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# *Neurim* – "the most important SPC judgment ever"

On 19th July 2012 the Court of Justice of the European Union (the "CJEU", Europe's highest court) issued its ruling in case C-130/11 *Neurim Pharmaceuticals*, a case handled by Hugh Goodfellow and Edward Oates of this firm, described by one leading commentator as "the most important SPC judgment ever".

The judgment has a liberalising effect on supplementary protection certificate ("SPC") law and presents new opportunities for extending patents through SPC filings.

Prior to the *Neurim* judgment, and based on a line of jurisprudence that was generally considered to be anti-patentee, it was thought that an SPC was precluded (or its duration was truncated) if the active ingredient in question had been authorised in any earlier marketing authorisation within the EU, even if the earlier authorisation related to a different use in a different species. Today's ruling clarifies that that is not the case and thereby provides an incentive for companies to engage in the research of new uses of previously authorised actives.

## The facts underpinning the dispute

The UK Intellectual Property Office (IPO) had refused to grant Neurim an SPC in respect of Circadin, a patented formulation of melatonin for use in treating sleep disorders by oral administration to human patients over 55. In the marketing authorisation procedure, Circadin had been treated as a new chemical entity by the regulatory authorities on account of the fact that melatonin had not previously been approved for use in humans and, therefore, a full stand-alone marketing authorisation dossier had been required. As a result, 15 years of the life of the basic patent for Circadin had passed before Circadin obtained marketing approval.

The basis of the refusal of the SPC application by the IPO was that, although Circadin was the subject of a basic patent in force, there was an earlier marketing authorisation in the hands of a third party for a different formulation of melatonin called Regulin for regulating the reproductive capacity of sheep by subcutaneous administration behind the ears of ewes to be mated. The IPO held that, because each formulation contained melatonin as an active ingredient, the earlier marketing authorisation for Regulin was the first relevant marketing authorisation under Article 3(d) of the SPC Regulation (EC Regulation 469/2009) and hence the SPC application which relied on the Circadin MA was refused. A further objection was raised under Article 13 (based on an earlier Dutch authorisation relating to fur growth in mink).

The IPO's refusal was initially appealed to the High Court of England and Wales which agreed with the IPO's view that the existing case law was "fatal" to Neurim's position. A further appeal to the Court of Appeal resulted in questions being referred to the Court of Justice.

## The arguments

In a move which surprised many in the industry, Neurim's team did not confine the issues referred to the CJEU to the factual situation at hand (i.e. the situation where the earlier authorisation was a veterinary authorisation and the later authorisation was in humans, requiring a full marketing authorisation dossier). Instead, they asked a broad question based on a new proposition of law. Their proposition was that an earlier authorisation should preclude the SPC application (or truncate its term under Article 13) only if its subject matter is within the scope of the basic patent (with reference to Article 4 which limits the scope of the SPC to being no broader than the basic patent).

Neurim's proposition garnered support from the European Commission but was met by stiff opposition from the

UK Government and the Portuguese Government. Neurim supported its position by referring to the underlying scheme and objectives of the Regulation, highlighting the importance of incentivising the type of research which Neurim had undertaken and the consequences of not providing such incentives. The other parties argued against Neurim based on the earlier jurisprudence of the CJEU, C-31/03 *Pharmacia*, C-431/04 *MIT*, C-202/05 *Yissum*, C-195/09 *Synthon*, C-427/09 *Generics* and C-322/10 *Medeva*. The UK and Portugal also argued that Neurim's approach could lead to evergreening. Both Neurim and the Commission disagreed, highlighting that any SPC granted under Neurim's approach (which requires the basic patent not to extend to the subject matter of the earlier MA) could not, by reference to Article 4, cover the subject matter of the earlier MA – a proposition that the CJEU appears to have confirmed.

## The ruling

The precise terms of the CJEU's ruling are as follows.

> "1. Articles 3 and 4 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that, in a case such as that in the main proceedings, the mere existence of an earlier marketing authorisation obtained for a veterinary medicinal product does not preclude the grant of a supplementary protection certificate for a different application of the same product for which a marketing authorisation has been granted, provided that the application is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate.
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> 2. Article 13(1) of Regulation (EC) No 469/2009 must be interpreted as meaning that it refers to the marketing authorisation of a product which comes within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the supplementary protection certificate."

In referring to "a case such as that in the main proceedings" and "an earlier marketing authorisation obtained for a veterinary medicinal product", the above ruling at first sight avoids explicitly addressing the question of whether the CJEU would have reached the same conclusion had the earlier marketing authorisation related to human use. However, the CJEU's reasoning makes it apparent that the CJEU would indeed have reached the same conclusion had the earlier marketing authorisation related to human use (our emphasis):

> "25. Therefore, if a patent protects a therapeutic application of a known active ingredient which has already been marketed as a medicinal product, for veterinary or human use, for other therapeutic indications, whether or not protected by an earlier patent, the placement on the market of a new medicinal product commercially exploiting the new therapeutic application of the same active ingredient, as protected by the new patent, may enable its proprietor to obtain an SPC, the scope of which, in any event, could cover, not the active ingredient, but only the new use of that product.
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> 26. In such a situation, only the MA of the first medicinal product, comprising the product and authorised for a therapeutic use corresponding to that protected by the patent relied upon for the purposes of the application for the SPC, may be considered to be the first MA of 'that product' as a medicinal product exploiting that new use within the meaning of Article 3(d) of the SPC Regulation ...
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> 30. ... Therefore, the MA referred to in Article 13(1) of the SPC Regulation is the authorisation of a product which is within the limits of the protection conferred by the basic patent relied upon for the purposes of the application for the SPC."

As such, the judgment widens the possibility of obtaining SPC protection and will be enthusiastically received by holders of pharmaceutical and agrochemical patents. It also raises some fascinating questions which have kept us talking and which we look forward to exploring in due course.

## Need advice?

We hope that the above first impression of this decision has been of interest to you. If you have any questions about this decision, or SPCs more generally, our team would be delighted to help:

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