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Locke Lord QuickStudy: The Supreme Court Arguments on ?Enablement in Amgen v. Sanofi

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The oral arguments at the Supreme Court in Amgen v. Sanofi did not make the ultimate decision clear but did clarify many of the likely issues to be addressed.

Is there a dispute over the legal standard for enablement?

Several of the Justices, including Justice Gorsuch, asked whether there was a dispute on the legal standard or whether this case was factual. There were also questions on whether “cumulative effort” to make and use the claimed antibodies was dispositive, relevant, or irrelevant.

Perhaps demonstrating that the dispute may simply be the application of the law to the facts, Amgen argued the long-standing *Wands* factors “can be useful” but often become a checklist replacing the statutory test – namely, what is reasonable and important to a skilled artisan. Amgen also argued that although enablement might vary with claim scope, broad claims do not necessarily require difficult or lengthy experimentation.

Sanofi argued that both the time and effort, as well as the nature, of experimentation required to practice an invention’s full scope are relevant. Sanofi conceded some play in the “undue experimentation” standard, and that “tweaks” would not doom a claim, especially where predictable.

Amgen’s rebuttal arguments again rejected the “cumulative effort” test, arguing that how much testing was not the test for undue experimentation.

What is Amgen’s invention?

The Justices, particularly Justice Thomas, wanted to define the claimed invention. Do the claims cover only the 26 antibodies with amino acid sequences in the patents or the about-400 antibodies that Amgen identified via mouse immunizations? Or is the invention millions of antibodies potentially within the claims via conservative substitution? The Justices asked several questions that illuminated the tension created by functionally claiming a composition, as compared to process or product-by-process claims.

The Justices had a fairly good grasp of the complicated biotechnology, at least at a base level, and had little time for analogies offered by the parties regarding bats, paint, steam engines or metal airplanes. The Justices consistently focused on the invention and technology at hand.

Amgen's arguments

Amgen argued for a high burden – but not for its functionally-defined genus. Amgen argued that a granted patent, subjected to trial and upheld by two jury decisions, should not be invalidated for lack of enablement without clear and convincing evidence of failure to make an embodiment.

Amgen proposed that the claims are enabled without both: (1) evidence of some category of claimed antibodies that required "painstaking" experimentation to be made and (2) a reason why that would matter to the skilled artisan. On the first point, Amgen asserted there was no evidence that even a single antibody could not be easily made by a skilled artisan following the roadmap in its patents. On the second point, Amgen intimated that even if one antibody could not be made, that didn't matter as many antibodies could be made and used.

Amgen argued that the degree of experimentation to get all embodiments (plural) is irrelevant, and how to make any singular antibody was adequately disclosed in its patents.

Amgen also argued that companies would not invest billions of dollars to find new antibodies if genus claims were unavailable. Amgen referred to recent PTAB decisions applying the Federal Circuit's decision to require a higher showing of enablement for functionally-defined genus claims.

Sanofi's arguments

Sanofi argued the "heart" of the patent bargain (which requires more enablement for broader claims – the so-called full scope test) doomed Amgen's claims. Sanofi asserted that Amgen's claims cover millions of antibodies, claim antibodies binding at sixteen residues, but only disclose embodiments that bind nine.

Sanofi agreed the 26 antibodies identified by amino acid sequences, ("the recipe"), were enabled but otherwise Amgen's patents merely identified a laborious (although routine) process with a "hope" for an acceptable antibody. Sanofi focused on the unpredictability in this art and touted the amicus brief by Nobel Laureate Sir Gregory Winters as a must-read for the Justices. Sanofi indicated that even Amgen agreed that a single amino acid change in an antibody requires retesting for the binding and blocking attributes.

The U.S. Government's arguments

The Government jumped in where Sanofi left off, agreeing with all Sanofi had argued. Indeed, the government went further, proposing that amino acid sequences were (all but) required for enablement. As to the supposed death of genus claims, the Government argued that if new rules were required, it was up to Congress, not the Court, and that standard enablement and doctrine of equivalents law was, and has been, adequate to protect innovation.

The Government argued that patent claims should cover only what is invented and not cover what still needs to be or could be invented, pointing out that it is not required to make a "better mousetrap" to obtain a patent just a "different" one.

Many friends of the court

The Justices and parties referred several times to arguments made in amicus briefs. The Justices asked Sanofi, why is “Lemley” wrong?, referring to the serially cited law review article, D. Karshtedt, M. Lemley & S. Seymore, *The Death of the Genus Claim*, 35 Harv. J.l. & Tech. (rev. Apr. 19, 2021). Sanofi responded with the argument that the Federal Circuit has not foreclosed all genus claims, and the government went further to point to a more recent publication from Lemley suggesting that the very patents at issue are not enabled.

The amicus brief of Sir Gregory Winters was also mentioned, almost akin to an expert opinion in support of Sanofi’s position.

Conclusion

We will have to wait for the decision to see which of these arguments resonated most with a majority of the Court. Based on the fact-specific questions of the Justices, we expect the opinion to be similarly fact-based without a wide-sweeping pronouncement that dooms or upholds all genus claims.

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