No second chances for insomnia drug SPC

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The grant of supplementary protection certificates (SPCs) has been the subject of numerous recent cases in Europe. In the UK, the latest development in *Neurim Pharmaceuticals (1991) Limited v. Comptroller-General of Patents* [2010] EWHC 976 (Pat) concerned the issue of whether a previously authorised product can be the subject of an SPC for a different indication in a different species.

Neurim applied to the UK Intellectual Property Office (UKIPO) for an SPC in respect of melatonin. The application was based upon a marketing authorization (MA) for Circadin-melatonin which is used to treat insomnia in humans. The UKIPO rejected the application on the basis that melatonin had been previously authorised as the product Regulin for improving the reproductive performance of sheep.

Neurim appealed the decision to the Patents Court on the basis that the Regulin MA was not a relevant MA as it related to the administration of melatonin to a different species and for different indications to Circadian. The UKIPO submitted that the appeal should fail as the SPC Regulation referred to an SPC being granted in respect of the first authorization to place the product on the market as any medicinal product.

Mr Justice Arnold considered the scope of the SPC Regulation and the decisions of the European Court of Justice (now the "CJEU") in the *Pharmacia*, *MIT* and *Yissum* cases. He concluded that the *Yissum* decision was fatal to Neurim's appeal as it confirmed that the grant of a second patent in respect of a particular product did not change what constitutes the first authorization to place that product on the market as a medicinal product. The fact that Regulin was a veterinary product and Circadian was a product for humans did not matter. The crucial issue was that melatonin had already been place on the market as a medicinal product prior to the authorisation of Circadian.

This decision of the UK Patents Court is not surprising given the approach taken in previous cases by the European Court of Justice. However, it does provide a further example of how far patentees are prepared to fight for the right to an SPC. In the meantime, the decision of the English Court of Appeal in the *Medeva* SPC case is eagerly awaited. It is known that a reference to the CJEU will be made but the exact form of the questions has not been released and is not expected until later in May.

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