

Newsletter October 2012 for Health & Life Science Industry

Neurim – Supplementary Protection Certificates may now be available for previously authorised active ingredients

by Kilian Schärli, author of a Ph.D. (to be published) about SPC in Switzerland

On July 19, 2012, the Court of Justice of the European Union ("CJEU") issued a hotly anticipated decision in the case C-130/11 Neurim Pharmaceuticals (1991) Ltd v. Comptroller-General of Patents. This important judgement, which is binding upon all EU patent offices and courts, has significantly liberalised the system of supplementary protection in Europe.

In its ruling, the CJEU upheld the validity of a Supplementary Protection Certificate ("SPC") for a new medical use of a known pharmaceutically active ingredient. Thus, the decision should allow SPCs to be based upon patents on (and marketing authorisations for) such new therapeutic applications, regardless of the existence of earlier authorisations of the compound for other medical uses.

SPCs

SPCs are national rights that protect authorised uses of a "product" (an active ingredient or a combination of active ingredients) that was the subject of patent protection. The protection provided by a SPC is particularly valuable, since it can effectively prevent generic competition for up to five (or even five and a half years for pediatric indications) years beyond patent expiry.

Issue

The requirements for the grant of a SPC and for the computation of its duration are set forth in Arts. 3 and 13 par. 1 of the European Regulation 469/2009 ("SPC-Regulation"). According to those provisions a SPC can only be granted based on the first marketing authorisation issued for the concerned product in the EU or EEA. Based on a consistent line of jurisprudence by the CJEU throughout the past years (*Dostinex*, C 31/03; *MIT*, C 431/04; *Yissum*, C 202/05), it was commonly assumed that the earliest marketing authorisation that was issued for a respective active ingredient, even if concerning a different indication as covered by the basic patent for which an SPC was sought, was considered to be the "first" marketing authorisation in view of Arts. 3 and 13 of the SPC Regulation.

This had the far-reaching consequence that such earlier marketing authorisation, when issued in the same jurisdiction for which SPC protection was sought, was deemed to be prejudicial to the grant of a SPC relying on another, later marketing authorisation. Furthermore, earlier marketing authorisations issued in any (other) member state of the EU/EEA could at least potentially cut short the duration of SPCs based on a later marketing authorisation for the same active ingredient, also irrespective of the therapeutic indication in question.

Procedural History and Ruling of the CJEU

In essence, the UK Court of Appeal asked the CJEU to clarify whether the existence of earlier (veterinary) authorisations for the active ingredient melatonin precluded the grant of (or determined the duration of) a SPC application based upon Neurim Pharmaceuticals' authorisation for the first human medicinal product containing melatonin (for the full procedural history and the ruling [click here](#)).

In response to the questions, the CJEU ruled that the existence of an earlier marketing authorisation as such did not preclude the grant of an SPC, as long as the later marketing authorisation (and the SPC) concerns a different application of the same active ingredient for which a marketing authorization had been granted.

In this context the CJEU specified that *"a patent protects a therapeutic application of a known active ingredient which has already been marketed as a medicinal product, for veterinary or human use, for other therapeutic indications, whether or not protected by an earlier patent, the placement on the market of a new medicinal product commercially exploiting the new therapeutic application of the same active ingredient, as protected by the new patent, may enable its proprietor to obtain an SPC, the scope of which, in any event, could cover, not the active ingredient, but only the new use of that product."* (par. 25)

Additionally, the CJEU decided that the term of Neurim Pharmaceuticals' SPC should be set by the marketing authorisation of a product that comes within the limits of protection conferred by the basic patent relied upon for the purpose of the application for the SPC (par. 26).

Commentary

The judgement appears to be good news for the innovative pharmaceutical industry as companies that provide valuable new treatments by finding new therapeutic applications for "old" active ingredients, i.e. compounds licensed in the past for a specific indication, could become entitled to an extended monopoly period for those new treatments. After some previous rulings of the CJEU, which inter alia decided that SPCs should not be granted if the active ingredients of the concerned products are not specified in the wording of the claims of the basic patent, research-based pharmaceutical companies have been compensated to some extent again with this landmark judgment.

As for now, due to the rather broad and general wording of the decision, it is not entirely clear what is meant by new "therapeutic application". Nevertheless, it should be fair to conclude that new therapeutic applications *at least* encompass new indications. It is open, however, whether other new inventions based on the same active ingredient (such as new formulations, new routes of administration, new dosage regimes, etc.) would be equally deemed new therapeutic applications, in cases where the active ingredient has already been used in the same indication. Based on the purpose of the SPC-legislation, there are arguments in favor of an equal treatment.

More than ten years ago, the Swiss courts decided two cases in line with the recent judgment of the CJEU. Pursuant to the *Arzneimittel*-decision of the Swiss Federal Supreme Court dated November 17, 1998 (sic! 1999, p. 153 ff.) and the *Ciclosporin*-decision of the former RKGE dated April 30, 1999 (sic! 1999, p. 449 ff.) the mere presence of the same active ingredients does not necessarily mean that it is the same "product" in view of the Swiss SPC-legislation. If a further invention has been made based on the "old" active ingredient, and the new invention is claimed in the basic patent, then the later invention can

form the basis for a new, independent product, for which a new SPC can be granted. This interpretation does not apply only to new indications but also to more effective dosages (see Guidelines of the Swiss Federal Institute of Intellectual Property, p. 106 ff., [click here](#)).

It should be noted that the CJEU did not comment on one point which the Advocate-General had sought clarification for, namely whether it is possible to obtain more than one SPC for each basic patent. Fortunately, the CJEU will soon have the opportunity to answer this significant issue.

While a range of questions on the precise scope of the decision remains, it is clear that the less literal interpretation of the SPC-legislation offers new opportunities to patent proprietors for obtaining SPC protection in cases where an active ingredient has already been authorized and hence commercialized.

The CJEU has handed down a decision that will have considerable impact on the filing and prosecution of patent term extensions. This will open new strategies not only for the pharmaceutical innovator industry seeking to extend the lifetime of their products but also for generic companies trying to enter the market.

The SPC will continue to be a very hot topic as plenty more excitement, such as the determination of the criteria for deciding whether the product is protected by a basic patent in force or the amount of SPC per patent, is expected in the coming year.

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