UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SANDOZ INC.,
Petitioner,

v.

ELI LILLY & COMPANY,
Patent Owner.

Case No: IPR2016-00318
Patent No. 7,772,209

DECLARATION OF GREGORY T. BROPHY, Ph.D.

I, Gregory T. Brophy, hereby declare as follows:

I. INTRODUCTION

1. I am over the age of eighteen and otherwise competent to make this declaration.

2. I have been asked to provide a declaration attesting to the authenticity of certain exhibits reflecting communications between Eli Lilly and Company ("Lilly") and the Food and Drug Administration ("FDA").

II. QUALIFICATIONS AND BACKGROUND

3. I am a former employee of Lilly. From 2010 to 2011, I was Senior Director, Global Regulatory Affairs at Lilly in Indianapolis, Indiana.

4. From 1996 to 2010, I was Director, U.S. Regulatory Affairs, at Lilly. In that capacity, I directed the team responsible for regulatory submissions to the FDA for a variety of Lilly pharmaceutical products, including the cancer chemotherapy drug now known as ALIMTA®.

5. Since 2011, I have been the President of GB PharmaRegConsult LLC, a consulting company I founded and which provides pharmaceutical regulatory consulting services. I am being compensated at my current billing rate ($400 per hour) for my time spent in preparing this declaration. I also receive a pension from Lilly. My compensation does not depend on the outcome of this proceeding.

III. FDA COMMUNICATIONS

6. In the 1990s, Lilly sought regulatory approval from the FDA to conduct clinical trials, and ultimately to market, the product that is now known as ALIMTA®. The active ingredient in ALIMTA® is sometimes referred to as "pemetrexed," "LY231514," "MTA," or "multi-targeted antifolate." In my position as the Director of U.S. Regulatory Affairs, I frequently communicated with the FDA concerning this product.

7. I am familiar with the way in which Lilly keeps its records related to FDA communications. These communications, including the communications referenced in paragraph 8–20 below, were and are required to be maintained by Lilly in the usual and ordinary course of its business, including during the time period of July 1998 to March 2000.

8. Exhibit 2098 at 1–2 is a letter I sent to the FDA on behalf of Lilly on July 29, 1998 entitled "Briefing document for End-of-Phase II Meeting (mesothelioma, non-small cell lung cancer and head/neck cancer)." Exhibit 2098 also contains the enclosure to the letter, a briefing document dated July 28, 1998. *See id.* at 3–340.

9. Exhibit 2099 is a letter I sent to the FDA on behalf of Lilly on September 8, 1998 entitled "End-of-Phase II Meeting (mesothelioma and non-small cell lung cancer)."

10. Exhibit 2100 is Lilly's version of the minutes of the September 25, 1998 meeting between Lilly and the FDA, which I attended.

11. Exhibit 2101 at 1 is a letter I sent to the FDA on behalf of Lilly on November 18, 1998 entitled "End-of-Phase 2 Meeting Minutes Compound LY231514 (MTA, Multitargeted Antifolate)." Exhibit 2101 also contains the enclosure to the letter, Lilly's version of the minutes of the September 23, 1998 meeting between Lilly and the FDA. *See id.* at 2–24.

12. Exhibit 2102 at 1–2 is a letter I sent to the FDA on behalf of Lilly on November 24, 1999 entitled "Letter to Investigators Regarding Patients with High Baseline Homocysteine Levels." Exhibit 2102 also contains the enclosure to the letter, a copy of the letter Lilly sent to clinical investigators regarding pemetrexed on November 24, 1999. *See id.* at 3–4.

13. Exhibit 2103 at 1–5 is a letter I sent to the FDA on behalf of Lilly on December 3, 1999 entitled "Supplementation with Folic Acid and Vitamin B_{12} To Reduce Toxicity in Patients Receiving LY231514." Exhibit 2103 also contains the enclosures to the letter, a paper entitled "LY231514 (MTA Safety Analysis)" and a copy of Lilly's letter sent to clinical investigators regarding pemetrexed on December 2, 1999. *See id.* at 6–28.

14. The FDA responded to Lilly's November 8 and December 3, 1999 letters in a fax to John Worzalla dated December 21, 1999. Exhibit 2104 is this

fax. Mr. Worzalla was a Lilly employee who reported directly to me. I subsequently obtained a copy of the fax.

15. I responded in a letter, on behalf of Lilly, to the FDA's fax on December 22, 1999. Exhibit 2105 is this letter. The letter was entitled "Response to FAX to Lilly from the FDA on December 21, 1999."

16. The FDA responded to Lilly's December 22, 1999 letter in a fax to Mr. Worzalla dated January 6, 2000. Exhibit 2106 is this fax. I subsequently obtained a copy of the fax.

17. Exhibit 2107 at 1–2 is a letter I sent to the FDA on behalf of Lilly on February 16, 2000 entitled "Briefing Document for March 1 Meeting to Discuss Vitamin Supplementation in the Ongoing Mesothelioma Registration Trial." Exhibit 2107 also contains the enclosure to the letter, a briefing document dated February 16, 2000. *See id.* at 3–36.

18. Exhibit 2108 are the FDA's version of the minutes for a March 1, 2000 meeting between Lilly and the FDA, which I attended. An FDA representative prepared the minutes and sent them to me, among others at Lilly.

19. Exhibit 2109 at 1–3 is a letter I sent to the FDA on behalf of Lilly on March 20, 2000 entitled "Meeting Minutes from the March 1 Meeting to Discuss Vitamin Supplementation in the Ongoing Mesothelioma Registration Trial." Exhibit 2109 also contains the enclosures to the letter, including Lilly's version of

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