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Arnold J refers question to the CJEU on Article 3(d) of the SPC Regulation and calls for clarifications on past CJEU jurisprudence

Brian Cordery (Bristows) · Monday, January 16th, 2017

by Steven Willis

In a judgment handed down at the end of last week, Arnold J has indicated his intention to make a reference to the CJEU concerning the interpretation of Article 3(d) of the SPC Regulation i.e. the requirement for the marketing authorisation ("MA") on which an SPC application is based to be the first MA placing the product (active ingredient or combination of active ingredients) on the market as a medicinal product.

The case before him was Abraxis' appeal of the UKIPO's 26 August 2016 decision to reject its application for an SPC for "paclitaxel formulated as albumin nanoparticles" ("nab-paclitaxel"), the formulation of Abraxis' anti-cancer drug Abraxane®.

Arnold J followed the UKIPO Hearing Officer in rejecting Abraxis' submission that nab-paclitaxel is a different active ingredient to paclitaxel such that they are different "products" within the meaning of Article 1(b) of the SPC Regulation. Arnold J considered this to be *acte éclairé** in view of the narrow interpretation of Article 1(b) adopted by the CJEU in **MIT** (C-431/04), **GSK** (C-210/13) and **Forsgren** (C?631/13).

Abraxis' alternative submission, which had also been rejected by the Hearing Officer, was that the CJEU decision in **Neurim** (C-130/11) extends to new formulations of previously approved medicaments as well as new indications. In **Neurim**, it was held that the existence of an earlier MA for a medicinal product, whether for an earlier veterinary or human use, does not preclude the grant of an SPC following the grant of a later MA, provided that the earlier MA would not fall within the limits of the patent relied upon as the basis for the SPC application. Notwithstanding the fact that Abraxis accepted that "*on the face of it*" the reasoning in **Neurim** "*is limited to new therapeutic uses old active ingredients*" and that "*it appears from **MIT**, **GSK** and **Forsgren** that SPCs cannot be granted merely for new formulations*", Arnold J considered that the issue remained unclear and proposed to refer a question to the CJEU. Although the parties have been asked to make submissions as to the form of the question, the substance of it will be as follows:

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?

Not for the first time, Arnold J has proffered his own view as to how the question should be answered, opining that it should not be possible to obtain an SPC for a new formulation in circumstances such as those before him. Arnold J emphasised the importance of providing a "*simple and predictable system*" and suggested that if Article 3(d) was to be interpreted in the manner contended for by Abraxis, it could lead to "*uncertainty and inconsistency as to the circumstances in which SPCs for new formulations could be obtained*". Furthermore, Arnold J took the view that the Explanatory Memorandum to the SPC Regulation supports the availability of an SPC for new therapeutic uses but not for new formulations.

It is interesting to note that, on reviewing the authorities, Arnold J once again expressed concern regarding the compatibility of **Neurim** on the one hand and **Pharmacia** (C-31/03) and **Yissum** (C-202/05) on the other. In **Pharmacia**, it was held that an SPC would not be available where the product had been approved as a veterinary medicinal product prior to 18 June 1992 while in **Yissum**, the Court held that "product" must be interpreted strictly such that it does not include intended therapeutic use. As Arnold J points out, these decisions appear to be at odds with **Neurim** and he suggested that it might be possible to infer that the CJEU no longer considers **Pharmacia** and **Yissum** to be authoritative or that they should be considered to be confined to their facts. However, Arnold J suggested that it might be helpful if the CJEU was to alert national courts if this was indeed the intention.

Arnold J also drew attention to the tension between **Neurim** on the one hand and **Synthon** (C-195/09) and **Generics** (C-427/09) on the other. In those cases, it was held that a product which was placed on the market prior to receiving a marketing authorisation in accordance with Directive 65/65/EEC was outside the scope of the Regulation and could not therefore be the subject of an SPC. It is therefore unclear whether the reasoning in **Neurim** would apply to such a compound. In this author's opinion, it seems strange that a distinction should be drawn between old drugs and very old drugs. The purposive reasoning applied in **Neurim** (i.e. that it is the objective of the SPC Regulation to encourage research into new treatments including new uses for old drugs) would appear to apply just as much to very old drugs. As Arnold J points out, the tension was highlighted by the Advocate-General in **Neurim**, "*yet the court proceeded as if there was no problem*".

It will be interesting to see whether the CJEU addresses Arnold J's concerns in relation to the irreconcilability of its jurisprudence in its judgment.

*This author must admit to not having been previously familiar with the distinction between the *acte éclairé* and *acte clair* doctrines. For any readers in a similar position, the former relates to the situation "*when the question raised is materially identical with a question which has already been the subject of a preliminary ruling in a similar case*" (C-28-30/62 **Da Costa**). The latter relates to the situation where "*the correct application of the Community law may be so obvious as to leave no scope for any reasonable doubt about the answers to the questions raised*" (C-283/81 **CILFIT**). The quotations are taken from, and the principles are summarised in, Kapteyn VerLoren van Themaat's **Introduction to the Law of the European Communities** (1989), 2nd ed. pp. 325-329

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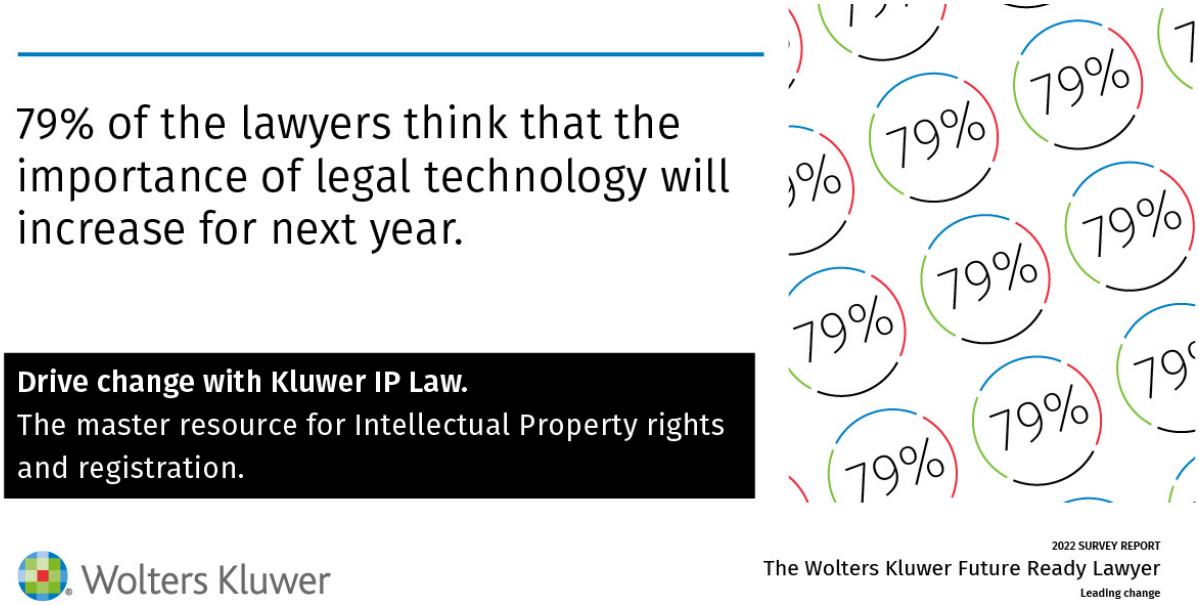

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