

SPC law update: French Supreme Court confirms that an antibody product is “specifically identifiable” by its antigen-binding property

[Andy Nicoll](#), [Jens Grabenstein](#) and [Oliver Kingsbury](#) discuss the relevance of this decision.

Supplementary Protection Certificates

In Europe, Supplementary Protection Certificates (SPCs) of up to 5 years are available for patents covering active ingredients found in newly licensed medicinal products, if a set of specified conditions are met. In particular, the product in question must be protected by the basic patent. In its [Royalty Pharma](#) decision, the Court of Justice of the European Union (CJEU) held that a product protected by a functionally defined claim if it “necessarily comes within the scope of the invention covered by that patent [and] it is specifically identifiable”. The court also held that an SPC should not be allowed where the active ingredient “was developed after the filing date of the application for the basic patent, following an independent inventive step”. The CJEU did not explain how these requirements could be fulfilled, and there are currently only few instances in which the decision has been applied by higher national courts.

Decision of the French Supreme Court

The French Supreme Court has now affirmed an earlier judgement of the Court of Appeal overturning the decision of the French Patent Office refusing Dana-Farber Cancer Institute’s (DFCI’s) request for grant of an SPC based on basic patent [EP 1 210 424 B1](#) (EP’424) and Merck’s marketing authorisation for Bavencio (avelumab). The patent office had argued that DFCI’s SPC application failed to meet the requirements of Article 3(a) of the EU SPC Regulation No 469/2009.

The [French Supreme Court’s decision](#) is of interest because it sheds light on how the CJEU’s decision in *Royalty Pharma* is applied to generic antibody patents by national patent offices. In *Royalty Pharma*, the CJEU held that Article 3(a) must be interpreted as meaning that a product is not protected by a basic patent in force, if, although it is covered by the functional definition given in the claims of that patent, it was developed after the filing date of the application for the basic patent, following an independent inventive step.

EP’424 is *inter alia* directed to an antibody which selectively binds to a polypeptide of SEQ ID NO: 2 or 4. The Court of Appeal held that avelumab falls within this functional definition, so that it is “implicitly but necessarily covered” by the patent. It also held that the fact that Merck later filed another patent application relating to anti-PD-L1 antibodies, covering, *inter alia*, avelumab, was not sufficient to show that avelumab was developed as a result of an independent inventive step. The Court of Appeal reasoned that it was entirely routine (and thus not inventive) to develop antibodies once an antigen had been identified, as was the case in EP’424, pointing to the EPO Guidelines in support of its position.

It seems that, in affirming the Court of Appeal’s decision, the Supreme Court has provided much needed clarity as to how the French Patent Office will apply the *Royalty Pharma* decision to SPC applications based on generic antibody patents in the future. Unfortunately, aside from a Belgian SPC, there appear to be no other SPC applications based on EP’424 that would allow a comparison with other national jurisdictions. The decision could be persuasive in other European courts.

The decision gives credit to research institutions that lay the groundwork for the development of future therapies. It also provides a "patentee friendly" interpretation of the law as it stands.

The interpretation of the EU SPC Regulation keeps evolving at a national level. A further decision in a related case is expected from the French Supreme Court in the summer.

For more detailed advice in relation to any of the issues discussed above, or for advice relating to other matters regarding European practice, please do not hesitate to get in contact with your E+F representative or email us at elkfife@elkfife.com.

