IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRACCO DIAGNOSTICS INC., Plaintiff, v. MAIA PHARMACEUTICALS, INC., Defendant.	Case No. 3:17-cv-13151-PGS-TJB **CONFIDENTIAL – SUBJECT TO DISCOVERY CONFIDENTIALITY ORDER**

DEFENDANT MAIA PHARMACEUTICALS, INC.'S INVALIDITY CONTENTIONS PURSUANT TO L. PAT. R. 3.3 AND 3.6(c)-(d)

Pursuant to Local Patent Rules 3.3 and 3.6(c)–(d), Defendant/Counterclaimant Maia Pharmaceuticals, Inc. (hereinafter "Maia") hereby provides Plaintiff Bracco Diagnostics Inc. (hereinafter "Bracco" or "Plaintiff") with Maia's Invalidity Contentions as to U.S. Patent No. 6,803,046 ("the '046 patent" or "the patent-in-suit"). Pursuant to L. Pat. R. 3.6(d), and subject to the reservation of rights outlined herein, concurrently with service of these contentions, Maia is also producing the documents and things it currently intends to rely on in support of its Invalidity Contentions.

A. GENERAL STATEMENTS

Discovery is just beginning and is ongoing. Maia bases these Invalidity Contentions, in part, upon the positions taken by Bracco in its Complaint and the information in Maia's possession as of the date of these Invalidity Contentions. Maia anticipates that the subject matter of these Invalidity Contentions will be the subject of further extensive fact and expert discovery. Additionally, expert discovery has not started and Maia reserves the right to amend or supplement these Invalidity Contentions and accompanying document production as a result of new information disclosed through discovery, including through the parties' experts.

These Invalidity Contentions are based on information available to Maia at this time. These Invalidity Contentions are necessarily preliminary and may require subsequent amendment, alteration or supplementation.

Maia reserves the right to amend, alter or supplement these contentions based on further investigation, fact or expert discovery, any claim construction ruling, or as a result of Bracco's Infringement Contentions and/or any amendments or supplements thereto. Maia's contentions may be in the alternative and do not constitute any concession by Maia for purposes of claim construction or infringement.

Furthermore, these Invalidity Contentions are provided without prejudice to the rights of Maia to introduce at trial any subsequently discovered evidence or expert opinions relating to currently known facts and to produce and introduce at trial all evidence, whenever discovered, relating to the proof of subsequently-discovered facts. Moreover, facts, documents and things now known may be imperfectly understood and, accordingly, such facts, documents and things may not be included in the following Invalidity Contentions. Maia reserves the right to conduct discovery with reference to, or offer into evidence at the time of trial, any and all facts, expert opinion testimony, documents and things notwithstanding the Invalidity Contentions herein.

To the extent that Maia inadvertently discloses information that may be protected from discovery under the attorney-client privilege, the attorney work product immunity, the common interest privilege or any other applicable privilege or immunity, such inadvertent disclosure does not constitute a waiver of any such privilege or immunity.

The information set forth below is provided without in any manner waiving: (1) the right to object to the use of any statement for any purpose, in this action or any other actions, on the grounds of privilege, relevance, materiality, or any other appropriate grounds; (2) the right to

object to any request involving or relating to the subject matter of the statements herein; or (3) the right to revise, correct, supplement or clarify any of the statements provided below at any time.

Maia reserves the right to supplement or amend these Invalidity Contentions to the full extent consistent with the Court's Rules and Orders, including Local Rules, as additional information becomes available through discovery or otherwise.

1. Asserted Claims

Plaintiff asserts that Maia infringes claims 1–108 of the '046 patent ("the Asserted Claims"). These Invalidity Contentions address all claims of the '046 patent, for which Maia seeks declaratory judgment of invalidity and non-infringement.

2. **Claim Construction**

The Court has not yet construed the Asserted Claims. Maia's position on the invalidity of particular claims will depend on how those claims are construed by the Court. The Invalidity Contentions Maia presents herein are based, at least in part, on Maia's current understanding of the Asserted Claims. To the extent that these Invalidity Contentions reflect constructions of claim terms that may be consistent with or implicit in Bracco's construction of the claim terms, no inference is intended, nor should any inference be drawn, that Maia agrees with such claim constructions. Any statement herein describing or tending to describe any claim element is provided solely for the purpose of understanding the relevant prior art. Maia expressly reserves the right to propose any claim construction it considers appropriate and/or contest any claim construction it considers inappropriate.

In part, because of the uncertainty of claim construction, the Invalidity Contentions may be made in the alternative and are not necessarily intended to be consistent with each other, and

should be viewed accordingly. Further, Maia's inclusion of prior art that would render a claim obvious based on a particular scope or construction of the claim is not, and should in no way be seen as, an adoption or admission as to the accuracy of such scope or construction. Maia reserves all rights to further supplement or modify the positions and information in these Invalidity Contentions, including without limitation, the prior art and grounds of invalidity set forth herein, after the Court has construed the claims of the patent-in-suit.

B. PRIOR ART

In addition to all of the prior art references found on the face of the patent-in-suit, which Maia incorporates fully herein, Maia identifies the following items of prior art which, separately or in any reasonable combination, render obvious one or more of the claims of the patent-in-suit under 35 U.S.C. § 103. Maia further incorporates by reference, in full, all references cited in the following prior art references and their prosecution histories, where applicable. Maia further incorporates by reference, in full, any prior art or other supporting references cited in Maia's Non-Infringement Contentions. The citations provided are representative of the references and are not exhaustive. To the extent that similar claim limitations occur in one or more claims, the disclosures below should be read to apply to all similar claim limitations. Moreover, many of the references discussed herein are representative of additional prior art references in the relevant field. Persons of ordinary skill in the art at the time of the filing of the patent-in-suit knew or read references as a whole, and in the context of other publications, literature and the general knowledge in the field. Maia may rely on all such information, including other portions of the prior art references listed herein and other publications and expert testimony, to provide context and as aids to understanding and interpreting the listed references, or to establish that it would have been obvious for a person of ordinary skill in the art to modify or combine any of the cited

references. Maia reserves the right to modify these Invalidity Contentions to add additional prior art references in light of the information gained through discovery, expert discovery, arguments or positions advanced by Bracco, or the Court's claim construction rulings.

U.S. Patent No. 3,937,819 to Ondetti *et al.*, entitled "Method of Stabilizing an Injectable Composition of a Cholecystokinin Active Octapeptide" ("*Ondetti*")

Ondetti issued on February 10, 1976, more than one year prior to the earliest priority date of the '046 patent, and therefore qualifies as prior art under 35 U.S.C. § 102(b). *Ondetti* discloses a lyophilized pharmaceutical composition of the sulfated octapeptide sincalide. *See Ondetti* at 1:24–36, 50–55. *Ondetti* discloses that the composition of sincalide is obtained by lyophilizing an aqueous solution of the octapeptide and NaCl (a stabilizer/tonicity agent). *Id.* at Abstract. *Ondetti* discloses a sincalide solution prepared by adding 2500 mcg of sincalide and 21.42 g of NaCl to 900 mL of water for injection, adjusting the pH to between 5.50 and 6.50, and creating a solution of approximately 1 liter. *Id.* at 2:33–47. The solution is filled into vials and lyophilized. *Id.* at 2:47–57. *Ondetti* discloses that this enhances "the stability of the octapeptide against degradation upon storage." *Id.* at 2:60–66. *Ondetti* further discloses that the "lyophilized material is readily reconstituted for injection by the addition of sterile water for injection," preferably in a quantity "that forms an isotonic solution." *Id.*at 2:18–23. *Ondetti* discloses that each vial of lyophilized composition contains 5.25 mcg of sincalide and 45.0 mg of sodium chloride. *Id.* at 2:14–16. The lyophilized composition "is reconstituted by addition of 5 ml of sterile water for injection." *Id*. at 2:57–58.

Bracco Diagnostics, Kinevac® Sincalide for Injection (1994) ("*Kinevac Label*")

Kinevac Label published in 1994, more than one year prior to the earliest priority date of the '046 patent, and therefore qualifies as prior art under 35 U.S.C. § 102(b). *Kinevac Label* discloses Kinevac®, also known as Sincalide for Injection. *Kinevac Label* at page 1. *Kinevac*

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