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End of the Road for Jepson Format Claims in the Life Sciences?

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In *In re: Xencor, Inc.*,[1] the US Court of Appeals for the Federal Circuit confirmed that the limiting preamble of a Jepson claim must be supported by the specification with "sufficient written description." In its decision, the court affirmed the United States Patent and Trademark Office (USPTO) Appeals Review Panel (ARP) finding[2] that Xencor's claims to an improvement to methods of treatment with anti-C5 antibodies lacked sufficient written description. The *Xencor* decision is particularly significant for patents covering antibodies and other biologics because Xencor tried to use the Jepson format to get broader antibody claims than might have been possible under written description case law from the past two decades.[3] After the *Xencor* decision, Jepson claiming is unlikely to be a successful strategy to obtain broader patent claims on antibodies and likely other biologics.

Patent at issue

So-called Jepson claims are a style of patent claim that allows a patentee to use the preamble to recite "elements or steps of the claimed invention which are conventional or known," followed by the transitional language, "the improvement comprising," in which the inventor's claimed novel contribution is recited.[4] "When this form is employed, the claim preamble defines not only the context of the claimed invention, but also its scope."[5]

In re: Xencor involved Xencor's Patent Application No. 16/803,690, which relates to modifying anti-C5 antibodies with certain amino acid substitutions that provide longer staying power in the body and allows for less frequent treatment. The application included the following claim to a method of treatment with an anti-C5 antibody in "Jepson" format:[6]

> "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.

Claim 9 of the '690 application was similar but had a non-Jepson preamble that required "[a] method of treating a patient by administering an anti-C5 antibody comprising."[7]

The USPTO decisions

The '690 application was rejected multiple times at the USPTO. After the examiner finally rejected the pending claims for lack of written description, Xencor appealed to the Patent Trial and Appeal Board (PTAB). The PTAB twice affirmed the examiner's decision and maintained the rejection for lack of written description. Xencor appealed to the Federal Circuit but, before the appeal could be heard, the USPTO asked the Federal Circuit to remand the case for consideration by the ARP.

Consistent with the earlier USPTO decisions, the ARP found that the Jepson claim preamble (which includes reference to elements or steps of the claimed combination that are conventional or known) nevertheless defines

the scope of the claim and, therefore, was limiting. In addition, the ARP also found that the phrase "treating a patient" (even without the Jepson claim format) was limiting and held "that 'treating a patient' is necessary to give life, meaning, and vitality to both the 'increased in vivo half-life' limitation recited in the body of the claim, and also to 'administering,' which is the sole method step recited in the claim."[8] Likewise,"[t]he ARP found that the remainder of the language in claims 8 and 9, as well as the specification, indicated that 'treating a patient' should be considered limiting and that this language was necessary to understanding the scope of the claims."[9]

As a result, the ARP held that claims 8 and 9 lacked sufficient written description.[10]

The Federal Circuit decision

On appeal, Xencor argued that because the preamble of a Jepson claim is not part of the invention, it does not require adequate written description.[11] In response, the USPTO argued that "Jepson claim preambles are part of the inventions and, therefore, require written description."

The Federal Circuit agreed with the USPTO and found that:

> "[T]he Jepson claim invention is the totality of what is set out in the claim, just as it is for a non-Jepson claim. The invention is not only the claimed improvement, but **the claimed improvement as applied to the prior art**, so the inventor must provide written description sufficient to show possession of **the claimed improvement to what was known in the prior art**. 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, indeed, possess what the patent contends was in the prior art."[12]

Additionally, the court further noted that in order to provide adequate written description for a Jepson claim, the specification "must establish that what is claimed to be well-known in the prior art is, in fact, well-known in the prior art."[13]

The court further explained why the preamble of a Jepson claim must have sufficient written description support with an analogy to a claim to an improvement to a time machine:

> "A patentee cannot be permitted to use a Jepson claim to avoid the requirement that she be in possession of the claimed invention simply by asserting something is well-known in the art. For example, a patentee cannot obtain a Jepson claim with a preamble that says that a time machine is well-known in the art without describing a time machine, in sufficient detail to make clear to a person of ordinary skill in the art that the inventor is in possession of such a time machine. Adoption of Xencor's position would leave the patent system vulnerable to such abuse."

The Federal Circuit further found that USPTO correctly determined that the Jepson preamble of claim 8 lacked written description. In particular, the court found no error in the PTAB's finding that "the examples of anti-C5 antibodies in the prior art were insufficient to establish that anti-C5 antibodies were well-known and thus, did not require further written description support in the specification," and that "Xencor had not otherwise shown adequate written description support."[14]

As to claim 9, Xencor argued that the "'treating a patient' portion [of claim 9] is not limiting because 'administering' inherently includes 'administering to a patient' and nothing else in the claim relies upon treatment or a patient."[15] Thus, Xencor contended that only the requirement that an anti-C5 antibody is administered required adequate written description.[16]

The court disagreed and held that "treating a patient" is limiting in the context of the preamble of claim 9.[17] Moreover, because the disclosure did not "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," the Federal Circuit affirmed the ARP's rejection of claim 9 for lack of written description.[18]

Implications of the Federal Circuit decision

The Federal Circuit's holding requires that Jepson claims contain full written support in the specification, including showing that the inventor had possession of the invention as applied to what was known in the prior art. As a result, to satisfy the written description requirements for Jepson format claims, it will be necessary for patent applications to sufficiently describe the prior art or show that the skilled artisan had sufficient knowledge such that additional description is not required. As the court explained, "[f]or example, while using the claim term 'automobile' in the nineteenth century would have been insufficient without extensive explanation in the specification, the same term today in a patent directed to mechanical engineering is likely to be well known and need no further elaboration."[19] In the context of life sciences cases in which structure/function relationships are generally considered to be unpredictable, the use of Jepson claiming is unlikely to lead to allowance of broader antibody claims than non-Jepson claiming. However, as discussed in our January 2025 alert on this matter, means-plus-function claiming may remain a viable strategy to obtain broader claims to antibodies and other biologics.

Notes

1. *In re: Xencor, Inc.,* Appeal No. 2024-1870 (Fed. Cir. March 13, 2025).
2. We previously reported on the ARP's decision.
3. See *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1366 (Fed. Cir. 2010) (*en banc*); *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th, 1330 (Fed. Cir. 2021).
4. See 37 CFR § 1.75(e); see also, e.g., *Rowe v. Dror*, 112 F. 3d 473, 479 (Fed. Cir. 1997); *Ex parte Jepson*, 243 O.G. 525 (Ass't Comm'r Pat. 1917).
5. *Rowe*, 112 F.3d 479.
6. Jepson format claims include, "(1) [a] preamble comprising a general description of all of the elements or steps of the claimed combination which are conventional or known, (2) [a] phrase such as 'wherein the improvement comprises,' and (3) [t]hose elements, steps and/or relationships which constitute that portion of the claimed combination which the applicant considers as the new or improved portion," (37 Code of Federal Regulations 1.75(e)).
7. *In re: Xencor* at page 6.
8. Id at page 6.
9. Id at pages 6 – 7.
10. Id at page 15.
11. Id at page 17 (emphasis added).
12. Id at page 18.
13. Id at pages 18 – 19.
14. Id at page 9.
15. Id.
16. Id at pages 13 – 15.
17. Id at page 14.
18. Id at page 18.

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