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Amgen Petitions for En Banc Rehearing for Federal Circuit to Reconsider Enablement of Genus Claims

by Tina Williams McKeon , Christopher Thomas

As we reported last month, the Federal Circuit panel in *Amgen v. Sanofi* affirmed the district court's judgment as a matter of law invalidating genus claims in U.S. Patent Nos. 8,829,165 and 8,859,741 that recite functional limitations covering Amgen's cholesterol medication Repatha® by focusing on full scope enablement. Now, Amgen has filed a petition for *en banc* rehearing arguing that the panel improperly created a new and heightened test for enablement of genus claims with functional limitations.[1] In the petition, Amgen poses the following questions:

> [Question 1:] Whether the panel's new enablement test for genus claims with functional limitations . . . conflicts with Supreme Court decisions . . . .
>
> [Question 2:] Whether enablement is a question of fact, as the Supreme Court has held, or a question of law, as [the Federal Circuit] holds . . . .[2]

Amgen argues that the panel decision announces a new standard for enablement that stymies breakthrough inventions. According to Amgen, the new test for enablement of genus claims reciting functional language is evaluated according to how much "time and effort" is required to make and test every embodiment so as "to reach the full scope of claimed embodiments," thereby requiring the Applicant to identify every embodiment meeting the claimed function.[3] In other words, an Applicant claiming a genus reciting functional language would have to make, identify, and test *all* potential embodiments to satisfy the heightened enablement standard. Amgen argues that this new standard, in effect, would invalidate any genus claim reciting functional language, which is a common claiming strategy for biotechnology innovations.

Notably, Amgen argues that Sanofi failed to identify even one embodiment of the claimed genus that could not be quickly or easily made by a person of ordinary skill in the art. Amgen states that generating and testing the "millions" of potential embodiments was routine to one skilled in the art. Amgen went on to say that the patent's written description "showed exactly how to make the claimed antibodies, every time." [4] Amgen asks that the Federal Circuit return to evaluating enablement by looking at whether undue experimentation would be required to practice particular embodiments, a standard that should require "concrete proof" that an embodiment is not enabled.[5]

This particular case started in 2014, and Amgen previously sought rehearing *en banc* and filed a petition for writ of certiorari with the Supreme Court when the first Federal Circuit panel to hear this case remanded to the district court for further analysis. Both the request for rehearing *en banc* and the cert petition were denied at that time. Unless Amgen is successful in reversing the panel's decision this time, claims to antibodies based on their function (e.g., binding a target and/or blocking a function) will continue to be at peril before the USPTO and courts. Claims to therapeutic antibodies would require structural features, such as sequences of CDRs, which are narrower than functional claims. Amgen is right—the stakes are high for biotechnology inventions.

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Footnotes

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[1] Appellants' Petition for Rehearing En Banc, Amgen Inc. v. Sanofi, 987 F.3d 1080 (Fed. Cir. 2021) (No. 20-1074).

[2] *Id*. at 12-13.

[3] *Id*. at 13 (emphasis omitted).

[4] *Id*. at 16.

[5] *Id*. at 14.