IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BRACCO DIAGNOSTICS INC., Plaintiff, v. MAIA PHARMACEUTICALS, INC., Defendant.	**Confidential** **Attorney's Eyes Only** Case No. 3:17-cv-13151-PGS-TJB
MAIA PHARMACEUTICALS, INC. Counterclaimant, v. BRACCO DIAGNOSTICS INC., Counterclaim Defendant.	

PLAINTIFF'S RESPONSES TO INVALIDITY CONTENTIONS

I. Bracco's Responses to Maia's Invalidity Contentions

Plaintiff Bracco Diagnostics Inc. ("Bracco") provides Bracco's Responses to Invalidity Contentions pursuant to the Local Patent Rules, including L.Pat.R. 3.6(h), which states:

> Not more than 45 days after the disclosure of "Invalidity Contentions" as required by L. Pat. R. 3.6(c), the party defending the validity of the patent shall serve on each other party its "Responses to Invalidity Contentions" as required under L. Pat. R. 3.4A.

L.Pat.R. 3.4A, referred to in the rule recited above, states:[1]

> [Not later than 14 days after service upon it of the "Invalidity Contentions,"] each party defending the validity of the patent shall serve on all parties its "Responses to Invalidity Contentions" which shall include the following:
>
> [(a) For each item of asserted prior art, the identification of each limitation of each

[1] Bracco notes that the preamble to L.Pat.R. 3.4A states 14 days (in brackets above) but that is not applicable because of L.Pat.R. 3.6(h). Bracco also notes that Maia has not asserted that any claim of the '046 patent is invalid for anticipation in Maia's Invalidity Contentions so 3.4A(a) (also in brackets above) does not apply to Bracco.

asserted claim that the party believes is absent from the prior art, except for design patents, where the party shall supply an explanation why the prior art does not anticipate the claim;]

(b) If obviousness is alleged, an explanation of why the prior art does not render the asserted claim obvious;

(c) The party's responses shall follow the order of the invalidity chart required under L. Pat. R. 3.3(c), and shall set forth the party's agreement or disagreement with each allegation therein and the written basis thereof; and

(d) For each asserted grounds of invalidity under L.Pat.R. 3.3(d), a detailed explanation of how the asserted claim complies with 35 U.S.C. §112; and

(e) The production or the making available for inspection and copying of any document or thing that the party intends to rely on in support of its Responses herein.

Accompanying this disclosure is also Bracco's production of documents required under L.Pat.R. 3.4A(e), recited immediately above. This includes documents that were already produced, including Bracco's Infringement Contentions that were provided to Maia separately. They show that Maia [redacted]

In addition, Bracco refers to and will rely on Maia's production of documents and certain positions that it has taken that support validity, namely:

Maia's 505(b)(2) NDA in its entirety along with Bracco's Infringement Contentions. The Maia 505(b)(2) NDA, as explained in detail in Bracco's Infringement Contentions, demonstrates [redacted]

Maia's May 2, 2018 letter to the Court. In that letter Maia stated that it "is not contending that a single prior art reference teaches every element of the asserted claims." In addition, Maia stated that "Maia has agreed to strike the portion of its Invalidity Contentions, on page 4, that incorporates by reference any prior art (including prosecution histories) that has not been produced by Maia in this case." This includes the references cited on the face of the '046 patent and prosecution histories mentioned on page 4 of Maia's Invalidity Contentions. Maia made many other representations in its letter but these representations were not correct. For example,

the letter alleges that Maia is asserting 55 references. However, only 40 references are specifically addressed in Maia's Invalidity Contentions.

II. Maia's Invalidity Contentions

Maia asserted purported defenses of obviousness, lack of enablement and lack of written description in its Invalidity Contentions. Maia made no other arguments based on any other grounds (e.g., Maia made no anticipation arguments). Thus, Maia's Invalidity Contentions serve as an admission that the claimed subject matter of the '046 is novel and not anticipated by any prior art or prior work of anyone pursuant to 35 U.S.C. § 102.

Maia also failed to assert a competent ground of obviousness pursuant to 35 U.S.C. § 103 against a single claim of the '046 patent. Pursuant to the Court's March 27, 2018 Letter Order, Maia was required "to provide Plaintiff with the written basis for its Invalidity Contentions along with any disclosures under L.Pat.R. 3.4 (L.Pat.R. 3.6(c)-(d))" by April 26, 2018. Maia's submission did not comply with the rules in several respects, including by failing to identify any particular prior art combinations it was asserting regarding its obviousness challenge to the claims of '046 patent. Maia also did not provide translations to two references it cited and failed to provide or otherwise define a "Kinevac Label" referred to in its contentions. Instead Maia provided groups of references without ever identifying any particular combinations of them it was asserting. Without providing any specific combinations, Maia then also failed to provide the *Graham* factor analysis for any combination, including failing to provide any motivation to combine the references and any likelihood of success. Maia's obviousness challenge thus fails for these reasons alone. Maia also failed to show how any "separate" reference it was asserting could alone render any '046 patent claim obvious. Maia also did not provide translations to references it cited and failed to provide or otherwise define a "Kinevac Label" and other documents referred to in its contentions. In light of the foregoing, Bracco contends that nothing more is required of it to overcome Maia's obviousness challenge. Any further response by Bracco should not be construed as implying that Maia made a prima facie case of obviousness anywhere in Maia's Invalidity Contentions. By making the showing set forth below, Bracco is not waiving its right to move to strike and otherwise render inadmissible any further and/or withheld arguments by Maia concerning obviousness.

Bracco raised the issue about the failure to provide any specific single reference or combinations of references in its April 30, 2018 and May 7, 2018 letters to the Court and the Court clarified for Maia at the May 1, 2018 telephonic hearing that amendment of Maia's Invalidity Contentions must comply with L.Pat.R. 3.7, which requires an order of the Court upon a timely application and showing of good cause, and the Federal Rules. The Court made it clear that under the scenario presented by Bracco, that if it were correct, Maia would not be permitted to amend its contentions in the future. The parties then met and conferred on the issue and Maia, lacking knowledge of what its contentions said, declined to amend its contentions. In sum, Bracco attempted to meet and confer on the issue on April 27, 2018 (Maia ignored this effort), Maia was clearly warned of the consequences of incomplete contentions and was given ample opportunity to amend its Invalidity Contentions due on April 26, 2018, but Maia declined to do so and should not be permitted to do so in the future. E.g., *Warner Chilcott Co., LLC v. Milan Inc.*, 2015 WL 3630970, Civil Action No. 13-6560 (MLC) (D.N.J. June 9, 2015) (states "Not For Publication").

Maia's assertion that the '046 patent claims lack an adequate written description and enablement also fail for lack of support and the failure to present a colorable argument as required by the Local Patent Rules and as a matter of law, as described below.

III. Maia's Prior Art Does Not Render The '046 Patent Claims Obvious

Maia raises only obviousness as a defense in relation to the prior art. This operates as an admission from Maia that the claimed subject matter of the '046 patent is novel over the prior art. An invention that would have been obvious to a person of ordinary skill at the time of the invention is invalid. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007); *Graham v. John Deere Co.*, 383 U.S. 1 (1966). Maia's invalidity arguments are fatally flawed for at least thirteen overarching reasons that render Maia's arguments legally insufficient and without a colorable factual basis, as described below.

1. The Local Patent Rules required Maia to provide, with its obviousness challenge, "an explanation of why the prior art renders the asserted claim obvious, including an identification of any combinations of prior art showing obviousness." L.Pat.R. 3.3(b). Maia never applied the *Graham* factors to assert a colorable claim of obviousness. *KSR; Graham*. Maia never provided a description of the level of ordinary skill in the art, which is a required showing in an obviousness challenge as a matter of law.

2. Maia also did not comply with the Local Patent Rules because it never provided a single "identification of a combination of prior art showing obviousness." L.Pat.R. 3.3(b). Instead, Maia just presents very large groups of references without combining particular references together to attempt to make a *prima facia* case of obviousness. Specifically, Maia produced a list of forty prior art references and stated that they "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" (page 4 of Maia's Contentions). Maia's assertion has no specificity and provides no notice of a colorable defense. Bracco pointed this out, giving Maia an opportunity to amend its contentions, and the Court warned Maia that amendments could not be made in the future if Maia had not complied with the rules, but Maia never made a single amendment and never made a single combination, which is evidence that a combination of references to render the claims obvious cannot be made.

3. Without a single combination of prior art references made, Maia also failed to show why a person of ordinary skill in the art would be motivated to combine specific references. Motivation proof is required in a *prima facia* obviousness challenge as a matter of law. *KSR; Graham*.

4. Maia cites a very large number of references (i.e., 40) and requires virtually all of them to be somehow used to render the '046 patent claims allegedly obviousness. The use of such a large number of references needed to make an argument is evidence that the subject matter of the '046 patent claims is non-obvious, as a person of ordinary skill in the art would not be led to pick and choose from so many references in the manner used by Maia, which uses impermissible hindsight and knowledge of the '046 patent to choose some embodiments from the prior art but not others without justification.

5. Maia never addressed how its invalidity arguments overcome the presumption of validity afforded the '046 patent claims.

6. In particular, Maia never compared the references it was citing to what the USPTO Examiner considered during the prosecution of the '046 patent to show that they were not cumulative to what had already been reviewed and overcome. For example, Maia's closest prior art and most oft cited reference is the Nema and Wang references. These references were cited to the USPTO Examiner and overcome as not invalidating by themselves, together and in light of the other references of record in the prosecution of the '046 patent.

7. Maia never even attempted to overcome the Nema reference teaching that the art area applicable to the '046 patent was unpredictable and the results literally "unforeseen." Nema states "there is no guarantee that the new drug product will be safe as excipients are combined with other additives and/or with a new drug, creating ***unforeseen*** potentiation or synergistic toxic effects." (p. 166, emphasis added). See also, Bayol (col. 2, lines 54-64), Waterman (p. 19, 20, 27), Arakawa (p. 308, 323), Wang 1999 (p. 175, 178), Li 1995 (p. 498), Audhya (pp. 5-7), Wang (p. S8, S22), Wang 2000 (pp. 50-51).

8. Maia never addressed the fact that each of its non-sincalide, non-patent references were reported in journals of novel and non-obvious scientific work directed to other drugs, peptides and proteins besides sincalide, demonstrating that the art is not predictable and it is "news" when stabilization attempts work on a new drug, peptide or protein. Likewise, the patent references Maia cited were non-obviousness inventions for their claims directed to what they had done and the inventors were attempting to obtain patents for a wide variety of different drugs, peptides and proteins, with particular sets of excipients, again demonstrating that the art is not predictable and the '046 patent claims are valid.

9. Maia never addressed that before the '046 patent, for more than 30 years, no one attempted to make a more stabilized, physiologically acceptable sincalide formulation, or any new sincalide formulations at all. If it were obvious as Maia asserts, then someone else would have done it before Bracco.

[redacted]

12. Maia never addressed the fact that its Kinevac® references directed to an early formulation from the 1970's teach away from any combination of references, a motivation to combine them,

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.