

When it Comes to Method of Use Claims, Preamble Language Regarding Intended Use is Limiting

Article By:

McDermott Will & Emery

The US Court of Appeals for the Federal Circuit issued three separate but related rulings (two precedential, one non-precedential) affirming decisions by the Patent Trial & Appeal Board (Board) regarding the validity of nine US patents and addressing the limitations of preamble language and motivation to combine. *Eli Lilly Co. v. Teva Pharmaceuticals*, Case Nos. 20-1876, -1877, -1878 (Fed. Cir. August 16, 2021) (Lourie, J.); *Teva Pharmaceuticals v. Eli Lilly Co.*, Case Nos. 20-1747, -1748, -1750 (Fed. Cir. August 16, 2021) (Lourie, J.); *Teva Pharmaceuticals v. Eli Lilly Co.*, Case Nos. 20-1749, -1751, -1752 (Fed. Cir. August 16, 2021) (Lourie, J.). These decisions come as the latest events in a dispute between Teva and Eli Lilly Company over competing products for the treatment of migraine headaches.

Teva owns nine patents directed to humanized antagonist antibodies that target calcitonin gene-related peptide. In 2018, the Food and Drug Administration (FDA) first approved Teva's version of the biologic fremanezumab (Ajovy®) and then approved Lilly's biologics license application for galcanezumab (Emgality®) eight days later. Both drugs are part of a new class of migraine therapeutic agents called calcitonin gene-related peptide antagonists.

Lilly challenged the validity of Teva's nine patents covering Ajovy® in a series of *inter partes* review (IPR) petitions, arguing that the claims were obvious. The Board instituted IPR for all nine Teva patents. The similarity of subject matter and arguments led to three separate written opinions, each addressing three of the patents. In these decisions, the Board upheld the validity of three of the patents at issue (which covered methods of treating migraines with the antibodies) but found the claims of the six other patents directed to the antibodies themselves invalid.

Lilly appealed the first Board ruling covering methods of treating migraines to the Court. Lilly argued that the Board erred by (1) "reading a result into the constructions of the preambles and the term 'effective amount,'" which led the Board to erroneously require Lilly to prove that a skilled artisan would have had "a reasonable expectation of achieving a result that was not claimed," and (2) applying a too-high standard when weighing evidence to determine whether a skilled artisan would have a reasonable expectation of success. Lilly contended that a claim preamble containing only a statement of purpose cannot be a claim limitation and that no weight should have been given to the preambles. Teva argued that Lilly was basing its analysis on a false dichotomy between "limiting preambles" and preambles that are mere statements of purpose.

The Federal Circuit found the claim preambles to be limiting, reasoning that claims directed to methods of using compositions “are not directed to what the method ‘is’” but rather to “what the method ‘does,’” which usually is recited in the preamble. The preambles provided the only metric by which one practicing the claim could determine whether the amount administered is an “effective amount” and provided the antecedent basis for at least one later claim term in the independent claims.

After finding the preambles to be limiting, the Federal Circuit held that Teva’s patents were not obvious because a reasonable artisan would not have expected the treatment to be effective—despite the fact that Lilly proved that such reference “discloses or suggests each and every element of the challenged claims” and that a skilled artisan would have been motivated to combine the prior art teachings.

Teva appealed the second and third Board decisions, finding that the prior art rendered the challenged claims obvious because a skilled artisan would have been motivated to combine the teachings of the prior art and would have had a reasonable expectation of successfully achieving the claimed invention. Teva argued that the Board failed to consider “demotivating factors” that would have led a skilled artisan away from the claimed uses in combining the cited prior art. The Federal Circuit rejected this argument, stating that “the relevant inquiry . . . is whether those concerns would have dissuaded a skilled artisan from making the claimed antibodies to study their therapeutic potential in the first place.” The Court also rejected Teva’s argument for secondary considerations of nonobviousness, finding that there was no “nexus” between the “extremely broad” parts of the challenged patents and the commercial products.

© 2025 McDermott Will & Emery

National Law Review, Volume XI, Number 238

Source URL: <https://natlawreview.com/article/when-it-comes-to-method-use-claims-preamble-language-regarding-intended-use-limiting>