TEVA PHARMS. INT'L GMBH V. ELI LILLY & CO., Appeal No. 2024-1094 (Fed. Cir. April 16, 2026). Before Prost, Cunningham, and Andrews. Appealed from D. Mass. (Judge Burroughs).

Background:

Teva sued Eli Lilly for infringement of its patents directed toward methods of treating a headache by administering an effective amount of a humanized monoclonal antibody. At trial, a jury found that Eli Lilly willfully infringed and further that the patents were valid. The district court then granted judgment as a matter of law, stating that the patents were invalid for a lack of written description and enablement. In doing so, the district court reasoned that the patents were too broad, as they covered all humanized antibodies for anti-CGRP antagonistic antibodies that could be discovered for treating a headache, and the specification only disclosed one humanized anti-CGRP antagonistic antibody. Teva appealed.

Issue/Holding:

Did the district court err in finding that the patents were invalid for a lack of written description and enablement? Yes, reversed and remanded.

Discussion:

The Federal Circuit held the written description requirement was met because the claims were directed toward a method of treating a headache with a humanized antibody, not the antibodies themselves. Thus, the Federal Circuit held that the district court improperly focused on the specification's disclosure of the antibodies. This was because making and humanizing this antibody were both routine and well understood in the art. For instance, the district court acknowledged a person of ordinary skill in the art would have known the methods for making this specific antibody and known humanizing the antibodies was routine. The Federal Circuit also held that there was substantial evidence to support each of these findings. Although the specification disclosed just one humanized antibody, it disclosed several murine (rodent) versions and prior art methods of humanization against a backdrop that humanization was routine. Based on this, the Federal Circuit held a jury could have reasonably found the specification disclosed a representative number of antibodies.

Eli Lilly also argued that the claims were invalid for a lack of enablement. Specifically, Eli Lilly asserted that the number of antibodies in the claimed genus is very large and that the specification does not tell a skilled artisan how to determine which antibodies will be effective. Thus, this determination requires undue experimentation.

The Federal Circuit once again pointed out that the claims themselves are not directed toward the antibodies but rather toward treating headaches with the antibodies. Thus, in light of the well-known status of the antibodies and the routine nature of humanization, the correct question is: does determining which of the humanized antibodies in this genus effectively treat headaches constitute undue experimentation? In this regard, the Federal Circuit held that there is no undue experimentation because the specification makes clear, and the district court agreed, that all of these antibodies would be effective.