FORRESTERS
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Supplementary Protection Certificates (SPCs) – Are sheep medicines relevant?

The UK Court of Appeal has referred another set of questions on SPCs to the Court of Justice, the highest court in Europe.

The case concerns Neurim's European patent for the natural hormone melatonin, to treat insomnia in humans. Neurim applied for the patent in 1992, but it took over 15 years to obtain a marketing authorisation, in 2007. Neurim sold the product as "Circadin".

Once it had the marketing authorisation, Neurim applied for an SPC for melatonin. Neurim argued that this was the first marketing authorisation for the product. The UK Intellectual Property Office (UK-IPO) rejected the application because it considered a 2001 marketing authorisation, for using melatonin in sheep, to be the first. That product was sold as "Regulin".

The regulatory authority, granting the Circadin marketing authorisation, considered Circadin as a new chemical entity, because melatonin had not previously been approved for use in humans. Therefore, the authority required full pre-clinical and clinical trial data.

The courts looked at whether the earlier Regulin marketing authorisation was the first for the "product". The UK-IPO argued that it was, because melatonin was the "product". The UK-IPO argued that it could have granted an SPC, based on the Regulin marketing authorisation, even though the SPC would have been of "zero scope" because the authorisation did not overlap with the scope of the patent. However, as soon as Neurim obtained the Circadin marketing authorisation, the SPC would extend to protect Circadin.

Neurim argued that an SPC supplements the protection of the patent. Because each patent can have only one SPC, the relevant marketing authorisation for that patent must be one for a product covered by the patent. Neurim's patent is limited to use of melatonin in humans. and so Regulin does not fall within its claims. Neurim argued that a marketing authorisation is only relevant if the product would have infringed the SPC.

The High Court upheld the UK-IPO's approach. However, the Court of Appeal took a more commercial view, and looked at the object of the SPC regulation. The Court said that it would be detrimental to research if SPCs were not awarded for new uses for known active ingredients.

The Court of Appeal asked the Court of Justice whether an SPC application should be allowed where:

a. An earlier marketing authorization (A) has been granted; and
b. the SPC application is based on:

i. a later marketing authorization (B) for a different medicinal product containing the same active ingredient as A; and
ii. a basic patent that does not cover the product of A.

Conclusion

A patent holder must apply for an SPCs within 6 months of the the earliest marketing authorization or the grant of the patent, whichever is later. Until the Court of Justice decides the issue, we recommend that when you have patent granted for a medical product, you conduct a thorough check for earlier marketing authorizations for the product. If one exists, even if it is not related to the patented use, you should apply for an SPC immediately.

This case joins a long queue of cases before the Court of Justice, concerning the interpretation of the SPC regulation. There are busy times are ahead for the Court!