NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CHIESI USA INC., et al., ***Plaintiffs*,** **v.** **MSN PHARMACEUTICALS INC., et al.,** ***Defendants*.**	**Civil Action No. 19-18564** **OPINION**

ARLEO, UNITED STATES DISTRICT JUDGE

THIS MATTER comes before the Court by way of a joint application for claim construction pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996), presented by Plaintiffs Chiesi USA, Inc. and Chiesi Farmaceutici S.P.A. ("Plaintiffs") and Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Ltd., MSN Life Sciences Private Ltd. (collectively, "MSN"), Endo Procurement Operations Limited ("Endo"), and Gland Pharma Ltd. ("Gland" and together with MSN and Endo, "Defendants"). This Opinion contains the Court's construction of patent terms disputed by the Parties.

I. BACKGROUND

This consolidated action arises from Defendants' alleged infringement of eight patents owned by Plaintiffs related to injectable cangrelor, an antiplatelet drug marketed as Kengreal. Defendants have filed Abbreviated New Drug Applications ("ANDAs") seeking approval to market generic versions of cangrelor. Plaintiffs generally allege that the filing of the ANDAs, and any attempt to market products covered by the ANDAs, infringe upon eight patents owned by Plaintiffs: (1) U.S. Patent No. 9,295,687, Declaration of Hailey S. Verano ("Verano Decl.") Ex. B

(the "'687 Patent"), ECF No. 87.3; (2) Patent No. 9,439,921, id. Ex. C (the "'921 Patent"), ECF No. 87.4; (3) Patent No. 9,700,575, id. Ex. D (the "'575 Patent"), ECF No. 87.5; (4) Patent No. 10,039,780, id. Ex. E (the "'780 Patent") ECF No. 87.6; (5) Patent No. 9,925,265, id. Ex. F (the "'265 Patent"), ECF No. 87.7; (6) Patent No. 9,427,448, id. Ex. G (the "'448 Patent"), ECF No. 87.8; (7) Patent No. 8,680,052, id. Ex. H (the "'052 Patent"), ECF No. 87.9; and (8) Patent No. 6,130,208, id. Ex. I ("'208 Patent"), ECF No. 87.10 (collectively, the "Patents-in-Suit").

Plaintiffs initiated this action against MSN and Endo on September 30, 2019 through a Complaint alleging infringement of the '687, '921, '575, '780, '265, '448, and '052 Patents.[1] ECF No. 1. Separately, Plaintiffs brought two actions against Gland, collectively alleging infringement of each Patent-in-Suit. See Chiesi USA Inc. v. Gland Pharma Ltd., No. 19-18565 (D.N.J.); Chiesi USA Inc. v. Gland Pharma Ltd., No. 19-21204 (D.N.J.). Defendants have asserted counterclaims seeking declarations of invalidity and noninfringement with respect to each patent. See, e.g., ECF No. 11. On November 5, 2020, this Court consolidated Plaintiffs' suits against Gland with this action for purposes of discovery. ECF No. 79.

The Parties exchanged opening Markman briefs on January 22, 2021, ECF Nos. 86, 87, and responsive briefs on March 23, 2021, ECF Nos. 95, 96. The Court conducted a claims construction hearing on June 22, 2021. This Opinion follows.

II. LEGAL STANDARD

The meaning and scope of patent claims are questions of law to be decided by the Court. Markman, 517 U.S. at 372. "The words of a claim are generally given their ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips v. AWH Corp., 415 F.3d 1303, 1312-

[1] Plaintiffs do not allege infringement of the '208 Patent against MSN or Endo.

13 (Fed. Cir. 2005) (citation and quotation marks omitted). To ascertain a term's meaning, the Court looks first to "intrinsic evidence, including the claims themselves, the specification, and the prosecution history of the patent." Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc., 731 F.3d 1271, 1276 (Fed. Cir. 2013). In particular, a patent's specification is considered the "single best guide to the meaning of a disputed term," and "[u]sually, it is dispositive." Phillips, 415 F.3d at 1315 (citation and quotation marks omitted).

While "less significant" than the intrinsic record, the Court may also rely on "extrinsic evidence," i.e., "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Id. at 1317 (citation and quotation marks omitted). The Federal Circuit has specifically endorsed the use of technical dictionaries to permit a court "to better understand the underlying technology and the way in which one of skill in the art might use the claim terms." Id. at 1318 (citation and quotation marks omitted). But extrinsic evidence may not be used to "vary" or "contradict" the terms of a claim, and it should be discounted where "clearly at odds with the [intrinsic evidence]." Key Pharms. v. Hercon Lab'ys Corp., 161 F.3d 709, 716 (Fed. Cir. 1998).

III. ANALYSIS

The Parties have proposed the following patent terms for construction:

<table>
<tr><th colspan="3"><u>Plaintiffs' Proposed Terms</u></th></tr>
<tr><td><u>Disputed Term</u></td><td><u>Plaintiffs' Construction</u></td><td><u>Defendants' Construction</u></td></tr>
<tr><td>"(a) dissolving cangrelor or a salt thereof in a solvent to form a first solution"
'687 Patent, claims 1-24</td><td>"dissolving cangrelor in a solvent or a solvent mixture to form a cangrelor solution"</td><td rowspan="2">"dissolving cangrelor or a salt thereof in a solvent to form a first solution containing cangrelor, followed by mixing a pH-adjusting agent with the first solution containing cangrelor to form a second (i.e., compounding) solution with a pH between about 7.0 and 9.5."</td></tr>
<tr><td>"(b) mixing a pH-adjusting agent with the first solution to form a second solution, wherein the pH of the second solution is between about 7.0 and 9.5"
'687 Patent, claims 1-24</td><td>"mixing a pH-adjusting agent with a cangrelor solution (either added to the other, simultaneously, or a combination thereof) to form a compounding solution, wherein the pH of the compounding solution is between about 7.0 and 9.5"</td></tr>
<tr><th colspan="3"><u>Defendants' Proposed Terms</u></th></tr>
<tr><td><u>Disputed Term</u></td><td><u>Plaintiffs' Construction</u></td><td><u>Defendants' Construction</u></td></tr>
<tr><td>"treating"
'448 Patent, claims 1-14
'265 Patent, claims 1, 5, 7
'780 Patent, claims 1-23</td><td>"to manage a disease by medicinal, surgical, or other measures; to care for a patient medically or surgically"</td><td>"providing medication to cure or heal after onset of a disease or condition"</td></tr>
<tr><td>"preventing"
'448 Patent, claims 1-14
'265 Patent, claims 5, 26</td><td>"action so as to avoid, forestall, or circumvent a happening, conclusion, or phenomenon (<u>e.g.</u>, disease)"</td><td>"keeping an event from happening"</td></tr>
<tr><td>"chronic treatment"
'052 Patent, claims 1-12, 22-30</td><td>This term does not require construction, as it is non-limiting. To the extent construction is required:
"chronic" means "referring to a health-related state, lasting a long time,"
"treatment" means "medical or surgical management of a patient"</td><td>"treatment on a long term, ongoing basis"</td></tr>
</table>

"**high purity cangrelor**" '687 Patent, all claims '921 Patent, all claims '575 Patent, all claims '780 Patent, all claims	"cangrelor and one or more salts thereof having low levels of impurities"	"Cangrelor and the recited hydrolysis and oxidation degradants of cangrelor in the recited amounts, which is formed by a process including the steps of dissolving cangrelor in a solvent or solvent mixture to form a first solution containing cangrelor, followed by mixing a pH-adjusting agent with the first solution containing cangrelor to form a second (i.e. compounding) solution, and removing the solvent from the second (i.e. compounding) solution."[2]
"**a pharmaceutical formulation consisting of . . . mannitol and/or sorbitol as a pharmaceutically acceptable excipient**" '780 Patent, claims 7-13, 18-23 '687 Patent, claims 14-24 '575 Patent, claims 14-26 '921 Patent, claims 14-26	"a pharmaceutical formulation consisting of high purity cangrelor, or a salt thereof, as an active ingredient and mannitol or sorbitol, or both mannitol and sorbitol"	"a pharmaceutical formulation with high purity cangrelor or a salt thereof as an active ingredient and either mannitol or sorbitol (but not both) as a pharmaceutically acceptable excipient"
"**glass forming additives**" '208 Patent, claims 1-9	"sucrose, trehalose, lactose, sorbitol, dextran, PVP, or a sugar or polymer with a Tg above room temperature, especially above 50°C, in the dried state"	"agents which have a glass transition temperature of above room temperature"[3]

See Pl. Opening Br. at 6-22, 24-26; Def. Opening Br. at 8-14, 22-34, 38-40. The Court addresses each disputed term in turn.[4]

[2] This construction of "high purity cangrelor" is proposed only by MSN and Endo.

[3] This construction of "glass forming additives" is proposed only by Gland.

[4] Defendants also contend that several claim terms are indefinite. See Pl. Opening Br. at 22-23, 27-30; Def. Opening Br. at 14-22, 34-38. The Court will defer consideration of those arguments for the reasons discussed infra Section III.C.

A. Plaintiffs' Proposed Terms

Plaintiffs request construction of two terms within the '687 Patent, which claims the following formulation for "high purity cangrelor":

> A pharmaceutical formulation comprising high purity cangrelor, or a salt thereof, as an active ingredient and one or more pharmaceutically acceptable excipients prepared by a method comprising:
>
> > (a) dissolving cangrelor or a salt thereof in a solvent to form a first solution;
> >
> > (b) mixing a pH-adjusting agent with the first solution to form a second solution, wherein the pH of the second solution is between about 7.0 and 9.5; and
> >
> > (c) removing the solvent from the second solution to produce high purity cangrelor or a salt thereof under conditions wherein a level of moisture of less than about 2.0% by weight is achieved, . . .

'687 Patent at 41:55-67. The Parties principally dispute whether this claim requires steps (a) and (b) to be performed in a certain order. Plaintiffs contend that despite the use of ordinal numbers, the term "the first solution" in step (a) means "a cangrelor solution," while the term "the second solution" in step (b) means "a compounding solution." Defendants counter that the use of the terms "first" and "second" shows that step (a) must be performed before step (b), and that the specific solution formed in step (a) must be mixed in step (b). The Court agrees with Defendants.

A process claim is properly limited "to a certain order of steps" where "the claim language logically requires that the process steps . . . be performed in sequence." Amgen Inc. v. Sandoz Inc., 923 F.3d 1023, 1028 (Fed. Cir. 2019). Here, as a matter of logic, before the first solution may be "mixed" in step (b), it must first be "formed" in step (a). The plain language of the Patent provides no alternative method to obtain the first solution.

Plaintiffs make two unavailing arguments in support of their proposed construction. First, they argue that the '687 Patent specification uses the terms "first solution" and "cangrelor solution" interchangeably. Following a detailed description of the step (a) dissolving process, the specification provides: "The solution resulting from dissolving cangrelor in the solvent is referred to here as the 'cangrelor solution' or alternatively the 'first solution.'" '687 Patent at 17:15-17. The Court disagrees, however, that the specification's use of the phrase "the cangrelor solution" can support Plaintiffs' preferred construction of "a cangrelor solution." See Wi-Lan, Inc. v. Apple, Inc., 811 F.3d 455, 462 (Fed. Cir. 2016) ("Subsequent use of the definite articles 'the' or 'said' in a claim refers back to the same term recited earlier in the claim.") (citation omitted). Elsewhere, the specification confirms that "the cangrelor solution" should be mixed with a pH-adjusting agent in step (b). See '687 Patent at 18:29-36. Thus, whether referred to as "the first solution" or "the cangrelor solution," the result is the same. The solution formed in step (a) is the same solution that must be mixed with a pH-adjusting agent in step (b).

Second, Plaintiffs argue that the specification's discussion of alternate methods to complete the step (b) mixing process supports their proposed construction. Here, the specification provides:

> The pH-adjusting agent may . . . be mixed with the cangrelor Solution to form a compounding solution (also referred to herein as a "second solution"). This mixing may occur by adding the pH-adjusting agent to the cangrelor solution. Alternatively, the cangrelor solution may be added to the pH-adjusting agent, or the pH-adjusting agent and the cangrelor Solution may be added simultaneously (into a separate vessel), or there may be a combination of these addition methods.

'687 Patent at 18:29-36. As Defendants correctly observe, however, this language merely discusses ways to mix the first and second solutions in step (b), and sheds no light on the separate question of whether step (a) must precede step (b). Again, before the cangrelor solution may be

"mixed" with the adjusting agent using any of the above methods, it must first be "formed" in step (a).

The Court therefore adopts the following construction:

Disputed Terms	Adopted Construction
"(a) dissolving cangrelor or a salt thereof in a solvent to form a first solution" **"(b) mixing a pH-adjusting agent with the first solution to form a second solution, wherein the pH of the second solution is between about 7.0 and 9.5"** '687 Patent, claims 1-24	"(a) dissolving cangrelor or a salt thereof in a solvent to form a first solution containing cangrelor, followed by (b) mixing a pH-adjusting agent with the first solution to form a second solution with a pH between about 7.0 and 9.5."

B. Defendants' Proposed Terms

1. "treating" and "preventing"

Defendants contend that the words "treating" and "preventing" embody two wholly distinct concepts and should be construed so that each term has an independent definition, without any overlap. Plaintiffs, on the other hand, maintain that these terms should be given their plain and ordinary meaning. Plaintiffs propose constructions drawn directly from a technical medical dictionary and argue that any overlap between "treating" and "preventing" is irrelevant. The Court agrees with Plaintiffs.

Unless the patentee unequivocally imparted a "novel meaning" to a term, the Court must "indulge a 'heavy presumption' that claim terms carry their full ordinary and customary meaning." Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323 (Fed. Cir. 2003) (citations omitted). In turn, the Court may ascertain the ordinary "meaning of particular terminology" by reference to technical dictionaries. Phillips, 415 F.3d at 1318. Here, Defendants thus have the burden to demonstrate why the evidence supports their preferred construction. They have failed to do so.

Defendants first maintain that because the Patents-in-Suit distinguish between the terms "treating," "preventing," and "reducing the incidence of," each of these terms must therefore have an independent meaning. See, e.g., '448 Patent at 53:53-56. (claiming "[a] method of treating, reducing the incidence of, or preventing an ischemic event in a patient undergoing percutaneous coronary intervention (PCI)"). Typically, the use of "different terms" in a claim "connotes different meanings." Bd. of Regents of the Univ. of Tex. Sys. v. BENQ Am. Corp., 533 F.3d 1362, 1371 (Fed. Cir. 2008) (citation and quotation marks omitted). Yet a mere "overlap" amongst terms in a party's favored construction "is not fatal, nor does it compel [the Court] to adopt an otherwise unsupported construction of the claims." L.A. Biomedical Rsch. Inst. at Harbor-UCLA Med. Ctr. v. Eli Lilly & Co., 849 F.3d 1049, 1063 (Fed. Cir. 2017); cf. Bd. of Regents of the Univ. of Tex. Sys., 533 F.3d at 1368 (observing that the terms "word" and "syllabic element" were not "coextensive" and construing "syllabic element" as "[a] one-syllable letter group that either comprises a word or can be combined with other one-syllable letter groups to form a word").

Here, the Court is satisfied that Plaintiffs' proposed interpretation of "treating" and "preventing" sufficiently distinguishes between the terms. For example, as Defendants observe, "treating" includes the concept of care after a disease or condition has manifested, whereas under either party's construction, a condition can only be "prevented" before it has occurred. Def. Responsive Br. at 21. Consequently, any overlap is not fatal to Plaintiffs' construction.

With regards to "treating," Defendants argue that treatment must occur "after onset of a disease or condition," and be designed "to cure or heal." Def. Opening Br. at 9. Plaintiffs favor a broader construction drawn from Steadman's Medical Dictionary: "to manage a disease by medicinal, surgical, or other measures; to care for a patient medically or surgically." Pl. Opening Br. at 13. Beyond the fact that the Patents distinguish between "treating" and "preventing"—

which the Court finds inapposite for the reasons expressed above—Defendants present no basis to conclude that "treating" must in all cases (a) occur "after the onset" of a condition or (b) be designed to "cure or heal" the condition, excluding actions that merely "manage" the condition.[5] Cf. Amag Pharm., Inc. v. Sandoz, Inc., No. 16-1508, 2017 WL 3076974, at *22 (D.N.J. July 19, 2017) ("Generally, for a negative limitation to be recited in a claim language, the specification should expressly recite the negative limitation.") (citation omitted). The Court will therefore adopt Plaintiffs' construction as the plain and ordinary meaning of "treating."

With regards to "preventing," Plaintiffs again rely on a definition pulled directly from Steadman's Medical Dictionary: "action so as to avoid, forestall, or circumvent a happening, conclusion, or phenomenon (e.g., disease)." Pl. Opening Br. at 16. Defendants take issue with the word "forestall," which they argue improperly "implies a delay, but not a complete aversion, of an event." Def. Opening Br. at 13. Again, no evidence suggests that "preventing" in the context of the Patents-in-Suit excludes the concept of "forestalling" (beyond the inconsequential threat of overlap with other terms).

Defendants further maintain that their construction is required because the '448 Patent "equates 'preventing' with prophylaxis." Id. But as the medical definition of "prophylaxis" is "[p]revention of disease or of a process that can lead to disease," Verano Decl. Ex. O at CHI KEN 9245028, this comparison leads the Court in a circle. Defendants' citation to the McGraw-Hill Medical Dictionary is similarly unhelpful, as it merely defines "preventative" as "intended to prevent disease." Quinn Decl. Ex. P at JDG_CANG_0005948. On the other hand, Plaintiffs have identified several instances where the relevant specifications contemplate the "prevention" of an

[5] Defendants' citation to the McGraw-Hill Medical Dictionary for Allied Health does not support these limitations. See Quinn Decl. Ex. P at JDG_CANG 0005949 (defining "treat" as "to deal with a patient or a disease in a manner designed to cure or alleviate the problem") (emphasis added).

event for a certain period, but not necessarily indefinitely. See '265 Patent at 17:38-41 ("[Cangrelor] may thus be administered to a subject to prevent myocardial infarction for about 1, 2, 3, 4, 5 or more hours after early or initial symptoms of myocardial infarction are detected."); id. at 8:47-51 (explaining that in certain embodiments of the invention, "the prevention of stent thrombosis may be prevention in the course of stent implantation during percutaneous coronary intervention (PCI) or other vascular stent implantation procedure"); '448 Patent at 2:61-63 ("The method of the present invention may treat, reduce the incidence of, and/or prevent an ischemic event during or after PCI.") (emphasis added).

In short, there is no basis to depart from the plain and ordinary meaning of "preventing," which includes the concept of "forestalling." The Court therefore adopts the following constructions:

Disputed Terms	Adopted Construction
"**treating**" '448 Patent, claims 1-14 '265 Patent, claims 1, 5, 7 '780 Patent, claims 1-23	"to manage a disease by medicinal, surgical, or other measures; to care for a patient medically or surgically"
"**preventing**" '448 Patent, claims 1-14 '265 Patent, claims 5, 26	"action so as to avoid, forestall, or circumvent a happening, conclusion, or phenomenon (*e.g.*, disease)"

2. "chronic treatment"

Defendants next ask the Court to construe the phrase "chronic treatment" in the '052 Patent as "treatment on a long term, ongoing basis." Def. Opening Br. at 22. Plaintiffs counter that this term need not be construed because it appears only in the preamble of claims and does not limit the scope of the '052 Patent. The Court agrees with Plaintiffs.

Claim 1 of the '052 Patent provides:

> A method of transitioning a patient from administration of cangrelor during percutaneous coronary intervention (PCI) to administration of ticagrelor for chronic treatment, the method comprising:
>
> > (1) administering intravenously a 30 μg/kg bolus of cangrelor before the start of PCI;
> >
> > (2) administering intravenously a 4 μg/kg/min continuous infusion of cangrelor after administration of the bolus;
> >
> > (3) continuing the administration of the continuous infusion for the longer of (a) at least two hours, or (b) the duration of PCI; and
> >
> > (4) administering an oral dose of ticagrelor either (a) during administration of the continuous infusion, or (b) after discontinuation of the administration of the continuous infusion, wherein the oral dose comprises a 180mg loading dose of ticagrelor[.]

'052 Patent at 67:2-17 (emphasis added). Claim 8 further provides:

> The method of claim 1, wherein the method further comprises administering one or more oral doses of ticagrelor subsequent to the loading dose.

Id. 67:33-35.

Generally, language in a preamble does not limit the scope of the claim, particularly where it "merely states the purpose or intended use of an invention," or "is duplicative of the limitations in the body of the claim and merely provides context for the limitations." Summit 6, LLC v. Samsung Elecs. Co., 802 F.3d 1283, 1292 (Fed. Cir. 2015) (citations omitted). However, "a preamble limits the [claimed] invention if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality' to the claim." Eaton Corp. v. Rockwell Int'l Corp., 323 F.3d 1332, 1339 (Fed. Cir. 2003) (citation and quotation marks omitted). This occurs, for instance, "[w]hen limitations in the body of the claim rely upon and derive antecedent basis from the preamble;" in such case, "the preamble may act as a necessary component of the claimed invention." Id. Preamble language may also be limiting if it "recit[es] additional structure or steps

underscored as important by the specification." Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808 (Fed. Cir. 2002).

The Court finds the term "chronic treatment" to be non-limiting because it merely helps describe the purpose and intended use of the invention—to transition from the administration of cangrelor during PCI to the administration of ticagrelor for chronic treatment. Initially, "chronic treatment" does not provide an antecedent basis for terms used in the body of the claim. The only allusions to "chronic treatment" outside the preamble discuss specifically defined actions, namely, the administration of an oral "loading dose" of ticagrelor, to be in some cases followed by "one or more oral doses of ticagrelor subsequent to the loading dose." '052 Patent at 67:17, 34-35. The meaning of these claimed steps can be ascertained without reference to the preamble, and any additional "chronic treatment" that occurs thereafter falls outside the parameters of the patent.

Moreover, nothing in the specification suggests that the inventor viewed the scope of "chronic treatment" as important to the invention. Defendants point to two provisions that largely reiterate the invention's purpose, as stated in the preamble. See '052 Patent at 3:12-17 ("An aspect of the invention is directed to a method of transitioning a patient undergoing PCI from administration of cangrelor during PCI to administration of a chronic or maintenance treatment of a $P2Y_{12}$ inhibitor . . . .); id. at 9:5-10 ("[A]dministering the P2Y-receptor inhibitor . . . in a patient undergoing PCI may also transition the patient to chronic or maintenance treatment with the P2Y-receptor inhibitor.") (emphasis added). These excerpts do not demonstrate that the patentee intended "chronic treatment" to have a limiting effect. If anything, the inclusion of the additional phrase "maintenance" treatment in the specification suggests an intent to encompass a broader application, bounded only by the specifically claimed limitations recited above.

Defendants' cited cases are unavailing. In Jansen v. Rexall Sundown, Inc., the Federal Circuit found the preamble language "a method of treating or preventing macrocytic-megaloblastic anemia in humans" limiting because the body of the claim referred to administration on a patient "in need thereof." 342 F.3d 1329, 1330 (Fed. Cir. 2003). A person of ordinary skill in the art therefore could not determine what a patient was "in need of" without reference to the preamble. Id. Here, by contrast, no language in the relevant claims refers back to the preamble.

Likewise, in Purdue Pharm. Prod., L.P. v. Actavis Elizabeth, LLC, the court found the preamble clause "a solid unit dosage composition for the treatment of MOTN insomnia" limiting based on language in the body stating that the composition was comprised of "an effective amount of Zolpidem." No. 12-5311, 2014 WL 2624787, at *6 (D.N.J. June 11, 2014), aff'd, 627 F. App'x 931 (Fed. Cir. 2016). Consequently, a person of ordinary skill in the art's understanding of the "effective amount" of Zolpidem was dependent on what specific ailment the composition was intended to treat. Id. On the other hand, the '052 Patent outlines specific dosages for each phase of the transition that require no further interpretation.

Finally, in Pacing Technologies, LLC v. Garmin International, Inc., the Federal Circuit found the preamble "[a] repetitive motion pacing system for pacing a user" limiting because the terms "repetitive motion pacing system" and "user" were recited as positive limitations in the body of the claim. 778 F.3d 1024 (Fed. Cir. 2015). Here, the term "chronic treatment" appears only in the preamble.

For these reasons, the Court finds the term "chronic treatment" non-limiting and declines to construe it.

3. "high purity cangrelor"

MSN and Endo[6] further argue that the term "high purity cangrelor" found in the '687, '921, '575, and '780 Patents (collectively the "High Purity Patents") must be limited to the process for making "high purity cangrelor" recited in the specification. The Court agrees.

The Court again begins by examining the language of the relevant claims. As discussed supra Section III.A, the '687 Patent claims "[a] pharmaceutical formulation comprising high purity cangrelor . . . prepared by a method comprising:" (a) dissolving cangrelor in a solvent to form a first solution; (b) mixing in a pH-adjusting agent to form a second solution; and (c) removing the solvent from the second solution. '687 Patent 41:55-67. As an "explicit process-based limitation," these steps properly define the term "high purity cangrelor" for purposes of the '687 Patent.[7] See Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1371 (Fed. Cir. 2007).

The remaining High Purity Patents require closer examination. The '921 and '575 Patents each claim "[a] pharmaceutical formulation comprising high purity cangrelor," wherein the formulation has certain characteristics related to moisture, pH, and degradants. See '921 Patent at 43:12-47:10; '575 Patent at 43:28-47:47. But unlike the '687 Patent, the '921 and '575 Patents explicitly claim only an end product. The claims do not explain the process for producing "high purity cangrelor" and do not otherwise define that term. Similarly, the '780 Patent claims only a method of "administering . . . an effective amount of a pharmaceutical formulation comprising high purity cangrelor." '780 Patent at 42:3-48:30. Again, the '780 Patent describes certain

[6] Gland does not join in this argument and instead maintains that the term "high purity cangrelor" is indefinite. As discussed infra Section III.C, the Court defers consideration of this argument.

[7] Each subsequent reference to "high purity cangrelor" in the '687 Patent appears in a claim dependent on the process steps noted above. For example, after reciting the steps, claim 1 provides that "the high purity cangrelor or salt thereof has a combined total of selected hydrolysis and oxidation degradants of cangrelor not exceeding about 1.5% by weight of the high purity cangrelor." Therefore, the Court need not interpret "high purity cangrelor" as used in the '687 Patent separately from the process steps defined in Section III.A.

characteristics of the required "high purity cangrelor" but does not expressly require a process for generating it. The Court must therefore examine the intrinsic evidence to determine whether to import a process-based limitation into the '921, '575, and '780 Patents. See Andersen Corp., 474 F.3d at 1371.

Generally, "product claims are not limited to the methods of manufacture disclosed in the specification." Id. at 1375 (citing Vanguard Prods. Corp. v. Parker Hannifin Corp., 234 F.3d 1370, 1372-73 (Fed. Cir. 2000)). "However, process steps can be treated as part of a product claim if the patentee has made clear that the process steps are an essential part of the claimed invention." Id. The specification must contain an "expression[] of manifest exclusion or restriction, representing a clear disavowal of claim scope" to justify a limiting construction. Cont'l Cirs. LLC v. Intel Corp., 915 F.3d 788, 796-97 (Fed. Cir. 2019). Language that merely describes a suggested or preferred method for manufacturing a product does not act as a disavowal of claim scope. Id. at 798. To differentiate these two scenarios, the wording used by the patentee is critical. "Language of requirement" often suggests disavowal, while language of "preference" does not. Andersen Corp., 474 F.3d at 1372; see also Cont'l Cirs. LLC, 915 F.3d at 797 ("[P]hrases such as 'one technique,' 'can be carried out,' and 'a way' indicate that [a recited process] is only one method for making the invention and does not automatically lead to finding a clear disavowal of claim scope.").

The High Purity Patents share a common specification. See '921 Patent at 1:14-43:10; '575 Patent at 1:16-43:10; '780 Patent at 1:17-41:67; '687 Patent at 1:6-41:53; see also Pl. Opening Br. at 12 n.8.[8] Under the heading "DETAILED DESCRIPTION," this specification provides a

[8] For this reason, the Court hereafter cites only to the specification for the '921 Patent when addressing issues common to the High Purity Patents.

broad explanation of the "present invention" that discusses, inter alia, the production of high purity cangrelor, the resulting formulations, and uses for high purity cangrelor. See '921 Patent at 12:61-37:21. The Federal Circuit has observed that statements in a common specification may limit claim language where the statements do not simply "describe[e] a preferred embodiment, but more broadly describe the overall inventions of all [underlying] patents." Andersen Corp, 474 F.3d at 1368 (citing Microsoft Corp. v. Multi–Tech. Sys., Inc., 357 F.3d 1340, 1348 (Fed. Cir. 2004)).

Here, an examination of the common specification reveals that a process for producing high purity cangrelor is an essential piece of the underlying inventions. Initially, the patentee noted that "[h]igh purity cangrelor, and salts thereof, and pharmaceutical formulations comprising the same are produced using a novel compounding process." '921 Patent at 15:52-55 (emphasis added). The emphasized phrase in the common specification is language of requirement that provides for no alternate method of producing high purity cangrelor besides a "novel compounding process."

The specification then describes particular steps required by "the compounding process of the present invention," which are likewise presented in mandatory terms. Id. at 15:57-60; see Baxter Healthcare Corp. v. HQ Specialty Pharma Corp., 133 F. Supp. 3d 692, 700 (D.N.J. 2015) (holding that disavowal may be found through language such as "the present invention includes," and "the present invention is"). First, "cangrelor is dissolved in a solvent or a solvent mixture to form a cangrelor solution." '921 Patent at 15:55-60. Second, "[t]he compounding process further comprises mixing a pH-adjusting agent with the cangrelor solution to form a compounding solution." Id. at 17:44:46; see In re SP Controls, Inc., 453 F. App'x 990, 994 (Fed. Cir. 2011) ("'Comprising' is a term of art used in claim language which means that the named elements are

essential, but other elements may be added."). Third, "the compounding process further comprises removing solvents from the compounding solution." Id. at 23:11-12.[9]

Language elsewhere in the specification further suggests that the patentee considered the novel compounding process essential. For instance, in describing the "background of the invention," the patentee highlighted the "problematic" generation of impurities in other compounding processes and noted that "development of a compounding process for formulating cangrelor that consistently generates formulations having low levels of impurities is desirable." Id. at 2:11-24, 21-30; see also id. at 15:42-45 ("It is . . . critical that processes be put in place to manufacture pharmaceutical compositions of cangrelor with sufficiently high purity to be generated, stored and administered to patients."). The patentee further contends that an example provided in the specification "supports the use of the process described in the invention for the generation of high purity cangrelor formulations that can be stored for a long period of time and be useable in patients." Id. at 43:7-10 (emphasis added). The Federal Circuit has held that substantially similar language weighed in favor of importing a process limitation. Med. Co. v. Mylan, Inc., 853 F.3d 1296, 1304 (Fed. Cir. 2017) ("The specification, for example, states that "development of a compounding process for formulating bivalirudin that consistently generates formulations having low levels of impurities is desirable" . . . and that "the compounding process . . . of the invention described herein may consistently generate pharmaceutical batches . . . having the same characteristics[.]") (emphasis in original).[10]

[9] By contrast, the specification uses softer language to describe exemplary methods of completing each step. See, e.g., '987 Patent at 16:44-45 ("Cangrelor can be dissolved in the solvent by methods known in the art."); id. at 23:14-15 ("Solvent removal from the compounding solution may be achieved through lyophilization."). The steps themselves, however, are mandatory.

[10] In the common specification's "summary of the invention" section, the patentee explains that "[h]igh purity cangrelor is cangrelor having a combined total of selected hydrolysis and oxidation degradants of cangrelor not exceeding about 1.5% by weight of the high purity cangrelor." See, e.g., '921 Patent at 4:43-52. While this language

Finally, the Court disagrees with Plaintiffs' contention that MSN's and Endo's proposed construction would impermissibly render the process steps in the '687 Patent "superfluous." Pl. Opening. Br. at 26. As MSN and Endo correctly note, the Federal Circuit rejected this argument in a nearly identical context in holding that to import process limitations from a related patent would mean only that "that the claims of the patents in suit . . . overlap, and overlapping patent claims are not unusual." Medicines Co., 853 F.3d 1296, 1305 (Fed. Cir. 2017) (citation and quotation marks omitted).

For these reasons, the Court limits the term "high purity cangrelor" to the process recited in the specification[11] and adopts the following construction:

Disputed Term	Adopted Construction
"**high purity cangrelor**" '687 Patent, all claims '921 Patent, all claims '575 Patent, all claims '780 Patent, all claims	"cangrelor, or one or more salts thereof, having low levels of impurities, which is formed by a process including the steps of (a) dissolving cangrelor or a salt thereof in a solvent or a solvent mixture to form a first

could conceivably be read as providing a definition for "high purity cangrelor," the Court declines to adopt it as such for two reasons.

First, this statement appears only in a discussion of particular embodiments of the invention. Id. at 2:42-9:6. It is therefore less persuasive then the detailed description of the invention as a whole. See Andersen Corp, 474 F.3d at 1368 (citing Microsoft Corp., 357 F.3d at 1348).

Second, and more critically, this statement "lacks the clear expression of intent necessary for a patentee to act as its own lexicographer." Med. Co., 853 F.3d at 1306; see also Cont'l Cirs. LLC, 915 F.3d at 796 ("When the patentee acts as its own lexicographer, that definition governs."). In Medicines Co., the Federal Circuit rejected a construction "taken verbatim from the specification" because it departed from the "linguistic formula used by the patentee to signal . . . designation of other defined terms." Id. Indeed, the patentee here defined terms using the same format discussed in Medicines Company: "the defined term in quotation marks, followed by the terms 'refers to' or 'as defined herein.'" Id.; see, e.g., '921 Patent at 15:46-49 ("The term 'drug product' herein refers to an active ingredient of a pharmaceutical formulation"), 19:37-40 ("'[H]ot spots,' . . . are defined here as concentrated sites in the compounding solution that have much different pH levels than the surrounding environment."). The description of "high purity cangrelor" above does not follow this format and thus "does not purport to be definitional." Med. Co., 853 F.3d at 1306.

[11] Consistent with its analysis in Section III.A, supra, the Court also concludes that the relevant process must be performed in the order recited in the specification. The Court further adopts the teaching of the specification that "reference to cangrelor should be understood to include both cangrelor in a neutral form, as well as one or more salts of cangrelor." '921 Patent at 13:42-44. Finally, the Court declines to adopt Defendants' proposed introductory phrase, "[c]angrelor and the recited hydrolysis and oxidation degradants of cangrelor in the recited amounts." Each claim of the High Purity Patents already expressly limits the permissible "hydrolysis and oxidation degradants" in high purity cangrelor; an additional reference to these "recited amounts" adds no substantive value.

	solution containing cangrelor, followed by (b) mixing a pH-adjusting agent with the first solution to form a second solution, followed by (c) removing the solvent or solvent mixture from the second solution."

4. "a pharmaceutical formulation consisting of . . . mannitol and/or sorbitol as a pharmaceutically acceptable excipient"

Next, Defendants argue that the "pharmaceutically acceptable excipient" contemplated by certain claims of the High Purity Patents may include either mannitol or sorbitol, but not both. Plaintiffs contend that the use of the term "and/or" allows for an excipient including both mannitol and sorbitol. The Court agrees with Plaintiffs.

At the outset, the plain language of the claim supports Plaintiffs' view. The use of the term "and/or" plainly "indicate[s] two words or expressions are to be taken together or individually." Cipher Pharms. Inc. v. Actavis Lab'ys FL, Inc., 99 F. Supp. 3d 508, 518 (D.N.J. 2015). While Defendants contend that the claims' reference to "a" pharmaceutically acceptable excipient necessarily implies the use of a single "excipient," rather than multiple excipients, the Court perceives no reason why the plain language of the claim prohibits the use of one "excipient" comprised of both mannitol and sorbitol.[12] The use of "and/or" resolves any potential ambiguity in that regard.

The other intrinsic evidence further supports Plaintiffs' construction. For example, the common specification permits the combination of both mannitol and sorbitol to form one "excipient." See '921 Patent at 9:64-10:1 ("In one aspect, the invention relates to a pharmaceutical formulation consisting of high purity cangrelor, or a salt thereof, as an active ingredient and

[12] The specification explains that "excipients are components of a pharmaceutical formulation that serve to maintain, stabilize or alter the physico-chemical or physiological behavior of the active ingredient of a pharmaceutical formulation." See, e.g., '921 Patent at 17:4-8.

mannitol or sorbitol, or both mannitol and sorbitol, as a pharmaceutically acceptable excipient[.]") (emphasis added). There is consequently no basis for the exclusion sought by Defendants.

The Court thus adopts Plaintiffs' construction, as modified below:

Disputed Terms	Adopted Construction
"**a pharmaceutical formulation consisting of . . . mannitol and/or sorbitol as a pharmaceutically acceptable excipient**" '780 Patent, claims 7-13, 18-23 '687 Patent, claims 14-24 '575 Patent, claims 14-26 '921 Patent, claims 14-26	"a pharmaceutical formulation consisting of high purity cangrelor, or a salt thereof, as an active ingredient and mannitol, or sorbitol, or both mannitol and sorbitol, as a pharmaceutically acceptable excipient"

5. "glass forming additives"

Gland asks the Court to limit the term "glass forming additives" in the '208 Patent to "agents which have a glass transition temperature of above room temperature."[13] Plaintiffs request a broader construction encompassing specific examples listed in the specification. The Court again agrees with Plaintiffs.

The '208 Patent claims "[a] pharmaceutical composition comprising a nucleotide analog and one or more glass forming additives. . . ." '208 Patent at 24:29. Both Parties ground their preferred constructions on the specification, which provides, in relevant part:

> A glass forming modifying agent suitable for use in the present invention is generally one which has a glass transition temperature of above room temperature, more especially above about 50° C. in the dried state. . . . Examples of suitable modifying agents include sugars (for example sucrose, trehalose, lactose or sorbitol) or polymers (such as dextran or polyvinylpyrrolidone (PVP)).

'208 Patent at 4:25-34.

[13] As Plaintiffs allege infringement of the '208 Patent only against Gland, MSN and Endo do not join in this proposed construction.

Plaintiffs argue that Gland's proposal is unduly restrictive because it ignores the specification's use of the word "generally" and would exclude sorbitol, which is cited in the specification as a preferred embodiment but does not have a glass transition temperature of above room temperature. See Verano Decl. Ex. P at CHI_KEN_9245233 (scientific literature identifying the "dry" glass transition temperature of sorbitol as -2 ºC).[14]

"A claim construction that excludes the preferred embodiment 'is rarely, if ever, correct and would require highly persuasive evidentiary support.'" Adams Respiratory Therapeutics, Inc. v. Perrigo Co., 616 F.3d 1283, 1290 (Fed. Cir. 2010) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583-84 (Fed. Cir. 1996)). Beyond the "general" rule articulated in the specification, Gland has failed to provide evidence that sorbitol must be excluded from the claim and has not explained why the Court should ignore the qualifying word "generally" from the specification. At the same time, the Court agrees with Gland that typically, "claims of a patent are not limited to . . . the examples listed within the patent specification." Dow Chem. Co. v. United States, 226 F.3d 1334, 1342 (Fed. Cir. 2000).

Plaintiffs' proposal accounts for the rules of construction articulated in Adams and Dow Chemical because it incorporates both the specification's general rule and its identification of an exception to that rule, i.e., sorbitol. The Court will therefore adopt Plaintiffs' construction, as modified below:[15]

[14] Gland does not dispute that sorbitol has a glass transition temperature below room temperature.

[15] Plaintiff's proposed construction reads "sucrose, trehalose, lactose, sorbitol, dextran, PVP, or a sugar or polymer with a Tg above room temperature, especially above 50°C, in the dried state." The Court agrees with Gland that the phrase "especially above 50°C" suggests that "above 50°C" is not a requirement of the Patent. The Court therefore omits that clause from its adopted construction.

Disputed Term	Adopted Construction
"**glass forming additives**" '208 Patent, claims 1-9	"sucrose, trehalose, lactose, sorbitol, dextran, polyvinylpyrrolidone (PVP), or a sugar or polymer with a glass transition temperature above room temperature in the dried state"

C. Defendant's Indefiniteness Arguments

Defendants last argue that several terms of the Patents-in-Suit are indefinite.[16] Indefiniteness renders a claim invalid and must be proven by clear and convincing evidence. See Par Pharm., Inc. v. Sandoz, Inc., No. 18-14895, 2020 WL 1130387, at *8 (D.N.J. Mar. 9, 2020) (citing Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 902 (2014)). Because questions of definiteness are "potentially dispositive, require a high burden of proof, and may more profitably be considered in connection with patent validity," courts in this District typically decline to resolve them at the Markman stage, instead deferring consideration until summary judgment or trial to allow for a fully developed record. Fresenius Kabi USA, LLC v. Fera Pharms., LLC, No. 15--3654, 2016 WL 5109142, at *9 (D.N.J. Sept. 20, 2016); see also Par Pharm., Inc., 2020 WL 1130387, at *8 (collecting cases); Sanofi-Aventis U.S. LLC v. Mylan GmbH, No. 17-9105, 2019 WL 2067373, at *10 (D.N.J. May 9, 2019) ("[T]his Court addresses invalidity disputes, of which indefiniteness is one, at summary judgment or at trial.").

The Court likewise declines to consider Defendants' indefiniteness arguments at this juncture.

IV. CONCLUSION

For the reasons stated above, the Court adopts the following constructions:

[16] Defendants specifically challenge the terms "reducing the incidence of," "reducing mortality," "mortality is reduced," "likelihood of mortality is reduced," "reduced over a period if about one year," and "reducing the risk." Def. Opening Br. at 14-22. Gland further contends that the term "high purity cangrelor" is indefinite. Id. at 34-38.

Disputed Terms	Adopted Construction
"(a) dissolving cangrelor or a salt thereof in a solvent to form a first solution" **"(b) mixing a pH-adjusting agent with the first solution to form a second solution, wherein the pH of the second solution is between about 7.0 and 9.5"** '687 Patent, claims 1-24	"(a) dissolving cangrelor or a salt thereof in a solvent to form a first solution containing cangrelor, followed by (b) mixing a pH-adjusting agent with the first solution to form a second solution with a pH between about 7.0 and 9.5."
"**treating**" '448 Patent, claims 1-14 '265 Patent, claims 1, 5, 7 '780 Patent, claims 1-23	"to manage a disease by medicinal, surgical, or other measures; to care for a patient medically or surgically"
"**preventing**" '448 Patent, claims 1-14 '265 Patent, claims 5, 26	"action so as to avoid, forestall, or circumvent a happening, conclusion, or phenomenon (e.g., disease)"
"**high purity cangrelor**" '687 Patent, all claims '921 Patent, all claims '575 Patent, all claims '780 Patent, all claims	"cangrelor, or one or more salts thereof, having low levels of impurities, which is formed by a process including the steps of (a) dissolving cangrelor or a salt thereof in a solvent or a solvent mixture to form a first solution containing cangrelor, followed by (b) mixing a pH-adjusting agent with the first solution to form a second solution, followed by (c) removing the solvent or solvent mixture from the second solution."
"**a pharmaceutical formulation consisting of . . . mannitol and/or sorbitol as a pharmaceutically acceptable excipient**" '780 Patent, claims 7-13, 18-23 '687 Patent, claims 14-24 '575 Patent, claims 14-26 '921 Patent, claims 14-26	"a pharmaceutical formulation consisting of high purity cangrelor, or a salt thereof, as an active ingredient and mannitol, or sorbitol, or both mannitol and sorbitol, as a pharmaceutically acceptable excipient"
"**glass forming additives**" '208 Patent, claims 1-9	"sucrose, trehalose, lactose, sorbitol, dextran, polyvinylpyrrolidone (PVP), or a sugar or polymer with a glass transition temperature above room temperature in the dried state"

An appropriate Order follows.

Date: October 18, 2021

/s/ ***Madeline Cox Arleo***
Hon. Madeline Cox Arleo
UNITED STATES DISTRICT JUDGE