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Genus Claims Questions After Justices Deny Juno Rehearing

By **Anne Li and Judy He** (February 24, 2023, 4:43 PM EST)

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The case of Juno Therapeutics Inc. v. Kite Pharma Inc. has captured the attention of the legal community and beyond, as it delves into the complex world of written description in patent law. The U.S. Supreme Court recently made a significant decision in Juno by denying certiorari on appeal from the U.S. Court of Appeals for the Federal Circuit. On Jan. 9, the Supreme Court denied Juno's petition for rehearing.[1]

Juno presented the question of whether a patent's written description for a genus claim must

> demonstrate the inventor's "possession" of 'the full scope of the claimed invention' including all 'known and unknown' variations of each component.[2]

Thus, this Federal Circuit decision has major implications for the technology industry and beyond.

This denial of rehearing is significant because it may take written description off the table as the Supreme Court considers whether full scope enablement is required for genus claims in Amgen v. Sanofi.

Brief Overview of Juno

Juno Therapeutics and the Memorial Sloan Kettering Institute for Cancer Research filed a petition for a writ of certiorari to the Supreme Court to seek review on a Federal Circuit decision that invalidated claims 3, 5, 9, and 11 of U.S. Patent No. 7,446,190 for lack of written description.[3]

The claims at issue in Juno were generally directed to a chimeric T-cell receptor, or CAR, comprising single chain antibodies, or scFv, that can recognize and interact with selected target antigens, including a protein called CD19, for cancer treatment purposes.[4] The '190 patent disclosed two scFvs, but it did not disclose their amino acid sequences.[5]

Claims 3 and 9 were broadly directed to "all scFvs, as part of the claimed CAR, that bind to any target."[6] The Federal Circuit found no written description support for these claims because the specification "disclose[d] only two scFv examples and provide[d] no details regarding the characteristics, sequences, or structures that would allow a person of ordinary skill in the art to determine which scFvs

will bind to which target."[7]

As a result, the "patent provide[d] nothing to indicate that the inventors possessed the full scope of the genus that they chose to claim."[8]

Claims 5 and 11 were limited to scFVs that can bind to CD19.[9] However, as with claims 3 and 9, the Federal Circuit found no written description support, noting that "the realm of possible CD19-specific scFvs was vast and the number of known CD19-specific scFvs was small (five at most)," but the '190 patent "provide[d] no details about which scFvs bind to CD19 in a way that distinguishes them from scFvs that do not bind to CD19."[10]

On Nov. 7, 2022, the Supreme Court denied Juno's petition for a writ of certiorari[11] — just three days after it had granted certiorari in Amgen v. Sanofi, which presented the question of whether full scope enablement was required.[12]

Juno filed a petition for rehearing on Nov. 23, 2022, asserting that "the question the Court agreed to review in Amgen is closely 'related' to the question presented in [Juno]" and that the Court should either grant its instant petition or at least hold off on denying certiorari until after Amgen is resolved.[13] The court denied Juno's petition for rehearing.

So, Where Does Juno Leave Us on Written Description?

With the Supreme Court's denial of rehearing in Juno, we are left with the Federal Circuit's decision.

But Juno does not hold that a specification must describe everything for genus claims to meet this requirement; rather, what the Federal Circuit seemed to take more issue with was the specification's failure to provide enough details of defining characteristics, common structural features, and shared traits that could be used to sufficiently identify what exactly the inventors were in possession of.

As such, while Juno does not ask for everything, it does provide a cautionary tale against disclosing too little.

Conclusion

Written description remains a very fact-intensive inquiry, and while it is separate and distinct from enablement, the two can rise and fall together.

As the patent community continues to monitor the fate of enablement in Amgen v. Sanofi, the Supreme Court's denial of rehearing in Juno leaves in place the Federal Circuit's language for full scope written description, along with the question of how much detail needs to be provided for a genus claim to satisfy this requirement.

Indeed, while Juno does not require one to describe everything and there is no perfect number of examples that a specification must have to meet this requirement, it can be very hard from a practical perspective for a patent prosecutor to continuously balance the pros and cons with including too much — e.g., costly and unrealistic — with including too little — e.g., may be invalidated later.

And the challenge may be compounded for unpredictable arts. As for litigators, the denial of rehearing ends the road for Juno, but the outlook for additional guidance on written description and what "full

scope" really means in the context of Section 112 disputes remains strong as the Supreme Court continues to consider enablement in Amgen v. Sanofi.

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[1] Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1333-34 (Fed. Cir. 2021),cert. denied,143 S. Ct. 402 (2022),reh'g denied,No. 21-1566, 2023 WL 124509 (Jan. 9, 2023).

[2] Petition for Writ of Certiorari, Juno Therapeutics, Inc. v. Kite Pharma, Inc., No. 21-1566 (2022).

[3] Id.

[4] Juno Therapeutics, Inc. v. Kite Pharma, Inc., 10 F.4th 1330, 1333-34 (Fed. Cir. 2021),cert. denied,143 S. Ct. 402 (2022),reh'g denied,No. 21-1566, 2023 WL 124509 (Jan. 9, 2023).

[5] Id. at 1333.

[6] Id. at 1339.

[7] Id.

[8] Id. at 1337.

[9] Id. at 1340.

[10] Id. at 1342.

[11] 143 S. Ct. 402 (2022).

[12] Amgen Inc. v. Sanofi, 143 S. Ct. 399 (2022) (limited grant to Question 2 presented by the Petition for Writ of Certiorari, which asks whether enablement must "enable those skilled in the art 'to reach the full scope of claimed embodiments' without undue experimentation – i.e., to cumulatively identify and make all or nearly all embodiments of the invention without substantial 'time and effort'" (emphasis in original).).

[13] Petitioners' Petition for Rehearing at 2-3, Juno Therapeutics, Inc. v. Kite Pharma, Inc., No. 21-1566 (2022).