



#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Title:

TREPROSTINIL

ADMINISTRATION USING A METERED DOSE INHALER

Horst OLSCHEWSKI et al.

Appl. No.:

11/748,205

Filing Date:

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Examiner:

Unassigned

Art Unit:

1616

Confirmation

6003

Number:

## DECLARATION OF RACHEL TUROW IN SUPPORT OF PETITION UNDER 37 C.F.R. § 1.47(a)

Mail Stop Petition Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

- I, Rachel Turow, hereby declare the following:
- 1. I am employed by United Therapeutics Corporation as Associate Counsel & Director of Legal Affairs. As part of my job responsibilities, I was asked to collect signatures from inventors for a declaration under 37 C.F.R. § 1.63 for US patent application no. 11/748,205. My employer, United Therapeutics Corporation, is the assignee of US patent application no. 11/748,205. I have not received any compensation, other than my regular salary, for submitting this declaration.
- 2. US patent application no. 11/748,205 lists the following seven persons as inventors: (1) Horst Olschewski; (2) Robert Roscigno; (3) Lewis J. Rubin; (4) Thomas Schmehl; (5) Werner Seeger; (6) Carl Steritt and (7) Robert Voswinckel. Inventor (2) Roscigno; Inventor (3) Rubin and Inventor (6) Steritt each executed a declaration for the



present application. However, Inventor (1) Olschewski, Inventor (4) Schmehl, Inventor (5) Seeger and Inventor (7) Voswinckel never executed the declaration for the present application.

- 3. It is my belief that each of Inventor (1) Olschewski, Inventor (4) Schmehl, Inventor (5) Seeger and Inventor (7) Voswinckel exhibited conduct indicating that they have refused to execute a declaration for the present application. My reasons are explained more fully below.
- 4. The present application lists the same seven inventors: (1) Olschewski, (2) Roscigno, (3) Rubin, (4) Schmehl, (5) Seeger, (6) Steritt and (7) Voswinckel, as US provisional application no. 60/800,016, to which the present application claims priority. Previously, Mr. Andrew Fisher, Senior Vice President and Deputy General Counsel of both United Therapeutics Corporation and Lung Rx, Inc., which is a separately managed affiliate of United Therapeutics Corporation, collected signatures from each of the seven inventors for an assignment in US provisional application no. 60/800,016. In the present application, I used the same approach for contacting the inventors that Mr. Andrew Fisher used in US provisional application no. 60/800,016.
- 5. Using the approach that Mr. Andrew Fisher employed in US provisional application no. 60/800,016, I contacted directly Inventor (2) Roscigno, Inventor (3) Rubin and Inventor (6) Steritt forwarding each of them a declaration for the present application. Each of Inventor (2) Roscigno, Inventor (3) Rubin and Inventor (6) Steritt timely executed the declaration and forwarded it back to me. The declaration for the present application executed by each of Inventor (2) Roscigno, Inventor (3) Rubin and Inventor (6) is filed with the petition under 37 C.F.R. § 1.47(a).
- 6. Each of Inventor (2) Roscigno, Inventor (3) Rubin and Inventor (6) Steritt executed the declaration on his behalf and on behalf of Inventor (1) Olschewski, Inventor (4) Schmehl, Inventor (5) Seeger and Inventor (7) Voswinckel, as indicated by signature blocks for each of the non-signing inventors. Indeed, at no time did any of Inventor (2) Roscigno,



Inventor (3) Rubin and Inventor (6) Steritt claim that any of Inventor (1) Olschewski, Inventor (4) Schmehl, Inventor (5) Seeger and Inventor (7) Voswinckel were not inventors.

- 7. The approach that Mr. Andrew Fisher used for contacting Inventor (1) Olschewski, Inventor (4) Schmehl, Inventor (5) Seeger and Inventor (7) Voswinckel, collectively known as the "Giessen team" or "Giessen", in US provisional application no. 60/800,016 was as follows: Mr. Andrew Fisher sent documents to be executed to Inventor (5) Seeger, who in turn coordinated the execution of the documents by Inventor (1) Olschewski, Inventor (4) Schmehl and Inventor (7) Voswinckel. In the present application, I used the same approach. Accordingly, on June 15, 2007, I sent an email to Inventor (5) Seeger with an attached declaration as an MS Word file. In this email, I asked Inventor (5) Seeger a) to execute the declaration himself and b) to forward the declaration to other three members of the Giessen team, i.e. Inventor (1) Olschewski, Inventor (4) Schmehl and Inventor (7) Voswinckel. My June 15<sup>th</sup> email clearly stated that the declaration is for a Metered Dose Inhaler Patent Application. Within approximately a week, Ms. Rosmarie Hebelstadt, a personal assistant to Inventor (5) Seeger, copied me on an email forwarding the declaration to each of Inventor (1) Olschewski, Inventor (4) Schmehl and Inventor (7) Voswinckel. Ms. Rosmarie Hebelstadt's email clearly stated that the declaration is for the Metered Dose Inhaler Patent Application. Both my June 15<sup>th</sup> email to Inventor (5) Seeger and Ms. Hebelstadt's email forwarding the declaration to Inventor (1) Olschewski, Inventor (4) Schmehl and Inventor (7) Voswinckel were automatically erased by my email system without my knowledge. Accordingly, these emails are not submitted with my declaration.
- 8. On August 22, 2007, I reminded Inventor (5) Seeger via email of my request to obtain signatures on the declaration from himself and from Inventor (1) Olschewski, Inventor (4) Schmehl and Inventor (7) Voswinckel. My reminder clearly stated that the declaration is for the Metered Dose Inhaler Patent Application. A redacted copy of this reminder is attached as Exhibit 1.
- 9. After receiving no response, I asked Mr. Paul Mahon, Executive Vice President and General Counsel of both United Therapeutics Corporation and Lung Rx, Inc., to contact Inventor (5) Seeger. Following my request, on September 4, 2007, Mr. Paul



Mahon sent an email to Inventor (5) Seeger following up on my August 22<sup>nd</sup> reminder again with an attached declaration as an MS Word file. A redacted copy of this email, on which I was copied, is attached as Exhibit 2. On September 5, 2007, Inventor (5) Seeger responded to Mr. Paul Mahon's September 4<sup>th</sup> email confirming that he had received the emails and attachments concerning the declaration and indicating that he had issues that he wanted to discuss in a telephone conversation. A redacted copy of this email is attached as Exhibit 3. On the same day, September 5, 2007, Mr. Paul Mahon responded to Inventor (5) Seeger with a reference to Mr. Andrew Fisher or me as appropriate contact persons. A redacted copy of this email is attached as Exhibit 4.

- 10. After an email exchange on September 21, 2007, and September 26, 2007, between Mr. Paul Mahon, Inventor (5) Seeger and Ms. Rosmarie Hebelstadt, a telephone conference was arranged between Mr. Andrew Fisher and Inventor (5) Seeger for September 26, 2007. The subject line in the email exchange clearly states that it relates to the Metered Dose Inhaler Patent Application. A redacted copy of this email exchange is attached as Exhibit 5. The telephone conference between Mr. Andrew Fisher and Inventor (5) Seeger took place as scheduled in the email exchange. During the telephone conference, Inventor (5) Seeger raised an issue of additional compensation for the subject matter claimed in the present application. I listened silently to the telephone conference with Mr. Andrew Fisher via another phone connected to the line on which Mr. Andrew Fisher was speaking.
- 11. On October 1, 2007, Mr. Paul Mahon, on behalf of United Therapeutics Corporation and Lung Rx, Inc., responded via email to the concerns expressed by Inventor (5) Seeger. In particular, Mr. Paul Mahon pointed out that all the inventors, including Inventor (1) Olschewski, Inventor (4) Schmehl, Inventor (5) Seeger and Inventor (7) Voswinckel, had executed an assignment to United Therapeutics Corporation previously, referring to an assignment executed in US provisional application no. 60/800,016, to which the present application claims priority. Mr. Mahon also pointed out that under clinical study agreements between Lung Rx, Inc., and Giessen, the results of the clinical studies would be owned by Lung Rx, Inc. A redacted copy of Mr. Mahon's October 1<sup>st</sup> email is attached as Exhibit 6. The assignment made in US provisional application no. 60/800,016 to United Therapeutics



Corporation executed by each of Inventor (1) Olschewski, Inventor (4) Schmehl, Inventor (5) Seeger and Inventor (7) Voswinckel is attached as Exhibit 7.

- On October 11, 2007, Inventor (5) Seeger responded to Mr. Paul Mahon in an 12. email to Dr. Martine Rothblatt, Chief Executive Officer of both United Therapeutics Corporation and Lung Rx, Inc. In this email, Inventor (5) Seeger expresses the collective views of the Giessen team, which includes Inventor (5) Seeger himself as well as Inventor (1) Olschewski, Inventor (4) Schmehl, and Inventor (7) Voswinckel. Inventor (5) Seeger discusses the contribution of the Giessen team to the subject matter of the present application. Additionally, Inventor (5) Seeger expresses a collective belief of the Giessen team that compensation received under the clinical study agreements between Lung Rx, Inc., and Giessen covered only costs of the clinical studies and, thus, the Giessen team should be entitled to additional compensation for the subject matter claimed in the present application. In his October 11<sup>th</sup> email, Inventor (5) Seeger further mentioned that the Giessen team sought legal advice on this matter from TransMIT GmbH and that, according to TransMIT GmbH, the Giessen team lacked any legal basis for claiming the additional compensation for the subject matter of the present application. Concluding his October 11th email, Inventor (5) Seeger stated that the Giessen team was willing to withdraw from the patent application, should they receive no additional compensation for the subject matter of the present application. A redacted copy of the October 11th email from Inventor (5) Seeger to Dr. Rothblatt, as forwarded by Mr. Paul Mahon to me, is attached as Exhibit 8.
- asking him again to sign and return the declaration previously sent to him. The subject line of this email clearly states that it relates to a Metered Dose Inhaler Patent Application (MDI patent). A redacted copy of this email, on which I was copied, is attached as Exhibit 9. In response, on October 12, 2007, Inventor (5) Seeger sent an email asking Mr. Paul Mahon to remove the names of the Giessen team members, i.e. the names of Inventor (1) Olschewski, Inventor (4) Schmehl, Inventor (5) Seeger and Inventor (7) Voswinckel, from the patent application. A redacted copy of this email, on which I was copied, is attached as Exhibit 10. On the same day, October 12, 2007, Mr. Paul Mahon sent an email to Inventor (5) Seeger, in which he explained that the names of the inventors could not be removed from the patent



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