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The Court Of Appeal Allows Correction of a Supplementary Protection Certificate (SPC) Pediatric Extension

Background to the case

Du Pont applied for a 6 month extension to their SPC for the active ingredient Losartan (Cozaar) for pediatric use. They submitted an opinion from the Pediatric Committee confirming that they had completed the required pediatric investigation plan (PIP). The work had been carried out in The Netherlands, and Du Pont was still waiting to receive its amended marketing authorization (MA) containing formal confirmation of the PIP completion.

The UK-IPO refused the application. It did so because, when Du Pont applied for extension the amended MA had not been granted.

The High Court upheld the UK-IPO decision. It held that the opinion from the pediatric Committee was not a substitute for issuance of the amended MA.

Proceedings before the Court of Appeal

The Court of Appeal overturned the decision of the High Court. The Court of Appeal agreed that an opinion from the Pediatric Committee was insufficient to replace formal confirmation of the PIP completion.

However, the Court of Appeal argued that the extension is a reward for complying with the PIP and getting the necessary amended MA, but it should not be dependant upon the timing of that compliance. It found that, if an application does not meet the required conditions, **the UK-IPO should set a time limit for the applicant to cure the "irregularity".**

The Court of Appeal clarified that "irregularity" means matters, missing from the application, which were available at the time or which could only be rectified **after** the date of application.

The Court of Appeal also provided guidance to the UK-IPO on how to judge when an applicant can cure any irregularity. The UK-IPO should take into account the extent to which the applicant is guilty of unreasonable conduct or delay in providing any missing information.

This decision corresponded with the decision of the Dutch, Danish, Irish, Italian and Latvian Patent Offices to allow the extension in The Netherlands, Denmark, Ireland, Italy and Latvia, respectively and so harmonized the procedure.

Background to the Regulation

The Medicines for Pediatric Use Regulation is intended to encourage companies to research and develop medicines for children, in response to the difficulties in getting approval for pediatric medicines, which are generally less lucrative.

Under the Regulation, a pediatric investigation plan (PIP) is approved by the regulator. If the holder of the SPC completes the studies of the PIP they can apply for a 6 month extension to the term of the SPC for the relevant drug.

It is possible to vary an existing marketing authorization (MA) to comply with all measures contained in the PIP.

Until 26 January 2012, the applicant must apply for the extension at least 6 months before the SPC expires. After that date, the applicant must apply for the extension at least two years before the SPC expires.