

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 LOU ANN EADER

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I, Lou Ann Eader, hereby declare as follows:

1. I am employed by Merck Sharp & Dohme Corp. (“Merck”) as a Director, Global Regulatory Affairs. I joined Merck in October 1997, and became the custodian of the Januvia® regulatory file at Merck in February 2012.

2. In the regular course of Merck’s business, a Regulatory Liaison is assigned to be a point of contact with the FDA for his/her assigned project(s). This individual is responsible for submissions for that program’s NDA(s) during the time of their assignment to the program. I am, and have been since February 2012, the current Regulatory Liaison for the Januvia® NDA.

3. NDA submissions and correspondence are archived in an electronic database. That database is maintained as the official copy of the NDA at Merck. As the Regulatory Liaison for the Januvia® NDA, I have personal knowledge of the contents of the Januvia® NDA electronic database. One of my routine responsibilities as a Regulatory Liaison is to maintain and update during the regular course of Merck’s business, the official copy of the Januvia® NDA archive.

4. EX2106 is a true and correct copy of the Synopsis and Comprehensive Study Summary from the Clinical Study Report for Protocol 005, dated November 15, 2005, as submitted to the FDA as part of the Januvia® NDA.

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5. EX2107 is a true and correct copy of the Synopsis and Comprehensive Study Summary from the Clinical Study Report for Protocol 006, dated April 1, 2005, as submitted to the FDA as part of the Januvia® NDA.

6. EX2108 is a true and correct copy of Module 3.2.P.5.4 Batch Analyses, dated November 14, 2005, as submitted to the FDA as part of the Januvia® NDA.

* * *

I hereby declare that all statements made herein of my own knowledge true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: August 19, 2020

/Lou Ann Eader/
Lou Ann Eader

Lou
Eader_9360(Signature)

Digitally signed by Lou
Eader_9360(Signature)
Date: 2020.08.19 23:55:12 -04'00'