IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BRACCO DIAGNOSTICS INC., Plaintiff, v. MAIA PHARMACEUTICALS, INC., Defendant.	Case No. 3:17-cv-13151-PGS-TJB
MAIA PHARMACEUTICALS, INC. Counterclaimant, v. BRACCO DIAGNOSTICS INC., Counterclaim Defendant.	

AMENDED JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Plaintiff/Counterclaim Defendant, Bracco Diagnostics Inc. ("Bracco"), and Defendant/Counterclaimant Maia Pharmaceuticals, Inc. ("Maia"), pursuant to L.Pat.R. 4.3 and the Court's June 29, 2018, Letter Order, provide this Joint Claim Construction and Prehearing Statement.

I. Introduction

This action concerns United States Patent No. 4,803,046 (the "'046 patent") and potentially issues of infringement and validity of the '046 patent.

The Court's June 29, 2018, Letter Order, requires the Parties to file this Joint Claim Construction and Prehearing Statement pursuant to L.Pat.R. 4.3 concerning the '046 patent claims. L.Pat.R. 4.3 states:

> 4.3. Joint Claim Construction and Prehearing Statement.
>
> Not later than 30 days after the exchange of "Preliminary Claim Constructions" under L. Pat. R. 4.2(a), the parties shall complete and file a Joint Claim Construction and Prehearing Statement, which shall contain the following information:
>
> (a) The construction of those terms on which the parties agree;
>
> (b) Each party's proposed construction of each disputed term, together with an identification of all references from the intrinsic evidence that support that

construction, and an identification of any extrinsic evidence known to the party on which it intends to rely either to support its proposed construction or to oppose any other party's proposed construction, including, but not limited to, as permitted by law, dictionary definitions, citations to learned treatises and prior art, and testimony of all witnesses including experts;

(c) An identification of the terms whose construction will be most significant to the resolution of the case. The parties shall also identify any term whose construction will be case or claim dispositive or substantially conducive to promoting settlement, and the reasons therefor;

(d) The anticipated length of time necessary for the Claim Construction Hearing; and

(e) Whether any party proposes to call one or more witnesses at the Claim Construction Hearing, the identity of each such witness, and for each witness, a summary of his or her testimony including, for any expert, each opinion to be offered related to claim construction.

(f) Any evidence that is not identified under L. Pat. R. 4.2(a) through 4.2(c) inclusive shall not be included in the Joint Claim Construction and Prehearing Statement.

(g) This rule does not apply to design patents.

II. The Joint Claim Construction And Prehearing Statement Under L.Pat.R. 4.3

A. The Agreed Term Constructions Pursuant To L.Pat.R. 4.3(a)

The Parties have put the construction of three patent claim terms in issue: "buffer," "surfactant/solubilizer," and "surfactant," in this proceeding. The Parties have not put the construction of any of the other patent claim terms in issue and also have not agreed upon the construction of any of the terms of the '046 patent.

B. The Parties' Proposed Constructions Of Each Disputed Term And Identification Of Intrinsic And Extrinsic Evidence Pursuant To L.Pat.R. 4.3(b)

1. Bracco's Proposed Constructions Of Each Disputed Term And Identification Of Intrinsic And Extrinsic Evidence Pursuant To L.Pat.R. 4.3(b)

a. Buffer Terms Construction and Evidence

Claim Term	Bracco's Proposed Construction Of "Buffer"[1]
"a buffer"	Excipients that "stabilize the pH" and "include, but are not limited to, phosphoric acid, phosphate (e.g. monobasic or dibasic sodium phosphate, monobasic or dibasic potassium phosphate, etc.), citric acid, citrate (e.g. sodium citrate, etc.), sulfosalicylate, acetic acid, acetate (e.g. potassium acetate, sodium acetate, etc.), methyl boronic acid, boronate, disodium succinate hexahydrate, amino acids, including amino acid salts (such as histidine, glycine, lysine, imidazole), lactic acid, lactate (e.g. sodium lactate, etc.), maleic acid, maleate, potassium chloride, benzoic acid, sodium benzoate, carbonic acid, carbonate (e.g. sodium carbonate, etc.), bicarbonate (e.g. sodium bicarbonate, etc.), boric acid, sodium borate, sodium chloride, succinic acid, succinate (e.g. sodium succinate), tartaric acid, tartrate (e.g. sodium tartrate, etc.), tris(hydroxymethyl)-aminomethane, biological buffers (such as N-2-hydroxyethylpiperazine,N'-2-ethanesulfonic acid (HEPES), CHAPS and other 'Good's' buffers), and the like." '046 patent, col. 9, lines 45-65.

'046 patent, original application and prosecution history citations in Bracco's identification of evidence pursuant to L.Pat.R. 4.2(a) through 4.2(c), including, without limitation:

> All 108 claims of the '046 patent include an embodiment of a "buffer" in their elements and thus all 108 claims, as issued and as originally filed, are relevant intrinsic evidence to the construction of these terms. This evidence includes the '046 patent and the prosecution history of the '046 patent, which contains the claims as issued and as originally filed, and the references cited therein. B0017245-18314; B0020091-20552.
>
> Dependent claims such as claims 3, 23, 41, 60, and 87 provide examples of particular buffers within the meaning of the terms, including amino acids, and these claims are relevant evidence of the meaning of the "buffer" claim term.
>
> The '046 patent also describes buffering "at extreme pH values" (e.g., col. 9, lines 45-47; Example 1), which may be encountered, for example, in the processes for making peptide formulations, final and intermediate peptide preparations, and their uses.
>
> The entire '046 patent specification is relevant to the construction of the buffer claim term. These relevant portions of the '046 patent specification include but are not limited to the description of these claim terms found in the Abstract; col. 1, lines 56-69 (e.g., "Suitable buffers include … amino acid buffers"); col. 2, lines 13-29; col. 4,

[1] Bracco's proposed constructions will change if Maia's motion to amend its infringement contentions filed August 17, 2018 is granted and Bracco is given an opportunity to respond by amending Bracco's infringement and claim construction contentions.

lines 7-32; col. 4, lines 33-43 (e.g., "The concentration ranges of the various ingredients in Table 1 can be adjusted upward or downward if necessary in conjunction with: … obtaining the desired pH"); Table 1; Table 2; col. 9, line 44 to col. 10, line 9 (e.g., "Buffering agents are employed to stabilize the pH of sincalide formulations of the invention, and consequently reduce the risk of chemical stability at extreme pH values. Buffering agents useful in the preparation of formulation kits of the invention include … amino acids, including amino acid salts (such as … lysine …"); col. 12, line 65 to col. 13, line 10 (e.g., "Buffering agents useful in the preparation of formulation kits of the invention are discussed herein and include, for example … amino acids (including amino acid salts);" col. 13, lines 24-32; col. 13, lines 33-39; Example 1 at col. 16, line 43 to col. 18, line 14; and the original claims filed with the specification. Amino acids and their functions are described in other portions of the '046 patent specification also.

For example, amino acids that provide "stability" results are described at col. 10, line 42 to col. 11, line 4. L-arginine monohydrochloride, L-lysine monohydrochloride, and L-methionine are disclosed as particularly preferred. Col. 11, lines 2-4. Furthermore, Example 6 of the '046 patent (col. 31, line 1 to col. 34, line 25) is entitled "Effect of Amino Acids on Sincalide Formulations." It relates to relevant properties and results of amino acid excipients that are described in the '046 patent. For example, it states that:

"During formulation studies it was observed that both exposure to air and lyophilization were areas of concern for scale-up manufacturing due to reduced potency of sincalide in the formulation. The reduced potency was a result of surface adsorption/denaturation resulting from exposure of sincalide to air, and yielding degradants via oxidation. Exposure of sincalide formulations to thermal stress during lyophilization also resulted in degradation and reduced recovery of sincalide."

"Experiments were conducted to evaluate several amino acids as potential stabilizers of sincalide, including the non-polar (hydrophobic) methionine residue, aspartic acid and glutamic acid, the polar glycine and cysteine residues, and the basic lysine and arginine amino acids." Col. 31, lines 4-18.

Example 1 of the '046 patent (col. 16, line 43 to col. 18, line 14) is directed to the "Effect of Buffering Agent and Formulation pH on Sincalide Formulations." There it is stated that "Experiments were conducted to determine the effect of pH on the chemical stability of sincalide. Chemical instability, or degradation, may be caused by, for example, oxidation, reduction, deamidation, hydrolysis, imide formation, racemization, isomerization, and/or β-elimination." A pH range of 3.0 to 9.1 was examined. The Example states that "By measure of the percentage recovery, sincalide was stable in 35 mM phosphate buffer solution at pH values ranging from 5.0-9.1 over a 24-hour period. At pH values <5.0, sincalide degradation was evident even at the initial time point." It is reported that buffers may provide stability to the formulation,

and, also, that amino acids, such as arginine and lysine, may serve as buffers in formulations of relevant peptide and protein drugs. See references cited below.

Amino acids in particular are described in the '046 patent specification and claims as meeting the buffer claim terms: claims 3, 23, 41, 60, 87 (see Table B above, and these were original claims filed with the original application and thus form part of the specification); col. 1, lines 56-69 (e.g., "Suitable buffers include … amino acid buffers"); col. 9, line 44 to col. 10, line 9 (e.g., "Buffering agents are employed to stabilize the pH of sincalide formulations of the invention, and consequently reduce the risk of chemical stability at extreme pH values. Buffering agents useful in the preparation of formulation kits of the invention include … amino acids, including amino acid salts (such as … lysine …"); col. 12, line 65 to col. 13, line 10 (e.g., "Buffering agents useful in the preparation of formulation kits of the invention are discussed herein and include, for example … amino acids (including amino acid salts)").

The '046 patent specification at col. 4, lines 23-28 and lines 29-30 states that "a single excipient may perform more than one function" and "multiple excipients serving the same function may be used":

"… in some embodiments of the invention a single excipient may perform more than one function. For example, a single excipient may be multi-functional, e.g., amino acids may function as bulking agents, stabilizers and/or buffers and other excipients may function, for example, as both a stabilizer and a chelator or as both a bulking agent and a tonicity adjuster. Alternatively, multiple excipients serving the same function may be used. For example, the formulation may contain more than one excipient that functions as a stabilizer."

At col. 13, lines 24-28, and in Table 1, the specification also states that a component can serve more than one function. For example, col. 13, lines 24-28 states:

"As discussed, a component in a formulation kit can also serve more than one function. For example, an excipient which serves as a stabilizer may also serve as the chelator and an excipient which serves as a bulking agent may also serve as a tonicity adjuster."

Expert testimony in Bracco's identification of evidence pursuant to L.Pat.R. 4.2(a) through 4.2(c), including, without limitation:

Experts (Dr. Joel Bowen, Dr. Sally Look and/or Dr. Laird Forrest) will confirm the evidence from the '046 patent specification and claims and other information that is discussed herein and the references cited below. Their opinions will be on supporting Bracco's claim construction position and opposing Maia's claim construction position and cited evidence concerning (1) the meaning of the claim terms, which is set forth above, (2) the intrinsic

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