IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BELCHER PHARMACEUTICALS, LLC,	:	UNSEALED ON JUNE 11, 2019
Plaintiff,	:	
v.	:	C.A. No. 17-775-LPS
HOSPIRA, INC.,	:	
Defendant.	:	

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MEMORANDUM OPINION

May 30, 2019
Wilmington, Delaware

STARK, U.S. District Judge:

Presently before the Court is the issue of supplemental claim construction. The Court issued its first claim construction opinion and order on September 28, 2018. (D.I. 96, 97) After the parties presented new disputes (*see* D.I. 177, 183, 185), the Court ordered and received supplemental claim construction briefing. The Court hereby adopts the Legal Standards section from its earlier claim construction opinion. (*See* D.I. 96 at 2-5)

I. "said liquid formulation having a pH between 2.8 and 3.3"[1]

Plaintiff Refers to pH of an intermediate product
Defendants Refers to pH of final product
Court Refers to pH of final product

Plaintiff argues that the pH limitation of claim 6 is directed to an intermediate (i.e., during manufacture) product, due in part to the Court's prior claim construction (which found another claim limitation to be directed to an intermediate step). (D.I. 192 at 1-2) Defendant responds that the claim as a whole (including the pH limitation) is directed to a final product, as the claimed formulation must be injectable and sterile and have certain claimed properties "at release" and "over [its] shelf-life." (D.I. 193 at 4) The Court is persuaded that the claim as a whole, and in particular the pH limitation listed in the table above, is directed at a final product.

Claim 6 states (with emphasis added):

> An injectable liquid pharmaceutical formulation of l-epinephrine sterile solution; ***said liquid pharmaceutical formulation having a pH between 2.8 and 3.3***; said injectable liquid pharmaceutical formulation compounded in an aqueous solution as 1.0 to 1.06 mg/mL l-epinephrine, and further including a tonicity agent; said liquid pharmaceutical formulation including no more than about 6% d-epinephrine and no more than about 0.5% adrenalone at release, and no more than

[1] This term appears in claim 6 of the '197 Patent.

> about 12% d-epinephrine and no more than about 0.5% adrenalone over a shelf-life of at least 12 months.

A person of ordinary skill in the art ("POSA") would recognize that claim 6 is directed to "[a]n ***injectable*** liquid pharmaceutical formulation of [a] ***sterile*** solution." *Id.* (emphasis added). Such a POSA, reading the claim language in view of the specification, would conclude that the claim refers to a final product that is both sterile and injectable for the purposes identified in the '197 Patent. (D.I. 193-2 at ¶¶ 12-23) The Court finds no support in the record for Plaintiff's contention that a POSA would view an intermediate product as both injectable and sterile. (D.I. 192 at 2-3)

The specification discusses how past epinephrine formulations were "plagued" by problems of racemization and oxidation, which were handled by adding harmful additives to prevent oxidation or epinephrine overages to counteract racemization. '197 Patent, col. 1 l. 52-col. 2 l. 40. The specification then describes a desired solution: "[t]here exists a great need for a liquid formulation of l-epinephrine that is both preservative-free and sulfite-free, with minimal overage, if any, and with minimal levels of degradants, including d-epinephrine, ***while maintaining a sterility guarantee***." *Id.* at col. 2 ll. 50-54 (emphasis added). The specification goes on to describe an allegedly novel product and manufacturing process, including a sterilization step at the end of the manufacturing process, to produce an injectable and sterile final product. *Id.* at col. 4 l. 67-col. 5 l. 3; col. 5 ll. 36-45. The specification also refers to the "pharmaceutical preparations" as intended "for medicinal use," and provides several examples of their use (uses for which an intermediate product would not be proper). *Id.* at col. 5 l. 49-col. 6 l. 23.

Plaintiff is correct that the specification repeatedly refers to the "in-process" pH. But the ***claim*** does not use this term, instead it recites only "pH." In the Court's view, when the patentee was referring to the pH of an intermediate formulation, it used the term "in-process pH."[2]

Plaintiff is also correct that the specification discloses pH values and compounding limitations as part of an intermediate product. *See* '197 Patent, col. 3 ll. 15-22 ("This compounding step was performed to place the solid/powder active pharmaceutical ingredient into aqueous solution. . . . Mixing alone will not bring l-epinephrine into aqueous solution adequately. The pH of the solution must be lowered in order for the l-epinephrine base to dissolve properly."); *id.* at col. 4 ll.48-50 ("Inadvertently, increasing the in-process pH to 2.8-3.3, unexpectedly reduced the racemization of l-epinephrine"). Nonetheless, what is claimed is the final product, i.e., one that is both sterile and injectable, and has certain shelf-life features. *See id.* at col. 5 ll. 27-48 (describing a sterile and injectable final drug formulation having the claimed percentages of d-epinephrine and adrenalone at release and over a 12 month shelf-life). None of these aspects of the claimed product make sense in the context of an intermediate product.

II. "compounded in an aqueous solution as 1.0 to 1.06 mg/mL l-epinephrine"[3]

Plaintiff Product limitation
Defendants Product-by-process limitation
Court Product-by-process limitation

[2] Even if the patentee intended to claim the in-process pH described in the specification, the claimed pH is directed at the final liquid pharmaceutical formulation, and the Court cannot correct the patentee's errors. *See Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004) (refusing to redraft claim to preserve operability).

[3] This term appears in claim 6 of the '197 Patent.

Plaintiff argues that the Court's prior claim construction "mandates that the formulation is static and exists without any mentioning of processing steps," and thereby "Claim 6 is a product claim, not a product-by-process claim." (D.I. 192 at 4) Defendant responds that the limitation is a typical product-by-process claim, as the claimed compounding step describes how the product is made. (D.I. 193 at 5-6) The Court agrees with Defendant.

"A product-by-process claim is one in which the product is defined at least in part in terms of the method or process by which it is made." *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1315 (Fed. Cir. 2006) (internal quotation marks omitted).

Here, claiming that the formulation is "***compounded*** in an aqueous solution as 1.0 to 1.06 mg/mL l-epinephrine" discloses a process to arrive at "said injectable liquid pharmaceutical formulation." '197 Patent, cl. 6 (emphasis added). The specification discloses a "compounding step . . . performed to place the solid/powder active pharmaceutical ingredient into aqueous solution." *Id.* at col. 3 ll. 15-19. Stated differently, the specification does not disclose compounding the "liquid pharmaceutical formulation," but rather the liquid formulation is the product that arises from the compounding. *Id.*

Nothing in the Court's prior claim construction compels a different conclusion. At issue in the prior claim construction proceedings was "whether the claimed concentration range of epinephrine (1.0 to 1.06 mg/mL) refers to the concentration range at the end of the compounding step (Defendant's position) or to the concentration range at any time during the compounding step (Plaintiff's position)." (D.I. 96 at 5) That the Court agreed with Defendant is in no way inconsistent with the claim as a whole being a product-by-process claim.[4]

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[4] If either party is taking inconsistent positions with respect to either of the supplemental claim construction disputes, it appears to be Plaintiff, which does not deny the allegation that it "has taken the exact opposite position on the pH limitation in a separate litigation with Adamis

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