Amgen v. Sanofi: The Fallout

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The Supreme Court recently announced its decision in the widely-watched case of *Amgen v. Sanofi*.[1] The Court held that Amgen's generic, functional antibody claims were not enabled by a description of the method the inventors used to make the embodiments of the invention disclosed in the patent. While that statement by itself is, perhaps, breathtaking to consider, all is not lost. There is something useful to be learned from this case, and those drafting patent applications hoping to claim novel and nonobvious antibody functions in the future can do more than Amgen did to enable such claims.

First, the Court stated its belief that enablement of such claims is not impossible (slip op. at 13-14). The opinion, penned by Justice Gorsuch and joined by the unanimous Court, includes dicta suggesting that patentees include, as enablement, some quality or characteristic common to members of the claimed genus. The Court cites *The Incandescent Lamp Patent*[2] as providing this suggestion, but that case held the claims of the subject patent indefinite, with discourse more applicable to the written description requirement, and no mention of enablement.[3] Describing a characteristic common to members of the claimed genus, without describing some method that exploits the common characteristic, will not necessarily help anybody make embodiments. In fact, a quick (or perhaps not so quick, the specification is quite large) review of the Amgen patents reveals that Amgen identified a number, a large number, of common characteristics of embodiments of the invention throughout the disclosure, and Sanofi did not challenge the written description of the patents. Suffice it to say, however, that the Court seems to believe that broad, valuable, claims covering fundamentally important inventions in esoteric technologies such as antibodies can be successfully enabled.

Second, the Federal Circuit, in its opinion invalidating Amgen's claims, gave significant guidance regarding the lack of enablement that was repeated by the Supreme Court. Upon reading both opinions, what emerges is a skepticism common to both courts that the method described by Amgen can reliably make embodiments of the invention. Amgen's method relies on using a biological agent to make a broad collection of antigen binding proteins and then subjecting those proteins to a selectivity process that separates antigen binding proteins of the invention from other proteins. The Court characterized this process as "trial-and-error," but in fact this process amounts to nothing more than a chemical separation process. A substrate has a target substance applied to it, and the desired proteins are separated by their interaction, or lack of interaction, with the target substance. Such methods are ubiquitous in isolating products of chemical reactions.

Amgen could have done more to resist this characterization, by both courts, of their method as "trial-and-error." The fact is that the method is better described as "react-and-purify." That is

[1] No. 21-757 (May 18, 2023).
[2] 159 U.S. 465 (1895).
[3] "The question really is whether the imperfectly successful experiments of Sawyer and Man, with carbonized paper and wood carbon, conceding all that is claimed for them, authorize them to put under tribute the results of the brilliant discoveries made by others." *Id.* at 474.

not what we can learn from this case, however. Given the complexity of the enablement method, it is not unreasonable to want assurance of some kind that the method reliably makes embodiments of the invention. After all, if there is considerable uncertainly about whether embodiments of the invention result from practicing the method described in the specification, it can be successfully argued that enablement has not been provided. Amgen did not point to any description in the specification of using their enablement method to make embodiments other than the two examples, 21B12 and 31H4, that they describe at considerable length in the specification. Amgen would have had a better case for enablement had they described more syntheses of embodiments of the invention in the patents, and it would have been even better if the embodiments were diverse. The more such example syntheses (not just example proteins) they could have written into the specification, the better the case for enablement would have been.

I learn from this case that enablement becomes more important and more demanding the broader the claims and the more esoteric the technology. In cases like the *Amgen* case, the combination of technological sophistication and claim breadth demands the most painstaking enablement (and written description). While Amgen appeared to take great pains with written description in the patents at issue, the enablement was thin because there was no showing that the method would reliably create embodiments of the full scope of the claimed invention. It is clear that enablement would have been more convincing in the Amgen case if the specification had described multiple instances of practicing the method to produce embodiments, had included data that shows the resulting embodiments are embodiments of the invention, and had included data that shows the resulting embodiments are diverse.

In some ways, the result in *Amgen* parallels what the Federal Circuit held in *Ariad Pharms., Inc. v. Eli Lilly & Co.*[4] In that case, the court expressly stated the requirement that written description support for a broad genus claim include "either a representative number of species within the scope of the genus or structural features common to the genus so that one of skill in the art can visualize or recognize members of the genus."[5] Here, while not expressly stated by the Court as a requirement, the enablement of the Amgen claims would have been more convincing had Amgen included some "representative syntheses" of embodiments, preferably diverse embodiments, of the invention to show that the method described was not merely "trial-and error." It is worth taking time to compare the Amgen patents with patents at issue in other similar cases, such as *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*,[6] where written description, and not enablement, was the deciding factor. Future patent drafters in this space can take heart that, while the *Amgen* result is challenging, there does seem to be a path forward for broad antibody patents.

[4] 598 F.3d 1336 (Fed. Cir. 2010) (en banc).
[5] *Id.* At 1350, *quoting Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997).
[6] 10 F.4th 1330 (Fed. Cir. 2022) (*cert. denied* Nov. 7, 2022).