

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

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SANOFI-AVENTIS U.S. LLC et al.,	:	
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Plaintiffs,	:	Civil Action No. 17-9105 (SRC)
	:	
v.	:	
	:	
MYLAN GMBH et al.,	:	<b>OPINION &amp; ORDER</b>
	:	
Defendants.	:	
_____	:	

**CHESLER, U.S.D.J.**

This matter comes before the Court on the application for claim construction by Plaintiffs Sanofi Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH, and Sanofi Winthrop Industrie (“Sanofi”) and Defendants Mylan GmbH, Biocon Research Ltd., Biocon S.A., and Biocon Sdn. Bhd. (collectively, “Mylan”). In this patent infringement action, the parties seek construction of claim terms in six U.S. Patents. For the reasons that follow, this Court finds that, with the exception of “thread,” where Defendants’ proposed construction is unopposed, neither party has overcome the presumption that the claim terms carry their ordinary meaning.

**BACKGROUND**

This case arises from a patent infringement dispute involving a set of pharmaceutical patents related to a diabetes treatment. Plaintiffs own U.S. Patent Nos. 7,476,652 and 7,713,930 (the “formulation patents”) and U.S. Patent Nos. 8,603,044; 8,679,069; 8,992,486; and 9,526,844 (the “device patents”). The formulation patents, generally, are directed to insulin formulations; Sanofi markets such formulations under the Lantus® brand name. The device patents, generally,

are directed to prefilled delivery pen devices that are used to inject medication into the body; Sanofi markets such devices under the Lantus SoloSTAR® brand name. Defendants have submitted a 505(b)(2) New Drug Application seeking FDA approval to market products which, Plaintiffs contend, infringe these patents.

The parties' briefs refer to claim construction decisions in two cases before Judge Andrews in the District of Delaware, Sanofi-Aventis U.S. LLC v. Eli Lilly & Co., 14-cv-113 (RGA) (D. Del.) ("the Lilly case") and Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp., 16-cv-812 (RGA) (D. Del.) ("the Merck case"). In these cases, Sanofi asserted some of the formulation and device patents at issue against other defendants.

## ANALYSIS

### **I. The law of claim construction**

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). "[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

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. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the

patentee regards as his invention.’

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

We have frequently stated that the words of a claim ‘are generally given their ordinary and customary meaning.’ We have made clear, moreover, that the ordinary and customary meaning of a claim term 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. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .

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. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

## **II. Claim construction of the disputed terms**

### **A. The formulation patents**

The parties dispute the interpretation of four claim terms in the formulation patents: “chemical entity,” “esters and ethers of polyhydric alcohol,” “at least one chemical

entity chosen from,” and “effective amount to avoid turbidity.”

1. “chemical entity”

The parties dispute the meaning of the phrase, “chemical entity,” which appears in claims 1, 2, 7, 17, 18, 19, 23, and 24 of the ’652 Patent, as well as claims 1, 14, 15, and 16 of the ’930 Patent. Plaintiffs contend that the term has its ordinary meaning, which a skilled artisan would understand to be “chemical compound.” Defendants contend that the term should be construed to mean, “surfactant that reduces turbidity.” Defendants here attempt to import limitations from the embodiments without any demonstration that the patentees used “expressions of manifest exclusion or restriction.” Defendants ignore this requirement, and cite VirnetX, Inc. v. Cisco Sys., 767 F.3d 1308, 1318 (Fed. Cir. 2014) for this statement: “The fact that anonymity is ‘repeatedly and consistently’ used to characterize the invention strongly suggests that it should be read as part of the claim.”<sup>1</sup> As Plaintiffs note in response, Defendants have taken this out of context. Crucially, in VirnetX, the Federal Circuit began the analysis of the construction of “secure communication link” with this foundation: “As an initial matter, we note that there is no dispute that the word ‘secure’ does not have a plain and ordinary meaning in this context, and so must be defined by reference to the specification.” Id. at 1317. Defendants have not established that premise here. A typical use of this phrase appears in claim 1 of the ’652 patent: “at least one

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<sup>1</sup> Defendants also point to a statement made during prosecution, in a March 19, 2008 Request for Continued Examination. It is sufficient to note that Defendants have not here pointed to any use of the claim term, “chemical entity,” nor explained how the identified statement relates to the meaning of this claim term. In the absence of any argument that this prosecution statement meets the requirements for prosecution disclaimer, see Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003), this Court does not discern how this impacts the present claim construction inquiry.

chemical entity chosen from polysorbate 20 and polysorbate 80.”<sup>2</sup> The meaning of “chemical entity” in this example is clear on its face; Defendants point to no ambiguity. Unlike Virnetx, the term here, in the context of the claim, has a plain meaning.

In the absence of expressions of manifest exclusion, the Court declines to narrow the meaning of a claim term that is, on its face, unambiguous, and used in claim phrases which are precise. Defendants have not overcome the presumption that “chemical entity” carries its ordinary meaning which, as Plaintiffs state, is “chemical compound.”

## 2. “chosen from”

The parties dispute the meaning of “chosen from,” as used in the phrase, “at least one chemical entity chosen from.” Plaintiffs propose that the term has its plain and ordinary meaning. Defendants propose that “chosen from” means “selected to be included in the pharmaceutical formulation from.” Defendants seek to insert into the claim language a scienter requirement. Defendants point to nothing in any of these patents that indicates that the inventors patented a formulation process requiring a particular mental state when deciding between polysorbate 20 and polysorbate 80. Consider, again, claim 1 of the ’652 patent, which begins as follows: “A pharmaceutical formulation comprising . . .” The claim on its face covers a formulation, not a method for formulating. As Plaintiffs argue, the patentees drafted these claims using a Markush group. Gillette Co. v. Energizer Holdings, Inc., 405 F.3d 1367, 1372 (Fed. Cir. 2005) (“A Markush group lists specified alternatives in a patent claim, typically in the form: a member selected from the group consisting of A, B, and C.”) “Chosen from” has its

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<sup>2</sup> If there is more than one reasonable interpretation of this claim phrase, Defendants have not pointed to it.

ordinary meaning.

3. “the polysorbate 20 is present in an effective amount to avoid turbidity”

The parties agree that this phrase, which appears only in claim 8 of the '652 patent, has its ordinary meaning, but they dispute what that ordinary meaning is. Plaintiffs propose that the ordinary meaning is “the polysorbate 20 is present in an effective amount to prevent cloudiness.” Defendants propose that the ordinary meaning is “the amount of polysorbate chosen prevents cloudiness.” Defendants explain that the only meaningful difference between the two constructions involves the question of whether the claim language requires the polysorbate 20 to be chosen, as previously discussed. For the reasons already stated, the Court will not insert a scienter requirement into these formulation claims. The ordinary meaning of this phrase does not require any particular mental state.

4. “esters and ethers of polyhydric alcohols”

Although this term involves chemistry, the parties appear to agree on the meaning within chemistry. Neither party identifies any remaining ambiguity in the claim language. The parties' briefs, which give very short treatment to this dispute, identify no actual question about the meaning of this term. Instead, the briefs debate the question of whether Plaintiffs' proposed construction is redundant. Since the parties agree about how a chemist would understand this phrase, the Court concludes that the parties do not have any substantive dispute over the meaning of this term.

B. The device patents

The parties dispute the construction of thirteen terms in the device patents. These four patents descend from one application, No. 10/790,225, through chains of continuation

applications. The parties agree that the device patents share a common specification.

With the exception of “thread,” where Defendants’ proposed construction is unopposed, this Court resolves all of the claim construction disputes before it by application of one fundamental principle of Federal Circuit law: “There is a heavy presumption that claim terms are to be given their ordinary and customary meaning.” Aventis Pharm., Inc. v. Amino Chems. Ltd., 715 F.3d 1363, 1373 (Fed. Cir. 2013). “Properly viewed, the ‘ordinary meaning’ of a claim term is its meaning to the ordinary artisan after reading the entire patent.” Phillips, 415 F.3d at 1321. “An accused infringer may overcome this ‘heavy presumption’ and narrow a claim term’s ordinary meaning, but he cannot do so simply by pointing to the preferred embodiment or other structures or steps disclosed in the specification or prosecution history.” CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). In short, this Court finds that neither party, for any claim term in dispute, has overcome the presumption that each term has its ordinary meaning.

1. “piston rod”

Plaintiffs propose this construction: “A rod that engages with the drive sleeve/driver/driving member to advance the piston during dose dispensing.” Defendants propose this construction: “a rod that moves axially to advance the piston.” Neither party contends that the term has its ordinary meaning.

In their opening brief, Plaintiffs present only one argument to support their proposed construction: “it aligns with the intrinsic record. . .” (Pls.’ Br. 28.) Under Federal Circuit law, this is not sufficient to overcome the presumption of ordinary meaning. In particular, as to the proposed subphrase, “that engages with the drive sleeve/driver/driving member,” Plaintiffs point

to three claims, from three of the device patents, which require such engagement. These do not support their position. Two of the three examples point to characteristics of other components: 1) claim 1 of the '069 patent (“internal threading [of drive sleeve] adapted to engage an external thread of said piston rod”) (Pls.’ Br. 29); and 2) claim 1 of the '486 patent (“internal threading [of driver] adapted to engage an external thread of said piston rod”) (id.) Note that, in both of these examples, the language states characteristics of the threading of the drive sleeve and driver, as well as characteristics of the interaction between the “external thread of said piston rod” and the internal thread of the other component. Plaintiffs do not explain why these expressly stated characteristics should be incorporated into the construction of “piston rod.” In these two examples, the claim expressly discloses that the piston rod has an external thread with a particular interaction with other components. Since this is expressly stated, why should it be made implicit in the construction of “piston rod?” Given that there is no dispute that the drive sleeve and driver are separate and different components from the piston rod, why would this Court expand the concept<sup>3</sup> of the piston rod to incorporate aspects of other components, or of the interaction between the piston rod and another component?

Plaintiffs’ third example is claim 21 of the '844 patent, quoting as follows: “piston rod . . . that is engaged with the third thread [of the driving member]” (Pls.’ Br. 29.) Plaintiffs do not recognize that their proposed construction, if accepted, would introduce redundancy into this claim language, which would become: “rod that engages with the driving member to advance the

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<sup>3</sup> While the Court here describes this as expanding the concept, the effect is to narrow the scope of coverage of the claim term: “piston rod” necessarily has a broader scope than a “rod that engages with the drive sleeve/driver/driving member to advance the piston during dose dispensing.” Ultimately, both parties propose narrowing constructions of many terms.



piston during dose dispensing . . . that is engaged with the third thread [of the driving member.]” This unwieldy and redundant interpretation demonstrates that the meaning of “piston rod” should not be expanded to incorporate other components.

Overall, the parties’ claim construction briefs repeatedly run into this problem.<sup>4</sup> Both sides propose a number of constructions and arguments that ask the Court to narrow the scope of claim terms by incorporating characteristics of other components or of the interaction between components. “It is settled law that when a patent claim does not contain a certain limitation and another claim does, that limitation cannot be read into the former claim in determining either validity or infringement.” SRI Int’l v. Matsushita Elec. Corp., 775 F.2d 1107, 1122 (Fed. Cir. 1985). Constructions that create redundancy are also likely to render the incorporated claim language superfluous, in whole or in part. “A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so.” Vederi, LLC v. Google, Inc., 744 F.3d 1376, 1383 (Fed. Cir. 2014) (quoting Merck & Co. v. Teva Pharm. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005)). If this Court incorporates into the meaning of “piston rod” the express claim language that describes the interaction between the piston rod and the drive sleeve, this renders that claim language superfluous.

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<sup>4</sup> A similar recurring problem in both parties’ briefing of these claim construction disputes is the failure to distinguish the meaning of a claim term from the characteristics of embodiments of the invention. One might have a patent for an insulated coffee mug, for example, and every embodiment might have a Styrofoam insulation layer, but that fact alone does not prove that the meaning of the claim term “insulated” means “insulated by a Styrofoam layer.” “Generally, a claim is not limited to the embodiments described in the specification unless the patentee has demonstrated a clear intention to limit the claim’s scope with words or expressions of manifest exclusion or restriction.” i4i Ltd. P’ship v. Microsoft Corp., 598 F.3d 831, 843 (Fed. Cir. 2010). In resolving these claim construction disputes, this Court will frequently rely on this principle, when the parties have overlooked it.

Defendants' proposed construction of "piston rod" runs into the same problems.

Defendants present examples from the claims and embodiments in the specification that manifest the narrowing characteristics they wish to import into their construction. For the reasons already stated, this Court rejects this approach to claim construction.

This Court finds that neither party has overcome the presumption that "piston rod" carries its ordinary meaning. The Court derives the ordinary meaning of "piston rod" from the attributes that the parties agree on. The intersection of the proposed constructions is: "a rod that advances the piston." The Court modifies this slightly to reflect that, while the piston rod advances the piston<sup>5</sup> only during dose delivery, it remains a piston rod even at rest. Thus, the ordinary meaning of "piston rod" is "a rod that can advance the piston."

## 2. "clutch"

Plaintiffs propose this construction: "a structure that couples and decouples a moveable component from another component." Defendants propose that clutch is a means-plus-function term or, in the alternative, that it has this construction: "a component that, during dose setting, operates to reversibly lock two components in rotation."

Plaintiffs' sole argument in support of their proposed construction is that it was adopted by the Lilly court, 2015 U.S. Dist. LEXIS 5946 at \*14. This Court has great respect for its sister court, but this is not a valid claim construction argument under Federal Circuit law. No one contends that any preclusion doctrine applies here. The Lilly court had before it a different set of

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<sup>5</sup> The Court notes that, while some claims in the device patents disclose a "plunger" instead of a "piston," the parties have not argued that the construction of "piston rod" must take this into account.

patents, a different defendant, and different constructions proposed by the parties. Id. The Lilly court resolved the particular claim construction disputes that those parties presented to it. As to “clutch,” the Lilly opinion clearly states what that dispute was: “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. at \*15. The present parties have not presented that point of contention to this Court.<sup>6</sup> The present parties have presented to this Court different proposed constructions and a different dispute: the word “clutch” may be the same, but the dispute is not. The Lilly court’s resolution of a different dispute over “clutch” does not help this Court resolve the present one. Plaintiffs’ argument does not begin to rebut the presumption of ordinary meaning.

Defendants argue primarily that “clutch” is a means-plus-function term, pursuant to 35 U.S.C. § 112(6). Under § 112(6), a claim limitation “may be expressed as a means or step for performing a specified function without the recital of structure . . . , and such claim shall be construed to cover the corresponding structure . . .” 35 U.S.C. § 112(6). When a claim limitation does not include the word “means,” as is the case here, there is a presumption that it is not a means-plus-function limitation, and § 112(6) does not apply. Williamson v. Citrix Online, LLC, 792 F.3d 1339, 1349 (Fed. Cir. 2015). To overcome that presumption, Defendants have the burden to demonstrate by a preponderance of the evidence that the “claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for

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<sup>6</sup> Moreover, as Defendants note, the Lilly claim construction decision preceded the Federal Circuit’s decision in Williamson, which substantially revised the law applicable to the construction of means-plus-function terms.

performing that function.” Zeroclick LLC v. Apple, Inc., 891 F.3d 1003, 1007 (Fed. Cir. 2018) (citations omitted).

Defendants therefore bear the burden of rebutting the presumption that “clutch” is not a means-plus-function term under the Zeroclick standard just quoted. Despite the fact that Williamson sets forth exactly the same standard as Zeroclick, Defendants ignore those standards and offer a different one, snipped from Williamson: “A test for determining whether a claim element conveys sufficiently definite structure is asking whether it ‘sets forth the same black box recitation of structure for providing the same specified function as if the term ‘means’ had been used.’” (Defs.’ Br. 21.) Defendants have indeed snipped a piece of Williamson here, but the Federal Circuit did not state any alternate test. Here is what Williamson states: “Here, the word ‘module’ does not provide any indication of structure because it sets forth the same black box recitation of structure for providing the same specified function as if the term ‘means’ had been used.” Williamson, 792 F.3d at 1350. Defendants have not applied the correct standard for determining whether a claim term is a means-plus-function term. Defendants have not demonstrated, by a preponderance of the evidence, that “clutch” fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function.<sup>7</sup> The presumption that “clutch” is not a means-plus-function term has not been rebutted.

This leaves the Court to consider Defendants’ alternate construction: “a component that,

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<sup>7</sup> Moreover, Defendants’ expert, Dr. Ochoa, begins a paragraph about the construction of “clutch” with this statement: “The specification further defines the structure,” followed by a detailed summary of the structural information given. (Ochoa Dec. ¶ 68.) This alone negates Defendants’ position.

during dose setting, operates to reversibly lock two components in rotation.” This appears to be close to the ordinary meaning of clutch, except that the qualifying phrase, “during dose setting,” cannot be part of the ordinary meaning because, for example, a driver of a car with a manual transmission engages and disengages the clutch without ever setting a dose. The Court concludes that neither party has overcome the presumption that “clutch” has its ordinary meaning, which is: “a component that can operate to reversibly lock two components in rotation.”<sup>8</sup>

### 3. “drive sleeve,” “drive,” “driving member”

The device patents at issue each use one or more of these claim terms. “Drive sleeve” appears in claims in the ’844, ’069, and ’044 patents. “Driving member” appears in claims in the ’844 patent. “Driver” appears in claims in the ’486 patent. Thus, some claims in the ’844 patent specify a “drive sleeve,” and other claims in that patent specify a “driver.”

Defendants propose this construction for all three terms: “an essentially tubular component that moves axially to drive the piston rod.” Plaintiffs propose this construction for “drive sleeve:” “an essentially tubular component of essentially circular cross-section releasably connected to the dose dial sleeve that imparts motion during dose dispensing.” For “driver” and “driving member,” Plaintiffs propose this construction: “a component releasably connected to the dose dial sleeve that imparts motion during dose dispensing.”

As to the construction of “drive sleeve,” Plaintiffs argue that their proposed construction

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<sup>8</sup> The parties agree that the claim term “tubular clutch” should be construed in conformity with this construction.

is derived from<sup>9</sup> a “lexicographical definition” stated in the ’008 patent, and that this construction overcomes the presumption of ordinary meaning based on the lexicography exception. At the time of briefing, the ’008 patent was at issue in this case. Subsequently, the parties resolved the dispute over the ’008 patent and dropped it from this case. At the Markman hearing, however, Plaintiffs again asserted this lexicography argument.

There is no dispute that the four device patents presently at issue do not share a common specification with the ’008 patent, nor that the ’008 patent has no parent application in common with the device patents in the U.S. patent system. It is undisputed that the sole link between the ’008 patent and the four device patents rests on the fact that all five patents assert a priority date from one British patent application, GB 0304822.0. At the Markman hearing, the Court Ordered the parties to submit supplemental briefing on the issue of the relationship between the ’008 patent and the four device patents.

In the supplementary briefing, Defendants argued that the Court need not determine the precise relationship between the ’008 patent and the four device patents because, in any event, the specification of the ’008 patent is not the specification of the device patents at issue. This is correct. Under Federal Circuit law:

To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning. It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must clearly express an intent to redefine the term.

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<sup>9</sup> The ’008 patent states: “The term ‘drive sleeve’ according to instant invention shall mean any essentially tubular component of essentially circular cross-section and which is further releasibly connected to the dose dial sleeve.” ’008 patent, col.4 ll.1-4. Plaintiffs’ proposed construction adds “that imparts motion during dose dispensing” to the end of this definition.

Thorner v. Sony Comput. Entm't Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citation omitted). It is worth noting that, in this quoted passage, the Federal Circuit said not once, but twice, that, to act as lexicographer, the patentee must do so *clearly*. A definition in some other patent specification cannot meet the requirement of clearly expressing an intent to redefine the term. To the contrary, the most reasonable inference from the present facts is that the patentees did not clearly intend that a definition present in the specification of the '008 patent, but absent from the specification of the four device patents at issue, redefined the term “drive sleeve” in the four device patents. Plaintiffs have not demonstrated that the requirements of Thorner have been met here.

Plaintiffs further propose that the phrase “that imparts motion during dose dispensing” should be added to the definition of “drive sleeve” found in the '008 patent specification. Plaintiffs now appear to have forgotten about their lexicography argument and are proposing a *mélange* construction. Plaintiffs offer some extrinsic evidence of ordinary meaning in support, but the evidence does not support the proposition that the ordinary meaning of “drive” involves dose dispensing.

Defendants propose one construction for all three drive terms. Defendants argue:

Notably, aside from the abstracts and claims of the '486 and '844 patents, the Device Patents never refer to a “driver” or “driving member.” Ochoa, ¶ 56. Thus, the POSA would not understand the terms “driver” and “driving member” to refer to anything other than the “drive sleeve.”

(Def.' Br. 18.) The intrinsic evidence does not support this view. Defendants cannot dispute that some claims in the '486 and '844 patents refer not to a “drive sleeve,” but to a “driver” or

“driving member.”<sup>10</sup> Defendants’ position appears to be that the three different terms are just all the same thing, for no reason. This is not only unpersuasive, but the inference of sameness is not supported by the clear language of the claims of the ’844 patent. Claim 1 of the ’844 patent refers to a “drive sleeve.” Contrast that with claim 21 in that patent (emphasis added):

21. A drug delivery device comprising:  
a housing comprising a dose dispensing end and a first thread;  
a dose indicator comprising a second thread that engages with the first thread;  
a **driving member** comprising a third thread;  
a **sleeve** that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator; a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread;  
a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing;  
wherein:  
the housing is disposed at an outermost position of the drug delivery device;  
the dose indicator is disposed between the housing and the **sleeve** and is configured to (i) rotate and traverse axially away from the dose dispensing end during dose setting and (ii) rotate and traverse axially towards the dose dispensing end during dose dispensing;  
the **driving member** is configured to rotate relative to the piston rod;  
the **sleeve** is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator;  
and the piston rod and the **driving member** are configured to rotate relative to one another during dose dispensing;  
and the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.

The Court makes a few observations. Under Defendants’ theory, the patentees used “drive sleeve” in claim 1 but “driving member” in claim 21 for no reason, because they are the same.

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<sup>10</sup> In fact, Defendants point to the use of “driver” in claim 1 of the ’486 patent to argue that, because this claim also requires that the driver have “internal threading adapted to engage the external thread of said piston rod,” the driver must be tubular. This is a poor choice of claims to make that argument. Claim 1 requires, not once, but thrice, a “tubular clutch.” Had the inventors intended to limit the driver to tubular structures, they clearly knew how to do it. This supports the inference that, in claim 1, the inventors chose not to so limit the “driver.”



This conflicts with the following statement of Federal Circuit law: “when an applicant uses different terms in a claim it is permissible to infer that he intended his choice of different terms to reflect a differentiation in the meaning of those terms.” Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1119 (Fed. Cir. 2004). As applied to this case, the plain language of the claims provides support for an inference of differentiation. Note that claim 1 requires: “a drive sleeve that extends about the piston rod.” Note also that, in claim 21, the driving member has a third thread, and the piston rod has “either an internal or an external fourth thread that is engaged with the third thread.” This allows for the possibility that the driving member has a tubular, sleeve shape, or that it does not: it could itself be a threaded rod that engages with threading internal to the piston rod. A drive sleeve that “extends about the piston rod,” as in claim 1, cannot be the same as a “driving member” that engages with threading internal to the piston rod, as in claim 21. This suggests that the “driving member” does not have the same characteristics as the “drive sleeve” in the ’844 patent, and supports the inference that the patentees intended their choice of different terms to reflect a differentiation in the meaning of those terms.

The bottom line is that neither party has proposed constructions for “drive sleeve,” “driver,” and “driving member” that are supported both by patent law and the claim language. The Court finds that neither party has overcome the presumption that these terms have their ordinary meaning. The Court derives that ordinary meaning from the points of agreement between the parties. The parties agree that a “sleeve” is “an essentially tubular component.” The parties use different words, but essentially agree that the “drive” or “driving” element imparts motion to something. The Court concludes that the ordinary meaning of the “drive” aspect, in

the context of these patents, is “a component configured to transfer force to the piston rod.”

Therefore, the ordinary meaning of “drive sleeve” is: “an essentially tubular component configured to transfer force to the piston rod.” The ordinary meaning of both “driver” and “driving member” is: “a component configured to transfer force to the piston rod.”

4. “the piston rod and the driving member are configured to rotate relative to one another during dose dispensing”

Plaintiffs propose that this phrase, which appears only in claim 21 of the '844 patent, has its plain meaning, which is “during dose dispensing, the piston rod rotates while the driving member does not rotate, the driving member rotates while the piston rod does not rotate, or both rotate at different rates and/or directions.” Defendants propose this construction: “Both piston rod and driving member are configured to rotate, each at a different rate and/or direction during dose dispensing.”

Defendants first argue that this Court should adopt the construction used by the Merck court. As already explained, this alone is not a valid basis for construing a claim under Federal Circuit law. Defendants then argue, as do Plaintiffs, that their construction reflects the plain meaning of the claims.

This dispute turns on the plain meaning of “rotate relative to one another.” This Court agrees with the parties that the plain meaning of this phrase is clear: the ordinary meaning of the requirement that two components rotate relative to one another means that an observer situated on one component would observe the other component in rotation. Both components do not need to rotate to produce this outcome, so Defendants are incorrect. Plaintiffs are correct. All that is required is one of the following: the piston rod rotates while the driving member does not

rotate, the driving member rotates while the piston rod does not rotate, or both rotate at different rates and/or directions. Any one of those conditions produces relative rotation. This Court agrees with the parties that this dispute is resolved by examining the plain meaning of the claim language, which supports Plaintiffs' construction but not Defendants'. Relative rotation does not require that both components rotate simultaneously.

5. "main housing"

Plaintiffs propose this construction: "An exterior unitary or multipart component configured to house, fix, protect, guide, and/or engage with one or more inner components."

Defendants propose that this term has its plain meaning, which is: "the primary case or enclosure configured to house one or more inner components of the medication dispensing apparatus."

To support their construction, Plaintiffs argue that their construction was adopted by the Merck court, and that it "follows" a description in the '008 patent. (Pls.' Br. 22.) As already explained, the fact that another court construed a term does not, without more, justify a construction under Federal Circuit law. As to the '008 patent, Plaintiffs have not stated any cognizable theory of meaning. Plaintiffs do not contend that this is a lexicographic theory.<sup>11</sup> Plaintiffs' contention that their proposed construction "follows" language in the '008 specification appears to be the same as saying that they see some similarities. Here is the '008 language Plaintiffs rely on: "The term 'housing' according to instant invention shall preferably mean any exterior housing ('main housing', 'body', 'shell') or interior housing ('insert', 'inner

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<sup>11</sup> Even if they did argue that this was a lexicographic theory, as already discussed, the requirements for a lexicographic theory are not met where, as here, the definition is found in some other patent.

body’) having a helical thread.” ’008 patent, col.2 l.66-col.3 l.2. Note that the essence of this definition is circular: it states that a housing is any housing having a helical thread. The Court observes that Plaintiffs’ proposed construction says nothing about a helical thread. Even if Plaintiffs have followed the description in the ’008 patent, as they claim, they haven’t followed it very much. The Court finds no support for Plaintiffs’ proposed construction.

The Court agrees with Defendants: “main housing” has its ordinary meaning, and no construction is necessary.

6. “thread,” “threaded,” “threading”

The parties listed a dispute over these terms in the joint claim construction statement, but Plaintiffs did not brief it, while Defendants did. This Court finds that Defendants’ proposed construction is unopposed: “a 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.”

7. “clicker,” “holder,” and “insert”

For each of these three terms, Defendants argue that the term is indefinite or, in the alternative, that it is a means-plus-function term. Plaintiffs propose a construction for “clicker,” and propose that “insert” and “holder” have their ordinary meaning and that no construction is necessary.

As to Defendants’ indefiniteness arguments, this Court addresses invalidity disputes, of which indefiniteness is one, at summary judgment or at trial. Defendants may raise their indefiniteness arguments down the road.

As to Defendants’ arguments that these terms are means-plus-function terms, these terms

do not include the word “means,” which raises the rebuttable presumption that they are not means-plus-function terms. As already discussed, to overcome that presumption, Defendants have the burden to demonstrate by a preponderance of the evidence that the “claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function.” Zeroclick, 891 F.3d at 1007 (citations omitted).

As to “clicker,” Defendants do not even address, much less satisfy, the Zeroclick standard. Defendants’ argue only that, if “‘clicker’ is not construed as a means-plus-function element, the claims themselves make it nearly impossible to determine what the clicker is.” (Defs.’ Br. 28.) In support, Defendants then point to claim 15 of the ’044 patent which states: “The housing part of claim 14, wherein said clicker comprises, at least one flexible arm, said flexible arm comprising at least one tooth member, and at least one spline, wherein when said dose dial grip is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one spline so as to provide said audible feedback.” This does not support Defendants’ position. This claim clearly recites definite structure, and Defendants have not shown otherwise.

In support, Defendants cite Diebold Nixdorf, Inc. v. ITC, 899 F.3d 1291, 1298 (Fed. Cir. 2018), which does not support their position but is valuable to discuss as a point of contrast. In Diebold, the Federal Circuit concluded that § 112, para. 6 applies to the term, “cheque standby unit:”

None of the dependent claims add limitations that either describe particular structural features or flesh out whether the term has a particular structural meaning. And the specification similarly explains that the “cheque temporary standby unit” is “formed on the main transfer path 106a” and is used to “temporarily stop[ ] a transfer of authentic cheques,” without making clear what,

if any, structures correspond to the claim term. *Id.* col. 2, l. 62-col. 3, l. 2. Indeed, although the specification includes a drawing, Figure 2, which purports to illustrate the term, it depicts “cheque temporary standby unit 120” as a vertical line indistinguishable from the “main transfer path 106a” that both precedes and follows it and on which it is “formed.” *Id.* at Fig. 2.

Although these passages suggest that the “cheque standby unit” must have some structure to perform the function of holding checks and then either returning them to the user or continuing to process them pending a user instruction, the '235 patent does not offer any clues as to what such a structure might be. Indeed, the written description does not include any examples of what structures or class of structures fall within the definition of a “cheque standby unit.”

Id. Note the analysis followed by the Diebold Court: the Court looked at not only the language of the claim at issue, but also at dependent claims and the specification. Id. In particular, the Federal Circuit noted that the written description did not include any examples of structure and stated that “the '235 patent does not offer any clues as to what such a structure might be.” Id. Although the Diebold Court then focused on the role of extrinsic evidence in the inquiry, the passage quoted above contains their entire inquiry into the evidence within the four corners of the patent itself.

Plaintiffs contend that, *inter alia*, Defendants’ § 112, para. 6 analysis errs because Defendants scrutinize claim terms in isolation, rather than in the context of other claims and the specification. Diebold supports Plaintiffs’ criticism, not Defendants’ position. Crucially, in the instant case, Defendants acknowledge that, unlike Diebold: 1) claim 15 of the '044 patent provides many details about the structure of the clicker; and 2) the “detailed description” section of the common specification offers a very detailed description of the structure of an exemplary clicker. See, e.g., '844 patent, col.4 ll.42-57.

The Court concludes that Defendants have not carried their burden of demonstrating by a

preponderance of the evidence that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function. “Clicker” is not a means-plus-function term.

Plaintiffs propose that “clicker” means “a structure that provides audible and/or tactile feedback when the dose knob is rotated.” In support, Plaintiffs argue that this “conforms to how a POSITA would understand [the] term ‘clicker’ in view of the intrinsic record.” (Pls.’ Br. 35.) This indicates that Plaintiffs believe that “clicker” has its ordinary meaning.

The Court notes the very first sentence of Defendants’ argument about the construction of clicker: “By its nature, a ‘clicker’ is a thing that clicks.” (Defs.’ Br. 28.) The Court also takes judicial notice that the website “dictionary.com” defines “clicker” as follows: “someone or something that clicks.”<sup>12</sup> Thus, having just argued that “clicker” is indefinite, Defendants proceed to offer a definition of “clicker” that is virtually identical to an ordinary dictionary definition. The Court concludes that “clicker” has its ordinary meaning, which is, “a component that clicks.”

The disputes over the construction of “holder” and “insert” differ only slightly from “clicker.” Plaintiffs contend that these terms have their ordinary meaning and need no construction. Defendants contend that they are indefinite, or means-plus-function terms. Again, the Court defers the invalidity arguments to summary judgment or trial.

As to the question of whether “insert” is a means-plus-function term, Defendants’ in the course of their argument, state: “The only way to define it is by referencing structures disclosed

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<sup>12</sup> <https://www.dictionary.com/browse/clicker> (accessed May 3, 2019.)

in the specification.” (Defs.’ Br. 31.) Defendants have thus conceded that the structure of “holder” is disclosed in the specification, which undermines their argument.

As for “holder,” the parties point only to claim 21 of the ’844 patent, where it appears in this context: “a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing . . .” As Plaintiffs have argued, Defendants support their means-plus-function arguments by looking at words in isolation from their context. Claim 21 does disclose a “holder,” but the context tells us that it is a “piston rod holder,” and gives limitations which contain significant information relevant to its structure. Defendants have not overcome the presumption against finding that “holder” is a means-plus-function term.

This Court agrees with Plaintiffs that “holder” and “insert” have their ordinary meanings and do not need construction.

This Court concludes that, with the exception of “thread,” where Defendants’ proposed construction is unopposed, no party has overcome the presumption that the disputed claim terms carry their ordinary meaning. The ordinary meaning of “chemical entity” is “chemical compound.” “Chosen from” and “the polysorbate 20 is present in an effective amount to avoid turbidity” have their ordinary meaning and do not need construction. The Court finds no substantive dispute over the construction of “esters and ethers of polyhydric alcohols.” The ordinary meaning of “piston rod” is “a rod that can advance the piston.” The ordinary meaning of “clutch” is “a component that can operate to reversibly lock two components in rotation.” The ordinary meaning of “drive sleeve” is: “an essentially tubular component configured to transfer



force to the piston rod.” The ordinary meaning of both “driver” and “driving member” is: “a component configured to transfer force to the piston rod.” The phrase, “the piston rod and the driving member are configured to rotate relative to one another during dose dispensing” has its ordinary meaning and does not need construction; the ordinary meaning of relative rotation of two components does not require that both components rotate. The term “main housing” has its ordinary meaning, and no construction is necessary. As to “thread,” “threaded,” and “threading,” Defendants’ proposed construction is unopposed: “a 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.” The ordinary meaning of “clicker” is: “a component that clicks.” Finally, “holder” and “insert” have their ordinary meanings and do not need construction.

**SO ORDERED.**

s/ Stanley R. Chesler  
Stanley R. Chesler, U.S.D.J.

Dated: May 9, 2019