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Client Alert: Supreme Court Affirms High Enablement Bar for Drug Patents

Publications

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On May 18, 2023, the Supreme Court affirmed the Federal Circuit's (CAFC) decision on enablement in *Amgen Inc. v. Sanofi*, 987 F.3d 1080 (CA Fed. 2021). The Court thus left in place a significant decision making it more difficult for drug companies to block competitive products that are functionally equivalent, but structurally different. In particular, the Court held that the Federal Circuit's approach to determining enablement in functional genus claims is consistent with the statute and Supreme Court case law.

The Patent Claims

The case involved Amgen's patents on monoclonal antibodies that block a protein (PCSK9) that increases bad (LDL) cholesterol levels. Amgen's patent claims encompassed any monoclonal antibody that would bind to residues on PCSK9. Thus, if Amgen's claims survived, they would have blocked any competitive antibody drug that treated high LDL levels by blocking PCSK9.

Amgen's patent only disclosed 26 examples of antibodies that met its functional claim language. But Amgen could not deny that there are a "vast" number of other possible antibodies that would fall within the scope of Amgen's claims.

Lower Court Proceedings

A jury found Amgen's claims enabled, but the trial judge invalidated the claims on a motion for judgment as a matter of law. The Federal Circuit affirmed. The CAFC focused on the functional nature of the claims—i.e., that the claims defined the antibodies solely by whether they would bind to the protein in question. The CAFC noted that Amgen's claims define the claimed composition "not by structure, but by meeting functional limitations." The court acknowledged that "functional claim limitations are not necessarily precluded in claims that meet the enablement requirement" but admonished that "such limitations pose high hurdles in fulfilling the enablement requirement for claims with broad functional language."[1]

The CAFC also explained that "while some need for testing by itself might not indicate a lack of enablement" the testing Amgen disclosed was inadequate. Amgen's testing was either "trial and

error, by making changes to the disclosed antibodies and then screening those antibodies for the desired binding and blocking properties," or else "by discovering the antibodies *de novo*" according to a randomization-and-screening "roadmap." The CAFC concluded, "Either way, we agree with the district court that the required experimentation 'would take a substantial amount of time and effort.'"[2]

The Supreme Court Decision

Amgen petitioned for Supreme Court review, which was granted. However, contrary to most recent patent cases the Supreme Court has taken over the past two decades, the Court unanimously affirmed the Federal Circuit.[3]

The Court reviewed its enablement jurisprudence and noted that under Supreme Court case law, enablement may be satisfied even if a patent specification "calls for a reasonable amount of experimentation to make and use the patented invention." The Court acknowledged that "[w]hat is reasonable in any case will depend on the nature of the invention and the underlying art."[4]

However, the Court stated that Amgen's proposed methods for finding patented antibodies amounted to "little more than advice to engage in 'trial and error.'" The Court distinguished a case where preliminary testing had to be done to determine the composition of a claimed material from the situation where a scientist would have to prepare "a wide range of candidate antibodies and then screen each to see which happen to bind to PCSK9 in the right place and block it from binding to LDL receptors." In the case involving preliminary testing, one test would almost always provide the information necessary to practice the invention. A trial and error approach, however, requires an unknown and unpredictable amount of effort and even then, absent some luck, may not lead to a positive result.[5]

Nevertheless, the Court was careful to point out that "enablement is not measured against the cumulative time and effort it takes to make every embodiment within a claim." And it acknowledged that in some cases, the very same techniques that Amgen relied on—its "roadmap" and "conservative substitution" methods—might be enough to enable other patent claims. However, the Court concluded that "they do not here."

This is perhaps the least satisfying part of the opinion. The Court stated that for the claims at issue, Amgen's proposed search methods "leave a scientist…forced to engage in 'painstaking experimentation' to see what works." But the Court did not provide a legal test for distinguishing painstaking experimentation from reasonable experimentation. The issue is purely one of law—the jury found for Amgen, meaning that all factual disputes must be assumed to fall Amgen's way. It would have been better had the Court provided more guidance on how a judge or court of appeals is supposed to distinguish between reasonable and painstaking experimentation. However, the Court appears to be leaving that to the Federal Circuit to continue to develop in future cases.

Fortunately, however, the Court went on to expressly reject Amgen's argument that the Federal Circuit's decision was a change in the law and "raise[d] the bar" for enablement of genus claims that "defined by their function." Significantly, the Court agreed with Amgen that there is only one enablement standard applicable to all types of claims, including functional genus claims. In applying this single enablement standard to Amgen's claims, the Supreme Court recognized that "the more a party claims for itself the more it must enable."

In fact, the Court suggested that a patent with broad functional claims may need to "identif[y] a quality common to every functional embodiment," citing to *dicta* from its own case of *The Incandescent Lamp Patent*, 159 U. S. 465 (1895). Earlier in its decision, the Court hypothesized 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.'"[6]

Conclusion

Thus, the two key take-aways from the Supreme Court decision are:

1. The Federal Circuit's enablement test for functional genus claims is consistent with the Patent Act and Supreme Court precedent; and

2. The legal tests for whether the level of experimentation required is reasonable or not is left to the Federal Circuit to develop.

In addition, the Federal Circuit decision—and its holdings—are binding precedent in all district court and Patent Trial and Appeal Board cases. That means that chemical, pharmaceutical, or biological patents that claim a broad genus solely by its function (or with limited structural limitations) are likely vulnerable if the patent specification fails to provide some principle for finding compositions with the claimed function beyond simply using a trial and error approach.

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Footnotes

[1] 987 F.3d at 1087.

[2] *Id.* 1087-88.

[3] No. 21-757 *Amgen Inc. v. Sanofi*, 598 U.S. __ (May 19, 2023) *available at* https://www.supremecourt.gov/opinions/22pdf/21-757_k5g1.pdf

[4] *Id.* 15.

[5] *Id.* 17-18.

[6] Citing *id.* at 475

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