

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WATSON LABORATORIES, INC.
Petitioner

v.

UNITED THERAPEUTICS, INC.
Patent Owner

Patent No. 9,339,507
Issue Date: July 13, 2017
Title: TREPROSTINIL ADMINISTRATION BY INHALATION

Inter Partes Review No. 2017-01622

DECLARATION OF DR. WERNER SEEGER

4833-8838-6637.1

I, Dr. Werner Seeger, hereby declare as follows:

1. I am a named inventor of U.S. Patent No. 9,339,507 and am the director of University of Giessen and Marburg Lung Center (“UGMLC”), a research center at the University Hospital Giessen studying pulmonary hypertension.

2. I am a paid consultant for United Therapeutics, which I understand is the assignee of U.S. Patent No. 9,339,507, in connection with IPR2017-01622. 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.

3. I am a co-author of the German language article: Hossein Ardeschi Ghofrani *et al.* “Neue Therapieoptionen in der Behandlung der pulmonalerteriellen Hypertonie,”¹ *Herz*, 30, 4 (June 2005): 296-302 (“the Ghofrani article”). I understand that Watson Laboratories, Inc. (“Watson”) submitted an English language translation of the Ghofrani article in this proceeding as Exhibit 1005, which I have reviewed.

4. The Ghofrani article was an overview review article, drafted under my direction and control by members of my research center at University Hospital

¹ The title is translated as “New therapies in the treatment of pulmonary hypertension” in Exhibit 1005.

Giessen. The intent of the article was to compile and review information, not to communicate primary data. Each of the listed authors was selected based on their expertise in particular areas covered in particular sections of the Ghofrani article.

5. Dr. Hossein A. Ghofrani – the first listed author – has experience in the use of phosphodiesterase inhibitors for treatment of pulmonary hypertension. He drafted the section of the Ghofrani article relating to phosphodiesterase inhibitors. I know Dr. Ghofrani drafted this section of the Ghofrani article because I asked him to draft this section and communicated with him about it. In Exhibit 1005, this section begins at the bottom of page 3 and continues through page 5. Dr. Ghofrani was listed as a co-author on the Ghofrani article because he drafted this portion of the article and the other portions noted below.

6. Drs. Frank Reichenberger and Friedrich Grimminger both have experience in the use of selective endothelin A receptor agonists for treating pulmonary hypertension. I know Drs. Reichenberger and Grimminger drafted this section of the Ghofrani article because I asked them to draft this section and communicated with them about it. Together they drafted the section of the Ghofrani article relating to selective endothelin A receptor agonists. In Exhibit 1005, this section is on page 3. Drs. Reichenberger and Grimminger were listed as a co-author on the Ghofrani article because they drafted this portion of the article.

7. Dr. Robert Voswinckel and I both have experience in the use of inhaled iloprost and inhaled treprostinil for treatment of pulmonary hypertension. Together, we drafted the sections of the Ghofrani article relating to inhaled iloprost and inhaled treprostinil. In Exhibit 1005, this section begins at the bottom of page 2 and continues through page 3. Although the bulk of the Ghofrani article is a review of prior literature, additional information not previously reported in the literature was contributed by Dr. Voswinckel and myself in the inhaled treprostinil section and is contained in the following excerpt:

Initial trials in Giessen have shown proof of efficacy of inhaled treprostinil for the effective reduction of the pulmonary vascular resistance (PVR) [6]. In this first study, 17 patients with severe pre-capillary pulmonary hypertension were administered inhaled treprostinil (15 mcg/inhalation). This led to a major reduction in pulmonary selective pressure and resistance with an overall duration of action of > 180 min. In direct comparison with inhaled iloprost, inhaled treprostinil showed a stronger pulmonary selectivity, so that it is possible to increase the dosage to up to 90 mcg (absolute inhaled dose per inhalation exercise) without adverse effects occurring [6]. Due to these unique properties (pronounced pulmonary selectivity and long duration of action after an individual inhalation), it is possible to reduce the number inhalations necessary to up to four per day; the inhalation period can be reduced to < 1 min. by selecting a suitable device. Additionally, the initial data shows that it is technically feasible for there to be only one to two breaths in an application.

The information in this excerpt was compiled and composed by Dr. Voswinckel and myself. The idea to perform the underlying work described in this section originated with Dr. Voswinckel and myself, in view of our work with other inventors listed on the '507 patent. The other authors listed in the Ghofrani article – Drs. Ghofrani, Reichenberger and Grimminger – did not contribute to this excerpt or the underlying work.

8. The remaining sections on vasoactive therapy, inhaled iloprost, combination therapies, and treatment of early forms of treatment of pulmonary hypertension, as well as the introduction and compiled literature were drafted by Dr. Hossein A. Ghofrani and myself.

9. Upon completion of the draft and prior to submission thereof, I reviewed and edited the Ghofrani article in my capacity as director of my research center. In addition to myself, the four members of my research center who had contributed to the aforementioned sections of the Ghofrani article were listed as authors.

10. The selection of authors for the Ghofrani article fits with the normal practice in my research center. In general, when my research center submits abstracts to a conference or articles for publication, we include members of the research group who contributed in some way to the abstract or article as authors.

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