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CJEU provides new guidance on combination SPCs in Teva v. MSD (C-119/22) and MSD v. Clonmel (C-149/22)

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The eagerly awaited CJEU decision on the two joined referrals *Teva v. MSD* (C-119/22) and *MSD v. Clonmel* (C-149/22) relating to SPCs for combination products was handed down today on December 19, 2024.

The two referrals arose from national litigation involving SPCs for a combination of active ingredients, i.e., the combination of sitagliptin and metformin in C-119/22 and the combination of ezetimibe and simvastatin in C-149/22. In both cases, SPC holder Merck/MSD had previously obtained an SPC for one single component of the respective drug combination, i.e., sitagliptin alone or ezetimibe alone. The questions referred to the CJEU thus revolved around the interpretation of Article 3(c) of the SPC Regulation, requiring that no prior SPC must have been granted for the same product to the same patent holder, and the interpretation of Article 3(a), requiring that the product is protected by the basic patent.

Falling back into old habits, the CJEU reformulated no less than six of the carefully phrased questions referred by the Market Court of Finland and the Supreme Court of Ireland into a single new question, namely whether Article 3(c) of the SPC Regulation precludes the grant of an SPC for a product consisting of two active ingredients where one of these active ingredients alone has already been the subject of an earlier SPC (and where the other active ingredient was already known in the art).

According to the CJEU, it follows from the strict interpretation of the term “product” endorsed in its prior decisions *Abraxis Bioscience (C-443/17)* and *Santen (C-673/18)* that a product which is a combination of two active ingredients A+B must necessarily be regarded as different from a product which is a single active ingredient A or B. There is no basis for giving the term “product” a different meaning in the context of Article 3(c) than in connection with Article 3(a). Therefore, an SPC for the combination A+B generally cannot be refused under Article 3(c) merely because a prior SPC has already been granted for one of the respective single active ingredients A or B alone. In line with this, the disclosure-content of the basic patent is plainly irrelevant in the context of Article 3(c).

While it may appear self-evident that A+B is a product different from A alone, this decision puts an end to the CJEU’s prior *Actavis* case law (*Actavis v. Sanofi, C-443/12*, and *Actavis v. Boehringer Ingelheim, C-577/13*), in which it had been held, simply put, that a combination product is different from a single active ingredient claimed in the same basic patent only if it

concerns “a totally separate innovation” (using the Court’s words in *Actavis v. Sanofi*). Under the new approach established in the present decision C-119/22, no such assessment is required in the context of Article 3(c) anymore.

The CJEU did not miss the opportunity to point out that its new interpretation of Article 3(c) is consistent with the intention of the EU legislature “*to establish a simple system based on conditions which are, in principle, easy to verify*”.

Turning to the other referred questions relating to the interpretation of Article 3(a), the Court of Justice found that the express mentioning of a product in the claims of the basic patent does not suffice to conclude that the condition of Article 3(a) is satisfied. Rather, the two-part test established in *Teva v. Gilead (C-121/17)* must also be applied in such a case.

While an express mentioning of the product in the claims of the basic patent is indeed enough to meet the second prong of the two-part test, requiring that the product must be specifically identifiable based on the disclosure of the patent, it does not necessarily suffice to meet the first prong of this test, requiring that the product must “fall under the invention” covered by the basic patent. Rather, what the CJEU seems to call for in relation to this first prong is an “*explanation as to how the product is required for the solution of the technical problem disclosed by the basic patent*” or, in other words, “*the patent specification disclosing how that product constitutes a technical feature required for the solution of the technical problem disclosed by that patent*”.

Specifically in the case where a basic patent teaches that a single active ingredient A can be used alone or in combination with a previously known active ingredient B, the CJEU held that under the first prong of the two-part test, “*the specification of that patent must still disclose how the combination of those two active ingredients is a feature required for the solution of the technical problem disclosed by the same patent*”. Alluding to the Advocate General’s opinion, the Court observed that: “*If the basic patent discloses that the combination of the two active ingredients has a combined effect going beyond the mere addition of the effects of those two active ingredients and which contributes to the solution of the technical problem, it may be concluded that the combination of those two active ingredients necessarily falls under the invention covered by that patent.*”

Arguably, it could be held that the assessment of combination SPCs has not changed much after all. Despite the radical simplification of the Article 3(c) condition, an evaluation similar to that under the *Actavis* case law might now be required under Article 3(a) – and that in all cases, not only where there is a prior SPC for a single active ingredient. Yet, contrary to the *Actavis* decisions, it may not be necessary to show the presence of separate or distinct inventions but rather to explain that the combination product solves a technical problem disclosed in the patent. There still seems to be ample room for arguments as to how exactly this condition should be applied, and it will be interesting to see how the national courts will make use of the guidance provided by the CJEU.

Further insights might also follow with the forthcoming CJEU decision in *Halozyme (C-456/24)*. While the main focus of this pending referral is the question under which conditions a substance that is expressly designated as an excipient in the marketing authorization documents may nevertheless be regarded as an active ingredient, it also addresses the application of Article 3(a) in the case of combination SPCs and the required disclosure in the basic patent.

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