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Protecting Antibody Innovations: Searching for Equivalents under The Doctrine of Equivalents —A Discussion of Teva v. Eli Lilly and beyond

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United States courts have recently tightened the written description requirements for antibody claims. The scope of issued claims is now often limited to antibodies with specific sequences of the CDR and the heavy chain and light chain variable domains. Patentees are concerned that competitors can easily design around patent claims by making minimum changes to the specifically claimed structural elements. Since such a design-around will not be liable for literal infringement of the claims, the question is whether a patentee can be found liable for infringement under the Doctrine of Equivalents ("DOE"). DOE applies when the accused product or process contains elements identical or equivalent to each claimed element of the patented invention. Although the U.S. Supreme Court established the tests of DOE more than five decades ago —the function-way-results ("FWR") test and the insubstantial differences test, case law addressing DOE issues related to biologics, especially antibodies, are scarce. This article discusses antibody case law, where in each case, the patentee failed to convince the court to find that the accused infringed the patentee's claims under DOE.

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