

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

IN RE: SITAGLIPTIN PHOSPHATE ('708
& '921) PATENT LITIGATION

MDL No. 19-2902-RGA

C.A. Nos. 19-310-RGA,
19-311-RGA,
19-312-RGA,
19-313-RGA,
19-314-RGA,
19-316-RGA,
19-317-RGA,
19-318-RGA,
19-319-RGA,
19-321-RGA,
19-347-RGA,
19-1489-RGA,
19-2192-RGA

DECLARATION OF PROFESSOR ALLAN S. MYERSON, Ph.D.
REGARDING CLAIM CONSTRUCTION

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I, Allan S. Myerson, declare as follows:

I. INTRODUCTION

1. I have been asked to opine on how a person of ordinary skill in the art would interpret the terms:

- “the salt of claim 1 [or 2]” as used in claims 2, 3, and 21 of U.S. Patent No. 7,326,708 (“the ’708 patent”);
- “crystalline monohydrate [of the dihydrogenphosphate salt of sitagliptin]” as used in claims 4 and 24 of the ’708 patent;
- “characteristic absorption bands obtained from the X-ray powder diffraction pattern at spectral d-spacings of” as used in claims 5–7 of the ’708 patent; and
- “crystallizing the dihydrogenphosphate salt of [sitagliptin] at 25°C” as used in claim 24 of the ’708 patent.

2. In reaching the opinions I express herein, I have considered the ’708 patent and its prosecution history, the materials cited in this declaration, as well as my training, general knowledge, basic principles, and experience in the relevant scientific disciplines.

II. QUALIFICATIONS AND EXPERIENCE

3. I am the Professor of the Practice in the Department of Chemical Engineering at the Massachusetts Institute of Technology (“MIT”) in Cambridge, Massachusetts. The following is a brief summary of my background, experience, publications, and achievements, which are more fully set out in my curriculum vitae, J.A. 18.

4. I am a chemical engineer by training. I have a particular interest in industrial crystallization and have conducted research in this area for over 30 years.

5. I began my training at Columbia University in New York, where I obtained my Bachelor of Science in Chemical Engineering in May 1973. Thereafter, I obtained Masters and

Ph.D. degrees in Chemical Engineering from the University of Virginia in January 1975 and January 1977, respectively. I am a registered Professional Engineer in New York and Ohio.

6. In January 1977, I began my academic career as an Assistant Professor of Chemical Engineering at the University of Dayton, where I worked until August 1979.

7. From September 1979 to December 1984, I was a faculty member at the Georgia Institute of Technology in Atlanta, serving first as an Assistant Professor of Chemical Engineering and subsequently as an Associate Professor.

8. In January 1985, I joined the faculty of the Polytechnic University in Brooklyn, New York. While there, I served in various positions including as Joseph and Violet J. Jacobs Professor of Chemical Engineering, Head of the Department of Chemical Engineering, Dean of the School of Chemical and Materials Science and as Vice Provost for Research and Graduate Studies.

9. In January 2000, I moved to the Illinois Institute of Technology in Chicago (“IIT”). I began as Professor of Chemical Engineering and Dean of the Armour College of Engineering and Science. I remained in that position until January 2003, when I became the Philip Danforth Armour Professor of Engineering. Between 2003 and 2008, I was also Provost and Senior Vice President at IIT. In August 2010, I moved to my current position as Professor of the Practice in the Department of Chemical Engineering at MIT.

10. My current research focuses on crystallization from solution with an emphasis on nucleation, solid forms of pharmaceuticals, impurity-crystal interactions, and industrial applications of crystallization, as well as on the manufacturing of pharmaceutical products, including novel pharmaceutical dosage forms.

11. I served as a co-principal investigator in the Novartis-MIT Center for Continuous

Manufacturing (2019-2018) and a co-principal investigator in the DARPA funded project, “Pharmacy on Demand” (2012-2018). In both of these projects, my work has focused on pharmaceutical manufacturing methods for both the active pharmaceutical ingredient and final dosage form, and has included work on both solid and liquid based formulations.

12. Over the course of my career, I have supervised the Ph.D. dissertations of approximately 50 students and have supervised the research of approximately 30 post-doctoral research associates. I currently supervise a research group consisting of one Ph.D. students and two post-doctoral research associates. In the last two years, I have taught graduate level elective courses entitled “Crystallization Science and Technology” and “Pharmaceutical Engineering.”

13. I have presented the results of my research, including in the area of crystallization, at numerous national and international meetings. I have also published approximately 280 papers in refereed scientific journals. Many of those papers pertain to crystallization and related subjects.

14. I have taught short courses in crystallization (sponsored by the Center of Professional Advancement, the American Chemical Society, and MIT Continuing Education) in the United States, Europe, and Singapore and have taught special crystallization courses at pharmaceutical and chemical companies in the United States, Europe, India and Japan. I have also consulted for major chemical and pharmaceutical companies in those same regions.

15. In addition, I have edited five books in the area of crystallization, including the *Handbook of Industrial Crystallization* (1st edition 1991, 2nd edition 2001, 3rd edition 2019).

16. I have received several awards and honors for my research accomplishments. These include the American Institute of Chemical Engineers (“AICHE”) Separations Division, Clarence G. Gerhold Award in 2015, AIChE Process Development Division, Excellence in

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