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In the Aftermath of *Amgen v. Sanofi*, Federal Circuit Finds Functional Antibody Claims Invalid for Lack of Enablement

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Applying the Supreme Court's *Amgen v. Sanofi* decision for the first time,[1] the Federal Circuit recently affirmed a district court decision finding claims to antibodies characterized by their ability to bind a particular complex and increase its pro-coagulant activity.

The appeal in this case stemmed from a district court case in which Baxalta sued Genentech for patent infringement based on claims that were generally directed to isolated antibodies or antibody fragments that (1) bind Factor IX or Factor IXa and (2) increase the pro-coagulant activity of Factor IXa.

At the district court, Baxalta's claims were held invalid for lack of enablement at the summary judgment stage. On appeal, Baxalta argued that persons skilled in the art can follow the established hybridoma-screening process described in its patent to obtain antibodies within the scope of its claims. According to Baxalta, that sort of routine screening does not amount to undue burden.

The Federal Circuit rejected this argument, finding the claims in the Baxalta patent materially indistinguishable from the claims held invalid by the Supreme Court in *Amgen v. Sanofi*. In *Amgen*, the Supreme Court explained that "[i]f a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class. In other words, the specification must enable the full scope of the invention as defined by its claims. The more one claims, the more one must enable."

In reaching its decision in *Baxalta*, the Federal Circuit relied heavily on *Amgen*. Specifically, the court held that the claims of Baxalta's patent potentially covered millions of antibodies, while the specification disclosed the amino acid sequences of just 11 antibodies. As in *Amgen*, "nothing in the specification [teaches] how to identify any antibodies complying with the claim limitations other than by repeating the same process the inventors used to identify the . . . examples disclosed in the specification." "The patent does not disclose any common structural (or other) feature delineating which antibodies will bind to Factor IX/IXa and increase pro-coagulant activity from those that will not. Nor does the patent describe why the eleven disclosed antibodies perform the claimed functions, or why the other screened antibodies do not." Instead, it leaves it to a person of skill in the art to make and test antibodies through trial and error.

Finally, the Federal Circuit provided its understanding that there is "no meaningful difference between *Wands*' 'undue experimentation' and *Amgen*'s '[un]reasonable experimentation' standards," further stating that it did not interpret *Amgen* to have disturbed the *Wands* factor analysis.

Practice Tip: Under current law, broad genus claims are unlikely to be enabled by a specification that merely describes methods by which species of that genus can be identified. Instead, the specification should venture to identify some general quality common to members of the genus.

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

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1 *Amgen Inc. v. Sanofi*, 143 S. Ct. 1243 (2023).

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