EIP

Novartis overloaded with reasons its iron overload treatment Exjade is obvious and not infringed by Teva

Teva v Novartis[2022] EWHC 2847 (Pat)

In another patent revocation and infringement counterclaim action between Teva and Novartis, in this instance involving a swallowable tablet version of Novartis's "Exjade®" used to treat blood iron overload, previously only available as a dispersible tablet in Europe since 2006, His Honour Judge Hacon found, in a decision handed down on 10 November 2022, lack of inventive step with respect to two Novartis formulation patents (EP 2,964,202 and EP 3,124,018), and that Teva's generic product "Teva DFX" did not infringe the patents on either normal construction or on equivalents.

~~Novartis's patents are obvious~~

The patents were found to be obvious over two of the three prior art documents asserted by Teva on the basis that the invention was "an obvious modification" to each document. Adopting Birss J's (as he then was) comments in Hospira UK v Genentech, HHJ Hacon rejected the relevance of Technograph as asserted by Novartis, and instead found that the steps which the skilled team would take at the priority date could readily be ascertained without the taint of hindsight, namely, that the use of deferasirox in swallowable film-coated form and the selection of MCC and poloxamer 188 would have been obvious to try with a reasonable expectation of success[1]. The judge made this finding despite the "limited commercial pressure to try"[2] a reformulated deferasirox into a swallowable tablet.

~~Inventive concept cannot include matter not in the claims~~

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Novartis argued the inventive concept was a swallowable film-coated tablet containing a high load of deferasirox with the claimed excipients, but without sodium lauryl sulphate and lactose, with higher bioavailability compared to Exjade®, and that could be taken with food rather than an empty stomach, the latter of which was only raised in closings. Teva's inventive concept was simply a film-coated tablet formulation with an amount of 45-60% deferasirox.

HHJ Hacon found that because bioavailability and reduced food effect were not set out in the claims of the patents, Novartis could not import these features into in the claims or the inventive concept even if the skilled team reading the patent description would regard them as the most significant technical insight. The reason for this was that the inventive concept of a claim cannot encompass matter which forms no part of the invention as a whole[3].

The judge further found that the relevant question was whether it was obvious at the priority date to make a swallowable tablet as claimed and "nothing more than that"[4]. Matter not within the claim is irrelevant to the assessment of the third and fourth Pozzoli steps. If a product is obvious over a piece of prior art, the validity of a claim to that product cannot be salvaged by pointing to an unexpected "bonus effect" experienced when the product is used, even if it is the "clever bit" as Novartis argued[5]. HHJ Hacon devised his own inventive concept as,

"a swallowable film-coated tablet containing deferasirox in an amount between 45% and 60% of total weight and (subject to variation in conformity with the skilled person's common general knowledge) containing (i) microcrystalline cellulose, (ii) crospovidone, (iii) povidone, (iv) poloxamer 188, (v) colloidal silicon dioxide and (vi) magnesium stearate, and containing no SLS or lactose."**[6]**

~~No infringement by Teva~~

Teva's application for a declaration of non-infringement turned solely on the percentage content of deferasirox in Teva DFX, as outlined in its inventive concept. Novartis's construction of "total weight" which included the tablet coating was favoured by the judge. However, as the amount of deferasirox in Teva DFX was, at its lowest, above the claimed range of 45-60%[7], Teva was outside of the patented claims on normal construction.

On the basis of the judge's inventive concept, and having considered the Actavis questions [8], the variant could not be substantially the same as the inventive concept unless it

strictly complied, and thus there was no finding of equivalence.

p3 [1]Hospira UK Ltd v Genentech Inc [2014] EWHC 3857 (Pat), [127].

[2] [180].

[3] s.125(1) of the Patents Act 1977; Conor Medsystems Inc v Angiotech Pharmaceuticals Inc [2008] UKHL 49, [17]; Actavis UK Ltd v Eli Lilly & Co. [2017] UKSC 48, [65].

[4] [78].

[5]Regen Lab SA v Estar Medical Ltd [2019] EWHC 63 (Pat), [222].

[6] [217].

[7] The exact figures of deferasirox in Teva DFX were treated as confidential.

[8]Actavis UK Ltd v Eli Lilly & Co [2017] UKSC 48.