IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

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

Plaintiffs,

v.

Civil Action No. 14-113-RGA-MPT

ELI LILLY AND COMPANY,

Defendant.

MEMORANDUM OPINION

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January <u>20</u>, 2015

ANDREWS, U.S. DISTRICT JUDGE:

Pending before the Court is the issue of claim construction for the disputed terms found in U.S. Patent Nos. 7,476,652 and 7,713,930 (collectively, the "Formulation Patents") and 8,556,864; 8,603,044; and 8,679,069 (collectively, the "Device Patents").

I. BACKGROUND

Plaintiff Sanofi-Aventis ("Sanofi") filed this action for patent infringement on January 30, 2014. The Court has considered the parties' joint claim construction brief (D.I. 137), joint appendix (D.I. 138), and oral argument (D.I. 178).²

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) (internal quotation marks omitted). ""[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 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324). When construing patent claims, a matter of law, 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

¹ Except for the claims, the '044 patent and '069 patent are almost identical. For the sake of simplicity, all citations are to the '044 patent, unless specified otherwise.

² The parties did not argue all disputed terms. (D.I. 162).

analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal quotation marks and citations 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, i.e., as of the effective filing date of the patent application."

Phillips, 415 F.3d at 1312–13 (internal quotation marks and citations omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent."

Id. at 1321 (internal quotation marks omitted). "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 (internal citations omitted).

A court may consider extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises," in order to assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* at 1317–19 (internal quotation marks and citations omitted). 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) (internal quotation marks and citation omitted).

III. AGREED-UPON CONSTRUCTIONS

- 1. "poloxamers" ('652 patent: claims 7, 24)
 - a. *Agreed-upon construction*: Compounds with the following structure:

- 2. "a piston rod having <u>a first external thread and a second external thread</u>" ('864 patent: claim 3)
- a. Agreed-upon construction: A piston rod with two different external threads.
- 3. "said piston rod comprises <u>a first thread and a second thread</u>" ('044 patent: claims 7, 17)
 - a. Agreed-upon construction: A piston rod with two different threads.
- 4. "where the first external thread is <u>threadedly engaged</u> with an insert" ('864 patent: claim 3)
- a. Agreed-upon construction: The first external thread of the piston rod interlocks with a threading of an insert.

IV. CONSTRUCTION OF DISPUTED TERMS

A. The Formulation Patents

- 1. "at least one chemical entity chosen from" ('652 patent: claims 1, 7, 24; '930 patent: claim 1)
 - a. *Plaintiffs' proposed construction*: Plain and ordinary meaning.

- b. Defendant's proposed construction: At least one ingredient selected for inclusion in the claimed formulation from the set of specified ingredients.
 - c. *Court's construction*: No construction is necessary.

During oral argument, the parties agreed that no construction is necessary for this term.

(D.I. 178 at 32:6–33:18). The Court has no trouble understanding this term, and thus adopts the term's plain and ordinary meaning.

- 2. "esters and ethers of polyhydric alcohols" ('930 patent: claim 1)
- a. Plaintiffs' proposed construction: Chemical compounds in which one or more of the hydroxyl groups of a polyhydric alcohol has been replaced by or converted to an ester (RCOO-X) or ether (RC-O-X) group.
- b. Defendant's proposed construction: Surfactant compounds with the following structures: R-O-C-C-X (esters); and R-O-C-X (ethers) where R is an alcohol with one or more OH groups, and X is unspecified.
- c. *Court's construction*: Chemical compounds in which one or more of the hydroxyl groups of a polyhydric alcohol instead of being a hydroxyl group is an ester (RCOO-X) or ether (RC-O-X) group.³

Sanofi argues that Lilly's proposed construction "narrow[s] the scope of this claim term by requiring that the ester or ether of a polyhydric alcohol *also* be an alcohol." (D.I. 137 at 27). Lilly, on the other hand, objects to Sanofi's proposed construction because it defines the claimed product by reference to a synthetic process, *i.e.*, requiring that "one or more of the hydroxyl groups of a polyhydric alcohol has been replaced by or converted to an ester (RCOO-X) or ether

³ Notwithstanding the different nomenclature in the proposed constructions, the parties claim to agree on the definitions of esters, ethers, alcohols, and hydroxyl groups. (D.I. 137 at 26 n.10 & 28).

(RC-O-X) group." (*Id.* at 29). Lilly does not point to any meaningful intrinsic record support for its position that an ester or ether of a polyhydric alcohol must also be an alcohol. Thus, the Court finds that Sanofi's proposed construction more clearly conveys the term's meaning. The Court, however, replaces the phrase "has been replaced by or converted to" with "instead of being a hydroxyl group is" to account for Lilly's objection to Sanofi's construction.⁴

3. "polysorbate" ('652 patent: claims 7, 24)

During oral argument, the Court scheduled a hearing for Friday, January 23, 2015 at 2:00 p.m., where each party will present an expert witness to testify about the construction of the terms: "polysorbate"; "polysorbate 20"; and "polysorbate 80." (D.I. 178 at 167:22–170:8). The parties must submit written declarations from their expert witnesses by the close of business on Friday, January 16, 2015. (*Id.* at 170:10–171:10).

- a. Plaintiffs' proposed construction: Plain and ordinary meaning.
- b. Defendant's proposed construction: Compounds with the

following structure:

where w+x+y+z is approximately 4, 5, or 20, and where R is a fatty acid.

c. Court's construction: To be determined at a later date.

⁴ Sanofi does not oppose the substance of Lilly's objection. (D.I. 137 at 27 n.11).

- 4. "polysorbate 20" and "polysorbate 80" ('652 patent: claims 1, 2, 8, 23)
 - a. Plaintiffs' proposed construction: Plain and ordinary meaning.
 - b. Defendant's proposed construction: Compounds with the

following structure:

where w+x+y+z is approximately 20, and R is fatty acids present in the following amounts:

[for polysorbate 20]

Carbon- Chain Length	Number of Double Bonds	Percentage
6	0	≤ 1.0
8	0	≤ 10.0
10	0	≤ 10.0
12	0	40.0–60.0
14	0	14.0-25.00
16	0	7.0–15.0
18	0	≤ 7.0
18	1	≤ 11.0
18	2	≤ 3.0

[for polysorbate 80]

Fatty Acid	Percentage
Myristic acid	≤ 5.0
Palmitic acid	≤ 16.0
Palmitoleic acid	≤ 8.0
Stearic acid	≤ 6.0
Oleic acid	≥ 58.0
Linoleic acid	≤ 18.0
Linolenic acid	≤ 4.0

c. Court's construction: To be determined at a later date.

Lilly makes clear that "[t]he dispute between the parties is about the different fatty acid chains that constitute the different polysorbates at issue." (D.I. 137 at 39). As noted above, the Court will take further evidence on the polysorbate 20 and 80 terms.

- 5. "the polysorbate 20 is present in an effective amount to avoid turbidity" ('652 patent: claim 8)
- a. Plaintiffs' proposed construction: The polysorbate 20 is present in an effective amount to prevent visible cloudiness in daylight for at least 28 days.
- b. Defendant's proposed construction: The amount of polysorbate 20 (as defined above) present must prevent turbidity.
 - c. *Court's construction*: No construction is necessary.

The Court does not find either parties' construction particularly helpful. Sanofi's proposed construction adds a limitation that is not supported by the intrinsic record—*i.e.*, that polysorbate 20 must prevent turbidity "for at least 28 days." (D.I. 137 at 42). Lilly's proposed construction does not provide any additional clarity to the claim language. The parties agree that polysorbate 20 must be present in an amount that prevents "turbidity," *i.e.*, "visible cloudiness." (*Id.*). Thus, the Court has no trouble understanding the words of this term, and gives the words their plain and ordinary meaning. Therefore, no construction is necessary.

- 6. "phenols" ('652 patent: claim 3; '930 patent: claim 2)
- a. Plaintiffs' proposed construction: Chemical compounds containing a phenol group.
 - b. *Defendant's proposed construction*: No construction is necessary.
- c. Court's construction: Chemical compounds containing a phenol group.

Lilly does not oppose Sanofi's proposed construction. (D.I. 137 at 44). Therefore, the Court adopts Sanofi's construction.

B. The Device Patents

- 1. "thread/threading" ('864 patent: claims 2, 3; '044 patent: claims 1, 7, 10, 11, 17, 20; '069 patent: claim 1)
- a. *Plaintiffs' proposed construction*: A rib or groove on a first structure that engages a corresponding groove or rib on a second structure.
- b. *Defendant's proposed construction*: A helical rib or groove on a first structure that engages a corresponding helical groove or rib on a second structure.
- c. Court's construction: A rib or groove on a first structure that engages a corresponding groove or rib on a second structure.

The only point of dispute between the parties is whether the word "helical" should be included before "groove" in the construction. (D.I. 137 at 45). The Court agrees with Sanofi that Lilly's proposed construction places a limitation on the claim term that is not required by the claim language. Claim differentiation requires that "claims are interpreted with an eye toward giving effect to all terms in the claim." *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006). For example, the Federal Circuit has held that the use of the term "steel baffles" in a claim "strongly implies that the term 'baffles' does not inherently mean objects made of steel." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005). In the '864 patent, claims 1 and 2 refer to the "housing" and the "dose dial sleeve" as having a "helical thread" (D.I. 95, Ex. C at 47, 17:4–18), while claim 3 refers to the "piston rod" as having a "first external thread" and a "second external thread," with no description of those threads as being "helical." (*Id.* at 47, 17:35–39). When some components are referred to as having "helical threads," and others are

referred to as simply having "threads," it is logical to interpret "thread" as being broader in scope than "helical thread." Lilly makes no argument that the invention requires a helical thread to work where it does not expressly state that the thread is helical. Therefore, the Court will not import the word "helical" into its construction of the term "thread/threading."

- 2. "drive <u>sleeve</u>" ('864 patent: claims 2, 3; '044 patent: claims 1, 3, 11, 13; '069 patent: claim 1)
 - a. *Plaintiffs' proposed construction*: Plain and ordinary meaning.
- b. Defendant's proposed construction: A continuous cylindrical or tubular component of circular cross-section that encloses another part.
- c. Court's proposed construction: An essentially tubular component of essentially circular cross-section which is further releasably connected to the dose dial sleeve.

The parties submitted supplemental letter briefs on Friday, January 9, 2015, providing additional analysis as to whether the Court should import the lexicographical definition of "drive sleeve" from the '864 patent into the '044 and '069 patents. (D.I. 183 & 184). The '864 patent defines "drive sleeve" as "any essentially tubular component of essentially circular cross-section and which is further releasably connected to the dose dial sleeve." (D.I. 95, Ex. C at 40, 3:61–64). The Federal Circuit has made clear that courts are to "presume, unless otherwise compelled, that the same claim term in the same patent or related patents carries the same construed meaning." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003). The parties agree that the three device patents claim priority to a common foreign patent application—GB 0304822.0. (D.I. 183 at 2).

Sanofi argues that only part of the lexicographical definition of "drive sleeve" should be adopted because the limitation requiring the drive sleeve to be "releasably connected to the dose

dial sleeve" is not included in the '044 and '069 claims. (D.I. 183 at 1). Sanofi contends that this limitation only appears once in the '044 and '069 specifications, in a preferred embodiment, and should not be imported into the claims. (D.I. 95, Ex. D at 11, 1:62–66). Lilly, on the other hand, argues that all three patents claim priority to the same patent application, and thus the same claim terms in each patent should be given the same construction. (D.I. 184 at 2). Lilly further maintains that Sanofi cannot pick and choose which parts of the lexicographical definition to keep and which parts to discard. (*Id.*). The Court agrees with Lilly that the term "drive sleeve" is used in the same manner throughout the three device patents. Further, Sanofi has not presented a compelling reason to disregard the Federal Circuit's presumption in favor of construing the same terms in related patents the same. Therefore, the Court adopts the construction provided by the patentee in the '864 patent.

- 3. "a drive sleeve <u>releasably connected</u> to the dose dial sleeve" ('864 patent: claim 2)
- a. Plaintiffs' proposed construction: Configured to be coupled and decoupled at least with respect to axial or rotational movement.
- b. Defendant's proposed construction: A drive sleeve that is connected to the dose dial sleeve during one phase of operation and disconnected from the dose dial sleeve during another phase of operation.
- c. Court's construction: A drive sleeve that is reversibly joined to the dose dial sleeve, which allows coupling and decoupling.

The '864 patent defines "releasably connected" as "two components of instant mechanism or device are reversibly joined to each other, which allows coupling and decoupling, *e.g.* by means of a clutch." (D.I. 95, Ex. C at 40, 4:7–11). This is a lexicographical definition.

Thus, the Court adopts this construction in the context of the drive sleeve and the dose dial sleeve.

- 4. "clutch mechanism" ('864 patent: claim 2) and "tubular clutch" ('044 patent: claims 1, 2, 6, 8, 11, 12, 16, 18; '069 patent: claims 1, 3)
- a. Plaintiffs' proposed construction: A first component that couples and decouples at least a second component to a third component.
- b. Defendant's proposed construction: A structure that couples and decouples a moving component from another component.
- c. *Court's construction*: A structure that couples and decouples a moveable component from another component.

The '864 patent defines "clutch means" as:

[A]ny means, which releasably connects the dose dial sleeve and the drive sleeve and which is designed to allow rotation of the dose dial sleeve and the drive sleeve with respect to the housing when the dose dial sleeve and the drive sleeve are coupled and, when both are decoupled, allows rotation of the dose dial sleeve with respect to the housing, but does not allow rotation of the drive sleeve with respect to the housing and allows axial movement of the drive sleeve.

(D.I. 95, Ex. C at 40, 4:56–64). During oral argument, Sanofi agreed to the inclusion of "a moveable component" in the construction of "clutch mechanism." (D.I. 178 at 127:13–129:10). The parties further agree that "clutch" as used in "clutch mechanism" and "tubular clutch" should be construed the same, and that a "clutch" couples and decouples two different components. (D.I. 137 at 67). The only point of contention is "whether the claims require that the 'clutch' be a separate component of the claimed devices . . . or merely a 'structure' that could reside on another, separately claimed component." (*Id.*). Sanofi argues that "use of the term 'clutch' in the claims requires that it be an independent 'first component that couples and

decouples at least a second component to a third component." (*Id.*). The Court disagrees with Sanofi, and finds that "structure" is a suitable word to describe the term "clutch mechanism." Therefore, the Court adopts Lilly's proposed construction, but replaces "a moving component" with "a moveable component."

- 5. "<u>tubular</u> clutch" ('044 patent: claims 1–2, 6, 8, 11–12, 16, 18; '069 patent: claims 1, 3)
 - a. Plaintiffs' proposed construction: Plain and ordinary meaning.
- b. Defendant's proposed construction: A clutch in the shape of a continuous hollow cylinder of circular cross-section.
- c. *Court's construction*: A clutch having the shape of a hollow cylindrical structure.

During oral argument, the parties agreed that the word "tubular" means both "hollow" and "cylindrical." (D.I. 178 at 114:12–18). The parties also agreed that a "tubular clutch" does not need to be "continuous" or have "circumferential ends." (*Id.* at 123:18–21 & 126:17–22). In light of this, the Court finds that a "tube" is "a hollow cylindrical structure," and that "tubular" means "having the shape of a tube." Lilly argues that the construction should include "of circular cross-section," but nothing in the intrinsic record requires that the cross-section be "circular." The cross-section could, for example, be oval. Therefore, the Court construes the term "tubular clutch" as "a clutch having the shape of a hollow cylindrical structure."

- 6. "a clutch mechanism <u>located between</u> the dose dial sleeve and the drive sleeve" ('864 patent: claim 2)
- a. Plaintiffs' proposed construction: A clutch mechanism spatially positioned to engage with the dose dial sleeve and the drive sleeve.

- b. *Defendant's proposed construction*: A clutch mechanism positioned in the cylindrical space that separates the dose dial sleeve and the drive sleeve.
 - c. *Court's construction*: No construction is necessary.

The Court agrees with Sanofi that Lilly's "in the cylindrical space" limitation is not supported by the intrinsic record, and agrees with Lilly that Sanofi's "spatially positioned" language is vague and unhelpful to construction. (D.I. 137 at 79–80). The Court finds that "located between" is made of ordinary English words, which the Court has no trouble understanding. Therefore, the Court adopts the term's plain and ordinary meaning.

- 7. "the clutch mechanism is configured such that . . . when the dose dial sleeve and the drive sleeve are decoupled . . . rotation of the drive sleeve with respect to the housing is prevented" ('864 patent: claim 2)
 - a. *Plaintiffs' proposed construction*: Plain and ordinary meaning.
- b. Defendant's proposed construction: A clutch mechanism design that stops the drive sleeve from rotating with respect to the housing when the dose dial sleeve and drive sleeve are decoupled.
 - c. *Court's construction*: No construction is necessary.

Sanofi argues that Lilly's proposed construction "rearranges the plain language of the claim, adds a new term ('clutch mechanism design') not found in either the claim or the specification, and assigns an active role to that new term by requiring it to actively prevent rotation of the drive sleeve with respect to the housing ('a clutch mechanism design that stops')."

(D.I. 137 at 84). Further, Sanofi argues that the claim language "does not require that any particular element actively prevent the rotation," but rather "only requires that when the dose dial sleeve and the drive sleeve are decoupled, rotation of the drive sleeve 'is prevented." (*Id.*).

Lilly relies upon the specification, which states that when the dose dial sleeve and drive sleeve are decoupled the "clutch means" "does not allow rotation of the drive sleeve with respect to the housing and allows axial movement of the drive sleeve." (D.I. 95, Ex. C at 40, 4:61–64). The Court agrees with Sanofi that Lilly's proposed construction places an unsupported limitation on the claim language by requiring "a clutch mechanism design that stops the drive sleeve from rotating." The Court finds that the term is made of ordinary English words and words that have already been construed in this opinion. Therefore, the Court has no trouble understanding the meaning of the term, and adopts the term's plain and ordinary meaning.

- 8. "dose dial grip" ('044 patent: claims 1–2, 4–5, 11–12, 14–15; '069 patent: claims 1–3)
- a. Plaintiffs' proposed construction: A component that a user rotates to dial a dose.
- b. Defendant's proposed construction: A component secured to the dose dial sleeve that a user rotates to dial a dose.
- c. Court's construction: A component that a user rotates to dial a dose.

The only point of dispute is whether the "dose dial grip" must be "secured to the dose dial sleeve." (D.I. 137 at 86). Lilly argues that the '044 specification discloses that "[t]he dose dial grip 76 is secured to the dose dial sleeve 70 to prevent relative movement therebetween." (D.I. 95, Ex. D at 13, 5:26–28). Further, Lilly argues that the claim language is "expressly tied to its usage in the specification" because the applicants for both the '044 and '864 patents amended the claim language from "dose knob" to "dose dial grip" after the PTO rejected the "dose knob" term for lack of written description. (*Id.*, Exs. P at p.9 & N at p.4). Sanofi argues

that the claims do not require that the dose dial grip be "secured to" the dose dial sleeve, and that Lilly seeks to limit "dose dial grip" to a preferred embodiment. (D.I. 137 at 87). The Court agrees with Sanofi and finds that the '044 specification describes the "dose dial grip" as "secured to the dose dial sleeve" in a preferred embodiment, which does not, by itself, limit the claim language. Therefore, the Court adopts Sanofi's construction.

- 9. "said piston rod is non-rotatable during a dose setting step relative to said main housing" ('044 patent: claims 1, 11; '069 patent: claim 1)
 - a. Plaintiffs' proposed construction: Plain and ordinary meaning.
- b. Defendant's proposed construction: A rotatable piston rod that is prevented from rotating at the time when the dose is being set.
- c. *Court's construction*: A piston rod that is prevented from rotating at the time when the dose is being set.

The parties only disagree on whether the construction should include a "rotatable piston rod." (D.I. 137 at 91). The '864 specification defines "piston rod" as "a component adapted to operate through/within the housing, designed to translate axial movement through/within the drug delivery device, preferably from the drive sleeve to the piston, for the purpose of discharging/dispensing an injectable product." (D.I. 95, Ex. C at 40, 4:14–18). The patentee's definition does not require the piston rod to be "rotatable." Lilly's proposed construction adds a limitation to the claim that is not reflected in the claim language or the specification. Therefore, the Court adopts Lilly's construction without "rotatable."

- 10. "said housing" ('044 patent: claims 1, 11; '069 patent: claim 1)
 - a. *Plaintiffs' proposed construction*: The main housing.

- b. Defendant's proposed construction: Not capable of construction; no antecedent basis.
 - c. Court's construction: The main housing.

Lilly argues that claims 1 and 11 of the '044 patent identify two housing components, and that "said housing" refers to "[a] housing part" rather than "a main housing." (D.I. 95, Ex. D at 13, 6:57–60 & 14, 8:7–10). Sanofi, on the other hand, argues that "[t]here is only one housing in the body of the claims: the main *housing*," and thus all references to "housing" in the body of claims 1 and 11 are to the "main housing." (D.I. 137 at 96). The Court agrees with Sanofi that the preambles to claims 1 and 11 do not limit the scope of the claims, and that all references in the body of the claims refer to the "main housing" and not the "housing part." Therefore, the Court adopts Sanofi's construction. The Court does so while acknowledging that the use of "said housing" and "said main housing" in the same limitation (e.g., '044 patent, 6:61–63) makes the issue less than crystal clear. The Court is convinced, however, that, in context, it is clear that "said housing" is referring to the main housing.

- 11. "plunger" ('069 patent: claim 2)
 - a. Plaintiffs' proposed construction: Cartridge piston.
 - b. *Defendant's proposed construction*: No construction is necessary.
 - c. Court's construction: Cartridge piston.

Lilly does not object to Sanofi's proposed construction. (D.I. 137 at 97). Therefore, the Court adopts Sanofi's construction.

V. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.