

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

_____))
BRACCO DIAGNOSTICS INC.,)
Plaintiff,)
v.)
MAIA PHARMACEUTICALS, INC.,)
Defendant.)
_____))
MAIA PHARMACEUTICALS, INC.)
Counterclaimant,)
v.)
BRACCO DIAGNOSTICS INC.,)
Counterclaim Defendant.)
_____))

Case No. 3:17-cv-13151-PGS-TJB

DECLARATION OF LAIRD FORREST, Ph.D.

I, Laird Forrest, PhD, declare as follows:

1. I make this declaration concerning the Opening Markman Claim Construction Submission of Bracco Diagnostics Inc. (“Bracco”) and the subject matter of United States Patent No. 6,803,046 (the “’046 Patent”), which is Exhibit 1 attached to the Declaration of Donald L. Rhoads.

2. I have reviewed the specification and claims of the ‘046 Patent, which is entitled “Sincalide Formulations.” I have also reviewed the prosecution history of the ‘046 Patent. Exhibit 67. I am an expert in this subject matter. I have been asked by counsel for the Plaintiff to express my opinions regarding the meaning of certain terms in the claims of the ‘046 Patent.

3. I am currently a Professor in the Department of Pharmaceutical Chemistry at the University of Kansas in Lawrence, Kansas, a position I have held since 2017. I am also Professor in the Bioengineering Center, a position I have held since 2011, and Professor in the

Department of Medicinal Chemistry, a position I have held since 2015, both also at the University of Kansas. I have been a faculty at the University of Kansas since 2007.

4. I received a Bachelor of Science in Chemical Engineering from Auburn University in 1998, a Master of Science in Chemical Engineering from the University of Illinois in 2001, and a Ph.D. in Chemical and Biomolecular Engineering from the University of Illinois in 2003. I was a Postdoctoral Fellow in the Division of Pharmaceutical Sciences at the University of Wisconsin, Madison, from 2004 to 2006. In 2006, I became Adjunct Assistant Professor in the Department of Pharmaceutical Sciences at Washington State University, a position I held until 2011. In 2007, I accepted a position as Assistant Professor in the Department of Pharmaceutical Chemistry at the University of Kansas. I was promoted to Associate Professor at the University of Kansas in 2013. I was then promoted to the rank of Professor in 2017.

5. Since 2009, I have been a Member of the Scientific and Medical Advisory Board of Exogenesis Corporation, which develops nanoscale surface modifications for implantable medical devices. I am the co-founder of HylaPharm LLC, founded in 2011, which specializes in reformulation of anti-cancer chemotherapeutics by modification of the delivery route and pharmacokinetics. Also, I am a co-founder of Hafion LLC, founded in 2016, which specializes in development of vaccines, and AeroByx LLC, founded in 2017, which specializes in the development of medications for treatment of neurological and metabolic disease. In addition, I am a co-founder of Vesarex LLC, founded in 2018, which specializes in ultrasound-based imaging and treatment of vein thrombosis. My research toward drug formulation has been competitively funded by multiple awards from the National Institutes of Health and the National Cancer Institute, the National Institute of Allergy and

Infectious Disease, the National Institute on Aging, the National Heart, Lung and Blood Institute, the American Cancer Society, the Department of Defense, the Susan G. Komen Race for the Cure, and the Pharmaceutical Research and Manufacturers of America Foundation ("PhRMA"), among others. In addition, I have been funded by the Food and Drug Administration ("FDA") to develop methodologies for the in vitro determination of bioequivalence in follow-on complex botanical and biosimilar drug formulations.

6. I have received many awards and honors, including the Baxendale Innovation Award (2016), the University of Kansas Leading Light award (2014), the Japan Society for Promotion of Science Visiting Scholar Fellow (2010), the American Cancer Society Research Scholar (2008 to 2012), the American Association of Colleges of Pharmacy, New Investigators Award (2007), and the PhRMA Foundation Postdoctoral Fellow (2006), among others.

7. I am currently or have been in the past a member of various professional societies, including the American Association for Cancer Research, the American Association of Pharmaceutical Scientists, and the American Institute of Chemical Engineers. I serve currently or have served recently on numerous scientific review panels for the National Institutes of Health and the American Cancer Society, and the Association for International Cancer Research (United Kingdom).

8. I have authored more than 85 peer-reviewed journal articles and 5 book chapters. I have also edited 2 special journal issues on drug delivery and formulation and a book on drug delivery and formulation.

9. I have taught drug formulation and biopharmaceutics, including all aspects of drug excipient choice and the effects of excipient modification on drug pharmacokinetics,

drug chemical stability, drug dissolution, and drug absorption, to clinical pharmacy students and graduate students studying pharmaceutical sciences since 2007.

10. I have experience in all aspects of parenteral and oral drug formulation, stability testing and formulation analysis, and pharmacokinetics testing through my research and teaching. Additionally, as part of my work with HylaPharm, Exogenesis Inc., Atrin Pharmaceuticals, and Akari Therapeutics Inc., I have worked on pharmaceutical formulations for intramuscular, subcutaneous, intravenous, topical, and oral formulation.

11. In the past six years, I have testified in the following litigations: Medac Pharma, Inc., et al. v. Antares Pharma Inc., et al., Civ. No. 1:14-cv-01498-JBB (D. NJ); Par Pharmaceutical, Inc., et al. v. Breckenridge Pharmaceutical, Inc., et al., Civ. No. 1:15-cv-00486-SLR (D. DE); Merck Sharp & Dohme Corp. v. Savior Lifetec Corp., Civ. No. 5:15-cv-415 (E.D.N.C); Mylan Pharmaceuticals Inc. v. Astrazeneca AB; PTAB IPR2016-01326; PTAB IPR2016-01325; PTAB IPR2016-01324; PTAB IPR2016-01316; Horizon Pharma, Inc., Horizon Pharma USA, Inc. and Pozen Inc. v. Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc; Civ. No. 3:15-cv-03327-MLC-DEA, 3:16-cv-04921 (D. NJ); joint Horizon Pharm, Inc., Horizon Pharma USA, Inc., and Pozen Inc. v. Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories; Civ. No. 3:15-cv-03324 (D. NJ), 3:16-cv-04918 (D. NJ), 3:16-cv-09035 (D.NJ); joint Horizon Pharm, Inc., Horizon Pharma USA, Inc., and Pozen Inc. v. Lupin Ltd. and Lupin Pharmaceuticals Inc.; Civ. No. 3:15-cv-03326 (D. NJ), 3:16-cv-04920 (D.NJ); and Halozyme, Inc. v. Joseph Matal (on behalf of USPTO), Civ. No. 1:16-cv-1580 (E.D. Va) (2017).

12. I am being compensated for my time at my standard consulting rate of \$550/hour. In addition, Thomson Reuters receives a fee for case management and billing.

Neither the amount of my compensation nor the fact that I am being compensated has altered the opinions that I have given in this Declaration. My compensation is in no way dependent on the outcome of this proceeding. My curriculum vitae is attached hereto as Appendix A.

13. I have been asked to render my expert opinion on the construction of the claims of the '046 Patent. A list of my opinions, and a summary and the subject matter of my opinions, as well as subject matter I will rely on in rendering those opinions, were identified in "Plaintiff's Identification of Opposing Intrinsic and Extrinsic Evidence Concerning Claim Construction," the "Joint Claim Construction and Prehearing Statement," "Plaintiff's First Amendment to Plaintiff's Disclosure of Infringement Contentions," "Plaintiff's First Amendment to Plaintiff's Identification of Opposing Intrinsic and Extrinsic Evidence Concerning Claim Construction and the Joint Claim Construction and Prehearing Statement," and the "Amended Joint Claim Construction and Prehearing Statement." I incorporate these documents into this declaration.

Standards

14. In rendering my opinions, I was informed that claim terms "are generally given their ordinary and customary meaning" to a person of skill in the art: I should consider "those sources available to the public that show what a person of skill in the art would have understood the disputed claim language to mean." The "ordinary" meaning of a claim term is that meaning to a person of skill in the art.

15. The sources I should consider include, first, the intrinsic record, which is composed of the claims, the specification and the prosecution history. Second, and perhaps to be given less weight, it is all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.

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.