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A Narrow Ruling on Broad Patent Claims: *Baxalta* v. *Genentech* Elongates the *Amgen v. Sanofi* Line of Authority

The United States Court of Appeals for the Federal Circuit recently delivered a precedential opinion in *Baxalta v. Genentech*,[1] affirming the invalidity of patent claims directed to a genus of antibodies—defined solely by their function—for lack of enablement. The decision can largely be seen as an affirmance that the enablement requirement of 35 U.S.C. §112 remains unchanged post-*Amgen v. Sanofi*,[2] but it can also be viewed as a distillation of *Amgen*'s most important takeaways for patent holders hoping to assert genus claims in the life science fields. This seems evident given the Federal Circuit's statement that the facts of *Baxalta* are "materially indistinguishable from those in *Amgen*."[3] For patent holders and innovators alike, the silver lining is that this decision seems to be fairly narrow and stops short of foreclosing patent protection on genus claims altogether.

Background

Baxalta involves U.S. Patent No. 7,033,590 ("the '590 patent") directed to antibodies and antibody derivatives that trigger a coagulation cascade to promote blood clotting in patients suffering from Hemophilia A. Baxalta alleged that Genentech's product, Hemlibra®, infringed Baxalta's '590 patent. After the Federal Circuit vacated an earlier claim construction decision and sent the case back to district court, Genentech moved for summary judgment. Genentech argued that, among other things, the asserted genus claims of the '590 patent were invalid for lack of enablement. After the district court ruled in favor of Genentech, Baxalta appealed.

The enablement requirement under §112(a) requires that a patent's specification describe an invention and "the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains…to make and use the same." In other words, the specification must teach a person of skill in the art how to make and use the full scope of the claimed invention without "unreasonable experimentation."[4] As it relates to genus claims, this requirement creates a natural tension between inherently large genera and obtaining patentable claims covering their full scope.

Claim 1 of the '590 patent, the only independent claim under scrutiny, is a functional genus claim covering antibodies, that (1) bind to a specific enzyme, Factor IX/IXa, necessary to induce the coagulation cascade; and (2)

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[1] *Baxalta Inc.* v. *Genentech, Inc.*, 81 F.4th 1362 (Fed. Cir. 2023).

[2] *Amgen Inc.* v. *Sanofi*, 598 U.S. 594 (2023).

[3] *Baxalta*, 81 F.4th at 1366.

[4] *Id.* at 1367 (citing *Amgen*, 598 U.S. at 613).

increase its procoagulant activity. The Federal Circuit was thus tasked with determining whether the specification allowed a person of skill in the art to "obtain[] new antibodies" that performed these functions without "unreasonable experimentation."

The Federal Circuit's Decision

Drawing factual parallels to the *Amgen* case,[5] the Federal Circuit in *Baxalta* relied on similar reasoning to hold that the claims of the '590 patent are invalid for lack of enablement. In *Amgen*, the United States Supreme Court invalidated the claims at issue by relying heavily on the policy behind the enablement requirement. With reference to decades-old precedent, the Court stated that "the more a party claims for itself the more it must enable."[6] Because the amount of experimentation necessary to practice the "full scope" of what was claimed was "unreasonable," the claims were held invalid.

The Federal Circuit in *Baxalta* builds on the Supreme Court's reasoning in *Amgen*, providing a more contemporary buttress. Citing *In re Wands*,[7] the Federal Circuit pointed out that following the '590 patent's specification would require "undue experimentation"[8] to practice the "full scope" of what was claimed. Specifically, the patent's written description:

- disclosed only eleven antibody sequences out of millions of potential candidate antibodies,
- failed to detail why the eleven disclosed antibodies perform the functions claimed, or why other screened antibodies do not,
- failed to provide an adequate "roadmap" that would lead a person of skill in the art to produce the undisclosed but claimed antibodies, and
- failed to disclose "a quality common to every functional embodiment,"[9] that would have allowed a skilled artisan to predict which antibodies could perform the claimed functions.

The Federal Circuit elaborated on the inadequacy of Baxalta's roadmap by pointing out that, as in *Amgen*, the '590 patent's specification simply instructed others to perform the same trial-and-error process undertaken by the inventors of the patent.[10]

Implications

What does this decision mean for patent owners seeking to enforce genus claims? Patent infringement suits involving genus claims are still viable.[11] *Baxalta* and *Amgen* appear to be holdings that are limited to genus claims the

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[5] The claims are similar to the extent that they are directed to a "genus" of embodiments defined by their function.

[6] *Amgen* at 616.

[7] *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).

[8] The *Baxalta* court sees "no meaningful difference between *Wands*' 'undue experimentation' and Amgen's '[un]reasonable experimentation' standards." *Baxalta*, 81 F.4th at 1367 n.4.

[9] *Id.* at 1366.

[10] *See Amgen*, 598 U.S. at 613-615.

[11] Several recent decisions have maintained the validity of genus claims in the life sciences fields, *See, e.g.*, *Bayer Healthcare LLC* v. *Baxalta Inc.*, 989 F.3d 964 (Fed. Cir. 2021) (holding a genus claim to "polypeptide conjugate[s]" not invalid for lack of enablement); *Ajinomoto Co.* v. *Int'l Trade Comm'n*, 932 F.3d 1342 (Fed. Cir. 2019) (upholding the validity of a claim reciting a method for producing an aromatic L-amino acid requiring the use of a genus of "more potent promoter[s]"); *Par Pharm., Inc.* v. *Hospira, Inc.*,

embodiments of which are defined solely by their function and which encompass an extraordinary number of potential candidates.

In the context of functional genus claims, *Baxalta* teaches that enablement of an especially large genus must be more reasonably defined—for example, by describing a "quality common to every embodiment."[12] Of course, it is important to remember that including a common quality limitation will require that the patent include a sufficient degree of certainty that the limitation exists throughout the entire genus claimed. It should also be noted that this holding has no bearing on claims directed to individual species embodiments of genus claims. In other words, increasing the number of claimed embodiments can also help to preserve a defensible patent boundary.

Furthermore, this decision has no bearing on the enforceability of other patents that can cover the make, use, and manufacture of embodiments of genus claims. Therefore, it is always advisable to seek out patent protections on many aspects of innovation related to life sciences developments.

Conclusion

While the fallout from *Amgen* is still settling, patent holders can maintain a cautious optimism that genus claims in the life sciences are still viable and can be asserted.

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If you have any questions about the issues addressed in this memorandum, or if you would like a copy of any of the materials mentioned in it, please do not hesitate to contact authors Gerald Flattmann (Partner) at 212.701.3645 or gflattmann@cahill.com; Andrew Cochran (Counsel) at 212.701.3320 or acochran@cahill.com; Anthony Rea (Associate) at 212.701.3409 area@cahill.com; or email publications@cahill.com.

No. 2020-1273, 2020 WL 6846347 (Fed. Cir. 2020) (affirming the validity of a claimed composition reciting multiple chemical genera defined by their function).

[12] *Baxalta*, 81 F.4th at 1366.