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SPCS: ECJ leaves Medeva behind after correcting its own clumsy transcription of Commission's 1990 explanatory memorandum

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As my colleague Rik Lambers, from Brinkhof, reported in the blog he posted last Thursday (12 December 2013), that day was a big day for Supplementary Protection Certificate ("**SPC**") *aficionados*, since the European Court of Justice ("**ECJ**") published three new judgments that will further feed the long-running saga of SPC decisions. Readers will no doubt have heard that for the good of legal certainty, the ECJ clarified what it meant when in the judgment of 24 November 2011 (Case C-322/10, *Medeva BV v. Comptroller General of Patents, Designs and Trade Marks*, "**Medeva**") it wrote that "*article 3(a) of Regulation (EC) No. 469/2009 of the European Parliament and the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as precluding the competent industry property office of a Member State from granting a supplementary protection certificate relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the application for such a certificate*."

This conclusion had been interpreted within some circles as a triumph of the so-called "literal test", which would require the active ingredients to be "mentioned" in the wording of the claims of the basic patent, as opposed to the less stringent "scope of protection test," which would simply demand that the active ingredients be "covered" by the claims of the basic patent. Whilst the Medeva decision had been interpreted as apparently leaning towards the first test, the decisions published last Thursday have clearly embraced a more finely balanced test. In particular, in the judgment of 12 December 2013 handed down in Case C-493/12 *Eli Lilly Company Ltd v. Human Genome Sciences Inc* ("**Eli Lilly**"), the ECJ concluded that:

"*Article 3(a) of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that, in order for an active ingredient to be regarded as 'protected by a basic patent in force' within the meaning of that provision, it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula. Where the active ingredient is covered by a functional formula in the claims of a patent issued by the European Patents Office, Article 3(a) of that regulation does not, in principle, preclude the grant of a supplementary protection certificate for that active ingredient, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted inter alia in the light of the description of the invention, as required by Article 69 of the Convention on the Grant of European*

Patents and the Protocol on the interpretation of that provision, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, which is a matter to be determined by the referring court".

Interestingly, in spite of the different conclusions reached (most notably, the sentence "*the wording of the claims*" has disappeared), in both Medeva and Eli Lilly the ECJ sought to construe the legal reasoning of those decisions departing from the same premises: (i) the judgment of 16 September 1999 in Case C-392/97, *Farmitalia Carlo Erba SRL* ("**Farmitalia**"); (ii) the Commission's Memorandum to the proposal of Council Regulation (EEC) of 11 April 1990 concerning the creation of a supplementary protection certificate for medicinal products (COM (90) 101 final), the "**Commission's 1990 Explanatory Memorandum**"); and (iii) Regulation (EC) No. 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products.

One may wonder about the reasons that have prompted the ECJ, after departing from the same foundations, to put clear blue water between article 3 a) and the "literal test" only two years after publishing one of the most – if not *the* most – controversial decisions of the SPC saga (i.e. Medeva). One reason may of course be the fierce criticism encountered by Medeva, particularly from the English Judges who had referred the questions to the ECJ (see, for example, judgment of the Patents Court dated 10 February 2012, *Novartis Pharmaceuticals UK Limited and Medimmune Limited et altri* [2012] EWHC 181 (Pat)). However, as shown below, there may well be a more mundane reason based on such a human phenomenon as clumsy reading, a nuisance that seems not to be alien to Europe's highest Court:

In paragraph 25 of Medeva, after citing the Farmitalia decision, the ECJ wrote that "*It follows that Article 3(a) of the regulation precludes the grant of a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent*." As one of the Judges (The Honourable Mr Justice Arnold) who had referred the questions to the ECJ highlighted in paragraph 41 of the aforementioned judgment of 10 February 2012 "*Leaving aside for now the question of what "specified in the wording of the claims" actually means, how does this follow? I cannot see that it does*."

Leaving also aside that the conclusion did not stem from the reasons that were meant to sustain it, one of the most awkward aspects of Medeva is that in paragraph 27 the ECJ wrote that "*That approach is also borne out by the second subparagraph of paragraph 20 of the explanatory memorandum to the proposal for Council Regulation (EEC) of 11 April 1990 concerning the creation of a supplementary protection certificate for medicinal products (COM(90) 101 final) ("the explanatory memorandum"), which, in so far as concerns what is "protected by the basic patent", refers expressly and solely to the wording* [sic] *of the claims of the basic patent*."

But guess what? The ECJ's transcription is wrong!

It is unfortunate for a good administration of justice that the sentence "*[…] expressly and solely to the claims of the basic patent*", which is the sentence actually used by the Commission's 1990 Explanatory Memorandum, was replaced by the ECJ's creative drafting with the sentence "*[…] expressly and solely to <u>the wording of</u> the claims of the basic patent.*" The addition by the ECJ of the terms "*the wording of*" to a legal text that does not include them is no small beer, particularly when whether the "literal test" was the right test was at the very heart of the dispute.

Fortunately, in the Eli Lilly judgment published last Thursday the Judge Rapporteur who drafted the decision revisited the original source (the Commission's 1990 Explanatory Memorandum) instead of taking the easy option, which would have been to take the quote from Medeva. As a result, unlike in Medeva, the transcription of the Explanatory Memorandum inserted in paragraph 35 of the Eli Lilly judgment of 12 December 2013 is a fair reflection of what the second subparagraph of paragraph 20 really says.

All in all, in spite of the rivers of ink poured by learned authors in trying to scrutinize what led the ECJ to get a little bit close to the "literal test" in Medeva, for the reasons explained in this blog the answer may be as simple as that this was a pitfall derived from clumsy reading…

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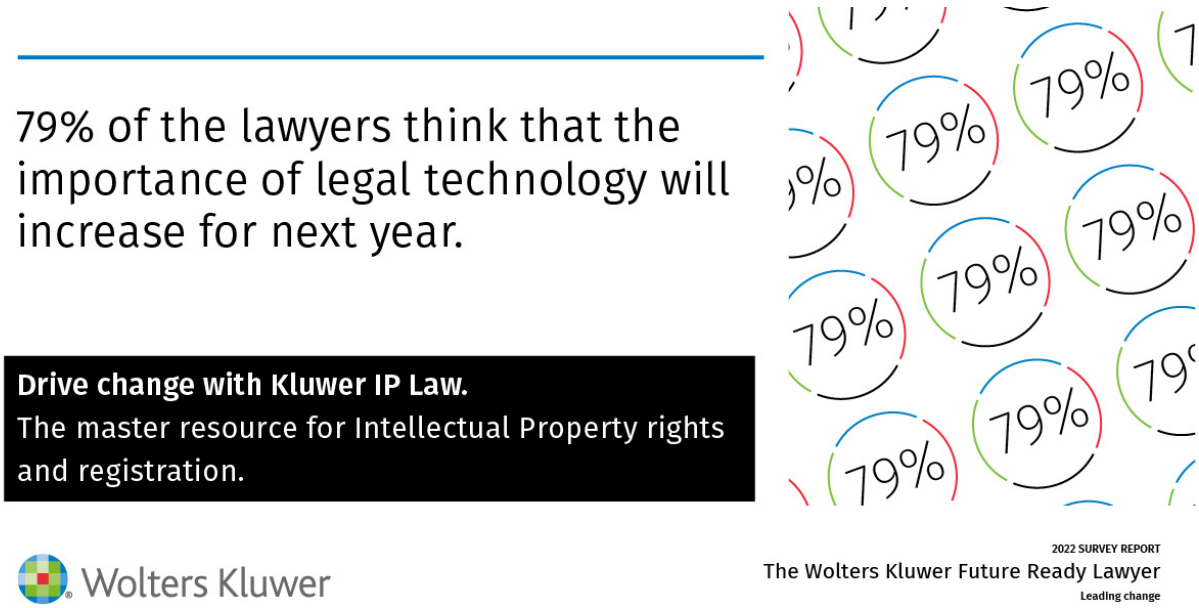

This entry was posted on Monday, December 16th, 2013 at 1:31 pm and is filed under European

Union, SPC

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