the sole subject matter of the invention, for which the holder of that patent has already obtained a supplementary protection certificate, as well as a subsequent claim to a product comprising a combination of that active ingredient and another substance, that provision precludes the holder from obtaining a second supplementary protection certificate for that combination.



The judgment suggests that the parties had agreed that telmisartan constituted the "sole subject matter of the invention" and so it is perhaps not surprising that the CJEU came to this decision in light of its earlier judgment in *Actavis v Sanofi* (C 443/12). However, the concept of the "subject matter" of an invention seems unclear. The hydrochlorothiazide was not claimed and therefore could reasonably be said not to be part of the "subject matter of the invention". In contrast, the combination was claimed (albeit after a post-grant amendment), so why did it not constitute part of the subject matter of the invention? It is not clear whether the CJEU considered this option given the parties' apparent agreement that telmisartan alone was the "sole" subject matter of the invention in the patent.

The second and still very important issue regarding post-grant amendment was not answered by the CJEU in view of its answer to the first issue. It is disappointing that the CJEU did not tackle this point head-on given its potential impact on patentees. We can expect it to be referred to the CJEU again.

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