UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

MERCK SHARP & DOHME CORP.,
Patent Owner.

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

DECLARATION OF REBECCA LEIGH SHULTZ, PH.D.

I, Rebecca Leigh Shultz, Ph.D., hereby declare as follows:

I. INTRODUCTION & BACKGROUND

1. I am an employee of Merck Sharp & Dohme Corp. ("Merck") and currently serve as Merck's Associate Vice President, Global Project & Alliance Management. I have been a Merck employee since 2001.

2. I joined Merck shortly after receiving my Ph.D. in inorganic chemistry from the University of North Carolina at Chapel Hill. I received my B.S. in chemistry from the University of Florida in 1995. From 2001 to 2004, I was a Senior Research Chemist in the Pharmaceutical Research & Development Department ("PR&D") of Merck Research Laboratories ("MRL").

3. In late 2001, I joined the project team at Merck responsible for developing an inhibitor of dipeptidyl peptidase-IV ("DPP-IV") into a treatment for type 2 diabetes. Over the course of the DPP-IV project, I led a functional sub-team responsible for the physicochemical characterization of candidate compounds that had been identified through Merck's drug discovery program as well as evaluating their performance in proposed formulations for clinical studies. In this role, I personally performed many analytical tests and formulation studies and also reviewed the results of experiments performed by other scientists on the DPP-IV project. As such, I have first-hand knowledge of the data generated by the DPP-IV project team over the course of sitagliptin's development.

4. One of the lead compounds at the time I joined the DPP-IV project was sitagliptin, which had received the internal Merck designation "L-224715." Subsequently, during Phase III development, the compound also received the designation "MK-0431." Merck's research and development of sitagliptin, and the work of the DPP-IV project team, culminated in an FDA-approved dosage form of sitagliptin for the treatment of type 2 diabetes, which Merck markets today under the tradename JANUVIA®.

5. Sitagliptin's formal chemical name is 4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4] triazolo[4,3-a]pyrazine-7(8H)-yl]-1-(2,4,5-trifluorophenyl) butan-2-amine and the structural formula of the compound is shown below:

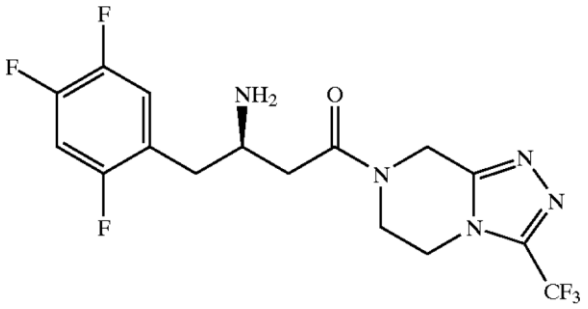

Figure 1. Chemical structure of sitagliptin (L-224715 or MK-0431).

6. The active pharmaceutical ingredient ("API") in JANUVIA® is a crystalline monohydrate of a phosphoric acid salt of sitagliptin in which the dihydrogenphosphate ("DHP") counterion from phosphoric acid and sitagliptin are present in a 1:1 stoichiometric ratio.

7. I understand that Merck is the owner and assignee of U.S. Patent No. 7,326,708 ("the '708 patent") and that the subject matter of the '708 patent is generally directed to the 1:1 DHP salt of sitagliptin and its crystalline monohydrate form. I further understand that the named inventors of the '708 patent are Stephen Howard Cypes, Alex Minhua Chen, Russell R. Ferlita, Karl Hansen, Ivan Lee, Vicky K. Vydra, and Robert M. Wenslow. The named inventors and I were all members of the DPP-IV project team and worked closely together to develop sitagliptin, including with respect to selecting the specific salt and crystal form of sitagliptin used in JANUVIA®.

8. In this declaration, I provide facts based on my personal knowledge regarding Merck's research and development of sitagliptin, including the contributions of the named inventors of the '708 patent to the DPP-IV project, the synthesis and characterization of sitagliptin's salt and crystal forms, the discovery of the crystalline monohydrate of the 1:1 DHP salt, and its selection as the solid form of sitagliptin used in the final market formulation for JANUVIA®. I have first-hand knowledge concerning the work of the DPP-IV project team and am familiar with the information that became known to the team and how key decisions in the project were made.

9. Members of the DPP-IV project team, including the inventors and myself, recorded experimental observations in laboratory notebooks issued by

Merck. I am familiar with Merck's practices and procedures with respect to laboratory notebooks. In the usual and ordinary course of its business, and at the time of the DPP-IV project, Merck issued numbered laboratory notebooks to scientists for the purpose of recording their daily research activity. Each laboratory notebook page was individually numbered, and shorthand references to lab notebooks include both the lab notebook number as well as the page number, for example, "NB 60659-110." Sample materials and experimental procedures often incorporate such shorthand references so that other project team members can easily identify the source of the sample or procedure in question. In accordance with Merck's standard practices, I recorded the entries in my lab notebook at or near the time that I ran my experiments.

10. I maintained several lab notebooks for my work on the DPP-IV project, true and correct excerpts of which may be found in the following exhibits:

- EX2141 – Lab Notebook ("LNB") 60659
- EX2142 – Supplemental Data for LNB 60659
- EX2143 – LNB 26180
- EX2144 - Supplemental Data for LNB 26180
- EX2145 – LNB 72917

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