

BAXALTA INC. v. GENENTECH, INC., Appeal No. 2019-1527 (Fed. Cir. August 27, 2020).
Before Moore, Plager, and Wallach. Appealed from D. Del. (Judge Dyk).

Background:

Baxalta sued Genentech for infringement of its patent directed to preparations for treating hemophilia. The claims were directed to "an isolated antibody or antibody fragment thereof" that binds to a clotting factor in the enzymatic coagulation cascade responsible for blood clotting and increases the procoagulant activity of that factor.

The district court narrowly construed the term "antibody" based on a passage in the specification, which described antibodies as molecules that only bind to antigens that induce their synthesis or to very similar antigens. The passage also described antibodies as being molecules that consist of two identical heavy chains and two identical light chains. Even though this construction would exclude embodiments recited in the dependent claims, the court held that this inconsistency was insufficient to overcome what it considered to be an express definition in the specification. The court considered the non-encompassed embodiments recited in the dependent claims to be "antibody derivatives," which the patentee disclaimed during prosecution by amending the claims to replace the term "antibody derivative" with "antibody fragment."

Based on the court's construction, the parties stipulated to non-infringement. Baxalta appealed, arguing that the claim construction was improper.

Issue/Holding:

Did the district court properly construe the claim term "antibody"? No—vacated and remanded.

Discussion:

The Federal Circuit considered several factors in determining that the district court's construction was improper:

(1) The district court's narrow construction was inconsistent with the plain language of the claims because it would exclude many of the embodiments recited in the dependent claims.

(2) Considering the specification as a whole, the passage cited by the district court serves only as a "generalized introduction to antibodies" rather than a definition of the term "antibody." Other passages in the specification described preparing "antibodies" with techniques that would produce antibodies that do not satisfy the district court's narrow construction.

(3) The substitution of the term "antibody derivative" with "antibody fragment" during prosecution did not constitute a disavowal of the antibodies recited in the dependent claims because there were no clear statements regarding what scope (if any) the patentee was giving up by the amendment. And any such disavowal would be inconsistent with the examiner's allowance of the dependent claims.

Accordingly, the Federal Circuit construed the term "antibody" more broadly to mean an immunoglobulin molecule comprising two heavy chains and two light chains.