

SANOFI-AVENTIS U.S. LLC, et al.,

Plaintiffs,

v.

MERCK SHARP & DOHME CORP.,

Defendant.

Civil Action No. 16-812-RGA

MEMORANDUM OPINION

Douglas E. McCann, Martina Tyreus Hufnal, Ronald P. Golden III, FISH & RICHARDSON P.C., Wilmington, DE; John S. Goetz (argued), Brian D. Coggio, FISH & RICHARDSON P.C., New York, NY; Ahmed J. Davis, Min Woo Park, Sarah M. Cork, FISH & RICHARDSON P.C., Washington, DC; Matt Colvin, FISH & RICHARDSON P.C., Dallas, TX; D. Michael Underhill (argued), Jon R. Knight, BOIES SCHILLER & FLEXNER LLP, Washington, DC; William D. Marsillo, Alex Potter, BOIES SCHILLER & FLEXNER LLP, Armonk, NY; Bill Ward, Martin Ellison, BOIES SCHILLER & FLEXNER LLP, Santa Monica, CA.

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Sanofi Exhibit 2166.001

Presently before the Court is the issue of claim construction of multiple terms in U.S. Patent Nos. 8,603,044 (the “’044 patent”), 8,679,069 (the “’069 patent”), 8,992,486 (the “’486 patent”), 9,526,844 (the “’844 patent”), 9,533,105 (the “’105 patent”), 9,457,152 (the “’152 patent”), 9,592,348 (the “’348 patent”), 7,476,652 (the “’652 patent”), 7,713,930 (the “’930 patent”), and 9,604,008 (the “’008 patent”).<sup>1</sup> The Court has considered the parties’ joint claim construction brief. (D.I. 127). The Court heard oral argument on November 6, 2017. (D.I. 164) (“Tr.”).

## I. BACKGROUND

On September 16, 2016, Plaintiffs filed this action against Defendant Merck Sharp & Dohme Corp. alleging infringement of ten patents. (D.I. 1). With the Court’s permission, Plaintiffs filed First Amended (D.I. 58) and Second Amended (D.I. 93) complaints on April 5, 2017 and June 28, 2017, respectively, in which they asserted additional patents. The patents-in-suit generally relate to a diabetes pharmaceutical, or to pen-type injectors used to administer the pharmaceutical.

## II. LEGAL STANDARD

“It is a bedrock principle of patent law that the 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) (en banc). “[T]here is no magic formula or catechism for conducting claim construction.’ Instead, the court is free to attach the appropriate weight to appropriate sources ‘in light of the statutes and policies that inform patent law.’” *SoftView LLC v. Apple Inc.*, 2013

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<sup>1</sup> Plaintiffs no longer assert U.S. Patent No. 9,486,587. Plaintiffs have also reduced the number of asserted claims substantially since the *Markman* hearing. (D.I. 169). The opinion refers to the ’587 patent and now unasserted claims.

WL 4/58195, at \*1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, “the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Phillips*, 415 F.3d at 1315.

“[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, i.e., as of the effective filing date of the patent application.” *Id.* at 1312–13. “[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent.” *Id.* at 132. “In some cases, the ordinary meaning of claim language as understood by a person of skill in the art 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.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court’s construction is a determination of law. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Phillips*, 415 F.3d at 1317–19. Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the

art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

“A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent.” *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GMBH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007).

### III. CONSTRUCTION OF DISPUTED TERMS

1. **“chemical entity” (’652 patent, claims 1, 2, 7, 17, 18, 19, 23, 24; ’930 patent, claims 1, 14, 15, 16)**
  - a. *Plaintiffs’ proposed construction*: no construction necessary; plain and ordinary meaning
  - b. *Defendant’s proposed construction*: “surfactant that stabilizes the formulation, in a concentration of 5-200 µg/mL”
  - c. *Court’s construction*: no construction necessary; plain and ordinary meaning

Plaintiffs argue the Court need not construe the term “chemical entity” because its plain and ordinary meaning is apparent to a person of ordinary skill in the art. (D.I. 127 at 14). They fault Defendant for “attempt[ing] to re-write the claim entirely.” (*Id.* at 15). Defendant’s proposed construction, according to Plaintiffs, improperly imports into the claims a function and a limitation from the specification. (*Id.*). Plaintiffs also assert that Defendant’s proposed construction runs afoul of the claim differentiation doctrine. (*Id.* at 16).

Defendant responds by arguing that the scope of the claims is limited in two principal ways. First, Defendant argues the scope is limited by the “present invention” description in the specification, which according to Defendant, makes clear the invention requires that the “chemical entity” be present in an amount sufficient to stabilize the formulation, that is, in a

concentration of 5-200 µg/ml. (*Id.* at 19). Defendant primarily relies upon the following sentence from the “detailed description of the invention” in the ’652 patent: “The surfactants are present in the pharmaceutical composition in a concentration of 5-200 µg/ml, preferably 5-120 µg/ml and particularly preferably of 20-75 µg/ml.” (*See id.* at 18; Tr. at 18:10–14). Second, Defendant argues the scope of the ’652 patent is limited by disavowal. Specifically, Defendant argues that because the “patent specification distinguished two prior art references on the basis that they did not describe surfactants that provided ‘stabilization in an acidic solution,’” the term should “be construed to require an amount sufficient to stabilize the preparation.” (D.I. 127 at 20). Finally, Defendant asserts that Plaintiffs’ statements during patent prosecution provide another basis upon which to find disavowal of claim scope. (*Id.*).

I am not persuaded by Defendant’s argument that Plaintiffs have limited the scope of the claims by disavowal such that the surfactant in the claims must “stabilize[] the formulation, in a concentration of 5-200 µg/mL.” A patentee may disavow claim scope through a description in the specification of the “present invention.” *E.g., Luminara Worldwide, LLC v. Liown Elecs. Co. Ltd.*, 814 F.3d 1343, 1353 (Fed. Cir. 2016). To do so, however, the patentee must make “clear and unmistakable statements . . . that limit the claims, such as ‘the present invention includes . . .’ or ‘the present invention is . . .’ or ‘all embodiments of the present invention are. . . .’” *Id.* “When a patentee ‘describes the features of the present invention as a whole,’ he implicitly alerts the reader that ‘this description limits the scope of the invention.’” *Id.*

In my opinion, the patentee has not done so here. The sentence upon which Defendant primarily relies is far from a “clear and unmistakable” statement limiting the claims. *See id.* The sentence begins, “The surfactants are present in the pharmaceutical composition . . . .” (’652 patent, 3:55–56). It does not purport to describe “features of the present invention as a whole,”

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