UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., APOTEX CORP., APOTEX PHARMACEUTICALS HOLDINGS INC., AND APOTEX HOLDINGS, INC.,

Petitioners,

v.

OSI PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2016-01284
U.S. Patent No. 6,900,221

DECLARATION OF MR. MARK L. REISENAUER

OSI 2023
APOTEX V. OSI

I, Mr. Mark L. Reisenauer, declare as follows:

1. My name is Mark L. Reisenauer.

I. BACKGROUND

2. I joined Astellas Pharma, the ultimate parent of patent owner, OSI Pharmaceuticals, in 2011 as Vice President, Sales and Marketing, Oncology. As part of my responsibilities, I led commercial activities supporting Tarceva®. In order to fulfill my responsibilities with respect to the Tarceva brand, I became familiar with the historical commercial performance of the product, the market segments in which it competes and has competed, and the products it has competed with over time. I held that position until 2016, when I was promoted to my current position as Senior Vice President, Oncology Business Unit. In my current position, I continue to have responsibility for commercial activities related to Tarceva.

3. Prior to joining Astellas, I held a variety of positions in innovator pharmaceutical companies. I served as Senior Vice President and Chief Commercial Officer of Micromet Inc. (now part of Amgen), where I led investor and public relations, new product planning, and commercial launch planning. Prior to that position, I held various sales and marketing leadership roles at Abbott, Pharmacia, Bristol-Myers Squibb, and AstraZeneca.

4. My complete curriculum vitae is attached hereto as Appendix 1.

II. TARCEVA, ITS USE, AND ITS COMMERCIAL SUCCESS

5. OSI Pharmaceuticals, LLC ("OSI") is a pharmaceutical company that specializes in the development of molecular targeted therapies. OSI developed erlotinib and markets it under the brand name Tarceva. Tarceva is an oral, once-a-day tablet, classified as an inhibitor of epidermal growth factor ("EGFR") tyrosine kinase. Tarceva is marketed jointly in the United States by OSI and Genentech, Inc.

6. Tarceva was approved by the United States Food and Drug Administration ("FDA") on November 18, 2004. Initially, the approved indication on the label for Tarceva was for treatment of patients with locally advanced or metastatic non-small cell lung cancer ("NSCLC") after failure of at least one prior chemotherapy regimen. That was the only approved indication on the label for the first year Tarceva was on the market in the United States. A second indication for first-line treatment of patients with locally advanced, unresectable or metastatic pancreatic cancer, in combination with gemcitabine, was added to the label in November 2005.

7. Other NSCLC indications were added to the Tarceva label over time. In 2010, an indication for maintenance treatment of patients with locally advanced

or metastatic NSCLC whose disease has not progressed after four cycles of platinum-based first-line chemotherapy was added to the label, and in 2013, an indication for first-line treatment of patients with metastatic NSCLC whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test. From October 2016 to present, the sole NSCLC-related indication on the Tarceva label is for first-line treatment of patients with metastatic NSCLC whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test receiving first-line, maintenance, or second or greater line treatment after progression following at least one prior chemotherapy regimen.

8. Tarceva has been a very commercially successful product since its launch and throughout the time period it has been on the market in the United States. As stated in OSI's Form 10-K for 2005, Tarceva was the most successful oncology drug launch in the United States in terms of number of patients treated during the first 12 months of launch, and was the fourth most successful oncology drug launch in terms of sales in the United States, at that time. OSI 2005 10-K at 4 (Exhibit 2033). Total U.S. net sales for Tarceva for the 2005 calendar year were approximately $275 million. *Id*.

9. By 2006, yearly net U.S. sales of Tarceva reached $400 million and continued to rise, exceeding $500 million in OSI's 2010 fiscal year. Exhibit 2034 (U.S. net sales 2004-2016).[1] In OSI's 2011 fiscal year, Tarceva net sales in the U.S. were $567 million, $629 million in the 2012 fiscal year, $641 million in the 2013 fiscal year, $704 million in the 2014 fiscal year, $638 million in the 2015 fiscal year, and $540 million in the 2016 fiscal year. Exhibit 2034.

10. The revenue figures cited in paragraph 9 and contained in Exhibit 2034 are financial data based on records of Tarceva revenue that OSI tracks and maintains in the course of its regularly conducted business activities, and that are generated from OSI's accounting records. The tracking and maintaining of these revenues was a regular practice in the course of OSI's business activities, and the

[1] Exhibit 2034 provides net sales data on a yearly basis for Tarceva according to OSI fiscal years, which currently run from April 1-March 31. OSI's fiscal year prior to 2010 (i.e., before OSI was acquired by Astellas), was based on the calendar year. To facilitate comparison of Tarceva revenues over time, however, the data have been presented on an annual basis according to the fiscal year time period currently employed by OSI and which has been used by OSI since its 2010 acquisition.

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