Proskauer

The Supreme Court Kept the Door Open to Genus Claims

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The U.S. Supreme Court on May 18, 2023 delivered its decision on the scope of the patent enablement requirement, set forth in 35 U.S.C. § 112, in the antibody dispute *Amgen, Inc. v. Sanofi*. While the parties obtained finality, many in the pharmaceutical and biotechnology industries received the opinion under a cloud of uncertainty and concern for exclusivity rights broad enough to both protect clinical candidates and deter competitors. While the patent bar may remain apprehensive, the Supreme Court kept the door open to genus claims. The impact of the decision may not be as far-reaching as feared.

At the center of the dispute were Amgen's U.S. Patent Nos. 8,829,165 and 8,859,741, which are directed to genera of anti-PCSK9 antibodies. Instead of protecting the antibodies based on their sequence, these patents claimed the antibodies functionally by their ability to bind to a specific region on PCSK9 and their ability to block PCSK9 from binding and degrading the LDL receptor.

While the parties stipulated to infringement, the case still included two jury trials, two appeals to the CAFC, and the demise of the U.S.P.T.O.'s "antibody exception" for satisfying the written description requirement before arriving at the Supreme Court. The second jury found claims 19 and 29 of the '165 Patent and claim 7 of the '141 Patent not invalid for lack of written description and not invalid for lack of enablement. The district court then denied Sanofi's motion for judgment as a matter of law regarding written description but granted its motion regarding enablement—overriding the jury's determination.

On appeal, Amgen argued, *inter alia*, "that the embodiments in the patent are structurally representative for the purpose of fulfilling the written description requirement, and such evidence is sufficient to indicate a structure/function correlation establishing enablement." The CAFC disagreed. Relying on its own precedent of *In re Wands*, the court affirmed the determination that the patents required undue experimentation to practice the full scope of the claims and accordingly were not enabled.

The CAFC reiterated that "[w]hile functional claim limitations are not necessarily precluded, such limitations pose high hurdles for fulfilling the enablement requirement for claims with broad functional language." The court further stated (seemingly akin to the representative species analysis for written description) that: "[i]t is appropriate, however, to look at the amount of effort needed to obtain embodiments outside the scope of the disclosed examples and guidance."

The Court took up the case to assess whether the CAFC applied a heightened enablement standard to genus claims. A multitude of amicus briefs were filed, with many warning of a potentially dire impact on investment in research and development. However, oral arguments dealt little with this issue. As discussed by the Court, the parties appeared to agree on the controlling law and appropriate standard. The parties' dispute focused on the theoretical size of the claimed genus and the number of species necessary to enable the full scope.

In a unanimous decision, the Court implicitly affirmed *In re Wands* and the CAFC's undue experimentation test for enablement. Relying on 19th and early 20th century precedent, the Court confirmed that the full scope of a claim must be enabled. However, the Court made clear that it is not necessary to describe how to make and use every embodiment within a genus. While the number of examples necessary to enable a claim will vary from case to case, the Court stated that "it may suffice to give an example (or a few examples) if the specification also discloses 'some general quality running through' the class that gives it 'a peculiar fitness for the particular purpose.'"

Exactly how *Amgen v. Sanofi* will impact *functional* genus claims remains to be seen, but the Court kept the door open for finding such claims valid and enforceable. As the CAFC noted in its *en banc* decision *Ariad v. Eli Lilly*, "written description and enablement often rise and fall together." Maybe Amgen's argument tying the written description standard to the enablement standard was not that farfetched—enablement's "general quality running through" and written description's structure-function correlation are similar concepts with different emphasis. It remains the most prudent course for patent drafters to provide robust examples and clear guidance on how to make and identify species within a well-defined genus in order to ensure a patent can withstand validity attacks based on § 112.

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