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Cladribine SPC – a Potential Dilemma for the English Court of Appeal?

Brian Cordery (Bristows) · Monday, February 12th, 2024

It took longer to arrive than expected but here it is. The UK Courts have been given an opportunity to depart from the jurisprudence of the CJEU in their interpretation of the SPC Regulation.

The opportunity has arisen in the following way. In December 2023 the English High Court dismissed an appeal by Merck against a decision of the UKIPO to refuse an application for an SPC for cladribine based on a basic patent entitled "*cladribine for treating multiple sclerosis*". The UKIPO refused the application for lack of compliance with Article 3(d) of the SPC Regulation which requires that the MA relied upon for the SPC is the first MA to place the product on the market as a medicinal product. It was held that the MA relied on by Merck was not the first MA because there were earlier authorisations for cladribine as a treatment for hairy cell leukaemia. Following the decisions of the CJEU in *Abraxis* and *Santen*, it has been clear that the ruling in *Neurim* which first permitted SPCs for second medical uses is no longer good law in the EU. Accordingly the UKIPO refused the application. On appeal to the High Court, Merck raised three points: (i) *Santen* is wrong and the UK should follow its own trajectory in the case-law; (ii) the facts of the case were distinguishable from *Santen;* and (iii) *Santen* had *ex nunc* rather than *ex tunc* effect such that Merck had a legitimate expectation that it would be granted an SPC in accordance with the law as stated in *Neurim*. Ultimately, the High Court found against Merck on points (ii) and (iii) and in relation to (i) it was agreed that a first instance court did not have the power to depart from CJEU case law. The High Court has recently granted Merck permission to appeal to the Court of Appeal and so the latter (which is empowered to depart from CJEU authority) should have the opportunity to choose between following the CJEU case-law and not permitting second medical use SPCs or following a different path. Given that *Neurim* was a reference from the English Court of Appeal (on appeal from a decision of Arnold J) in which Jacob LJ stated: "*In short, if Neurim are wrong [*and an SPC should not be granted*], then the Regulation will not have achieved its key objects for large areas of pharmaceutical research: it will not be fit for purpose*", it will be interesting to see what happens.

Like Natalie Imbruglia in 1997, this author is torn. On the one hand, he despises Brexit with every fibre of his being. Therefore the closer the harmony with continental Europe, the better. However, he has equally strong feelings for the need to incentivise the research and development of further uses for known medicines. Thankfully, the decision is out of his hands and he will await with interest the ruling of the Court of Appeal which could be expected towards the end of this year – possibly sooner since the issues are self-contained.

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