Two new SPC references to the CJEU

Two new references to Europe's highest court consider what constitutes the 'first' marketing authorisation for a supplementary protection certificate and what it means for a product to be 'protected by a basic patent in force'

The English High Court this morning handed down its judgment in Abraxis Bioscience LLC v The Comptroller-General of Patents [2017] EWHC 14 (Pat), in which Mr Justice Arnold refers the following question to the Court of Justice of the European Union (CJEU) on the interpretation of Article 3(d) of the SPC Regulation:

"Is Article 3(d) of the SPC Regulation to be interpreted as permitting the grant of an SPC where the marketing authorisation referred to in Article 3(b) is the first authorisation within the scope of the basic patent to place the product on the market as a medicinal product and where the product is a new formulation of an old active ingredient?"

Articles 3(b) and 3(d) require the marketing authorisation supporting an SPC application to be the 'first' authorisation for that product. Abraxis applied for an SPC on the basis of its ABRAXANE® marketing authorisation, which relates to albumin bound nanoparticles of paclitaxel referred to as 'nab-paclitaxel'.

Today's judgment follows an appeal by Abraxis against the UK patent office's refusal of its SPC application, in view of earlier authorisations for conventional, solvent-based paclitaxel products. Abraxis argued that those earlier authorisations are not relevant given the CJEU's decision in *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents* (C-130/11), because the ABRAXANE® marketing authorisation is the first authorisation falling within the scope of the patent upon which Abraxis' SPC application was based.

Mr Justice Arnold did not accept the UK patent office's argument that *Neurim* is clearly confined to the grant of SPCs for new therapeutic uses of active ingredients, acknowledging at paragraph 62 of his judgment the policy considerations that arguably support its broader application to new formulations as well:

"In my judgment it is not clear how far the reasoning of the Court of Justice in Neurim extends. (…) As Abraxis contends, however, it is arguable that the same policy considerations support Article 3(d) being interpreted in the same way in the case of new formulations of old active ingredients even if the therapeutic use is the same. This was certainly the view of Jacob LJ in the cases mentioned above [Generics (UK) v Daiichi Pharmaceuticals [2009] EWCA Civ 646 and Draco's Application [1996] RPC 417]. On the other hand, as the Comptroller argues, it appears from MIT, GSK and Forsgren that SPCs cannot be granted merely for new formulations . But since none of those decisions squarely addresses this issue, the position is not clear. Accordingly, I shall refer a question to the CJEU (…)."

CJEU to consider Article 3(a)…again

The English High Court handed down a second SPC judgment this morning, in Teva & others v Gilead Sciences Inc [2017] EWHC 13 (Pat). In this judgment, Mr Justice Arnold referred another question to the CJEU, this time on the interpretation of Article 3(a) of the SPC Regulation:

"What are the criteria for deciding whether 'the product is protected by a basic patent in force' in Article 3(a) of the SPC Regulation?"

The judgment concerned Gilead's SPC based on its marketing authorisation for TRUVADA®, which contains a combination of tenofovir disoproxil and emtricitabine. Teva (and others) had challenged the validity of the SPC on the ground that the basic patent did not 'protect' the combination of tenofovir disoproxil and emtricitabine as required by Article 3(a) of the SPC Regulation, because the basic patent does not mention emtricitabine. However, Gilead argued that the combination of tenofovir disoproxil and emtricitabine falls within the scope of protection of, and is therefore 'protected' by, claim 27, which claims a pharmaceutical composition comprising tenofovir disoproxil *"together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients".*

The CJEU has previously been asked to consider Article 3(a) many times, but despite these earlier references to the CJEU, Mr Justice Arnold held that the test to be applied under Article 3(a) remains unclear. At paragraph 91, he held:

"In my judgment the test to be applied in order to determine whether a product is "protected" by a basic patent within the meaning of Article 3(a) remains unclear. It is clear that it is not sufficient that dealings in the product would infringe a claim applying the Infringing Act Rules. It is also clear that it is necessary that the product falls within at least one claim of the basic patent applying the Extent of Protection Rules. But it is not clear whether that is sufficient. It appears from the case law of the CJEU that it is not sufficient, and that more is required; but it is not clear what more is required. Accordingly, it is necessary to refer the question once more to the Court of Justice in the hope that finally a clear answer will be given."

The issues underlying both of these cases are fundamental to many pharmaceutical and biotechnology products, and the life sciences industry will be eagerly awaiting welcome clarification from the CJEU on how the conditions for grant of an SPC under Articles 3(a) and 3(d) of the SPC Regulation should be applied.

Authors: Jennifer Antcliff, Matthew Georgiou, Natalia Wegner-Cribbs, Paul Kaufman

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