IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| SANOFI-AVENTIS U.S. LLC, et al.,<br><br>Plaintiffs,<br><br>v.<br><br>MERCK SHARP & DOHME CORP.,<br><br>Defendant. | Civil Action No. 16-812-RGA |

MEMORANDUM OPINION

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**ANDREWS, U.S. DISTRICT JUDGE:**

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").[1] 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

[1] 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 4758195, 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,"

*Luminara*, 814 F.3d at 1353, and, in fact, it never refers to the "present invention" at all. Rather, when read in context, the sentence cannot properly be understood to limit the claims. The entire paragraph generally relates to the types of surfactants that "can be used" or are "preferred." (*See* '652 patent, 3:50–56). Nor do any of the other portions of the specification upon which Defendant relies constitute "clear and unmistakable" statements limiting the claims. *Luminara*, 814 F.3d at 1353. Those portions generally refer to the object or goals of the invention, and, accordingly, cannot be characterized as unambiguous statements of disavowal. (*See* D.I. 127 at 18 (quoting '652 patent, 3:32–36)).

Further, I am not persuaded that Plaintiffs have disavowed claim scope by "distinguish[ing] or disparag[ing] prior art based on the absence of [a particular] feature." *Poly-Am., L.P. v. API Indus., Inc.*, 839 F.3d 1131, 1136 (Fed. Cir. 2016). The standard for finding disavowal is "exacting." *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2015). "To find disavowal, [the court] must find that the specification is 'both so clear as to show reasonable clarity and deliberateness, and so unmistakable as to be unambiguous evidence of disclaimer.'" *Openwave Sys., Inc. v. Apple Inc.*, 808 F.3d 509, 513 (Fed. Cir. 2015).

In my opinion, it is not clear that Plaintiffs distinguished prior art references WO 00/23098 and WO 02/076495 on the basis that they do not describe "stabilization by the surfactant." (*See* D.I. 127 at 19–20). The prosecution history indicates that Plaintiffs distinguished those references on the basis that they "do[] not describe the stabilization in an acidic solution." (*Id.* at 26). Plaintiffs argue, therefore, that the present invention was distinguished from the prior art by "pH and insulin type, not stabilization." (*Id.*). I do not think the prosecution history is entirely clear on this point. In any event, where the reason for distinguishing the prior art is ambiguous, there can be no basis for concluding that Plaintiffs

clearly and deliberately disavowed claim scope. *See Openwave*, 808 F.3d at 513. Similarly, it is not clear that Plaintiffs distinguished prior art references before the patent examiner on the basis that they did not disclose a formulation that would be stable. For the same reasons, therefore, I find Plaintiffs have not disavowed claim scope through their statements during patent prosecution.

Finally, I agree with Plaintiffs that Defendant's proposed construction runs afoul of the claim differentiation doctrine. Under the doctrine, there is "a presumption that distinct claims, particularly an independent claim and its dependent claim, have different scopes." *World Class Tech. Corp. v. Ormco Corp.*, 769 F.3d 1120, 1125 (Fed. Cir. 2014); *see also Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1360 (Fed. Cir. 2010) ("Under the doctrine of claim differentiation, [] dependent claims give rise to a presumption that the broader independent claims are not confined to that range." (citation omitted)).

Here, the asserted independent claims do not include concentration limitations, while dependent claims in the '652 and '930 patents recite several specific ranges. These ranges include 5-200 μg/ml, required by Defendant's proposed construction, as well as 5-120 μg/ml and 20-75 μg/ml. ('652 patent, 12:13–18; '930 patent, 12:36–41). Defendant's proposed construction would render meaningless the difference in scope between these claims. Contrary to Defendant's contentions, this is not a case where claim differentiation is "overcome by a contrary construction dictated by the written description or prosecution history." *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005).

Accordingly, I will not adopt Defendant's proposed construction. I conclude that no construction is needed for the term "chemical entity." It will be construed according to its plain and ordinary meaning.

**2. "housing" ('844 patent, claim 21; '105 patent, claims 1, 4; '008 patent, claims 1, 3, 6, 11)**

The parties included the term "housing" in their joint claim construction brief. However, Defendant has agreed to Plaintiffs' proposed construction. (D.I. 127 at 36 n. 10). Thus, there is no need for the Court to construe this term.

**3. "main housing" / "external housing" ('044 patent, claims 1, 2, 3, 8-11, 20; '069 patent, claims 1, 2; '486 patent, claims 1, 3, 4, 26-28, 31, 35, 38-39, 43-45, 48)**

a. *Plaintiffs' proposed construction*: "an exterior unitary or multipart component configured to house, fix, protect, guide and/or engage with one or more inner components"

b. *Defendant's proposed construction*: "single, indivisible component that is an external case or enclosure"

c. *Court's construction*: "an exterior unitary or multipart component configured to house, fix, protect, guide and/or engage with one or more inner components"

Plaintiffs argue their proposed construction, which adds the word "exterior"[2] to the agreed-upon construction for the term "housing," is supported by the patentee's lexicography and is consistent with the plain meaning of the term. (*Id.* at 35). Plaintiffs argue that Defendant's proposed construction "violates the principle that all terms in a claim have meaning," by construing "external housing" the same way as "housing." (*Id.*). In contrast to their proposed construction, Plaintiffs assert, Defendant's construction is "divorce[d] [] entirely from the agreed definition of 'housing.'" (*Id.* at 45).

Citing several dictionary definitions, Defendant argues the plain meaning of "main housing" dictates that the component be a single part. (*Id.* at 37). Defendant further asserts that

[2] At the *Markman* hearing, Plaintiffs represented their proposed construction as including the word "external," rather than "exterior." (Tr. at 32:3–5). In the parties' joint claim construction brief, however, Plaintiffs' proposed construction includes the word "exterior." (D.I. 127 at 35). In any event, I do not see any meaningful difference between "external" and "exterior."

Plaintiffs' proposed construction would render the word "main" meaningless. (*Id.*). Defendant points to the specifications of the '069, '044, and '486 patents, which distinguish between "housing" and the "main housing part." (*Id.*). Further, Defendant contends that the prosecution history and the patent specifications indicate that "main housing" refers to a single component. (*Id.* at 37–40). Similarly, with respect to the term "external housing," Defendant argues that Plaintiffs' proposed construction eliminates the distinction between the "external housing" and the other components of the claims. (*Id.* at 43).

I disagree with Defendant's assertion that the patent specifications and the plain meaning of the terms "main housing" and "external housing" require single, indivisible components. The embodiments upon which Defendant relies do not make clear that the "main housing" and "external housing" are single, indivisible components, and, in any event, it is generally improper to import limitations from the specification into the claims. *E.g.*, *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014). Further, nothing in the plain language of the terms suggests the "main housing" and "external housing" cannot be made of multiple parts. The definitions upon which Defendant relies address the meaning of the word "main," defining it as, for example, "chief or principal in rank, importance, [or] size." (D.I. 127 at 37 (quoting Collins English Dictionary)). That a component is "chief or principal in rank," however, does not mean it cannot be a multipart component.

Further, I agree with Plaintiffs' inclusion of the language from the lexicography of the '105 and '008 patents, that is, "configured to house, fix, protect, guide and/or engage with one or more inner components." Although this definition appears only in the '105 and '008 patents, I believe it also makes sense to include it in the construction for the terms "main housing" and "external housing" in the '069, '044, and '486 patents.

Claim 1 of the '044 patent describes a "cartridge retaining part" being "coupled to said main housing." ('044 patent, 7:13–14; *see also* '486 patent, 10:3–4 (reciting "a tubular barrel retainer" being "operatively coupled to said external housing")). Claim 11 of the '044 patent and claim 1 of the '069 patent recite a "dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing." ('044 patent, 8:12–14; '069 patent, 6:41–43). These examples demonstrate the "main housing" and "external housing" being configured to fix or engage with inner components of the pen-type injector. Throughout the patent specifications, these terms are repeatedly described in a way that is consistent with the lexicography from the '105 and '008 patents. (*See, e.g.*, '044 patent, 5:9–11 ("The main housing 4 is further provided with a helical rib 46, adapted to be seated in the helical groove 74 on the outer surface of the dose dial sleeve 70.")). A construction that includes Plaintiffs' proposed language is therefore supported by the intrinsic record.

Accordingly, I will construe "main housing" and "external housing" to mean "an exterior unitary or multipart component configured to house, fix, protect, guide and/or engage with one or more inner components."

4. **"thread/threading" ('044 patent, claims 1, 7, 10, 11, 17, 20; '069 patent, claim 1; '486 patent, claims 1, 24, 25, 31, 43; '844 patent, claim 21; '105 patent, claims 3 and 4; '348 patent, claims 2 and 30; '152 patent, claim 14; '008 patent, claims 1, 6, 7, 11, 16, and 18)**

    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*: "rib or groove on a first structure that engages a corresponding groove or rib on a second structure and that allows rotational and axial movement between the first and second structures"

    c. *Court's construction*: "rib or groove on a first structure that engages a corresponding groove or rib on a second structure and that allows rotational and axial movement between the first and second structures"

Plaintiffs argue that Defendant is attempting to include the meaning of the word "helical" in its construction, which the Court rejected in *Lilly* when it construed the term "thread." (D.I. 127 at 50). Although Defendant's construction does not use the word "helical," Plaintiffs argue that Defendant's proposed construction "would achieve the same result," because a "helical" thread is "commonly understood as a thread that provides for both rotational and axial movement between structures." (*Id.*). Plaintiffs further point to the specifications of the '105 and '348 patents, which, according to Plaintiffs, show that Defendant is incorrect that a "thread" must "allow[] rotational and axial movement." (*Id.* at 51).

Defendant responds that Plaintiffs' proposed construction of "thread" would include a "spline," which is inconsistent with the plain meaning of the terms and the patent specifications, which distinguish between the two words. (*Id.* at 53). Contrary to Plaintiffs' assertions, Defendant argues, Defendant's proposed construction includes both helical and non-helical threads. (*Id.* at 54).

I agree with Defendant that Plaintiffs' proposed construction for "thread" would include a "spline," which conflicts with the patent specifications. The specifications do not appear to use the words "thread" and "spline" interchangeably. Nor do they suggest that a "spline" is a type of "thread." Rather, the patents differentiate between the two. For example, the '044 and '105 patents describe a "nut 40" having an "internal thread matching the intermediate thread 36," and the "nut 40" advancing along the intermediate thread "by the rotation of the drive sleeve." ('044 patent, 4:20–21, 6:4–6; '105 patent, 8:4–6, 9:58–60). They describe "splines," on the other hand, as being used "to prevent relative rotation between the nut 40 and the main housing 4, while allowing relative longitudinal movement there between." ('044 patent, 4:22–26; '105 patent,

8:6–10). According to the '044 and '105 patents,[3] therefore, a "thread" allows for rotational movement, while a "spline" does not. There is no reason to conclude that the patents use the word "spline" to refer to a type of "thread."

Further, I am not persuaded that a person of ordinary skill in the art, at the time of the invention, would have understood a "spline" to be a type of "thread." Plaintiffs point to a definition from 1917 in *The Mechanical Engineer*. (D.I. 127 at 58). Plaintiffs omit, however, that the definition is "supplementary" and "open to discussion." (*Id.*). It seems unlikely therefore that the definition reflects the general understanding of one of ordinary skill in the art at the time of the invention with respect to the meaning of the word "spline." Although Plaintiffs also cite to a 2013 publication, nowhere does the text upon which Plaintiffs rely refer to a "spline." (*See id.* (citing *Matrix Methods in the Design Analysis of Mechanism and Multibody Systems* (2013))). Rather, the text describes what happens to "threads" when "the pitch of a helical joint is made infinite." (*Id.*).

Finally, Plaintiffs point to a definition of "helical thread" in the '105 patent, which states: "The term 'helical thread' according to the instant invention shall preferably mean a full or part thread . . . designed to allow continuous free rotational and/or axial movement between components." (*Id.* at 58 (quoting '105 patent, 3:27–36)). Plaintiffs argue this lexicography contradicts Defendant's proposed construction, which requires "rotational and axial movement." (*Id.*). Although this definition seems to suggest that a "helical thread" could be construed in such a way so as to allow axial movement without "continuous free rotational movement," such axial movement can occur without splines but still not include "continuous free rotational movement."

[3] The parties do not argue this term should be construed differently for the other patents in which it appears.

Therefore, in the context of these patents, "thread" does not suggest a "spline." Accordingly, it will not be construed to mean "spline." I will construe "thread" as "rib or groove on a first structure that engages a corresponding groove or rib on a second structure and that allows rotational and axial movement between the first and second structures."

**5. "the piston rod and the driving member are configured to rotate relative to one another during dose dispensing" ('844 patent, claim 21)**

a. *Plaintiffs' proposed construction*: no construction necessary, plain and ordinary meaning

b. *Defendant's proposed construction*: "both piston rod and driving member are configured to rotate, each at a different rate and/or direction, during dose dispensing"

c. *Court's construction*: "both piston rod and driving member are configured to rotate, each at a different rate and/or direction during dose dispensing"

Plaintiffs argue, "The claim language is clear and further construction is unnecessary: during dose dispensing, the piston rod and the driving member are configured for *relative* rotation." (*Id.* at 61). According to Plaintiffs, Defendant's proposed construction would "violate core claim construction principles" by importing limitations unsupported by the intrinsic record and by excluding a preferred embodiment. (*Id.* at 62). Specifically, Plaintiffs point to Figure 11, which depicts an embodiment in which the piston rod, not the driving member, rotates relative to the housing. (*Id.*). They also point to column 6, lines 48 to 58, which they argue show that the specification "includes the possibility that one component rotates while the other does not." (*Id.* at 61).

Defendant counters that the plain language of the term "requires that each of the piston rod and the driving member be configured to rotate, albeit in different directions or to a different extent." (*Id.* at 62–63). If Plaintiffs sought to claim a device in which the piston rod did not rotate, Defendant contends, they could have done so. (*Id.* at 63). In fact, the claim limitations

show "the patentee knew how to draft claim limitations, where one or the other driving member and piston rod are configured to rotate." (Tr. at 76:24–77:2). In response to Plaintiffs' argument that Defendant's proposed construction would exclude a preferred embodiment, Defendant asserts that a claim in a patent, which is not asserted in this case, covers that preferred embodiment. (D.I. 127 at 63).

"A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so." *Merck & Co., Inc. v. Teva Pharmas. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005). In my opinion, a construction, like Defendant's, which requires both the "piston rod" and the "driving member" to be configured to rotate, appropriately gives meaning to all the terms of the claim. Claim 21 twice refers to the "driving member" being "configured to rotate relative" to another component of the pen-type injector. First, claim 21 recites, "the driving member is configured to rotate relative to the piston rod." ('844 patent, 8:40–41). Second, it recites the term at issue: "the piston rod and the driving member are configured to rotate relative to one another during dose dispensing." (*Id.* at 8:45–46). Plaintiffs essentially ask the Court to ignore that these two claim limitations are worded differently. Plaintiffs assert that the disputed term encompasses two configurations, one in which both the "piston rod" and the "driving member" are configured to rotate, and one in which only one or the other is configured to rotate. (Tr. at 69:12–14). Such a construction, however, renders meaningless the difference in the way the two limitations are written. The patentee understood how to write a limitation in which either the "piston rod" or the "driving member" is configured to rotate. (*See* '844 patent, 8:40–41).

Further, I am not persuaded by Plaintiffs' argument that Defendant's proposed construction is improper because it excludes a preferred embodiment. A construction that

excludes a preferred embodiment is generally "disfavored." *Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1026 (Fed. Cir. 2015). However, "where the patent describes multiple embodiments, every claim does not need to cover every embodiment." *Id.* "This is particularly true where the plain language of a limitation of the claim does not appear to cover that embodiment." *Id.* Here, the plain language of the disputed limitation does not appear to cover the embodiments upon which Plaintiffs rely. Those embodiments describe or depict configurations in which the "driving member" rotates, while the "piston rod" does not.

Finally, I agree with Defendant's including "each at a different rate and/or direction" in its proposed construction. In my opinion, that language appropriately reflects what is meant by the piston rod and driving member being configured to rotate "relative" to one another.

For the reasons stated above, I will construe this term to mean, "both piston rod and driving member are configured to rotate, each at a different rate and/or direction during dose dispensing."

**6. "abut" ('152 patent, claim 1)**

Although the parties included "abut" in their joint claim construction brief, they have since agreed upon a construction. (D.I. 160 at 1). Thus, there is no need for the Court to construe that term.

**7. "drive member" ('152 patent, claims 1, 2, 6-11)**

a. *Plaintiffs' proposed construction*: "single component or multiple components configured to transfer force to the piston rod"

b. *Defendant's proposed construction*: "single component, or multiple components moving as one, which transfers force or motion to the piston rod"

c. *Court's construction*: "single component or multiple components configured to transfer force to the piston rod"

The parties dispute whether the "multiple components" of the "drive member" must "move as one." Plaintiffs argue their proposed construction is correct because it is taken directly from the patent specification. (D.I. 127 at 69). According to Plaintiffs, Defendant's proposed construction is incorrect for three reasons. (*Id.*). First, Defendant's proposed "moving as one" language is ambiguous. (*Id.*). Second, according to Plaintiffs, Defendant "is making up limitations from whole cloth." (*Id.* at 70). Third, Plaintiffs argue that Defendant "nonsensically requires the drive sleeve to transfer force 'or motion' to the piston rod," while "the laws of physics decree that *motion* cannot be transferred." (*Id.*).

Defendant counters that unlike Plaintiffs' proposed construction, Defendant's construction preserves the distinction between a "member" and a "mechanism," as required by the specification. (*Id.*). Specifically, Defendant explains that the specification refers to the "drive member" as being part of the "drive mechanism." (*Id.*). Unlike a "mechanism," which in this field is a system of multiple parts, a "member" is part of a mechanism. (*Id.* at 71). Accordingly, Defendant asserts, "the specification repeatedly uses the term 'member' to refer to a single component or multiple components moving as one." (*Id.*).

I see no basis in the intrinsic record for including the limitation that when a "drive member" is made of multiple components, those components must "mov[e] as one." Further, I am not persuaded by Defendant's argument that Plaintiffs' proposed construction is improper because it equates "mechanisms" and "members." To support its argument, Defendant relies in part on dictionary definitions of the words "mechanism" and "member." *The Dictionary of Mechanical Engineering*, for example, states, "Any part of a structure or mechanism is called a member." (*Id.* at 72). That a "member" is part of a "mechanism," which may be made of

several moving parts, however, does not mean that the "member" itself cannot also be made of several parts, which may or may not move as one.

Further, although Defendant includes the language "or motion" in its proposed construction, Defendant does not provide any support for this additional language in the parties' joint claim construction brief. I agree with Plaintiffs that it does not make sense to include "or motion" in the construction for this term. The '152 patent specifically refers to the "drive member" being "configured to transfer force," not motion. ('152 patent, 8:25–29).

I will therefore adopt Plaintiffs' proposed construction for this term, "single component or multiple components configured to transfer force to the piston rod."

**8. "clutch member" ('348 patent, claims 1, 3-6)**

a. *Plaintiffs' proposed construction*: "a structure that couples and decouples a moveable component from another component"

b. *Defendant's proposed construction*: "single component, or multiple components moving as one, which is secured against any rotational movement with respect to the housing"

c. *Court's construction*: "a structure that couples and decouples a moveable component from another component"

The parties have agreed upon a construction for the term "clutch," which appears in the '486, '008, and '844 patents, and "tubular clutch," which appears in the '044, '069, and '486 patents. (D.I. 127 at 12). The parties now dispute whether the term "clutch member," which appears in the '348 patent, should be construed differently.

Plaintiffs assert that the parties' agreed-upon construction for "clutch" and "tubular clutch" should also apply for "clutch member." (*Id.* at 75). They argue their proposed construction is supported by the intrinsic records of the '348 patent. (*Id.*). Plaintiffs point to a preferred embodiment from the specification, which "describes a clutch member 28 that couples

and decouples dose member 23 to housing 13." (*Id.* (citing '348 patent, 5:11–21, 12:65–13:9, 15:61–16:3)). Further, Plaintiffs argue that nothing in the patent "overcomes the heavy presumption for the plain and ordinary meaning of 'clutch' as understood by a [person of ordinary skill in the art]." (*Id.*). According to Plaintiffs, Defendant's proposed construction would improperly import a limitation from the specification into the claims, by requiring that the "clutch" be "secured against any rotational movement with respect to the housing." (*Id.* at 76). Finally, Plaintiffs disagree with Defendant's proposal that the construction include the limitation "moving as one." (*Id.*). Plaintiffs assert that there is no support for this language in the specification and that the phrase is ambiguous. (*Id.*).

Defendant responds by arguing that, contrary to Plaintiffs' contentions, "clutch member" and "clutch" are not the same terms. (*Id.* at 77). Specifically, Defendant argues that the specification describes two components that perform the operations of a "clutch"—the "clutch member" and the "coupling unit." (*Id.*). Defendant asserts that Plaintiffs' proposed construction of "clutch member" would encompass the "coupling unit," even though the specification teaches that those two components are distinct. (*Id.* at 78). To support its proposed construction, Defendant points out that the specification explains that the "clutch member" is part of the mechanism that prevents the device user from setting a dose that is too high. (*Id.* (citing '587 patent, 9:59–62).[4] According to Defendant, a key aspect of that mechanism is that the "clutch member" cannot rotate, and, therefore, it is "secured against any rotational movement with respect to the housing." (*Id.* at 78–79). Finally, Defendant argues that this case is similar to

[4] Defendant notes that other than the claims, "the '587 and '348 patents are essentially identical. All citations to the '587 patent include citation to the corresponding specification of the '348 patent." (D.I. 127 at 78 n.25).

*Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158 (Fed. Cir. 2004), where the Federal Circuit limited the scope of a particular term according to its use in the specification. (*Id.* at 79).

First, I see no support for Defendant's attempt to import into the claims a limitation that when a "clutch member" is made of multiple components, those components must "mov[e] as one." I will therefore not include that language in the construction for this term.

Second, I am not persuaded by Defendant's argument that Plaintiffs' proposed construction is improper because it ignores that the patents distinguish between "clutch member" and "coupling unit." As Defendant points out, the specifications use the words "couples" and "decoupled" to describe the "coupling unit." (*See* '348 patent, 14:46–51). That the "coupling unit" couples and decouples, however, does not mean that the "clutch member" cannot also do so.

Third, I do not agree with Defendant that the "clutch member" must be "secured against any rotational movement with respect to the housing." That limitation appears in certain preferred embodiments in the patents. (*See* '348 patent, 5:12–13). It is generally improper, however, to import into the claims a limitation from a preferred embodiment. *E.g.*, *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 345 F.3d 1318, 1327 (Fed. Cir. 2003). Further, as Plaintiffs point out, including this limitation would seem to render superfluous certain claim language in both patents. Claim 1 in the '348 patent describes the "clutch member" as not rotating with respect to the housing during the setting of the dose. ('348 patent, 17:24–26). This language suggests that the "clutch member" may rotate with respect to the housing at times other than dose setting.

Finally, I am not convinced by Defendant's argument that because "clutch member" "has no accepted meaning to one of ordinary skill in the art," its scope must be limited "based on how

it [is] used in the specification." (D.I. 127 at 79 (quoting *Goldenberg*, 373 F.3d at 1664)). Defendant does not appear to dispute that the word "clutch" has an accepted meaning to one of ordinary skill in the art. Contrary to Defendant's assertions, I do not believe use of the word "member" after "clutch" means this term should not be construed to include the accepted meaning of the word "clutch."

Accordingly, I will adopt Plaintiffs' proposed construction, "a structure that couples and decouples a moveable component from another component."

**9. "dose member" ('348 patent, claims 1-6, 30)**

a. *Plaintiffs' proposed construction*: "a single component or multiple components for setting a dose of a drug"

b. *Defendant's proposed construction*: "single component, or multiple components moving as one, which has outer guide members and which is configured to move axially relative to the dose dial member"

c. *Court's construction*: "a single component or multiple components, which has outer guide members and which is configured to move axially relative to the housing"

Plaintiffs assert the same arguments against Defendant's inclusion of the limitation "moving as one" as they made with respect to "clutch member" and "drive member." (*Id.* at 82). Plaintiffs argue further, however, that Defendant's proposed construction is improper with respect to the phrase, "which has outer guide members and which is configured to move axially relative to the dose dial member." (*Id.*). According to Plaintiffs, Defendant's construction conflicts with the intrinsic record, which "expressly state[s] that the claims should not be restricted by exemplary embodiments." (*Id.* at 82–83). Further, Plaintiffs argue that Defendant's construction constitutes "a naked attempt to shoehorn an unclaimed component—a dose dial member—into the claims." (*Id.* at 83).

Defendant counters that Plaintiffs "do[] not even allege, much less provide evidence indicating, that 'dose member' has an ordinary and customary meaning in the art." (*Id.*). In the absence of a plain and ordinary meaning for the term, therefore, the Court's construction must be based on intrinsic evidence. (*Id.* at 84). The intrinsic evidence, Defendant contends, shows that the "dose member" is configured to move axially relative to the dose dial member and has outer guide members. (*Id.* at 85–86). Defendant further asserts that Plaintiffs cannot argue that "dose member" should be construed as any component "for setting a dose," because as the specification shows, a different component is used to perform that function. (*Id.* at 84). According to Defendant, Plaintiffs' proposed construction would result in all the components that rotate during dose setting meeting the definition of "dose member." (*Id.* at 85). Those components, however, are each "a distinct entity with [their] own design and function." (*Id.*).

I agree with Defendant that "dose member" does not have an ordinary meaning to one skilled in the art. Rather, as Plaintiffs acknowledged at the *Markman* hearing (Tr. at 84:15, 21–22), it is a coined term, and, accordingly, it should be "construe[d] only as broadly as is provided for by the patent itself." *Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1164 (Fed. Cir. 2004); *see also Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1287 (Fed. Cir. 2010) ("Idiosyncratic language, highly technical terms, or terms coined by the inventor are best understood by reference to the specification."). The Federal Circuit has cautioned, however, that "[c]onstruing the claims in light of the specification does not [] imply that limitations discussed in the specification may be read into the claims." *Intervet*, 617 F.3d at 1287. "It is therefore important not to confuse exemplars or preferred embodiments in the specification that serve to teach and enable the invention with limitations that define the outer boundaries of claim scope." *Id.*

Here, Plaintiffs' proposal is essentially a means-plus-function construction with no corresponding structure. It broadly covers any component or components of the pen-type injector for setting a dose of the drug. Defendant's proposal, on the other hand, includes structural limitations of the "dose member" taken from the patent specification. In particular, Defendant's proposal requires that the "dose member" (1) have outer guide members and (2) be configured to move axially relative to the dose dial member.

Since one must look to the specification to give "dose member" meaning, *see Goldenberg*, 373 F.3d at 1164, I agree with Defendant that it is appropriate to include "outer guide members" in the construction for this term. While the '348 patent refers to the "dose member" throughout, the essence of the "dose member" is contained at column 10, lines 29 to 62. That portion of the specification states in relevant part, "The dose member 23 comprises one or more (outer) guide members 25, e.g. guide ribs. Guide members 25 may extend axially. Guide members 25 may be arranged in the proximal section of the dose member 23 as seen from thread 24." ('348 patent, 10:51–54). Thus, the only detailed description of the "dose member" in the specification recites that the "dose member" has "outer guide members." It then goes on to describe optional features of those "outer guide members," including, for example, that they "may extend axially." (*Id.* at 10:14–15). Contrary to Plaintiffs' contentions, I do not think that to include "outer guide members" is to improperly import a limitation from an embodiment into the claims. Rather, including that limitation is appropriate in light of the specification and is necessary to give meaning to the term. Nor am I persuaded by Plaintiffs' argument that including "outer guide members" would render superfluous dependent claim 21. That claim refers to "outer guide members" with respect to the "insert member," not the "dose member." (*See* '348 patent, 18:44–45).

Further, as Plaintiffs point out, the specification also describes the "dose member" as being "provided with a (outer) thread 24." I do not agree with Plaintiffs, however, that including "outer guide members" means the construction must also include a limitation that the "dose member" have any such thread. The patent separately claims a "dose member" that is "threadedly connected to the housing." (*Id.* at 17:42–43).

I agree with Plaintiffs, however, that it would be improper to include the second limitation in Defendant's proposal, that is, "which is configured to move axially relative to the dose dial member." While that limitation appears in the same paragraph as the reference to "outer guide members," the "dose dial member" is not claimed in the patent. Instead, I think it would be better to include the following language: "which is configured to move axially relative to the housing." This language is consistent with the specification, which describes the "dose member" as being "configured to be displaced in the proximal direction with respect to the housing 13 during setting of the dose of the drug 5 and/or in the distal direction with respect to the housing during delivery of the dose." (*Id.* at 10:29–33; *see also id.* at 17:21–23).

Finally, I see no support, and Defendant does not provide any, for including the limitation that when a "dose member" is made of multiple components, those components must "mov[e] as one." I will therefore not include that limitation in the construction for this term.

For the reasons stated above, I will construe "dose member" to mean, "a single component or multiple components, which has outer guide members and which is configured to move axially relative to the housing."

## IV. CONCLUSION

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