IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON RESEARCH, LTD., Plaintiff, v. WATSON LABORATORIES, INC., Defendant.	)	Civ. No. 15-1159-SLR (Consolidated)

ALCON RESEARCH, LTD., Plaintiff, v. LUPIN LTD. and LUPIN PHARMACEUTICALS, INC., Defendant.	)	

MEMORANDUM ORDER

At Wilmington this 18th day of November, 2016, having heard argument on, and having reviewed the papers submitted in connection with, the parties' proposed claim construction;

IT IS ORDERED that the disputed claim language of U.S. Patent No. 8,791,154 ("the '154 patent"), shall be construed consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), as follows:

1. **Preamble:**[1] The **preamble** is limiting. "In general, a preamble is limiting if it is necessary to give life, meaning, and vitality to the claim." *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1357 (Fed. Cir. 2012) (internal citations and quotation marks omitted). The preamble to the asserted claims recites: "An aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising." (*See, e.g.*, 26:28-29) At bar, the preamble does more than describe the intended use of the invention; it explains that the pharmaceutical formulation is "an aqueous ophthalmic solution." *Cf. Am. Med. Sys., Inc. v. Biolitec, Inc.*, 618 F.3d 1354, 1358-59 (Fed. Cir. 2010) (The preamble does not limit the claim "when the claim body describes a structurally complete invention" or "the preamble merely gives a descriptive name to the set of limitations in the body of the claim that completely set forth the invention.") (citations omitted). Moreover, the preamble additionally provides antecedent basis for the term "the solution." *Proveris Scientific Corp. v. Innovasystems, Inc.*, 739 F.3d 1367, 1372 (Fed. Cir. 2014) ("Additionally '[w]hen limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention.'") (citations omitted).

2. **"At least 0.67 w/v % olopatadine dissolved in the solution"**[2] **and "at least 0.67 w/v % but no greater than 1.0 w/v % olopatadine dissolved in the solution:"**[3] "An aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis that contains at least 0.67 w/v % [but no greater than 1.0 w/v % olopatadine] dissolved in the solution." The specification explains that "it is preferred that the entire concentration of

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[1] Found in claims 1, 4, 8, and 21.
[2] Found in claim 1.
[3] Found in claims 4, 8, and 21.

olopatadine is dissolved in the composition as a water based or aqueous solution. However, it is contemplated that olopatadine could be only partially dissolved. For example, a portion of the olopatadine could be in solution with the remainder being in suspension." (4:24-29) The specification also provides that "[i]t is also contemplated that the compositions can be suspensions or other types of solutions." (10:1-3) The summary of the invention explains that "[t]he composition will include a relatively high concentration of olopatadine, preferably at least 0.67 w/v % olopatadine, preferably dissolved in solution." (2:42-45; *see also* 2:29-33) In describing the "advantages and problems overcome," the specification explains that

> the composition can solubilize the relatively high concentration of olopatadine in solution form suitable as an eyedrop where other formulations have failed. Further yet, the composition can solubilize the higher concentrations of olopatadine while maintaining efficacy in treatment of the symptoms of allergic conjunctivitis where other efforts to develop such a solution have failed.

(11:24-30) The court concludes that, while the specification somewhat conflates "composition" and "solution," in addition to disclosing compositions with undissolved olopatadine, it does repeatedly relate dissolved olopatadine to a "solution."

3. During prosecution, the applicants amended the claims in response to an office action rejecting claim 9 of the application for obviousness and objecting to claim 13, which depended therefrom (but that the examiner stated would be allowable if rewritten in independent form). Specifically, claim 9 (now claim 1) was amended to recite:

> An aqueous ophthalmic solution ~~composition~~ for treatment of ocular allergic conjunctivitis, the solution ~~composition~~ comprising:
> at least 0.67 w/v % olopatadine dissolved in the solution;
> PEG having a molecular weight of 300 to 500;
> polyvinylpyrrolidone; ~~and~~

hydroxypropyl-γ-cyclodextrin;
benzalkonium chloride; and
water. ~~cyclodextrin derivative selected from β cyclodextrin derivative, γ cyclodextrin or both.~~

(D.I. 50, ex. 2 at 81-84, 89, and 95)[4] The modification narrows the claim from "an ophthalmic composition" to "an aqueous ophthalmic solution." When the specification's disclosures are viewed in light of the narrowing amendment, the court is persuaded that "the solution" does not include olopatadine in undissolved form, as alleged by defendant.

4. The court has provided a construction in quotes for the claim limitations at issue. The parties are expected to present the claim construction consistently with any explanation or clarification herein provided by the court, even if such language is not included within the quotes.

United States District Judge

[4] Citations for this exhibit are to ECF assigned page numbers.