

Keywords: Jepson claim; written description; limiting preamble

General: The limiting preamble of a Jepson claim must be supported with sufficient written description, and what constitutes sufficiency varies depending on the knowledge of the pertinent person of ordinary skill in the art.

IN RE: XENCOR, INC.

United States Court of Appeals for the Federal Circuit

No. 2024-1870

Decided March 13, 2025

I. Facts

A. Background

Xencor, Inc. (“Xencor”) is a biopharmaceutical company, specializing in the development of monoclonal antibodies for the potential treatment of patients with cancer and autoimmune diseases. Xencor owns U.S. Patent Application No. 16/803,690 (the “’690 application”), which is directed towards treating a patient by administering an anti-C5 antibody.

Anti-C5 antibodies are monoclonal antibodies that bind to C5. One specific type of monoclonal antibody, 5G1.1, can bind human C5 protein. The Specification in the Application listed three classes of diseases/conditions that might benefit from administration of various antibodies with a fragment crystallizable (Fc) modification. The specification provided only one example of an anti-C5 antibody, 5G1.1, and did not state any examples of treating patients with 5G1.1.

The claims at issue are Claim 8 (Jepson claim) and Claim 9 (method claim). Claim 8 (Jepson claim) is shown below.

8. In a method of *treating a patient by administering an anti-C5 antibody with an Fc domain*, the improvement comprising
said Fc domain comprising amino acid substitutions M428L/N434S as compared to a human Fc polypeptide,
wherein numbering is according to the EU index of Kabat,
wherein said anti-C5 antibody with said amino acid substitutions has increased in vivo half-life as compared to said antibody without said substitutions.

(Emphasis added.)

B. Procedural History

Both claims were rejected by the Examiner for lack of written description. Xencor then appealed to the Patent Trial and Appeal Board (“Board”). The Board determined that the preambles to the claims were limiting, and the Board concluded that Xencor failed to prove that the application had sufficient written description for either claim. The Board also determined that Xencor did not show that anti-C5 antibodies or methods of treating patients with anti-C5 antibodies were well-known in the art. The case was then considered by an Appeals Review Panel (“ARP”).

First, the ARP determined whether written descriptions were required for Jepson claim preambles. The ARP decided that written descriptions were required because Jepson preambles define the scope of the claim. The ARP then looked at whether the preamble language of “treating a patient,” even without the Jepson claim format, was limiting. The ARP determined that the language of “‘treating a patient’ is required to give life, meaning, and vitality to both the ‘increased in vivo half-life’ limitation recited in the body of the claim, and to ‘administering,’ which is the sole method step recited in the claim.” J.A. 13. The ARP determined that the language in the claims, as well as the specification, showed that “treating a patient” should be considered limiting because this language was essential to understanding the scope of the claims.

Second, the ARP considered whether the claims had sufficient written description. The ARP determined that claim 8 lacked written description because the specification did not state a representative number of species to sufficiently claim the broad genus of anti-C5 antibodies. The ARP concluded that the preamble claim language of “treating a patient” was not supported with adequate written description in the specification. The ARP concluded that the limited disclosure of three potential uses was insufficient to prove possession of “treating a patient” with the claimed anti-C5 antibodies.

Xencor appealed the ruling, which rejected the claims of its patent application as unpatentable for lack of written description. On appeal, Xencor argued that the Board and the ARP mistakenly interpreted the requirement for a written description for the preamble of the claims. For the Jepson claim (Claim 8), Xencor did not dispute that the preamble was limiting.

II. Issue

- (1) Is there a written description requirement for the preamble of a Jepson claim?
- (2) If so, does the preamble of the Jepson claim meet the written description requirement?
- (3) If not, is there sufficient extrinsic evidence to establish that the limiting recitations in preamble of the Jepson claim is well-known in the art?

III. Discussion

- (1) Yes, the preamble of a Jepson claim must satisfy the written description requirement.
- (2) No, Xencor’s specification did not contain sufficient written description for the Jepson claim preamble.
- (3) No, extrinsic evidence did not establish that the limitations of the Jepson claim preamble was well-known in the art.

A. Jepson claims require a written description.

In a Jepson claim, the court noted that a patentee uses the preamble to recite “elements or steps of the claimed invention which are conventional or known.” 37 C.F.R. § 1.75(e) (1996). The court concluded that a Jepson claim preamble requires written description because when the Jepson form is employed, the claim preamble is used “to define the claimed invention, thereby limiting claim scope.” *Catalina Mktg. Int’l*, 289 F.3d at 808; *see Rowe*, 112 F.3d at 479 (“When [the Jepson] form is employed, the claim preamble defines not only the context of the claimed invention, but also its scope.”); *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 315 (Fed. Cir. 1985) (“Although a preamble is impliedly admitted to be prior art when a Jepson claim is used, . . . the claimed invention consists of the preamble in combination with the improvement.”)

The court referenced 35 U.S.C. § 112, pointing out that a specification must “contain a written description of the invention . . . , in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.” The court also stated that the description is context-specific: “[T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology.” *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010); *see also Univ. of Rochester*, 358 F.3d at 923 (explaining that merely stating “automobile” in a claim would not have been sufficient written description at the time of invention of the automobile).

Here, Xencor argued that because the “invention” in a Jepson claim is the improvement, it needed only to have written description for that improvement. However, the court disagreed, pointing out that the Jepson claim invention is the totality of what is set out in the claim, just as it is for a non-Jepson claim. The court further stated that the invention is not only the claimed improvement, but *the claimed improvement as applied to the prior art*, so the inventor must provide a written description sufficient to show possession of *the claimed improvement to what was known in the prior art*. The court further stated that while a Jepson claim is directed to the improvement it makes to the prior art, the claim is a singular thing and cannot be separated; its totality is what must have written description support, which necessarily includes support sufficient to lead an ordinary artisan to understand that the inventor did possess what the patent contends was in the prior art (i.e., a patentee cannot be permitted to use a Jepson claim to avoid the requirement simply by asserting something is well-known in the art).

The court argued that accepting Xencor’s contention would be doing away with the requirement that the written description “clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.” *Ariad*, 598 F.3d at 1351 (alteration in original). The court stated that if an inventor were permitted to simply assert, without showing, that an inventor possessed what is claimed to be in the prior art, the inventor might improperly be able to obtain a patent on something the inventor did not actually possess.

Therefore, the court held that a Jepson claim preamble required a written description. To determine whether the written description requirement was sufficient, the court looked at the specification and evidence outside of the patent.

B. The application did not provide sufficient written description for a Jepson claim.

The court noted that to provide adequate written description for a Jepson claim, the applicant must establish that what is claimed to be well-known in the prior art is, in fact, well-known in the prior art. The court stated that the amount and content of the disclosure that is necessary to supply an adequate written description will vary depending on factors including the level of knowledge of the person of ordinary skill in the art, the unpredictability of the art, and the newness of the technology.

Here, the court found that the application did not define the term treating and it did not describe or provide any data associated with treating any patient with any disease or condition with any anti-C5 antibody, including an anti-C5 antibody with the claimed Fc modifications. For example, there was not one single working example describing treatment of patients with a disease or condition with an anti-C5 antibody possessing the claimed Fc modifications. Instead, the specification only listed three classes of diseases/conditions that might benefit from administration of various antibodies with an Fc modification, and only listed various unmodified antibodies, including an anti-C5 antibody (5G1.1), that could be modified and used to that end. Additionally, the specification only disclosed one anti-C5 antibody, 5G1.1, which was found to be inadequate given the “various specificities and epitopes” of the genus. Therefore, the court held that the ARP correctly determined that it was inadequate to demonstrate possession of a method of treating any particular disease/condition with the claimed anti-C5 antibodies, let alone all diseases/conditions within the three enumerated classes.

C. Evidence outside of the patent was insufficient to establish that anti-C5 antibodies were well-known in the art.

The court noted that the finder of fact conducting the written description inquiry may consider evidence outside the patent to understand what a person of ordinary skill in the art would have known as of the pertinent date. Here, the court agreed with the fact-finders (ARP and the Board) that Xencor had not established that the limitation in the Jepson preamble, the anti-C5 antibodies, was well-known in the art, that Xencor’s expert was not credible, and that none of the other evidence, such as examples of anti-C5 antibodies in the prior art, indicated that anti-C5 antibodies were well-known in the art. Accordingly, the court agreed with the findings of the ARP that the extrinsic evidence presented was insufficient to establish that anti-C5 antibodies were well-known in the art and, accordingly, the extrinsic evidence in the case was insufficient to meet the written description requirement for the preamble of the claims.

IV. Conclusion

Due to the substantial evidence supporting a lack of written description, the court held that Xencor’s arguments were unpersuasive and affirmed the ARP’s decision. The preamble of a Jepson claim requires a written description, and Xencor’s application did not contain sufficient written description for its preamble. In addition, evidence outside the patent did not establish that the limiting preamble was well-known in the art.