

Newsletter July 2013 for Health & Life Science Industry

Law & Politics in EMEA

Another SPC question referred to the European Court of Justice regarding the key term "product"

by Dr Kilian Schärli, LL.M.

Introduction

The European Court of Justice ("CJEU") has been asked to decide another SPC question by learned Justice Arnold in the case of GlaxoSmithKline ("GSK") v Comptroller General of Patents [2013] [EWHC 619 \(Pat\)](#).

This is the third time in six months that Justice Arnold has had to refer – with considerable regret – questions of interpretation of Regulation 469/2009/EC concerning the supplementary protection certificate for medicinal products ("SPC regulation") to the CJEU. This demonstrates the dysfunctional state of the SPC system at present.

The key issue of this new case is the important interpretation of the term "product". An SPC is a unique (*sui generis*) intellectual property right that extends – in simple terms – the duration of the exclusivity period for a "product" (active ingredient or a combination of active ingredients) that is protected by a patent. For many SPC applications, there is no controversy about the definition of the word "product" or whether it is protected by the patent upon which the SPC application was based. However, there are other SPC applications (particularly for medicinal products containing multiple active ingredients) where there may not be clear answers to questions such as what is a permissible definition of a "product", and what test should be applied for determining whether a patent protects that "product".

Background of the case

On 10 October 2008 GSK applied for an SPC relating to the product "an oil in water emulsion comprising squalene, DL- α -tocopherol and polysorbate 80", an adjuvant known as AS03, which is protected by the European Patent (UK) No. 0 868 918.

On 18 August 2011 GSK filed an additional SPC application for a pandemic influenza vaccine containing the adjuvant AS03 which is protected by the European Patent (UK) No. 1 618 889.

In both applications GSK relied upon a marketing authorisation for a pre-pandemic influenza vaccine against the H5N1 subtype of influenza A virus marketed by GSK under the trade mark "Prepandrix".

By a decision dated 19 December 2012, the Deputy Director of the UK Intellectual Property Office, acting on behalf of the Comptroller, decided that neither application was allowable as it stood since AS03 was not an "active ingredient" of Prepandrix. The Deputy Director decided that, applying the reasoning of the CJEU in *MIT* (C-431/04), AS03 was not an "active ingredient" within the meaning of Article 1(b) of the SPC regulation whether in its own right or in combination with the antigen contained in Prepandrix because AS03 did not have a therapeutic effect on its own.

Questions

The following questions were referred to the CJEU:

1. *Is an adjuvant which has no therapeutic effect on its own, but which enhances the therapeutic effect of an antigen when combined with that antigen in a vaccine, an "active ingredient" within the meaning of Article 1(b) of the SPC regulation?*
2. *If the answer to question 1 is no, can the combination of such an adjuvant with an antigen nevertheless be regarded as a "combination of active ingredients" within the meaning of Article 1(b) of the SPC regulation?*

Earlier case law on the term "product"

The issue arising in this case, now referred to the CJEU for decision, involves consideration of a number of previous CJEU decisions, in particular *Pharmacia* (C-31/03), *MIT* (C-431/04), *Yissum* (C-202/05), *Neurim* (C-130/11), and the earlier case referred to the CJEU, *Bayer CropScience* (C-11/13).

In *Pharmacia* the CJEU held that the decisive factor for the grant of the SPC is not the intended use of the medicinal product and that the purpose of the protection conferred by the SPC relates to any use of the product as a medicinal product without any distinction between use of the product as a medicinal product for human use and as a veterinary medicinal product.

In the *MIT* case it was decided that a substance that is used to obtain a pharmaceutical form of a medicinal product is not covered by the concept of an "active ingredient" under the SPC regulation, even if it supports the therapeutic efficacy of the active agent. This decision bolsters a strict interpretation of the terms "product" or "active substance", which are limited to substances which have a direct therapeutic effect.

In *Yissum* the CJEU confirmed that the concept of the term "product" in Article 1(b) of the SPC regulation was to be interpreted strictly and could not include the therapeutic use of the active ingredient or even whether the medicinal product was for human use or for veterinary use.

Hence, in *Pharmacia*, *MIT* and *Yissum* the CJEU held that the term "product" should be strictly interpreted.

However, the reasoning which the CJEU relied on in *Neurim* is that the research required to obtain a patent and marketing authorisation for a second medical use of an active ingredient justifies the grant of an SPC for the second medical use despite the fact that the same active ingredient has already been lawfully marketed as a medicinal product. Consequently, that decision showed that the term "product" should not be narrowly interpreted.

In *Neurim* it appears that the CJEU was intending to depart from its earlier decisions in *Pharmacia*, *MIT* and *Yissum*. However, this is not entirely clear since it did not refer to those decisions. Hence, we do not know if those decisions have been overruled.

Divergence of interpretation between the different national authorities

The questions referred to the CJEU have been decided differently by national patent offices:

- The patent offices in Austria, Italy, Luxembourg and Spain have granted SPCs in respect of both AS03 and the combination of the antigen and AS03 based on the '918 patent;
- The Portuguese patent office has refused an SPC in respect of AS03 alone but granted one in respect of the combination based on the '918 patent.
- The Swedish patent office, like the UK Deputy Director, has refused both applications.
- The patent offices in Cyprus and Italy have granted SPCs for the combination based on the '889 patent.

Is the refusal of an SPC for AS03 correct?

Despite the fact that the Deputy Director's decision is based on reasonable arguments, there are convincing arguments against it:

First, the Explanatory Memorandum to the Commission's Proposal for Regulation 1768/92/EEC, i.e. the predecessor of the SPC regulation stipulates that it was intended to be applied to all new products which are the subject of innovative research. Only minor variants such as new doses, the use of a different salt or ester or a different pharmaceutical formulation should be excluded.

Secondly, the major purpose of the SPC regulation is to guarantee a sufficient protection for the promotion of research in the pharmaceutical field which significantly contributes to a constant improvement of public health (*Farmitalia* (C-392/97)). This was an important argument in CJEU's reasoning in *Neurim*.

Thirdly, it appears to be reasonable to argue that the present reference was to be distinguished from previous CJEU's decisions. *MIT* concerned an excipient which had no physiological effect on the body, whereas the present case concerns an adjuvant which has physiological effects on the body and which thereby enhances the therapeutic effect.

Uncertainty and inconsistency of the SPC regulation

For the industry, uncertainty and inconsistency of the SPC regulation is an unsolved issue. Matters have not been assisted by the fact that the CJEU's recent case law interpreting the SPC regulation has not provided the level of clarity and consistency that is required.

If you would like to read more about the key term "product" or the CJEU decisions addressed in this article you may be interested to have a look at the newly published dissertation authored by Kilian Schärli "[Das ergänzende Schutzzertifikat für Arzneimittel](#)".