



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

COURT FOR OF

U.S. Plaintiffs, V.

DOHME CORP.,

MEMORANDUM OPINION

P. P.C., P.C.,

Park, P.C.,

P.C., Underhill BOIES LLP, Potter, BOIES LLP, BOIES LLP,

Plaintiffs

P. CONNOLLY LLP,

P. P. QUINN EMANUEL URQUHART SULLIVAN, LLP,

11, 2018

IN THE UNITED STATES DISTRICT

THE DISTRICT DELA WARE

SANOFI-AVENTIS LLC, et al.,

Civil Action No. 16-812-RGA MERCK SHARP &

Defendant.

Douglas E. McCann, Martina Tyreus Hufnal, Ronald Golden III, FISH & RICHARDSON

Wilmington, DE; John S. Goetz (argued), Brian D. Coggio, FISH & RICHARDSON New York, NY;



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

Ahmed J. Davis, Min Woo Sarah M. Cork, FISH & RICHARDSON Washington, DC; Matt Colvin, FISH & RICHARDSON Dallas, TX; D. Michael (argued), Jon R. Knight, SCHILLER & FLEXNER Washington, DC; William D. Marsillo, Alex SCHILLER & FLEXNER Armonk, NY; Bill Ward, Martin Ellison, SCHILLER & FLEXNER Santa Monica, CA. Attorneys for Arthur G. Connolly III, Ryan Newell, Mary Akhimien, GALLAGHER Wilmington, DE; Raymond N. Nimrod (argued), Brian Biddinger, Gregory D. Bonifield (argued), John Galanek, Amanda K. Antons, Matthew Traupman (argued),

& New York, NY. Attorneys for Defendant

January

Presently U.S. Patent 8,603,044 "'044 patent"), "'069 patent"), "'486 patent"), "'844 patent"), 9,533,105 "'105 patent"), "'152 patent"), "'348 patent"), "'652 patent"), "'930 patent"), 9,604,008 "'008 patent"). 1

2017. ("Tr.").

On September 2016, Plaintiffs Sharp

Plaintiffs Second 2017 2017,

"It

exclude." 1303, 2005) "'

law.'" 2013

U.S. Patent

! i before the Court is the issue of claim construction of multiple terms in Nos. (the 8,679,069 (the 8,992,486 (the

9,526,844 (the (the 9,457,152 (the 9,592,348 (the 7,476,652 (the 7,713,930 (the and (the The Court has considered the parties' joint claim construction brief. (D.I. 127). The Court heard oral argument on November 6, (D.I. 164)

I. BACKGROUND

16, filed this action against Defendant Merck & Dohme Corp. alleging infringement often patents. (D.I. 1). With the Court's permission,



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

filed First Amended (D.I. 58) and Amended (D.I. 93) complaints on April 5, and June 28, 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

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 Phillips v. AWH Corp., 415 F.3d 1312 (Fed. Cir. (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 Soft View LLC v. Apple Inc.,

1 Plaintiffs no longer assert 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.

Sept. 2013)

977-80 U.S. 370 Of "the

Usually, term."

"[T]he

"[T]he

patent." "In

words."

S. (2015).

"consists

treatises." WL 4758195, at *1 (D. Del. 4, (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, (Fed. Cir. 1995) (en banc), aff'd, 517 (1996). these sources, specification is always highly relevant to the claim construction analysis. it is dispositive; it is the single best guide to the meaning of a disputed Phillips, 415 F.3d at 1315.

words of a claim are generally given their ordinary and customary meaning [Which is] the meaning



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

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. ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire Id. at 132. 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 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 *TevaPharms. USA, Inc. v. Sandoz, Inc.*, 135 Ct. 831, 841 The court may also make factual findings based upon consideration of extrinsic evidence, which of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned 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

2

"A

patent." PLC 1250 "a

505 2007). CONSTRUCTION OF DISPUTED TERMS

'930

"surfactant 5-200 µg/mL"

Plaintiffs "chemical entity"

"attempt[ing] entirely."

Plaintiffs,

Plaintiffs

"present invention"

"chemical entity" 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.

claim construction is persuasive, not because it follows a certain rule, but because it defines terms in



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

the context of the whole *Renishaw v. Marposs Societa 'per Azioni*, 158 F.3d 1243, (Fed. Cir. 1998). It follows that claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GMBH v. Int 'l Trade Comm 'n*, F.3d 1351, 1358 (Fed. Cir. III.

1. "chemical entity" ('652 patent, claims 1, 2, 7, 17, 18, 19, 23,

24; patent, claims 1, 14, 15, 16)

a. Plaintiffs' proposed construction: no construction necessary; plain and

ordinary meaning b. Defendant's proposed construction: that stabilizes the formulation,

in a concentration of c. Court's construction: no construction necessary; plain and ordinary meaning

argue the Court need not construe the term 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 to re-write the claim (Id at 15). Defendant's proposed construction, according to improperly imports into the claims a function and a limitation from the specification. (Id). 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 description in the specification, which according to Defendant, makes clear the invention requires that the

be present in an amount sufficient to stabilize the formulation, that is, in a

3

5-200 µg/ml. "detailed invention" "The

5-200 µg/ml." 18:10-14). Second,

disavowal. "patent

solution," "be preparation." 20).

"stabilize[] 5-200 µg/mL."

"present invention."

"clear



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

"" "When

invention.""

"clear unmistakable" See "The "

"features whole," concentration of (Id. at 19). Defendant primarily relies upon the following sentence from the description of the in the '652 patent: surfactants are present in the pharmaceutical composition in a concentration of $\mu\text{g/ml}$, preferably 5-120 $\mu\text{g/ml}$ and particularly preferably of 20-75 (See id. at 18; Tr. at Defendant argues the scope of the '652 patent is limited by Specifically, Defendant argues that because the specification distinguished two prior art references on the basis that they did not describe surfactants that provided 'stabilization in an acidic the term should construed to require an amount sufficient to stabilize the (D.I. 127 at

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 the formulation, in a concentration of A patentee may disavow claim scope through a description in the specification of the 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 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.

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 Id.

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

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"present invention"



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

"can used" "preferred." (See

"clear unmistakable"

(See

Plaintiffs "distinguish[ing] feature." Poly-

L.P. AP! 2016).

"exacting." Sols., 750 1304, 1309 2015). "To

disclaimer.'" Sys., 808 509, 2015).

Plaintiffs WO 00/23098 WO 02/076495 "stabilization surfactant." (See 19-20). Plaintiffs

"do[] solution." Plaintiffs

"pH stabilization."

Plaintiffs I

,

Luminara, 814 F.3d at 1353, and, in fact, it never refers to the 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 be or are '652 patent, 3:50-56). Nor do any of the other portions of the specification upon which Defendant relies constitute and 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. D.I. 127 at 18 (quoting '652 patent, 3:32-36)).

Further, I am not persuaded that have disavowed claim scope by

or disparag[ing] prior art based on the absence of [a particular] Am., v. Indus., Inc., 839 F.3d 1131, 1136 (Fed. Cir. The standard for finding disavowal is GE Lighting LLC v. AgiLight, Inc., F.3d (Fed. Cir. 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 Openwave Inc. v. Apple Inc., F.3d 513 (Fed. Cir.

In my opinion, it is not clear that distinguished prior art references



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

and on the basis that they do not describe by the

D.I. 127 at The prosecution history indicates that distinguished those references on the basis that they not describe the stabilization in an acidic (Id. at 26). argue, therefore, that the present invention was distinguished from the prior art by and insulin type, not (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

5

See 808 Similarly, Plaintiffs

Plaintiffs

Plaintiffs

Under "a

scopes." 1120, 2014); Sys., 1360 2010) ("Under

range."

'930 5-200 5-120 20-75 '930

"overcome history." 2005).

"chemical entity." clearly and deliberately disavowed claim scope. Openwave, F.3d at 513. it is not clear that 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 have not disavowed claim scope through their statements during patent prosecution.

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

Here, the asserted independent claims do not include concentration limitations, while dependent claims in the '652 and patents recite several specific ranges. These ranges include µg/ml, required by Defendant's proposed construction, as well as µg/ml and



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

µg/ml. ('652 patent, 12:13-18; 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 by a contrary construction dictated by the written description or prosecution. *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir.

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

6

"housing" Plaintiffs' (D.1. 10).

I

"an components"

"single, enclosure"

"an components" Plaintiffs "exterior" 2

"housing,"

Plaintiffs "violates meaning," "external housing" "housing."

Plaintiffs "divorce['housing. "'

"main housing"

"external," "exterior."

"exterior." "external" "exterior." 2. "housing" ('844 patent, claim 21; '105 patent, claims 1, 4; '008 patent, claims 1,

3, 6, 11) The parties included the term in their joint claim construction brief. However, Defendant has agreed to proposed construction. 127 at 36 n. 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)



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

a. Plaintiffs' proposed construction: exterior unitary or multi part component

configured to house, fix, protect, guide and/or engage with one or more inner

b. Defendant's proposed construction: indivisible component that is an

external case or c. Court's construction: exterior unitary or multi part component configured

to house, fix, protect, guide and/or engage with one or more inner

argue their proposed construction, which adds the word to the agreed-upon construction for the term is supported by the patentee's lexicography and is consistent with the plain meaning of the term. (Id. at 35). argue that Defendant's proposed construction the principle that all terms in a claim have

by construing the same way as (Id.). In contrast to their proposed construction, assert, Defendant's construction is d] [] entirely from the agreed definition of (Id. at 45).

Citing several dictionary definitions, Defendant argues the plain meaning of

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

rather than (Tr. at 32:3-5). In the parties' joint claim construction brief, however, Plaintiffs' proposed construction includes the word (D.I. 127 at 35). In any event, I do not see any meaningful difference between and

7

"main" '069, '044, "housing" "main part."

"main housing" 37-40). "external housing,"

"external housing"

"main housing" "external housing"

"main housing" "external housing"

2014). "main housing" "external housing"



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

"main," "chief size."

"chief rank,"

'105 '008 "configured

components." '105 '008

"main housing" "external housing" '069, '044, Plaintiffs' proposed construction would render the word meaningless. (Id.). Defendant points to the specifications of the and '486 patents, which distinguish between

and the housing (Id.). Further, Defendant contends that the prosecution history and the patent specifications indicate that refers to a single component. (Id. at Similarly, with respect to the term Defendant argues that Plaintiffs' proposed construction eliminates the distinction between the 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 and require single, indivisible components. The embodiments upon which Defendant relies do not make clear that the and

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. Further, nothing in the plain language of the terms suggests the and cannot be made of multiple parts. The definitions upon which Defendant relies address the meaning of the word defining it as, for example, or principal in rank, importance, [or] (D.I. 127 at 37 (quoting Collins English Dictionary)). That a component is or principal in however, does not mean it cannot be a multipart component.

Further, I agree with Plaintiffs' inclusion of the language from the lexicography of the and patents, that is, to house, fix, protect, guide and/or engage with one or more inner Although this definition appears only in the and patents, I believe it also makes sense to include it in the construction for the terms and

in the and '486 patents.

8

Claim '044 "cartridge part" "coupled housing." ('044 10:3-4 "a barrel retainer" "operatively housing"). Claim '044 claim '069 "dose sleeve



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

housing." ('044 '069 "main housing" "external housing"

'105 '008 '044 ("The

70.")). includes Plaintiffs'

"main housing" "external housing" "an

components."

('044 10, 20; '069

'105 30; '008

"a

structure" "rib

structures" "rib

structures"

I 1 of the patent describes a retaining being to said main patent, 7:13-14; see also '486 patent, (reciting tubular

being coupled to said external 11 of the patent and 1 of the patent recite a dial comprising a helical groove configured to engage a threading provided by said main patent, 8:12-14; patent, 6:41- 43). These examples demonstrate the and 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 and patents. (See, e.g., patent, 5 :9-11 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 A construction that proposed language is therefore supported by the intrinsic record.

Accordingly, I will construe and to mean exterior unitary or multipart component configured to house, fix, protect, guide and/or engage with one or more inner

4. "thread/threading" patent, claims 1, 7, 11, 17, patent, claim 1;

'486 patent, claims 1, 24, 25, 31, 43; '844 patent, claim 21; patent, claims 3 and 4; '348 patent, claims 2 and '152 patent, claim 14; patent, claims 1, 6, 7, 11, 16, and 18)



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

a. Plaintiffs' proposed construction: rib or groove on a first structure that

engages a corresponding groove or rib on a second b. Defendant's proposed construction: 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 c. Court's construction: 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

9

Plaintiffs "helical"

"thread." 50). "helical," Plaintiffs

"would result," "helical" "commonly structures." Plaintiffs '105

"thread" "allow[] movement."

"thread" "spline,"

"thread" "spline,"

"thread" "spline" "spline" "thread." '044 '105

"nut 40" "internal 36," "nut 40" "by sleeve." ('044

'105 9:58-60). "splines," "to 40

f f between." ('044 '105 J

10

I

I argue that Defendant is attempting to include the meaning of the word in its construction, which the Court rejected in Lilly when it construed the term (D.I. 127 at Although Defendant's construction does not use the word argue that Defendant's proposed construction achieve the same because a



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

thread is understood as a thread that provides for both rotational and axial movement between (Id.). further point to the specifications of the and '348 patents, which, according to Plaintiffs, show that Defendant is incorrect that a must

rotational and axial (Id. at 51). Defendant responds that Plaintiffs' proposed construction of would include a 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 would include a which conflicts with the patent specifications. The specifications do not appear to use the words and interchangeably. Nor do they suggest that a is a type of

Rather, the patents differentiate between the two. For example, the and patents describe a having an thread matching the intermediate thread and the advancing along the intermediate thread the rotation of the drive patent, 4:20-21, 6:4-6; patent, 8:4-6, They describe on the other hand, as being used prevent relative rotation between the nut and the main housing 4, while allowing relative longitudinal movement there patent, 4:22-26; patent,

8:6-10). '044 '105 "thread"

"spline" "spline" "thread."

"spline" "thread."

"supplementary" "open discussion."

"spline." 2013 "spline." (See

"threads" "the infinite."

"helical thread" '105 "The

components." '105

"rotational movement." "helical thread" "continuous movement,"

"continuous movement."

Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

1

I According to the and patents, 3

therefore, a allows for rotational movement, while a does not. There is no reason to conclude that the patents use the word to refer to a type of

Further, I am not persuaded that a person of ordinary skill in the art, at the time of the invention, would have understood a to be a type of Plaintiffs point to a definition from 1917 in The Mechanical Engineer. (D.I. 127 at 58). Plaintiffs omit, however, that the definition is and to (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 Although Plaintiffs also cite to a publication, nowhere does the text upon which Plaintiffs rely refer to a

id (citing Matrix Methods in the Design Analysis of Mechanism and Multibody Systems (2013))). Rather, the text describes what happens to when pitch of a helical joint is made (Id).

Finally, Plaintiffs point to a definition of in the patent, which states: 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

(Id at 58 (quoting patent, 3:27-36)). Plaintiffs argue this lexicography contradicts Defendant's proposed construction, which requires and axial (Id.). Although this definition seems to suggest that a could be construed in such a way so as to allow axial movement without free rotational such axial movement can occur without splines but still not include free rotational

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

11

"thread" "spline." "spline." "thread" "rib

structures." "the

"both dispensing"

"both

dispensing" "The



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

rotation." (Id. "violate

principles"

(Id.). "includes not." (Id.

"requires

extent."

I (

I Therefore, in the context of these patents, does not suggest a Accordingly, it will not be construed to mean I will construe as 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

5. 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: piston rod and driving member are

configured to rotate, each at a different rate and/or direction, during dose

c. Court's construction: piston rod and driving member are configured to

rotate, each at a different rate and/or direction during dose Plaintiffs argue, claim language is clear and further construction is unnecessary: during dose dispensing, the piston rod and the driving member are configured for relative

at 61). According to Plaintiffs, Defendant's proposed construction would core claim construction 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. They also point to column 6, lines 48 to 58, which they argue show that the specification the possibility that one component rotates while the other does at 61).

Defendant counters that the plain language of the term that each of the piston rod and the driving member be configured to rotate, albeit in different directions or to a different



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

(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

12

"the

rotate." Plaintiffs'

"A

so." USA, 2005). "piston rod" "driving member"

"driving member" "configured relative" "the

rod." Second, "the

dispensing." (Id. Plaintiffs

Plaintiffs "piston rod" "driving member"

Such

"piston rod" "driving member" (See

Plaintiffs' show patentee knew how to draft claim limitations, where one or the other driving member and piston rod are configured to (Tr. at 76:24-77:2). In response to 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).

claim construction that gives meaning to all the terms of the claim is preferred over one that does not do Merck & Co., Inc. v. Teva Pharms. Inc., 395 F.3d 1364, 1372 (Fed. Cir. In my opinion, a construction, like Defendant's, which requires both the

and the to be configured to rotate, appropriately gives meaning to all the terms of the claim. Claim 21 twice refers to the being to rotate to another component of the pen-type injector. First, claim 21 recites, driving member is configured to rotate relative to the piston ('844 patent, 8:40-41).

it recites the term at issue: piston rod and the driving member are configured to rotate relative to one another during dose at 8:45-46). essentially ask the Court to ignore that these two claim limitations are worded differently. assert that the disputed term encompasses two configurations, one in which



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

both the and the

are configured to rotate, and one in which only one or the other is configured to rotate. (Tr. at 69:12-14). 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 or the is configured to rotate. '844 patent, 8:40-41).

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

13

"disfavored." Pacing 1021, 1026 "where

embodiment." "This

embodiment."

"driving member" "piston rod"

"each direction"

"relative"

"both

dispensing."

"abut"

160

"single

rod" "single

rod" "single

rod" excludes a preferred embodiment is generally Techs., LLC v. Garmin Int'l, Inc., 778 F.3d (Fed. Cir. 2015). However, the patent describes multiple embodiments, every claim does not need to cover every Id is particularly true where the plain language of a limitation of the claim does not appear to



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

cover that

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 rotates, while the does not.

Finally, I agree with Defendant's including at a different rate and/or 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 to one another.

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

6. "abut" ('152 patent, claim 1) Although the parties included in their joint claim construction brief, they have since agreed upon a construction. (D.I. 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: component or multiple components

configured to transfer force to the piston b. Defendant's proposed construction: component, or multiple

components moving as one, which transfers force or motion to the piston c. Court's construction: component or multiple components configured

to transfer force to the piston

14

"multiple components" "drive member" "move one."

"moving one" (Id.). Second, "is cloth." 70). "nonsensically

rod," "the transferred." (Id.).

"member" "mechanism," (Id.). "drive member" "drive mechanism." (Id.). Unlike "mechanism,"

"member" (Id. "the



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

one." (Id.).

"drive member" "mov[e] one."

"mechanisms" "members."

"mechanism" "member."

"Any member." (Id. "member" "mechanism,"

I • I The parties dispute whether the of the must as 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 as language is ambiguous. according to Plaintiffs, Defendant making up limitations from whole (Id. at Third, Plaintiffs argue that Defendant requires the drive sleeve to transfer force 'or motion' to the piston while laws of physics decree that motion cannot be

Defendant counters that unlike Plaintiffs' proposed construction, Defendant's construction preserves the distinction between a and a as required by the specification. Specifically, Defendant explains that the specification refers to the

as being part of the a which in this field is a system of multiple parts, a is part of a mechanism. at 71). Accordingly, Defendant asserts, specification repeatedly uses the term 'member' to refer to a single component or multiple components moving as

I see no basis in the intrinsic record for including the limitation that when a

is made of multiple components, those components must as Further, I am not persuaded by Defendant's argument that Plaintiffs' proposed construction is improper because it equates and To support its argument, Defendant relies in part on dictionary definitions of the words and The Dictionary of Mechanical Engineering, for example, states, part of a structure or mechanism is called a

at 72). That a is part of a which may be made of

15

"member"

"or motion"



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

Plaintiffs "or motion" "drive member" "configured force,"

Plaintiffs' "single

rod." "clutch

Plaintiff "a

component" "single housing"

"a

component"

"clutch," '008, "tubular clutch," '044, '069,

"clutch member,"

Plaintiffs "clutch" "tubular clutch" "clutch member."

Plaintiffs "describes

I I

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

Further, although Defendant includes the language in its proposed construction, Defendant does not provide any support for this additional language in the parties' joint claim construction brief. I agree with that it does not make sense to include

in the construction for this term. The '152 patent specifically refers to the being to transfer not motion. (' 152 patent, 8:25-29). I will therefore adopt proposed construction for this term, component or multiple components configured to transfer force to the piston

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

a. 'proposed construction: structure that couples and decouples a

moveable component from another b. Defendant's proposed construction: component, or multiple



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

components moving as one, which is secured against any rotational movement with respect to the c.
Court's construction: structure that couples and decouples a moveable

component from another The parties have agreed upon a construction for the term which appears in the '486, and '844 patents, and which appears in the and '486 patents. (D.I. 127 at 12). The parties now dispute whether the term which appears in the '348 patent, should be construed differently.

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

16

13." Plaintiffs "overcomes

art]." Plaintiffs,

"clutch" "secured housing."

Plaintiffs "moving one." Plaintiffs

Plaintiffs' "clutch member" "clutch"

"clutch"-the "clutch member" "coupling unit." Plaintiffs'

"clutch member" "coupling unit,"

"clutch member"

"clutch member" "secured

housing."

"the

patent."

f I

I and decouples dose member 23 to housing (Id (citing '348 patent, 5:11-21, 12:65-13:9, 15:61-16:3)).
Further, argue that nothing in the patent the heavy presumption for the plain and ordinary meaning



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

of 'clutch' as understood by a [person of ordinary skill in the (Id). According to Defendant's proposed construction would improperly import a limitation from the specification into the claims, by requiring that the

be against any rotational movement with respect to the (Id at 76). Finally, disagree with Defendant's proposal that the construction include the limitation

as (Id). 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 contentions, and are not the same terms. (Id at 77). Specifically, Defendant argues that the specification describes two components that perform the operations of a

and the (Id). Defendant asserts that proposed construction of would encompass the 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 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 cannot rotate, and, therefore, it is against any rotational movement with respect to the (Id at 78-79). Finally, Defendant argues that this case is similar to

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

17

2004),

(Id.

"clutch member" "mov[one."

Plaintiffs'

"clutch member" "coupling unit." "couples" "decoupled" "coupling unit." "coupling unit" "clutch member"

"clutch member" "secured housing."



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

2003). Plaintiffs

"clutch member"

"clutch member"

"clutch member" "has art," "based Goldenberg v. Cytogen, Inc., 373 F.3d 1158 (Fed. Cir. where the Federal Circuit limited the scope of a particular term according to its use in the specification. at 79).

First, I see no support for Defendant's attempt to import into the claims a limitation that when a is made of multiple components, those components must e] as

I will therefore not include that language in the construction for this term. Second, I am not persuaded by Defendant's argument that proposed construction is improper because it ignores that the patents distinguish between and As Defendant points out, the specifications use the words and

to describe the (See '348 patent, 14:46-51). That the couples and decouples, however, does not mean that the cannot also do so.

Third, I do not agree with Defendant that the must be against any rotational movement with respect to the 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. Further, as

point out, including this limitation would seem to render superfluous certain claim language in both patents. Claim 1 in the '348 patent describes the as not rotating with respect to the housing during the setting of the dose. ('348 patent, 17:24-26). This language suggests that the may rotate with respect to the housing at times other than dose setting.

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

18

specification."

"clutch" skill "member" "clutch"

"clutch." will Plaintiffs' "a



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

component." "dose 30)

"a drug" "single

member" "a housing" Plaintiffs inclusion "moving one" "clutch member" "drive member." Plaintiffs

"which

member." Plaintiffs,

"expressly embodiments." Plaintiffs "a claims."

I ,

It [is] used in the (D.I. 127 at 79 (quoting Goldenberg, 373 F.3d at 1664)). Defendant does not appear to dispute that the word has an accepted meaning to one of ordinary in the art. Contrary to Defendant's assertions, I do not believe use of the word

after means this term should not be construed to include the accepted meaning of the word

Accordingly, I adopt proposed construction, structure that couples and decouples a moveable component from another

9. member" ('348 patent, claims 1-6,

a. Plaintiffs' proposed construction: single component or multiple

components for setting a dose of a b. Defendant's proposed construction: component, or multiple

components moving as one, which has outer guide members and which is configured to move axially relative to the dose dial c. Court's construction: single component or multiple components, which has

outer guide members and which is configured to move axially relative to the

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



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

19 1

"do[]

art."

"dose member"

"dose member" "for dose,"

"dose member." "a function."

"dose member"

"construe[d] itself." 2004);

2010) ("Idiosyncratic

specification."). "[c]onstruing

claims." "It

scope."

20 Defendant counters that Plaintiffs not even allege, much less provide evidence indicating, that 'dose member' has an ordinary and customary meaning in the (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 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

should be construed as any component setting a 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 (Id. at 85). Those components, however, are each distinct entity with [their] own design and (Id).

I agree with Defendant that 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 only as broadly as is provided for by the patent *Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1164 (Fed. Cir. see also *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1287 (Fed. Cir.



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

language, highly technical terms, or terms coined by the inventor are best understood by reference to the

The Federal Circuit has cautioned, however, that the claims in light of the specification does not [] imply that limitations discussed in the specification may be read into the Intervet, 617 F.3d at 1287. 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 Id.

l I

Plaintiffs'

"dose member"

"dose member"

Since "dose member"

"outer members" "dose member" "dose member" 10,

"The

24." "dose member"

"dose member" "outer members."

"outer members," "may axially." (Id. 10:14-15). Plaintiffs'

"outer members"

Plaintiffs' "outer members" "outer members" "insert member," "dose member." (See

Here, 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 taken from the patent specification. In particular, Defendant's proposal requires that the (1) have outer guide members and (2) be configured to move axially relative to the dose dial member.

one must look to the specification to give meaning, see *Goldenberg*, 373 F.3d at 1164, I agree with Defendant that it is appropriate to include guide in the construction for this term. While the '348 patent refers to the



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

throughout, the essence of the is contained at column lines 29 to 62. That portion of the specification states in relevant part, 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 ('348 patent, 10:51-54). Thus, the only detailed description of the in the specification recites that the has guide It then goes on to describe optional features of those guide including, for example, that they

extend at Contrary to contentions, I do not think that to include guide 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 argument that including guide would render superfluous dependent claim 21. That claim refers to guide with respect to the not the

'348 patent, 18:44-45).

21

Plaintiffs "dose member" "provided 24." Plaintiffs, "outer members" "dose member" "dose member" "threadedly housing."

Plaintiffs,

"which member." "outer members," "dose member"

"which housing." "dose member" "configured

dose." 10:29-33;

"dose member" "mov[one."

"dose member" "a

housing." IV. CONCLUSION

Further, as point out, the specification also describes the as being with a (outer) thread I do not agree with however, that including

guide means the construction must also include a limitation that the

have any such thread. The patent separately claims a that is



Sanofi-Aventis U.S. LLC et al v. Merck Sharp & Dohme Corp.

2018 | Cited 0 times | D. Delaware | January 12, 2018

connected to the (Id. at 17:42-43). I agree with however, that it would be improper to include the second limitation in Defendant's proposal, that is, is configured to move axially relative to the dose dial While that limitation appears in the same paragraph as the reference to

guide the dial is not claimed in the patent. Instead, I think it would be better to include the following language: is configured to move axially relative to the This language is consistent with the specification, which describes the

as being 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 (Id. at 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 is made of multiple components, those components must e] as

I will therefore not include that limitation in the construction for this term. For the reasons stated above, I will construe to mean, single component or multiple components, which has outer guide members and which is configured to move axially relative to the

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