



THE FIRST FORMAL CLINICAL TRIALS CONDUCTED ON AN “OLD” ACTIVE INGREDIENT DO NOT GIVE RISE TO THE RIGHT TO AN SPC

On 28 July 2011, the Court of Justice of the European Union (CJEU) provided rulings in two cases relating to Supplementary Protection Certificates (SPCs). The rulings clarify the law and are binding upon all national patent offices and courts.

The CJEU has effectively closed a loophole in the law relating to SPCs by confirming that SPCs will not be available for any “product” (active ingredient or combination of active ingredients) that was present in a previously authorised medicinal product, even if the prior authorisation was not compliant with the safety and efficacy standards that were introduced in the 1970s. The rulings also affect the validity of existing SPCs granted in such circumstances.

SPCs

SPCs provide additional protection, beyond patent expiry, for products (medicinal or plant protection) that require a marketing authorisation. The purpose of SPCs is to compensate patent holders for at least part of the delay in commercialising a patented active ingredient (or combination of active ingredients) caused by the need to conduct trials on safety and efficacy (and thereafter to obtain regulatory approval).

Memantine and Galantamine

The principles underlying the SPC legislation were considered in relation to medicinal products containing the “old” active ingredients memantine and galantamine.

Memantine was the active ingredient in a product (Akatinol®) that had been sold in Europe for many years as a treatment for Parkinson’s disease. Similarly, galantamine was the active ingredient of the product Nivalin®, which was first authorised for sale in Austria in 1963, for the treatment of poliomyelitis.

After the first marketing of Akatinol® and Nivalin®, legislation was introduced in Europe (Directives 65/65/EEC and 75/319/EEC) that set standards for the testing of safety and efficacy of human medicaments prior to their authorisation for sale. Nonetheless, both Akatinol® and Nivalin® remained on the market for some time after the introduction of that legislation.

In the late 1980s, a new medical use (the treatment of Alzheimer’s disease) was discovered for each of memantine and galantamine, and separate patents were filed, by Merz and Synaptech, to protect the new use of those products. Applications for new marketing authorisations (MAs) were then filed. The MAs that subsequently issued for Ebixa® and Reminyl® were the first ever European authorisations for medicinal products containing, respectively, memantine and galantamine that were compliant with the safety and efficacy standards set by Directive 65/65/EEC.

Merz and Synaptech then filed SPC applications for, respectively, memantine and galantamine, citing the second medical use patents and the MAs for Ebixa® and Reminyl®. The validity of some resulting SPCs were then challenged by the generic manufacturers Synthon BV and Generics (UK) Ltd.. Those challenges led the English Patents Court (in the case of Synthon v Merz) and the English Court of Appeal (in the case of Generics (UK) v Synaptech) to ask the CJEU to clarify whether the SPCs were valid and, if so, whether they were granted with the correct term.

The CJEU Decision

The cases of Synthon v Merz (C-195/09) and Generics (UK) v Synaptech (C-427/09) were handled separately by the CJEU. However, they were both decided on the same day.

The decision in C-195/09 contains the key reasoning of the CJEU. In essence, the CJEU decided that

Article 2 of the SPC Regulation 1768/92 (now 469/2009) should be interpreted to mean that the SPC legislation only applies to those "products" that:

- (i) are protected by a patent;
- (ii) have been subject to an administrative authorisation procedure; and
- (iii) have not been placed on the market anywhere in the European Economic Area as a medicinal product prior to the date(s) of the MA(s) specified in the SPC application.

Contravention of Article 2 is not one of the formal grounds of invalidity of an SPC (as defined in Article 15 of the regulation). Nevertheless, the CJEU found there to be a direct connection between Articles 2 and 3 of the regulation, in so far as there exists a common concept of the "product" that can be the subject of an SPC. Contravention of Article 3 is a ground of invalidity of an SPC, so the CJEU decided that the SPCs for memantine and galantamine were invalid, as they each related to a "product" that falls outside of the scope of the regulation.

Action points

Please contact us for advice if you have questions regarding the validity of an SPC for a "product" that may have been marketed in Europe prior to the date of the marketing authorisation(s) specified in the SPC application. Our SPC experts are ideally placed to answer any such questions.

If you would like more information please contact: [John Miles](#), [Mike Snodin](#), [Michael Pears](#)

The information in this Newsletter was correct at the date of release. More up to date information is available by contacting Potter Clarkson LLP. All comments contained here are of a general nature and full professional advice should be sought on any specific problem. Please note that all our Newsletters can be found on our website: www.potterclarkson.com.

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