

# Kluwer Patent Blog

## Another decision on SPCs for combination products

Brian Cordery (Bristows) · Tuesday, July 27th, 2010

The torrent of UK cases concerning applications for supplementary protection certificates (SPCs) shows no sign of abating. Following the reference from the Court of Appeal in June to the CJEU in [Medeva's SPC Applications](#) regarding the scope of the SPC Regulation (see previous post), the issue of SPCs for combination products has arisen again in [Yeda's SPC Applications](#).

Yeda's patent EP (UK) 0 667 165 B1 was filed in 1989 and claimed a therapeutic composition comprising a monoclonal antibody and an anti-neoplastic agent. The patent was previously the subject of an entitlement dispute which was ultimately decided by the House of Lords (see [Yeda v. Rhone-Poulenc](#)). A Marketing Authorization was granted by the European Commission on 26 June 2004 for the monoclonal antibody cetuximab which has since been used to treat various forms of cancer under the brand name Erbitux®. The Marketing Authorization made passing reference to the use of cetuximab in combination with the anti-neoplastic agent, irinotecan.

Yeda subsequently filed two SPC applications with the UK Intellectual Property Office (UKIPO). The first specified the product to be protected as "cetuximab in combination with irinotecan" and the second specified the product as "cetuximab". UKIPO rejected the first application as the Marketing Authorization relied on was for cetuximab alone and rejected the second application because cetuximab (as opposed to the combination of cetuximab and irinotecan) was not protected by the patent.

On appeal, the Patents Court upheld the decision of UKIPO. For the first application, Mr Justice Lewison held that the Marketing Authorization covered cetuximab only and there was no basis to support a conclusion that it covered cetuximab in combination with irinotecan. The brief references to irinotecan in the Summary of Product Characteristics for cetuximab explaining how cetuximab was to be used were insufficient to amount to a marketing authorisation of a product consisting of both cetuximab and irinotecan. The Judge also rejected Yeda's reliance on an earlier Swiss Marketing Authorisation which described the use of irinotecan in more detail as what was relevant was what had been authorised for use in the EU.

For the second application, cetuximab alone was clearly the subject of a Marketing Authorisation so the issue was whether cetuximab alone was "*protected by a basic patent in force*". Claim 1 of the patent claimed the combination of a monoclonal antibody and an anti-neoplastic agent so did not protect the manufacture or supply of cetuximab alone. Yeda argued that the provision of cetuximab on its own could amount to secondary infringement of the basic patent since the Marketing Authorisation said the cetuximab was to be used in conjunction with irinotecan and so it

would have been obvious to the supplier of cetuximab that it was intended for the invention of the patent to be into effect. Irrespective of whether an analysis of infringement was the correct test for assessing whether a product was protected by a basic patent in force, the Judge held that relying on the making of a therapeutic composition in a patient's bloodstream when cetuximab was prescribed along with irinotecan was actually a method of treatment and so not patentable in any event. The second application was therefore also rejected.

This decision highlights the difficulties for patentees in obtaining SPCs when the Marketing Authorisation for a product does not mirror the underlying patent for that product and reinforces the importance of regulatory and patent prosecution teams working together to ensure the future grant of SPCs remains possible. The problem here could have been avoided if the Marketing Authorisation had been framed in such a way that it would have resulted in an authorisation for a combination of cetuximab and irinotecan.

*Medeva's SPC Applications [2010] EWCA Civ 700*

*Yeda's SPC Applications [2010] EWHC 1733 (Pat)*

*Yeda v. Rhone-Poulenc [2007] UKHL 43*

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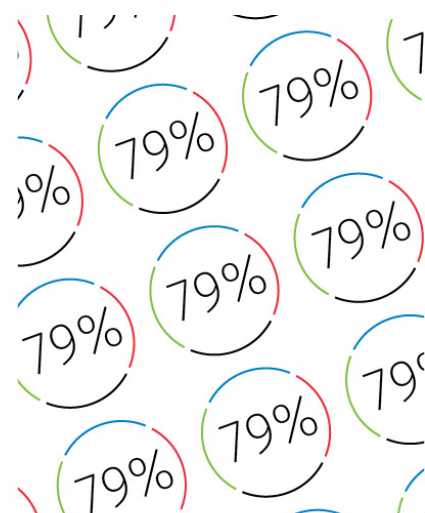
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