

UNITED STATES PATENT AND TRADEMARK OFFICE

---

**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

---

MAIA PHARMACEUTICALS, INC.,  
Petitioner

v.

BRACCO DIAGNOSTICS INC.,  
Patent Owner

---

Case No. IPR2019-00345  
U.S. Patent No. 6,803,046

---

**DECLARATION OF CHRISTIAN SCHÖNEICH, PH.D. IN SUPPORT OF  
PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,803,046**

MAIA Exhibit 1003 MAIA V. BRACCO IPR PETITION
---

## TABLE OF CONTENTS

	Page No.
I. INTRODUCTION.....	1
II. QUALIFICATIONS.....	6
III. LEGAL BACKGROUND .....	8
A. Relevant Legal Standards.....	8
B. Person of Ordinary Skill in the Art.....	11
IV. BACKGROUND OF THE TECHNOLOGY.....	12
A. Peptides and Proteins .....	13
B. Peptide and Protein Drug Products.....	14
C. Cholecystokinin and Sincalide.....	15
D. Sincalide’s Chemical and Physical Instability.....	17
1. Sincalide Chemical Instability: Sulfated Tyrosine Residue.....	20
2. Sincalide Chemical Instability: Methionine Residues .....	21
3. Sincalide Physical Instability .....	25
E. Stable Lyophilized Parenteral Formulations.....	27
1. Stabilizers .....	29
a. Antioxidants .....	30
b. Amino Acids.....	31
2. Surfactant/Solubilizers .....	35
3. Chelators.....	36
4. Bulking Agents/Tonicity Adjusters.....	37
5. Buffers .....	38
V. THE ’046 PATENT .....	39
VI. THE CHALLENGED CLAIMS OF THE ’046 PATENT WOULD HAVE BEEN OBVIOUS .....	47
A. Claims 1-4, 6-11, 13, 15, 16, 19, 21-24, 26-31, 33, 35, 36, 40-42, 44-49, 51, 53, 55, and 104 Would Have Been Obvious Over the PDR in Combination with Sato.....	47

# TABLE OF CONTENTS

(cont'd)

	<b>Page No.</b>
1. Independent Claim 1 .....	49
a. An Effective Amount of Sincalide .....	50
b. At Least One Stabilizer .....	51
c. A Surfactant/Solubilizer .....	54
d. A Chelator .....	56
e. A Bulking Agent/Tonicity Adjuster .....	57
f. A Buffer .....	58
2. Independent Claim 21 .....	61
3. Independent Claim 40 .....	62
4. Independent Claim 104 .....	64
5. Claims 2, 22 .....	65
6. Claims 3, 4, 23, 24, 41, 42 .....	66
7. Claims 6-9, 26-29, 44-47 .....	67
8. Claims 10, 11, 13, 30, 31, 33, 48, 49, 51 .....	67
9. Claims 15, 16, 35, 36 .....	68
10. Claim 19 .....	69
11. Claim 55 .....	69
B. Ground 2: Claims 5, 12, 14, 17, 18, 25, 32, 34, 37, 38, 43, 50, 52, and 54 are unpatentable under 35 U.S.C. § 103(a) over the PDR in combination with Sato and Nema .....	70
1. Claims 5, 25, 43 .....	70
2. Claims 12, 32, 50 .....	71
3. Claims 14, 34, 52 .....	73
4. Claims 17, 37, 54 .....	75
5. Claims 18, 38 .....	76

..

# TABLE OF CONTENTS

(cont'd)

	<b>Page No.</b>
C. Ground 3: Claims 77-88, 90-95, 97, 99, 100, and 105 are unpatentable under 35 U.S.C. § 103(a) in view of the PDR in combination with Sato and ENMS .....	77
1. Independent Claim 77 .....	77
2. Claim 78 .....	79
3. Claims 79-80 .....	80
4. Claims 81-82 .....	80
5. Claim 83 .....	81
6. Claims 84-85 .....	81
7. Claims 86-88, 90-95, 97, 99, 100 .....	81
8. Claim 105 .....	82
D. Ground 4: Claims 89, 96, 98, 101, and 102 are unpatentable under 35 U.S.C. § 103(a) in view of the PDR in combination with Sato, ENMS, and Nema .....	83
VII. CONCLUSION .....	84

...

I, Christian Schöneich, Ph.D. declare and state as follows:

## I. INTRODUCTION

1. My name is Christian Schöneich, Ph.D. My findings, as set forth herein, are based on my education and background in the fields discussed below.

2. I have been retained on behalf of Petitioner Maia Pharmaceuticals, Inc. (“Maia” or “Petitioner”) to provide this Declaration relating to U.S. Patent No. 6,803,046 (“’046 patent,” MAIA1001). I understand that Bracco Diagnostics, Inc. (“Bracco”) is the Patent Owner in this *inter partes* review.

3. I reserve the right to supplement this Declaration in response to additional evidence that may come to light. I am over 18 years of age. I have personal knowledge of the facts stated in this Declaration and could testify competently to them if asked to do so.

4. I am not currently, nor have I ever been, employed by Maia, or any affiliates of Maia. To the best of my knowledge, I have no financial interest in Maia, or any affiliates.

5. I am being compensated by Maia for my time, billed at my normal hourly rate, for time actually spent reviewing materials, and performing my analysis of the technical issues relevant to this matter. My compensation is in no way dependent on the opinions I formulate or offer below, nor will I receive any additional compensation based on the outcome of this proceeding.

# 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.