



# CAFC Invalidates Claims of Centocor Patent Covering Fully-Human Antibody

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On February 23, 2011, the Court of Appeals for the Federal Circuit (CAFC) reversed a decision of the US District Court for the Eastern District of Texas by invalidating certain claims of U.S. Patent No. 7,070,775 ("the '775 patent"), which covered an isolated recombinant anti-TNF-alpha antibody comprising a human constant region and a human variable region. All of the asserted claims covered Abbott's Humira®, a fully-human antibody. The case is *Centocor Ortho Biotech, Inc. and NYU v. Abbott*.

The '775 patent disclosed a chimeric antibody comprised of a human constant region and a mouse variable region. The specification included a number of examples providing techniques for making a mouse antibody with high affinity activity and making a corresponding chimeric antibody based on the mouse antibody. Even in view of these examples, the court determined that the claims to a fully-human antibody lacked written description under 35 USC § 112, 1st paragraph, because the specification did not disclose any fully-human antibodies that would have fallen within the claim.

While the Plaintiff argued that the specification of the '775 patent described the structure and binding characteristics of the chimeric antibody in great detail, as well as the sequence of the human TNF-alpha protein, the court noted that the specification only provided amino acid sequence information for a single mouse variable region. According to the court, "the mouse variable region sequence does not serve as a stepping stone to identifying a human variable region within the scope of the claims."

The court also distanced the facts of this case from the USPTO's written description guidelines for antibodies, as well as *Noelle v. Lederman* (CAFC 2004).

We note that claim 1 of the '775 patent, which covers antibodies with a human constant region and a variable region from any source, was not at issue in this appeal.

If you have questions about this case, or any other aspect of biotechnology patent law, please do not hesitate to contact any member of Lathrop Gage's Boston Office.