NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC et al., Plaintiffs, v. FRESENIUS KABI USA, LLC, et al., Defendants.	Civil Action No. 14-7869 (MAS) (LHG) Civil Action No. 14-8082 (MAS) (LHG) Civil Action No. 15-2631 (MAS) (LHG) Civil Action No. 14-8079 (MAS) (LHG) Civil Action No. 15-2520 (MAS) (LHG) **MEMORANDUM OPINION**

SHIPP, District Judge

This is a consolidated action involving three patents covering Plaintiffs Sanofi-Aventis U.S. LLC ("Sanofi U.S."), Aventis Pharma S.A. ("Aventis"), and Sanofi's (collectively, "Plaintiffs") Cabazitaxel Injection, which is prescribed and sold in the United States under the trademark JEVTANA® KIT ("Jevtana"), and a method for treating prostate cancer. Defendants have filed Abbreviated New Drug Applications ("ANDAs") with the United States Food and Drug Administration ("FDA"), seeking to market generic versions of Jevtana and challenging the validity of Plaintiffs' patents. This matter comes before the Court for the construction of claims in two of Plaintiffs' patents: U.S. Patent No. 7,241,907 (filed Dec. 18, 2014) (the "'907 Patent") and U.S. Patent No. 8,927,592 (filed Mar. 3, 2015) (the "'592 Patent"). (ECF Nos. 58, 59.) The Court has considered the parties' submissions, heard oral argument on February 23, 2016, and thereby conducted its *Markman* hearing. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). Based on the parties' arguments and the intrinsic evidence, discussed below, the Court adopts Defendants' construction of the disputed terms in the '592 Patent and the '907 Patent.

I. Background

In 2004, the FDA approved the use of the drug combination docetaxel and prednisone for hormone refractory metastatic prostate cancer. (Pls.' Opening Br. 2, ECF No. 59.) Thereafter, however, some patients' cancer became resistant to docetaxel, which led to cancer progression during or after docetaxel treatment. (*Id.*) The '592 Patent discloses and claims methods of treating patients with prostate cancer, which has progressed after docetaxel treatment, by administering cabazitaxel, and the '907 Patent discloses and claims acetone solvate solid state forms of cabazitaxel. (Decl. of Roger J. Kiley ("Kiley Decl."), Ex. 2 ("'907 Patent"), ECF No. 57-7; Kiley Decl., Ex. 3 ("'592 Patent), ECF No. 57-8.) The parties dispute the meanings of the terms of the '907 Patent and '592 Patent for Jevtana. (Joint Claim Construction and Prehearing Statement, Exs. A, C ("Proposed Constructions"), ECF No. 51-1.) The parties dispute the meaning of the term "acetone solvate" in the '907 Patent and the meanings of the following terms in the '592 Patent: "a method for treating a patient"; "administering . . . to the patient"; "wherein the cabazitaxel is in the form of an acetone solvate"; and "wherein the cabazitaxel is in the base form." (Proposed Constructions A-1 to A-5, A-10 to A-16, C-1 to C-5.)

II. Legal Standard

Claim construction is a threshold issue that must be addressed before analyzing claims of infringement and/or invalidity. Claim construction is a question of law to be decided by a judge, not a jury. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). "[W]ords of a claim 'are generally given their ordinary and customary meaning.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (3d Cir. 2005) (quoting *Vitrionics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question [the "POSA"] at the

time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1313. "Claim construction begins with the intrinsic evidence of the patent—the claims, the specification, and the prosecution history—and may require consultation of extrinsic evidence to understand the state of the art during the relevant time period." *Horizon Pharma Ireland Ltd. v. Actavis Labs., UT, Inc.*, No. 14-7992, 2016 WL 4408990, at *2 (D.N.J. Aug. 17, 2016) (citing *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831. 841 (2015)). "Extrinsic evidence—testimony, dictionaries, learned treatises, or other material not part of the public record associates with the patent—may be helpful but is 'less significant than the intrinsic record in determining the legally operative meaning of claim language.'" *MBO Labs., Inc. v. Beckton, Dickinson & Co.*, 474 F.3d 1323, 1329 (Fed. Cir. 2007) (quoting *Vitrionics Corp.*, 90 F.3d at 1317). "[I]f the meaning of the claim limitation is apparent from the intrinsic evidence alone, it is improper to rely on extrinsic evidence other than that used to ascertain the ordinary meaning of the claim limitation." *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp. Inc.*, 262 F.3d 1258, 1268-69 (Fed. Cir. 2001).

III. Analysis

A. Construction of "Acetone Solvate" in '907 and '592 Patents

The '907 Patent provides a method of making an acetone solvate of cabazitaxel. Claim 1 of the '907 Patent provides that it is "[a]n ***acetone solvate*** of [cabazitaxel]." ('907 Patent col. 3 l. 61-64 (emphasis added).) Claim 2 of the '907 Patent provides that it is "an ***acetone solvate*** of [cabazitaxel] comprising from about 5 to about 7 percent by weight of acetone." (*Id.* at col. 4 l. 1-5 (emphasis added).) The '592 Patent is directed to a method for treating a patient with prostate cancer by administering cabazitaxel. Claim 3 of the '592 Patent provides "[t]he method according to claim 1, where the cabazitaxel is in the form of an ***acetone solvate***," and claim 4 of the '592

Patent provides "[t]he method according to claim 3, in which the acetone solvate contains between 5% and 8% by weight acetone." ('592 Patent col. 18 l. 61-64.) The parties agree that the term "acetone solvate" should be construed to have the same meaning in both the '907 Patent and '592 Patent. (*See* Pls.' Opening Br. 10, ECF No. 59 ("[T]he term 'acetone solvate' as used in the two patents necessarily means the same thing."); Defs.' Opening Br. 4 ("The parties agree that the term "acetone solvate" has the same meaning in both patents . . . ."), ECF No. 58.) The parties, however, dispute the construction of this term. In the joint claim construction brief, the parties propose the following constructions:

Plaintiffs' Proposed Construction	**Defendants' Proposed Construction**
A crystalline solid containing between about 0.02% and 7.2% by weight acetone and exhibiting a powder x-ray diffraction pattern consistent with that of Figure 1 of the '907 [P]atent.	A solid crystalline material that incorporates between 5% and 8% by weight of acetone molecules within the crystal lattice.

(Proposed Constructions A-1.) Importantly, the parties dispute the amount of acetone required to be present in the acetone solvate and whether the phrase "and exhibiting a powder x-ray diffraction pattern consistent with that of Figure 1 of the '907 [P]atent" should be read into the construction of "acetone solvate." (*Id.*) The crux of the parties' dispute is whether a POSA reading the specifications and claims in the '907 Patent and '592 Patent would understand "acetone solvate" to mean a channel solvate, such that the amount of acetone could vary from as little as 0.02% to as high as 7.2%, or whether a POSA would understand the term to mean a non-channel solvate, such that the amount of acetone could only vary from 5% to 8% by weight, which represents approximately the acetone stoichiometry.

In support of their position that "acetone solvate" should be construed in the '907 and '592 patents to mean a channel solvate, Plaintiffs rely on, among other things, a "Drying Study"

described in the '907 patent. (Pls.' Opening Br. 3.) This "Drying Study" provides that when the "product" was placed at 100°C for twenty-one hours the "residual acetone content" was 0.02%. Citing this "Drying Study," Plaintiffs assert that "the '907 Patent expressly describes an acetone solvate containing as low as 0.02% acetone and teaches a POSA how to make such a solvate." (*Id.* at 4.) Defendants, however, argue that the "Drying Study" "is nothing more than a demonstration that excessive heating over 70°C *destroys* the claimed acetone solvate." (Defs.' Opening Br. 8 (emphasis in original).)

As an initial matter, the "Drying Study," which is included in the specifications in the '907 Patent, is an important part of the intrinsic evidence and must be considered in construing the claim. *McNeil-PPC, Inc. v. Perrigo Co.*, 443 F. Supp. 2d 492, 502 (S.D.N.Y. 2006) ("Because the specification is an important part of the intrinsic evidence, claims are construed in light of the specification of which they are part."); *see also Phillips*, 415 F.3d at 1315 (stating that the specification is the "single best guide to the meaning of disputed terms"). The Drying Study begins by referencing Example 1 of the acetone solvate, which contains 7.2% of acetone, and states that:

> [t]he product is ***again*** placed in an oven and successively dried for 18 hours at 60°C under a reduced pressure of 0.7 kPa, for 3 hours at 60°C under a relative humidity of approximately 80% (reduced pressure of 160 mmHg). At this stage, the content of water is 0.2% and the content of acetone is 4.7% (194g). At this same stage, 1 aliquot of 1g of the bath is dried under a reduced pressure of 5 mmHg successively for 18 hours at 80°C (residual acetone content of 0.5%) and then for 21 hours at 100°C (residual acetone content of 0.02%). The remainder is dried at about 90°C under a reduced pressure of 5 mm Hg for 31 hours (acetone 1.7% water 0.3%, assay with regard to such of 96.5%, purity greater than 99%).

('907 Patent col. 3 l. 4-19 (emphasis added).) The '907 Patent does not, however, indicate whether the products of the Drying Study are intended to be embodiments of acetone solvate. The reference to the Drying Study in the Description of the Invention suggests the contrary. Specifically, the

Description of the Invention provides that "[t]he drying of the product was studied" and when the product was "deliberately treated at a temperature above 70°C (70 to 100°C) [it] shows an increasing loss in the content of acetone with the increase in temperature." (*Id.* at col. 2 l. 31.) In addition, the Description of the Invention provides that:

> For the drying, the preferred temperature is thus between 30 and 60°C and more preferably still is in the region of 40°C. A mean value of the content of acetone is 7%, which represents approximately the acetone stoichiometry, which is 6.5%, for a solvate comprising one molecule of acetone.

(*Id.* at col. 2 l. 31-42.) In light of the reference to a "preferred temperature" for drying, a 7% "mean value of the content of acetone," and the reference to 0.02% acetone as "***residual*** acetone," the Drying Study does not appear to be a method for making acetone solvate. Rather, as Defendants contend, it appears to be a "demonstration that excessive heating over 70°C destroys the claimed acetone solvate." (Defs.' Opening Br. 8.) This interpretation is also supported by the fact that, notwithstanding the statement in the specification that the claimed acetone solvate is "fully characterized from the chemical viewpoint" ('907 Patent col. 1 l. 37-41), there is "no characterization data-x-ray or otherwise" for the products of the Drying Study (Defs.' Opening Br. 8). In contrast, there is characterization data, namely a powder x-ray diffraction pattern ("PXRD") and H NMR Spectrum Data ("NMR"), for the acetone solvate described in Example 1, which contains 7.2% acetone. ('907 Patent fig. 1, col. 3 l. 48-59.)

While the Court recognizes that the inclusion of the PXRD of Example 1, which describes a stoichiometric solvent, supports Defendants' construction of "acetone solvate," the Court rejects Plaintiffs' proposal to read the phrase "and exhibits a powder x-ray diffraction pattern consistent with that of Figure 1 of the '907 [P]atent" into the claim term. (Proposed Constructions A-1.) The subject claims do not refer to Figure 1 or to an x-ray diffraction pattern. Accordingly, the Court

refuses to add limitations from the specification to the subject claims. *Phillips*, 415 F.3d at 1323 (stating that limitations from the specification should not be imported into the claims); *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014) ("While we read claims in view of the specification, of which they are a part, we do not read limitations from the embodiments in the specification into the claims."); *Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*, No. 09-651, 2012 WL 1753670, at *4 (D. Del. May 16, 2012) (finding no basis to import PXRD pattern into the claim).

Finally, the Court recognizes that Defendants' proposed construction renders the phrase "between 5% and 8% acetone" in claim 4 of the '592 Patent superfluous. ('592 Patent col. 18 l. 64.) Generally, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips*, 415 F.3d at 1314-15. However, "no canon of claim construction is absolute in its application [and] surplusage may exist in some claims." *See Decisioning.com, Inc. v. Federated Dep't Stores, Inc.*, 527 F.3d 1300, 1312 n.6 (Fed. Cir. 2008) (internal citations omitted). Thus, construing "acetone solvate" in the context of the entire patent, including the specification, the Court adopts Defendants' proposed construction. *See Phillips*, 415 F.3d at 1313 ("[T]he [POSA] is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.").

B. Construction of "A Method for Treating a Patient" in the '592 Patent

As noted above, the '592 Patent is directed to a method for treating a patient with prostate cancer by administering cabazitaxel. Claim 1 of the '592 Patent states:

> ***A method for treating a patient with prostate cancer that has progressed during or after treatment with docetaxel*** comprising of administering to said patient a dose of 20 to 25 mg/m2 of

> cabazitaxel, or a hydrate or solvate thereof, in combination with a corticoid.

('592 Patent col. 18 l. 54-58 (emphasis added).) The portion of the claim before the word "comprising" is known as the "preamble" of the claim. The parties agree that the portion of the preamble that states "a patient with prostate cancer that has progressed during or after treatment with docetaxel" limits the claim. (Pls.' Opening Br. 11; Defs.' Opening Br. 14.) The parties, however, dispute whether the balance of the preamble – "a method for treating" – is limiting. Plaintiffs argue that this language is limiting, and Defendants argue to the contrary. As discussed below, based on the parties' arguments and the intrinsic evidence, the Court finds that this language is not limiting.

"No litmus test defines when a preamble limits claim scope." *Catalina Mktg. Int'l, Inc. v. Coolsavings,com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). "Whether a preamble stating the purpose and context of the invention constitutes a limitation of the claimed process is determined on the facts of each case in light of the overall form of the claim, and the invention as described in the specification and illuminated in the prosecution history." *Applied Materials, Inc. v. Advanced Semiconductor Materials, Am., Inc.*, 98 F.3d 1563, 1572-73 (Fed. Cir. 1996). In *Catalina*, however, the Federal Circuit recognized that "[s]ome guideposts . . . have emerged from various cases discussing the preamble's effect on claim scope." *Catalina Mktg, Int'l Inc.*, 289 F.3d at 808. In particular, the court noted that preambles were found to be limiting in cases where they: (1) "recite[d] essential structure or steps"; (2) provided antecedent basis for terms in the body of the claim; (3) were repeated in the specifications; and (4) were "clearly and unmistakably" relied upon during the prosecution to distinguish the claimed invention from prior art. *Id.* at 808-09. Following these guideposts in this case, the Court finds that the preamble is not limiting.

Here, the preamble does not recite an essential structure or step. As in *Bristol-Myers Squibb Co v. Ben Venue Laboratories, Inc.*, here the "method [is] performed in the same way regardless of whether or not the patient experiences" an efficacious result. 246 F.3d 1368, 1375 (Fed. Cir. 2001). Likewise, the use of the phrase "method of treating" in the specification does not suggest that it is significant to claim construction. The Summary states, "[t]he invention also relates to ***the methods of treating*** patients with prostate cancer comprising administering an effective amount of antitumoral agent cabazitaxel to said patient." ('592 Patent col. 2 l. 58-60 (emphasis added).) In addition, the Detailed Description states that "one aspect of the invention is ***a method of treating*** prostate cancer comprising administering to a patient in need thereof an effective amount of cabazitaxel in combination with a corticoid, such as prednisone or prednisolone" and "[t]he present invention therefore also relates to ***a method of treating*** prostate cancer with cabazitaxel comprising administering cabazitaxel to the patient, monitoring blood counts in the patient, and measuring neutrophil levels." (*Id.* at col. 5 l. 33-35, col. 7 l. 32-33.) In all of these statements, "a method of treating" states only the purpose of use not a unique aspect of the claimed invention. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999) ("[When] the preamble offers no distinct definition of any of the claimed invention's limitations, but rather merely states . . . the purpose or intended use of the invention, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation."). *Cf. Proveris Sci. Corp. v. Innovasystems Inc.*, 739 F.3d 1367, 1373 (Fed. Cir. 2014) (finding preamble limiting where specification highlighted the importance of an aspect of claimed invention that was mentioned only in the preamble); *Poly-America, L.P. v. GSE Lining Tech., Inc.*, 383 F.3d 1303, 1310 (Fed. Cir. 2004) (finding preamble limiting where

"analysis show[ed] that the inventor considered that the 'blown-film' preamble language represented an important characteristic of the claimed invention").

Next, as discussed above, it is undisputed that the portion of the preamble that described the "patient" for whom the treatment is intended provides antecedent basis for the phrase "said patient" in the body of the claim. Plaintiffs, however, argue that because this portion of the preamble is intertwined with the balance of the preamble, the entire preamble should be deemed limiting. (Pls.' Resp. Br. 11, ECF No. 70.) This argument is not persuasive. As "[a] method for treating" merely states the intended use or purpose for the claimed invention, and the actual method—dosage of cabazitaxel and statement that it must be combined with a corticoid—is provided in the body of the claim, this portion of the preamble is not "intimately meshed with the . . . . language in the claim." *Pitney Bowes, Inc.*, 182 F.3d at 1306; *see also TomTom, Inc. v. Adolph*, 790 F.3d 1315, 1323 (Fed. Cir. 2015) ("That the phrase in the preamble 'destination tracking system of at least one mobile unit' provides a necessary structure for claim 1 does not necessarily convert the entire preamble into a limitation, particularly one that only states the intended use of the invention."). Furthermore, "a method for treating" is not so intertwined with the description of the targeted patient that it cannot be parsed from this portion of the preamble. *Cf. Blue Calypso, Inc. v. Groupon, Inc.*, 93 F. Supp. 3d 575, 594 (E.D. Tex. 2015) ("[H]ere, in all of the claims at issue, the language relied upon for antecedent basis is intertwined with the entireties of the preambles such that the preambles cannot be parsed into limiting and non-limiting portions.).

Finally, Plaintiffs argue that the preamble is limiting because it was relied upon during prosecution to distinguish prior art. (Pls.' Opening Br. 13-15.) In particular, citing the discussion of the Mita study in the prosecution history, Plaintiffs note that the use of cabazitaxel in cancer

patients was already being studied before the TROPIC study cited in the '592 Patent. (*Id.* at 13-14.) Thus, Plaintiffs argue the applicant distinguished the claimed invention from the Mita study in two ways: (1) type of patient to be treated, namely "a patient with prostate cancer that has progressed during or after treatment with docetaxel"; and (2) the efficacy of the claimed invention in treating that particular type of patient. (*Id.*; *see also* Decl. of Jason Leonard ("Leonard Decl."), Ex. F at SA_JEV_0004401 (stating that Mita reference studied "a limited number of patients with a ***variety of solid tumors***" and "[w]hile ***eight of the twenty-five patients had prostate tumors*** . . . anti-cancer activity was noted in [only] two patients, including ***one patient with 'hormone-and docetaxel-refractory cancer metastatic to bone and iliac lymph nodes***" and "[t]he evidence of anticancer activity in a single patient does not provide an expectation that the claimed method would successfully treat prostate cancer").) In addition, Plaintiffs rely on the statement by the Examiner in the Allowance regarding the declaration of Dr. Alton Oliver Sartor to argue "the applicants distinguished the present invention from the prior art based on the preambles' teaching of clinical effectiveness in prostate cancer during or after treatment with docetaxel." (Pls.' Opening Br. 14.) In the Allowance the Examiner stated that Dr. Sartor's declaration "provides convincing evidence that while the art was full of promising early clinical results, these failed to predict whether therapies would ultimately provide a clinically meaningful benefit to the desired patient populations . . . ." (Leonard Decl., Ex. F at SA_JEV_0004765.)

Defendants, however, argue that, notwithstanding the discussion of the efficacy of the claimed invention in deciding whether the claimed invention was nonobvious, Plaintiffs have failed to show that "clear reliance" on the preamble during prosecution to distinguish prior art. (Defs.' Resp. Br. 12, ECF No. 69.) In particular, Defendants note that in contrast to the cases cited by Plaintiffs, here "[Plaintiffs] do[] not point to a single statement where either applicants or

Examiner stated that the claims require 'a method of treating,'" and "[Plaintiffs] do[] not argue that the disputed portions of the preamble were added to overcome a rejection of the claims. (*Id.*) Moreover, Defendants note that Plaintiffs cannot make the latter argument because "the disputed portion of . . . [the] preamble was in the claim from the very beginning of prosecution." (*Id.*) Furthermore, Defendants argue that even if the efficacy of the claimed invention was considered in finding that the patent was non-obvious, that finding is not sufficient for limiting the claim. (*Id.* at 13.)

The Court agrees with Defendants that the preamble is not limiting. While the Examiner noted the unexpected result in allowing the patent, Plaintiffs have failed to show that the claim requires the unexpected results. *See Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006) ("While it is true that Purdue relied on its 'discovery' of the four-fold dosage range to distinguish its claimed oxycodone formulations from other prior art opioids, Purdue's statements do not amount to a clear disavowal of claim scope."); *see also McNeil-PPC, Inc. v. Perrigo Co.*, 443 F. Supp. 2d 492, 505 (S.D.N.Y. 2006) ("The submission of extraordinary results that are narrower in scope than the claims does not, by itself, impose a limitation on the construction of the claims."). "Under the doctrine of prosecution disclaimer, a patentee may limit the meaning of a claim term by making a clear and unmistakable disavowal of scope during prosecution." *Purdue Pharma L.P.*, 438 F.3d at 1136. Here, Plaintiffs have not shown that the applicants clearly disclaimed or disavowed the claimed invention when it does not produce unexpected or efficacious results. Thus, Plaintiffs have failed to show the requisite "clear reliance" on the preamble necessary to convert the preamble into a claim limitation. *See Catalina Mktg. Int'l Inc.*, 289 F.3d at 808 ("[C]lear reliance on the preamble during prosecution to distinguish the

claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention.").

Having considered the parties' arguments and reviewed the intrinsic evidence discussed above, the Court finds that the phrase "a method for treating," which states the purpose of the claimed invention and was not added during patent prosecution, is not limiting.[1] *Cf. MBO Labs, Inc.*, 474 F.3d at 1330 (finding that prosecution history and specification showed the "immediate" needle safety was an essential feature of the claimed invention).

C. Construction of "Administering to Said Patient" and "Administering . . . to the Patient" in the '592 Patent

Claims 1 and 27 of the '592 Patent include the phrases "administering to said patient" and "administering . . . to the patient," respectively. The parties dispute the construction of "administering" in these claims. In the joint claim construction brief, the parties propose the following constructions for "administering":

Plaintiffs' Proposed Construction	Defendants' Proposed Construction
Prescribing, supervising, or managing the formal taking of	Delivering into the body of the patient

Plaintiffs argue that Defendants' construction is inconsistent with the fact that actual delivery of the claimed invention occurs in two steps: "(1) the patient swallowing the prednisone and (2) a health care provider infusing cabazitaxel." (Pls.' Opening Br. 24.) In addition, Plaintiffs

[1] The Court notes that Plaintiffs also argue that "if the preamble[] [is] not limiting, dependent Claim 24 and 28 would have the same scope, which the doctrine of claim differentiation is designed to prevent." (Pls.' Opening Br. 13.) Claim differentiation may not, however, be used to expand the scope of the claim, *see Seachange Int'l, Inc., v. C-Cor Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005), and as noted above, the canons of claim construction are not to be rigidly applied, *see Latiram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed. Cir. 1991). Here based on the intrinsic record, discussed above, the Court finds that the preamble is not limiting, and the Court is not persuaded by Plaintiffs' claim differentiation argument to depart from this finding.

argue that "[b]ecause cabazitaxel, prednisone, and prednisolone are prescription medications, there can be no act of treatment without the prescription from, or involvement of, a physician," so "administering . . . must include 'prescribing, or supervising or managing the formal taking of." (*Id.* at 25.) Finally, Plaintiffs note that "the 2003 version of Merriam Webster's Collegiate Dictionary [defines administering as] . . . 'to manage or supervise the execution, use, or conduct of'" and thus argues that its construction is also supported by extrinsic evidence. (*Id.* at 26.)

Defendants argue that the repeated use of "administer" in the patent specification to "refer to the delivery of cabazitaxel into the body" supports its construction. (Defs.' Opening Br. 26.) In particular, Defendants cite the following uses of "administer" in the specification:

- "In some aspects of the invention, cabazitaxel may be administered by intravenous infusion at a dose of between 15 and 25 mg/m2."
- "Cabazitaxel may be administered parenterally, such as via intravenous administration."
- "Preferably, a patient is pre-medicated with the medication, for example, at least 30 minutes prior to administering each dose of cabazitaxel."
- "Table 3 lists 'Administration Site Conditions,' such as pain swelling or a rash at the particular location on the patient's body where the cabazitaxel was delivered as an 'adverse reaction' of cabazitaxel treatment."

(*Id.* at 27 (citing '592 Patent col. 3 l.16-21, col. 6 l. 38-40, col. 13).) In addition, Defendants assert that "[t]his usage of 'administer' extends to the prosecution history" citing the Unites States Patent and Trademark Office's focus on the "*actual delivery* of cabazitaxel to a patient in determining the boundaries of the inventions set forth in the original application." (*Id.* (emphasis added).)

In its responsive brief, Plaintiffs argue that Defendants' reliance on uses of "administration" in the specification is misplaced, because the disputed term is "administering" not "administration," and courts have found that "administration" and "administer" may have different meanings. (Pls.' Resp. Br. 26.) Plaintiffs argue that the other instances of "administered"

and "administering" that Defendants cite would be understood by a POSA "as referring to prescription by a physician." (*Id.* at 27.) The Court disagrees. In particular, "prescribing, supervising, or managing the formal taking of" could not be substituted for "administering" or "administered" in the following sentences in the specification:

- "The combination is administered repeatedly according to a protocol that depends on the patient to be treated (age, weight, treatment history, etc.), which can be determined by a skilled physician."
- "In one aspect of the invention, cabazitaxel is administered by perfusion to the patient according to an intermittent program with an interval between each administration of 3 weeks, which may be prolonged by 1 to 2 weeks depending on tolerance to the preceding administration."
- "Preferably, a patient is pre-medicated with the medication, for example, at least 30 minutes prior to administering each dose of cabazitaxel."
- "Cabazitaxel may cause fetal harm when administered to a pregnant woman."

('592 Patent col. 5 l. 38-40, col.5 l. 41-45, col. 6 l. 38-40, col. 8 l. 30-31.) Furthermore, the usage of "administering" in the specification contravenes Plaintiffs' assertion that "administering must include involvement of a physician . . . ." (Pls.' Resp. Br. 28.) For example, construing "administering" to include physician involvement, would render the specific reference to a skilled physician in the following sentence with respect to determining the protocol for treatment redundant: "The combination is administered repeatedly according to a protocol that depends on the patient to be treated (age, weight, treatment history, etc.), which can be determined by a skilled physician." ('592 Patent col. 5 l. 38-40.) Moreover, this sentence distinguishes between "administering" the combination and determining the protocol for administering the combination, and specifies physician involvement with respect to only the latter. This usage in the specification is consistent with Defendants' construction of administering in claims 1 and 27 of the '592 Patent. Thus, as the use of a disputed term in the specification "is always highly relevant to claim

construction analysis" and usually . . . "the single best guide to the meaning of a disputed term", the Court adopts Defendants' construction of "administering." *See Phillips*, 415 F.3d at 1315.

D. Construction of "Where the Cabazitaxel is in the Form of an Acetone Solvate" and "Wherein Cabazitaxel is in the Base Form" in the '592 Patent

Claim 3 of the '592 Patent provides: "The method according to claim 1, where the cabazitaxel is in the form of an acetone solvate" and claim 6 of the '592 patent provides: "The method according to claim 1, wherein the cabazitaxel is in base form. The parties dispute the construction of the term "cabazitaxel" in both of these claims. Plaintiffs argue that because cabazitaxel in the form of an acetone solvate is a crystalline material, the only known route of administration of cabazitaxel when the '592 Patent application was filed as intravenous, and "presence of solid crystals in an intravenous formulation was considered a problem," the phrase "where the cabazaitaxel is in the form of an acetone solvate" in claim 3 should be construed as "where the cabazitaxel active pharmaceutical ingredient is an acetone solvate." (Pls.' Opening Br. 28.) For the same reasons, Plaintiffs argue that the reference to cabazitaxel in claim 6 should be construed as the "cabazitaxel active pharmaceutical ingredient." Defendants, however, argue that Plaintiffs are attempting to improperly rewrite claims 3 and 6, by substituting "cabazitaxel active pharmaceutical ingredient" for cabazitaxel. (Defs.' Resp. Br. 29.) In addition, Defendants argue that Plaintiffs' "argument is premised on an incorrect assumption: that the '592 [P]atent claims are limited to intravenous administration" and that this premise is "without support because the plain language of the '592 [P]atent claims do not limit the claimed method to administration by liquid intravenous infusion." (Defs.' Resp. Br. 27-28.) The Court agrees with Defendants. While the Summary of the Invention states that "[i]n some aspects of the invention, cabazitaxel may be administered by intravenous infusion at a doses of between 15 and 25 mg/m2 . . . ," the claimed

invention is not limited to this embodiment. ('592 Patent col. 3 l. 15-16.) Specifically, the Description of the Invention states that "[c]abazitaxel may be administered in base form . . . or in the form of a hydrate [and] . . . . may also be a solvate." (*Id.* at col. 4 l. 40-41.) Accordingly, the Court finds that the intrinsic evidence supports giving the disputed terms in claims 3 and 6 of the '592 Patent their plain meaning.

IV. Conclusion

For the reasons discussed above, the Court adopts Defendants' construction of the disputed terms. An order consistent with this Memorandum Opinion will be entered.

MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE

Dated: September 2nd, 2016