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What the Federal Circuit's Recent Amgen v. Sanofi *Decision Tells Us About the State of Enablement Law*

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On February 11, 2021, the Federal Circuit affirmed the district court's judgment as a matter of law ("JMOL") that Amgen's asserted claims to genera of antibodies were invalid for lack of enablement.[1] The panel consisting of Chief Judge Prost and Judges Lourie and Hughes unanimously affirmed the District of Delaware's holding that undue experimentation would be required to practice the full scope of the claims-at-issue.[2]

Although this decision was highly fact-dependent, turning on the scope of particular antibody claims and the level of detail in the attendant specifications, its implications potentially stretch beyond the biotech space to the state of enablement law more generally. In particular and as further explained below, the decision appears to take steps to harmonize the prior cases that appropriately were guided by the *Wands* factors with the cases discussing the "full scope" of enablement that have engendered some confusion in the law.

Background of the Decision

Amgen Inc., Amgen Manufacturing, Ltd., and Amgen USA, Inc. (collectively, "Amgen") appealed from a decision of Judge Andrews of the District Court for the District of Delaware granting JMOL of lack of enablement of claims 19 and 29 of U.S. Patent 8,829,165 (the "'165 patent") and claim 7 of U.S. Patent 8,859,741 (the "'741 patent").[3] The '165 patent and the '741 patent claim antibodies that bind to one or more of fifteen amino acid residues of the proprotein convertase subtilisin/kexin type 9 ("PCSK9") protein and block PCSK9 from binding to low-density lipoprotein ("LDL") receptors.[4] This, in turn, allows LDL receptors to continue regulating the amount of circulating LDL cholesterol linked to heart disease. The court found that the claimed antibodies were defined by their function: binding to specific amino acid residues on the PCSK9 protein and blocking the PCSK9/LDL receptor interaction.[5] The specification was said to disclose amino acid sequences for twenty-six antibodies that fall within the claims, including the antibody evolocumab, marketed by Amgen as Repatha®.[6]

The procedural history dates back to October 17, 2014, when Amgen filed suit against Sanofi, Aventisub LLC, Regeneron Pharmaceuticals Inc., and Sanofi-Aventis U.S. LLC (collectively, "Sanofi/Regeneron") alleging infringement of the '165 patent and the '741 patent.[7] Sanofi/Regeneron stipulated to infringement of selected claims and the case was tried to a jury during which the district court granted

JMOL of nonobviousness and no willful infringement.[8] The jury determined that the patents were not shown to be invalid for lack of enablement and written description.[9]

Sanofi/Regeneron appealed and the Federal Circuit held that the district court erred in its evidentiary rulings and jury instructions regarding Sanofi/Regeneron's defenses that the patents lack written description and enablement, and remanded for a new trial.[10] On remand, the parties tried the issues of written description and enablement to a jury, and this second jury again found that Sanofi/Regeneron failed to prove that the asserted claims were invalid for lack of written description and enablement.[11] Sanofi/Regeneron then moved for JMOL and in the alternative for a new trial.[12] The district court granted Sanofi/Regeneron's motion for JMOL for lack of enablement and denied the motion for lack of written description.[13] Amgen appealed, and the matter proceeded to the Federal Circuit for the second time.[14]

The Federal Circuit's Affirmance on Enablement

35 U.S.C. §112 requires patent specifications to "enable any person skilled in the art . . . to make and use" the patented invention.[15] "To prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without 'undue experimentation.'"[16] *In re Wands* is the "go to" precedent for guidance on enablement.[17] When evaluating enablement, "the factors set forth in *Wands* . . . provide the factual considerations that a court may consider when determining whether the amount of that experimentation is either 'undue' or sufficiently routine such that an ordinarily skilled artisan would reasonably be expected to carry it out."[18]

The Federal Circuit first discussed certain of its prior decisions on enablement of what it characterized as functional claims. It stated that "what emerges" from those cases is that the enablement inquiry for claims that include functional requirements can be "particularly focused on the breadth of those requirements, especially where predictability and guidance requirements fall short."[19] The court then turned to the specific *Wands* factors.[20]

Breadth of the Claims. In determining the claim breadth, the court found that the scope of the claims was indisputably broad.[21] Instead of looking only at the number of possible embodiments falling within the claims, the court focused on the "functional breadth."[22] In doing so, the court found that the claims are significantly broader in functional diversity than what is supported by the disclosed exemplary antibodies.[23]

Predictability or Unpredictability of the Art, the Nature of the Invention, and the Amount of Direction or Guidance Presented. The court held that the invention is in an unpredictable field of science, noting the evidence that only a small subset of examples of antibodies could be predictably generated.[24] The court found that the disclosed roadmap for producing the claimed antibodies combined with the unpredictability of the art would lead a reasonable fact finder to conclude that the patent does not provide significant guidance or direction to a person of ordinary skill in the art ("POSA").[25]

Quantity of Experimentation Necessary. The court also determined that obtaining the claimed embodiments outside the scope of the disclosed examples and guidance would take undue experimentation.[26] A POSA could only do so through an involved trial and error process by making changes to the exemplary antibodies and screening for functionality or by discovering them *de novo* via a randomization-and-screening roadmap.[27]

The court further determined that this process on the facts would be undue experimentation.[28]

Key Takeaways

Five years after the *In re Wands* decision, the Federal Circuit began to discuss the "full scope" of the claim in the context of enablement—language that does not appear in 35 U.S.C. § 112.[29] Some cases seemed to focus on this question of whether the "full scope" of the claim is enabled apparently without placing it in the context of the *Wands* factors.[30] This kind of analysis had the potential to create confusion since the law has never required that every embodiment arguably covered by a claim be operative.[31]

These cases also potentially created tension with *Wands*.[32] For example, the full scope of enablement analysis could improperly put the burden on the patent owner to defend validity rather than the accused infringer to prove invalidity—the patent owner having to defend the breadth of claims as opposed to the accused infringer having to prove undue experimentation under a *Wands* analysis. Further, if the full scope of enablement analysis required operability for every hypothetical embodiment argued to fall within the scope of a patent's claims, no claim would likely survive, since an accused infringer could always dream up ways to fall within the words of a claim but be inoperative. For this reason, as noted above, the test for enablement has *not* involved a *per se* rule that inoperative embodiments render the claim invalid.[33]

Amgen v. Sanofi reaffirms that enablement, although ultimately a question of law, involves underlying factual inquiries based on the *Wands* factors.[34] The patent owner does not have to show the absence of inoperative embodiments.[35] Instead, after understanding the full scope of the claims, the *Wands* factors are applied to determine if undue experimentation is required for a POSA to be able to practice the invention, including determining whether embodiments are operative or not. This framework for a claim with a functional (operable) requirement has consonance with the original *Wands* and pre-*Wands* framework of assessing whether the number of inoperative embodiments is significant such that it "in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention."[36] The inoperative embodiment inquiry "informs the enablement inquiry" but they are not the same inquiry.[37]

Time will tell whether *Amgen v. Sanofi* resolves any confusion potentially created by the language of the "full scope" cases.[38] Innovators would do well to monitor how the law continues to develop post-*Amgen v. Sanofi*, especially in the rapidly expanding field of antibody therapeutics.[39]

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If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings New York lawyers:

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[1] *Amgen Inc. v. Sanofi*, No. 2020-1074, 2021 WL 501114 (Fed. Cir. Feb. 11, 2021).

[2] *Id.*

[3] *Amgen Inc. v. Sanofi*, 2021 WL 501114, at *3.

[4] *Id.*

[5] *Id.*

[6] *Id.*

[7] *Amgen Inc. v. Sanofi*, 227 F. Supp. 3d 333, 336 (D. Del. 2017).

[8] *Id.* at 337.

[9] *Id.*

[10] *Amgen Inc. v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017).

[11] *Amgen Inc. v. Sanofi*, No. CV 14-1317-RGA, 2019 WL 4058927 (D. Del. Aug. 28, 2019).

[12] *Id.*

[13] *Id.*

[14] *Amgen Inc. v. Sanofi*, 2021 WL 501114.

[15] 35 U.S.C. §112(a).

[16] *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F. 3d 1180, 1188 (quoting *In re Wands*, 858 F.2d 731, 736–37 (Fed. Cir. 1988)).

[17] *See In re Wands*, 858 F.2d 731 (Fed. Cir. 1988). The "*Wands* factors" are: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.* at 737.

[18] *Alcon Research*, 745 F. 3d at 1188 (quoting *Wands*, 858 F.2d at 737).

[19] *Amgen Inc. v. Sanofi*, 2021 WL 501114, at *5.

[20] *Id.*

[21] *Id.* at *6.

[22] *Id.*

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] *Id.* at *7.

[27] *Id.*

[28] *Id.*

[29] 35 U.S.C. §112(a); *see In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

[30] *See In re Wright*, 999 F.2d at 1561; *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1380 (Fed. Cir. 2007); *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1285 (Fed. Cir. 2007); *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008).

[31] *See Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576–77 (Fed. Cir. 1984) (claiming some inoperative embodiments does not necessarily invalidate the claim if a POSA could determine operative embodiments without undue experimentation); *see also Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1380 (Fed. Cir. 2002) ("[I]noperative embodiments do not necessarily invalidate the claim.").

[32] *See In re Wands*, 858 F.2d 731.

[33] *See In re Wands*, 858 F.2d 731.

[34] *See Amgen Inc. v. Sanofi*, 2021 WL 501114.

[35] *See id.*

[36] *Atlas Powder Co.*, 750 F.2d at 1576–77.

[37] *Senju Pharm. Co. v. Apotex Inc.*, 717 F. Supp. 2d 404, 428 (D. Del. 2010), *aff'd*, 485 F. App'x 433 (Fed. Cir. 2012) ("A discrete, but related, inquiry considers the presence of inoperative embodiments and informs the enablement inquiry."); *see Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1196 (Fed. Cir. 1999) ("Whether [an invention] is operable is a different inquiry than whether a particular claim is enabled by the specification.").

[38] *See Amgen Inc. v. Sanofi*, 2021 WL 501114.

[39] *See id.*