IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALCON RESEARCH, LTD.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 16-129-LPS-SRF
	:	
WATSON LABORATORIES, INC.,	:	
	:	
Defendant.	:	

MEMORANDUM ORDER

WHEREAS, Magistrate Judge Fallon issued a Report and Recommendation (D.I. 58) on February 15, 2017, recommending that the Court adopt certain claim constructions for disputed terms in U.S. Patent Nos. 7,947,295 and 8,921,337;

WHEREAS, on March 1, 2017, Watson Laboratories, Inc. ("Watson") objected to the Report (D.I. 63), specifically objecting to recommended construction of the "viscosity" term;

WHEREAS, on March 1, 2017, Alcon Research, Ltd. ("Alcon") objected to the Report (D.I. 62), specifically objecting to recommended construction of the "particle size" term;

WHEREAS, on March 15, 2017, Alcon responded to Watson's objections (D.I. 72) and Watson responded to Alcon's objections (D.I. 73);

WHEREAS, the Court has considered the parties' claim construction disputes addressed in the Report *de novo*, *see St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co., Ltd.*, 691 F. Supp. 2d 538, 541-42 (D. Del. 2010); 28 U.S.C. § 636(b)(l); Fed. R. Civ. P. 72(b)(3);

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. Watson's objections (D.I. 63) are OVERRULED, Alcon's objections (D.I. 62) are OVERRULED, and Judge Fallon's recommended constructions (D.I. 58) are ADOPTED.

2. Watson objects to the recommendation that the term "a viscosity enhancing amount of combination of two polymers having a synergistic effect on the composition's viscosity and wherein the combination of two polymers is selected from the group consisting of hydroxypropyl methylcellulose and guar gum; a carboxyvinyl polymer and guar gum; and hyaluronic acid and guar gum" requires no construction.[1] (*See* D.I. 58 at 7-12) Watson contends that the patent contains a clear disavowal of claim scope, making it appropriate to require "that if the composition comprises a carboxyvinyl polymer then the composition does not contain sodium chloride or boric acid." (D.I. 63 at 1-2)

As the Report observes, "Watson's argument hinges primarily on one sentence in the detailed description of the invention which refers to 'the compositions of the present invention,' but does not precisely indicate that it encompasses all embodiments." (D.I. 58 at 11) (quoting '295 patent col. 3 ll. 26-33) In particular, Watson relies on the following passage in the specification:

> If the compositions contain a carbomer [i.e., a carboxyvinyl polymer] as one of the two polymers, then the compositions of the present invention do not contain any ionic tonicity-adjusting agent, such as sodium chloride, or other ionic excipients, such as boric acid, as these ingredients have a significant, detrimental effect on the composition's viscosity.

'295 patent col. 3 ll. 26-33. The Court is not persuaded that, in the context of the patent as a whole, this sentence amounts to a clear and unmistakable disavowal. The patent goes on to

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[1]This term appears in claims 10 and 18 of the '295 patent.

clarify the concern with using ionic excipients in combination with a carbomer:

> If the compositions contain a carbomer, it is critical that the compositions are formulated so that the target pH is not exceeded. Once a target pH has been exceeded in compositions containing a carbomer, adding an acid such as hydrochloric acid to adjust the pH downward can compromise the synergistic viscosity. It is known that relatively small amounts of acid or salts, on the order of 0.005%, can have a significant effect on the viscosity of compositions containing a carbomer.

Col. 3 ll. 35-44. This passage teaches that the issue with acids or salts is that, once the pH is in the optimal range, small amounts of ionic excipients can negatively impact viscosity. But the passage does not suggest that ionic excipients are always inappropriate to use, such as for the purpose of achieving the targeted pH. Indeed, Example 1 uses ionic excipients (sodium hydroxide and hydrochloride acid) for this very purpose in a composition containing a carbomer. *See* col. 4 ll. 57-64.

Thus, the statement relied on by Watson cannot mean that ***all*** ionic excipients must be avoided at ***all*** times. Perhaps recognizing this, Watson's proposed construction seeks to impose a disavowal only of the exemplary ionic excipients, sodium chloride and boric acid. But while the examples demonstrate that sodium chloride or boric acid can negatively impact viscosity, col. 8 l. 35 - col. 9 l. 52, this criticism is not, in the full context of the patent, a sufficient basis to find a disclaimer of even these two ionic excipients. *See Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012) ("Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal.").

Having resolved the parties' dispute regarding the purported disclaimer, the Court agrees with Judge Fallon that no construction is necessary.

3. Alcon objects to the recommended construction of the "particle size" term.[2] Claim 1 recites "a sparingly soluble particulate compound, said compound having . . . a particle size of 50 to 700 nm, and wherein said sparingly soluble particular compound is nepafenac at a concentration of 0.25 to 0.35 w/v %," which Judge Fallon recommended means "0.25 to 0.35 w/v % nepafenac, wherein the nepafenac particles have a particle size between 50 and 700 nm." (D.I. 58 at 14-17) Claim 15 recites "0.3 w/v % nepafenac having a particle size of 50 to 700 nm," which Judge Fallon recommended means "0.3 w/v % nepafenac, wherein the nepafenac particles have a particle size between 50[] and 700 nm." (*Id.*) Judge Fallon understood "particle size of 50 to 700 nm" "to mean a distribution of nepafenac particle sizes falling within a range of 50 to 700 nm." (*Id.* at 17)

Alcon contends that instead of requiring particles to fall within range of sizes, this limitation requires there to be an ***average*** particle size of 50 to 700 nm. The Court disagrees. The claims at issue use the term "particle size," whereas dependent claim 14 uses the term "average particle size," indicating that there is a difference between the two terms. Like the Report, the Court concludes that the different terms represent different requirements, as otherwise the added modifier "average" is superfluous. Thus, claim 1 recites that the particles must be in the range from 50 to 700 nm, and claim 14 adds that the average size of the particles, which fall within that range, is 400 nm. This conclusion is not inconsistent with the teachings of the specification, which neither defines either term nor clearly demonstrates that the terms are used interchangeably.

4. Given the detailed reasoning provided in the Report, and that the parties have not

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[2]This term appears in claims 1 and 15 of the '337 patent.

raised any arguments that are not adequately addressed in the Report, the Court finds it unnecessary to discuss the parties' objections any further.

November 9, 2017
Wilmington, Delaware

HON. LEONARD P. STARK
UNITED STATES DISTRICT JUDGE