Insights: Alerts

# The More You Claim, The More You Must Enable – The Supreme Court rules that Amgen's Genus-Level Antibody Claims Lack Enablement

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In a unanimous opinion announced on Thursday, May 18, 2023, the Supreme Court affirmed a Federal Circuit opinion invalidating claims in two patents owned by drugmaker Amgen for failing to properly enable claims directed to Amgen's antibody therapy drugs used to treat high cholesterol. The invalidated claims, Claim 9 and 29 of U.S. Patent No. 8,829,165 and Claim 7 of U.S. Patent No. 8,859,741, together covered millions of antibodies that bind to and deactivate the "sweet spot" of PCSK9, a naturally occurring protein in the human body. Overactive PCSK9 has been linked to high cholesterol, heart disease, and strokes. The Court's decision brings an end to litigation between Amgen and its competitor Sanofi, whom Amgen sued for infringing the now-invalidated claims back in 2014.

Amgen acknowledged in arguments to the Supreme Court that its patents covered millions of potential amino combinations that make up the therapeutic antibodies, but only disclosed the specific sequences of twenty-six potential combinations. Amgen argued that the unrecited combinations were nonetheless properly enabled because the patents' specifications provided researchers with a "roadmap" to identify other therapeutically viable antibodies. Amgen pointed to sections of the specification instructing researchers to make small amino acid changes to the twenty-six disclosed combinations and test those novel sequences for binding affinity to the PCSK9 sweet spot.

The Court rejected this argument, holding that the "roadmap" Amgen offered in its specification was nothing more than an assignment to researchers to engage in the very same testing protocols that led to the discovery of the original twenty-six antibodies. The Court explained that what Amgen did here, to instruct a person of ordinary skill in the art to engage in "random trial-and-error discovery" without identifying a "quality common to every functional embodiment" did not fulfill the enablement requirement of 35 U.S.C. 112. In doing so, the Court emphasized that the "cumulative time and effort" required to make and test the various embodiments of the challenged claims was not the proper test for enablement.

The Court likened Amgen's patent to a "combination lock with 100 tumblers, each of which can be set to 20 different positions." By claiming "all successful combinations" while instructing others in the art "to randomly try a large set of combinations and then record the successful ones," Amgen had provided a kind of "roadmap" that would produce functional combinations. But, as the Court explained, "it would not enable others to make and use functional combinations" with any increased expectation of success beyond that of simple trial-and-error.

The Court also rejected Amgen's other argument that the Federal Circuit improperly applied a higher enablement bar to claims that cover an entire genus as opposed to more narrow “species claims.” The Court reaffirmed that the Federal Circuit properly applied a single enablement standard to all claims, but that in accordance with what Congress intended “the more a party claims for itself the more it must enable.”

Cecelia Rivera, Kilpatrick Townsend law clerk and editor of University of California, Davis's, *Business Law Journal*, contributed to the contents of this article.

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