Fed. Cir. Panel Holds that Judge Dyk Erred in Construction of Antibody Claims

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Recently, in the appeal of a noninfringement opinion by Judge Dyk, riding circuit in D. Del., a three Judge panel of Judges Moore, Plager and Wallach held that Judge Dyk erred in his overly narrow construction of the claim terms “antibody” [Ab] and “antibody fragment”. Baxalta v. Genentech, Appeal No. 2019-1527 (Fed. Cir., August 27, 2020). Judge Dyk had construed the claims of U.S. Pat. No. 7,033,590 that covered the hemophilia drug Hemlibra® using a “generalized introduction to antibodies” in the specification to limit the claim terms “antibody” and “antibody fragment”. Claims 1 and 4 read as follows:

1. An isolated antibody or antibody fragment thereof that binds Factor IX or Factor IXa and increases the procoagulant activity of Factor IXa.

4. The antibody or antibody fragment according to claim 1, wherein said antibody or antibody fragment is selected from the group consisting of...chimeric antibody, a humanized antibody, a single chain antibody, and bispecific antibody....

The paragraph in question, that Judge Dyk found to be “definitional” ended with the statement “Each [A] molecule consists of large identical heavy chains (H chains) and tow light also identical chains (L chains)”. Hemlibra® is a bispecific Ab that has
“different heavy chains and/or different light chains.” The panel noted that the narrow construction Ab in claim 1 caused, inter alia, claim 4 to be broader than claim 1. Judge Dyk had tried to avoid this fact by defining the claim 4 terms to be “antibody derivatives” rather than “antibodies.” During prosecution, Baxalta had canceled the term “antibody derivatives” from claim 1 following a s. 112 rejection and replaced it with “antibody fragments” and Judge Dyk held than Baxalta had disclaimed all antibody derivatives, including bispecific antibodies.

The panel found that Judge Dyk had erred in relying on one generalized, introductory paragraph, while ignoring the plain language in claim 1 that did not limit the type of antibody to one having identical heavy and light chains. The panel pointed out the written description of specific embodiments of Ab’s in the specification was also not so limited, and that the paragraph relied on by Judge Dyk was not definitional, since it did not contain any language such as “the invention is directed to” such Ab’s, while such language was used in accord with descriptions in the specification of antibodies recited in claim 4. The panel noted that “[t]he district court’s construction which excludes these explicitly claimed embodiments [as in claim 4] is inconsistent with the plain language of the claims...The plain language of these dependent claims weighs heavily in favor of adopting Baxalta’s broader claim construction [rather than simply invalidating the dependent claims.]”

With respect to the prosecution history, the panel held that “we do not apply the doctrine of prosecution history disclaimer where the alleged disavowal is less than clear.” It did not matter to the effective claim scope that “antibody derivatives” had been replaced with “antibody fragments” since claim 4 recited various classes of Ab’s, and such claimed “embodiment [is] directly at odds with a disclaimer theory. The claim term “antibody fragment” was construed simply to be a portion of an Ab comprising two heavy chains and two light chains”, i.e., of the broadly defined term “Ab”. The panel reversed and remanded.

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