

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: OZEMPIC (SEMAGLUTIDE)	)	
PATENT LITIGATION	)	MDL NO. 22-MD-3038 (CFC)
	)	ANDA CASE
	)	
	)	
NOVO NORDISK INC. and	)	
NOVO NORDISK A/S,	)	
	)	
Plaintiffs,	)	
	)	C.A. No. 22-294 (CFC)
v.	)	CONSOLIDATED
	)	ANDA CASE
RIO BIOPHARMACEUTICALS INC.,	)	
et al.,	)	
	)	
Defendants.	)	
NOVO NORDISK INC. and	)	
NOVO NORDISK A/S,	)	
	)	
Plaintiffs,	)	
	)	C.A. No. 22-1040 (CFC)
v.	)	ANDA CASE
	)	
MYLAN PHARMACEUTICALS INC.	)	
	)	
Defendant.	)	

JOINT CLAIM CONSTRUCTION BRIEF

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Exhibit	Description	Abbreviation
	Novo Nordisk's Opening Claim Construction Position	Opening
	Defendants' Answering Claim Construction Position	Answering
	Novo Nordisk's Reply Claim Construction Position	Reply
A	U.S. Patent No. 10,335,462	'462 Patent
B	U.S. Patent No. 8,920,383	'383 patent
C	U.S. Patent No. 9,775,953	'953 Patent
D	Definition of "Limiter," Collins English Dictionary	
E	Definition of "Driver," Merriam-Webster Collegiate Dictionary	
F	U.S. Patent No. 9,764,003	'003 Patent
G	Declaration of Kimberly K. Cameron, Ph.D., P.E. (Apr. 6, 2023)	Cameron Decl.
H	PCT Pub. No. WO2002/092153A2	
I	Definition of "Housing," Merriam-Webster Collegiate Dictionary	
J	Definition of "Coupled," Oxford English Dictionary	
K	U.S. Patent No. 6,235,004	
L	U.S. Patent No. 8,920,383 prosecution history excerpt: Jan. 2010 Response to Office Action	
1	Excerpt of Novo's Resp. to Defs. Initial Invalidity Contentions	
2	Excerpt of Novo's Initial Infringement Contentions	
3	Generic Drugs-Specific Labeling Resources	
4	US9,968,659 (SEMAJDG_0003107-32)	
5	US11,278,596 (SEMAJDG_0003085-3106)	
6	Meriam, J. L., and L. G. Kraige. <i>Engineering Mechanics</i> . Statics. 7th ed., J. Wiley, 2012 (SEMA(JDG)_0002989-3081)	
7	Academic Press Mechanical Engineers Handbook 2001 (SEMA(JDG)_0002936-964)	
8	Khurmi, R S. <i>Textbook of Engineering Mechanics</i> . S Chand & Co Ltd, 2010 (SEMA(JDG)_0002966-985)	
9	Luebke, Chris, and Peting, Donald. "What Are Couples?" Architectonics The Science of Architecture, 1995,	

Exhibit	Description	Abbreviation
	web.mit.edu/4.441/1_lectures/1_lecture12/1_lecture12.html. Accessed 20 Jan. 2023 (SEMA(JDG)_0002986-2988)	
10	The American Heritage Dictionary – New College Edition – ISBN: 0-395-20360-0 (SEMA(JDG)_0002965)	
11	Friction-Induced Vibration in Lead Screw Drives, Ch. 2, Lead Screws (Springer 2011)	
12	Declaration of Karl R. Leinsing, MSME, PE	Leinsing Decl.
13	The Oxford American Dictionary and Thesaurus with Language Guide (2003)	
14	U.S. Patent No. 8,920,383 prosecution history excerpt: Amendment (July 1, 2010)	

I. INTRODUCTION

A. Novo Nordisk's Opening Position

This case concerns Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S's (collectively, "Novo Nordisk") blockbuster diabetes medicine Ozempic®. The parties dispute claim construction of nine terms, one of which appears in Novo Nordisk's U.S. Patent No. 10,335,462 (the "'462 patent"), which claims methods of treating diabetes. The remaining claim terms are found in U.S. Patent Nos. 8,920,383 (the "'383 patent") and 9,775,953 (the "'953 patent," and together with the '383 patent, the "end-of-content patents"), and concern aspects of the pen injector device that patients use to self-administer Ozempic® via subcutaneous injection.

The '462 patent claims novel methods of treating type 2 diabetes with semaglutide, Ozempic®'s active ingredient. The patent's inventor discovered that administering 1.0 mg of semaglutide once weekly provided dramatic and unexpected improvements in controlling blood sugar.

Defendants dispute that the preamble of the '462 patent's claims—"a] method for treating type 2 diabetes"—is a limitation. Binding Federal Circuit precedent, however, dictates that preambles like this one, which identify the disorder to be treated by the claimed method, are limiting. Moreover, the preamble provides necessary antecedent basis for the later claim term "a subject in need thereof."

The parties also dispute how to construe the preamble of the '462 patent's claims. Novo Nordisk's construction matches the phrase's plain meaning and tracks the specification's definition of "treating," which should control the preamble's construction. Defendants' construction builds in limitations redundant of other claim terms and improperly limits "treating" to certain treatment outcomes, contrary to the patent's definition and the plain and ordinary meaning of the word.

The end-of-content patents are in the same family and use similar (often identical) terms to claim novel mechanisms that prevent patients from injecting themselves with incorrect doses of the medication, thus providing an important safety benefit. Defendants urge the Court to construe seven terms from the end-of-content patents, proposing constructions that are redundant of other claim terms and would improperly limit the scope to embodiments from the specification. By contrast, Novo Nordisk's constructions are consistent with the intrinsic evidence and the terms' plain and ordinary meanings. For these reasons and those given below, Novo Nordisk respectfully requests that the Court enter its proposed constructions of the disputed claim terms.

B. Novo Nordisk's Reply Position

Defendants fail to overcome the numerous reasons for construing the preamble of the claims in the '462 patent as limiting. They do not distinguish binding Federal Circuit precedent for construing a method of treatment preamble,

like the one in the '462 patent, as a limitation. Defendants also concede that the phrase “a subject in need thereof,” which is recited in the body of claim 1 of the '462 patent, requires an antecedent basis. They assert instead that the antecedent basis is found not in the preamble, but elsewhere in the claim. Defendants' arguments fail in light of the claim language as a whole and contrary case law.

Regarding the preamble's construction, Defendants do not dispute that in a patent specification the phrase, “as used herein,” generally signals a term's definition. They instead pursue a construction that limits “treating” to certain outcomes listed in the specification, without explaining the inclusion of some and omission of others. The Court should adopt Novo Nordisk's straightforward construction of the preamble, which is based on the '462 patent's definition of “treating.”

Defendants seek to construe the end-of-content patent terms by adding extraneous requirements to straightforward device elements. Not only are Defendants' constructions excessively complicated, but they import limitations from select embodiments and read out others entirely. Novo Nordisk's constructions, by contrast, draw on the intrinsic evidence in plainly understood language. The Court should adopt Novo Nordisk's proposed constructions.

II. AGREED UPON CONSTRUCTIONS

CLAIM TERMS AGREED UPON IN THE '833 PATENT		
Term or Phrase for Construction	Claim(s)	Agreed Upon Construction
“about”	1, 7, 16, and 22	When used in connection with pH, “[plus] or [minus] 0.1 pH units from [the stated number]”
“A method for reducing deposits on production equipment during production of a GLP-1 agonist formulation”	23	The phrase is an express limitation of claim 23 and it carries its plain and ordinary meaning.
“A method for reducing deposits in the final product during production of a GLP-1 agonist formulation”	26	The phrase is an express limitation of claim 26 and it carries its plain and ordinary meaning.
“A method for reducing the clogging of injection devices by a GLP-1 agonist formulation”	29	The phrase is an express limitation of claim 29 and it carries its plain and ordinary meaning.
“replacing the isotonicity agent previously utilized in said formulation with propylene glycol”	23, 26, and 29	“Having a first formulation that utilized an isotonicity agent other than propylene glycol and having a second formulation wherein the isotonicity agent used in the first formulation is substituted or replaced with propylene glycol”
“the isotonicity agent to be replaced by propylene glycol”	25, 28, and 31	“Having a first formulation that utilized an isotonicity agent other than propylene glycol and having a second formulation wherein the isotonicity agent used in the first

		formulation is substituted or replaced with propylene glycol”
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CLAIM TERMS AGREED UPON IN THE '383 PATENT		
Term or Phrase for Construction	Claim(s)	Agreed Upon Construction
“dose setting member”	1	Plain and ordinary meaning, which is “the member used to set the dose”
“medicament”	1	Plain and ordinary meaning, which is “medication”
“reservoir”	1	Plain and ordinary meaning, which is “a component that contains the medication, which component is included only once in the injection device”
“locking means”	3	Plain and ordinary meaning, which is “a mechanism for locking the piston rod against rotation in at least one direction”
“engaging surface”	5, 8, and 9	Plain and ordinary meaning, which is “a surface adapted to engage a corresponding surface”
“ratchet mechanism”	10	Plain and ordinary meaning, which is “a mechanism that allows linear or rotary motion in only one direction while preventing motion in the opposite direction”

CLAIM TERMS AGREED UPON IN THE '953 PATENT		
Term or Phrase for Construction	Claim(s)	Agreed Upon Construction
“longitudinal direction”	1	Plain and ordinary meaning, which is “running lengthwise”

“dose setting member”	1	Plain and ordinary meaning, which is “the member used to set the dose”
“medicament”	1	Plain and ordinary meaning, which is “medication”
“reservoir”	1	Plain and ordinary meaning, which is “a component that contains the medication, which component is included only once in the injection device”
“causes the piston rod to be displaced relative to the housing in a longitudinal direction”	1, 2, 7, and 17	Plain and ordinary meaning, which is “causes the piston rod to move, relative to the housing, in the longitudinal direction”
“engaging surface”	4, 7, and 17	Plain and ordinary meaning, which is “a surface adapted to engage a corresponding surface”
“ratchet mechanism”	8, 9, 19, 21, and 24	Plain and ordinary meaning, which is “a mechanism that allows linear or rotary motion in only one direction while preventing motion in the opposite direction”
“adapted to be locked”	9	Plain and ordinary meaning, which is “adapted such that movement can be restricted”

CLAIM TERMS AGREED UPON IN THE '343 PATENT		
Term or Phrase for Construction	Claim(s)	Agreed Upon Construction
“N-ε26-[2-(2-[2-(2-[2-(2-[4-(17-Carboxyheptadecanoylamino)-4(S)-carboxybutyrylamino]ethoxy)ethoxy]acetylamino)ethoxy]ethoxy) acetyl]”	4 and 5	Plain and ordinary meaning, which is “the compound corresponding to the chemical name N-ε26-[2-(2-[2-(2-[2-(2-[4-(17-Carboxyheptadecanoylamino)-4(S)-carboxybutyrylamino]ethoxy)ethoxy]acetylamino)ethoxy]ethoxy) acetyl]”

[Aib8,Arg34] GLP-1-(7-37) peptide”		ethoxy]ethoxy) acetyl] [Aib8,Arg34] GLP-1-(7-37) peptide, which is also called ‘semaglutide’”
The chemical structure identified in claims 1 and 2	1 and 2	Plain and ordinary meaning, which is “a compound corresponding to the claimed structure, which is also called ‘semaglutide’”

CLAIM TERMS AGREED UPON IN THE '462 PATENT		
Term or Phrase for Construction	Claim(s)	Agreed Upon Construction
“once weekly in an amount of 1.0 mg”	1	Plain and ordinary meaning, which is “one administration per week in an amount of 1.0 mg”
“solution”	3, 4, 5, 7, and 9	Plain and ordinary meaning which is “a solution comprising semaglutide”
“sodium dihydrogen phosphate”	8 and 9	Plain and ordinary meaning, which is “sodium dihydrogen phosphate, the molecular formula for which may be written as NaH ₂ PO ₄ ”

III. DISPUTED CONSTRUCTIONS

A. THE '462 PATENT

1. Novo Nordisk’s Opening Position on the Preamble

a. Introduction to the Patent

The invention of the '462 patent claims methods of using semaglutide as a therapeutic agent to treat diabetes. '462 patent, 2:51-52 (Ex. A at JA009). The inventor discovered novel “dosage regimes” for semaglutide that “provide improved

effect in diseases or conditions, such as . . . type 2 diabetes.” *Id.*, 2:52-55 (Ex. A at JA009). In particular, “the methods of the present invention . . . surprisingly showed improved reduction of HbA1c [i.e., blood sugar].” *Id.*, 2:56-58 (Ex. A at JA009). The specification describes methods for treating type 2 diabetes including relevant dosages, dosing frequencies, and treatment outcomes. *E.g., id.*, 2:51-3:28, 3:35-55, 16:56-17:3 (Ex. A at JA009-10, JA016-17).

The ’462 patent’s specification provides a detailed description of a clinical study conducted in 411 subjects with type 2 diabetes. *Id.*, 20:63-23:26 (Ex. A at JA018-20). The study compared treatment with once *weekly* dosages of semaglutide to once *daily* dosages of an older medication, liraglutide, across several metrics, including effectiveness in treating type 2 diabetes. *Id.*, 21:27-29 (Ex. A at JA019). The results were remarkable for semaglutide. For example, once weekly semaglutide doses of 0.8 mg and greater “appeared to bring *more* subjects to target” blood sugar levels than even the highest daily dose of liraglutide (1.8 mg). *Id.*, 23:21-23 (Ex. A at JA020) (emphasis added). These dramatic results are disclosed in the specification and led the USPTO to grant the ’462 patent.

b. “A Method for Treating Type 2 Diabetes”

Claim 1, the ’462 patent’s sole independent claim, recites: “A method for treating type 2 diabetes comprising administering semaglutide once weekly in an

amount of 1.0 mg to a subject in need thereof.” The parties dispute whether claim 1’s preamble is limiting, and if so, how it should be construed.

**(1) The Preamble Gives “Life, Meaning, and Vitality”
to the Claim and Therefore Is a Limitation**

The Federal Circuit has explained that a claim’s preamble is limiting if it is “necessary to give life, meaning, and vitality” to the claim. *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). Put another way, a preamble is limiting “if it recites not merely a context in which the invention may be used, but the essence of the invention without which performance of the recited steps is nothing but an academic exercise.” *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003).

The Federal Circuit has consistently construed preambles to method of treatment claims as limiting. *Eli Lilly & Co. v. Teva Pharms. Int’l GmbH*, 8 F.4th 1331, 1341-42 (Fed. Cir. 2021) (explaining that the Federal Circuit “has not hesitated to hold preambles limiting when they state an intended purpose for methods of using a compound”); *Boehringer*, 320 F.3d at 1345 (holding method of treatment claim preamble to be limiting); *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333 (Fed. Cir. 2003) (same); *see also Novartis Pharms. Corp. v. Accord Healthcare Inc.*, 387 F. Supp. 3d 429, 435-38 (D. Del. 2019) (holding three method of treatment claim preambles to be limiting). “[C]laims to methods of using . . .

compositions are not directed to what the method ‘is,’ but rather they typically rely entirely on what the method ‘does.’ And what a method does is usually recited in its preamble.” *Eli Lilly*, 8 F.4th at 1341.

The preamble of claim 1 of the ’462 patent is no exception. It establishes “what the method ‘does’” and its “purpose,” which is treating subjects who have type 2 diabetes. *See Eli Lilly*, 8 F.4th at 1341; *Boehringer*, 320 F.3d at 1345. The preamble does “not merely [offer] circumstances in which the method may be useful, but instead [is] the *raison d’être* of the claimed method itself,” and therefore must be a limitation. *Boehringer*, 320 F.3d at 1345. If it was not limiting, the claim would encompass the administration of semaglutide for any disorder, which is clearly not what the inventor intended.

(2) The Preamble Provides Antecedent Basis for “A Subject in Need Thereof” and Therefore Is a Limitation

“When limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention” and serve as a limitation. *Eaton Corp. v. Rockwell Int’l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003). Here, the body of claim 1 requires administration of semaglutide to “a subject in need thereof.” The claim’s preamble is necessary to define what the subject “needs,” which is treatment of type 2 diabetes. Thus, the preamble provides essential antecedent basis for a subsequent claim term

and must be a limitation. The Federal Circuit reached the same conclusion in *Jansen*, which also construed a method of treatment claim for a human “in need thereof.” In the *Jansen* case, the Federal Circuit held that “the claims’ recitation of a patient or a human ‘in need’ gives life and meaning to the preambles’ statement of purpose.” 342 F.3d at 1333; *see also Eli Lilly*, 8 F.4th at 1343 (construing preamble identifying disorder to be treated as limiting because it provided antecedent basis for the claim term “effective amount”); *Rapoport v. Dement*, 254 F.3d 1053, 1059 (Fed Cir. 2001) (“[W]ithout treating the phrase ‘treatment of sleep apneas’ as a claim limitation, the phrase ‘to a patient in need of such treatment’ would not have a proper antecedent basis.”) ; *see also Sanofi Mature IP v. Mylan Lab'ys Ltd.*, 757 F. App’x 988, 993 (Fed. Cir. 2019) (construing preamble identifying disorder to be treated as limiting under *Jansen* and *Rapoport* because it provided antecedent basis for “patient in need thereof”).

(3) The Specification Supports Construing the Preamble As Limiting

The Federal Circuit has held that intrinsic evidence informs the analysis of whether a preamble is limiting. *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1572-73 (Fed. Cir. 1996) (assessing whether preamble is limiting requires consideration of the claims, specification, and prosecution history). The specification of the '462 patent discusses the use of GLP-1 agonists such as semaglutide to treat various conditions, including type 2 diabetes specifically. '462 patent, 1:31-33, 2:51-55 (Ex. A at JA009). Moreover, as explained above, the patent describes in detail a clinical study demonstrating semaglutide's efficacy in treating diabetes (among other things). *See id.*, 20:63-23:26 (Ex. A at JA018-20). If a specification discloses a specific method of treatment and the claim preamble recites that method, the preamble should be limiting.

As expressed above, Federal Circuit precedent supports construing the preamble of method of treatment claims in pharmaceutical patents as limiting. *E.g.*, *Eli Lilly*, 8 F.4th at 1341-42; *Boehringer*, 320 F.3d at 1345. In the case of the '462 patent, this construction is necessary to define the purpose of the claimed method and provide necessary antecedent basis for terms in the body of the claim. Therefore,

the Court should accept Novo Nordisk's construction, and construe claim 1 to be limited to a method of treating type 2 diabetes.

(4) The Preamble Should Be Construed According to the Definition Provided in the Specification

Claim 1's preamble requires "treating type 2 diabetes." The patent states that "the term 'treatment' or 'treating' *as used herein* means the management and care of a patient for the purpose of combating a condition, such as a disease or a disorder." '462 patent, 5:16-19 (Ex. A at JA011) (emphasis added). This sentence thus defines "treating" in the '462 patent through its use of the phrase "as used herein means." *Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1210 (Fed. Cir. 2007) (holding "as used herein, means" unambiguously provides a definition); *Intercept Pharms., Inc. v. Apotex Inc.*, C.A. No. 20-1105, 2022 WL 856859, at *3 (D. Del. Mar. 23, 2022) ("[T]he phrase 'as used herein' has been recognized as definitional in a wide host of Federal Circuit and district court cases."). Novo Nordisk's construction—"a method of caring for or managing the care of a patient so as to combat type 2 diabetes"—matches the patent's definition.

Defendants propose that "a method of treating type 2 diabetes" means "administering semaglutide to alleviate the symptoms and complications, and/or to cure or eliminate or prevent, and/or to prevent the onset of symptoms associated with type 2 diabetes." This construction violates one of the canons of claim construction

by improperly limiting the scope of the claim to certain cherry-picked embodiments.

In re Katz Interactive Call Processing Pat. Litig., 639 F.3d 1303, 1323-24 (Fed. Cir. 2011) (holding it was “erroneous [to] limit the proper scope of the claims by importing limitations from a single embodiment.”).

The specification clearly states:

In one embodiment the term ‘treatment’ or ‘treating’ is intended to include the full spectrum of treatments for a given condition, such as administration of the active compound to alleviate the symptoms or complications; to delay the progression of the disease, disorder, or condition; to alleviate or relieve the symptoms and complications; and/or, to cure or eliminate the disease, disorder, or condition as well as to prevent the condition. In one embodiment prevention is to be understood as the management and care of a patient for the purpose of combating the disease, condition, or disorder and includes the administration of the active compounds to prevent the onset of the symptoms or complications.

’462 patent, 5:19-27 (Ex. A at JA011) (emphasis added). Defendants’ construction would improperly limit “treating” to a selection of examples listed in this embodiment. Ignoring the patent’s definition of treatment and importing select limitations from one embodiment is inconsistent with precedent established by this Court and the Federal Circuit. *In re Katz*, 639 F.3d at 1323-24; *Bioverativ Inc. v. CSL Behring LLC*, C.A. No. 1:17-cv-00914-RGA, 2019 WL 1276030, at *8 (D. Del. Mar. 20, 2019) (construing “administering” consistent with the specification’s definition, preceded by “as used herein, means . . . ,” and rejecting construction that built in preferred routes of administration recited in the specification, which were

“clearly exemplary, rather than definitional”).

2. Defendants’ Answering Position on the Preamble

a. ’462 Patent: “A Method for Treating Type 2 Diabetes”

Independent claim 1 of the asserted method of treatment patent recites:

A method for treating type 2 diabetes, comprising
administering semaglutide once weekly in an amount of
1.0 mg to a subject in need thereof.

’462 patent at 35:42-44 (JA026). Example 1 of the ’462 patent describes a 12-week study of once-weekly doses of semaglutide compared to placebo and once-daily liraglutide. *Id.* 20:55-23:26 (JA018-020). The specification does not describe administration of a 1.0 mg weekly dose of semaglutide. *Id.* It concludes that “semaglutide dose-dependently reduced HbA1c and body weight,” and that “[t]he effect of semaglutide 0.4 mg on glycaemic control and body weight was comparable to that of liraglutide 1.2 mg, while semaglutide ≥ 0.8 mg appeared to bring more subjects to target and provided better weight loss than liraglutide 1.8 mg.” *Id.* 23:18-23 (JA020). Another section titled “Pharmacological Methods,” describes prophetic assays, but without any results. *Id.* 23:26-28:36 (JA020-022).

(1) The preamble is a statement of intended result

The preamble here gives no “life, meaning, and vitality” to the claim.. Instead, it describes only the “purpose or intended use for the invention.” *Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (citation

omitted). The Federal Circuit’s decision in *Bristol-Myers Squibb Co. v. Ben Venue Lab’s, Inc.*, 246 F.3d 1368 (Fed. Cir. 2001), is instructive. In *BMS*, the asserted patents were directed towards methods of treatment, with preambles that recited a “method for reducing ... toxicity” and a “method for treating a cancer patient.” *Id.* at 1371-72. As the court noted, the claims recited specific dosing limitations. *Id.* The Federal Circuit also stated that “Bristol would have us construe the claims as limited to those instances of practicing the claimed method that achieve the stated result for purposes of validity, but as encompassing all instances of carrying out the physical steps for purposes of infringement” and concluded “Bristol cannot have it both ways.” *Id.* 1376.

Like in *BMS*, the claims here recite a specific dose—1.0 mg weekly—that is administered regardless of outcome. Thus, the preamble simply states the *intended* effect. Moreover, Plaintiffs seek to impose an “efficacy requirement” for purposes of validity without offering the same for infringement. In their validity contentions, Plaintiffs argue the prior art did not disclose “the specific, *efficacious* method of treatment ... that is claimed in the ’462 patent.” EX1 at 199-200, 203-204 (JA258-261). Conversely, Plaintiffs cite only the use indication and Plaintiffs’ clinical data that the FDA requires Defendants to put on their label to support infringement. *See, e.g.*, EX2 at 9-10, Ex. A at 1 (JA262-269); *see also* EX3 at SEMAJDG_0003082 (JA271). Plaintiffs cannot have it both ways. *BMS*, 246 F.3d at 1375-76.

And while Plaintiffs argue that “[t]he Federal Circuit has consistently construed preambles to method of treatment claims as limiting,” Novo Nordisk’s Opening Position at 8-9, there is no applicable bright-line rule. Indeed, Plaintiffs’ cases are inapposite. First, *Boehringer* analyzed a “method of growing and isolating” a virus; not a method of treatment. *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1344-45 (Fed. Cir. 2003). Regardless, the court held that without the preamble the steps performed were an “academic exercise.” *Id.* 1345. Here, the steps of the claims require administering a specific amount of semaglutide to a subject in need of such administration, which is hardly “academic.”

Jansen v. Rexall Sundown, Inc., similarly does not apply here because in that case the claims were allowed only “after almost twenty years of repeatedly unsuccessful attempts to gain allowance of claims without” the “treating or preventing” limitations. 342 F.3d 1329, 1333-34 (Fed. Cir. 2003). Here, there is no comparable prosecution history.

Plaintiffs’ third case, *Eli Lilly & Co. v. Teva Pharma. Int’l GmbH*, is likewise distinguishable. There, the court found it significant that the claimed method step recited administration of an “effective amount,” and stated the preamble was “the only metric by which one practicing the claim could determine whether the amount administered is an ‘effective amount.’” 8 F.4th 1331, 1340-43 (Fed. Cir. 2021).

Here, however, the claims specifically recite a specific dosing regimen, and nothing about efficacy. '462 patent at 35:42-44 (JA026).

In Plaintiffs last case, *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, the Court, construed the preambles as limitations where the scopes of three claims were identical, but for the preamble. 387 F.Supp.3d 429, 437-38 (D. Del. 2019).¹ Again, this is not the case here.

(2) Plaintiffs' "antecedent basis" and specification arguments also fail

(a) The claim body provides all the context needed

Plaintiffs' argument that including the phrase "in need thereof" converts the full preamble into a claim limitation should be rejected. Novo Nordisk's Opening Position at 10-11. Here, the language following the preamble—"administering"—provides an antecedent basis. Indeed, the claim can be understood to require administering the claimed dose without the preamble.

Plaintiffs' cases are, again, inapposite. As above, the *Eli Lilly* and *Jansen* cases are distinguishable. Moreover, in *Rapoport*, unlike here, there was no dispute that the preamble was limiting. *Rapoport v. Dement*, 254 F.3d 1053, 1059 (Fed. Cir.

¹ In finding the preamble limiting, the court nevertheless stated that the method did not include an efficacy requirement because the claim did not recite it.

2001). And in *Sanofi*, the Court reviewed claims directed towards “methods of survival” and found the specification emphasized “increasing survival.” *Sanofi Mature IP v. Mylan Lab’ys Ltd.*, 757 F. App’x 988, 992-93 (Fed. Cir. 2019). Conversely, while the specification provides clinical data related to treating type 2 diabetes, it puts no emphasis on the claimed dose of 1.0 mg; in fact, the clinical trial discussed does not even mention it. ’462 patent at 20:63-23:26 (JA018-020). Finally, Plaintiffs’ passing reference to *Eaton* is unavailing. In *Eaton*, the Court considered claims reciting a driveline system with method steps requiring “the manipulation of particular structures that are identified and described only by the preamble.” *Eaton Corp. v. Rockwell Int’l Corp.*, 323 F.3d 1332, 1340 (Fed. Cir. 2003). That has no relevance because here the action (administering) and the object (a subject in need) are both in the body of the claim. Thus, Plaintiffs’ antecedent basis argument fails.

(b) Any need for antecedent basis does not convert the full preamble into a claim limitation nor impart efficacy

Even if the Court finds the phrase “in need thereof” requires an antecedent basis, that is not cause to add an “efficacy” limitation. In their argument Plaintiffs stated the preamble defines “what the subject ‘needs,’ which is treatment of type 2 diabetes.” Novo Nordisk’s Opening Position at 10. But that is no reason to add an efficacy requirement to claims that fail to recite any version of the word “efficacy,” let alone any specified result or endpoint. ’462 patent at 35:40-36:53 (JA026).

Indeed, had Plaintiffs wanted the claims to recite an efficacy requirement, they could have done so, as they have, in other patents. *See, e.g.*, EX4 (US9,968,659) at claim 1 (JA299); *see also* EX5 (US11,278,596) at claim 1 (JA323).

Moreover, the *Novartis* case cited by Plaintiffs supports a lack of efficacy in the claims in the event an “antecedent basis” is deemed necessary. *Novartis*, 387 F.Supp.3d at 437-38. There, the Court found that certain method of treatment preambles were limiting regarding which patients could be administered treatment. *Id.* Regardless, the Court rejected Novartis’s argument that the claims “require an actual effect” because nothing in the intrinsic record warranted “reading into the claims an efficacy limitation,” and “[w]hile the general purpose of the invention is to achieve a safe and effective manner of treating MS, such efficacy is *not a limitation of the claims.*” *Id.* Here, even if the preamble is deemed limiting to provide an “antecedent basis,” the preamble certainly does not require efficacy. *Id.* at 436; *Novartis Pharms. Corp. v. Actavis, Inc.*, 2013 WL 6142747, *9-11 (D. Del. Nov. 21, 2013) (not incorporating an efficacy limitation, and noting that “treating” is an attempt to cause an outcome, “without necessarily having assurance of what the outcome will be”); *Bristol-Myers Squibb Co. v. Merck & Co., Inc.*, 2016 WL 11711498, *1 n.1 (D. Del. June 6, 2016) (same).

(c) Plaintiffs’ specification argument fails

The Court should also reject Plaintiffs’ specification argument. Novo

Nordisk’s Opening Position at 12-13. Plaintiffs rely on the ’462 patent’s discussion of the treatment of type 2 diabetes, and the clinical trial allegedly demonstrating “efficacy in treating diabetes (among other things).” *Id.* However, the clinical trial does not include administering 1.0 mg of semaglutide as in the claims. Moreover, Plaintiffs are careful to state that semaglutide is disclosed as treating “*various conditions*, including type 2 diabetes” and allegedly demonstrating efficacy in “treating diabetes (*among other things*).” *Id.* at 12 (emphasis added). Given Plaintiffs’ own broad reading of the patent as disclosing the treatment of “various” conditions, their request to limit the claims based on the specification rings hollow. Indeed, the specification fails to convert the preamble into a claim limitation. *Catalina*, 289 F.3d at 808.

(3) If the entire preamble is a limitation, Defendants’ definition is correct based on the specification

If the Court finds the entire preamble is limiting and further adds an otherwise unclaimed result, Defendants’ proposed definition more accurately comports with the specification. Plaintiffs insist that Defendants’ definition improperly limits the scope of the claims to an embodiment, ignoring that their construction is more severely flawed.

First, despite Plaintiffs asserting that their definition is *the* definition in the specification, and Defendants’ is limited to an embodiment, Plaintiffs fail to

accurately quote the portion of the specification on which they rely. In particular, the specification states that “[i]n one embodiment the term ‘treatment’ or ‘treating’ as used herein means the management and care of a patient.” ’462 patent at 5:16-17 (JA011). Plaintiffs’ reliance on the phrase “as used herein” ignores that the sentence they quote starts with “in one embodiment.” *Id.* So Plaintiffs’ proposal is not *the* definition of the term; it is an embodiment.

Second, Defendants’ construction is supported by the specification. The specification repeatedly mentions reducing HbA_{1c} and the data relates to changed symptoms, namely HbA_{1c} and body weight, after administering semaglutide. *See e.g.*, ’462 patent *generally*, 23:17-23 (JA020). In contrast, it is unclear what “management and care” of patients would entail. Plaintiffs’ definition leaves to the imagination what aspects of “treatment” remain uncaptured by Defendants’ definition. *See, e.g., Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, No. 07-1299, 2009 WL 44745, at *3 (D.N.J. Jan. 5, 2009) (rejecting constructions that “diffuse the particularity or blur the distinctness of that language”). In sum, Defendants’ definition is supported by the specification and provides more clarity.

3. Novo Nordisk's Reply Position on the Preamble

a. "A Method for Treating Type 2 Diabetes"

(1) Contrary to Defendants' Argument, the Preamble Is Far More Than a Statement of Intended Result

Defendants argue that "a method of treating type 2 diabetes" should not be construed as a limitation because it is merely a statement of "purpose or intended use for the invention." Defendants' Answering Position at 15. In support of this position, and against the weight of contrary authority, Defendants identify only one case, *Bristol-Myers Squibb Co. v. Ben Venue Lab'ys, Inc.*, 246 F.3d 1368 (Fed. Cir. 2001), with very different facts. Defendants focus on the *BMS* court's construction of two preambles as non-limiting: "[a] method for reducing hematologic toxicity" and "[a] method for treating a cancer patient to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity." *BMS*, 246 F.3d at 1371-72. Defendants analogize the *BMS* claims to the '462 patent claims by arguing that the claims "recited specific dosing limitations." Defendants' Answering Position at 16. The similarities end there.

The bodies of the claims in *BMS* provided context by reciting a purpose for the drugs administered in the claimed methods (*e.g.*, "an *antineoplastically* effective amount," which indicates the drug is used to treat cancer, and "a medicament that *reduces or eliminates hypersensitivity reactions*") (emphases added). The *BMS*

claims did not rely on their preambles to provide this context, as is the case with the '462 patent. Accordingly, the *BMS* court did not find the preambles at issue necessary to give “life, meaning and vitality,” to the claims but rather “merely expressing a purpose.” *Id.* at 1375. In fact, as to “[a] method for reducing hematologic toxicity,” the *BMS* court found that “the language of the claim itself strongly suggests the independence of the preamble from the body of the claim.” *Id.* at 1375.

The opposite is true concerning the '462 patent's preamble, which is the *only* part of the claim that establishes the heart of the claimed invention, i.e., treating diabetes. See Novo Nordisk's Opening Position at 9-10. The body of the '462 patent claims does not hint at any reason for the subject's need for administration of 1.0 mg of semaglutide, relying instead on the preamble for this detail. Accordingly, the preamble should be construed as a limitation because it establishes “what the method ‘does,’” without which the claim would encompass administration of semaglutide for any disorder. See *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1341-42 (Fed. Cir. 2021).

BMS is further distinguishable because the plaintiff in *BMS* asked the court to “construe the claims as limited to those instances of practicing the claimed method that achieve the stated result.” *BMS*, 246 F.3d at 1376. To the contrary, Novo Nordisk's proposed construction, “a method of caring for or managing the care of a

patient so as to combat type 2 diabetes” does not include an efficacy *requirement* as Defendants incorrectly argue. See Novo Nordisk’s Opening Position at 13-14; Defendants’ Answering Position at 16. Nevertheless, the specification discloses results from a clinical study of 411 subjects that demonstrates the effectiveness of once weekly semaglutide doses of 0.8 mg and greater to treat type 2 diabetes. ’462 patent, 21:20-22, 23:21-23 (Ex. A at JA019-20). A successful outcome for every patient who receives the treatment, however, is not required to care for a patient so as to combat type 2 diabetes through administration of 1.0 mg semaglutide. See *Novartis Pharms. Corp. v. Accord Healthcare Inc.*, 387 F. Supp. 3d 429, 436, 438 (D. Del. 2019) (“While the general purpose of the invention is to achieve a safe and effective manner of treating MS, such efficacy is not a limitation of the claims.”).

Defendants fail to meaningfully distinguish any of Novo Nordisk’s Federal Circuit authority for construing the preamble as a limitation. Defendants’ Answering Position at 17-18. Defendants attempt to distinguish *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329 (Fed. Cir. 2003) based on its consideration of the prosecution history, but there the limiting construction was “*bolstered* by an analysis of the prosecution history,” (emphasis added), only *after* the Federal Circuit’s thorough analysis of the claim language “compel[led]” a limiting construction. *Id.* at 1333.

Defendants attempt to distinguish *Eli Lilly* because the claimed method there recited an “effective amount,” and the claims of the ’462 patent do not. That claim language, however, was only “further support” contributing to the limiting construction, *in addition to* the preamble “embody[ing] the essence of the claimed invention,” “stat[ing] the intentional purpose for which the methods must be performed,” and “provid[ing] antecedent basis” for a later claim term. *Eli Lilly*, 8 F.4th at 1342-43. The Federal Circuit clarified in *Eli Lilly* that for claims to “methods of using a composition for a specific purpose”—like the claims at issue here—the Court has “generally construed statements of intended purpose in such method claims as limiting.” *Id.* at 1340.

Finally, Defendants attempt to distinguish *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339 (Fed. Cir. 2003) for involving a method of “growing and isolating” a virus rather than a method of treatment. The Federal Circuit and this District, however, have found *Boehringer* instructive in construing method of treatment preambles like the one here, suggesting Defendants’ distinction is one of no consequence. *See Eli Lilly*, 8 F.4th at 1341-42 (citing *Boehringer*); *Forest Lab’s., LLC v. Apotex Corp.*, 2016 WL 6645784, at *1 n.5 (D. Del. Nov. 8, 2016) (same).

**(2) The Body of Claim 1 Lacks the Necessary
Antecedent Basis for “A Subject in Need
Thereof”**

The body of claim 1 recites administration of semaglutide to “a subject in need thereof.” Only the claim’s preamble identifies what the subject needs (i.e., treatment of type 2 diabetes), thereby providing the necessary antecedent basis for this phrase in the body of the claim. In method of treatment claims, where the preamble provides necessary antecedent basis for a later claim term, the preamble should be treated as a limitation. *Sanofi Mature IP v. Mylan Lab’ys. Ltd.*, 757 F. App’x 988, 992-93 (Fed. Cir. 2019).

Apparently conceding that “a subject in need thereof” requires antecedent basis, Defendants identify the term “administering” in the body of the claim as providing that antecedent basis. Defendants’ Answering Position at 18. Defendants misunderstand the antecedent basis analysis. The relevant inquiry is “what is the subject in need of?” The answer—treatment of type 2 diabetes—is found only in the preamble. Similarly, in *Rapoport*, the preamble that recited “treatment of sleep apneas”—and not the term “administration,” recited in the claim body—provided antecedent basis to “a patient in need of such treatment.” *See Rapoport v. Dement*, 254 F.3d 1053, 1055-56, 1059 (Fed. Cir. 2001).

Novo Nordisk identified four instructive cases in which antecedent basis supported a limiting construction for a preamble to a method of treatment claim.

Novo Nordisk's Opening Position at 11-12. Defendants present no convincing counterargument or case law to the contrary. Defendants' Answering Position at 18-20. First, Defendants simply state in one sentence that *Eli Lilly and Jansen* are "distinguishable" on this point but fail to provide any reason why. Defendants' Answering Position at 18-19. Defendants next discount *Rapoport* because the parties had agreed that the preamble was limiting. This alleged distinction ignores that the Court independently emphasized that the preamble was limiting because "without treating the phrase 'treatment of sleep apneas' as a claim limitation, the phrase 'to a patient in need of such treatment' would not have a proper antecedent basis." *Id.* at 1059. Finally, unable to distinguish *Sanofi* on its antecedent basis holding, Defendants ignore it, and instead argue that the specification there "emphasized" the subject of the preamble. Defendants' Answering Position at 19. As described in Novo Nordisk's Opening Position and below, the same is true of the '462 patent.

(3) The Focus of the Specification Supports Construing the Preamble as a Limitation

The specification of the '462 patent emphasizes treating type 2 diabetes and reducing body weight and is replete with references to each. *See, e.g.*, '462 patent, 1:31-36, 1:45-50; 1:56-62; 2:51-5; 2:63-66; 3:4-5; 3:19-28; 6:5-9; 6:17-19; 16:58-60; 16:65-66; 23:18-23 (Ex. A at JA009-11, JA016, JA020). When a

specification emphasizes a specific method of treatment and the claim preamble recites that method, Federal Circuit precedent instructs that the preamble should be limiting. *Eli Lilly*, 8 F.4th at 1341-42.

While the specification focuses on two conditions, the claims of the '462 patent are directed only to type 2 diabetes. A patent in the same family with a common specification, U.S. Patent No. 9,764,003 (the "'003 patent") (Exhibit F), claims "method[s] for reducing body weight" that have dosage ranges that include 1.0 mg of semaglutide once weekly. '003 patent, 35:29-36:37 (Ex. F at JA094). If the preamble of the '462 patent is not construed as a limitation, its claims would read on any administration of 1.0 mg of semaglutide once weekly, including on a method for reducing body weight. The specification's dual emphasis on type 2 diabetes and reduction in body weight, and the existence of the '003 patent, offer additional reason why the preamble of the '462 patent claims—the *only* part of the claim that specifies which condition is being treated by the claimed method—must be construed as a limitation. *See Eli Lilly*, 8 F.4th at 1342 ("[t]he preambles limit the scope of the claims because these claims would not read on, for example, the performance of the same method step to treat other conditions.").

(4) Defendants Cannot Refute that "As Used Herein" Signifies a Definition, But Nonetheless Persist with Their Arbitrary Construction

Since service of Novo Nordisk's Opening Position, a Defendant in this case,

Mylan Pharmaceuticals Inc. (“Mylan”), filed a petition for *inter partes* review of the ’462 patent, in which Mylan took a different position on construction of the preamble than Defendants take here. According to Mylan, “the plain and ordinary meaning of ‘[a] method for treating type 2 diabetes’ would be understood by POSAs to broadly encompass administering semaglutide to alleviate or reduce symptoms and complications associated with type 2 diabetes or otherwise manage the disease.” *Mylan Pharms. Inc. v. Novo Nordisk A/S*, Case No. IPR2023-00724, Paper 1, 14-15 (PTAB March 16, 2023). Mylan’s new position combines elements of Plaintiffs’ and Defendants’ proposed constructions and, at a minimum, undercuts Defendants’ proposed construction here by highlighting its arbitrary nature.²

Additionally, Defendants cannot refute Plaintiffs’ authority holding that “as used herein” signifies a definition. See Novo Nordisk’s Opening Position at 13-14. Instead, Defendants discount the definitional statement for “treating” because of the phrase “in one embodiment” that precedes it. Defendants’ Answering Position at 21-22. However, the use of “in one embodiment” is unremarkable here given that at least 64 paragraphs in the specification begin with the phrase, including each of the nine paragraphs that provide a definition. In each instance, the specification

² Notably, Mylan does not suggest in its IPR petition that the preamble is not limiting.

states: “[i]n one embodiment the term ‘[defined term]’ as used herein,” followed by a definitional statement. *See, e.g.*, ’462 patent at 4:62-5:49; 15:13-14 (Ex. A at JA010-11, JA016) (defining “amount equivalent to,” “effective amount,” “‘treatment’ or ‘treating,’” “hydrophilic spacer,” “analogue,” “GLP-1 peptide,” “exendin-4 peptide,” “DPP-IV protected,” and “Aib”). Contrary to Defendants’ argument, the consistent use of “in one embodiment” does not change the definitional status of “as used herein.”

Defendants feign ignorance concerning which “aspects of ‘treatment’ remain uncaptured” by their proposed construction. Defendants’ Answering Position at 22. The specification quoted in Novo Nordisk’s Opening Position, however, makes abundantly clear that Defendants’ construction omits at least “delay[ing] the progression” and “reliev[ing] the symptoms and complications.” *See* Novo Nordisk’s Opening Position at 13-14, citing ’462 patent, 5:19-27 (Ex. A at JA011). By omitting these “aspects of ‘treatment,’” Defendants have arbitrarily selected examples from the specification, which is improper. *In re Katz Interactive Call Processing Pat. Litig.*, 639 F.3d 1303, 1323-24 (Fed. Cir. 2011).

Finally, Plaintiffs’ proposed construction is clearly understood in view of the intrinsic evidence, contrary to Defendants’ argument. *See* Defendants’ Answering Position at 21-22. *Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 2009 WL 44745 (D.N.J. Jan. 5, 2009), which Defendants cite in support, is inapposite. In *Tyco*, the

court declined to construe “consisting essentially of,” in a way that would broaden the “meaningfully precise” numerical limitation recited in the claim. *Id.* at *3. Novo Nordisk does not propose a broadening construction of a numerical limitation. Rather, Novo Nordisk proposes a straightforward construction for the preamble based on the definition of “treating,” identified by “as used herein,” which the Court should adopt as the term’s construction.

4. Defendants’ Sur-Reply Position on the Preamble

a. The Preamble is Not a Limitation

Plaintiffs’ attempt to distinguish *BMS* fails. Novo Nordisk’s Reply Position at 22-24. The claims are not so different. Plaintiffs hang their hat on the *BMS* claim body limitation “an antineoplastically effective amount.” *Id.* However, the court found the phrase an intended result. *Bristol-Myers Squibb Co. v. Ben Venue Lab’ys., Inc.*, 246 F.3d 1368, 1375 (Fed. Cir. 2001). Plaintiffs’ distinction is thus without practical difference.

As to antecedent basis—Defendants do not “misunderstand.” Novo Nordisk’s Reply Position at 26-27. *If* the Court deems an antecedent basis necessary, the phrase “administration” provides it. A patient may need “administration” of the claimed dosage amount for the *intended purpose*. In any event, antecedent basis issues are not always cause to convert intended results into limitations. *Civix-DDI*,

LLC v. Cellco P'ship, 387 F.Supp.2d 869, 890 (N.D. Ill. 2005) (antecedent basis issue “not dispositive”).

And as to the specification, its discussion of treating type-2 diabetes and reducing body weight reinforces the purpose of the claimed doses. Moreover, Plaintiffs’ ’003 patent argument fails. Claim 1 of the ’003 patent has different limitations—reciting the purpose of “reducing body weight” in its preamble. Claim 1 also recites administering semaglutide in “an amount of at least 0.7 mg and up to 1.6 mg” and “without another therapeutic agent.” Both the dose amount and the “without another therapeutic agent” element distinguish the two patents’ claims. The ’003 preamble is thus not cause for the preamble to be a limitation here.

b. The Preamble Imparts No Efficacy Requirement

Plaintiffs admit that even if the preamble is a limitation, it imparts no efficacy requirement. Plaintiffs offer no response to Defendants’ Section III.A.2.(2)(b), and state “Novo Nordisk’s proposed construction [for the preamble] does not include an efficacy *requirement*.” Novo Nordisk’s Reply Position at 24. Plaintiffs also embrace the holding in *Novartis* that efficacy is not a limitation of claims reciting the general purpose of achieving treatment. *Id.* Given this, to the extent the Court finds the preamble limiting, it should confirm that the claims do not require efficacy.

c. Plaintiffs’ “Antecedent Basis” and Specification Argument Also Fail

Plaintiffs rely on the language “as used herein” but ignore the rest of the paragraph, including that their alleged “definition” is a single embodiment. ’462 patent at 5:16-17 (JA011). Moreover, Plaintiffs criticize Defendants’ definition as omitting “delay[ing] the progression” and “relieving the symptoms and complications.” Novo Nordisk’s Reply Position at 25, 31. Yet Defendants’ construction recites “alleviating symptoms and complications,” and “to cure or eliminate or prevent, and/or to prevent the onset of symptoms.” Plaintiffs’ concern is thus unclear. Finally, Plaintiffs’ mention of MPI’s IPR is irrelevant—it is a different proceeding, and not even Plaintiffs suggest any positions are inconsistent.

B. THE ’383 AND ’953 PATENTS

1. Introduction to the Patents

a. Novo Nordisk’s Opening Position

Ozempic® is an injectable solution that patients self-administer using Novo Nordisk’s FlexTouch® pen injector device. Self-administration is a critical aspect of modern diabetes care because it allows patients to independently control their blood sugar. To ensure the devices are safe for self-administration, device designers incorporate safety mechanisms into their injection pens, such as the “end-of-content” mechanism of the ’383 and ’953 patents.

The basic steps of self-administration begin with the patient selecting the desired dose using a dose setting wheel on the exterior of the device, seen below on the FlexTouch®.



After setting the dose, the patient injects by pressing the grey button at the top of the device.

The end-of-content patents describe a safety mechanism that prevents the patient from setting a dose that exceeds the amount of medicine remaining in the device. Without such a mechanism, the patient could set a dose for 2 mg of medicine when only 1 mg remains in the device, resulting in the patient unknowingly taking an insufficient dose of the medication. *See* '383 patent, 1:28-32 (Ex. B at JA037).

The end-of-content patents integrate three key pen components—the driver, limiter, and piston rod—together in a novel, “nested” design. Nesting the components permits an efficient, compact design, in contrast to prior dose-limiting

mechanisms, which placed the limiter outside the driver and sometimes outside the pen itself. *See id.*, 1:21-24 (Ex. B at JA037). The patents illustrate this nesting structure in Figures 5 and 6 below, with the driver (green) on the outside, the limiter (yellow) inside the driver, and the piston rod (blue) inside the limiter:

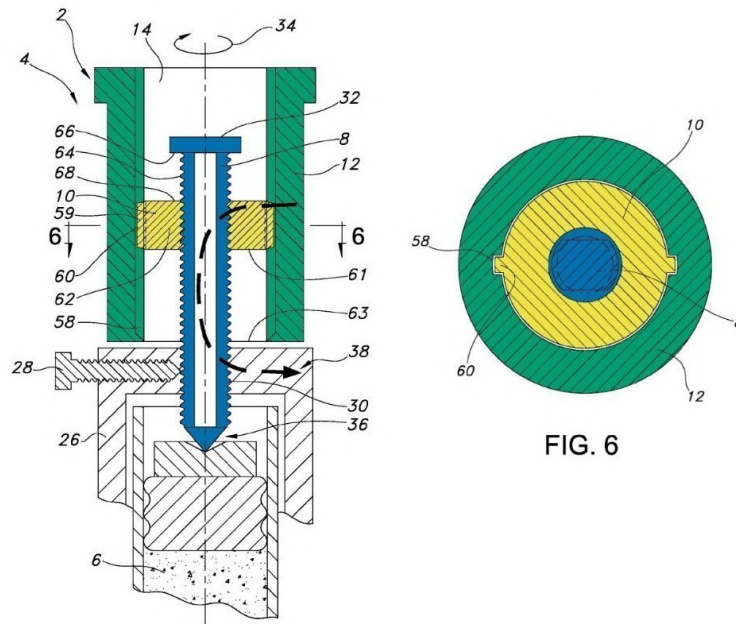


FIG. 5

FIG. 6

When the patient sets a dose, the piston rod remains static, but the driver rotates in an amount commensurate with the size of the dose. *Id.*, 5:7-10 (Ex. B at JA039). The limiter, interposed between the other two parts, either (depending on the embodiment): (1) rotates with the driver while the piston rod remains fixed; or (2) remains fixed with the piston rod while the driver rotates. In either case, the

limiter moves closer to a “stopping position” with each dose that the patient sets. For example, in Figure 5 (reproduced above), the stopping position is the “head” of the piston rod (blue) and the limiter (yellow) moves upward in the figure.

The limiter’s cumulative movement over the course of multiple doses correlates to the decreasing amount of medicine in the pen. When the limiter hits the stopping position, insufficient medicine remains to satisfy the dose the patient attempts to set. Because the limiter has hit the stopping position, the driver cannot rotate, and therefore the patient cannot set a dose.

b. Defendants’ Answering Position

The ’383 and ’953 patents (“the Device Patents”) involve an injection pen device utilizing a torsional pen design. Leinsing Decl. ¶15 (JA493-494). The Device Patents describe two embodiments having “[e]nd-of-content mechanisms” that “ensure that [a dose] does not exceed the remaining amount of medication in a reservoir in a syringe device.” ’383 patent at 1:32-57³ (JA037); Leinsing Decl. ¶15 (JA493-494).

³ The Device Patents share a common specification. Defendants cite the ’383 patent unless noted.

2. “Limiter” and “Driver”

a. Novo Nordisk’s Opening Position

Both end-of-content patents use the claim terms “limiter” and “driver.” The parties disagree as to whether they are means-plus-function limitations under 35 U.S.C. § 112, ¶ 6 and how they should be construed.

(1) “Limiter” Should Be Given Its Plain and Ordinary Meaning

The term “limiter,” if construed, should receive its plain and ordinary meaning. The patents provide no definition for “limiter.” However, the term “limiter” has a plain English meaning that is no different to a person of ordinary skill in mechanical engineering: a component or mechanism with a limiting purpose.⁴

Moreover, the patents clearly convey the essential function of the limiter (to limit the rotation of the driver when a patient attempts to set a dose greater than the amount of medicament remaining in the device) and the claims provide structural requirements, such that the term “limiter” need not be re-written to interpose structure. *See infra* § III.B.2.a.(3). This is consistent with the term’s plain English meaning. Accordingly, Novo Nordisk’s proposed construction is: “a component or

⁴ See, e.g., Collins Dictionary, Definition of “Limiter,” available at <https://www.collinsdictionary.com/us/dictionary/english/limiter> (defining “limiter” as “a person or thing that limits”) (Ex. D at JA059).

mechanism with a limiting purpose.”

Defendants contend that “limiter” means “a toroid component that is axially movable within a space defined by the walls of a driver and has (i) a single continuous thread from one axial end to the other and (ii) a spline.” First, the term “toroid” appears nowhere in the end-of-content patents; it is a narrowing construct invented by Defendants. Second, while the patents describe threading, they do not insist that the limiter have it, let alone “a single continuous thread from one axial end to the other.” Third, the patents describe embodiments without the “spline” that Defendants would require—for example, the limiter illustrated in Figure 3 has a threaded exterior (engaging with the driver) and a spline-free interior. See ’383 patent, col.6 lines 14-18 (Ex. B at JA039) (describing this approach); *Nobel Biocare Servs. AG v. Intradent USA, Inc.*, 903 F.3d 1365, 1381 (Fed. Cir. 2018) (“We have cautioned against interpreting a claim term in a way that excludes disclosed embodiments.”). Ultimately, Defendants’ proposal constitutes the “cardinal sin” of improper claim construction as it attempts to limit the term to certain embodiments from the specification. *Phillips*, 415 F.3d at 1320.

(2) “Driver” Should Be Given Its Plain and Ordinary Meaning

Like “limiter,” if the term “driver” is construed, it should be given its plain and ordinary meaning, which is “a component which causes movement of another

component.”⁵ While the patents provide no definition for “driver,” they clearly convey its essential function: to cause the piston rod to move. *See, e.g.*, ’383 patent, col.9 lines 34-42 (Ex. B at JA041). And, as with “limiter,” other claim terms describe the structure for the “driver” (*see, infra*, § III.B.2.a.(3) (explaining why “driver” is not a means-plus-function term)) and there is no reason to write in structure, as Defendants propose. The function of the “driver” in the patent is consistent with the term’s plain meaning, and the term should be construed accordingly.

Defendants propose that “driver” means: “a component having a thread or spline for engaging the limiter, and that during dose setting transfers rotational torque from the dose setting member to a part that stores energy for injection.” This construction seeks to import multiple limitations from the specification into the claims. First, contrary to Defendants’ proposed construction, nothing in the patents requires the driver to engage with the limiter through a thread or spline. Defendants’ construction would therefore improperly import a limitation from the specification into the claims. *Phillips*, 415 F.3d at 1320. Second, Defendants’ proposed

⁵ *See* Merriam-Webster Dictionary, Definition of “Driver,” available at <https://www.merriam-webster.com/dictionary/driver> (defining “driver” as “a mechanical piece for imparting motion to another piece”) (Ex. E at JA068).

requirement that the driver “transfers rotational torque from the dose setting member to a part that stores energy for injection” appears to require a torsion spring. Nothing in the intrinsic record indicates that the claims are limited to devices that use a torsion spring. On the contrary, the patents show multiple embodiments without a torsion spring. For example, Figures 4 and 7 *add* torsion springs to the designs of Figures 1 and 5, respectively. See ’383 patent, col.6 lines 11-39 and col.7 lines 44-65 (Ex. B at JA039-40) (describing inclusion of spring-aided injection assistance systems). The Court should reject Defendants’ unduly narrow construction in favor of Novo Nordisk’s plain meaning proposal.

(3) “Limiter” and “Driver” Are Not Means-Plus-Function Limitations

Defendants contend that “limiter” and “driver” are “means-plus-function” terms under 35 U.S.C. § 112, ¶6. However, a claim term is presumptively *not* a means-plus-function term if it does not include the word “means,” as is the case here with both “limiter” and “driver.” *TEK Global S.R.L. v. Sealant Sys. Int’l, Inc.*, 920 F.3d 777, 785 (Fed. Cir. 2019). Defendants can overcome that presumption only by showing that a person of ordinary skill would not understand the terms to convey a sufficiently definite structure. *Id.* To assess this issue, courts review the intrinsic evidence. *Id.* at 785-86; *see also Dyfan LLC v. Target Corp.*, 28 F.4th 1360, 1365 (Fed. Cir. 2022) (“Intrinsic evidence, such as the claims themselves and the

prosecution history, can be informative in determining whether the disputed claim language recites sufficiently definite structure . . .”).

The end-of-content patents give ample information about the structures of both “limiter” and “driver.” As explained above, the patents describe a nesting structure, wherein the driver has a hollow internal space for the limiter, and the limiter has a hollow internal space for the piston rod. The claims capture this concept by requiring the driver to “defin[e] a passage for the limiter,” and the limiter to “defin[e] a passage for the piston rod.” ’383 patent, claim 1 (Ex. B at JA041); ’953 patent, claim 1 (Ex. C at JA056). As a result, a person of ordinary skill would understand that the driver and limiter are broadly circular components with hollow centers to “define a passage” for other components, which is consistent with the patents’ claims, written description, and figures.

The claims also require that “the limiter is coupled to the driver and the piston rod such that relative rotation between the driver and the piston rod during dose setting causes the limiter to move towards a stopping position.” ’383 patent, claim 1 (Ex. B at JA041); ’953 patent, claim 1 (Ex. C at JA056). A skilled artisan reviewing the intrinsic record would readily appreciate the structural features needed to permit the claimed “relative rotation” in view of the claimed nesting structure.

For example, the embodiment of Figure 3 involves a driver with a threaded inner surface that engages a threaded outer surface of a limiter, and a tongue-and-

groove connection between the limiter and piston rod. '383 patent, 5:7-13, 6:14-18 (Ex. B at JA039) (describing the driver-limiter threaded arrangement preserved in Fig. 3). This arrangement allows the driver to rotate independently of the limiter and piston rod, which are rotationally fixed, thus permitting the required “relative rotation . . . caus[ing] the limiter to move towards a stopping position” of the claims. *Id.*, 3:24-27, 5:16-19 (Ex. B at JA038-39). Dependent claims capture this specific arrangement. *See, e.g.*, '383 patent, claim 4 (Ex. B at JA041).

In sum, the intrinsic evidence conveys extensive information about the structures of the limiter and driver, and thus these terms are not means-plus-function terms. *TEK Global*, 920 F.3d 785. Both are broadly circular components with hollow centers to “define a passage” for other components. Additionally, both engage with other components using structures that permit “relative rotation between the driver and the piston rod during dose setting [to] cause[] the limiter to move towards a stopping position,” examples of which are provided in the claims and elsewhere in the intrinsic evidence. Thus, Defendants cannot overcome the presumption that limiter and driver are not means-plus-function terms.

b. Defendants' Answering Position

(1) "Limiter"

(a) "Limiter" is a means-plus-function limitation.

The term is "limiter" as a "means plus function" limitation that means "a three-dimensional toroid structure with (A) a threaded radially outer surface, a tongue extending from its radially inner surface, and teeth extending from its lower surface, (B) a threaded radially inner surface and a radially extending spline extending from the radially outer surface, or (C) equivalents thereof."

Under Section 112, ¶6, claims are construed to cover "the structure, materials, or acts described in the specification as corresponding to the claimed function and equivalents thereof." *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1347 (Fed. Cir. 2015). Here, the specification describes the limiter as a three-dimensional toroid structure with either (a) a threaded radially outer surface, a tongue extending from its radially inner surface, and teeth extending from its lower surface, or (b) a threaded radially inner surface and a radially extending spline extending from the radially outer surface. '383 patent at 5:11-22, 6:46-56, Figs. 1-8 (JA030-036, JA039). Thus, "limiter" should be construed as only covering these structures and equivalents thereof.

While the lack of the phrase "means" raises a rebuttable presumption that

Section 112, ¶6, does not apply, the presumption collapses “when a limitation lacking the term ‘means’ nonetheless relies on functional terms rather than structure or material to describe performance of the claimed function.” *Apex Inc. v. Raritan Comput., Inc.* 325 F.3d 1364, 1372 (Fed. Cir. 2003) (citation omitted); *see also Al-Site Corp. v. VSI Int’l, Inc.*, 174 F.3d 1308, 1318 (Fed. Cir. 1999) (“[W]hen...the [claim] element invokes purely functional terms ...the claim element may be a means-plus-function element despite the lack of express means-plus-function language.”).

Here, “limiter” is a non-structural generic placeholder defined by its function. *See Apex*, 325 F.3d at 1372; *Al-Site*, 174 F.3d at 1318. Specifically, “limiter” reiterates the element’s function (i.e., dose limiting). For example, claim 1 of the ’383 patent recites that the limiter “prevents the setting of a dose which exceeds the amount of medication in a reservoir in the device.” (JA041) The remainder of the respective claim limitations do not provide “specific structure or material for performing that function.” *Al-Site*, 174 F.3d at 1318. Therefore, the Court should adopt Defendants’ position. *Kyocera Senco Indus. Tools Inc. v. ITC*, 22 F.4th 1369, 1379-81 (Fed. Cir. 2022) (“lifter member” was a means-plus-function limitation because it did not have “a sufficiently definite [structural] meaning” and was “a non-structural generic placeholder...modified by functional language”); *Williamson*, 792 F.3d at 1350-51 (“distributed learning control module” was a means-plus-function

because the applicant merely replaced the term “means” with “module,” and provided no notice as to the claimed structure).

Plaintiffs argue that “limiter” is not a means-plus-function term because there is evidence of structure in the specification. Plaintiffs fundamentally misunderstand the §112, ¶6 analysis. The first step is to determine whether the claims themselves connote sufficiently definite structure, and if not, means-plus-function applies, and the intrinsic evidence must be reviewed to find corresponding structure. *See MTD Prods. Inc. v. Iancu*, 933 F.3d 1336, 1344 (Fed. Cir. 2019). Plaintiffs do the opposite, looking first to the intrinsic evidence to find structure, and then concluding that the term is not means-plus-function. This type of circular reasoning was rejected by the Federal Circuit. *Id.* Plaintiffs provide no evidence that the claim term *itself* supplies sufficiently definite structure, and resort first to cherry-picking structural limitations from the specification trying to avoid §112, ¶6. Even then, Plaintiffs abandon these structural limitations in their construction.

**(b) If not a means-plus-function limitation,
“limiter” should be construed
commensurate with the specification.**

“Limiter” does not have an accepted meaning in the relevant art. Plaintiffs cite to a lay dictionary definition to support their construction, but submit no evidence that this reflects the meaning in the pen injector art. To give meaning to their construction, Plaintiffs consult the Device Patents’ embodiments, which

underscores that there is no commonly accepted meaning of “limiter.” Under these circumstances, the specification provides “the single best guide to the meaning of a disputed term.” *E.g., Meds. Co. v. Mylan, Inc.*, 853 F.3d 1296, 1307 (Fed. Cir. 2017) (citation omitted). Moreover, such terms must be “construed only as broadly as is provided for by the patent itself.” *Sanofi-Aventis U.S., LLC v. Merck Sharp & Dohme Corp.*, 2018 WL 389183, at *11 (D. Del. Jan. 12, 2018) (cleaned up).

Based on the specification, “limiter” means “a toroid component that is axially movable within a space defined by the walls of the driver and has (i) a single continuous thread from one axial end to the other and (ii) a spline.” Both embodiments disclosed in the Device Patents disclose the “limiter” as a distinct toroidal-shaped component capable of axial movement in the space defined by the walls of the driver. *See, e.g.*, ’383 patent at Abstract, 1:50-52, 5:16-19, 6:53-56, 10:3-4 (JA028, JA037, JA039, JA041). Consistent with Plaintiffs’ own recitation of structural components defining the shape of the “limiter” (*see supra* § III.B.2.b.(1)(a)), Defendants’ construction articulates this structure with the term “toroid,” meaning a circular object with a hollow center. To accomplish the function of preventing setting a dose that exceeds what is left remaining in the device, both embodiments disclose the “limiter” component moving toward its stopping position based on the single continuous thread extending from one end to the other and a spline. ’383 patent at 5:11-19, 6:46-53 (JA039). The two disclosed embodiments

differ only in the placement of the thread and spline structures. As such, “the specification read as a whole suggests that the very character of the invention requires” such structures. *Alloc, Inc. v. ITC*, 342 F.3d 1361, 1370 (Fed. Cir. 2003).

Plaintiffs are unable to provide any evidence that “limiter” has a commonly understood meaning in the relevant art. Instead, Plaintiffs pluck their construction from a general-purpose dictionary. Novo Nordisk’s Opening Position at 38. This approach is disfavored because “the specification, not dictionaries or colloquial use, dictates a term’s ‘plain and ordinary meaning.’” *Choon’s Design, LLC v. IdeaVillage Prods. Corp.*, 776 F. App’x 691, 696 (Fed. Cir. 2019) (citation omitted). Nevertheless, Plaintiffs’ construction of anything with “limiting purpose” is “essentially a MPF construction with no corresponding structure” and improperly covers **any** component or mechanism with a “limiting” purpose. *Sanofi-Aventis*, 2018 WL 389183 at *11 (declining to construe “dose member” as a component “for setting a dose” because it would cover any component performing such function). Such a construction runs afoul of well-established precedent that disallows a construction broader than the disclosure in the specification. *E.g., id.; TDM Am., LLC v. U.S.*, 85 Fed. Cl. 774, 803 (2009); *see Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2001) (“[T]he claims [do not] enlarge what is patented beyond what the inventor has described as the invention.”).

Despite Plaintiffs’ construction that captures anything with “limiting purpose,” Plaintiffs cherry-pick two features (“broadly circular” with a “hollow center[.]”) from the disclosed embodiments to contend the “*intrinsic evidence conveys extensive information about the structure[] of the limiter*” Novo Nordisk’s Opening Position at 41 (emphasis added). That Plaintiffs are forced to resort to the disclosed embodiments underscores Defendants’ argument that “limiter” has no commonly accepted meaning. In their final construction, however, Plaintiffs desert these and other structural components that perform the “limiting” function.

(2) “Driver”

(a) “Driver” is a means-plus-function limitation.

The term “driver” is a “means plus function” limitation that means “a hollow cylindrical component having an inner surface that is either threaded or has a groove for engaging a corresponding spline, the component being (a) rotatable in a first direction without translating in a longitudinal direction during dose setting, and (b) rotatable in a second direction opposite the first direction without translating in the longitudinal direction during dose administration, or equivalents thereof.”

Again, claims are construed to cover only “the structure, materials, or acts described in the specification as corresponding to the claimed function and

equivalents thereof” under Section 112, ¶6. *Williamson*, 792 F.3d at 1347. Here the specification describes the driver as being a hollow cylindrical component having an inner surface that is either threaded or has a groove for engaging a corresponding spline, the component being (a) rotatable in a first direction without translating in a longitudinal direction during dose setting, and (b) rotatable in a second direction opposite the first direction without translating in the longitudinal direction during dose administration. ’383 patent at 5:4-13, 41-46, 52-56, 6:46-48, 7:3-17, Figs. 1-8 (JA030-036, JA039-040).

The term “driver” is a non-structural generic placeholder defined by its function. *See Apex*, 325 F.3d at 1372; *Al-Site*, 174 F.3d at 1318. The term “driver” merely reiterates the function it performs (i.e., driving). The remainder of the claim limitation does not provide “specific structure or material for performing that function.” *Al-Site*, 174 F.3d at 1318. Therefore, the Court should adopt Defendants’ construction. *Supra* §III.B.2.b.(1)(a); *see also Kyocera*, 22 F.4th at 1379-81; *Williamson*, 792 F.3d at 1350-51.

Further, Plaintiffs erroneously rely on structures disclosed in the specification to attempt to avoid a means-plus-function interpretation of “driver.” As explained *supra* § III.B.2.b.(1)(a), this reasoning fails.

**(b) If not a means-plus-function term,
“driver” should be construed
commensurate with the specification.**

The principal sources of claim construction evidence are in the “intrinsic record”—i.e., “[1] the words of the claims themselves, [2] the remainder of the specification, [and] [3] the prosecution history.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (citation omitted); *supra* §III.B.2.b.(1)(b) (when no commonly accepted meaning, specification is the best guide). The claims, with the specification, support Defendants’ construction. Specifically, each embodiment requires the driver to have a thread or spline for engaging the limiter. ’383 patent at 5:11-13, 6:46-48, 9:6-7 (JA039, JA041); *see also* Leinsing Decl. ¶¶59-62 (JA519-520). Moreover, in each embodiment, during dose setting, the driver transfers rotational torque from the dose setting member to a part that stores energy for injection. ’383 patent at 5:60-6:3, 6:24-28, 7:52-56 (JA039-040); *see also* Leinsing Decl. ¶¶28, 63-66 (JA499, JA520-521) (explaining that the disclosed device would not operate without a driver that transfers rotational torque from the dose setting member to a part that stores energy).

Plaintiffs accuse Defendants of improperly importing limitations into the “driver” term (Novo Nordisk’s Opening Position at 39-41), but here “the specification read as a whole suggests that the very character of the invention requires the limitation be a part of every embodiment.” *Alloc*, 342 F.3d at 1370. Indeed, “where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible

and proper to limit the claims.” *Id.*; *see also Howmedica Osteonics Corp. v. Zimmer, Inc.*, 822 F.3d 1312, 1323 (Fed. Cir. 2016) (if courts were not permitted to limit terms based on descriptions provided in embodiments, this “would quite severely limit any understanding of the claims in light of the written description”). Here each embodiment requires the driver to have the elements of Defendants’ construction.

Plaintiffs state that “nothing in the patents requires the driver to engage with the limiter through a thread or spline.” Novo Nordisk’s Opening Position at 40. But the specification describes that the driver engages with the limiter through a thread or spine in *every* disclosed embodiment. ’383 patent at 5:11-13, 6:46-48, 9:6-7 (JA039, JA041); *see also* Leinsing Decl. ¶¶59-62 (JA519-520). Plaintiffs also allege that “[n]othing in the intrinsic record indicates that the claims are limited to devices that use a torsion spring.” Novo Nordisk’s Opening Position at 40. However, Defendants’ construction does not require including a torsion spring: it requires including an element that stores energy.⁶ Indeed, the very nature of the disclosed

⁶ Defendants’ construction is proper for the reasons discussed. Nonetheless, as a compromise, Defendants would be amenable to a construction stating: “a component having a thread or spline for engaging the limiter, and that during dose setting transfers rotational torque from one component to another component.” Every embodiment explicitly describes the driver transferring rotational torque. Leinsing Decl. ¶¶68-70 (JA522-523).

injection device is a torsion-type pen design where the parts rotate, rather than a linear push button where the parts simply move axially with the application of force. Leinsing Decl. ¶16 (JA494). Without including an element for storing energy, the device would fail to operate. Leinsing Decl. ¶¶28, 64 (JA499-500, JA520).

Moreover, Defendants’ construction provides necessary clarity that is missing from Plaintiffs’ construction, which is so general that it is “more unhelpful than the term by itself.” *Depomed, Inc. v. Sun Pharma Global FZE*, 2012 WL 3201962, at *5 (D.N.J. Aug. 3, 2012). Specifically, Plaintiffs ignore the disclosures throughout the specification of how the driver operates relative to other components of the torsion type pen. Plaintiffs’ construction is also so broad that it captures other components of the injection device described in the specification. For example, Plaintiffs’ construction—“a component or mechanism which causes movement of another component”—covers not only the driver, but also, for example, the dose setting member and spring. Leinsing Decl. ¶¶72-73 (JA523-524). Thus, Defendants’ construction should be adopted.

c. Novo Nordisk’s Reply Position

(1) “Limiter” Should Be Given Its Plain and Ordinary Meaning

Despite Defendants’ suggestion otherwise, persons of ordinary skill in the field of injection devices would understand “limiter” to refer to a “component with

a limiting purpose.” In the end-of-content patents the “limiter” is a component that limits the amount of medicine that can be administered in a dose. See Declaration of Kimberly Cameron, Ph.D., P.E. (“Cameron Declaration”) (Exhibit G)⁷ ¶¶20-25 (Ex. G at JA104-06; ’383 patent, 1:59-63 (Ex. B at JA037). As a compromise, Plaintiffs propose that “limiter” be construed as “a component that acts to limit the dose that can be set to not exceed the amount of medicine remaining in the device.” Cameron Decl. ¶25 (Ex. G at JA106).

Claims should not be construed to import limitations from embodiments in the specification. *WesternGeco LLC v. ION Geophysical Corp.*, 889 F.3d 1308, 1323-24 (Fed. Cir. 2018) (“It is well established that claims are not limited to preferred embodiments, unless the specification clearly indicates otherwise.”). Here, Defendants attempt to do just that. Defendants seek to restrict “limiter” to a “toroid” geometric shape, a term that does not appear in the patent or elsewhere in the intrinsic record. Nor does the intrinsic evidence suggest that “limiter” is restricted to any specific shape.

⁷ Novo Nordisk submits herewith the Cameron Declaration in response to the 37-page Declaration of Karl R. Leinsing, MSME, PE (the “Leinsing Declaration”), served with Defendants’ Answering Position.

Defendants next seek to restrict “limiter” to a component that is “axially movable within a space defined by the walls of the driver.” Defendants’ Answering Position at 46. Defendants’ argument ignores that the claims themselves dictate the limiter’s movement in relation to other components. *See Howmedica Osteonics Corp. v. Zimmer, Inc.*, 822 F.3d 1312, 1322 (Fed. Cir. 2016) (“When the claims leave little doubt as to what is intended, re-shaping the claims with material[s] from the written description is clearly unwarranted.”). Specifically, claim 1 of both end-of-content patents requires that the “driver defin[e] a passage for the limiter,” and that “relative rotation between the driver and the piston rod during dose setting causes the limiter to move towards a stopping position.” ’383 patent, 9:54-10:4 (Ex. B at JA041); ’953 patent, 10:7-12 (Ex. C at JA056). The claims thus clearly indicate how the limiter moves in relation to other components.

Next, Defendants argue that “limiter” should be construed to require “a single continuous thread from one axial end to the other and ... a spline.” Defendants’ Answering Position at 46. Requiring that the limiter be coupled to other components by threads and splines contradicts the claims as a whole, which recite the manner in which the limiter is coupled to other components. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (other claims “can also be valuable sources of enlightenment as to the meaning of a claim term”). As discussed above, the claims here specify the engagement of the limiter to other components. Claim 1 of the ’383

patent recites that the limiter “is coupled to the driver and the piston rod,” but does not specify how it is so coupled. ’383 patent, 10:1-4 (Ex. B at JA041). Further, requiring “limiter” to have a spline engagement would read out other connections for the limiter such as flat surfaces (’383 patent, 6:14-18 (Ex. B at JA039)), which are alternatives to splines. *See EPOS Techs. Ltd. v. Pegasus Techs. Ltd.*, 766 F.3d 1338, 1347 (Fed. Cir. 2014) (claim interpretation reading out preferred embodiments is “rarely, if ever[,] correct”).

Finally, Defendants’ proposal that the limiter have “a single continuous thread from one axial end to the other” is based only on their interpretation of figures in the patents. This argument fails because the specification nowhere indicates that the figures are intended to be limiting. *See GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1308-09 (Fed. Cir. 2014) (reading in a limitation from an illustrative figure is unwarranted).

(2) “Driver” Should Be Given Its Plain and Ordinary Meaning

Persons of ordinary skill in the field of injection devices understand “driver” to be “a component which causes movement of another component.” Cameron Decl. ¶¶26-31 (Ex. G at JA106-09). Consistent with the claims and specification of the end-of-content patents, Novo Nordisk offers a compromise construction of “driver,” as “a component that transmits force to the piston rod, which moves to cause

expulsion of medicine from the device.” See ’383 patent, 9:54-10:4 (Ex. B at JA041); ’953 patent, 10:7-17 (Ex. C at JA056); Cameron Decl. ¶31 (Ex. G at JA108-09).

Defendants propose a narrow construction of “driver” based on how it is coupled to the limiter in specific embodiments. Defendants’ Answering Position at 49-50. Courts routinely reject constructions limited to specific embodiments. See *Liquid Dynamics Corp. v. Vaughan Co.*, 355 F.3d 1361, 1369 (Fed. Cir. 2004). Moreover, the claims contradict this approach. Claim 1 of the ’383 patent requires that “the limiter is coupled to the driver,” and claim 4 further requires that the limiter and driver have a threaded engagement. ’383 patent, 9:54-10:4, 10:17-22 (Ex. B at JA041). When the Applicants wanted to specify how the limiter and driver are coupled, they did so in the claims.

Defendants further overreach by arguing that “during dose setting, the driver transfers rotational torque from the dose setting member to a part that stores energy.” Defendants’ Answering Position at 50-51. The end-of-content patents describe two general embodiments and, for each, include a description of the device without a stored energy “injection assisting mechanism” such as a spring. ’383 patent, Figs. 1-3 and 5-6; 2:1-45; 5:4-6:18; 6:40-7:43 (Ex. B at JA030-31, JA033-34, JA037, JA039-40). Defendants’ proposed construction would thus read a stored energy requirement into the scope of “driver,” improperly excluding most of the patents’

embodiments. *See EPOS Techs.*, 766 F.3d at 1347.

Defendants attempt to justify limiting the scope of driver by arguing that “without including an element for storing energy, the device would fail to operate.” Defendants’ Answering Position at 52. Not only is this contradicted by multiple embodiments in the specification without an energy assistance mechanism, the devices of Figures 1-3 and 5-6 could clearly operate without one by including a manual push button assembly. Cameron Decl. ¶29 (Ex. G at JA107-08).

Moreover, an “ejection assisting system” is recited as a dependent limitation in claims 12 and 13 of the ’383 patent and claims 10 and 11 of the ’953 patent. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004) (importing a dependent claim limitation into the claim from which it depends violates claim differentiation and is rarely warranted).

(3) Defendants Fail To Show Why “Limiter” and “Driver” Should Be Treated as Means-Plus-Function Limitations

Defendants have not presented evidence to overcome the presumption that in the absence of the word “means,” “limiter” and “driver” are *not* means-plus-function limitations. *See TEK Glob. v. Sealant Sys. Int’l Inc.*, 920 F.3d 777, 785 (Fed. Cir. 2019). Other than the conclusory assertion that “limiter” and “driver” are non-structural generic placeholders (Defendants’ Answering Position at 44, 49-50), Defendants offer little substantive response to the evidence that both “limiter” and

“driver” have sufficiently definite structure as used in the claims and in the patents’ specification. *See* Novo Nordisk’s Opening Position at 41-43.

Like other elements that take their names from the functions they perform (*e.g.*, filter, clamp, and lock), “limiter” and “driver” also have “a reasonably well understood meaning in the art.” *See Greenberg v. Ethicon Endo Surgery, Inc.*, 91 F.3d 1580, 1583 (Fed. Cir. 1996). Far from generic placeholders, “limiter” and “driver” have a plain and ordinary meaning in the field of injection devices. Cameron Decl. ¶¶20-31 (Ex. G at JA104-09).

Defendants criticize Novo Nordisk for citing to the specification for evidence of structure. Defendants’ Answering Position at 45. The Federal Circuit instructs, however, that it is “proper to consult the intrinsic record, including the written description, when determining if a challenger has rebutted the presumption that a claim lacking the term ‘means’ recites sufficiently definite structure.” *See Inventio AG v. ThyssenKrupp Elevator Ams. Corp.*, 649 F.3d 1350, 1357 (Fed. Cir. 2011).

In any event, the claims provide more than sufficient structure. Novo Nordisk’s Opening Position at 41-43. The claimed limiter must “defin[e] a passage for the piston rod” and it must be “coupled to the driver and the piston rod such that relative rotation between the driver and the piston rod during dose setting causes the limiter to move towards a stopping position.” ’383 patent, 9:51-53, 10:1-4 (Ex. B at JA041); ’953 patent, 10:6, 11-15 (Ex. C at JA056). The driver, meanwhile, must

“defin[e] a passage for the limiter” and be “coupled to the dose setting member such that rotation of the dose setting member during dose setting causes the driver to rotate.” ’383 patent, 9:54-57 (Ex. B at JA041); ’953 patent, 10:7-10 (Ex. C at JA056). Defendants provide no explanation why these claim limitations do not provide a sufficiently definite structure of “limiter” and “driver.”⁸

d. Defendants’ Sur-Reply Position

(1) “Limiter”

(a) “Limiter” Has No Plain Meaning

Even with their compromise construction, Plaintiffs provide no credible evidence that “limiter” has a plain meaning in the art. Plaintiffs’ expert declaration⁹ fails to establish the lay dictionary definition reflects the POSA’s understanding. *Diebold Nixdorf, Inc. v. ITC*, 899 F.3d 1291, 1299-1301 (Fed. Cir. 2018). Plaintiffs’ compromise construction also fails because it is purely functional. Therefore, consistent with *Sanofi*, this Court should review the embodiments to discern the

⁸ Undercutting Defendants’ position in this case, in a separate proceeding involving the end-of-content patents, to which Defendants Sun Pharmaceutical Industries Ltd. and Sun Pharmaceuticals Industries, Inc. are also parties, no party proposes that “limiter” or “driver” is a means-plus-function limitation. *Novo Nordisk Inc. et al. v. Orbicular Pharm. Techs. Pvt. Ltd.*, C.A. No. 22-856-CFC, D.I. 69 (D. Del. Mar. 24, 2023).

⁹ This Declaration is untimely under D. Del. LR 7.1.3.(c)(2).

meaning of “limiter.” *Sanofi-Aventis U.S. LLC. v. Merck Sharp & Dohme Corp.*, Civ. Action No. 16-812-RGA, 2018 WL 389183, at *11 (D. Del. Jan. 12, 2018). *See also Par Pharm., Inc. v. Hospira, Inc.*, Civ. Action No. 17-944-JFB-SRF, 2019 WL 2004756, at *4 (D. Del. Apr. 30, 2019) (construing term having no commonly understood meaning in the relevant art as limited to the disclosed embodiments). Defendants’ construction does not read out the preferred embodiments, but instead incorporates all that has been described and enabled from the disclosed embodiments.

**(b) Plaintiffs’ Construction Underscores the
Need to Construe “Limiter” as a Means-
Plus-Function Limitation**

Regardless of whether “limiter” has any plain meaning in the art, it does not have a plain meaning denoting structure. As in *MTD Products, Inc. v. Iancu*, 933 F.3d 1336, 1341 (Fed. Cir. 2019), the critical question is “whether the claim term is used in common parlance or by persons of skill in the pertinent art to designate structure including either a particular structure or a class of structures.” (Cleaned up). Plaintiffs’ proposed constructions confirm that “limiter” has no meaning in the art denoting “a particular structure or class of structures.” Plaintiffs’ expert declaration parroting Plaintiffs’ purely functional construction does not change

that.¹⁰ See, e.g., *Barry v. Stryker Corp.*, No. 20-1787-RGA, 2023 WL 1765651, at *16 (D. Del. Feb. 3, 2023) (construing “linking member” as means-plus-function, and finding expert testimony that a term means any structure performing a particular function “is not sufficient when the claim term is not well understood as a name for sufficiently definite structure.”).

Plaintiffs err by pointing to embodiments in the specification to allegedly show “sufficiently definite structure,” but then not including any of those structural features in their construction. Novo Nordisk’s Opening Position at 41-42. Plaintiffs’ own constructions belie their assertion that “limiter” denotes sufficiently definite structure. *Id.* Moreover, identifying structure in preferred embodiments is not proper to show the term “limiter” has sufficiently definite structure in the claims. *MTD Prods.*, 933 F.3d at 1344; *Kyocera Senco Indus. Tools Inc. v. ITC*, 22 F.4th 1369, 1381 (Fed. Cir. 2022) (“[E]ach of these passages provides an example of *a* lifter member, rather than a definition of *the* lifter member.”).

Plaintiffs also incorrectly contend the claims recite sufficient structure. Novo Nordisk’s Reply Position at 58-60. “The question is not whether a claim term recites

¹⁰ Plaintiffs’ expert recites a list of mechanical “limiters” to support the contention that “limiter” has an ordinary meaning. But, these neither define nor provide structural meaning to the term and are furthermore unrelated to injector pens so have little relevance.

any structure but whether it recites *sufficient* structure—a claim term is subject to §112(f) if it recites function without reciting sufficient structure *for performing that function.*” *Egenera, Inc. vs. Cisco Sys., Inc.*, 972 F.3d 1367, 1374 (Fed. Cir. 2020)(citation omitted); *see also Magnolia Med. Tech., Inc. v. Kurin, Inc.*, No. 19-97-CFC-CJB, 2020 WL 2559795, at *3 (D. Del. May 20, 2020). Plaintiffs argue the claim limitations “defining a passage” and “coupled to the driver and the piston rod” impart “sufficient structure” for the term limiter. Not so. These limitations define the relative orientation and movement between components and do not recite structure for performing the limiting function.

(2) “Driver”

As explained in Defendants’ Answering Brief, “driver” is a means-plus-function term, and Plaintiffs’ contrary arguments fail for reasons like those explained above regarding “limiter.” If not, Defendants’ construction (and compromise construction) best reflects the intrinsic record.

Plaintiffs’ principal argument is that the Device Patents do not require a component for stored energy, thus, Defendants’ construction is too limiting. Novo Nordisk’s Reply Position at 57. Not so. Each embodiment in the Device Patents requires this feature because the device will not operate without it. Leinsing Decl. ¶¶28, 64 (JA499-500, JA520). Plaintiffs’ only rebuttal is the device “could clearly operate without [a component for storing energy] by including a manual push button

assembly.” Novo Nordisk’s Reply Position at 57; Cameron Decl. ¶29 (JA107-108). But a push button injection device is a materially different type of pen injector. Leinsing Decl. ¶¶16, 67 (JA494, JA521-522). Indeed, the Device Patents ***never mention such a push button***. Plaintiffs do not explain how the claimed device could work with a push button or what would be required to reconfigure the device to use a push button. Additionally, the dependent claims requiring an “ejection assisting system” do not preclude the broader independent claims from having a component that stores energy. Rather, those claims cover a specific type of component for storing energy, as the specification discussed. Plaintiffs thus fail to show the component for storing energy recited in Defendants’ construction is unwarranted.¹¹

Notably, Plaintiffs do not dispute that every embodiment requires that the driver have “a thread or spline for engaging the limiter,” as recited in Defendants’ construction. Plaintiffs point only to claim 4, where the driver has a thread for engaging the limiter, and say Defendants’ construction is narrower. Novo Nordisk’s Reply Position at 56-57. But Defendants’ construction allows for a thread or spline engagement between the driver and limiter, the two types of connections used in

¹¹ Plaintiffs do not address Defendants’ compromise that no longer requires a component for stored energy (instead reciting that rotational torque is transferred *from one component to another*).

each embodiment. Leinsing Decl. ¶69 (JA522).

Plaintiffs’ compromise construction is also inaccurate because it broadly requires that the driver transmits a **force** to the piston rod. As described throughout the specification, the driver transmits a **torque** to the piston rod, not simply **force** in general. Moreover, Plaintiffs’ alternate proposal suffers the same problems as their original construction—for example, it captures multiple components described in the Device Patents, such as the “piston rod guide,” which causes the piston rod to move. Leinsing Decl. ¶72 (JA523).

3. “Defining a Passage”

a. Novo Nordisk’s Opening Position

Novo Nordisk’s proposed construction of “defining a passage” is: “having an inner space for another component, through which the other component can pass.” A person of ordinary skill would come to this conclusion based on the intrinsic evidence. The claims of both end-of-content patents use the term “defining a passage” to specify the physical relationships between various components. The patents stress that “it is an object of the present invention to provide an end-of-content mechanism which may be positioned in the space defined by the inner walls of a driver.” ’383 patent, 1:50-52 (Ex. B at JA037). The patents describe the concept of components having an inner space that contains other components throughout the specification—for example, the driver has an inner space for the limiter, which has

an inner space for the piston rod. *Id.*, 3:14-22, 4:16-23, 6:46-53 (Ex. B at JA038-39). In each case, the patent uses the phrase “defining a passage” to mean that the component has an inner space, in which another component is positioned, and through which the other component can pass.

Defendants propose that “defining a passage” means “[h]aving a radially inner surface that forms an entire circumference of an outer boundary of an opening in which the [piston rod or limiter] is positioned.” To the extent Novo Nordisk understands it, the phrase “forms an entire circumference of an . . . opening” is unduly narrow and would limit the term to specific embodiments described in the patents. The patents do not exclude, for example, a C-shaped driver that “defin[es] a passage” for a limiter but does not form the “entire circumference” of the passage in which the limiter is positioned. Nor does any mechanical engineering principle compel a different conclusion. Furthermore, the meaning of the phrase “radially inner surface” is unclear and not in the intrinsic record. The Court should reject Defendants’ unduly narrow and complex construction in favor of Novo Nordisk’s.

b. Defendants’ Answering Position

Because the patents provide no definition for “defining a passage,” the principal sources of evidence are in the “intrinsic record.” *Phillips*, 415 F.3d at 1314. Here, the claims, together with the specification, support Defendants’ construction.

The claims of the ’383 patent require: “the limiter defining a passage for the

piston rod” (claim 1), “a driver defining a passage for the limiter” (claim 1), and “a housing defining a passage for the piston rod (claim 2) (Ex. B at JA41). Moreover, the claims specify that the passage defined by the housing has “a threaded inner surface for engagement with the threaded outer surface of the piston rod” (claim 2) (*Id.*). The ’953 patent recites the same. (Ex. C at JA56). Thus, according to the claims, there must be an inner surface which defines an outer boundary of an opening (i.e., passage) in which the piston rod or limiter is positioned.

The specification provides additional information regarding the passage, such as when referring to Fig. 1 (reproduced below) and stating the “inner surface 14 of the driver 12 has a threaded surface which is adapted to engage a corresponding thread of the outer surface 16 of the limiter 10. Moreover, the limiter 10 is locked for rotation in relation to the piston rod 8 by means of groove 18 in the piston rod 8 and a tongue 20 in the limiter 10 (in the figure the tongue is indicated by a dotted line).” ’383 patent at 5:9-16 (Ex. B at JA39).

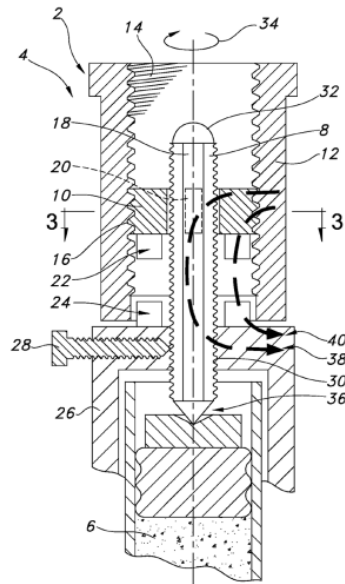


FIG. 1

The specification also provides: “it is an object of the present invention to provide an end-of-content mechanism which may be positioned in the space defined by the inner walls of a driver.” *Id.* 1:50-52 (Ex. B at JA37). Also stated is that with respect to Fig. 5, “the limiter 10 has a threaded inner surface 62 which engages a corresponding threaded outer surface 64 of the piston rod 8.” *Id.* 6:51-53 (Ex. B at JA39).

Thus, in “defining a passage,” the specification shows the passage encompasses (i.e., forms an entire circumference around) the limiter or piston rod. Accordingly, the patent provides that “defining a passage” is a component “having a radially inner surface that forms an entire circumference of an outer boundary of

an opening in which the [piston rod or limiter] is positioned.”

In contrast, Plaintiffs contend “the phrase ‘forms an entire circumference of an ... opening’ is unduly narrow and would limit the term to specific embodiments described in the patents.” Novo Nordisk’s Opening Position at 18. This is not the case. As above, this is the meaning of “defining a passage” according to the claims and specification of the patent.

Plaintiffs further states that the “patents do not exclude, for example, a C-shaped driver that ‘defin[es] a passage’ for a limiter but does not form the ‘entire circumference’ of the passage in which the limiter is positioned. Nor does any mechanical engineering principle compel a different conclusion.” *Id.* 18-19. This is inaccurate, as nowhere in the patents or prosecution history is there any mention of a “C-shaped driver” or any other equivalent. Further, “where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims.” *Alloc*, 342 F.3d at 1370 (citations omitted); *see also Howmedica*, 822 F.3d at 1323.

That is the case here. The configuration of the passage “forms an entire circumference” is in the disclosed embodiments. Moreover, the presence in the passage of a “threaded inner surface 62 which engages a corresponding threaded outer surface 64 of the piston rod 8” supports Defendants’ construction of “defining a passage,” which is “a radially inner surface that forms an entire circumference of

an outer boundary of an opening in which the [piston rod or limiter] is positioned.”

c. Novo Nordisk’s Reply Position

The term “defining a passage” conveys a spatial relationship between an outer component’s interior and an inner component that can pass through it. *See, e.g.*, ’383 patent, 3:14-22; 4:16-23 (Ex. B at JA038). Defendants once again seek to improperly limit claim scope by arguing that the figures and written description mandate that a passage “forms an entire circumference around” the limiter or the piston rod. Defendants’ Answering Position at 68. Thus, a component with even a small opening at some point around the perimeter of the passage would not “defin[e] a passage” under Defendants’ construction even though it would provide an interior space through which an inner component can pass.

Defendants cite specific embodiments and figures of the patents (Defendants’ Answering Position at 66-67), but no language suggesting that forming “an entire circumference” should limit the scope of “defining a passage.” This restrictive construction should be rejected.

d. Defendants’ Sur-Reply Position

The patents do not state that “defining a passage” includes a “small opening,” as Plaintiffs contend. Novo Nordisk’s Reply Position at 17. Nor do the patents show any components defining a passage with a “small opening.” In effect, Plaintiffs’ construction attempts to broaden the claims beyond what is actually disclosed and

supported by the intrinsic evidence.

Because the term “defining a passage” is not defined, its construction is governed by the intrinsic record, which Plaintiffs concede *includes* “specific embodiments and figures of the patents.” *Id.* These embodiments and figures show the passages form an entire circumference, and thus support construing “defining a passage” as Defendants propose. *Alloc, Inc. v. ITC*, 342 F.3d 1361, 1370 (Fed. Cir. 2003) (citations omitted); *see also Howmedica Osteonics Corp. v. Zimmer, Inc.*, 822 F.3d 1312 (Fed. Cir. 2016) (“where the specification makes clear at various points that the claimed invention is narrower than the claim language might imply, it is entirely permissible and proper to limit the claims.”).

4. “Housing”

a. Novo Nordisk’s Opening Position

The patents provide no definition for “housing” and do not suggest that it is limited to certain specific structures described in the patents’ specification. Accordingly, housing is presumed to have its plain and ordinary meaning, which is Novo Nordisk’s construction: “an enclosure that is designed to house at least one inner component.”

Defendants propose to construe “housing” as: “an outermost unitary component that contains at least the limiter, driver, and drum scale, and engages the piston rod.” Nothing in the intrinsic evidence compels such a narrow, specific

construction. The claims require the housing to “defin[e] a passage for the piston rod,” but neither the claims nor any other portion of the intrinsic record specifies that the housing must also contain the other components Defendants build into their construction. Nor does the intrinsic evidence require the housing to be an “outermost unitary component,” a phrase appearing nowhere in the patents. On the contrary, when describing the “housing defining a passage for the piston rod” (*i.e.*, the housing of the claims), the specification explains that this housing “*may form part of the housing of a syringe device into which the mechanism is integrated.*” ’383 patent, 2:18-26 (Ex. B at JA037). This suggests that the housing may *or may not* be a part of the exterior of the pen, contradicting Defendants’ proposed requirement that the housing be the “outermost unitary component” of the device.

b. Defendants’ Answering Position

Because the patents do not define “housing,” the “intrinsic record” is the principal source of evidence. *Phillips*, 415 F.3d at 1313. Here, “housing” does not have a plain meaning, and the specification and claims support Defendants’ construction.

Plaintiffs cite (Novo Nordisk’s Opening Position at 19) to one portion of the ’383 patent’s description of the housing, namely “the housing may form part of the housing of a syringe device into which the mechanism is integrated.” ’383 patent at 2:24-26 (Ex. B at JA37). But this passage only makes sense if the claimed housing

has specific characteristics. The specification teaches POSAs the unique characteristics of the housing. As in, e.g., Fig. 4, the housing 26 is the outermost unitary component in the device which contains the other parts of the device, including the limiter and driver, and engages the piston rod. *Id.* 5:31-34; Fig. 4 (Ex. B at JA39, JA32) . As in Fig. 8, this includes the drum scale 70.

The claims are consistent with this. For example, claim 2 recites the “housing defining a passage for the piston rod.” *Id.* 10:6. Because the housing defines a passage for the piston rod, the piston rod must be contained within the housing, and because the inner surface of the housing is described as engaging the outer surface of the piston rod, the housing “engages the piston rod.” As another example, claim 10 of the ’383 patent requires “a ratchet mechanism interconnecting the driver and the housing.” *Id.* 10:44-45 (Ex B at JA41). Because the driver is coupled to the piston rod and the limiter, which are contained within the housing (“the limiter is coupled to the driver and the piston rod” – claim 1), the driver and limiter must also be contained within the housing. The ’953 patent recites similar limitations. ’953 patent at 9:66-10:1; 11:18-19; 12:5-6; 12:14-15 (Ex. C at JA56-57).

Plaintiffs’ construction is an attempt to ignore the plain meaning of housing, which signifies the exterior shell of a device. While they focus on the phrase “the housing may form part of the housing of a syringe device” (’383 patent at 2:24-26, Ex. B at JA37), that allows the claimed housing to be integrated with other material

to form the housing. It does not suggest that the claimed housing could be part of the *interior* of the pen. Similarly, Plaintiffs’ assertion that the housing need not contain other components flies in the face of the plain definition—where other components exist, they are inside the housing, which is the exterior.

Notably, Plaintiffs’ brief and construction are inconsistent. For example, Plaintiffs describe the configuration of the injection device as having “three key pen components—the driver, limiter, and piston rod—together in a novel, ‘nested’ design.” Novo Nordisk’s Opening Position at 10. But the components are not outside the pen, which, again according to Plaintiffs, would be discouraged. (“Nesting the components permits an efficient, compact design, in contrast to prior dose-limiting mechanisms, which placed the limiter outside the driver and sometimes outside the pen itself. *See id.*, 1:21-24.”) *Id.* 10-11. They are nested *in* the housing, which is the outermost, exterior component. Plaintiffs’ construction should therefore be rejected.

c. Novo Nordisk's Reply Position

A person of ordinary skill in the field of injection devices would interpret housing as “an enclosure that houses at least one inner component.” This construction accords not only with the plain and ordinary meaning of housing but also with the intrinsic record. *See Unitherm Food Sys. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1345 (Fed. Cir. 2004) (proper construction is the “definition that one of ordinary skill in the art could ascertain from the intrinsic ... record.”).

Defendants begin their proposed construction by limiting the term's scope to a specific type of housing, an “outermost unitary component,” which they also term “the exterior shell of a device.” Defendants' Answering Position at 73. The specification's statement, however, that “[t]he housing *may* form part of the housing of a syringe device,” ('383 patent, 2:24-26 (Ex. B at JA037) (emphasis added)), signals that the claimed housing *may or may not* form part of the syringe housing or “exterior shell of a device.” Defendants attempt to explain away this statement as instead meaning that the housing of the claimed invention could “be integrated with other material to form the housing.” Defendants' Answering Position at 73. This explanation is not credible, particularly in light of the patents' use of “housing.”

In particular, claim 1 of the '953 patent requires that the housing define a passage, which has “a threaded inner surface for engagement with the threaded outer surface of the piston rod.” '953 patent, 9:66-10:1 (Ex. C at JA056). Defendants'

suggestion that the housing is limited to an “exterior shell of a device” is contradicted by the claims’ requirement that the housing’s singular engagement is with the innermost component, the piston rod.

A person of ordinary skill would understand that when “housing” is meant to be the outermost component, this is indicated in the art. For example, WO 02/092153 (Exhibit H), which is identified on the face of the end-of-content patents, describes an “outer housing” in multiple locations. WO 02/092153, 16:24-30, 23:5-12, 25:13-15 (Ex. H at JA144, JA151, JA153). Consistent with this understanding, Merriam-Webster’s Collegiate Dictionary defines “housing” as “something that covers or protects: as a): a case or enclosure (as for a mechanical part or an instrument) b): a casing (as an enclosed bearing) in which a shaft revolves c): a support (as a frame) for mechanical parts.” (Ex. I at JA228).

Defendants also attempt to narrow the scope of “housing” by requiring that it contain at least the limiter, driver, and drum scale. Defendants’ Answering Position at 72-73. At least Figures 1 (*infra*) and 5, however, show the housing **26** (orange) as underneath, rather than containing, both the driver **12** (green) and the limiter **10** (red).

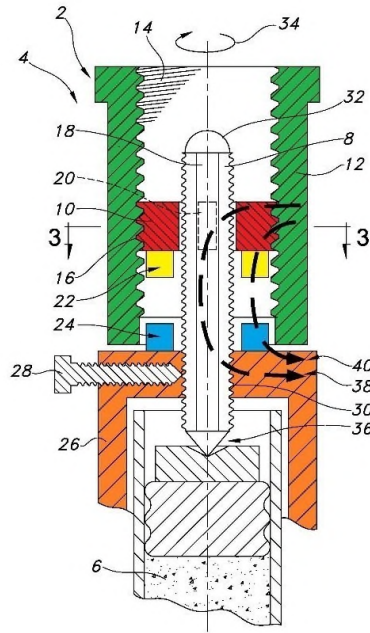
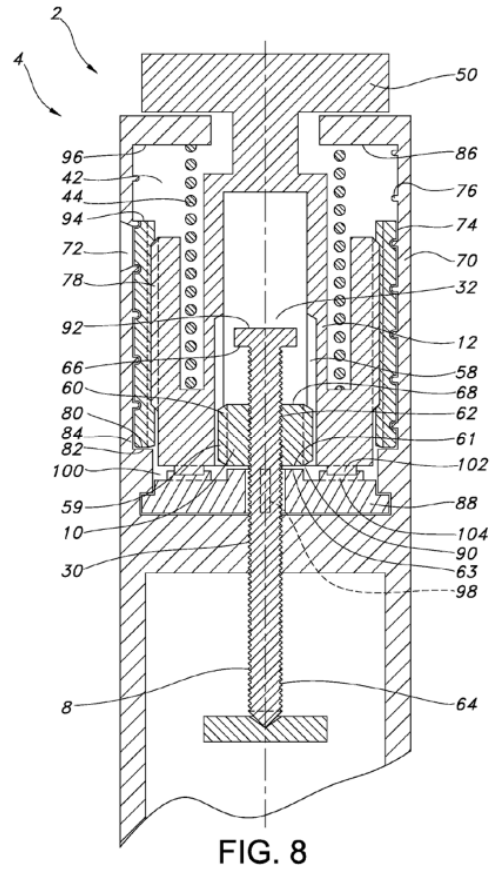


FIG. 1

End-of-content patents, Fig.1 (annotated with color). Defendants’ limited scope of “housing” should be rejected.

d. Defendants’ Sur-Reply Position

Plaintiffs’ construction ignores the plain meaning of housing, i.e., the exterior shell of a device. As shown in the figures below, the only embodiments describing a housing require it to encompass specifically recited components, including the scale drum (or drum scale) **70**, via a threaded inner surface **76** of the housing; the limiter **10**; the driver **12**; and the piston rod **8**. Ex. B at JA32, JA35, JA36).



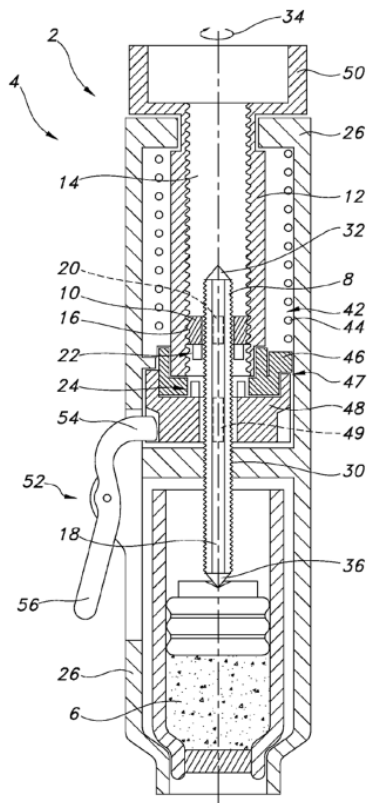


FIG. 4

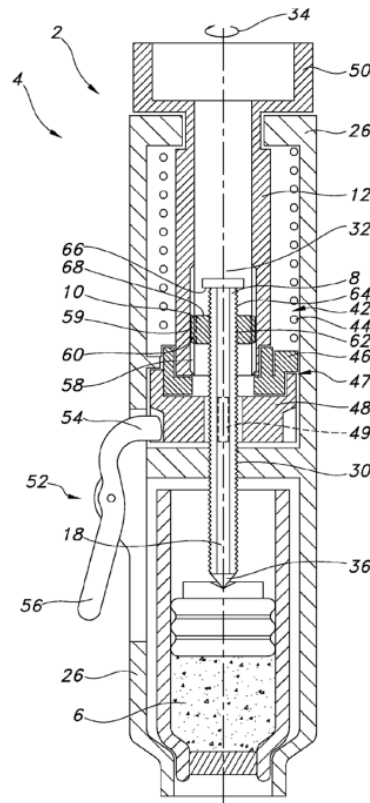


FIG. 7

Defendants' construction more closely aligns with the actual disclosure and intrinsic evidence and should be adopted here. *Medicines Co. v. Mylan, Inc.*, 853 F.3d 1296, 1309 (Fed. Cir. 2017); *Howmedica*, 822 F.3d at 1321.

5. "Coupled"

a. Novo Nordisk's Opening Position

"Coupled" means that the two components are "physically connected and either move together or remain connected while one component moves." The end-of-content patents use "coupled" in the claims to describe the connections between various components, including dose setting member and driver; driver and limiter;

and limiter and piston rod. Sometimes these components are connected such that they must move together. For example, when the dose setting member turns, in either direction, the driver turns as well. '383 patent, 5:7-11 (Ex. B at JA039). But a person of ordinary skill in the art would understand that other couplings described in the patent do not *require* the components to move together at all times. For example, a threaded connection between the driver and limiter permits the driver to rotate independently of the limiter and piston rod during dose setting. Or, a tongue-and-groove connection between the limiter and piston rod permits the piston rod to “translate,” i.e., move along the device’s longitudinal axis, while the limiter does not. Whether the components move together or independently depends on the force applied and the type of coupling, but in any case, the components remain connected.

Defendants contend that “coupled” means “engagement between two parts to exert a rotational torque but not a translational force.” That construction improperly limits “coupled” to only certain forms of engagement and introduces ambiguity as certain couplings, such as threaded connections that the patents describe and the claims cover, may or may not exert a “translational force,” a term that is itself ambiguous in the context of the claims. Defendants’ construction is thus improperly narrow and inappropriately introduces ambiguity into the claim.

b. Defendants' Answering Position

Based on “the words of the claims themselves [and] the remainder of the specification” (*Phillips*, 415 F.3d at 1313) as well as extrinsic evidence” (*id.* 1317), the Court should adopt Defendants’ construction of “coupled.”

The Device Patents relate to the field of mechanical injection devices. Here, “coupled” is known to mean an engagement “unable to produce any translatory motion (i.e., motion in a straight line)[,] [b]ut [one that] produces a motion of rotation in the body, on which it acts.” EX8 (Khurmi) at 49 (JA463); *see also* Leinsing Decl. ¶¶51-52 (JA514-515) (consistent definitions from EX6 (JA361), EX9 (JA470), EX10 (JA474)).

Consistent with a POSA’s understanding, Defendants’ construction explains that “coupled” means “engagement between two parts to exert a rotational torque, but not a translational force.” “Absent an express definition in the specification of a particular term, the words are given their ordinary and accustomed meaning; if a commonly-used term,” like coupled, is used, the term “is given the ordinary and accustomed meaning as understood by those of ordinary skill in the art.” *Zelinski v. Brunswick Corp.*, 185 F.3d 1311, at 1315 (Fed. Cir. 1999).

Rotational torque is a moment about the longitudinal axis exerted from one part to another. EX6 at 38 (JA349); EX7 at 95 (JA431); *see also* Leinsing Decl. ¶47 (JA509-510). Translational force is an axial force in a direction parallel to the

longitudinal axis. EX7 at 95 (JA431); *see also* Leinsing Decl. ¶47 (JA509-510). In other words, rotational torque is where applied force causes rotation about an axis, while translation is where applied force causes movement along the longitudinal axis. Leinsing Decl. ¶47 (JA509-510). Thus, when two parts are described as being “coupled,” this describes a particular engagement where, as a first part is rotated, it causes or exerts a rotational torque on a second part, without also exerting a translational force on the second part. *Id.*

The claims and corresponding two embodiments disclosed in the specification similarly and consistently use the term “coupled” to describe an engagement between two parts to exert a rotational torque, without imparting a translational force. *Id.* ¶¶48-50 (JA510-514). In claim 1 of both patents, “coupled” is used to describe the interaction between (i) the driver and the dose setting member; (ii) the limiter and driver; and (iii) the limiter and piston rod:

- i. For both embodiments, the specification explains that “[t]he driver is coupled to a dose setting member ... such that rotation of the dose setting member during dose setting, causes the driver to rotate in the same direction.” ’383 patent at 5:7-10, 6:42-45 (JA039); *see also id.* 6:24-26, 7:49-51 (JA039-040). When the dose setting member and driver rotate together, the dose setting member does not also exert a translational force on the driver that moves the driver along the longitudinal axis. Leinsing

Decl. ¶49(i) (JA511). In other words, the dose setting member only exerts a rotational torque on the driver. *Id.*

- ii. In the first embodiment, the driver and limiter are coupled in a threaded engagement, while in the second embodiment they are coupled in a splined engagement. '383 patent at 5:11-13, 6:46-48 (JA039). In both, the engagement causes the driver to exert a rotational torque on the limiter when the driver is rotated, but the driver does not also impart a translational force on the limiter that moves the limiter along the longitudinal axis. Leinsing Decl. ¶49(ii) (JA511-512).
- iii. In the first embodiment, the limiter and piston rod are coupled in a splined engagement, while in the second embodiment they are coupled in a threaded engagement. '383 patent at 5:13-19, 6:51-53 (JA039). Again, in both, the engagement causes the limiter to exert a rotational torque on the piston rod when the limiter is rotated, but the limiter does not also impart a translational force on the piston rod that moves the piston rod along the longitudinal axis. Leinsing Decl. ¶49(iii) (JA513-514).

In Claim 9 of the '953 patent, the term coupled describes the interaction between the driver and the first part of the ratchet mechanism interconnecting the driver and the housing. JA056. In both embodiments, the specification explains that “rotation is transferred to the driver 12 and the first part 46 of the ratchet

mechanism.” ’383 patent at 6:19-39, 7:44-65 (JA039-040). In other words, the driver exerts rotational torque on the first part of the ratchet mechanism, but not a translational force. Leinsing Decl. ¶50 (JA514).

Plaintiffs contend that Defendants’ construction introduces “ambiguity” into the claim. Novo Nordisk’s Opening Position at 21.¹² However, words like “coupled,” “rotational torque,” and “translational force” are commonly-used terms in this field, and readily understood by POSAs. Leinsing Decl. ¶54 (JA515-516). And the wealth of extrinsic evidence is consistent with Defendants’ construction, referring to terms like “translation” or “translatory motion.” *E.g.*, EX8 at 49 (JA463); EX10 (JA474); *see also* Leinsing Decl. ¶¶51-54 (JA514-516). Defendants’ construction is not “ambiguous” but rather easily understood by a POSA. *Id.*

Plaintiffs’ construction, however, is problematic. First, Plaintiffs use the word “coupling” to define “coupled.” “[U]sing a term to define itself is not helpful to the POSA.” *G.I. Sportz, Inc. v. Walken, Inc.*, 2019 WL 2724081 (D.N.J. June 30, 2019); *see also Huawei Techs. Co. Ltd. v. T-Mobile US, Inc.*, 2017 WL 2691227 (E.D. Tex.

¹² Defendants disagree that their construction is ambiguous, but propose the following compromise to remove reference to “translational force”: “engagement between two parts to exert a rotational torque, but not an axial force.” This compromise is supported by the specification for the same reasons discussed here. Leinsing Decl. n.4 (JA516).

June 22, 2017) (“the Court rejects Plaintiff’s construction because it uses the disputed term to define itself”). Second, Plaintiffs’ construction would encompass an engagement where one part exerts both a rotational and a translational force on another part. This is an “attached,” “snap-fit,” or “fixed” engagement, which is different from a “coupled” engagement. Leinsing Decl. ¶¶55-56 (JA516-517); ’383 patent at 3:32-33 (JA038). Third, Plaintiffs’ construction requires that the two pieces “move together.” This term itself is vague and ambiguous. For example, does this mean the pieces rotate together, translate axially together, or both? Defendants’ construction removes this ambiguity. Moreover, Plaintiffs concede that “a [POSA] would understand that other couplings described in the patent ***do not require*** the components to move together at all times.” Novo Nordisk’s Opening Position at 20 (emphasis added). Plaintiffs cannot square this concession with their construction that requires two pieces to “move together.”

c. Novo Nordisk’s Reply Position

Claim terms are given their plain and ordinary meaning as understood by a person of ordinary skill in the relevant field. *Phillips*, 415 F.3d at 1312-13. In the field of injection devices, a person of ordinary skill would understand that the term “coupled” is used to describe components that are connected either to move together axially and rotationally or to remain connected while one component moves. Cameron Decl. ¶¶32-39 (Ex. G at JA109-13); *see also, e.g.*, The Oxford English

Dictionary, definition of “Coupled” as “tied, joined, linked, or associated together in pairs” (Ex. J at JA234); *see also* U.S. Patent No. 6,235,004, 3:34-40 (Ex. K at JA243) (describing a dose button that is “coupled” to the dose scale drum in order to move the dose button axially with the dose scale drum and also rotate freely with respect to the dose scale drum).

Defendants’ construction, which limits “coupled” to engagements “between two parts to exert a rotational torque, but not a translational [or axial] force,” misapprehends how “coupled” is used by persons of ordinary skill and runs afoul of the intrinsic record. The claims of the end-of-content patents all recite that the driver is “coupled to the dose setting member.” ’383 patent, 9:54-56 (claim 1) (Ex. B at JA041); ’953 patent, 10:7-10 (claim 1) (Ex. C at JA056). The specification states that the dose setting member and driver “may be made as one single unit” or “may be made [as] two separate elements attached or coupled to each other.” ’383 patent, 3:28-33 (Ex. B at JA038). This disclosure indicates that while the dose setting member and driver of the invention can be designed as a single element or two separate ones, they should be able to move together both rotationally and axially. Cameron Decl. ¶¶34, 36-38 (Ex. G at JA112-13). Defendants’ restrictive interpretation, contrary to this disclosure, would prohibit such axial movement. *Id.*

Finally, in defense of his position, Dr. Leinsing attempts to explain the axial movement of the piston rod even though it is “coupled” to the limiter in Figure 5.

He suggests that even though “there is a resulting axial movement between the limiter and piston rod” that are coupled by a threaded connection, “there is no axial force being exerted between the parts.” Leinsing Decl. ¶49 (Ex. 12 at JA510-14). This is plainly wrong. The piston rod only moves axially by virtue of an axial force. Cameron Decl. ¶38 (Ex. G at JA112-13).

d. Defendants’ Sur-Reply Position

Defendants’ construction (and compromise construction) aligns with the intrinsic record of the Device Patents.¹³ Plaintiffs raise only two instances in the specification allegedly inconsistent with Defendants’ construction, but Plaintiffs are incorrect as to each.

First, Plaintiffs argue the dose setting member and driver “may be made as one single unit” or “may be made [as] two separate elements attached or coupled to each other” (’383 patent, 3:28-33 (JA038)), which they say means the components must move together both rotationally and axially. Plaintiffs misread this clear disclosure. Rather, the specification explains the dose setting member and driver **(i)** “may be made as one single unit;” or **(ii)** “may be made [as] two separate elements”

¹³ Extrinsic evidence is also consistent with the intrinsic record showing how a POSA would understand “coupled” (Leinsing Decl. ¶51 (JA514-515)), notwithstanding Plaintiffs’ expert’s contention that definitions for “couple” are irrelevant to the meaning of “coupled.” Cameron Decl. ¶35 (JA110-111).

either **(a)** “attached” (e.g., a snap fit) or **(b)** “coupled” to each other. *Id.* Thus, the specification expressly distinguishes “attached” from “coupled.” This supports Defendants’ construction and contradicts Plaintiffs’ construction.¹⁴

Second, Plaintiffs wrongly argue that the piston rod, which is coupled to the limiter, “moves axially by virtue of an axial force.” Novo’s Reply Position at 21-22. Consistent with Defendants’ construction, the piston rod is “coupled” to the limiter such that there is rotational torque, but not axial force, exerted between the parts. Leinsing Decl. ¶49(iii) (JA513-514). This concept is exemplified in a coupled engagement between a nut and screw:



When moving a nut along a screw, torque is applied to the nut. If the threads

¹⁴ Plaintiffs do not address many of Defendants’ critiques that their construction is divorced from the Device Patents, ambiguous, and uses the term itself.

on the screw were horizontal, the nut would spin, but not move axially. The axial movement only occurs because the threads are angled. Thus, because of the coupled engagement, exertion of a rotational torque, not an axial force, **results in an axial displacement**. EX11 at 7 (JA476) (explaining that screws convert “rotary to translational motion”). Similarly, the piston rod moves axially relative to the limiter but **not** by virtue of an axial force.¹⁵

6. “Piston Rod” and “The Piston Rod Rotates and Translates Axially Forward”

a. Novo Nordisk’s Opening Position

Novo Nordisk’s proposed constructions of these two related claim terms are consistent with their plain and ordinary meanings, as understood by one of ordinary skill in light of the patents’ specification. Defendants’ constructions create redundancy, import limitations from the specification, and add unnecessary complexity. The Court should therefore reject them.

The parties agree that a piston rod is a shaft, and that it is involved in causing the piston to move and therefore expel medication. While the term “piston rod”

¹⁵ Plaintiffs’ expert takes issue with the use of “coupled” in a different section of Defendants’ brief discussing the **piston** and piston rod. Cameron Decl. ¶36. ***To be clear, the Device Patents never describe the piston and piston rod as “coupled” because they are not.***

requires no construction, if the Court construes it, the term should be construed consistent with this plain meaning. Thus, Novo Nordisk proposes “piston rod” be construed as: “shaft that causes the piston to be moved such that the medicament is expelled.”

The '383 patent includes the related phrase, “the piston rod rotates and translates axially forward.” This phrase specifies how the piston rod moves during injection of a dose. First, the piston rod “rotates” on the device’s longitudinal axis, as shown in (for example) Figure 1 (orange):

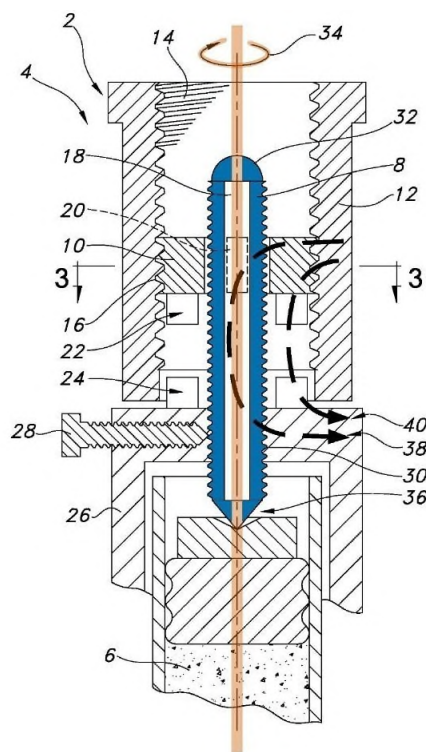


FIG. 1

Second, as a result of this rotation, the piston rod also “translates axially forward.” “Translates” means “moves,” and “axially” refers to the longitudinal axis of the device (*i.e.*, up and down the page in the image above). See ’383 patent, 5:17-19 (Ex. B at JA039) (“[T]he limiter and the piston rod may move translationally (*i.e.*, up and down in the figure) in relation to each other.”). Thus, Novo Nordisk proposes that this term be construed as: “the piston rod rotates and moves in the relative longitudinal direction that expels the medicament.”

Defendants’ complex constructions stand in stark contrast to Novo Nordisk’s straightforward proposals. First, Defendants seek to construe “piston rod” as: “a shaft which rotates and is translated axially within the syringe barrel in the distal direction to directly drive the plunger in the distal direction and thus expel medicament from the device.” Defendants’ construction also builds in components and concepts that do not appear in the claims or anywhere else in the intrinsic evidence, like “syringe barrel,” “plunger,” and “directly drive.” *Chaffin v. Braden*, 696 F. App’x 1001, 1007 (Fed. Cir. 2017) (holding limitation found “nowhere in the intrinsic record” was improperly read into claim term); *Galderma Labs., L.P. v. Sun Pharm. Indus. Ltd.*, 411 F. Supp. 3d 271, 315 n.14 (D. Del. 2019) (rejecting proposed construction found “nowhere in the intrinsic evidence”).

Additionally, Defendants’ construction of “the piston rod rotates and translates axially forward” builds in unnecessary limitations—specifically, it would

require the piston rod to “rotate relative to a housing.” Claim 1 of the ’383 patent, in which this term appears, does not require a housing. But dependent claims 2 and 3 do. Defendants’ construction would thus improperly import a limitation from those dependent claims into independent claim 1. *See, e.g., Trustees of Columbia Univ. in City of New York v. Symantec Corp.*, 811 F.3d 1359, 1370 (Fed. Cir. 2016) (“[T]he independent claim is not restricted by the added limitation in the dependent claim.”) (citing *Phillips*, 415 F.3d at 1314–15). Furthermore, nothing in the intrinsic evidence specifies that the piston rod’s rotation *must* be “relative to a housing.”

Furthermore, Defendants’ construction describes not only the piston rod, but how it moves, making it redundant of the separate claim term found in claim 1 of the ’383 patent (“the piston rod rotates and translates axially forward”). *Apple, Inc., v. Ameranth, Inc.*, 842 F.3d at 1238 (“[C]onstruing a claim term to include features of that term already recited in the claims would make those expressly recited features redundant.”).

b. Defendants’ Answering Position

(1) “Piston Rod”

Defendants’ construction is “a shaft which rotates and is translated axially within the syringe barrel in the distal direction to directly drive the plunger in the distal direction and thus expel medicament from the device.” Based on “the words of the claims themselves [and] the remainder of the specification” (*Phillips*, 415 F.3d

at 1314 (citation omitted)) as well as extrinsic evidence (*id.* 1317), the Court should adopt Defendants' construction.

(a) “a shaft...within the syringe barrel...to directly drive the plunger...and thus expel medicament from the device”

The parties agree, and the Figures show, that the structure of a piston rod includes a shaft. Novo Nordisk's Opening Position at 90; '383 patent at Figs. 1, 4, 5, 7, 8 (JA030, JA032-033, JA035-036). The parties also agree that a POSA would understand that the ordinary meaning of the term “piston rod” necessitates a corresponding “piston” that the rod acts upon to expel a medicament. Novo Nordisk's Opening Position at 90. The dictionary definition¹⁶ of the term “piston rod” also makes this clear, defining “piston rod” as “a rod or crankshaft attached to a piston to drive a wheel or to impart motion.”¹⁷ To find that the term “piston rod” does not require that it be coupled to a corresponding “piston” would render the word “piston” of “piston rod” meaningless. *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017); *Bicon, Inc. v. Straumann Co.*, 441 F.3d

¹⁶ “Within the class of extrinsic evidence, the court has observed that dictionaries and treatises can be useful in claim construction. We have especially noted the help that technical dictionaries may provide to a court.” *Phillips*, 415 F.3d at 1318 (citations omitted).

¹⁷ Oxford English Dictionary (emphasis added) (JA528).

945, 950 (Fed. Cir. 2006).

Reviewing the specification, to understand the claimed “piston rod,” a POSA must identify the structure(s) upon which the claimed piston rod must act. *Merck & Co. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1371 (Fed. Cir. 2003). A POSA would do so with an understanding of “piston”: *e.g.*, a “mechanical device consisting of a disc or cylindrical part attached to the end of a rod and fitting closely within a hollow cylinder or tube within which it can slide back and forth, so that it can impart motion to a fluid...”¹⁸

Each Figure that depicts an axial cross-sectional view of the claimed injector devices shows that the piston rod directly abuts a plunger within a syringe barrel. For example, annotated FIG. 1 below shows the piston rod (blue) directly acting on the plunger (green) positioned within the hollow cylinder of the syringe barrel (orange). The piston rod 8 rotates and translates forward (downward relative to the page) to cause the plunger (green element) to slide within the syringe barrel (orange element) and expel medication from the device. *See, e.g.*, ’383 patent at 5:47-52, 6:38-39, 7:9-14, 63-65, 9:38-41 (JA039-041).

¹⁸ Oxford English Dictionary (JA528).

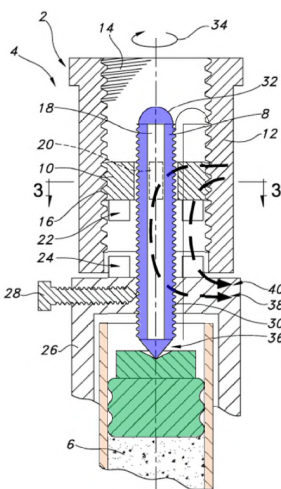


FIG. 1

The plunger, illustrated in each embodiment, is the only component described or shown in the intrinsic record that feasibly corresponds to this definition. The plunger is (1) cylindrical and (2) fits within a hollow cylinder (i.e., the syringe barrel) within which it can slide back and forth to (3) impart motion to a fluid (i.e., medicament). Similarly, the syringe barrel is the only component described or shown in the intrinsic record that feasibly corresponds to the “hollow cylinder” within which the plunger slides. A POSA would therefore understand that the “piston” on which the claimed “piston rod” acts is the plunger which slides within the syringe barrel. To construe “piston rod” without requiring that it directly drive the plunger is akin to construing “piston rod” without requiring that it directly drive any piston, which would render the word “piston” in “piston rod” meaningless. *Wasica*, 853 F.3d at 1288 n.10; *Bicon*, 441 F.3d at 950.

(b) The piston rod “rotates and translates axially ... in the distal direction”

The independent claims of the patents both require the piston rod (i.e., the shaft) to rotate and translate (“the piston rod rotates and translates axially forward”; “rotation of the piston rod...causes the piston rod to be displaced...in a longitudinal direction”). Further, the specification also repeatedly describes that the piston rod rotates and translates axially forward to eject a medicament. *See, e.g.*, ’383 patent at 5:50-52, 6:38-39, 7:63-65, 9:40-41 (JA039-041). Given the orientation of the piston rod with respect to the medicament and the piston (i.e., the plunger), the translation of the piston rod must be in the distal direction, i.e., toward the end of the injection device from which the medicament ejects. *Id.* 5:50-52, 7:12-14 (JA039-040) ; *see also id.* 5:38-46, Fig. 1 (JA030, JA039). Claim 1 of the ’383 patent further confirms this interpretation by requiring that the piston rod translate “axially forward” (corresponding to the “distal end”) to expel the medicament from the reservoir.

Therefore, Defendants’ construction of “piston rod” follows the description of the specification and claim language, and includes “a shaft which rotates and is translated axially within the syringe barrel in the distal direction to directly drive the plunger in the distal direction and thus expel medicament from the device.”

Plaintiffs contend that Defendants’ construction builds in components and concepts like “syringe barrel,” “plunger,” and “directly drive,” that do not appear in

the claims or the intrinsic evidence. Novo Nordisk’s Opening Position at 90. Yet it is Plaintiffs who have done this, not Defendants. Plaintiffs’ construction uses the generic term “piston”—a term with a wide range of definitions depending on the context and found nowhere in the claims, specification, or prosecution history. In contrast, Defendants’ construction focuses on features that are included in the intrinsic record as clearly and repeatedly in the drawings. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002) (“The words used in the claims are interpreted in light of the intrinsic evidence of record, including the written description, the drawings, and the prosecution history.” (emphasis added)). Despite Plaintiffs’ claims to the contrary, each of the “plunger,” “syringe barrel,” and piston rod “directly driving” the plunger is clearly and repeatedly shown in the Figures. See ’383 patent at Figs. 1, 4, 5, 7, 8 (JA030, JA032-033, JA035-036). Thus, Plaintiffs’ assertions are inaccurate.

(2) “The Piston Rod Rotates and Translates Axially Forward”

Defendants’ construction is “the piston rod rotates relative to a housing of the injection device and translates toward a distal end of the injection device through which the dose is administered during dose administration.” Based on “the words of the claims themselves [and] the remainder of the specification” (*Phillips*, 415 F.3d at 1314), the Court should adopt Defendants’ construction.

The purpose of this construction is to define the required movement of a piston rod to meet the piston-rod movement limitations of claim 1 of the '383 patent. Accordingly, construing this is not redundant with separately construing “piston rod.”

Claim 1 recites that the “piston rod rotates and translates axially forward during expelling of medication from the reservoir.” The claim therefore requires two distinct movements to expel medicament from the injection device: (1) rotation, and (2) translation axially forward.

(a) “Rotates” means “rotates relative to a housing of the injection device.”

This construction is supported by the claim language itself, the specification, and the prosecution history.

Claim 1 is directed to “a mechanism” of an injection device. A POSA would understand that the term “rotates” must describe movement of a specific component of the injection device relative to another component of the injection device. If this were not required, as Plaintiffs’ construction suggests, this claim limitation could be met by manually turning the entire injection device around its longitudinal axis. Such an interpretation is nonsensical. The term “rotates” therefore requires that there be another component that the piston rod rotate relative to. The specification and prosecution history confirm this.

The specification clarifies that the claimed “rotation” is “relative to the housing of injection device.” The description of FIG. 1 explains the piston rod 8 forms a threaded engagement 30 with the housing 26. ’383 patent at 5:31-32 (JA039). The description further explains “[d]ue to the threaded engagement 30 between the housing and the piston rod 8, the rotation of the piston rod causes the piston rod to move in the distal direction.” *Id.* 5:50-52 (JA039). For the “threaded engagement 30” between the piston rod 8 and the housing 26 to cause the piston rod to move in the distal direction, the piston rod 8 must rotate relative to the housing. That is, if the piston rod did not rotate relative to the housing, then the threaded connection between the piston rod and the housing could not “cause[] the piston rod to move in the distal direction.” *Id.* 5:50-52 (JA039). This same threaded engagement 30 between the piston rod 8 and the housing 26 is shown in every embodiment disclosed in the specification. *See, e.g., Id.* at Figs. 1, 4, 5, 7, 8 (threaded engagement 30) (JA030, JA032-033, JA035-036). Indeed, every embodiment of the claimed invention operates as described above, i.e., that the piston rod rotates relative to a housing via a threaded connection to drive movement of the piston rod in the distal direction. Accordingly, this term should require that the “rotation” is “relative to a housing of the injection device” as proposed by Defendants. *Alloc*, 342 F.3d at 1370.

The prosecution history further confirms that the claimed “rotation” is

“relative to the housing of the injection device.” In responding to a prior art-based rejection, Applicants argued that “the piston rod in [the prior art reference] is keyed to the housing so it cannot rotate as is required by the instant claims.”¹⁹ By Applicant’s own admission, having a piston rod “keyed to the housing” as taught by the prior art prevents the piston rod from rotating as required by the claims. And so, “rotates” as claimed means “rotates relative to the housing.”

**(b) “Translates axially forward” means
“translates toward a distal end of the
injection device through which the dose is
administered during dose
administration.”**

Defendants’ construction is supported by the claim language and the specification.

Claim 1 recites that the piston rod “translates axially forward during expelling of medication from the reservoir.” The use of the term “forward” imparts a specific directionality to this claim limitation. There are only two options for this specific direction: (1) toward a distal end of the injection device (i.e., end from which doses are ejected), or (2) toward a proximal end of the injection device (i.e., end opposite of the dose ejection). The claim cannot be construed so broadly as to encompass

¹⁹ NN-OZEM-000005667 (Applicants’ July 7, 2010 OA Response) (JA535) (emphasis added).

moving in either direction because that would render the term “forward” meaningless.²⁰ *Wasica*, 853 F.3d at 1288 n.10; *Bicon*, 441 F.3d at 950. Because the claim language itself recites that the forward movement occurs “during expelling of medication from the reservoir,” “forward movement” can only mean toward a distal end of the injection device through which the dose is administered during dose administration.

Moreover, the specification confirms that the term “translates axially forward” means “translates toward a distal end of the injection device through which the dose is administered during dose administration.” The specification uses the terms “forward” and “distal direction” interchangeably. *Compare* ’383 patent at 6:38-39 (JA039) (“rotation of the piston rod causes the piston rod to move forward”), and 9:40-41 (JA041) (“the rotating piston rod is forced to move forward and thus the medicament is expelled from the device”) with 5:50-52 (JA039) (“the rotation of the piston rod causes the piston rod to move in the distal direction”).

Further, the specification confirms that the forward/distal direction is toward the end of the injection device through which the dose is administered. The

²⁰ Plaintiffs’ construction (“moves in the relative longitudinal direction that expels the medicament”) does not define the specific direction of translational movement and therefore ignores the term “forward.”

specification identifies a “proximal end 32” of the piston rod as being oriented away from the end of the injection device through which medicament is ejected, and a “distal end 36” as being oriented toward the end of the injection device through which medicament is ejected. *Id.* Figs. 1, 4, 5, 7, 8 (JA030, JA032-033, JA035-036); *see also id.* 5:38-40 (JA039) (“In the initial state i.e. when the pen is delivered to the user, the limiter 10 is located in *proximal end 32 of the piston rod (i.e., the end opposite the needle of the syringe device.*” (emphasis added)). Thus, movement of the piston rod in the forward/distal direction is toward “the needle of the syringe device,” i.e., the end of the injection device through which the dose is ejected. *Id.* Further, both the claims and the specification specifically recite that the piston rod moves in the forward/distal direction as the dose is being injected. *See, e.g., id.* Claim 1 (JA041) (“translates axially forward during expelling of medication”), 5:49-52, 7:9-14 (JA039-040) (“when a dose is ejected...the rotation of the piston rod causes the piston rod to move in the distal direction), 9:40-41 (JA041) (“the rotating piston rod is forced to move forward and thus the medicament is expelled”) (emphases added).

Thus, the specification confirms that “translates axially forward” means “translates toward a distal end of the injection device through which the dose is administered during dose administration.”

c. Novo Nordisk's Reply Position

(1) "Piston Rod"

Injection device designs have long used piston rod/piston assemblies to expel medicine. The plain and ordinary meaning of "piston rod" follows from its regular use: "a shaft that causes the piston to move such that the medicament is expelled."

Defendants propose a construction that builds in multiple restrictions to the piston rod in relation to other components. Specifically, Defendants ask the Court to restrict the scope of "piston rod" to "a shaft which rotates and is translated axially within the syringe barrel in the distal direction." Defendants' Answering Position at 95.

The claims, however, already recite such details, making it unnecessary to import them from particular embodiments in the specification. *See RF Delaware, Inc. v. Pac. Keystone Techs., Inc.*, 326 F.3d 1255, 1264 (Fed. Cir. 2003) (rejecting proposed construction that would read other claim limitations into disputed term). In particular, claim 1 of the '383 patent recites that the piston rod "rotates and translates axially forward during expelling of medication." '383 patent, 9:49-50 (Ex. B at JA041). Since claim 1 is the only independent claim, this limitation carries through to all claims in the '383 patent.

Conversely, the claims of the '953 patent do not require that the piston rod rotate axially forward. '953 patent, 10:3-5 (Ex. C at JA056). Defendants'

construction is thus an improper attempt to rewrite the '953 patent claims to include such a requirement.

Defendants also propose that the piston rod must “directly drive” the piston (which Defendants also term “plunger”), suggesting that the end-of-content patents only describe piston rods in direct contact with the piston. Defendants’ Answering Position at 94-96. Defendants advance this argument by color coding Figure 1 to show the piston rod “directly acting on the plunger.” *Id.* at 91. As shown below, Defendants’ color coding misconstrues Figure 1, as the figure plainly has an intervening component (orange) between the piston rod (purple) and the piston (green). Cameron Decl. ¶40 (Ex. G at JA113-14).

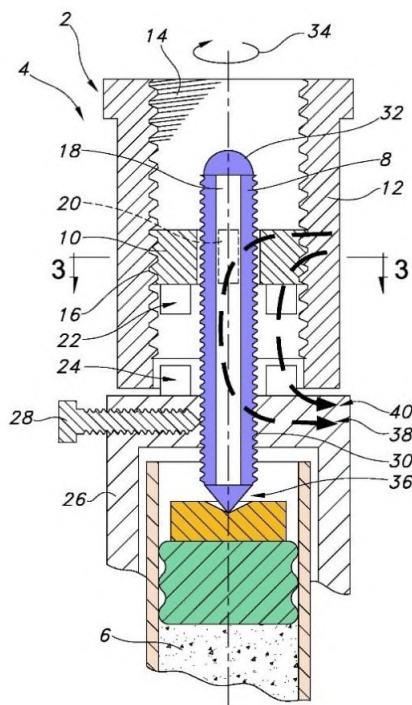


FIG. 1

End-of-content patents, Fig. 1 (annotated with color). The element colored in orange is known as a piston rod foot and is interposed between the piston rod and piston to distribute the force from the piston rod to the piston. Cameron Decl. ¶40 (Ex. G at JA113-14). This depiction, also shown in at least Figure 5, shows that for a number of embodiments, the piston rod of the end-of-content patents does not directly drive the piston.

(2) “The Piston Rod Rotates and Translates Axially Forward”

“The piston rod rotates and translates axially forward,” appears only in claim 1 of the ’383 patent. Novo Nordisk’s proposal is straightforward and consistent with the phrase’s plain meaning: “the piston rod rotates and moves in the relative longitudinal direction that expels the medicament.” Novo Nordisk’s construction aligns with the specification’s statement that when the piston rod “is forced to move forward ... the medicament is expelled from the device.” ’383 patent, 9:38-41 (Ex. B at JA041).

Defendants propose construing the piston rod’s movement “relative to the housing of the injection device.” Defendants’ Answering Position at 98. That phrase, however, is taken directly from claim 2 of the ’383 patent. ’383 patent, 10:5-12 (Ex. B at JA041) (“rotation of the piston rod in relation to the housing causes the piston rod to be displaced *relative to the housing* in a longitudinal direction”) (emphasis added). As a result, Defendants’ construction would elevate a dependent limitation of claim 2 to a requirement of all claims. *Liebel-Flarsheim Co.*, 358 F.3d at 910 (term of an independent claim should not be construed to include a dependent limitation).

The prosecution history does not support Defendants’ construction. See Defendants’ Answering Position at 98-99. During prosecution, Applicants’

statement that “the piston rod in Burroughs is keyed to the housing so it cannot rotate as is required by the instant claims,” is not a clear disclaimer, as is needed to narrow the claims under the law. *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1301-02 (Fed. Cir. 2003). Rather, Applicants’ statement only explains how one prior art design (Burroughs) does not meet the claimed scope. Earlier, when the claim language was added, Applicants explained that the claim “now require[s] that the piston rod rotate during dose administration” without tying that rotation to the housing. See Jan. 25, 2010 Response to Office Action at NN-OZEM-000005627 (Ex. L at JA254).

The parties appear to agree that “translates axially forward” means that the piston rod moves axially toward the end of the device that expels the medicament through the needle. Defendants’ Answering Position at 100-101. In light of this apparent agreement, Novo Nordisk offers the following compromise construction: “the piston rod rotates and moves axially toward the needle end that expels the medicament.”

d. Defendants’ Sur-Reply Position

(1) “Piston Rod”

Plaintiffs contend Defendants’ construction improperly “builds in multiple restrictions to the piston rod” because “[t]he claims...already recite such details.” Novo Nordisk’s Reply Position at 102. However, the independent claims of the ’383

and '953 Patents do not separately recite that the piston rod is “a shaft...within the syringe barrel...to directly drive the plunger.”²¹ Plaintiffs’ contentions are simply not true for this portion of Defendants’ construction. And while the terms “rotates and translates axially” (or equivalent limitations) are recited in the independent claims of the '383 and '953 Patents, use of these terms in Defendants’ construction does not introduce ambiguity.

Plaintiffs further allege the drawings do not show that the piston rod directly drives the piston because there is a “piston rod foot” positioned therebetween. Novo Nordisk’s Reply Position at 102-104. The “piston rod foot,” is a part of the “piston.” Therefore, the piston rod **does** directly drive the piston as proposed in Defendants’ construction, regardless of whether the piston rod abuts the piston rod foot or another portion of the piston.

Nevertheless, Defendants propose the following compromise construction for “piston rod” to address Plaintiffs’ concerns: “A shaft extending into the syringe barrel such that an end of the shaft drives the plunger in the distal direction to expel medicament from the device.”

²¹ As in Defendants’ Answering brief, it is proper to construe the term “piston rod” using structures shown in every embodiment of the Written Description and drawings. Defendants’ Answering Position at 91-94.

(2) “The Piston Rod Rotates and Translates Axially Forward”

Plaintiffs agree with Defendants on the meaning of “translates axially forward,” but object to Defendants’ construction of the term “rotates.” Novo Nordisk’s Reply Position at 105-106. Defendants do not agree with Plaintiffs’ overly broad construction of “rotates,” and propose separating the terms “rotates” and “translates axially forward” for construction.

Defendants propose construing “translates axially forward” as: “the piston rod moves axially toward the needle end that expels the medicament.” Other than removal of the term “rotates,” this construction is identical to Plaintiffs’ proposed compromise construction.

Plaintiffs’ construction for “rotates” remains overly broad because it fails to recognize the piston rod must rotate *relative to another component of the injection device*. If it did not, (1) the device would not be capable of dispensing a medicament, and (2) the “rotates” limitation could be met by turning the entire device about its longitudinal axis, as explained in Defendants’ Answering Position at 97. Plaintiffs have not addressed this.

Moreover, despite Plaintiffs asserting otherwise, the applicant’s comments during prosecution of the ’383 patent specify the piston rod rotates relative to another component of the device. The applicant’s statement that the “piston rod in

Burroughs is keyed to the housing *so it cannot rotate as required by the instant claims*” only distinguishes the claim from the prior art (Burroughs) if the claim requires the rotation be relative to another component of the device. Yet Plaintiffs now propose a construction that would read on the prior art they distinguished during prosecution, which is clearly improper. *Cordis Corp. v. Boston Sci. Corp.*, 658 F.3d 1347, 1356-57 (Fed. Cir. 2011). To avoid this improper result, the claimed rotation must be relative to another component of the device, which is the housing. Defendants’ Answering Position at 98. Nevertheless, to streamline claim construction, Defendants propose construing “rotates” as follows: “rotates relative to another component of the injection device.”

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