NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HELSINN HEALTHCARE S.A., et al.,	:	CIVIL ACTION NO. 11-3962 (MLC)
Plaintiffs,	:	**MEMORANDUM OPINION**
v.	:	
DR. REDDY'S LABORATORIES, LTD., et al.,	:	
Defendants.	:	

Cooper, District Judge

OUTLINE

PRELIMINARY STATEMENT

This is a consolidated action involving four patents listed as covering plaintiffs' marketed pharmaceutical product Aloxi®. Defendants have filed Abbreviated New Drug Applications ("ANDAs") with the Federal Food and Drug Administration ("FDA"),

seeking to market generic versions of the product and challenging those patents as invalid or unenforceable, pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j). This Court has jurisdiction under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2)(A), and 28 U.S.C. §§ 1331 and 1338(a). (See, e.g., dkt. 1.)[1]

Aloxi® contains the active pharmaceutical ingredient palonosetron hydrochloride, and is FDA-approved to treat chemotherapy-induced nausea and vomiting and postoperative nausea and vomiting. (Dkt. 178-2 at 3.) The four related patents-in-suit are United States Patents No. 7,947,724 ("'724 patent"), No. 7,947,725 ("'725 patent"), No. 7,960,424 ("'424 patent"), and No. 8,598,219 ("'219 patent"). (Dkt. 174 at 2.) Those are all composition patents. There are other patents in the same patent family history, including method patents.[2] Only the four composition patents listed above, however, are

[1] The Court will cite to the documents filed in the Electronic Case Filing System ("ECF") by referring only to their docket entry numbers by the designation of "dkt." All of those references are to the consolidated docket in the lead case, Civil Action No. 11-3962, unless another docket is specified. The two later-filed actions that have been consolidated into this lead case are Civil Actions No. 11-5579 and No. 13-5815. Copies of the four patents-in-suit are attached as exhibits to those respective complaints, and also to various Markman filings throughout the docket. We will simply cite to the patents by page or column and line number. The plaintiffs in this consolidated action are Helsinn Healthcare S.A. and Roche Palo Alto LLC. The originally-named defendants are Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc., Sandoz Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. For purposes of this claim construction opinion, we will refer to each side collectively as "plaintiffs" and "defendants."

[2] The parties supplied, upon request by the Court, a Diagram of the Patent Family History of the Patents-in-Suit, which we have had filed on the docket in this action. (Dkt. 289.) It is very helpful in showing all applications, and approved patents, stemming from an original Provisional Application No. 60/444,351, filed on January 30, 2003. That date is the critical date for all of the ensuing patents, and the patents-in-suit are subject to terminal disclaimers tied to the first-issued of those patents, the '724 patent.

asserted in this particular consolidated action.[3]

This opinion addresses certain language that appears in the preamble portion of the two independent claims of the '219 patent, including asserted claim 1. The entire preamble of claim 1 reads: "A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, [comprising....]." See n.7, infra (quoting '219 patent). Language in the body of claim 1 refers to "said formulation." Id.

The parties agree that all of the words of that preamble up to and including "formulation" constitute claim limitations, because those words provide antecedent basis for the "said formulation" language that follows in the claim body. However, the parties dispute whether the balance of the preamble text, consisting of the phrases "for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting," should be read as claim limitations. Plaintiffs argue that

[3] The parties have filed a Stipulation, narrowing and specifying the patents and claims at issue in this consolidated action. Those are as follows: '724 patent, claims 2 and 9; '725 patent, claim 2; '424 patent, claim 6; and '219 patent, claims 1, 2, 6, and 7. (Dkt. 174 at 2.) Here in the District of New Jersey, other patent cases involving this family of patents (those asserted here and a later-issued patent) are docketed as Civil Actions No. 12-2867, No. 14-4274, No. 14-6341, No. 15-1228, No. 15-2077, and No. 15-2078. Some of those are consolidated with each other, and others are not currently consolidated. There is also pending litigation in the District of Delaware involving the same patent family. See, e.g., Helsinn Healthcare S.A., et al. v. Cipla Ltd., et al., D. Del. Civil Action No. 13-688 (consol.).

the language is limiting, and defendants argue to the contrary. (Dkt. 175 at 6–9 (joint claim construction chart).)[4]

The Court has considered the written submissions of the parties and conducted oral argument on this issue. The evidence presented by the parties as relevant to this claim construction was all intrinsic evidence. That evidence included the claims, specification, and prosecution history of the '219 patent and related patents in the same family history, as well as some of the prior art references cited in those United States Patent and Trademark Office ("USPTO") filings. Based on the intrinsic evidence and the arguments of the parties presented in these claim construction proceedings, this Court concludes that the disputed preamble language in claim 1 of the '219 patent does constitute claim limitations of the patent.[5]

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[4] In addition to the Joint Claim Construction & Prehearing Statement (dkt. 175), the submissions on this claim construction issue are as follows: dkt. 176, Defs.' Opening Br.; dkt. 176-1 to 176-4, Barker I Decl.; dkt. 177, Pls.' Opening Br.; dkt. 178 to 178-4, Ni I Decl.; dkt. 182, Defs.' Responsive Br.; dkt. 182-1 to 182-17, Barker II Decl.; dkt. 181, Pls.' Responsive Br.; dkt. 181-1, Ni II Decl.; and dkt. 220, Markman Oral Arg. Tr. The attorney declarations contain numerous exhibits, which we will cite simply by reference to ECF page numbers. Following oral argument, the Court requested and received from the parties the complete '219 patent prosecution history file from the United States Patent and Trademark Office (three volumes, not docketed).

[5] Defendants have provided discovery and contentions relating to their invalidity arguments in alternative form, depending on whether the Court would find the disputed preamble language to be limiting. Those arguments include written description contentions. (Dkt. 182 at 17 n.12.)

I. BACKGROUND

A. Legal standard

Courts define the meaning and scope of patent claims by the process of claim construction. Markman v. Westview Instruments, 52 F.3d 967, 976, 978, 1026 (Fed.Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). A court first looks to the intrinsic evidence to construe claims. See Interactive Gift Express v. Compuserve, 256 F.3d 1323, 1331 (Fed.Cir. 2001) (en banc reh'g denied). Here, the parties have argued their positions primarily with reference to the intrinsic evidence and did not request an evidentiary hearing. (See dkt. 175.) Although some extrinsic evidence was identified in the parties Joint Claim Construction Statement (id.), the Court finds the briefing and the oral argument to be sufficient to resolve this issue without resort to extrinsic evidence.

The intrinsic record, which includes the claims, specification, and complete prosecution history, is the most significant source for the legally operative meaning of disputed claim language. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir. 1996). A patent's prosecution history consists of the record of proceedings before the USPTO and the prior art cited during the patent's examination. Phillips v. AWH Corp., 415 F.3d 1303, 1317 (Fed.Cir. 2005) (en banc).

It is well settled that "[t]he determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim." Manual of Patent Examining

Procedure § 2111.02 (Rev. Aug. 2012) (citing Catalina Mktg. Int'l v. Coolsavings.com, 289 F.3d 801, 808 (Fed.Cir. 2002)). (Dkt. 182-8 at 2.)

"Whether a preamble stating the purpose and context of the invention constitutes a limitation of the claim[s] ... 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." Catalina Mktg., 289 F.3d at 808 (quoting Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc., 98 F.3d 1563, 1572–73 (Fed.Cir. 1996)).

The Federal Circuit in Catalina Mktg. set forth certain "guideposts that have emerged from various decisions exploring the preamble's effect on claim scope." (Dkt. 182-8 at 2.) Here is a summary of those principles insofar as relevant to this case, as expressed in Catalina Mktg.:

> In general, a preamble limits the invention if it recites essential structure or steps, or if it is "necessary to give life, meaning, and vitality" to the claim.... Conversely, a preamble is not limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention."

289 F.3d at 808 (internal citations omitted).

> Additionally, dependence on a particular disputed preamble phrase for antecedent basis may limit claim scope because it indicates a reliance on both the preamble and claim body to define the claimed invention.... Likewise, when the preamble is essential to understand limitations or terms in the claim body, the preamble limits claim scope....
>
> Further, when reciting additional structure or steps underscored as important by the specification, the preamble may operate as a claim limitation.....

> Moreover, clear reliance on the preamble during prosecution to distinguish the claimed invention from prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention..... Without such reliance, however, a preamble generally is not limiting when the claim body describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or steps of the claimed invention.... Thus, preamble language merely extolling benefits or features of the claimed invention does not limit the claim scope without clear reliance on those benefits or features as patentably significant....
>
> Moreover, preambles describing the use of an invention generally do not limit the claims because the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure.... More specifically, this means that a patent grants the right to exclude others from making, selling, ... the claimed apparatus or composition for any use of that apparatus or composition, whether or not the patentee envisioned such use.... Likewise, this principle does not mean that apparatus claims necessarily prevent a subsequent inventor from obtaining a patent on a new method of using the apparatus where that new method is useful and nonobvious.

Id. at 808–09 (internal citations omitted).

Those are the general guiding principles in this discrete area of patent law. Cf. Am. Med. Sys., Inc. v. Biolitec, Inc., 618 F.3d 1354, 1363–64 (Fed.Cir. 2010) (Dyk, J., dissenting). Additional precedents cited by the parties are discussed in Sections II.A and II.B, infra.

B. The '219 patent and related patents

The '219 patent shares essentially the same specification with the related patents-in-suit. (See dkt. 220 at 6.) To summarize this group of patents, as relevant to the claim construction issues here, we will describe the precise claims of the four patents-in-suit, and the specification language common to them all.

Clearly, the primary focus of all four of these patents is shelf stability of the claimed palonosetron formulations. See, e.g., Civil Action No. 12-2867, dkt. 92 at 25–33 ('724 patent claim construction opinion (sealed)). The question raised in this claim construction proceeding, however, is whether certain other aspects of the '219 claim language (and, perhaps, corresponding parts of the claim preambles of the other three patents-in-suit) are claim limitations rather than merely non-limiting preamble language.

The aspects of the '219 patent that are placed in issue in this Markman proceeding derive from the two distinct prepositional phrases in the disputed portion of the preamble language in claim 1 of the '219 patent. Those read, in their entirety: "for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting." See n.7, infra.[6]

The parties make arguments addressed to each phrase separately, and to both phrases jointly. See Sections II.A & II.B, infra. However, for discussion purposes we will often refer to them separately as follows: (1) "for intravenous administration to a human" ("Phrase One"); and (2) "to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting" ("Phrase Two"). Portions of the '219 patent specification

[6] There are two independent claims in the '219 patent, claims 1 and 8. See n.7, infra (quoting '219 claims). Only claim 1 of the '219 patent, and its dependent claims 2, 6, and 7, are asserted in this litigation. (See dkt. 174 at 2.) Of course, all claims of the patents-in-suit and related patents may be relevant to claim construction. Nevertheless, because independent claims 1 and 8 of the '219 patent have identical preambles, and because claim 8 is not asserted, we will refer to the preambles of both claims 1 and 8 as "the preamble" of the '219 patent claims.

and various relevant prosecution history files pertain to those separate phrases, as described below.

The '219 patent, like all of its related patents in the same patent family, is entitled "Liquid Pharmaceutical Formulations of Palonosetron." It contains eight claims, of which independent claim 1 and dependent claims 2, 6, and 7 are asserted in this case. See n.3, supra. The full text of the '219 claim language is quoted here in the margin.[7]

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[7] The complete claims of the '219 patent are as follows:

What is claimed is:

1. A **pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting**, comprising a 5 mL sterile aqueous isotonic solution, said solution comprising:

palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;
from 0.005 mg/mL to 1.0 mg/mL EDTA; and
from 10 mg/mL to 80 mg/mL mannitol,
wherein said formulation is stable at 24 months when stored at room temperature.

2. The pharmaceutical formulation of claim **1**, wherein said EDTA is in an amount of 0.5 mg/mL.

3. The pharmaceutical formulation of claim **1**, wherein said mannitol is in an amount of 41.5 mg/mL.

4. The pharmaceutical formulation of claim **1**, wherein said solution further comprises a citrate buffer.

5. The pharmaceutical formulation of claim **4**, wherein said citrate buffer is at a concentration of 20 millimolar.

6. The pharmaceutical formulation of claim **1**, wherein said solution is buffered at a pH of 5.0 ±0.5.

7. The pharmaceutical formulation of claim **1**, wherein said EDTA is in an amount of 0.5 mg/mL, wherein said mannitol is in an amount of 41.5 mg/mL, wherein said solution further comprises a citrate buffer at a concentration of 20 millimolar, and wherein said solution is buffered at a pH of 5.0 ±0.5.

There is preamble language in each of the other three patents-in-suit that is similar but not identical to the disputed preamble phrases in the '219 patent. Here, also in the margin, we quote the corresponding portions of the other patents-in-suit, the '724 patent,[8]

> **8**. A **pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting**, comprising a 5 mL sterile aqueous isotonic solution, said solution comprising:
>
> palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;
>
> from 0.005 mg/mL to 1.0 mg/mL EDTA; and
>
> from 10 mg/mL to 80 mg/mL mannitol,
>
> wherein said formulation is stable at 18 months when stored at room temperature.

('219 patent, col. 10, lines 1–38 (emphasis added).)

[8] The '724 patent provides, in pertinent part:

> What is claimed is:
>
> **1**. A **pharmaceutically stable intravenous solution for reducing emesis or reducing the likelihood of emesis** comprising:
>
> ....
>
> **2**. The solution of claim **1** wherein ....
>
> ....
>
> **8**. A **pharmaceutically stable isotonic intravenous solution for reducing emesis or reducing the likelihood of emesis** comprising:
>
> ....
>
> **9**. The solution of claim **8** wherein ....
>
> ....
>
> **14**. The solution of claim **8** adapted for intravenous administration.

('724 patent, col. 9, lines 27–35, col. 10, lines 1–33 (emphasis added).)

the '725 patent,[9] and the '424 patent.[10]

As can be seen, all three of those patents contain preamble language directed to "reducing ... the likelihood of emesis," similar to the '219 preamble directed to "reducing the likelihood of cancer chemotherapy-induced nausea and vomiting." Also, the '724 and '424 patents contain preamble language specifying an "intravenous solution", or an "isotonic intravenous solution." See nn. 8 & 10, supra. Similarly, the '725 patent in the body of the claims refers to "sterile injectable" and "a tonicifying amount of mannitol" (features associated with injectable solutions, as explained infra). See n.9, supra.

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[9] The '725 patent provides, in pertinent part:

> What is claimed is:
>
> **1**. A **pharmaceutically stable solution for reducing emesis or reducing the likelihood of emesis** comprising:
>
> ....
>
> **2**. A **pharmaceutically stable solution for reducing emesis or reducing the likelihood of emesis** comprising:
>
> ....

('725 patent, col. 10, lines 3–19 (emphasis added).) Text in the body of the claims refers to "sterile injectable" and "a tonicifying effective amount of mannitol." (Id., lines 8–9; see also id., lines 14–19.)

[10] The '424 patent provides, in pertinent part:

> What is claimed is:
>
> **1**. A **pharmaceutically stable isotonic intravenous solution of palonosetron hydrochloride for reducing emesis or reducing the likelihood of emesis** comprising
>
> ....
>
> **2**. The solution of claim **1** wherein ....

('424 patent, col. 10, lines 5–15 (emphasis added).)

An earlier claim construction proceeding in this consolidated case pertained to the term "pharmaceutically stable" in the preambles of the '724, '725, and '424 patents.[11] In joining issue on that claim construction dispute, the parties agreed that the preamble language in those patents, up to and including the word "solution," was limiting. Thus, the words "pharmaceutically stable intravenous solution," in the '724 preamble, and the words "pharmaceutically stable isotonic intravenous solution," in the '424 preamble, were agreed by the parties to be limiting. Defendants, however, did not stipulate with respect to those three patents that the "reducing ... the likelihood of emesis" language of their preambles should be construed to be claim limitations. (Dkt. 182 at 5–6, 20.)

Defendants maintain their opposition here to interpreting the "reducing ... the likelihood of emesis" in the '724, '725 and '424 preambles, and the "reducing the likelihood of cancer chemotherapy-induced nausea and vomiting," in disputed Phrase Two of the '219 preamble, as claim limitations. They also contend that the disputed Phrase One language — "for intravenous administration to a human" in the '219 preamble — is not to be equated with the "intravenous solution" form that they acknowledged as limiting in the '724 and '424 preambles. (Id.) The parties' competing arguments on those points are discussed in Sections II.A and II.B, infra.

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[11] That claim construction dispute was considered by the Court during the earlier Markman proceedings here, but we declined to rule on briefs alone, deferring the issue for extrinsic evidence to be provided at the non-jury ANDA trial. (Dkt. 103 at 77–78.) See also Helsinn Healthcare S.A., et al. v. Cipla Ltd., et al., D. Del. Civil No. 13-688, dkt. 169 at 3 (same).

As previously noted, the four patents-in-suit share essentially the same specification, as do the other patents stemming from the same original provisional application. For purposes of the following summary of their specifications, we will quote the '219 specification, recognizing that the corresponding sections of the three other patents-in-suit are the same.

Most of the text of the '219 patent specification addresses the prior art stability problems with palonosetron in liquid formulations, and the new formulations claimed in this patent family to overcome those stability problems. See, e.g., Civil Action No. 12-2867, dkt. 92 at 25–33 (reviewing corresponding portions of '724 specification (sealed)). Furthermore, the specification gives examples of both intravenous and oral formulations, and all of the test results provided in the specification measure shelf life stability, rather than the therapeutic effects of the drug itself. Id. (See '219 patent, col. 2, line 42 to col. 9, line 35.)

There are, however, significant references to the anti-emetic properties of palonosetron in the '219 and related patent specifications. There are also discussions of intravenous and other types of formulations in those same specifications. Here we quote some of those portions of the '219 specification.

The references to intravenous medicaments and the use of palonosetron to reduce emesis are found throughout the specification. As those are somewhat entwined in the text, we will quote them together where they appear together, highlighting those two topics in bold type.

The Abstract states:

> The present invention relates to shelf-stable liquid **formulations of palonosetron for reducing chemotherapy and radiotherapy induced emesis with palonosetron**. The formulations are particularly useful in the preparation of **intravenous** and oral liquid **medicaments**.

('219 patent, p.1.)

The Background of the Invention states:

> **Emesis is a devastating consequence of cytotoxic therapy, radiotherapy, and post-operative environments that drastically affects the quality of life of people undergoing such treatments. In recent years a class of drugs referred to as 5-HT3 ... receptor antagonists has been developed that treat such emesis** by antagonizing cerebral functions associated with the 5-HT3 receptor.... **These 5-HT3 antagonists are often administered intravenously shortly before chemotherapy or radiotherapy is initiated, and can be administered more than once during a cycle of chemotherapy or radiotherapy**. In addition, they are often supplied as tablets for oral elixirs to either supplement intravenous administration, or to ease home usage of the drug if the patient is self-administering the chemotherapeutic regimen.
> ....
> **Recently, clinical investigations have been made concerning palonosetron, a new 5-HT3 receptor antagonist reported in [a prior art patent]. These investigations have shown that the drug is an order of magnitude more potent than most existing 5-HT3 receptor antagonists, ... and is effective to reduce delayed-onset nausea induced by chemotherapeutic agents.** However, formulating palonosetron in liquid formulations has not proven an easy task.
> ....
> Therefore, there exists a need for a palonosetron formulation with increased stability and thereby increased shelf life....
>
> **It is an object of the present invention to provide a formulation of Palonosetron hydrochloride with increased pharmaceutical stability for preventing and/or reducing emesis.**
> ....

(Id., col. 1, line 12 to col. 2, line 51.)

The Summary of the Invention states:

> The inventors have made a series of discoveries that support a **surprisingly effective and versatile formulation for the treatment and prevention of emesis using palonosetron**. These formulations are shelf stable for periods greater than 24 months at room temperature....
>
> In one aspect, **the inventors have discovered that formulations which include the active ingredient palonosetron require in some instances only 1/10th the amount of other previously known compounds for treating emesis, which surprisingly allows the use of concentrations of palonosetron far below those that would ordinarily be expected. Thus, in one embodiment the invention provides a pharmaceutically stable solution for preventing or reducing emesis** comprising....
>
> The inventors have further discovered that by adjusting the formulation's pH and/or excipient concentrations it is possible to increase the stability of palonosetron formulations. Therefore, **in another embodiment, the invention provides a pharmaceutically stable solution for preventing or reducing emesis** comprising.... **In another embodiment the invention provides a pharmaceutically stable solution for preventing or reducing emesis** comprising....

(Id., col. 2, line 53 to col. 3, line 14.)

The Discussion section repeats some of the above-quoted text. It also states:

> **A particular advantage associated with the lower dosages of intravenous palonosetron is the ability to administer the drug in a single intravenous bolus over a short, discrete time period**.... In one particular embodiment the palonosetron is supplied in vials that comprise 5 ml. of solution, which equates to about 0.25 mg of palonosetron at a concentration of about 0.05 mg/ml.[12]

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[12] It is perhaps noteworthy that the structural formulation described in this paragraph of the specification appears to correspond precisely with the claim language of the '219 patent itself. As stated in claim 1: "A pharmaceutical single-use, unit-dose formulation **for intravenous administration** to a human ... comprising a 5 mL sterile aqueous isotonic solution, said solution comprising: palonosetron hydrochloride in an amount of 0.25 mg...." ('219 patent, col. 10, lines 2–7 (emphasis added).)

....

The formulations of the present invention are particularly suited for use in injectable and oral liquid formulations, but it will be understood that the solutions may have alternative uses. For example, they may be used as intermediaries in the preparation of other pharmaceutical dosage forms. Similarly, they may have other routes of administration including intranasal or inhalation. **Injectable formulations may take any route including intramuscular, intravenous or subcutaneous.**

(Id., col. 4, line 59 to col. 6, line 24.)

We will refer to this summary of the '219 claim language and specification, and the corresponding text in the '724, '725, and '424 patents, in Sections II.A and II.B, infra, when we discuss the parties' contentions drawn from that intrinsic evidence.

C. Prosecution history

The entire prosecution history of the '219 patent, and the relevant portions of its rather complicated patent family history, have been supplied to the Court in the parties' Markman submissions. See n.4, infra.

Any patent file history includes both procedural and substantive aspects. First, we briefly summarize the pertinent procedural chronology relevant to the '219 file. The substantive aspects of these events are next described here, and discussed in Sections II.A and II.B, infra.

The '219 patent is recent, having been issued on December 3, 2013. ('219 patent, p.1.) The actual prosecution file for the '219 patent is fairly simple, but the patent comes from a long and complicated family tree. The original provisional application, No.

60/444,351, was filed on January 30, 2003. (Id.) The first generation of patents to be issued subsequent to that provisional application were the '724 and '725 patents-in-suit, dated May 24, 2011. (Dkt. 289.) Thus, the basic prosecution for this patent family took approximately eight-and-a-half years. The next patent-in-suit, the '424 patent, was issued on June 14, 2011. (Id.) Each of those three patents had their own application number, and their own prosecution file.

As stated on the cover page of the '219 patent, its application number was Application No. 13/901,437. The preceding United States application data for the '219 patent, following the original '351 provisional application in January, 2003, is quoted in the margin.[13] The other patents issued to date in this family tree, and abandoned applications, are listed in the chart supplied by the parties. (Dkt. 289.)

This procedural history establishes that the '724 patent is a parent patent to the '219 patent, and the two other patents-in-suit, the '725 and '424 patents, came from continuation-in-part applications derived from the application for the '724 patent. Thus, all four prosecution histories are relevant to the claim construction issues here, while it is recognized that the specific claims of the individual patents do contain differences.

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[13] The intermediate application history of the '219 patent is stated to be as follows:

> Continuation-in-part of application No. 13/087,012, filed on Apr. 14, 2011, **now Pat. No. 8,518,981**, which is a continuation of application No. 11/186,311, filed on Jul. 21, 2005, **now Pat. No. 7,947,724**, which is a continuation of application No. PCT/EP2004/000888, filed on Jan. 30, 2004.

('219 patent, p.1 (emphasis added).)

Masco Corp. v. United States, 303 F.3d 1316, 1324 (Fed.Cir. 2002) ("The prosecution history of a parent application may be considered in construing claim terms.").[14]

The '724, '725, and '424 patents, all stemming from the same original '351 provisional application and all issued prior to the '219 patent, had extensive prosecution histories. The patents were approved only after appeals in all three cases to the Commissioner for Patents. Much file history was accumulated in those prosecution files. Some of that file history is discussed by the parties as relevant here. The application file for the '219 patent itself, albeit not as extensive as those of its predecessor patents, also includes its share of dialogue with the USPTO. That too is referred to by the parties, insofar as now pertaining to this claim construction. Here we summarize those portions of the substantive file history relating to the disputed '219 patent preamble phrases.

There are several features in the substantive prosecution history that plaintiffs refer to in support of their position that the two disputed preamble phrases in the '219 patent are limiting. Those may be summarized as follows, with details provided in the margin:

1. The preambles of both independent claims of the '724 patent were amended during prosecution to add the adjective "**intravenous**," while deleting from a dependent claim [as-issued claim 7] the phrase "adapted for oral administration." This amendment was made to overcome an obviousness rejection based on certain oral formulations disclosed in prior art. [There were also intravenous formulations in prior art, but the applicants narrowed the field of prior art by eliminating all oral

[14] Plaintiffs' briefing also cites at least one abandoned patent application in this group of prosecution history files, but we find that unnecessary to discuss in this opinion. (See, e.g., dkt. 177 at 9, 12–13 (citing abandoned '269 application).)

references by this amendment.] In explaining that amendment, the applicants stated that "the present claims are drawn towards pharmaceutically stable **intravenous** solutions of palonosetron."[15] A similar amendment was made to introduce the term **intravenous** into the preamble of the '424 patent, the applicant stating that "the pending claims are **limited to intravenous formulations**."[16]

2. Likewise, on appeal to the Commissioner in prosecution of the '724 patent, the applicants explicitly stated that "the **claimed formulations are intravenous formulations**."[17] Applicant's appeal brief distinguished prior art on that basis, stating that "there would be no reason to include a sweetener from [the prior art's] oral formulation in an intravenous formulation."[18] In the next USPTO communication, the

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[15] (See dkt. 177 at 9–11 (citing dkt. 178-2 at 52) (emphasis added).) In the same amendment, when the applicants placed "intravenous" in the preamble, they deleted the phrase "adapted for intravenous administration" from dependent claim 40 (which issued as claim 6 of the '724 patent, simply listing ingredients). This was to overcome a Section 112 rejection. (Dkt. 177 at 10–11 (citing dkt. 178-2 at 48–56).) The same type of amendment was made to overcome a Section 112 rejection in prosecution of the '424 patent. (Id. at 12–13 (citing dkt. 178-2 at 58–67).)

The Court notes that the '724 patent did issue with a dependent claim 14, "The solution of claim **8** adapted for intravenous administration," which evidently escaped rejection under Section 112. ('724 patent, col. 10, lines 34–35.) The parties do not comment upon this apparent anomaly, given that they agree that the adjective "intravenous" in the preamble to the corresponding '724 patent independent claim 8 is limiting. We merely note this redundancy between the "intravenous" limitations in '724 patent preambles, claims 1 and 8, and the "adapted for intravenous administration" language in '724 patent dependent claim 14, when a similar redundancy criticized in the prosecution history of the '424 patent prompted elimination of similar language in a dependent claim there in order to overcome a Section 112 rejection.

[16] (See dkt. 177 at 12–13 (citing dkt. 178-2 at 58–67) (emphasis added).)

[17] (See dkt. 177 at 11 (citing dkt. 178-2 at 91) (emphasis added).)

[18] (See dkt. 177 at 11 (citing dkt. 178-2 at 91).)

examiner allowed the '724 claims to issue.[19] A similar appeal to the Commissioner in the '424 prosecution, explicitly stating that "the claimed formulation is **limited by ... an intravenous solution**," to overcome prior art,[20] was followed by allowance of the '424 patent.[21]

3. The examiner on the application for the '219 patent, while initially rejecting the application on grounds of prior art (that was later demonstrated not to be prior art), stated with reference to the "for intravenous administration" language in the preamble to claim 1, that the prior art disclosed the elements "**required** by instant claims 1, 3–4, 6," including an **IV** [i.e., intravenous] **formulation**.[22]

4. The application for the '724 patent received an initial rejection on grounds including Section 112 (enablement), based on the phrase "preventing emesis" in the preambles to its two independent claims.[23] The applicants overcame that ground for rejection by substituting the words "**for reducing emesis or reducing the likelihood of emesis**" that appear in as-issued claims 1 and 8.[24] Identical Section 112 rejections, and identical successful amendments, occurred in prosecution of the '725 patent[25] and the '424 patent.[26]

5. The examiner on the application for the '219 patent, when initially rejecting the '219 claims on grounds of prior art (that was later shown

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[19] (See dkt. 177 at 12 (citing dkt. 178-2 at 102–04).)

[20] (See dkt. 177 at 13 (citing dkt. 178-3 at 54–76) (emphasis added).)

[21] (See dkt. 177 at 13 (citing dkt. 178-3 at 78–80).)

[22] (See dkt. 177 at 15 (citing dkt. 178-4 at 45) (emphasis added).)

[23] (See dkt. 177 at 15 (citing dkt. 178-4 at 45).)

[24] (See dkt. 177 at 14, citing dkt. 178-4 at 105–44 (emphasis added).)

[25] (See dkt. 177 at 14–15 (citing dkt. 178-3 at 129–44).)

[26] (See dkt. 177 at 14–15 (citing dkt. 178-4 at 2–17).)

not to be prior art), alleged that the cited reference "teach[es] a pharmaceutical[ly] stable solution **for reducing emesis**."[27]

6. The examiner on the application for the '219 patent conducted a telephone interview with counsel for the applicants on September 30, 2013, shortly before the application was approved. The examiner's record of that interview states that in discussing the lack of a pH limitation in the claims, "**[applicants] highlighted the limitations that were in the claims, including** the concentration of palonosetron, the dose of palonosetron, the concentration of EDTA, the concentration of mannitol, the 24 month and 18 month stability requirements, and **cancer chemotherapy-induced nausea and vomiting**."[28]

7. The examiner reported that in the same interview, the parties discussed prior art including a publication by Tang. The examiner's notes state:

> Tang ... was also discussed. **Tang describes a dose ranging trial in PONV [post-operative nausea and vomiting] that evaluated doses of 0.1-30 µg/kg. [Applicants] pointed out Tang's statement in the abstract that "[o]nly 30 µg/kg RS-25259 (palonosetron) significantly decreased the incidence of vomiting and the requirement for rescue anti-emetics." [Applicants] further pointed out that the 30 µg/kg dose described in Tang corresponds to 2.1 mg for a 70 kg adult, which is higher than the 0.25 mg dose described in the claims**.[29]

The Notice of Allowability for the '219 patent, signed by the examiner on the same day as that interview, September 30, 2013, adopted the applicants' arguments in distinguishing the prior art Tang reference:

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[27] (See dkt. 177 at 15 (citing dkt. 178-4 at 45) (emphasis added).)

[28] (See dkt. 181 at 11 (citing dkt. 181-1 at 30) (emphasis added).)

[29] (Dkt. 181-1 at 30 (emphasis added).)

The following is an examiner's statement of reasons for allowance:

> The closest prior art Tang (Anesth Analg 1998 ...) specifically teach that implications in administering palonosetron (i.e., RS-25259) was effective only at a higher dose (i.e., 30 µg/kg which is 2.1 mg when an average weight 70 kg of the patient is considered). This dose is far greater than that recited by the applicant. Yes Tang teaches a concentration of 3.0 µg/kg which is the closest to the dose recited [in this application], however Tang also teaches that it fails to provide [sic: prevent] or reduce the post-operative vomiting.[30]

The arguments of the parties drawn from the above-cited prosecution history portions of the intrinsic evidence are discussed in Sections II.A and II.B, infra.

II. DISCUSSION

A. Phrase One: "for intravenous administration to a human"

The parties make several arguments going to both disputed preamble phrases, and they also argue several separate points directed to each phrase. As we have stated, the Court likewise considers the two phrases together, but also separately as Phrase One and Phrase Two.

The disputed Phrase One in claim 1 of the '219 patent, as we analyze the text, is "for intravenous administration to a human." ('219 patent, col. 10, lines 2–3.) That is actually two phrases, grammatically speaking, with the prepositional phrase "to a human" modifying the noun "administration." But we refer to all of those words as Phrase One.

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[30] USPTO Prosecution History for the '219 patent at HELSN0397770 (bracketed material added).

The disputed Phrase Two in claim 1 of the '219 patent is "to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting." ('219 patent, col. 10, lines 3–4.) The parties and the Court commonly abbreviate the last six words of this phrase as "CINV," and we will do so in this discussion.[31]

Most of the parties' arguments are based on the concepts articulated by the Federal Circuit in its 2002 decision, Catalina Marketing, 289 F.3d at 808–10 ("Catalina"), as described in Section I.A, supra, and its progeny. Where specific Federal Circuit opinions feature in their arguments, we will discuss those in analyzing their respective contentions.

Plaintiffs contend, by way of overview, that two of the recognized grounds for treating preamble language as limiting apply to all of the disputed text here. First, they say that all of that language modifies and provides antecedent basis for the words "said formulation" in the body of the claim, and that in the broader sense it is necessary to "give life, meaning, and vitality" to the claim. Catalina, 289 F.3d at 808. Second, they assert that the intrinsic evidence makes clear, through the applicants' clear reliance on that preamble language during the prosecution history, that it serves as a limitation of the claim. Id. (See dkt. 177; dkt. 181.)

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[31] As explained in Section I.B, supra, the narrow claim construction dispute requires only construction of the disputed preamble language of asserted claim 1 of the '219 patent. See n.4, supra, and accompanying text. We do recognize, of course, that as to disputed Phrase Two in that claim, there is analogous language in the asserted claims of the '724, '725, and '424 patents, which defendants also contend is not limiting.

Defendants contend that the Catalina "general rule" that preamble language is not limiting applies to the disputed phrases here, and that plaintiffs have made no showing that any of the recognized exceptions apply. Specifically, defendants argue that no terms in the body of the claim derive antecedent basis from the disputed phrases, and that the patentee defined a structurally complete invention in the claim body, using the disputed preamble language only to state a purpose or an intended use for the invention. Defendants further argue that the prosecution history fails to show clear reliance on that preamble language to distinguish the claimed invention from prior art. (See dkt. 176; dkt. 182.)

The discussion in this Section II.A is focused specifically on the parties' arguments directed to Phrase One, "for intravenous administration to a human." Section II.B, infra, will address Phrase Two, "to reduce the likelihood of CINV."

The parties first look at the language of claim 1 and its dependent claims 2–7. Defendants say that "antecedent basis" only applies to the undisputed portion of the preamble, "[a] pharmaceutical single-use, unit dose formulation," because the reference in the body of claim 1 is only to "said formulation." (See '219 patent, col. 10, lines 11–12 ("said formulation is stable at 24 months....").) Defendants point out that there is no reference in the body of the claims to "said intravenous administration," or "said human." (Dkt. 182 at 7 & n.1.)

Plaintiffs respond that all of Phrase One should be deemed to modify "formulation" in the preamble, because there is no reason why words appearing before and after "formulation" in the preamble should be so divided. "Just because some words come before and some come after" — plaintiffs argued during the Markman hearing — does not "change the fact that they're describing the formulation." (Dkt. 220 at 10.)

Defendants also contend, again looking just at the claim language, that the undisputed portion of the preamble, up to the term "formulation," is structural language defining that term. They say that in contrast, the disputed portion, including Phrase One, is functional and should not be deemed limiting. (Dkt. 182 at 7 (citing Marrin v. Griffin, 599 F.3d 1290, 1295 (Fed.Cir. 2010) (en banc reh'g denied) ("the mere fact that a structural term in the preamble is part of the claim does not mean that the preamble's statement of purpose or other description is also part of the claim.")).)

Plaintiffs make two responses to this argument. First, they say that the preamble language immediately preceding "formulation," namely "single-use, unit-dose," is not just structural. That language also helps to define how the formulation is designed to be used; that is to be administered once, to one patient, and then discarded. (Dkt. 181 at 6; dkt. 220 at 13–14.) Second, they say that the Phrase One preamble language following "formulation," namely "for intravenous administration to a human," is not just functional but also conveys essential structure for the formulation, because intravenous products require a unique formulation strategy. The formulated product has to be not only sterile

and isotonic, as required by the body of the claim, but also pyrogen free and free of particulate matter in order to qualify as an intravenous formulation, as opposed to an oral formulation. (Dkt. 177 at 9 & n.5; dkt. 181 at 7–8 & nn.5, 6 (citing prior art references listed in '219 patent disclosures).)

Thus, plaintiffs argue that comparing the language up to "formulation" with the Phrase One language following it in the '219 preamble, any attempt to distinguish between those groups of words as "structural" versus "functional" is unfounded. Another reason, according to plaintiffs, why the Phrase One preamble language conveys essential structure is to clarify that the claimed formulation is an intravenous composition rather than some other form of injectable formulation described in the specification, such as intramuscular or subcutaneous. (Dkt. 177 at 6–7.)

Plaintiffs also take issue with defendants' position that there is a difference between the "intravenous solution" or "intravenous isotonic solution" in the preambles of the '724 and '424 claims, and the "for intravenous administration" language in Phrase One of the '219 preamble. Defendants maintain that there is a substantive difference between using "intravenous" as an adjective positioned before the noun "solution," as in the '724 and '424 preambles where they stipulated the language was limiting, and using the prepositional phrase "for intravenous administration" after "formulation" in the '219 preamble. (Dkt. 182 at 10 & n.7; dkt. 220 at 61–64.) Plaintiffs reply that there is no material difference between "intravenous solution" and "formulation for intravenous

administration"; that the terms mean the same thing and should be treated alike as limiting. (Dkt. 220 at 15–19.) As to that argument, the Court finds itself squarely in agreement with plaintiffs.[32]

Defendants point out that the "intravenous" feature referred to in disputed Phrase One of the '219 preamble is not so limited in the specification of the patent. For example, none of the "objects of the invention" describe the invention as being "for intravenous administration," and the word "intravenous" is not found in the "summary of the invention." (Dkt. 182 at 16.) Instead, the specification lists a wide range of possible liquid formulations that could be made according to the invention, including oral and other injectable kinds. (See '219 patent, col. 4, line 59 to col. 6, line 24 (quoted supra, Section I.B).) Plaintiffs respond that the claim language of the '219 patent as discussed above, and the pertinent prosecution history, clearly establish that the "for intravenous administration to a human" phrase of the preamble is a claim limitation. (Dkt. 181 at 7–11.)

Turning to the prosecution history pertaining to the '219 patent, plaintiffs rely on several portions in support of their argument that the Phrase One preamble language is

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[32] Defendants cite no record support for this particular argument, and some of the intrinsic evidence appears to refute it. For example, the examiner in the '219 prosecution stated, with reference to the "**formulation for intravenous administration**" language in the preamble, that the prior art disclosed elements "required by instant claims 1, 3–4, 6, including an **IV formulation**." See n.22, supra. Similarly, the '219 specification, describing the very structural formulation claimed in the '219 patent, called it a "**single intravenous bolus**." See n.12, supra, and accompanying text.

limiting. First, they point to the amendments in the applications for both the '724 and '424 patents, omitting "adapted for oral administration" in dependent claim language and inserting "intravenous" in the preambles of the independent claims. Those amendments were made to overcome obviousness objections based on prior art references to oral formulations. See n.15, supra, and accompanying text. Defendants, while acknowledging that they have stipulated that "intravenous" in those preambles is limiting, respond only that for the '219 patent, the applicants chose to use the phrase "for intravenous administration to a human," rather than "intravenous" as in the prior patents. (Dkt. 182 at 10 & n.6.; dkt. 220 at 53–58.) We find that argument unpersuasive. See n.32, supra, and accompanying text.

This prosecution history, we find, fits squarely within the Catalina statement that even "use" language in a preamble can be limiting if it is "clearly and unmistakably relied on ... to distinguish prior art." Catalina, 289 F.3d at 809. We also agree with plaintiffs that this conclusion is further supported in the appeal files for the '724 and '424 patents, where the applicants distinguished prior art, in part, on the basis that the "intravenous" feature in the preambles constituted a claim limitation. See nn.17–21, supra, and accompanying text. Finally, as to the '219 prosecution history itself, the examiner for the '219 patent made express note of his understanding that the elements "required by instant

claims 1, 3–4, 6" included "an IV formulation." See n.22, supra, and accompanying text.[33]

This Court has considered the arguments of the parties, as summarized here, and the portions of the intrinsic evidence cited and discussed by them. We find that the points argued by plaintiffs regarding the claim text, specification, and prosecution history of the '219 patent and its related patents-in-suit support their position, and they have made a sufficient showing based on the intrinsic evidence that this preamble language is limiting. Accordingly, the Court construes Phrase One of the disputed preamble language, "for intravenous administration to a human," to be a limitation in asserted claim 1 of the '219 patent.

B. Phrase Two: "to reduce the likelihood of CINV"

Defendants' arguments against treating Phrase Two as a claim limitation are stronger than as to Phrase One, but on balance the Court finds that plaintiffs' arguments prevail on that issue as well.

Defendants argue first that there is no structural aspect to the phrase, "to reduce the likelihood of CINV," and therefore this is purely a "use" description that should fall

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[33] Defendants correctly state that the prosecution history of the patents-in-suit contains no portion where the applicants relied on administration of the formulation to humans to overcome prior art. (Dkt. 182 at 11.) While that is true, the shared specifications of all those patents make clear that the whole purpose of these formulations is to treat "people" and that emesis "drastically affects the quality of life of people...." See Section I.B, supra (quoting '219 specification). Also, the prepositional phrase "to a human" directly follows and modifies the noun "administration." If we find, as we do, that "for intravenous administration" is limiting language in the '219 preamble, in our view the record further supports including that additional language "to a human" in the same finding. There was little debate about this either in the briefing or at oral argument. (See, e.g., dkt. 220 at 17–18, 61.)

within the general rule that "a preamble is not limiting 'where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention;'" and that "preambles describing the use of an invention generally do not limit the claims because the patentability of ... composition claims depends on the claimed structure, not on the use or purpose of that structure." Catalina, 289 F.3d at 808–09 (internal citation omitted). (See, e.g., dkt. 176 at 5; dkt. 182 at 18–19.)

Plaintiffs do not dispute that there is really no structural aspect to Phrase Two. Nevertheless, they claim antecedent basis tied to the undisputed preamble claim term "formulation," reasoning that Phrase Two should, like Phrase One, be interpreted to be an integral part of all the words modifying "formulation" in the preamble. (See, e.g., dkt. 177 at 7–9.) That interpretation would, in our view, strain the antecedent basis exception to an unreasonable degree.

Plaintiffs also argue, however, that the specification is replete with references to the pharmaceutical purposes of the drug palonosetron in general, and of the specific formulations of the drug claimed in the '219 patent and related patents-in-suit. In that sense, according to plaintiffs, the Phrase Two preamble language, read in light of the specification, will support a finding that although shelf stability of the formulations is the primary stated objective of the claimed inventive formulations, their use in treating emesis and specifically CINV is another claimed aspect of the invention. Thus, in

plaintiffs' view, the specification supports the stated intended use of "reducing the likelihood of CINV" as a fundamental characteristic of the claimed invention. See Section I.C, supra (quoting specification excerpts). (See, e.g., dkt. 177 at 6, 9–10 & n.7 (citing Catalina case law progeny).) Defendants dispute plaintiffs' characterization of the those precedents (see dkt. 182 at 17–18), but we find that the cited case law does support plaintiffs' argument.[34]

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[34] In re Cruciferous Sprout Litigation, 301 F.3d 1343 (Fed.Cir. 2002) (en banc reh'g denied), involved a method patent rather than a composition patent, and had preamble language stating "[a] method of preparing a food product rich in glucosinolates, [comprising]...." The Federal Circuit held that both the specification and the prosecution history indicated that the phrase "rich in glucosinolates" helped to define the claimed invention and was a claim limitation. The court emphasized that language in the specification supported that finding, and that during reexamination of the patent the patentee clearly relied on it to distinguish prior art. Id. at 1347–48. While that was a method patent and did not otherwise claim a "use," its holding illustrates the effect that some specification language and prosecution history can have on preamble limitation disputes. In Vizio, Inc. v. Int'l Trade Comm'n, 605 F.3d 1330 (Fed.Cir. 2010) (en banc reh'g denied), the preamble did contain a "use" in an apparatus claim, namely, "[a]pparatus for decoding a datastream," and the court concluded that the "for decoding" preamble language was properly construed as a claim limitation, because "decoding" was "the essence or a fundamental characteristic of the claimed invention." Id. at 1340–41. Earlier Federal Circuit cases also support plaintiffs' arguments here. In re Stencel, 828 F.2d 751 (Fed.Cir. 1987), involved an apparatus patent with a use phrase in the preamble, "[a] driver for setting a joint of a threaded collar...." The court held that the patentee was "not inhibited from claiming his driver, limited by the statement of its purpose, and further defined by the remaining clauses of the claims...." This purpose, it said, "is more than a mere statement of purpose; and that language is essential to particularly point out the invention defined by the claims." Id. at 752, 755. Likewise, in Gen. Elec. Co. v. Nintendo, 179 F.3d 1350 (Fed.Cir. 1999), a circuitry systems patent containing "use" preamble language was held to be limiting in light of the claims and specification. There, the preamble said, "[a] system for displaying a pattern on a ... device by mapping bits from a display location..." The court held that the "invention so described is restricted to those display devices that work by displaying bits," and that to read the claims broader to cover all types of display systems would be "divorced from reality." Id. at 1361–62.

Defendants emphasize the fact that the '219 patent claims and specification are devoid of support for the effective use of the claimed formulations, providing no information about whether the claimed amounts of palonosetron are effective or clinical trial data. For that reason as well, defendants argue, it would be improper to read Phrase Two of the preamble as limiting. (See, e.g., dkt. 182 at 15–17 & nn.11, 12.) Plaintiffs respond that such arguments invoke the written description requirements of the patent law, Section 112 (which defendants have also asserted in this case), rather than claim construction arguments. (See, e.g., dkt. 220 at 22–24.)

It is sufficient for purposes of claim construction, plaintiffs contend, that if an apparatus or composition claim refers to a function or an intended use, that claim language would require the apparatus to be actually capable of performing as claimed. (Id. at 32–35, 92–93.) Such functional language in an apparatus or composition claim, according to plaintiffs, does not transform it into a method claim as defendants contend. (Id.) While these arguments back and forth become somewhat elusive in our view, the case law cited by plaintiffs appears to support their position on this point. See n.34, supra.

The parties next address the prosecution history pertaining to their dispute over Phrase Two, which is found in several locations. First, in the prosecution history of the parent '724 patent and related '725 and '424 patents, the examiners in each case rejected preamble language "for preventing emesis," under the Section 112 enablement

requirements. In response, the applicants did not delete the reference to the therapeutic capability of the claimed formulations. Instead, they amended each application to substitute the phrase, "for reducing emesis or the likelihood of emesis," and thus overcame the Section 112 rejections. See nn.24–26, supra, and accompanying text. The later appeals in those three prosecutions did not then concern those earlier and then-moot Section 112 problems.[35]

Defendants contend that in any event, the Catalina recitation of preamble principles only recognizes a prosecution history exception if it shows clear reliance on preamble language by the applicant to distinguish prior art. (See dkt. 182 at 13–14 (citing Catalina, 289 F.3d at 809).) However, we do not read Catalina as stating an exclusive listing of prosecution history events that can transform preamble language into claim limitations. Rather, it appears to us that the recitation in Catalina was a cogent summary of principles developed in a long body of Federal Circuit and prior case law, rather than an attempt at an exhaustive catalogue of all potentially significant bases for finding preamble language to be limiting.[36]

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[35] Defendants point out that the appeal briefs in the prosecution of the '724, '725, and '424 patents listed "intravenous" as claim limitations, but did not so list "reducing emesis or the likelihood of emesis" as limitations. (Dkt. 182 at 11–12.) We find that not to be dispositive for two reasons. First, by the time of those appeals the Section 112 rejections of those applications were moot. Second, there is strong evidence in the '219 patent prosecution history that the similar preamble language in Phrase Two, "for reducing the likelihood of CINV," was definitely viewed as a limitation by the examiner and the parties. See n.37, infra, and accompanying text.

[36] Plaintiffs cite Fantasy Sports Props., Inc. v. Sportsline.com, Inc., 287 F.3d 1108, 1118 n.3 (Fed.Cir. 2002) (en banc reh'g denied), as presenting an example of a claim-limiting

The dispositive aspect of the '219 prosecution history itself, as bearing on the Phrase Two claim construction dispute as we see it, was at the very end of the prosecution history when the examiner conducted the telephone interview with the applicants. The examiner documented that interview in the official notes preserved in the prosecution record. Furthermore, the examiner confirmed in the Notice of Allowability that the arguments by the applicants relying on that preamble language, in connection with dosage data in the body of the claim, overcame the examiner's prior art issue concerning the cited Tang reference. See nn.28–30, supra, and accompanying text.[37]

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preamble ruling based on prosecution history involving a Section 112 rejection, and an applicant's amendment of the very preamble word that was rejected. We have considered the parties' opposing arguments on interpretation of that very limited precedent, and find that plaintiffs' reading is accurate and applicable. (Compare dkt. 177 at 14–15, with dkt. 182 at 13–14.) Thus, we are of the view that the Federal Circuit has approved of the Fantasy Football ground of ruling, which relied on a Section 112 prosecution history event in finding preamble language to be limiting.

[37] We asked about that portion of the '219 patent prosecution history at oral argument here, and plaintiffs' counsel explained it as follows:

> COURT: So, in other words [applicants' counsel] is trying to distinguish prior art in the form of this Tang patent that addresses PONV [post-operative nausea and vomiting], whereas the current application is addressing CINV?
>
> PLAINTIFFS: CINV. And, if I can give you a little context of what's happening here, is this Tang reference discloses that you need at least 2 mg to have partial efficacy in PONV, and what we are arguing to the [USPTO] is ... look, if you need at least 2 mg for PONV and only get partial efficacy, there's no way 0.25 [mg] for CINV, which typically requires more dose[,] could be obvious. So we're using Tang to suggest that 0.25 [mg] for CINV, couldn't possibly be obvious based on the disclosure of Tang.
>
> COURT: So, it is not just the wooden distinction between a patent directed at a PONV therapy and another patent directed at CINV .... It is that the dosage .... comparison produced some surprises[?]

We find that this intrinsic evidence clearly proves that: (1) the applicants for the '219 patent considered the preamble language "reducing the likelihood of CINV" to be a limitation of the claim; and (2) the examiner relied on the applicants' arguments about that preamble language, and their arguments distinguishing the prior art Tang reference, in allowing the patent to be approved. Whether the examiner made a correct decision that the language was limiting, and that the prior art was successfully distinguished, is not relevant to the claim construction issue presented here. The fact is conclusively shown by this intrinsic evidence that the applicant clearly relied on that preamble language to distinguish the claimed invention from the prior art.

For all of these reasons, including the frequent references in the specification to the claimed formulations to treat emesis and the specific reference there to treating CINV, and the prosecution histories of the related patents-in-suit and of the '219 patent itself, this Court construes Phrase Two of the disputed preamble language, "to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting," to be a limitation in asserted claim 1 of the '219 patent.

> PLAINTIFFS: Yes. The Tang study we think ... would have found the results of Helsinn's clinical study showing a very low dose of palonosetron being effective for CINV to be very surprising in terms of what Tang taught in the prior art. Tang suggested you need a much higher dose.

(Dkt. 220 at 32–33.)

III. CONCLUSION

The parties submitted a Joint Claim Construction and Prehearing Statement identifying a dispute with respect to whether the preamble language "for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting" is a limitation of asserted claim 1 of the '219 patent (and dependent asserted claims 2, 6, and 7). (Dkt. 175 at 2.) The same Statement confirmed that the parties do not have any dispute about terms appearing in the asserted claims of the '219 patent, and they agree that plain and ordinary meaning of the claim terms should govern. (Id.)

The Court has considered the briefs and intrinsic evidence materials submitted by the parties, and conducted oral argument. No party requested an evidentiary hearing, and the Court has made its findings based on the intrinsic evidence pertaining to the '219 patent and asserted patents in the same patent family tree. A court's finding as to intrinsic evidence amounts "solely to a determination of law." Teva Pharm. USA v. Sandoz, 135 S.Ct. 831, 841 (2015).

"Whether to treat a preamble as a limitation is a determination 'resolved only on review of the entire[] ... patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim.'" Catalina, 289 F.3d at 808 (citations omitted). Based on the intrinsic evidence and the applicable legal principles, and for the

reasons stated in this Memorandum Opinion, the Court finds that the disputed preamble language is limiting in its entirety. The Court will issue an appropriate order.

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

Dated: April 22, 2015