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Yet another SPC referral to the CJEU – AstraZeneca v Comptroller General of Patents [2012] EWHC 2840 (Pat)

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When the legislation creating supplementary protection certificates (now consolidated in Regulation 469/2009/EC (the "SPC Regulation")) was first introduced in 1993 no-one could have foreseen the deluge of CJEU references on the interpretation of this "uniform solution" that was to follow. As recently as autumn 2011, one might have expected (or at least hoped) that the **Medeva** and **Georgetown** references would resolve, once and for all, any issues surrounding the interpretation of Articles 3(a) and 3(b) of the SPC Regulation. However this has not proved to be the case – just as one door arguably shut, several more have opened. Further, other aspects of the SPC Regulation have also been subject of references.

A recent reference from the English High Court (Arnold J.) involved the question of the duration of an SPC. The case involved an SPC for AstraZeneca's medicinal product IRESSA® which is used for the treatment of non-small-cell lung cancer. AstraZeneca owns a patent (EP(UK) 0 832 900) (the "900 patent") protecting gefitinib which is the active ingredient in IRESSA. The 900 patent will expire in April 2016. AstraZeneca applied for an SPC for gefitinib at the end of 2009 and an SPC was duly granted with an expiry date of March 2019. The extension of protection was calculated by reference to a marketing authorisation ("MA") granted by the Swiss regulatory authority in March 2004. The Swiss MA was automatically valid in Liechtenstein (which is part of the EEA). As most readers will be aware, under the SPC regime, the date used to calculate the duration of an SPC is that of the first authorisation to place the pharmaceutical product on the market in the EEA.

The Swiss MA had been granted under an accelerated procedure on the basis of Phase II data, and was subsequently suspended pending further data. The European Medicines Agency ("EMA") was not prepared to grant a corresponding MA on the same data set. Instead, AstraZeneca was obliged to perform further clinical trials which led to it being granted its first MA in the EEA a European MA in June 2009.

AstraZeneca contended that the expiry date of its SPC should be April 2021 because the duration of its SPC ought to be calculated by reference to the MA granted by the EMA in 2009, not the 2004 date (in so doing seeking to depart from the CJEU's ruling in *Novartis* that a Swiss MA, automatically recognised in Liechtenstein, will constitute the "*first authorisation to place the product on the market*" for the purposes of Article 13(1) of the SPC Regulation).

Although Arnold J. took a cautious approach (endorsing the Comptroller's position that the Swiss

MA should be used for the Article 13(1) calculation), he acknowledged that the interpretation of Article 13 of the SPC Regulation was not *acte clair*, not least because several national patent offices did not apply *Novartis* in this situation. Accordingly, Mr Justice Arnold referred the following questions to the CJEU:

1. Is a Swiss marketing authorisation not granted pursuant to the administrative authorisation procedure laid down in Directive 2001/83/EC, but automatically recognised by Liechtenstein, capable of constituting the 'first authorisation to place the product on the market' for the purposes of Article 13(1) of the SPC Regulation?

2. Does it make a difference to the answer to the first question if:
(a) the set of clinical data upon which the Swiss authority granted the marketing authorisation was considered by the European Medicines Agency as not satisfying the conditions for the grant of a marketing authorisation pursuant to Regulation 726/2004/EC; and/or
(b) the Swiss marketing authorisation was suspended after grant and was only reinstated following the submission of additional data?

3. If Article 13(1) of the SPC Regulation refers solely to marketing authorisations granted pursuant to the administrative authorisation procedure laid down in Directive 2001/83/EC, does the fact that a medicinal product was first placed on the market within the EEA pursuant to a Swiss marketing authorisation automatically recognised in Liechtenstein which was not granted pursuant to Directive 2001/83/EC render that product ineligible for the grant of a supplementary protection certificate pursuant to Article 2 of the SPC Regulation?

It remains to be seen whether the CJEU will take a less rigid approach.

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