Baxalta Inc. v. Genentech, Inc.: The Federal Circuit Addresses Enablement After *Amgen v. Sanofi*

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Baxalta Inc., v. Genentech, Inc., Appeal No. 2022-1461 (Fed. Cir. Sept. 20, 2023) is another in the line of cases where claims to biological compounds are drafted functionally and raise §112 issues. This decision was an appeal from a grant of summary judgment that held certain claims of Baxalta's '590 patent invalid for lack of enablement. The technology involved antibodies for enhancing the mechanism for blood clotting to treat patients with hemophilia type A. Claim 1 of the patent recited "[a]n isolated ***antibody*** or antibody fragment thereof ***that binds*** Factor IX or Factor IXa ***and increases the procoagulant activity*** of Factor IXa." (Emphasis added). The claim is drafted functionally; it describes what the antibody does, rather than what the antibody actually is, and it encompasses any antibody capable of achieving that function. The specification of the '590 patent disclosed only 11 actual antibodies that fell within the claim's scope, and referred to generally known methods for producing and screening antibodies.

Relying on the analysis provided by the Supreme Court's recent decision, *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023), the court found that the '590 patent's specification simply provided a roadmap for one to engage in the same iterative, trial-and-error process that the inventors used to find their 11 antibodies. It did not identify any common features that any potential antibody would have to include to function as claimed. The court therefore concluded that such an instruction, to make and screen antibodies to see if they functioned as claimed, was not enough to enable the broad functional claims of the '590 patent – "random trail-and-error discovery, without more, constitutes unreasonable experimentation that falls outside the bounds required by §112(a)."

Takeaways: The enablement standard varies based on the scope of claims sought, the unpredictability of the art, and the extent of the detailed description of the invention. Generally, claim drafters

should keep in mind that, for functionally claimed generic biological inventions, there should be some reasonable disclosure of common or representative features possessed by the molecules that will correlate with the performance of the function(s) claimed. For functionally defined generic claims, it is not enough to teach how to make the agents and how to test them to determine if they will work for the intended purpose. Therefore, as possible, attention should be paid as well to drafting various embodiments of sub-generic claims in various ways, such as varying scope top to bottom and bottom to top, that recite at least some physical or structural characteristics that the desired molecules will have.

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