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Extending pharmaceutical patents in the UK

The contentious world of patent extensions for pharmaceutical products has come under the spotlight again in a recent UK decision: Actavis v Boehringer. The decision signals that the UK courts are keen to extend pharmaceutical patents, even where the product is a combination of two known active ingredients, but the final say will now go to Europe's highest court (the CJEU).

What is an SPC?

A supplementary protection certificate (SPC) is a patent term extension for a patented drug that has received a marketing authorisation in Europe. The SPC is designed to compensate the patent holder when there is a significant delay between filing the patent and getting the marketing authorisation. As an SPC starts when the patent ends and the product is well known, it can provide substantial financial rewards for its owner.

Actavis v Boehringer

Boehringer had a patent for Micardis (telmisartan) which treats hypertension. The patent for Micardis expired in January 2012, but Boehringer's SPC provides protection until December 2013. Boehringer developed a follow on product MicardisPlus that contains telmisartan and hydrochlorothiazide (HCT). The UK patent office granted Boehringer a second SPC for MicardisPlus, which protects this product until January 2017. Both SPCs were based on the same patent, but the SPC for MicardisPlus lasts longer as MicardisPlus took longer to be authorised. Actavis wanted to launch a generic version of MicardisPlus, but was blocked by Boehringer's second SPC. Therefore, Actavis asked the UK High Court to revoke the second SPC, in part because it did not correctly "specify" the active ingredients when granted. Actavis' attacks illustrate the problems with this controversial aspect of SPC law.

When is a product "specified" in the claims?

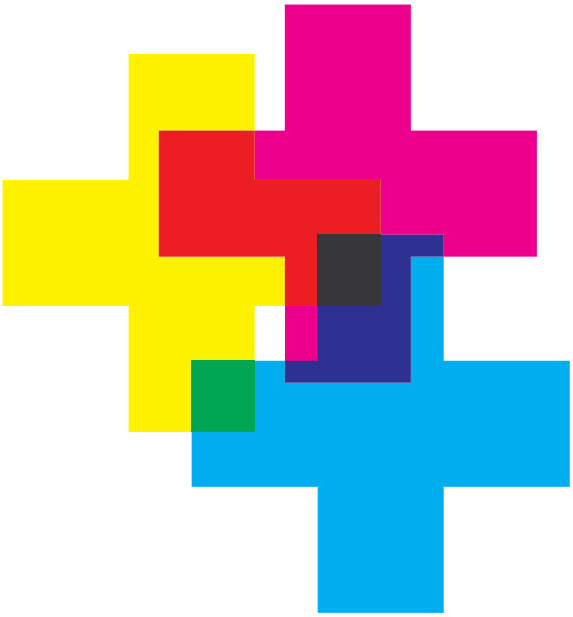
In order to get an SPC the patent must "protect" the product, which sounds like a simple test. However, the CJEU recently ruled that a product is "protected" only when it is "specified" in the wording of the claims. The "specified" test has caused considerable uncertainty in the world of SPCs, as the CJEU did not explain how this test should work.

The Micardis product passed the "specified" test, as the patent had a claim which mentioned the active ingredient (telmisartan) by its precise chemical name. The situation for MicardisPlus was more complex, because the patent as granted did not have a claim which specifically mentioned the combination of telmisartan and HCT. Conventionally, the patent still "protected" MicardisPlus, as a product containing telmisartan fell within the patent's claims. However, as there was no claim that mentioned both telmisartan and HCT by name, Actavis argued that the second SPC was invalid because the patent's claims did not "specify" this combination.

When is it allowable to amend?

Back when Boehringer applied for the SPC, the UK patent office suggested that the claims of the granted patent could be amended to include a claim to the combination of telmisartan and HCT. This post-grant amendment was allowed in the UK, as HCT was mentioned in the description. Actavis argued that because the amendment was made after the SPC application was filed, it was too late to fix the problem.

The judge decided that this issue required the CJEU to answer questions about how the "specified" test should work in practice. The judge asked the



CJEU whether Boehringer needed to make the amendment at all, as the patent read with its description always specified telmisartan and HCT. If an amendment was required, he also asked whether it mattered when the amendment was made.

What about duration?

Actavis argued that Boehringer should not be allowed a second SPC on the same patent, a live topic in several other SPC cases going to the CJEU. Actavis also argued that if the second SPC was allowed, then its duration should be cut to stop "evergreening" (the contentious practice of extending patent term for valuable pharmaceuticals). In particular, Actavis wanted both SPCs for Micardis and MicardisPlus to lapse simultaneously in December 2013.

New pro-SPC judge?

The judge, Colin Birss, has only just been appointed to the High Court and this was his first big SPC case. Birss' comments in the case suggest he is taking a pro-patentee view of SPCs. He suggests that there is nothing wrong with a patentee amending a patent to improve its chances of getting an SPC, even if the amendment is made post-grant. He also suggests that there is no reason for the term of Boehringer's second SPC to be cut. Therefore, it appears that the UK courts may continue to be a desirable venue for those enforcing an SPC.

Conclusion

Actavis v Boehringer highlights the chaotic world of SPC law in Europe. Pharmaceutical companies must hope that the CJEU will take a pro-patentee approach and allow Boehringer to keep their second SPC, following Birss' suggestions. Generic companies will hope that the CJEU will strike down the second SPC, or shorten its term. At the very least, the answers from the CJEU might bring a little clarity to this important area of law. For now, patentees could avoid these issues by ensuring that patent applications have claims that list any interesting combinations of products. Minor amendments like this just might provide up to five valuable years of additional exclusivity in Europe.

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