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Focusing on the Language Used in the Claims, the Federal Circuit Vacates a District Court's Construction of the Terms "Antibody" and "Antibody Fragment"

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Plaintiff Baxalta, Inc. sued defendant Genentech, Inc. alleging that Genentech's drug Hemlibra®, which includes a bispecific antibody that can be used to treat hemophilia, infringes claims of U.S. Patent No. 7,033,590. The claims generally cover antibodies or antibody fragments that increase the activity of a specific protein and can be used to treat certain patients with hemophilia. The district court adopted defendant's narrow construction of "antibody." According to the district court, the specification expressly defined "antibody" in a way that excluded bispecific antibodies and amendments made during prosecution similarly disclaimed bispecific antibodies. The district court construed "antibody fragments" in a similar way. In light of these constructions, the parties stipulated to non-infringement and the plaintiff appealed.

Walking through the *Phillips* analysis, the Federal Circuit explained that nothing in the plain language of claim 1 limits the term "antibody" to the specific types of antibodies that the district court required. Indeed, the dependent claims confirm that the term is not so limited. Claim 4, which depends from claim 1, expressly recites a bispecific antibody as a specific species of antibody or antibody fragment. Rather than construing terms in the independent claim in a way that would render invalid the dependent claims, the correct approach was to read the claims consistent with each other.

The Federal Circuit also disagreed that the specification expressly defined the term antibody —the passage that the district court relied on was a generalized introduction to antibodies, not a definitional statement. The district court failed to "consider the specification as a

whole, and [to] read all portions of the written description, if possible, in a manner that renders the patent internally consistent." For example, the specification provided numerous disclosures referring to antibodies that included bispecific and other types of antibodies. Finally, the Federal Circuit explained that the prosecution history statements did not reach the level of a clear and unmistakable disclaimer. There were no clear statements in the prosecution history explaining what claim scope, if any, was given up when the applicant amended the pending claims.

Turning to the term "antibody fragments," the Federal Circuit held that the district court erred its construction by again relying too heavily on a specific portion of the specification. The specification's use of "may also include," "e.g.," "such as" and "etc." made clear the patentee did not intend to provide a limiting definition of "antibody fragments." The Federal Circuit provided the proper construction for both terms and remanded for further proceedings.

Practice Tip: When proposing constructions for disputed terms, make sure the proposed construction is consistent with the language of the claims as a whole. If relying on portions of the specification or prosecution history, explain why those portions expressly redefine the term in a manner that is consistent with the rest of the disclosures or show that the applicant disclaimed part of the claim's scope.

Baxalta Inc. v. Genentech, Inc., No. 2019-1527, 2020 WL 5048435 (Fed. Cir. Aug. 27, 2020)