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Moving the SPC Goal Posts or a Necessary Amendment?

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It is hard to think of a recent SPC case before the UK courts where the judge has not had to refer questions to the CJEU in order to either clarify the terms of the SPC Regulation or the CJEU's earlier interpretations. This necessity has arisen at an early stage in an action between *Actavis* and *Boehringer Ingelheim* before the High Court of England & Wales ([2013] EWHC 2927 (Pat)) concerning the validity of an SPC for a combination product.

Boehringer Ingelheim were the proprietors of EP (UK) 0,502,314 which expired on 30 January 2012. Claim 5 of this patent was said to protect the active ingredient Telmisartan (used for the treatment of hypertension). This is the active ingredient in Boehringer's "Micardis" product. Boehringer's protection of Telmisartan was extended under an SPC which is due to expire in December of this year.

Claim 12 of the same patent is said to cover the combination of Telmisartan and hydrochlorothiazide. This combination product is also sold by Boehringer and is marketed as "Micardis Plus". Boehringer's protection of the combination product is currently extended under an SPC due to expire on 30 January 2017. EP (UK) 0,502,314 was also the basic patent behind this SPC.

However, claim 12 of EP (UK) 0,502,314, the claim relied upon as protecting the combination product for the purposes of Article 3(a) of the SPC Regulation, was only introduced after Boehringer filed its SPC application, only after the UK IPO notified it of a potential deficiency in the application, and specifically to enable the SPC application to proceed.

In this regard, the UK IPO wrote to Boehringer regarding its application stating that:

> *"It is a requirement under Article 3(a) that the product for which a supplementary protection certificate is sought is protected by a basic patent in force. Thus, for example, in relation to certificates for products which comprise a combination of active ingredients, it is necessary for the combination to be clearly claimed in order for the combination to be considered to be so protected…The basic patent identified for the current application only contains claims which relate to one of the active ingredients of the product, the telmisartan component. It is therefore suggested that you apply to amend the basic patent under s.27 of the Patents Act 1977 to insert a claim to the combination of telmisartan and hydrochlorothiazide. Such amendment, if allowed, would result in the requirement of Article 3(a) being satisfied."*

Wishing to sell the combination product in the UK, Actavis issued proceedings to clear the path arguing that Boehringer's SPC for the combination product was invalid. Given the detail set out above, one will not be surprised to read that one of the key issues in the case for invalidity relates to the SPC being granted in the aforementioned circumstances.

The parties agreed that four questions should be referred to the CJEU for a preliminary ruling before the trial. The matter came before Birss J, who agreed with the parties and made the requested reference. The first of these questions (repeated below for ease of reference) related to the amendment issue:

> 1. (a) If a patent does not, upon grant, contain a claim that explicitly identifies two active ingredients in combination, but the patent could be amended so as to include such a claim could this patent, whether or not such an amendment is made, be relied upon as a "basic patent in force" for a product comprising those ingredients in combination pursuant to Article 3(a) of Regulation No 469/2006/EC ("the Regulation")?
> (b) Can a patent that has been amended after the grant of the patent and either (i) before and/or (ii) after grant of the SPC be relied upon as the "basic patent in force" for the purposes of fulfilling the condition set out in Article 3(a) of the Regulation?
> (c) Where an applicant applies for an SPC for a product comprised of active ingredients A and B in circumstances where,

(i) after the date of application for the SPC but before the grant of the SPC, the basic patent in force, being a European Patent (UK) (the "Patent") is amended so as to include a claim which explicitly identifies A and B;

> and
>
> (ii) the amendment is deemed, as a matter of national law, always to have had effect from the grant of the Patent;
>
> is the applicant for the SPC entitled to rely upon the Patent in its amended form for the purposes of fulfilling the Art 3(a) condition?

Following CJEU guidance, Birss J provided his own views on the answers to this first question for the CJEU and expressed the view that an amendment should not be a bar to the granting of an SPC:

> *"My preliminary view about Question 1 is the following. The system of amending patents is an integral part of the patent system. Part of that system includes the retrospective effect of amendments. Amendments are only permitted if they comply with the law. There is nothing untoward or unusual or "wrong" in a patentee amending a patent. It does not and should not matter where an amendment is made. If the amendment is a lawful amendment, then I can see no good reason why it matters from the point of view of the validity of an SPC when the amendment took place. Indeed in many cases it is necessary to amend a patent in order to cure an invalidity as a result of a trial and that may well happen years after the grant of an SPC."*

In addition it is also worth bearing in mind the uncertainty that is facing the patentee in terms of SPC law, and that the goal posts for any SPC application (and associated claim language) may move between the time of a patent being granted and the time to make an SPC application. Indeed the requirements associated with claims covering combination products and the clarifications of the

CJEU are a good example of this. Allowing amendments to account for these changes helps to level the playing field.

Of course this additional detail is not something that necessarily would sit well in the papers to be sent to Luxembourg seeking to persuade the court to make the recommended decision.

As a final point, in addition to addressing the need for and nature of the questions to be referred to the CJEU, Birss J was faced with arguments concerning the nature of the cross undertaking in damages that Boehringer Ingelheim had agreed to provide in exchange for Actavis not coming to market with the combination product. In essence, Actavis wanted the undertakings to encompass "potential customers" whereas Boehringer Ingelheim contended that this was vague and uncertain and thus too wide.

The judge agreed with Boehringer Ingelheim finding that if third parties, such as the NHS, wanted the benefit of the undertakings, they are able to come to the court and ask for it.

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