Ben Pelletier in Life Sciences IP Review: 'The Uncertain Future of Antibody Claims'

April 8, 2021 Benjamin Pelletier

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Amgen v. Sanofi continues the Federal Circuit's trend of undermining certain antibody claims, explains Benjamin Pelletier of Haynes Boone.

A long string of decisions from the U.S. Court of Appeals for the Federal Circuit has undermined support for purely functional antibody epitope claims through the written description and enablement requirements of 35 USC §112.

The latest chapter in this series of cases, *Amgen v. Sanofi, Aventisub*, issued in February, appears to place the final nail in the coffin of these highly valuable claims.

In *Amgen*, the patents in suit (U.S. nos 8,829,165 and 8,859,741) are based on Amgen's discovery that a protein ligand, called PCSK9, binds to and disables low density lipoprotein (LDL, or "bad cholesterol") receptors, and that this ligand/receptor interaction can be blocked by antibodies that bind to a specific epitope on PCSK9, thereby helping patients achieve better cholesterol levels.

The specifications of the patents in suit disclose amino acid sequences for over 20 antibodies, one of which (designated as 21B12) is the specific composition marketed as Repatha. The specifications also disclose the 3D structures of 21B12 and another antibody, 31H4, and show how these two antibodies bind to an epitope on PCSK9, resulting in a blockade of the ligand/receptor interaction.

The claims at issue are epitope claims, reciting the function of the antibody, and providing a description of the epitope to which the antibody binds, without reciting structural details of the antibody itself.

The procedural posture of the case is notable in that two separate trials took place at the district court level, both resulting in a jury verdict finding in favour of *Amgen*, and concluding that the claims were not invalid for lack of written description and enablement.

Excerpted from *Life Sciences IP Review*. To read the full article, click here.