

<u>IN RE: XENCOR, INC.</u>, Appeal No. 2024-1870 (Fed. Cir. March 13, 2025). Before HUGHES, STARK, and <u>SCHROEDER</u>. Appealed from Appeals Review Panel of Patent Trial and Appeal Board.

Background:

The claims at issue in a continuation application filed by Xencor included a method claim and a Jepson claim related to treating a patient by administering an anti-C5 antibody with a modified Fc domain. The Examiner rejected both claims for lack of written description. Xencor appealed the Examiner's rejection to the PTAB, arguing that the claim preambles are not limiting and written description is not required for the Jepson claim preamble. The PTAB affirmed the Examiner's rejection, and found that the preambles of both claims were limiting. Xencor petitioned for reconsideration and the PTAB issued a second decision finding against Xencor on the same grounds. Xencor then appealed to the Federal Circuit, but, before the case could be heard, the USPTO asked for the case to be remanded to the ARP of the PTAB. On remand, the ARP issued a decision agreeing with the PTAB that the limiting preambles were not supported by sufficient written description. Xencor again appealed.

Issues/Holdings:

Did the ARP err in their interpretation of the preamble of the claims as limiting? No, affirmed. Did the ARP err in finding the claims unpatentable for lack of written description? No, affirmed.

Discussion:

For each of the two claims at issue, the Federal Circuit first considered whether the preambles were limiting and, second, whether the claims were supported by sufficient written description.

The first claim is a Jepson claim, reciting, "In a method of treating a patient by administering an anti-C5 antibody with an Fc domain, the improvement comprising..." Xencor argued that the invention was the "specific improvement to treating patients" and that it did not need to provide written description for what was already in the prior art. Because the invention is considered to be the claimed improvement *as applied to the prior art*, the Federal Circuit found that the inventor must provide sufficient support for the totality of the claim, including that which is contended to be in the prior art. The Federal Circuit agreed with the ARP that Xencor did not present sufficient evidence that anti-C5 antibodies were well-known in the art. Thus, the Federal Circuit affirmed the ARP's decision that the claim does not possess sufficient written description.

The preamble of the second claim recites "a method of treating a patient by administering an anti-C5 antibody." Xencor contended that only the limiting portion of the preamble requires written description and that the preamble term "treating a patient" should not be considered limiting. The Federal Circuit found, in agreement with the ARP, that the entire preamble should be limiting because the preamble language "provides a *raison d'être* for the claim". The claim recites that the modified anti-C5 antibody has an increased half-life, which would only make sense in the context of treating a patient. Xencor argued that, even if "treating a patient" was considered limiting, the claim was supported. The Federal Circuit agreed with the ARP that there was not sufficient support to show that the claimed anti-C5 antibody could be used to treat cancer, let alone all diseases and affirmed that the claim does not possess sufficient written description.



NON-FEDERAL CIRCUIT HIGHLIGHTS FOR APRIL 2, 2025

I. Miscellaneous

- A. A March 26 memo from the Acting Director of the USPTO announced new procedures for the institution of IPRs and PGRs where the deadline for the patent owner to file a preliminary response has not yet passed. Institution decisions will be bifurcated between (i) discretionary considerations and (ii) merits and other non-discretionary statutory considerations. If determined appropriate by the Director in consultation with at least 3 PTAB judges, the Director will issue a decision denying institution. If not appropriate, the petition will be referred to a three-member panel of the PTAB according to Standard Operating Procedure. Parties will be permitted to file separate briefings on requests for discretionary denial of institution.
- B. Chief Administrative Judge Scott Boalick told PTAB judges to prepare themselves for layoffs after current voluntary retirement and separation programs expire April 17. The layoffs are expected to be done according to seniority.