IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HELSINN HEALTHCARE S.A. and ROCHE PALO ALTO LLC, Plaintiffs, v. CIPLA LTD., CIPLA USA, INC., EUROHEALTH INTERNATIONAL SARL, WEST-WARD PHARMACEUTICAL CORP. and MYLAN INSTITUTIONAL LLC, Defendants.	C.A. No. 13-688-GMS **CONSOLIDATED**

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 7,947,724; 7,947,725; 7,960,424; 8,598,219 & 8,729,094

The court having considered the submissions of the parties and having heard oral argument on the matter—IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 7,947,724 ("the '724 Patent"); 7,947,725 ("the '725 Patent"); 7,960,424 ("the '424 Patent"); 8,598,219 ("the '219 Patent"); and 8,729,094 ("the '094 Patent"):

The '219 & '094 Patents

1. The term "said formulation is stable at 24 [18] months when stored at room temperature" is construed to have its plain and ordinary meaning, requiring no construction.[1]

[1] Only defendants Cipla Ltd. and Cipla USA, Inc. (collectively, "Cipla") seek construction of this claim term, which appears in several claims in both the '219 and '094 Patents. Specifically, Cipla argues that the claim term contains an implied pH limitation, in addition to the stability limitations, and proposes the following construction: "said formulation has a pH limitation that enables said formulation to be stable at 24 [18] months when stored at room temperature, wherein the pH is from 4 to 6." Cipla's primary support for its assertion comes from

statements in the prosecution history. The patent applications that Cipla highlights, however, ultimately issued as different patents—not the '219 and '094 Patents. Thus, the court must be careful not to import limitations based on a confused understanding of the prosecution history.

The court finds that the intrinsic record as a whole does not support Cipla's view. First, the claim language offers no indication that a pH limitation should be inferred. Rather, it does just the opposite. In particular, Claim 13 of the '094 Patent has the disputed claim term, as well as an additional element: "wherein said solution . . . optionally has a pH of from about 5.0±0.5." '094 Patent, claim 13. Were the court to adopt Cipla's proposal, Claim 13 would have two pH limitations—one that is optional and one that is mandatory. This result—even if the limitations are not altogether inconsistent—is counterintuitive and disfavored. *See Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) ("[T]he context in which a term is used in the asserted claim can be highly instructive."); *Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183 F.3d 1369, 1374 (Fed. Cir. 1999) ("Proper claim construction . . . demands interpretation of the entire claim in context, not a single element in isolation."). Although Claim 13 is the only one to include this optional pH limitation, terms are "presumed to have the same meaning throughout all of the claims in the absence of any reason to believe otherwise." *See Digital-Vending Servs. Int'l, LLC v. Univ. of Phx., Inc.*, 672 F.3d 1270, 1275 (Fed. Cir. 2012)).

The shared specification of the '219 and '094 Patents also does not support Cipla's view. The specification states that "[t]he 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." *See, e.g.*, '219 Patent, col. 3 ll. 4–6 (emphasis added). Thus, the specification did not identify a specific pH range necessary to obtain the desired stability. The court can see no "clear disavowal of claim scope" from the specification language. *See Golight, Inc. v. Wal-Mart Stores, Inc.*, 355 F.3d 1327, 1331 (Fed. Cir. 2004) (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002).

Finally, the court looks to the prosecution history, upon which Cipla relies most heavily. At the outset, the court notes that, in an Examiner-Initiated Interview conducted on September 30, 2013, the examiner for the '219 Patent specifically identified the "lack of a pH limitation in claims." (D.I. 128, Ex. 29.) Although the Examiner's summary is not binding, the court finds her conception of the claims noteworthy. The court rejects Cipla's suggestion that the Examiner interview during prosecution of the '219 Patent was a "litigation-driven attempt to claim more than what they actually invented." (D.I. 140 at 6.)

As for its affirmative support, Cipla points to statements in ancestor patent applications suggesting that a pH between 4 and 6 was required to obtain the corresponding stability limitation. Cipla was unable to find any evidence in the patent applications for the '219 and '094 Patents. Statements made in the context of initial applications *may be*—but are not necessarily—probative on later-issued patents. *See 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."). "When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that *contain the same claim limitation*." *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed . Cir. 1999). Importantly, however, the applications identified by Cipla all had *express pH limitations in the claims*. Thus, the value to be drawn from prosecution statements in those prior applications is greatly reduced, if not eliminated entirely.

Cipla's reliance on *Microsoft Corp v. Multi-Tech Systems, Inc.* is misplaced. 357 F.3d 1340 (Fed. Cir. 2004). Cipla argues that the drafters of the '219 and '094 Patents understood the "invention as a whole" to require a pH limitation, and this understanding is evidenced by the prosecution statements in the prior applications. (D.I. 128, Ex. 22 at A-241); *see Microsoft* at 1349 ("We cannot construe the claims to cover subject matter broader than that which the patentee itself regarded as comprising its inventions and represented to the PTO."). But the evidence of the patentees' "understanding" of the invention was much more explicit in *Microsoft*—both the specification and prosecution history statements were in agreement and "unambiguous[]." *See Microsoft* at 1348–49. Here, Cipla is only able to point to the drafter's quotation of the Manual of Patent Examining Procedure ("MPEP") in a traversal of an obviousness rejection for the '424 Patent. (D.I. 128, Ex. 22 at A-241 (quoting MPEP § 2141.02).) The court

The '219 Patent

2. The term "for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting" is construed to be limiting in its entirety.[2]

The '724, '725 & '424 Patents

3. The court declines to construe "pharmaceutically stable" at this time.[3]

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cannot agree that a pH limitation of 4 to 6 was "unambiguously" part of the patentees' understanding of the entire invention. *See Microsoft* at 1349. Thus, there was no clear disavowal of claim scope, and the disputed claim term is entitled to its plain and ordinary meaning. *See Golight*, 355 F.3d at 1331.

To the extent the parties disagree as to the meaning of "stable" within this term, the court will hear expert testimony at trial. *See infra* note 3.

[2] The Plaintiffs assert that the preamble language of Claims 1 and 8 of the '219 Patent is limiting. Of the defendants, only Cipla disagrees. The preamble provides in its entirety: "A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting." The parties agreed that the first portion—"A pharmaceutical single-use, unit-dose formulation"—was limiting. Moreover, following the February 18, 2015, *Markman* hearing, the parties entered a stipulation whereby they also agreed that "for intravenous administration to a human" was also limiting. (D.I. 159.) Therefore, the only remaining dispute is whether the final portion—"to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting"—is similarly 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). This maxim is especially appropriate here where the parties have dissected the preamble into different pieces. Nevertheless, there is no requirement that the entire preamble be treated as an "undifferentiated whole." *JobDiva, Inc. v. Monster Worldwide, Inc.*, No. 13-CV-8229 KBF, 2014 WL 5034674, at *13 (S.D.N.Y. Oct. 3, 2014). Thus, the court undertakes to determine whether the disputed portion "recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *See Catalina*, 289 F.3d at 808 (quoting *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999)).

Unfortunately, the parties devote the vast majority of their briefing to the issue of "intravenous administration," which has since been resolved. There is almost no discussion of chemotherapy-induced nausea and vomiting ("CINV"). The oral argument was likewise confined. But based on the evidence before it, the court is convinced that the remaining preamble language—"to reduce the likelihood of cancer [CINV]"—is limiting. For example, Claims 1 and 8 include elements that reference the "said formulation" of the preamble. "[D]ependence on a particular disputed preamble phrase for antecedent basis may limit claim scope . . . ." *Id.* The court is persuaded that the entirety of the preamble language—rather than bits and pieces—is "necessary to give life" to the subsequent reference in the body. In the court's view, a formulation that meets all other limitations but is not used to reduce CINV would not truly be "said formulation," as described in the preamble. Moreover, the summary of the Examiner-Initiated Interview stated: "Mr. Sullivan [the prosecutor] highlighted the limitations that were in the claims, including . . . [CINV]." (D.I. 128, Ex. 29.) Thus, the drafter and the Examiner understood the preamble to be limiting. The court agrees.

[3] The parties (which, this time, includes each of the Defendants) both assert that "pharmaceutically stable" should be given its plain and ordinary meaning, but they dispute what this meaning should be. "A determination that a claim term 'needs no construction' or has the 'plain and ordinary meaning' may be inadequate when a term

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UNITED STATES DISTRICT JUDGE

has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008). After reviewing the briefing, the court is convinced that additional extrinsic evidence from those skilled in the art is required to construe the term. The court will hear testimony on this issue at trial. Because this will be a bench trial, there are no jury concerns to manage.