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. INTR	ROD	UCTION	1
II. QU	ALIF	FICATIONS	6
III. LE	GAL	L BACKGROUND	8
A.	Rel	levant Legal Standards	8
В.	Per	son of Ordinary Skill in the Art	11
IV. BA	CKC	GROUND OF THE TECHNOLOGY	12
A.	Pep	otides and Proteins	13
В.	Pep	otide and Protein Drug Products	14
C.	Cho	olecystokinin and Sincalide	15
D.	Sin	calide'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.	Stal	ble 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. TH	E '0	46 PATENT	39
		HALLENGED CLAIMS OF THE '046 PATENT WOULD I	
A.	Cla 51,	aims 1-4, 6-11, 13, 15, 16, 19, 21-24, 26-31, 33, 35, 36, 40-42, 53, 55, and 104 Would Have Been Obvious Over the PDR in	1, 44-49, 1



TABLE OF CONTENTS

(cont'd)

1.	Indepe	ndent Claim 1	Page No 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.	Indepe	ndent Claim 21	61
3.	Indepe	ndent Claim 40	62
4.	Indepe	ndent Claim 104	64
5.	Claims	s 2, 22	65
6.	Claims	3, 4, 23, 24, 41, 42	66
7.	Claims	s 6-9, 26-29, 44-47	67
8.	Claims	3 10, 11, 13, 30, 31, 33, 48, 49, 51	67
9.	Claims	3 15, 16, 35, 36	68
10	. Claim	19	69
11	. Claim	55	69
Gro are with	ound 2: 0 unpaten h Sato ai	Claims 5, 12, 14, 17, 18, 25, 32, 34, 37, 38, 43 50, 52 table under 35 U.S.C. § 103(a) over the PDR in connd Nema	2, and 54 nbination70
1.	Claims	5 5, 25, 43	70
2.	Claims	s 12, 32, 50	71
3.	Claims	s 14, 34, 52	73
4.	Claims	3 17, 37, 54	75
5.	Claims	3 18. 38	76



В.

TABLE OF CONTENTS

(cont'd)

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	ige No le
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, ENM and Nema	5 S, 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.



DOCKET

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.

