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Neurim and SPCs: Justice for indication inventions

Article 4 of the EU SPC Regulation only grants purpose-bound protection for SPCs (special purpose certificates). Nevertheless, the specific drug's use (its purpose) is supposedly of no relevance concerning the obtaining provisions in article 3, as held by the Court of Justice of the EU (CJEU) in *Yissum*, where the court declined to recognise a marketing authorisation (MA) for a new medicinal indication of a formerly authorised substance as the first MA in terms of article 3(d). This appears to be contradictory.

As an answer, the CJEU recently held in *Neurim* that only the MA relating to a drug whose use is the subject of an SPC filing for the first time is deemed as the first MA. To that extent, the Court held, it would be the first MA of "this product".

The effect is that the decision in re *Pharmacia Italia* (which held that a previously granted MA for an animal use drug would be deemed the first MA for a human use drug with the same active ingredient) is overturned, which was the basis for the *Yissum* decision.

However it does not necessarily follow that indication patents may lead to a new SPC, since for its grant there must be, in addition, no previous grant of an SPC for the product, under article 3(c). Yet it seems a contradiction to interpret the term "product" differently within the scope of article 3(d) than within 3(c). It also seems a contradiction to apply article 3(c) restrictively to indication patents, and yet so liberally to cases like *AHP Manufacturing*, the case that made it possible to receive an SPC for a product, even if one has already been issued in the past.

Thus in cases like *Neurim*, a "new" first MA due to a different indication should also lead to a new product and a new SPC for this indication.

It still has to be considered that a new indication should not lead to a new SPC, if a certificate has already been issued for the relevant product with another use under the same basic patent. This is due to the fact that the market must not be additionally monopolised just because the inventor has all possible uses of its patented product authorised over time, and thus files "evergreen" SPCs.