

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

TEVA PHARMACEUTICALS  
INTERNATIONAL GMBH and TEVA  
PHARMACEUTICALS USA, INC.,

Plaintiffs and Defendants-in-  
Counterclaim,

v.

ELI LILLY AND COMPANY,

Defendant and Plaintiff-in-  
Counterclaim.

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Civil Action No. 18-cv-12029-ADB

**MEMORANDUM AND ORDER ON CLAIM CONSTRUCTION**

BURROUGHS, D.J.

In this patent infringement suit, Teva Pharmaceuticals International GmbH and Teva Pharmaceuticals USA, Inc. (collectively, “Teva”) allege that Eli Lilly and Company (“Lilly”) has infringed claims in nine patents owned by Teva related to a product marketed under the brand name Ajovy, which contains the active ingredient fremanezumab and is used to treat migraines. [ECF No. 1]. Lilly has brought counterclaims against Teva, seeking declaratory judgments that its product marketed under the brand name Emgality, which contains the active ingredient galcanezumab and is also used to treat migraines, does not infringe Teva’s patents and that Teva’s patents are invalid. [ECF No. 17]. The parties briefed claim construction for six disputed terms, [ECF Nos. 65, 66, 77, 79, 89, 90], and the Court conducted a hearing on December 15, 2020, at which the parties presented their proposed constructions, [ECF No. 88]. The Court construes the terms as set forth below.

## I. LEGAL STANDARD

### A. Claim Construction

Claim construction is the first stage of a patent infringement analysis and requires the Court to determine “the scope and meaning of the patent claims asserted.” Clearstream Wastewater Sys., Inc. v. Hydro-Action, Inc., 206 F.3d 1440, 1444 (Fed. Cir. 2000). Claim construction is a question of law for the Court, Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996), to be resolved with an eye toward the fact that the Court’s adopted construction “becomes the basis of the jury instructions, should the case go to trial” on the issue of infringement, AFG Indus., Inc. v. Cardinal IG Co., 239 F.3d 1239, 1247 (Fed. Cir. 2001).

“[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude.” Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (citation and internal quotation marks omitted). “[T]he words of a claim are generally given their ordinary and customary meaning,” which “is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” Id. at 1312–13 (internal quotation marks omitted). Certain terms “may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.” Id. at 1314.

“There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” Thorner v. Sony Comput. Ent. Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012). “To act as [his] own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning.” Id. (citation and internal quotation marks omitted). Similarly, to disavow the scope

of a claim term, “[t]he patentee may demonstrate intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.” Id. at 1366 (citation and internal quotation marks omitted).

“It is well-settled that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history.” Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996); see also Allergan Sales, LLC v. Sandoz, Inc., 935 F.3d 1370, 1373 (Fed. Cir. 2019). “First, we look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention.” Vitronics, 90 F.3d at 1582. “[S]econd, it is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning.” Id. “The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.” Id. For this reason, the specification “is always highly relevant to the claim construction analysis,” and “[u]sually, it is dispositive; it is the single best guide to the meaning of a disputed term.” Id. “Third, the court may also consider the prosecution history of the patent, if in evidence.” Id.

The prosecution history is relevant because

[it] was created by the patentee in attempting to explain and obtain the patent. . . . [T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.

Phillips, 415 F.3d at 1317.

“In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence.”

Vitronics, 90 F.3d at 1583. However, “[w]hen the intrinsic evidence is silent as to the plain

meaning of a term, it is entirely appropriate for the district court to look to dictionaries or other extrinsic sources for context—to aid in arriving at the plain meaning of a claim term.”

Helmsderfer v. Bobrick Washroom Equip., Inc., 527 F.3d 1379, 1382 (Fed. Cir. 2008).

“[E]xtrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.”

Phillips, 415 F.3d at 1319.

### **B. Indefiniteness**

Patent law speaks to indefiniteness by requiring that “[t]he specification . . . conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112. The Supreme Court has held that “a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 901 (2014). The requirement is aimed at providing the public with clear notice about what is being claimed. Id. at 911.

“Indefiniteness is a matter of claim construction, and the same principles that generally govern claim construction are applicable to determining whether allegedly indefinite claim language is subject to construction.” Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1319 (Fed. Cir. 2008). “Of course, claims are not indefinite merely because they present a difficult task of claim construction.” Halliburton Energy Servs. v. M-I LLC, 514 F.3d 1244, 1249 (Fed. Cir. 2008). “Instead, ‘[i]f the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds.’” Id. (alteration in

original) (quoting Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001)). On the other hand, “[i]t cannot be sufficient that a court can ascribe *some* meaning to a patent’s claims; the definiteness inquiry trains on the understanding of a skilled artisan at the time of the patent application, not that of a court viewing matters post hoc.” Nautilus, 572 U.S. at 911. “[A]n accused infringer [must] show[] by clear and convincing evidence that a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area.” Halliburton, 514 F.3d at 1249–50.

## II. DISCUSSION

The terms submitted for claim construction are found across nine patents: U.S. Patent Nos. 8,586,045 (“the ’045 patent”); 8,597,649 (“the ’649 patent”); 9,266,951 (“the ’951 patent”); 9,340,614 (“the ’614 patent”); 9,346,881 (“the ’881 patent”); 9,884,907 (“the ’907 patent”); 9,884,908 (“the ’908 patent”); 9,890,210 (“the ’210 patent”); and 9,890,211 (“the ’211 patent”). [ECF No. 65 at 7, 8 n.3; ECF No. 66 at 6]. Six of the patents claim as inventive anti-Calcitonin Gene-Related Peptide (“CGRP”) antibodies (composition patents), while three patents claim methods of treating migraines by using the anti-CGRP antibodies (method of treatment patents). [ECF No. 65 at 8].<sup>1</sup> Since all of the patents share a common specification, for the purposes of claim construction the parties primarily focus on the ’045 patent. [ECF No. 59-1 at 2 nn.1–2].

The parties present six disputed claim terms for construction: (1) “anti-CGRP antagonist antibody” or “anti-Calcitonin Gene-Related Peptide (CGRP) antagonist antibody”;

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<sup>1</sup> Through the *inter partes* review process, the Patent Trial and Appeals Board found that all challenged claims in the composition patents were invalid as obvious, but upheld the validity of the challenged claims in the method of treatment patents. [ECF No. 65 at 13]. Both parties are appealing the decisions to the Federal Circuit. [Id.; ECF No. 66 at 6 n.3].

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