UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WATSON LABORATORIES, INC.
Petitioner

v.

UNITED THERAPEUTICS CORP.
Patent Owner

Cases[1] IPR2017-01621; Patent 9,358,240
IPR 2017-01622; Patent 9,339,507

DECLARATION OF DEAN BUNCE

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[1] The word-for-word identical paper is filed in each proceeding identified in the heading.

I, Dean Bunce, hereby declare as follows:

1. I am currently Executive Vice President of Regulatory Affairs at United Therapeutics Corporation ("UTC").

2. I have been involved in regulatory affairs and compliance at UTC since 1999. I currently oversee all interactions of UTC with regulatory agencies, including the Food and Drug Administration ("FDA"). I was ultimately responsible for the New Drug Application ("NDA") and supplements thereto for UTC's Tyvaso® product.

3. Exhibit 2049 is a true and correct copy of excerpts of the Tyvaso® NDA Integrated Summary of Efficacy (ISE). This is a document created in the regular course of UTC's business and was submitted to FDA as part of the process of obtaining regulatory approval to market Tyvaso® in the United States.

4. Exhibit 2050 is a true and correct copy of the Clinical Investigation Report Synopsis for Study LRX-INH-0004. This is a document created in the regular course of UTC's business and was submitted to FDA as part of the process of obtaining regulatory approval to market Tyvaso® in the United States.

5. Exhibit 2051 is a true and correct copy of the Clinical Investigation Report Synopsis for Study LRX-INH-0007. This is a document created in the regular course of UTC's business and was submitted to FDA as part of the process of obtaining regulatory approval to market Tyvaso® in the United States.

6. Exhibits 2049-2051 are records made from information regularly kept and maintained by UTC in the course of its regular clinical testing activities and thus contain accurate information generated and maintained for the purposes of ensuring compliance with regulatory and best practices requirements. For example, FDA regulations require that a drug sponsor maintain, prepare, and submit accurate information concerning clinical studies. *See e.g.* 21 CFR § 312.33.

7. Exhibit 2083 is a true and correct copy of the TRIUMPH I Clinical Trial Protocol. This is a document created by January 11, 2005 (as reflected on the document) in the regular course of UTC's business and was submitted to FDA as part of the process of obtaining regulatory approval to market Tyvaso® in the United States. More specifically, the protocol was submitted to FDA on March 28, 2005 as part of UTC's original Investigational New Drug Application ("IND") 70,362 for Inhaled Treprostinil. Exhibit 2052 is a true and correct copy of an acknowledgement letter dated April 13, 2005 from FDA acknowledging receipt of IND 70,362 on March 29, 2005.

8. Exhibits 2049 (at page 59) and 2050 (at page 3) state that study LRX-INH-004 was performed in 2003.

9. Exhibits 2049 (at page 61) and 2051 (at page 3) state that LRX-INH-007 was performed in 2003.

10. Exhibit 2083 includes the following information:

i. Reference to investigator studies in Germany (at pages 17, 21, 25) including "approximately 200 patients in the five investigations, and the 13 patients in the clinical and chronic compassionate use trials";

ii. "Treatment doses" indicating the investigational product planned is treprostinil sodium at "600 mcg/mL delivered via an ultrasonic nebulizer (0, 4, 8, 12 hours daily)" with "[e]ach of the four doses will consist of 9 breaths. Each breath will deliver 5 mcg of TRE to the mouthpiece of the nebulizer (emitted dose)." (at page 11); and

iii. A section on "Clinical Investigations Following Inhalation of Treprostinil" that summarizes five investigations (at pages 22-25):

1. Investigation 1: Inhalation of Treprostinil and of Iloprost
2. Investigation 2: Inhalation of treprostinil and of placebo
3. Investigation 3: Inhalation times of Treprostinil sodium with higher concentrations with reduced inhalation time;
4. Investigation 4: Inhalation of metacresol free treprostinil;
5. Investigation 5: Inhalation of Treprostinil and Sildenafil.

11. Exhibit 2083 states that the original Phase II Protocol was finalized by January 11, 2005 with an anticipated First Patient In (FPI) in April/May 2005.

12. As reflected in Exhibit 2049, the first patient was enrolled in the Phase II study in June 2005.

13. The United States National Library of Medicine ClinicalTrials.gov database, which is a database of clinical studies conducted around the world, https://clinicaltrials.gov/ct2/show/NCT00147199, gives a date of "June 2005" as the date a first participant was enrolled for TRIUMPH I. A true and correct copy of this record is labelled as Exhibit 2084.

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