

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
Petitioner,

v.

MERCK SHARP & DOHME CORP.,  
Patent Owner.

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Case IPR2020-00040  
U.S. Patent 7,326,708

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**DECLARATION OF GARY HERMAN, M.D.**

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I, Gary Herman, M.D., hereby declare as follows:

**I. INTRODUCTION**

1. I understand that this proceeding involves issues related to U.S. Patent No. 7,326,708 (“the ’708 patent”). I understand that Merck Sharp & Dohme Corp. (“Merck”) is the owner and assignee of the ’708 patent.

2. I understand that claim 17 of the ’708 patent claims a pharmaceutical composition comprising a therapeutically effective amount of the 1:1 dihydrogenphosphate salt of sitagliptin (“1:1 sitagliptin DHP”) in association with one or more pharmaceutically acceptable carriers.

3. I understand that claim 19 of the ’708 patent claims a method for the treatment of type 2 diabetes comprising administering to a patient in need of such treatment a therapeutically effective amount of 1:1 sitagliptin DHP, or a hydrate thereof.

4. In this declaration, I provide facts about which I have first-hand knowledge regarding the timing of the early clinical development of sitagliptin, which led to various FDA approved drugs, including Januvia®. I did not invent the subject matter claimed in the ’708 patent, but it is my understanding that I have relevant knowledge about the dates by which certain of the inventions conceived of by the inventors listed on the ’708 patent were actually reduced to practice.

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**II. BACKGROUND**

5. In 1982, I received a Bachelor's Degree in Biochemistry and Cell Biology from the University of California, San Diego.

6. After graduating from UCSD, I attended Harvard Medical School, from which I received an M.D. in 1988.

7. In 1988, I returned to California to train as a resident and postdoctoral fellow at the University of California, San Francisco. In 1995, I became an assistant professor at UCSF responsible for running a laboratory, taking care of patients, and teaching.

8. In 2001, I joined Merck as Associate Director, Clinical Pharmacology, and was promoted in 2003 to Director, Clinical Pharmacology, and in 2006 I was again promoted to Senior Director, Clinical Pharmacology.

9. In my roles at Merck as Associate Director, Director, and Senior Director, Clinical Pharmacology, I co-chaired the MK-0431 product development team and, among other things, lead the entire early clinical and clinical pharmacology program for Januvia®, from planning, first-in-human trials, and regulatory filing.

10. Between 2006 and 2015, I held various other position at Merck, including senior positions in Clinical Pharmacology, Experimental Medicine, and Early Stage Development.

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11. In 2015, I left Merck to become Vice President, Early Clinical Development at Regeneron Pharmaceuticals, Inc. I am now Senior Vice President, Early Clinical Development & Experimental Sciences at Regeneron.

**III. EARLY CLINICAL STUDIES INVOLVING MK-0431**

12. During 2002, I was heavily involved in planning, executing, and evaluating the results from the early clinical studies involving MK-0431, which I understand to be 1:1 sitagliptin DHP. MK-0431 was first administered to patients—that is, humans with type 2 diabetes—in October 2002, as part of a clinical study that I will refer to as “Protocol 005.” EX2106 is a true and correct copy of the Synopsis and Comprehensive Study Summary of the Clinical Study Report for Protocol 005, as submitted to the FDA as part of the Januvia® NDA. I am an author of Protocol 005. *See* EX2106 at 23.

13. A major objective of Protocol 005 was to evaluate whether administering doses of MK-0431 to patients would have the desired therapeutic effect in patients, i.e., lead to a dose-dependent decrease in glucose levels. If such dose-dependent decreases in glucose levels were observed, it would establish “proof-of-concept.”

14. The Protocol 005 Clinical Study Report is dated November 2005; however, the portion of the study that actually involved administering MK-0431 to patients ended no later than March 16, 2003, *see* EX2106 at 17, and I and others on

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the Merck team working to develop MK-0431 into an FDA-approved drug received data showing partial but reliable results from Protocol 005 well before then.

15. As part of Protocol 005, patients received treatments consisting of a 25 mg dose of MK-0431 and a 200 mg dose of MK-0431, formulated into simple oral capsules. *See* EX2106 at 17-18, 39-40. These simple capsules were formulated in three strengths: 5 mg, 20 mg, and 100 mg. *Id.*

16. It was Merck's ordinary and customary practice to assign a formulation number to each formulation, and the 5 mg, 20 mg, and 100 mg strengths were assigned formulation numbers 0431DFC001E001, 0431DFC001G001, and 0431DFCF002D001, respectively. *Id.*

17. It was also Merck's ordinary and customary practice to assign a number to each batch of drug substance, and the MK-0431 in the capsules used as part of Protocol 005 came from Drug Substance Batch No. L-000224,715-006F017. *See* EX2108 at 4-5. I understand that EX2108 is a true and correct copy of module 3.2.P.5.4 Batch Analysis submitted to the FDA as part of the Januvia® NDA.

18. In late November and early December 2002, I conducted an interim analysis on the first 18 patients who had completed Protocol 005. My interim analysis showed that administering MK-0431 to patients with type 2 diabetes led to

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