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. 150) on November 30, 2017, recommending that the Court adopt certain claim constructions for disputed terms in U.S. Patent No. 9,662,398 ("'398 patent");

WHEREAS, on December 14, 2017, Alcon Research, Ltd. ("Alcon") objected to the Report (D.I. 152), specifically objecting to the recommended constructions of "native guar," "nepafenac," and "a galactomannan at a concentration of 0.1 to 0.4 w/v %, said galactomannan selected from the group consisting of guar, native guar, and hydroxypropyl guar;"

WHEREAS, on December 28, 2017, Watson Laboratories, Inc. ("Watson") responded to Alcon's objections (D.I. 155);

WHEREAS, on February 12, 2018, Alcon filed a reply to Watson's response (D.I. 162);

WHEREAS, on February 19, 2018, Watson filed a surreply to Alcon's reply (D.I. 163);

WHEREAS, on February 26, 2018, the Court heard oral argument on the objections (*see* D.I. 168) ("Tr.");

WHEREAS, the Court has considered the parties' claim construction disputes addressed

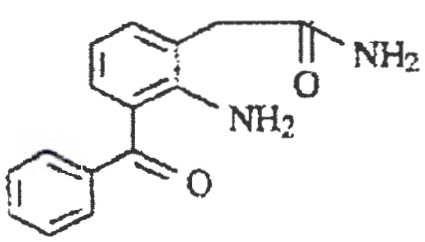
in the Report *de novo*, *see St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co., Ltd.*, 691 F. Supp. 2d 538, 541-42 (D. Del. 2010); 28 U.S.C. § 636(b)(l); Fed. R. Civ. P. 72(b)(3);

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. Alcon's objections (D.I. 152) to the Report's construction of the aforementioned terms are SUSTAINED. The constructions set forth in the Report (D.I. 150) are NOT adopted. The Court construes the disputed terms as follows:

A. "Native guar," as used in claims 1, 13, 14, 21, and 32, is construed to mean "naturally occurring guar, including such guar which has been processed to make it suitable for ophthalmic pharmaceutical use, so long as such guar also lacks the kind of chemical substitutions of the galactose and mannose groups of its galacatomannan polysaccharides discussed in the '398 patent at col. 4 ll. 1-7."

B. "Nepafenac," as used in claims 1, 13-15, and 32, is construed to mean "a known compound having the formula $C_{15}H_{14}N_2O_2$ and having the following structure:



"

C. "A galactomannan at a concentration of 0.1 to 0.4 w/v %, said galactomannan selected from the group consisting of guar, native guar, and hydroxypropyl guar," as used in claim 1, is construed to mean "guar, native guar, or hydroxypropyl guar at concentration of 0.1 to 0.4 w/v %."

Native guar

2. The Report recommended that the term "native guar" be found indefinite because it does not have a plain and ordinary meaning and the intrinsic record fails to provide sufficient clarity about its scope, in particular its structural and functional features. (*See* D.I. 150 at 7-9) Alcon contends that the meaning of the term is evident from considering the plain and ordinary meanings of its constituent words: "native" and "guar." (*See* D.I. 152 at 7; D.I. 162 at 6) Citing extrinsic evidence, Alcon argues that the commonly-understood meaning of a "native" substance in the context of pharmaceutical products is that the substance is naturally-occurring. (*See* D.I. 152 at 7) Thus, in Alcon's view, a person of ordinary skill in the art ("POSA") would have understood native guar to mean naturally-occurring guar that lacks chemical substitutions found in "synthetic guar." (*Id.*) The Court agrees.

As the Report correctly found, the patent does not explicitly define "native guar," nor does the patent define a "synthetic guar." (D.I. 150 at 7) But, in the Court's view, Watson has nonetheless failed to prove, by clear and convincing evidence, that a POSA would have lacked reasonable certainty as to how the patentee was using the term "native guar" in the claims of the '398 patent. *See Nautilus Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). Instead, the Court is persuaded that a POSA would have understood "native guar" to mean guar obtained from guar gum that has not been "chemically modified;" that is, the guar retains the natural composition of its polysaccharide groups without any chemical substitutions, such as those described in the '398 patent at col. 4 ll. 1-7.

The specification states that the patent "relates to compositions for ophthalmic drug delivery, and more specifically to nanoparticle suspensions comprising a carboxyvinyl polymer, ***a***

galactomannan, and borate." '398 patent, col.1 ll. 18-21 (emphasis added). Claim 1 recites a "topically administrable ophthalmic suspension composition comprising . . . ***galactomannan*** selected from the group consisting of guar, ***native guar***, and hydroxypropyl guar." *Id.* col. 8 ll. 59-67 (emphasis added). The specification explains that the galactomannans used in the claimed compositions could be derived from natural gums, such as guar gum, or synthetic gums, adding:

> The types of galactomannans that may be used in the present invention are typically derived from ***guar gum***, locust bean gum and tara gum. As used herein, the term "galactomannan" refers to polysaccharides ***derived from the above natural gums*** or similar natural or synthetic gums ***containing mannose or galactose moieties, or both groups, as the main structural components***. Preferred galactomannans of the present invention are made up of linear chains of (1-4)-ß-D-mannopyranosyl units with a-D-galactopyranosyl units attached by (1-6) linkages.

Id. col. 3 ll. 55-64 (emphasis added). Thus, according to the patent, galactomannans are "polysaccharides . . . containing mannose or galactose moieties, or both groups, as the main structural components," irrespective of whether they are derived from natural or synthetic gums. (*Id.*) Expressly included in this definition are "chemically modified variations of the polysaccaharides . . . [f]or example, hydroxyethyl, hydroxypropyl and carboxymethylhydroxypropyl substitutions," and other "non-ionic" and "anionic" substitutions. (*See id.*) The Court agrees with Alcon (as supported by its expert) that a POSA would understand these substitutions are man-made chemical modifications and are not present in galactomannans selected from native guar. (*See* D.I. 128 Ex. B ¶ 52)

A POSA would understand that native guar would have to undergo some form of processing in order to be suitable for use in the claimed pharmaceutical compositions. (*See, e.g.* D.I. 128 Ex. B ¶¶ 54-57) (Alcon's expert explaining that ingredients derived from natural sources

must undergo purification and sterilization, for example, to be made suitable) The Court is persuaded that a POSA would understand there to be a meaningful – and reasonably ascertainable – distinction between this sort of necessary process and processes which would result in chemical substitutions. (*See id.* ¶ 53) (explaining that prior art extensively used "native guar" term to denote guar with no chemical substitutions)

The specification refers to a preferred form of native guar commercially available in powder form and to a preferred process for obtaining native guar using a certain purification method:

> Native guar is particularly preferred, for example, USP or general grade ***native guar powder*** obtained from TIC Gums, Inc. A ***process for producing a particularly preferred native guar*** is disclosed in co-pending U.S. patent application Ser. No. 12/701,339, [("the '339 application")] entitled "Process for Purifying Guar" filed Feb. 5, 2010.

'398 patent, col. 4 ll. 24-30 (emphasis added). Thus, the patent refers to a commercial source – TIC Gums, Inc.[1] – for obtaining "native guar powder," and to a patent application – the '339 application[2] – for a process to produce native guar. This is further support for the Court's finding

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[1]Watson's principal position is that the term is indefinite. In the alternative, Watson's proposed construction of "native guar" is: "A galactomannan that is not guar or hydoxypropyl guar, that is exemplified by USP or general grade native guar powder sold by TIC Gums, Inc. in December 2009."

[2]The '339 application "relates to processes for purifying guar comprising combining borate and guar in an aqueous solution and treating the aqueous solution with an organic solvent to induce precipitation of purified guar." '339 application, Abstract. While the '339 application does not use the term native guar, it refers to the same "native guar powder" commercial product identified in the '398 patent in multiple ways, as, for example, "guar powder," "unprocessed guar," or "raw guar powder." *See* '339 application, [0021] ("A preferred guar gum powder is USP or general grade ***guar powder*** obtained from TIC Gum.") (emphasis added); *id.* [0039] ("A preferred process of the present invention utilizes USP grade ***guar powder*** obtained from TIC Gum, Inc. The ***raw guar powder*** is used to form a 0.8% aqueous guar solution.") (emphasis

that a POSA would be reasonably certain as to the meaning the patentee ascribed to "native guar."[3]

The Court has modified Alcon's proposed construction to eliminate any risk of confusion by the factfinder that "native guar" cannot include chemical subsitutions of its galactomannan molecules, including where such substitutions are accomplished as discussed in col 4. ll. 1-7 of the '398 patent.[4]

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added); *id.* [0042] ("TABLES 1 and 2 below show the result of an experiment comparing ***unprocessed guar*** (USP Grade; TIC Gum, Inc.) in aqueous solution compared to" guar purified using different methods.") (emphasis added) The '339 application further refers to the guar purified using the corresponding claimed invention as simply "purified guar." '339 application, [0043] ("As shown in TABLE 1, guar produced according to a process of the present invention ("***Purified Guar***") demonstrates better hydration characteristics compared to unpurified guar powder in aqueous solution ("Raw Guar") and guar purified using ethanol/acetone precipitation without the addition of borate.") (emphasis added). It further distinguishes guar having chemical substitutions (which it refers to as "guar derivatives") from guar without any chemical substitutions. *Compare* '339 application [0012] ("Embodiments of the present invention are directed to processes for manufacturing ***pharmaceutical grade guar compositions*** which comprise combining borate and guar in aqueous solution and precipitating guar by adding an organic solvent to the aqueous solution.") (emphasis added) *with* [0013] ("The present invention is further directed to processes for producing ***guar derivatives*** (e.g., hydroxyethyl guar and carboxymethylhydroxypropyl guar) that are particularly suitable for use in ophthalmic pharmaceutical compositions that are formulated for local administration.") *and* [0002] ("The present invention relates to guar and guar derivatives, and more particularly to processes for producing ***purified guar and guar derivatives***.") (emphasis added). In the Court's view, the '339 application, therefore, supports Alcon's position as to what a POSA would understand from the '398 patent's use of the term "native guar."

[3]The Court does not agree with the Report that borate condensation would be understood by a POSA as a chemical modification. (*Compare* D.I. 150 at 8-9 *with* D.I. 128 Ex. B ¶ 57)

[4]Given the Court's finding that the term "native guar" has not been proven to be indefinite, the Court does not reach Alcon's additional objection to that recommendation based on *Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340, 1372-73 (Fed. Cir. 2009). (*See, e.g.*, D.I. 150 at 9)

Nepafenac

3. Claim 1 recites "a sparingly soluble particulate compound . . . wherein said sparingly soluble particulate compound is nepafenac." The Report construed "nepafenac" to mean "3-benzoylphenylacetic acid and certain of its derivatives known to possess anti-inflammatory activity, ***including amfenac (2-amino-3-benzoylphenylacetic acid)*** and nepafenac (2-amino-3-benzoylbenzeneacetamide)." (D.I. 150 at 14) (emphasis added) Alcon objects because this construction deviates from nepafenac's commonly-understood meaning. (*See* D.I. 152 at 1-5) In particular, the Report includes within the construction of "nepafenac" a compound better known as "amfenac." The Court agrees with Alcon that a POSA reading the '398 patent and the entirety of the intrinsic evidence would understand "nepafenac" ***not*** to include amfenac.

The specification states:

> Nepafenac is a known nonsteroidal anti-inflammatory compound, and can be made by known methods. See, for example, U.S. Pat. Nos. 5,475,034 and 4,313,949, the entire contents of which are incorporated by reference. ***Nepafenac is also known as 2-amino-3-benzoylphenylacetic acid.*** The topical use of nepafenac and other amide and ester derivatives of 3-benzoylphenylacetic acid to treat ophthalmic inflammation and pain is disclosed in U.S. Pat. No. 5,475,034.

'398 patent col. 4 ll. 49-57 (emphasis added). The "also known as" portion of this statement describes ***amfenac***, that is, 2-amino-3-benzoylphenylacetic acid. While the patent expressly states that "nepanfenac is also known as" amfenac, the Court agrees with Alcon that a POSA would recognize this to be a misstatement, and would instead understand that nepafenac (as used in the '398 patent) does ***not*** include amfenac.

The plain and ordinary meaning of "nepafenac" does not include "amfenac." Instead, to a

POSA, the plain and ordinary meaning of nepafenac is 2-amino-3-benzoylphenyl***acetamide***, an amide derivative. (*See* D.I. 128 Ex. B ¶ 32) By comparison, amfenac is known to a POSA as 2-amino-3-benzoylphenyl***acetic acid***, a corresponding organic acid. (*Id.* ¶¶ 31-32)

"Absent lexicography or disavowal," the Court should "not depart from the plain meaning of the claims." *Luminara Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1353 (Fed. Cir. 2016) (citing *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)). Here, the patentee was not its own lexicographer; that is, the patentee did not redefine nepafenac to include amfenac. *See Luminara*, 814 F.3d at 1353 ("[The] standards for finding lexicography . . . are exacting.") (internal quotation marks omitted). The "also known as" passage (on which Watson bases its proposed construction) does not, with "reasonable clarity, deliberateness, and precision," redefine "nepafenac." *Typhoon Touch Techs., Inc. v. Dell, Inc.*, 659 F.3d 1376, 1383 (Fed. Cir. 2011) (internal citation omitted); *see also GE Lighting Sols.*, 750 F.3d at 1309 ("To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term, and clearly express an intent to define the term.") (internal quotation marks omitted). For the same reasons (as further explained below), neither the patent nor the prosecution history contains a clear and unmistakable disavowal of claim scope.

To the contrary, in the Court's view, a POSA would recognize the "also known as" portion of the specification to be an error. (*See* D.I. 152 at 3) The specification, taken in context, does not clearly, deliberately, and precisely indicate that the inventors redefined nepafenac to deviate from its plain and ordinary meaning.

In the sentence just before the "also known as" error, the specification refers to nepafenac as a "***known*** nonsteroidal anti-inflammatory compound." '398 patent, col. 4 ll. 49-51 (emphasis

added). Nepafenac is "known" customarily as 2-amino-3-benzoylphenyl***acetamide***, not 2-amino-3-benzoylphenylacetic ***acid***. (*See* D.I. 128 Ex. B ¶ 32) Numerous publications submitted to the examiner during the prosecution of the '398 patent identified nepafenac using its ***known*** chemical name: 2-amino-3-benzoylphenyl***acetamide***. (*See id.* ¶ 28)

Similarly, that same sentence immediately preceding the erroneous "also known as" sentence refers to "***known*** methods" of making nepafenac, citing to two patents, which are fully incorporated by reference. '398 patent, col. 4 ll. 49-52 (emphasis added). Both of those patents expressly disclose methods of making 2-amino-3-benzoylphenyl***acetamide***, i.e., nepafenac. (*See* D.I. 128 Ex. B ¶¶ 36-39)

Elsewhere in the specification, the '398 patent describes nepafenac and amfenac as distinct from one another. *See* '398 patent Fig. 3 (showing concentration of nepafenac and amfenac separately); *see also* D.I. 128 Ex. B ¶ 34. The patent also refers to amfenac as a metabolite of nepafenac. *See* '398 patent, col. 7 ll. 37-38 ("amfenac (a nepafenac metabolite))"; *id.* col. 7 l. 52 ("distribution of nepafenac and its metabolite, amfenac"). These references are consistent with the plain and ordinary meaning of nepafenac, and further indicate that the differences between amfenac and nepafenac include their chemical structures as well as their functions. Additionally, the '398 patent refers to NEVANAC®, Alcon's commercial nepafenac product, as "a commercial 0.1 w/v % suspension of nepafenac." *Id.* col. 7 ll. 40-41. This, again, is consistent with how a POSA would have understood the term to be used in the patent's claims. (*See* D.I. 128 Ex. B ¶¶ 25-27)

A galactomannan at a concentration of 0.1 to 0.4 w/v %, said galactomannan selected from the group consisting of guar, native guar, and hydroxypropyl guar

4. With respect to the final dispute, the parties agree that this term includes a Markush group. (*See* D.I. 150 at 10) The Report construed the term as referring to "only one, single galactomannan that is guar or native guar or hydroxypropyl guar, and not mixtures or combinations thereof, at a concentration of 0.1 to 0.4 w/v %." Alcon contends that this construction is incorrect because native guar and hydroxypropyl guar are both types of guar. (D.I. 152 at 10) Again, the Court agrees with Alcon.

The intrinsic evidence shows that the types of guar described in the claims' Markush group are open, not closed, to combinations of the selected guar types. The patent explains that the galactomannans of this type are obtained from the guar gum plant. *See* '398 patent col. 3 ll. 55-57. It is clear, then, that "guar" in this context encompasses both "native guar" and "hydroxypropyl guar," as anything that is native guar or hydroxypropyl guar is also "guar." As Alcon's expert explains, native guar and hydroxypropyl guar are types of guar. (D.I. 128 Ex. B ¶ 47) He points to the patent's examples 1 and 4, which use the terms "native guar" and "guar," respectively, to refer to the same substance. (*See id.* ¶ 59) Thus, the second and third substances listed in the Markush group – native guar and hydroxypropyl guar – come within the meaning of the first substance, guar, and do not constitute three different types of guar.

The prosecution history provides additional support for this conclusion. In response to an office action rejecting an earlier version of the claims, the patentees amended some claims reciting "guar" to recite "native guar." (*See* D.I. 137-1 pp. 38-41 of 45) They explained that the purpose of their amendment was to "more specifically recite components," not a new component.

(*See id.* at page 42 of 45) Nothing in the prosecution history indicates that combinations are excluded.

The Court has considered Watson's other arguments against Alcon's proposed construction, including the doctrine of claim differention, and concludes that they do not lead to a different result. Claim 21 recites the "composition according to claim 1 wherein said galactomannan is guar or native guar." '398 patent col. 10 ll. 11-12. As the Report correctly concludes, if native guar and hydroxypropyl guar are simply sub-types of guar, then claim 1 and claim 21 have identical scope. (*See* D.I. 150 at 12) But "claims that are written in different words may ultimately cover substantially the same subject matter." *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998) (internal citation omitted); *see also Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1269 (Fed. Cir. 1986) (affirming district court's construction of claim although it rendered dependent claim redundant). On occasion, as here, the same substance may be represented by more than one member of a Markush group, notwithstanding presumptions. *See Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1363 (Fed. Cir. 2016) ("Court decisions construe Markush clauses as meaning 'closed' unless other language or evidence alters that meaning.") (internal quotation marks and emphasis omitted). Redundancy, while not a preferred outcome, does not necessarily establish that a proposed construction is incorrect. *See generally Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1372 (Fed. Cir. 2017) ("[F]aced with an interpretation that would read redundancy into claim 1 and another that would violate the doctrine of claim differentiation, we hold that the claims here support the former result over the latter."). Because the intrinsic and extrinsic evidence, considered in totality, supports reading the

Markush group as open to combinations of the three listed types of guar, the Court adopts Alcon's construction.

April 17, 2018
Wilmington, Delaware

HON. LEONARD P. STARK
UNITED STATES DISTRICT JUDGE