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## Sanofi vs. Amgen: Successful first UPC revocation action and strict assessment of therapeutic antibodies patentability

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On 16 July 2024, the Munich Central Division revoked a patent for the first time in the litigation between Sanofi, Regeneron, and Amgen (UPC_CFI_1/2023). This decision is important not only because it is the first of its kind, but also because it establishes UPC's position on the patentability of therapeutic antibody inventions.

In this case, a revocation action was brought against EP 3,666,797, one of Amgen's patents relating to PCSK9 antibodies. The first claim of this title related to an antibody used to treat or prevent hypercholesterolemia or arteriosclerotic disease, in which the antibody "*binds to the catalytic domain of a PCSK9 protein of amino acid sequence SEQ ID NO: 1, and prevents or reduces binding of PCSK9 to LDLR*". Three Sanofi companies had filed a main action for revocation on 1 June 2023, the day the UPC came into force, before the Munich section of the UPC central division, while on the same day, a few minutes later, Amgen filed an infringement action against these three companies and Regeneron before the Munich local division. Regeneron then filed a counterclaim for revocation, which the Sanofi companies did not do. These were therefore parallel and similar revocation actions before the central and local divisions, so that all parties agreed that the revocation counterclaim should be referred to the central division. These actions come against a backdrop that is rich, to say the least. Amgen, Sanofi and Regeneron have been battling since 2014 over patents relating to Amgen's PSK9 antibodies, which Amgen claims cover both its Repatha and the Praluent marketed by Sanofi and Regeneron. Initially, the litigations were brought before the European national courts, before being brought before the UPC. A case relating to the U.S. patent corresponding to EP'797 was also brought before the U.S. Supreme Court.

The main contribution of the UPC decision lies in its teaching on the patentability of therapeutic antibodies. The Court first set about interpreting claim 1, and thus its method of interpretation. Firstly, the Court considers that a person skilled in the art who interprets a claim determines the technical meaning of the terms used with the aid of the description and drawings. Next, the Court examines the claim's functional feature "*links the catalytic domain of a PCSK9*". The focus here is on understanding the functional limitation of the claim. The Court considers that for the person skilled in the art, antibody binding serves a purpose, namely, to prevent or reduce PCSK9 binding to LDLR. However, in the absence of any indication in the claim or description that binding must take place exclusively, or only principally, in the catalytic domain for the technical function to be achieved, it follows that the person skilled in the art would not have understood this. In addition, the Court also held that the other functional limitation, the therapeutic effect of antibodies (i.e.,

cholesterol reduction), implied that the claim only concerned antibodies with a therapeutic effect (even if it is a "very small" one). Ultimately, the functional language of the claim should not be interpreted as covering "*all antibodies capable of binding to the catalytic domain*". Such an interpretation shows that the Court seems to want to give more weight to the description than the EPO Boards of Appeal generally do (e.g., T 169/20, "*the support of the description for interpreting the claims should only be resorted to in the exceptional cases where the subject-matter of the invention and/or its technical context needs to be clarified, and may only be applicable when the invention in the description corresponds to the invention as claimed*").

Secondly, the Court develops its analysis of the of the inventive step requirement (EPC, art. 56). It is interesting to note here that the Court chose not to follow the problem-solution approach classically employed at the EPO, by not starting from the closest state of the art, i.e. the most promising (EPO Guideline G-VII-5.1), but only from a realistic starting point. The Central Division considered that there was in this case an explicit orientation of the prior art towards the development of antibodies capable of blocking the link between PCSK9 and LLDR, because a person skilled in the art would have understood from the prior art that blocking this link could be explored for the treatment of hypercholesterolemia. Accordingly, in view of this orientation, the skilled person would have had a reasonable chance of success in obtaining the antibodies defined by my claims without engaging in an inventive step, even though he would have realized that manufacturing the antibodies and setting up the screening methods could require considerable time and resources. Thus, the Court revoked the patent in its entirety (i.e., here for all UPC member States), finding that the person skilled in the art was motivated to develop therapeutic antibodies against PCSK9 and that he would have arrived at the claimed antibodies with a reasonable chance of success without an "*undue burden*" (in reference to the time and resources required).

As we've already noted *supra*, The Munich Central Division deviates slightly from the EPO's positions on claim interpretation and assessment of inventive step. Nonetheless, the result concerning the patentability of antibodies is close to that of the EPO, and thus also differs from the U.S. approach. The Court's position is close to that of the EPO, which holds that "*the subject matter of a claim defining a novel antibody that binds to a known antigen does not involve an inventive step unless a surprising technical effect is demonstrated in the claim or unless there was no reasonable expectation of success in obtaining antibodies with the required properties*" (EPO Guideline G-II-5.6.2). Thus, in the words of the German local division, in the absence of particular difficulties, the development of antibodies for a known target is routine and therefore not inventive. This contrasts with the US revocation, based on enablement requirement, and where enablement was judged insufficient because, even from the description, the skilled person had to make an inventive effort to arrive at the millions of antibodies covered, according to the Supreme Court, by Amgen patents (21-757 Amgen Inc. v. Sanofi (05/18/23)). Eventually, UPC establishes a much higher threshold of antibodies patentability in Europe than in the United States.

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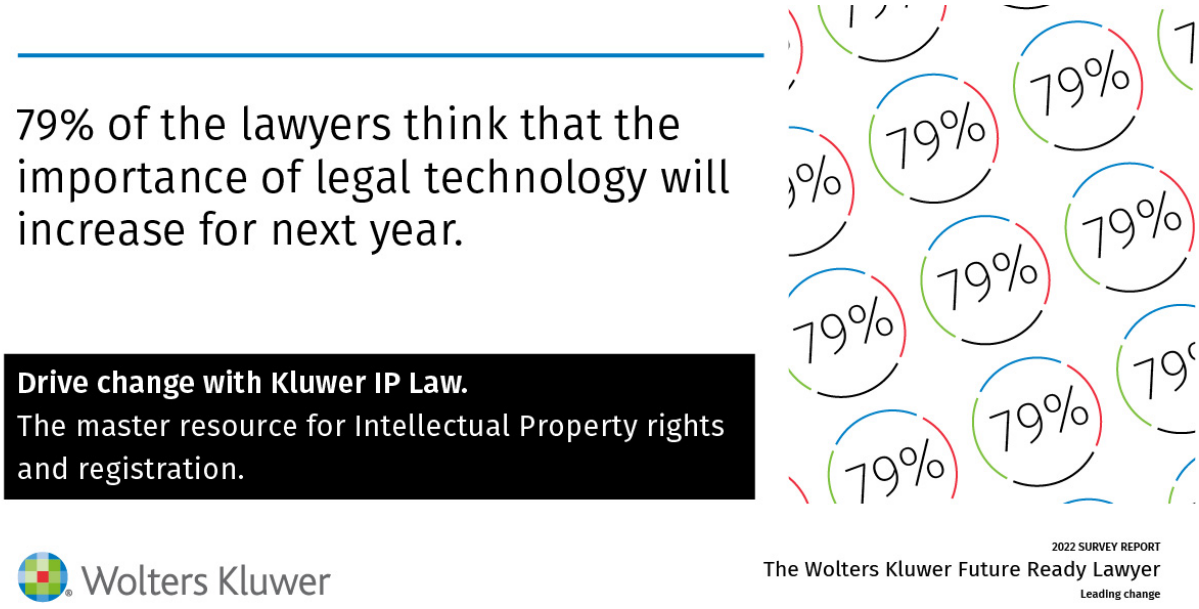



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