Court rejects challenge to paediatric extension of SPC for Lipitor

Contributed by **Arnold & Porter LLP**

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On December 20 2012 the Patents Court of England and Wales rejected a challenge brought by Dr Reddy's Laboratories against the six-month paediatric extension of the supplementary protection certificate (SPC) for Pfizer's cholesterol-lowering product atorvastatin (Lipitor).(1) This is the court's first judgment on a challenge to a paediatric extension under the Paediatric Regulation.(2)

Atorvastatin was covered in the United Kingdom by an SPC which originally extended patent protection until November 2011. In July 2008 the European Medicines Agency agreed on a paediatric investigation plan for atorvastatin. The plan required two studies to be completed and a third to be started (and then completed as part of a separate risk management plan). Pfizer completed the first two studies, started the third and applied for an indication for paediatric use. That indication was approved by the European Commission in July 2010 and then by the UK Medicines and Healthcare Products Authority (MHRA) in November 2010.

On that basis, Pfizer obtained a six-month paediatric extension of the SPC, lasting until May 2012. Dr Reddy's Laboratories challenged that extension, claiming that the first two studies under the paediatric investigation plan were insignificant, and that the third study had to be completed before any entitlement to the six-month extension arose.

The key findings of the court were:

- The requirement that studies be "significant" (under Article 45(3) of the Paediatric Regulation) is a transitional one which did not apply in this case, where all studies in the paediatric investigation plan were completed after the Paediatric Regulation entered into force in 2007. The court noted that both the European Medicines Agency's expert committee and the MHRA had stated that the completed studies were significant, but given its finding that the requirement did not apply, the court did not need to consider the point further.
- The requirement to start (but not complete) the third study was lawful under the Paediatric Regulation. A paediatric investigation plan must include studies to generate the "necessary data determining the conditions in which the medicinal products may be used to treat the paediatric population", but can also include requirements to start additional studies.
- Even if the requirement to start (but not complete) the third study had been a technical breach of the Paediatric Regulation, the court had a discretion to revoke the extension (under Article 16 of the SPC Regulation),(3) not an obligation, and this would be an appropriate case where the extension should not be revoked.

The Paediatric Regulation was intended to encourage research into the use of medicines for children. This judgment provides the pharmaceutical industry with greater clarity as to the scope of its obligations, as well as certainty that the reward of a paediatric extension will be upheld.

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Endnotes

(1) *Dr Reddy's Laboratories (UK) Ltd v Warner-Lambert Company LLC*, [2012] EWHC 3715 (Pat); judgment available at www.bailii.org/ew/cases/EWHC/ Patents/2012/3715.html. Dr Reddy's Laboratories have applied for leave to appeal. The *Tribunal de Grande Instance* in Paris rejected a rather different challenge to the paediatric extension for Merck's losartan (Cozaar) on June 8 2012 (in the United Kingdom, the application for that extension had already been

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considered by the Court of Appeal in *E I du Pont Nemours v UKIPO*, [2009] EWCA Civ 966).

(2) Paediatric Regulation 1901/2006.

(3) SPC Regulation 1768/92, now replaced by SPC Regulation 469/2009.