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UK – Merck seeks SPC relying on the law as set out in Neurim

Katie Cambrook (Bristows) · Wednesday, January 24th, 2024

Question: I applied for my SPC in reliance on the law as set out in *Neurim**[1]*, following *Santen**[2]* can I still obtain my SPC? Answer: No, according to the English High Court*[3]*.

In 2018, i.e. before the *Santen* decision from the CJEU, Merck applied to the UK IPO for an SPC for its medicinal product "MAVENCLAD", which contains the active ingredient cladribine, for relapsing remitting multiple sclerosis. In Spring 2023 this application was refused by the UK IPO on the basis that the MA for MAVENCLAD was not the first MA to place cladribine on the market. Cladribine had been previously approved in the 1990s and 2000s for the treatment of hairy cell leukaemia. The SPC application therefore did not satisfy Article 3(d) of the SPC Regulation.

Merck appealed the refusal of its application to the High Court. It relied on 3 grounds of appeal. These were taken in reverse order by the Court. The third ground Merck relied on was that *Santen* was wrongly decided. While Michael Tappin KC sitting as a judge of the High Court recognised that post-Brexit the UK has the ability the depart from CJEU case law, it was agreed that the High Court did not have the power to do this. That power lies with the Court of Appeal or Supreme Court only. This ground was therefore reserved for further appeals, if allowed.

Ground 2 relied on a difference in the facts of the *Santen* case and those before the Court. In the present case, the new MA was for a new indication and not a new dosage form (as had been considered in *Santen*). The judge dismissed this ground of appeal stating it was clear that the decision in *Santen* was a ruling on the interpretation of Article 3(d) of the SPC Regulation and is not only applicable to the facts as they were in that case.

Ground 3 was the most interesting ground of appeal. Under this ground Merck argued that: (1) the decision in *Santen* should only apply *ex nunc* and not *ex tunc* as those in the industry had an expectation of the continuation of the law in *Neurim;* and (2) Merck itself had an individual expectation that the law in *Nerium* would be applied and the UK IPO and the Court should give effect to that expectation. On this second aspect, while there was no formal evidence before the Court, the Court was willing to accept that the decision in *Neurim* was crucial to Merck continuing to develop the project in relation to cladribine in the expectation that it would receive an SPC. Despite this, none of Merck's arguments came to their aid. The Court held that while temporal limitations on judgments from the CJEU can be imposed – such that decisions apply *ex nunc* – these are done only in exceptional circumstances and only the CJEU itself can place such limitations on its judgments (as set out in *Denkavi Italiana**[4]*). In all other circumstances, even if there was a legitimate expectation relating to the law as it was, judgments of the CJEU apply *ex*

tunc. As there was nothing in the CJEU's decision in *Santen* which provided for any temporal limitation it was held by the Court to apply *ex tunc*. Reference to other Courts or the TBA departing from CJEU or their own decisions did not assist Merck either on the facts. Further there was no representation by the UK IPO that it would grant the SPC and as such it was not open to Merck to seek to rely on case law of a legitimate expectation arising out of reliance on such a representation.

The appeal was therefore dismissed. However, it would seem from Merck's grounds of appeal that it may seek to test whether the UK will look to forge its own way on SPCs post Brexit by taking its case to the Court of Appeal. Readers will have to wait and see.

A copy of the judgment can be found here

[1] C-130/11

[2] C-673/18

[3] Merck Sereno v Comptroller General of Patents [2023] EWHC 3240 (Ch)

[4] C-61/79

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