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Fifth referral on the scope of the SPC Regulation for Combination Products

Brian Cordery (Bristows) · Tuesday, January 25th, 2011

At the end of last year, the English Patents Court referred yet another case to the Court of Justice of the European Union (“CJEU”) on the scope of the SPC Regulation in *University of Queensland and CSL (C-630/10)*, making it the fifth English referral in 2010 regarding the interpretation of Articles 3(a) and 3(b) of the SPC Regulation. The questions have yet to be published by the CJEU but it is understood that a series of questions were referred, several of which were the same as in *Medeva (C-322/10)* and several of which were different.

The case concerned 8 separate SPC applications in relation to two Human Papillomavirus (“HPV”) vaccines, Gardasil and Cervarix, which are combination products consisting of four and two HPV products, respectively. Six of the applications were for single HPV products, and the remainder two were for a combination of HPV products. The applicants relied on three basic patents, each covering some, but not all of the HPV products contained in Gardasil and Cervarix. None of the individual HPV products were the subject of marketing authorisation.

The case before the English Patents Court was an appeal from the decision of the UK Intellectual Property Office (“UK-IPO”). The UK-IPO had had to consider (i) whether marketing authorisations for products comprising two or more HPV products can support SPC applications for single HPV product under Article 3(b), and (ii) whether patents for single HPV can be used as the basis for HPV combination SPC applications under Article 3(a). It had held that, although the applicants would be left in a situation where they would not be able to secure any SPC protection, both questions had to be answered in the negative on the basis of current case law of the English Patents Court.

On appeal, the English Patents Court decided to stay the proceedings and seek guidance from the Court of Justice of the European Union.

What distinguishes this case from the other four cases referred to the CJEU by the English Patents Court is that the three basic patents relied upon in the present case are all derived from a same parent application. Thus, although none of the individual patents claim all of the active ingredients in Gardasil and Cervarix, the patents as a family do. This could have implications on how the SPC Regulation is applied.

The questions referred are expected to be published on the [website](#) of the CJEU within the next few months.

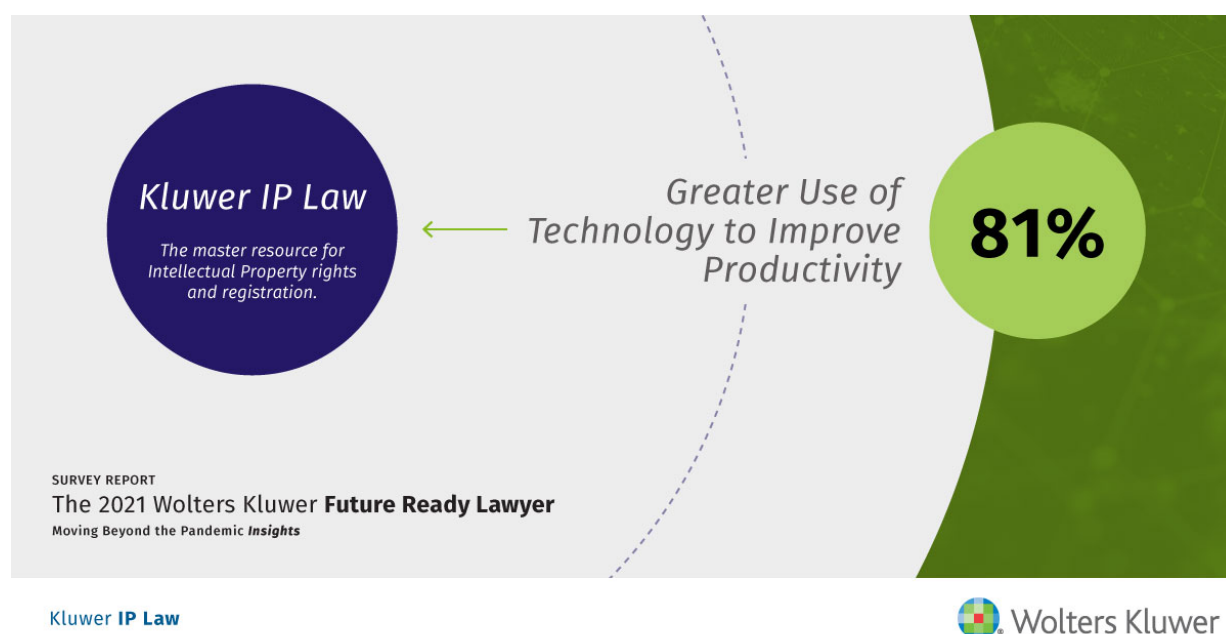
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