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Federal Circuit Holds Claim Construction Turns on Patentee Disclaimer

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Declining to hold that one epitope can count as two, the U.S. Court of Appeals for the Federal Circuit upheld a lower court's narrow construction of the term "anti-CD20 antibody," finding that patentees disclaimed the use of anti-CD20 antibodies targeted to either of two antigenic regions on the CD20 molecule. ***Biogen Idec, Inc. v. GlaxoSmithKline LLC***, Case No. 12-1120 (Fed. Cir., Apr. 16, 2013) (Reyna, J.) (Plager, J., dissenting).

Biogen owns a patent covering a method for treating patients with chronic lymphocytic leukemia (CLL) through antibody binding to the CD20 antigens present on the CLL cell surface. The patent broadly claims uses unlimited by any particular type of anti-CD20 antibody. Dependent claims recite uses of specific anti-CD20 antibodies such as Biogen's Rituxan® approved for treatment of CLL and other leukemias in the United States.

At the time Biogen filed its application for the patent, scientists thought that only one large loop, or epitope, of the CD20 antigen was available for an antibody-mediated therapy. Rituxan and the other anti-CD20 antibodies specifically taught by the patent specification bind to this large loop. Sometime later, however, scientists discovered that therapeutic antibodies could be targeted to a second small loop on CD20. GlaxoSmithKline LLC and Glaxo Group Ltd. (collectively "GSK") and their Arzerra® antibody targeted to this second CD20 epitope. Biogen sued GSK for infringement of the Biogen anti-CD20 patent in 2010. The district court adopted GSK's construction of key term "anti-CD20 antibody" as meaning antibodies "that bind to the same epitope of the CD20 antigen with similar affinity and specificity as" Rituxan, thereby excluding GSK's Arzerra product. Based on that construction, Biogen stipulated to non-infringement and, after the district court entered judgment, Biogen appealed.

A Federal Circuit panel affirmed, finding that during prosecution of the patent, Biogen disclaimed anti-CD20 antibodies that do not "**have a similar specificity and affinity for the specific epitope to which Rituxan® binds**," *i.e.,* the first large loop of CD20. Such a "clear and unmistakable" disavowal overcame the "heavy presumption" that the term "anti-CD20 antibody" "carrie[d] its full ordinary and customary meaning" of antibodies directed to any CD20 epitope. The Court's analysis cited long-standing claim construction precedents ***Phillips v. AWH Corp.*** **and** ***Omega Eng'g v. Raytek Corp.***, among others. Yet its holding turned on a fine reading of the file history, where the examiner had argued that Biogen only enabled uses of anti-CD20 antibodies such as Rituxan

directed to the first large epitope, and Biogen appeared to concede in response that some anti-CD20 antibodies might have different properties than its antibodies specific for that epitope. In the Court's view, antibodies directed to the second small epitope of CD20 thus fell outside the scope of the patent.

In dissent, Judge Plager arrived at a contrary interpretation, explaining the decision is one on which reasonable judges could differ. In Plager's view, Biogen's failure to expressly challenge the examiner's characterization of the specification during prosecution was not a "clear and unmistakable" disclaimer as found by the majority.

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