SPCs and paediatric obligations: the need for coordination

Contributed by Arnold & Porter LLP

January 23 2013

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Introduction

On October 24 2012 the UK Intellectual Property Office granted Neurim Pharmaceuticals a supplementary protection certificate (SPC) extending Neurim's patent protection for insomnia treatment Circadin (melatonin) to April 2017. This followed a European Court of Justice (ECJ) decision(1) on a reference by the Court of Appeal(2) concerning the interpretation of the SPC Regulation.(3) Previously, both the Intellectual Property Office(4) and the Patents Court(5) had refused to grant the SPC.

The decision has caused excitement among pharmaceutical companies because of the potential to receive additional SPCs on second medical use patents. However, while this may increase the length of patent protection, it could also trigger an obligation to carry out paediatric studies under the Paediatric Regulation.(6) The Paediatric Regulation requires such studies to be carried out for previously authorised medicinal products only if they are protected by an SPC or a patent that qualifies for an SPC. Therefore, extending the scope of SPC protection may also extend the scope of obligations under the Paediatric Regulation. This update highlights the need for a coordinated approach when considering applying for SPCs for 'old' active substances.

Original application

On September 26 2007 Neurim filed an application at the Intellectual Property Office for an SPC based on its marketing authorisation for Circadin (which includes melatonin as the active ingredient), used for the short-term treatment of insomnia. Melatonin had been previously authorised as the active ingredient in two medicinal products for different veterinary uses.

Until recently, it was generally believed that the applicant for an SPC had to refer to the earliest authorisation of the active ingredient in the European Union, even if the earlier authorisation related to a different use in a different species. Therefore, although the prior uses of melatonin were unrelated to insomnia in humans, the Intellectual Property Office refused to grant the SPC. Neurim challenged this refusal, but the Patents Court agreed with the Intellectual Property Office. However, upon further appeal, the Court of Appeal was not certain that this was correct and referred a number of questions to the ECJ.

ECJ interpretation and return to Intellectual Property Office

The SPC Regulation provides that an SPC will be granted if four criteria are met:

- The product is protected by a basic patent in force.
- A valid authorisation to place the product on the market as a medicinal product has been granted.
- The product has not already been the subject of a certificate.
- The authorisation is the first authorisation to place the product (active ingredient) on the market as a medicinal product.

The ECJ construed the fourth criterion as being limited to the first authorisation for a medicinal product authorised for a therapeutic use protected by the patent. Therefore, where a patent is limited to certain uses of an active ingredient, the relevant marketing authorisation is the first to cover those uses, which is not necessarily the first to cover

the active ingredient itself (or other uses).

As a result, it is now possible for patents for a second medical use of an active substance to be eligible for an SPC; Neurim was granted its SPC in October 2012. This has led many companies to re-evaluate their patent portfolios and consider filing additional SPC applications.

Paediatric Regulation

The Paediatric Regulation aims to facilitate the development and accessibility of medicinal products for use in the paediatric population by ensuring that appropriate studies are carried out. This is primarily done through the agreement of a paediatric investigation plan (PIP) with the European Medicines Agency. The Human Medicines Regulation 2012 sets out various offences in relation to the obligations under the Paediatric Regulation in the United Kingdom.(7)

The Paediatric Regulation requires any application for authorisation of a new medicinal product, including national applications to the Medicines and Healthcare products Regulatory Agency, to include the results of all studies in compliance with an agreed PIP (unless a deferral or waiver has been granted). The same obligation applies to applications for new indications for authorised medicinal products, but only for products that are protected by an SPC or by a patent that qualifies for an SPC.

The cost and time required to agree a PIP and conduct the studies within it can be significant, as the PIP must cover all existing and new indications and formulations. Although a six-month extension of an SPC may be available as a 'reward', companies with existing medicinal products need to consider carefully whether any PIP could be completed in time and, if so, whether the reward will justify the investment.

Comment

In light of *Neurim*, patent groups in many pharmaceutical companies are applying for SPCs on a 'what is there to lose?' basis where it was previously thought impossible. The answer to this apparently rhetorical question is that making such applications could trigger obligations to carry out expensive paediatric studies if the company wants to seek approval for new therapeutic indications for the product.

Timing may be critical. SPC applications must be filed within six months of the later of either the grant of the patent or the grant of the regulatory authorisation. However, similarly strict timing does not apply to the Intellectual Property Office when considering SPC applications (not to mention any subsequent appeal or reference to the ECJ), meaning that the application may still be pending when the next regulatory filing is made. Indeed, Neurim was granted its SPC five years after the application was filed. Therefore, even if the SPC application is ultimately rejected, in the meantime the company may have been prevented from filing for new regulatory approvals without carrying out paediatric studies.

The limitations of the decision in *Neurim* have not yet been tested, but the interpretation of 'first authorisation' certainly opens the door for companies to apply for an SPC on novel grounds. However, such applications should not be made without careful discussion with the company's regulatory group to ensure that the potential additional protection of the SPC is balanced against the potential cost of paediatric development or delayed grant of new therapeutic indications.

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Endnotes

(1) Case C 130/11 (July 19 2012), *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents*.

(2) *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents*, [2011] EWCA Civ 228, CA (Civ Div).

(3) EU Regulation 1768/92 of June 18 1992 concerning the creation of a supplementary protection certificate for medicinal products, now replaced by EU Regulation 469/2009 of May 6 2009 concerning the supplementary protection certificate for medicinal products.

(4) Decision of Dr C L Davies on behalf of the comptroller-general of patents, December 15 2009 (BL O/384/09).

(5) *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General Of Patents*, [2010] EWHC 976 (Pat).

(6) EU Regulation 1901/2006 of December 12 2006 on medicinal products for paediatric use and amending EU Regulation 1768/92, EU Directive 2001/20/EC, EU Directive 2001/83/EC and EU Regulation 726/2004.

(7) Human Medicines Regulation 2012, SI 2012/1916, Reg 89-94.