

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

BRACCO DIAGNOSTICS INC.,

Plaintiff,

v.

MAIA PHARMACEUTICALS, INC.,

Defendant.

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



**DECLARATION OF PROFESSOR ALEXANDER M. KLIBANOV
IN SUPPORT OF DEFENDANT MAIA PHARMACEUTICALS, INC.’S
OPENING CLAIM CONSTRUCTION BRIEF**

I, Alexander M. Klibanov, Ph.D., declare and state as follows:

1. I submit this declaration in support of Defendant Maia Pharmaceuticals, Inc.’s (“Maia”) Opening Claim Construction Brief. I have personal knowledge of the matters set forth herein and, if called upon, could and would testify competently thereto.

I. BACKGROUND AND QUALIFICATIONS

2. I am a Professor of Chemistry and Bioengineering at the Massachusetts Institute of Technology (“M.I.T.”), where I have been teaching and conducting research for over 39 years and currently hold the Novartis Endowed Chair Professorship (which I also held from 2007 to 2012). From 2012 to 2014, I held the Roger and Georges Firmenich Endowed Chair Professorship in Chemistry.

Prior to that, I was a Professor of Chemistry and a Professor of Bioengineering at M.I.T., positions I held from 1988 and 2000, respectively. From 1979 to 1988, I was an Assistant Professor, then Associate Professor, and thereafter a Full Professor of Applied Biochemistry in the Department of Applied Biological Sciences (formerly the Department of Nutrition and Food Science) at M.I.T.

3. I obtained my M.S. in Chemistry from Moscow University in Russia in 1971 and Ph.D. in Chemical Enzymology from the same University in 1974. Thereafter, I was a Research Chemist at Moscow University's Department of Chemistry for three years. From 1977 to 1979, following my immigration to the United States, I was a Post-Doctoral Associate at the Department of Chemistry, University of California in San Diego.

4. Over the last 45+ years as a practicing chemist, I have extensively researched, published, taught, and lectured in many areas of biological, medicinal, formulation, and polymer chemistry.

5. I have earned numerous prestigious professional awards and honors. For example, I was elected to the U.S. National Academy of Sciences (considered among the highest honors that can be given to an American scientist) and also to the U.S. National Academy of Engineering (considered among the highest honors that can be given to an American engineer or applied scientist). I am also a Founding Fellow of the American Institute for Medical and Biological Engineering

and a Corresponding Fellow of the Royal Society of Edinburgh (Scotland's National Academy of Science and Letters). In addition, I have received the Arthur C. Cope Scholar Award, the Marvin J. Johnson Award, the Ipatieff Prize, and the Leo Friend Award, all from the American Chemical Society, as well as the International Enzyme Engineering Prize.

6. I currently serve on the Editorial Boards of over a dozen scientific journals, including "Open Journal of Pharmacology," "Applied Biochemistry and Biotechnology," "Nanocarriers," "Open Access Academic Books in Chemistry," "Biotechnology and Bioengineering," "Journal of Biological Chemistry and Molecular Pharmacology," "Recent Patents in Biotechnology," "Archives of Medical Biotechnology," "Current Pharmaceutical Biotechnology," and "International Journal of Drug Design, Delivery, and Safety."

7. I have published over 315 scientific papers in various areas of chemistry. I am also a named inventor of 25 issued United States patents and of a number of pending ones. I have given over 370 invited lectures at professional conferences, universities, and corporations all over the world, many dealing with formulation, stability, delivery, and biological evaluation of pharmaceutically active compounds.

8. In addition to my research and teaching activities at M.I.T., I have consulted widely for pharmaceutical, medical device, chemical, and biotechnology

companies. They have included both innovator and generic pharmaceutical companies.

9. I have also founded six pharmaceutical companies and have been on the scientific advisory boards and/or boards of directors of those companies and of many others. A number of these consulting, advisory, and directorship activities have dealt specifically with the formulation, stability, delivery, administration (including parenteral), and biological evaluation of pharmaceutically active compounds.

10. I am being compensated at my standard consulting rate of \$950 per hour. My compensation is in no way dependent on the opinions rendered or the outcome of this litigation.

11. My *curriculum vitae*, attached as Exhibit A, summarizes my education and professional experience, including a list of publications that I have authored.¹

12. During the past four years, I have testified as a technical expert, either at deposition or trial, as set forth in Exhibit B.

II. MATERIALS CONSIDERED

13. My opinions expressed in this report are based on my review of U.S. Patent No. 6,803,046 (“the ’046 patent”), its prosecution history, the Declaration of

¹ Exhibits A-C of my declaration are attached hereto. All other exhibits cited herein are submitted with the Declaration of Gregory D. Miller, Esq.

Gregory D. Miller, Esq., and exhibits attached thereto, as well as the materials set forth in Exhibit C hereto and cited in this report. My opinions are further informed by my professional knowledge and experience in the field of pharmaceutical formulations (including injectables), which span over 45 years. Based on my education, research, and other work experience, I believe am competent to provide the opinions set out in this expert report.

III. SUMMARY OF OPINIONS

14. The plain and ordinary meaning of the claim term “surfactant” to a person of ordinary skill in the art (“POSA”), reading the ’046 patent at the time of its invention, would have been “a compound that reduces the tension of the air/liquid or liquid/solid interface.”

15. The plain and ordinary meaning of the claim term “surfactant/solubilizer” to a POSA, reading the ’046 patent at the time of its invention, would have been “a surfactant that is also a solubilizer.” A “solubilizer” is “a compound that aids in solubilization, thus preventing or reducing sincalide denaturation and/or degradation caused by peptide aggregation, precipitation, surface adsorption, or agitation at air/liquid or liquid/solid interfaces in solution.”

16. The plain and ordinary meaning of the claim term “buffer” to a POSA, reading the ’046 patent at the time of its invention, would have been “a compound that stabilizes the pH of a sincalide formulation.”

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