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“Nivolumab and pembrolizumab cases”: the French Supreme Court clarifies the interpretation of Article 3 a) of the SPC Regulation

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In two decisions rendered on February 1st, 2023, the French Supreme Court (“*Cour de cassation*”) overturned the decisions of the Paris Court of Appeal which had confirmed the rejections by the French PTO (“*INPI*”) of the supplementary protection certificate (“SPC”) applications for nivolumab and pembrolizumab. On this occasion, the Supreme Court clarified the interpretation of Article 3 a) of Regulation (EC) No. 469/2009 (the “SPC Regulation”), i.e., when to consider whether a product is protected or not by a basic patent if it is only claimed in a functional manner in the said patent, that is without being expressly named or identified structurally. The adopted approach is in line with the one already used by the Paris Court of Appeal in the avelumab case.

In the present instance, ONO Pharmaceutical and Professor H. had filed an SPC application (No. 15C0088), based on European Patent No. 1,537,878 (hereinafter EP’878) and on Marketing Authorization (MA) No. EU/1/15/1014 for nivolumab, granted to Bristol-Myers Squibb Pharma GEIE. Based on the same patent, ONO Pharmaceutical & Professor H. had subsequently filed a second SPC application (No. 16C0001) on January 6, 2016, based on marketing authorization (MA) No. EU/1/15/1024 for pembrolizumab, granted to Merck Sharp & Dohme. The INPI rejected these two SPC applications by two decisions dated March 02, 2018, which were confirmed by the Paris Court of Appeal on January 19, 2021. These two appeal decisions were overturned by the Court of Cassation in its decision of February 1, 2023.

In both cases, the basic patent was for “*immunopotential compositions*“, claiming in particular an “*anti-PD-1 antibody that inhibits the PD-1 immunosuppressive signal for use in the treatment of cancer*“.

The *Cour de Cassation* questioned the validity of the criteria adopted by the Paris Court of Appeal in ruling that nivolumab and pembrolizumab, which were not expressly named or identified structurally, but only claimed functionally in the basic patent, were not “*protected by*” the basic patent on which the SPC applications were based, according to Article 3(a) of the SPC Regulation.

It should be recalled that the CJEU has already ruled on this topic on several occasions. In TEVA, the Court clarified that the grant of an SPC was possible if “*from the point of view of a person skilled in the art and in the light of the description and drawings of the basic patent*”, “*the claims* [of the basic patent] *necessarily and specifically relate*” to the product (CJEU, July 25, 2018,

TEVA, C-121/17), while in ROYALTY PHARMA the same Court indicated that an SPC grant was impossible if the product at issue was obtained via an "*independent inventive step*" of the basic patent (CJEU, April 30, 2020, ROYALTY PHARMA, C-650/17). If all the necessary information had been disclosed and the person skilled in the art had mastered the techniques enabling him to obtain the functional product before the filing of the subsequent SPC, it must be considered that the said product is not covered by the basic patent within the meaning of Article 3 of the Regulation if it required an independent inventive step.

In our case, the INPI and the Paris Court of Appeal considered that nivolumab and pembrolizumab were implicitly and necessarily covered by the basic patent, because they fell within the functional definition contained in the claims of that patent. However, the SPC applications were rejected, in particular because of the grant of subsequent patents covering the structure of the antibodies, several years after the filing date of the basic patent. According to the Court of Appeal, the time required to file these patents was a strong indicator of the complexity of the research to be performed and the need to demonstrate, on the basis of EP'848, an "*independent inventive step*" to develop these antibodies.

The *Cour de Cassation* overturned these decisions because the Court of Appeal had failed to perform two analyses. First, it should have investigated whether the methods for developing monoclonal antibodies were well known to the person skilled in the art at the time of filing of the EP'878 patent, and whether the EP'878 patent, in its description, described how to screen the relevant antibodies to identify those that perform the function of the invention, i.e., those that inhibit the "*PD-1 immunosuppressive signal*". Second, the Court was also required to "*consider whether the person skilled in the art could, on reading the patent and using his general knowledge, obtain, by routine operation, all the antibodies performing the function covered by the patent, including nivolumab and pembrolizumab*".

These decision is to be compared with the decision of the Court of Appeal itself in the avelumab case, which also concerned an anti-PD-1 antibody, and in which the said Court had already gone back on its jurisprudence to overturn a decision of the INPI relating to avelumab. In this case, the ROYALTY PHARMA decision had also been decisive, in particular regarding the criterion of independent inventive step. Thus, the *Cour de Cassation* overturned two decisions rendered by the Paris Court of Appeal but validated the method that the latter had already used in the avelumab case.

This welcome clarification will undoubtedly facilitate the grant of SPC applications in that it obliges both the INPI and the Courts to carefully motivate a rejection by explaining how the person skilled in the art would not have arrived at the functional product, with regard to the function of the invention, the information available in the basic patent (examples, etc.) and his general knowledge, without deploying an independent inventive step.

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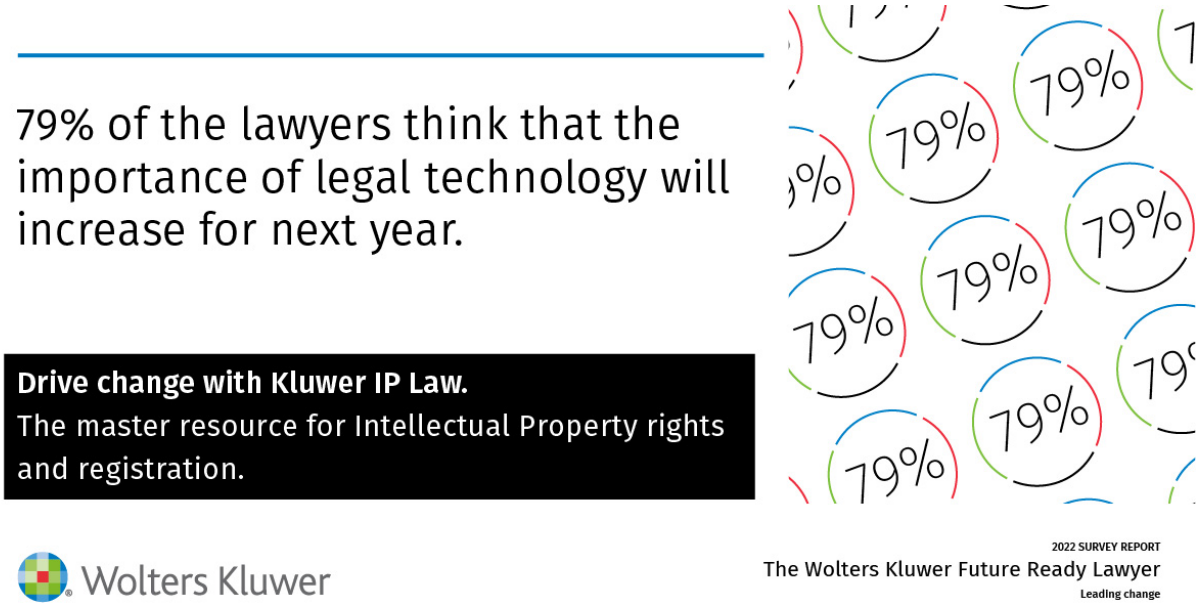

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