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# Enabling Biotech Genus Claims Defined Only by Function — A Nearly Impossible Goal — *Baxalta Incorporated v. Genentech Inc.* (Fed. Cir. Sept. 20, 2023)

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In the aftermath of *Amgen v. Sanofi*,[1] courts continue to invalidate genus claims for lacking enablement. *Baxalta Incorporated v. Genentech Inc*.[2] shows that it is nearly impossible to meet the enablement requirement for claims only reciting the activity of an antibody.

Balxalta Inc. and Baxalta GmbH ("Balxalta") own United States Patent No. 7,033,590 (filed Apr. 25, 2006). The claims are directed to the treatment of Hemophilia A using antibodies binding to Factor IX/IXa. The binding to factor IX/IXa results in an increase of the procoagulant activity of factor IXa and allows Factor IXa to activate Factor X in the absence of Factor VIII/VIIIa, therefore treating hemophilia A.

Baxalta sued Genentech for infringing the '590 Patent by making and selling Hemlibra® (emicizumab), a humanized bispecific antibody that binds to Factor IXa with one arm and Factor X with the other arm. The United States District Court for the District of Delaware granted summary judgment that claims are invalid for lacking enablement.[3] The Federal Circuit affirmed the district court's decision in a precedential decision.

**The Claims**

Claim 1 of Baxalta's '590 Patent recites:

> 1. An isolated antibody or antibody fragment thereof that binds Factor IX or Factor IXa and increases the procoagulant activity of Factor IXa.

'590 Patent col. 101 ll. 43-45.

**The Disclosure**

The inventors generated the antibodies claimed in the '590 Patent using a well-known technology: the hybridoma technology. The inventors then screened candidate antibodies from the four fusion experiments to determine whether the antibodies bind to Factor IX/IXa and increase procoagulant activity as claimed. The inventors discovered that only 1.6% of the thousands of screened antibodies increased the procoagulant activity of Factor IXa. The '590 Patent discloses the amino acid sequences of eleven antibodies that bind to Factor IX/IXa and increase the procoagulant activity of Factor IXa.

**The Court's Reasoning**

On appeal, the Federal Circuit held that the case was materially indistinguishable from the facts of Amgen. The court reasoned that there are millions of potential candidate antibodies, but the written description discloses the amino acid sequences for only eleven antibodies with the two claimed functions. The court stated that the Baxalta patent contains no disclosures—such as "a quality common to every functional embodiment"—that would allow a skilled artisan to predict which antibodies will perform the claimed functions. The court deemed that guidance "to create a wide range of candidate antibodies and then screen each to see which happen to bind" to Factor IX/IXa and increase procoagulant activity was not enough to enable the broad functional genus claims at issue.[4]

The court rejected Baxalta's argument that the case is distinct from *Amgen* because Baxalta uses a well-known hybridoma technology while Amgen uses a relatively newer, but also well-known technology[5] to produce antibodies. Baxalta argued that the hybridoma technology could reliably produce antibodies with the claimed function.[6] The Federal Circuit rejected this argument.

Notably, the hybridoma technology used by Baxalta was also used to generate antibodies in *Wands*, yet the court dismissed the analogy between this case and *Wands*, referring to an earlier decision, *Amgen Inc. v. Sanofi, Aventisub LLC*[7], noting the factual distinction between the two cases. In that earlier case, the Federal Circuit found that *Wands'* disclosure adequately taught using hybridoma technology to produce the needed claimed antibodies, and "no evidence was presented by either party on how many hybridomas would be viewed by those in the art as requiring undue experimentation to screen." *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080, 1086 (Fed. Cir. 2021) (quoting In re *Wands*, 858 F.2d 731, 740 (Fed. Cir. 1988)), cert. granted in part, 143 S. Ct. 399 (2022), aff'd, 598 U.S. 594.[8]

This case pushes the *Amgen v. Sanofi* result further in that, in a case highly similar to *In Re Wands*, the Federal Circuit decided to ignore the similarity of the underlying technologies and focus on the fact that only 1.6% of the thousands of screened antibodies in Baxalta increased the procoagulant activity of Factor IXa. When the Supreme Court struck down the *Amgen* claims, it did not mention *In Re Wands* or the undue experimentation test at all. In the instant case, the Federal Circuit saw "no meaningful difference between *Wands*' 'undue experimentation' and Amgen's '[un]reasonable experimentation' standards."[9] The Federal Circuit thus left no doubt that even *In re Wands* would not be able to save broad biotech genus claims defined by function only and closed the door to enablement for good for such claims, at least on analogous facts, where new embodiments of the claim are identified essentially only by "trial and error."[10]

**Takeaways**

It is expected that many Baxalta-type claims will be invalidated. When drafting applications, practitioners must add structural information to at least some claims or resort to alternative claim strategies to preserve any useful breadth of genus claims.

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**Footnotes**

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

[2]*Baxalta Inc. v. Genentech, Inc.*, No. 2022-1461, 2023 WL 6135930 (Fed. Cir. Sept. 20, 2023).

[3]*Baxalta Inc. v. Genentech, Inc.*, 579 F. Supp. 3d 595 (D. Del. 2022), *aff'd*, 2023 WL 6135930.

[4]*Baxalta Inc.*, 2023 WL 6135930, at *3, *4 (citation omitted).

[5]Amgen used XenoMouse technology to produce the antibodies at issue. *See*, U.S. Pat. No. 8,829,165 col. 53 ll. 30-45.

[6]*Baxalta Inc.*, 2023 WL 6135930, at *4.

[7]*Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080 (Fed. Cir. 2021).

[8]In *In Re Wands*, the declaration stated that a few of the high-binding monoclonal antibodies from two fusions were chosen for further screening. The remainder of the antibodies and the hybridomas that produced them were saved by freezing. Only nine antibodies were subjected to further analysis. Four (three from one fusion and one from another fusion) fell within the claims, that is, were IgM antibodies and had a binding affinity constant of at least $10^{9o}$ M−1-1. Of the remaining five antibodies, three were found to be IgG, while the other two were IgM for which the affinity constants were not measured (although both showed binding well above 50,000 cpm). *In re Wands*, 858 F.2d at 738.

[9]*Baxalta Inc.*, 2023 WL 6135930, at *5 n.4 (alteration in original).

[10]*Id*. at *4 (citation omitted).

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