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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2016-01693
Patent 6,407,213

DECLARATION OF IRENE LOEFFLER

Mylan v. Genentech

I, Irene Loeffler, declare as follows:

1. I am the Associate Director of Records and Image Management in Genentech's Corporate Records Management Program Group. I have personal knowledge of the facts set forth herein.

2. I have worked at Genentech since 1987 holding various records positions, including: Central Records Administrator; Manager, Biomedical Records; Manager, Records and Image Management; Senior Manager, Records and Image Management; and my current role as Associate Director, Records and Image Management.

3. In connection with my duties and responsibilities at Genentech, I oversee the ordering, assigning, tracking, recalling, scanning (previously microfilming), indexing, storing, and retrieving of laboratory notebooks.

4. The exhibits listed below are true and authentic copies of several Genentech laboratory notebooks. Each laboratory notebook receives a unique numerical identifier when it is issued, which allows Genentech to accurately track those records. The notebook numbers and scientists to whom they were issued are as follows:

- a. Exhibit 2001: Notebook No. 10098 (Leonard Presta)
- b. Exhibit 2002: Notebook No. 10823 (Leonard Presta)
- c. Exhibit 2003: Notebook No. 11268 (Paul Carter)

- d. Exhibit 2004: Notebook No. 11643 (Paul Carter)
- e. Exhibit 2005: Notebook No. 10840 (John Brady)¹
- f. Exhibit 2006: Notebook No. 11162 (John Brady)
- g. Exhibit 2007: Notebook No. 11008 (Ann Rowland)
- h. Exhibit 2008: Notebook No. 11297 (Tim Hotaling)
- i. Exhibit 2009: Notebook No. 11568 (Monique Carver).

5. At the time that these notebooks were issued, Genentech scientists were instructed to record all work in their assigned notebooks and to sign and date each entry on a daily basis; no data was to be held back for later entry. Any attachments, such as computer data, were to be permanently affixed to the notebooks without covering any other entries. These instructions are included behind the front cover of Genentech's laboratory notebooks to remind Genentech's scientists of their responsibility to maintain timely and accurate records of their research.

6. I am familiar with Genentech's practices regarding the creation, modification, and keeping of its laboratory notebooks through my employment with Genentech. Each of the laboratory notebooks listed above was created by

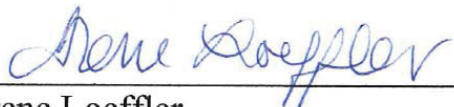
¹ At the time that Notebooks 10840 and 11162 were issued, Mr. Brady's name was John Ridgway. He subsequently changed his name to John Ridgway Brady.

Genentech personnel during the regular course of business. It was the regular practice of Genentech's personnel to create such records at or near the time the recorded act, event, condition, or opinion occurred. It was the general practice of Genentech's personnel to date such documents as of the date the record was created or modified. Such records would only be made by someone with knowledge or from information transmitted by someone with knowledge.

7. It was Genentech's general practice to recall for imaging laboratory notebooks one year after they were issued or as soon as they were completed. Genentech microfilmed the notebooks until November 2007 at which time Genentech began scanning the notebooks. Exhibits 2001-2009 were initially microfilmed approximately one year after they were issued and then scanned in high-resolution color in or around November 2016.

I declare under penalty of perjury of the laws of the United States of
America that the foregoing is true and correct.

Executed on: December 9, 2016



Irene Loeffler