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 DR. ROBERT ROSCIGNO

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

I, Dr. Robert Roscigno, hereby declare as follows:

1. I am a named inventor of U.S. Patent No. 9,358,240 and US Patent No. 9,399,507. My co-inventors on those patents include Horst Olschewski, Lewis Rubin, Thomas Schmehl, Werner Seeger, Carl Sterritt, and Robert Voswinckel.

2. I am currently Senior Vice President, Product Development at Liquidia Technologies.

3. I am a paid consultant for United Therapeutics Corporation ("United Therapeutics"), which I understand is the assignee of U.S. Patent No. 9,358,240 and US Patent No. 9,399,507, in connection with IPR2017-01621 and IPR2017-01622, respectively. My compensation does not depend on the content of this declaration, the substance of any other testimony that I may offer in connection with this proceeding or the disposition of this proceeding.

4. From the time period of June 2005-June 2007, I was the President and COO of Lung Rx, Inc., a subsidiary of United Therapeutics. From 2002-June 2005 I was Senior Vice President of Lung Rx, Inc.

5. Beginning by at least September 2003, I was tasked by United Therapeutics' CEO, Martine Rothblatt, with leading the company's development of an inhaled treprostinil treatment for pulmonary hypertension. I was the project leader for Lung Rx, Inc. for this development, which we termed TRIUMPH (Treprostinil Sodium Inhalation Used in the Management of Pulmonary Arterial

Hypertension) and was responsible for bringing what became Tyvaso® from early preclinical studies through Phase 3 development. Specifically, I was tasked with participating in the design of the protocols for clinical studies and coordinating the development of an inhaled program that formed the basis for Tyvaso®'s approval.

6. On October 22, 2003, I attended a meeting with Dr. Rothblatt in Dr. Rothblatt's New York City apartment to kick off the project, along with Drs. Rubin and Seeger. A task list for that meeting is labelled Exhibit 2102. As reflected in that task list, my initial responsibilities included writing up drafts of the initial clinical studies and providing drug material to Giessen for the studies. The other individuals reflected on that list were Martine Rothblatt ("MR"), Carl Sterritt ("CS"), Werner Seeger ("WS"), Lewis Rubin ("LR"), and Horst Olschewski ("HO").

7. All of the co-inventors had experience in and were focused in the project on the treatment of pulmonary hypertension. All of the inventors had critical roles and brought varied expertise to the project.

a. Carl Sterritt led United Therapeutics' Europe operations and engaged early with me and Drs. Seeger, Olschewski, Schmehl, and Voswinckel ("the Giessen researchers") and also contributed to the clinical protocol design and development due to his understanding and experience with Remodulin® and iloprost and his understanding of the potential for

inhalation of the treprostinil molecule. As with all of the co-inventors, he reviewed and contributed to the ideas concerning dosage, timing, formulation, and the device and engaged in much of the necessary work to effect the planning of the group. As with all of the co-inventors, he was involved in our discussions of the interpretation of data and the conclusions that could be drawn from them for the iterative design of the next set of experiments. Carl also directly interacted with Nebutec, the Germany-based device manufacturer.

b. I had a similar role and worked closely with Carl Sterritt on his involvement. I also engaged with our pharmacokinetic consultants and experts and engaged in interpreting the pharmacokinetic data. Due to my experience with clinical trial management and toxicology assessment, I also closely ensured that all studies were consistent with the necessary toxicology investigations and issues that would become important for regulatory approval. I was heavily engaged in collaborating with the investigators on study protocols and the necessary assessment and writing of the study results.

c. Dr. Seeger was the head of the program at Giessen and employed the expertise and contributions of Drs. Voswinckel, Schmehl, and Olschewski, based on, for example, their prior expertise and experience

with iloprost and respective clinical expertise with pulmonary hypertension. These investigators collectively executed the studies designed in collaboration among all of the inventors.

d. Dr. Rubin was involved as the co-head (with Dr. Seeger) of the clinical steering committee for TRIUMPH and engaged in similar tasks as described above with each of us co-inventors. Later, he was also the lead investigator on the early and late phase studies performed at UCSD.

8. Together with Carl Sterritt and Drs. Rubin, Seeger, Voswinckel, Schmehl, and Olschewski, we developed early protocols and methods for clinical studies, including developing the appropriate dosing regimen, dose titration strategies, drug product formulation, and device testing that resulted in the clinical trials necessary to support the TRIUMPH program. Together, we developed and implemented the strategy and details for moving forward with the clinical trials and creating the clinical development plan that led to the development of Tyvaso®.

9. As reflected in the October 22, 2003 meeting task list, this work began in earnest by at least October of 2003 and continued through the completion of Phase III trials. From October 2003 forward, I, and sometimes including Carl Sterritt, met quarterly with the steering committee including Drs. Rubin and Seeger to discuss progress and discuss and plan strategy for moving forward. The advancement of the program was an iterative process and we had to regroup

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