IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: COPAZONE '775 PATENT LITIGATION	)	Civil Action No. 16-1267-GMS CONSOLIDATED

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOs. 9,155,775 ("the '775 Patent") and 9,763,993 ("the '993 Patent").[1]

After considering the submissions of the parties and hearing oral argument on the matter, IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 9,155,775 ("the '775 Patent") and 9,763,993 ("the '993 Patent"):

1. The term "**controlled room temperature**" in the '775 patent is construed to mean "includes at least the range of greater than or equal to 17.8° C to less than or equal to 24.6° C."[2]

[1] All docket citations refer to Civil Action NO. 16-1267-GMS. The abbreviation "Tr." refers to the transcript from the *Markman* Hearing on November 2, 2017, D.I. 157.

[2] The parties' dispute centers on whether the person having ordinary skill in the art ("POSA") would know to consult the United States Pharmacopeia ("USP"), which is extrinsic to the patent, to determine the appropriate temperature during filtration. *Markman* Hr'g Tr. 36:3-4. The court adopts Defendants' construction of the term because its construction comports with the description of the term in the asserted patent and the intrinsic evidence. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317, 1320-21 (Fed. Cir. 2005) (explaining that extrinsic evidence is "less significant than the intrinsic record in determining the legally operative meaning of claim language.'") (citing *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)).

Plaintiffs' proposed construction relies solely on evidence extrinsic to the patent, namely the USP. First, Plaintiffs argue that "controlled room temperature" should have its plain and ordinary meaning as found in the USP. (D.I. 118 at 4.) To support this position, Plaintiffs argue that the USP-NF guidelines state that "controlled room temperature" means "[t]he temperature maintained at the usual and customary working environment of 20° to 25° (68° to 77° F)." (D.I. 118 at Ex. A.) Plaintiffs, argue that the Federal Food, Drug, and Cosmetic Act ("FDCA") tells the skilled artisan that the USP is where to look for the definition of "controlled room temperature" and that *Abbott Labs. v. Lupin Ltd.*, shows the USP decides the issue. (D.I. 118 at Ex. A); *Markman* Hr'g Tr. 37:21-25, 38:1-8, 11:20-25, 27:14-25; *Abbott Labs. v. Lupin Ltd.*, 753 F.Supp.2d 382, 418 (D. Del. 2010). Second, Plaintiffs argue that "controlled room temperature" has a specific definition because when the patent recites a temperature other than a controlled room temperature, it provides a numerical range. *Markman* Hr'g Tr. 16:11-14. Plaintiffs argue that it is a misreading of the range from Table 2 to include 17.8° to 24.6° C because the proper reading is the plain and ordinary meaning, in accordance with the USP, at 20°to 25° C. *Markman* Hr'g Tr. 17:8-24. Defendants cite to various

2. The term **"filtering the aqueous pharmaceutical solution at a temperature of above 0° C to 17.5° C to produce a filtrate"** in the '775 patent and the terms **"(iii) filtering the first filtrate at a temperature of above 0° C. to 17.5° C. through a second filter to produce a second filtrate"** and **"(ii) filtering the aqueous pharmaceutical solution at a temperature of above 0° C. to 17.5° C. to produce a filtrate"** in the '933 patent are construed to mean "filtering the aqueous pharmaceutical solution, wherein the temperature of the aqueous pharmaceutical solution is between 0° C and 17.5° C, inclusive of 17.5° C."[3]

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pharmacopeias, including Europe and Japan, to show that the definition of "controlled room temperature" is not uniform. (D.I. 125-1, Ex. 5 at 2); *Markman* Hr'g Tr. 30:20-23.

The court agrees with Defendants for three main reasons. First, the provision of the USP that Plaintiffs cite defines controlled room temperature in terms of storage and shipping conditions, not the temperature at which the solution is filtered. (D.I. 118, Ex. A at 317.) Indeed, the FDCA tells the POSA to refer to the USP-NF only where no storage requirements for a prescription drug are established. 21 C.F.R. § 205.50(c)(1). Second, the specification shows the controlled room temperature to include 17.8° to 24.6° C. '775 Patent at 11:35-65. The specification, therefore, explains that an improved filtration process was necessary to avoid the pressure buildup on the second filter. '775 Patent at 10:5-15; (D.I. 128 at JA23, 11:45-58.) Also, Table 2 for Experiment Number 1 identifies 17.8° to 24.6° C as the temperature of the solution held in the receiving vessel for the controlled room temperature at 13 hours. '775 Patent at 11:35-65. The range in Table 2 is the only place in the specification that indicates the temperatures encompassed by the control room temperature. *Markman* Hr'g Tr. 23:22-25. The court remains unconvinced that a POSA would look to the USP *storage conditions* for the *filtration* temperature. Finally, as noted above, the definition of "controlled room temperature" seems to vary among pharmacopeias which begs the question, what is the plain meaning of the term? *Phillips,* 415 F.3d at 1318. "[E]xtrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Phillips*, 415 F.3d at 1319.

The intrinsic record fully supports Defendants' proposed construction. *Markman* Hr'g Tr. 26:16-17. The specification explicitly states that controlled room temperature includes the range 17.8° to 24.6° C and that filtration in that range is undesirable because of the pressure buildup in the second filter. *Markman* Hr'g Tr. 22:18-21.

[3] The parties' dispute centers on: (1) whether the reduced temperature filtration, 0° to 17.5° C is maintained for the entirety of the filtration process; and (2) whether there was a clear disclaimer of all processes without "improved filterability" in the '775 parent that carries over to the '993 continuation. *Markman* Hr'g Tr. 61:1-7, 17-24.

First, Defendants argue that Plaintiffs' proposed construction broadens the claim by allowing filtration at virtually any temperature. *Markman* Hr'g Tr. 64:16-19. In contrast, Defendants claim their construction accounts for the POSA's understanding that the temperature is maintained throughout filtration. *Markman* Hr'g Tr. 62:18-25. Plaintiffs argue that when the patentee chose to use the words "is maintained" they did so. *Markman* Hr'g Tr. 49:11-14. Specifically, these words appear in Claim 14, not Claim 1 of the '775 Patent and do not appear in Claims 1 or 19 of the '993 Patent. *Markman* Hr'g Tr. 49:18-22. The court will, therefore, not read the limitation into the '993 Patent.

Second, Defendants argue that the '993 child must include the "improved filterability" steps in the '775 Parent. *Markman* Hr'g Tr. 72:1-2, 6-12; (D.I. 156 at JA6174-82.) Specifically, Defendants argue when the parent and child share related subject matter, the child applicant cannot recapture claim scope previously disclaimed without notifying the examiner they are rescinding the disclaimer. *Markman* Hr'g Tr. 73:1-9, 18-25. The close relation of subject matter, however, does not conclusively answer the question of whether the disclaimer travels between generations of patents. *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1314 (Fed. Cir. 2007). At least one court

3. The term **"wherein the filterability of the aqueous pharmaceutical solution is improved as compared to the filterability of the solution at controlled room temperature"** in the '775 patent is construed to mean "wherein the filterability of the aqueous pharmaceutical solution is improved as compared to the filterability of the solution if the solution were at controlled room temperature, as measured by, *e.g.*, a lower increase in pressure on the filter."[4]

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has determined that the disclaimer in the parent does not apply to the child when the parent's claim scope changed as a result of an amendment. *Sanofi v. Glenmark Pharm. Inc., USA*, 204 F. Supp. 3d 665, 703 (D. Del. 2016). In that case, the disclaimer made during prosecution of the parent did not carry over to the child because the amendment occurred through explicit claim language rather than arguments about the meaning of any common claim language. *Markman* Hr'g Tr. 58:24-25 – 59:1-11. The Court of Appeals for the Federal Circuit recently affirmed the district court's determination explaining that:

> Sanofi did not argue during prosecution that the unamended claim language of the [parent] patent, or the disclosed invention generally, excluded [the limitation]. In these circumstances, the process in this case fit a similar pattern: an applicant adopts an explicit claim-narrowing limitation to achieve immediate issuance of a patent containing the narrowed claims and postpones to the prosecution of a continuation application further arguments about claims that lack the narrowing limitation. Without more than exists here, that process does not imply a disclaimer as to claims, when later issued in the continuation, that lack of the first patents' express narrowing limitation.

Sanofi v. Watson Labs., Inc., 2017 WL 5180716 at *25 (Fed. Cir. Nov. 9, 2017). Here, the claims in the '993 and '775 Patents are similar, but not identical. (D.I. 149 at 5.) For example, Claim 1 of the '775 Patent is not limited to 40-milligrams, while Claim 19 of the '993 Patent is. *Markman* Hr'g Tr. 59:21-24. Because the disclaimer in the parent patent occurred through an amendment and the child does not contain identical language, as the parent the disclaimer should not apply to the child.

Moreover, Defendants argue in their letter to the court dated November 11, 2017, that Plaintiffs' "opening claim construction brief states that 'improved filterability' is the 'central and novel teaching' of the patents' common specification." (D.I. 159 at 2.) The '933 Patent, however, was not mentioned one time in Plaintiffs' Opening Claim Construction Brief—likely because the '993 Patent issued over two weeks after Plaintiffs brief was filed. (D.I. 118.) Defendants, therefore, improperly assert that statements made in Plaintiffs' Opening Claim Construction Brief about the '775 Patent apply to the '933 child.

[4] The parties' dispute centers on whether the construction should include the word "significantly" before the phrase "improved filterability." *Markman* Hr'g Tr. 85:18-20. The specification discloses "improved filterability" without the qualifier "significantly." '775 Patent at 18:19-24, 12:29-32. Specifically, the '775 Patent states that:

> Reducing the temperature of the bulk solution during the compounding stage or before passing through Filter A or reducing the temperature of Filter A also *improves the filterability* of GA 40 mg/mL solution . . .

'775 Patent at 18:19-24. During the *Markman* Hearing, Defendants made an indefiniteness argument to explain that "significantly" should be included. *Markman* Hr'g Tr. 95:18-21. The court will not entertain indefiniteness at this stage in the proceedings, and will therefore adopt the Plaintiffs' proposed construction.

Dated: December 1, 2017

UNITED STATES DISTRICT JUDGE