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

BRACCO DIAGNOSTICS INC.,	**VERIFIED COMPLAINT**
Plaintiff,	Docket No. 2:17-cv-13151
v.	
MAIA PHARMACEUTICALS, INC.,	
Defendant.	

COMPLAINT

Plaintiff Bracco Diagnostics Inc. ("Bracco"), by its attorneys, for its complaint against Maia Pharmaceuticals, Inc. ("Maia"), respectfully alleges as follows:

THE NATURE OF THE ACTION

1. This is an action for patent infringement of United States Patent No. 6,803,046 (the "'046 Patent") arising under the patent laws of the United States, Title 35, United States Code, that arises out of the filing with the U.S. Food and Drug Administration ("FDA"), under the Federal Food, Drug and Cosmetic Act ("FDCA"), by Defendant Maia, of a New Drug Application ("NDA") under FDCA Section 505(b)(2) ("505(b)(2) NDA"), which was assigned NDA No. 210850 (the "Maia 505(b)(2) NDA"). With the Maia 505(b)(2) NDA, Defendant Maia is seeking approval of a drug product containing Sincalide, with reference to Bracco's Sincalide formulation that is the subject of Bracco's NDA No. N017697, hereinafter referred to as Bracco's "KINEVAC® product." Bracco seeks all available relief under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and other applicable laws for Defendant Maia's infringement of the '046 Patent.

THE PARTIES

2. Bracco is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 259 Prospect Plains Road, Monroe Township, NJ 08831.

3. Upon information and belief, Maia is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 707 State Road #104, Princeton, NJ 08540. Upon information and belief, Maia was founded in 2013 and is headquartered in Princeton, New Jersey, and Maia markets and sells generic products for the United States market, including the New Jersey market and in this district.

JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq*. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338(a) (patent infringement). Relief is sought under 35 U.S.C. § 271(e)(2).

5. This Court has personal jurisdiction over Maia because, among other things, upon information and belief, Maia is a corporation with its principal place of business in this district and it markets and sells generic products in this district.

6. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

BRACCO'S KINEVAC® PRODUCT

7. Bracco's KINEVAC® product, which is the subject of NDA No. N017697, is the only FDA approved and labeled Sincalide formulation. As set forth in the "Indications and Usage" section of its Package Insert, KINEVAC® may be used: (1) to stimulate gallbladder contraction, as may be assessed by various methods of diagnostic imaging, or to

obtain by duodenal aspiration a sample of concentrated bile for analysis of cholesterol, bile salts, phospholipids, and crystals; (2) to stimulate pancreatic secretion (especially in conjunction with secretin) prior to obtaining a duodenal aspirate for analysis of enzyme activity, composition, and cytology; (3) to accelerate the transit of a barium meal through the small bowel, thereby decreasing the time and extent of radiation associated with fluoroscopy and x-ray examination of the intestinal tract.

8. Bracco is the holder of approved NDA No. N017697.

PATENT-IN-SUIT

9. The ’046 Patent, entitled “Sincalide Formulations,” issued to Edmund C. Metcalfe, Jo Anna Monteferrante, Margaret Newborn, Irene Ropiak, Ernst Schramm, Gregory W. White and Julius P. Zodda on October 12, 2004. A true and correct copy of the ’046 Patent is attached to this Complaint as Exhibit 1.

10. As set forth in the ’046 Patent, at least one of the claims of the ’046 Patent (incorporated by reference herein) covers the formulation of Bracco’s KINEVAC® product and at least one of the claims of the ‘046 Patent covers at least one of the approved indications of the product.

11. The ’046 Patent was duly and legally issued and all right, title and interest in the patent has been assigned to Bracco.

12. Pursuant to 21 U.S.C. § 355, the ’046 Patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with Sincalide and Bracco’s KINEVAC ® product.

INFRINGEMENT BY MAIA

13. By letters dated November 3, 2017 and November 6, 2017, Maia informed

Bracco that it had submitted the Maia 505(b)(2) NDA to FDA under Section 505(b)(2) of the FDCA (21 U.S.C. § 355(b)(2) and 21 C.F.R. § 314.95) seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of a drug product containing Sincalide (the "Maia 505(b)(2) Product") before the expiration of the '046 Patent. Upon information and belief, Maia intends to engage in commercial manufacture, use, importation, offers for sale, and sale of the Maia 505(b)(2) Product promptly upon receiving FDA approval to do so.

14. Upon information and belief, Maia has represented to FDA in the Maia 505(b)(2) NDA and informed Bracco that the established name for the Maia 505(b)(2) Product is Sincalide, and the proprietary name of the reference drug product as listed in the electronic edition of FDA's Orange Book is Bracco's KINEVAC® product.

15. Upon information and belief, Maia filed as part of the Maia 505(b)(2) NDA a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), asserting that the claims of the '046 Patent are invalid, unenforceable, and/or not infringed by the manufacture, use, importation, offer for sale, or sale of the Maia 505(b)(2) Product.

16. Upon information and belief, the Maia 505(b)(2) Product has the same Sincalide active pharmaceutical ingredient, route of administration, dosage form, uses, and strength as Bracco's KINEVAC® product and as claimed in claims 1-108, of the '046 Patent, and constitutes infringement of all 108 claims of the '046 Patent literally and/or under the doctrine of equivalents (e.g., at least literal and doctrine of equivalents infringement of claims 1-19, 21-105 and 107 of the '046 Patent and doctrine of equivalents infringement of claims 20, 106 and 108 of the '046 Patent).

17. Upon information and belief, the use of the Maia 505(b)(2) Product in accordance with and as directed by Maia's proposed labeling for the product will infringe claims 1-108 of the '046 patent, either literally or under the doctrine of equivalents by direct, contributory and/or inducement infringement.

EXCEPTIONAL CASE

18. This is an exceptional case under 35 U.S.C. § 285. Maia's November 3, 2017 and November 6, 2017 letters contained no good faith, reasonable or colorable grounds for any contention that the '046 Patent is invalid, unenforceable or not infringed by the Maia 505(b)(2) NDA, the Maia 505(b)(2) Product or its commercial sale. Thus, Maia's purported paragraph IV certification and challenge to the '046 Patent made to the FDA and Bracco, and any related contentions in this proceeding concerning the Maia 505(b)(2) NDA, Maia 505(b)(2) Product and the '046 Patent, lack any factual or legal basis under the laws and regulations governing the presentation of such information to agencies and courts (e.g., 18 U.S.C. ¶ 1001; Rule 11 of the Fed.R.Civ.P.) and were and are violations of those laws and regulations.

19. Maia's November 3, 2017 and November 6, 2017 letters contained substantial quantities of materially incorrect information, including an incorrect name for the reference product, false scientific and technical information, incorrect names for the parties, including Maia itself, and misapplication of rules and regulations, further evidencing a lack of a good faith or reasonable basis for the Maia 505(b)(2) NDA, the Maia 505(b)(2) Product, and Maia's paragraph IV certification and challenge to the '046 Patent.

20. In addition, Maia's November 3, 2017 and November 6, 2017 letters attached purported "Offers for Confidential Access" that contained substantial quantities of materially

incorrect information and they violated the applicable rules and regulations for what such offers can contain, thus also lacking a good faith and reasonable basis. In further contravention of the rules, pursuant to a purported "Offer for Confidential Access," Maia produced just a few pages from the Maia 505(b)(2) NDA, withholding large quantities of material and highly relevant information, further evidencing a lack of a good faith or reasonable basis for the Maia 505(b)(2) NDA, the Maia 505(b)(2) Product, and Maia's paragraph IV certification and challenge to the '046 Patent.

CLAIM FOR RELIEF

(Infringement Of The '046 Patent Under 35 U.S.C. § 271 (e)(2)(A))

21. Bracco incorporates each of the preceding paragraphs as if fully set forth herein.

22. Maia submitted the Maia 505(b)(2) NDA to FDA under section 505(b)(2) of the FDCA to obtain approval to engage in the commercial manufacture, use, importation, offer for sale, or sale, of the Maia 505(b)(2) NDA Product throughout the United States. By submitting the 505(b)(2) NDA, Maia has committed an act of infringement of the '046 Patent under 35 U.S.C. § 271 (e)(2)(A).

23. Upon information and belief, the Maia 505(b)(2) Product is covered by one or more claims of the '046 Patent.

24. If Maia's 505(b)(2) NDA is approved by FDA, the commercial manufacture, use, importation, offer to sell, or sale within the United States of the Maia 505(b)(2) NDA Product will constitute acts of direct, contributory and/or inducement infringement of the '046 Patent under 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

25. Upon information and belief, Maia has neither a good faith nor reasonable

basis for believing that the Maia 505(b)(2) Product will not infringe the claims of the '046 Patent. Maia posited no factually or legally colorable ground or theory of non-infringement in its November 3, 2017 and November 6, 2017 letters to Bracco concerning the '046 Patent. Maia presented no claim for invalidity or unenforceability of the '046 Patent whatsoever.

26. Upon information and belief, Maia had actual and constructive knowledge of the '046 Patent prior to filing the Maia 505(b)(2) NDA and was aware that filing this 505(b)(2) NDA with FDA constituted an act of infringement of the '046 Patent. In addition, upon information and belief, Maia had specific intent to infringe the '046 Patent when it filed the Maia 505(b)(2) NDA. Moreover, there are no substantial non-infringing uses for the Maia 505(b)(2) Product other than as the pharmaceutical claimed in the '046 Patent.

27. This is an exceptional case under 35 U.S.C. § 285.

28. The acts of infringement set forth above, including the commercial manufacture, use, importation, offer for sale, or sale of the Maia 505(b)(2) Product, in violation of Bracco's patent rights will cause irreparable harm to Bracco for which damages are inadequate, and they will continue unless enjoined by this Court.

PRAYER FOR RELIEF

Bracco respectfully requests the following relief:

a) A judgment that Maia has infringed the '046 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Maia 505(b)(2) NDA under Section 505(b)(2) of the FDCA, and that Maia's making, using, offering to sell, or selling in the United States, or importing into the United States, of the Maia 505(b)(2) Product will infringe one or more claims of the '046 Patent;

b) A finding that the '046 Patent is valid and enforceable;

c) An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Maia 505(b)(2) NDA shall be a date which is not earlier than the latest expiration date of the '046 Patent, as extended by any applicable periods of exclusivity;

d) An order under 35 U.S.C. § 27l(e)(4)(B) and 283 and Rule 65, Fed.R.Civ.P., permanently enjoining Maia, its subsidiaries, parents, officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture use, importation, offer to sell, or sale, of any drug product the use of which is covered by the '046 Patent, including the Maia 505(b)(2) Product;

e) A finding that this action for infringement is an exceptional case under 35 U.S.C. § 285, and that Bracco be awarded reasonable attorneys' fees and costs; and

f) An award of any such other and further relief as the Court may deem just and proper.

Date: December 15, 2017

Respectfully submitted,
s/ H. Danny Kao
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VERIFICATION

I, Vito DeBari, hereby verify that,

1. I am Vice President and General Counsel of the Plaintiff in this action.

2. I have reviewed the foregoing Verified Complaint.

3. I verify under penalty of perjury that the facts set forth in the Verified Complaint are true and correct to the best of my knowledge.

Executed on December 15, 2017

s/ Vito DeBari_____
Vito DeBari

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

The undersigned hereby certifies, pursuant to Local Civil Rule 11.2, that with respect to the matter in controversy herein, neither Plaintiff nor Plaintiff's attorney is aware of any other action pending in any court, or any pending arbitration or administrative proceeding, to which this matter is subject.

Date: December 15, 2017

Respectfully submitted,
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