

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WATSON LABORATORIES, INC.
Petitioner,

v.

UNITED THERAPEUTICS, CORP.
Patent Owner.

Case IPR2017-01621 and IPR2017-01622
Patents 9,358,240 B2 and 9,339,507 B2

Before TONI R. SCHEINER, ERICA A. FRANKLIN, and
DAVID COTTA, *Administrative Patent Judges*.

COTTA, *Administrative Patent Judge*.

ORDER

Conduct of the Proceeding
Filing of Supplemental Information
37 C.F.R. § 42.5; 37 C.F.R 42.123(a)

IPR2017-01621 (Patent 9,358,240 B2)

IPR2017-01622 (Patent 9,339,507 B2)

I. INTRODUCTION

Watson Laboratories, Inc. (“Petitioner” or “Watson”) filed Petitions requesting an *inter partes* review of claims 1–9 of U.S. Patent No. 9,358,240 B2 (Ex. 1001 in IPR2017-01621, “the ’240 patent”) and of claims 1–9 of U.S. Patent No. 9,339,507 (Ex. 1001 in IPR 2017-01622, “the ’507 patent”). IPR2017-01621, Paper 1; IPR 2017-01622, Paper 2. United Therapeutics Corp. (“Patent Owner” or “UTC”) filed Preliminary Responses to the Petitions, opposing institution. IPR2017-01621, Paper 6; IPR2017-01622, Paper 5. On January 11, 2018, after consideration of the Petition and Preliminary Response, we entered a Decision granting institution of *inter partes* review. IPR2017-01621, Paper 10; IPR2017-01622, Paper 9.

On February 9, 2018, by email within one month of our Decision, Petitioner requested authorization to file a motion to submit supplemental information pursuant to 37 C.F.R. § 42.123(a). Ex. 3004.¹ On March 9, 2018, as authorized by the Board (Paper 22), Petitioner filed a Motion to File Supplemental Information pursuant to 37 C.F.R. § 42.123(a). Paper 26 (“Motion” or “Mot.”). Petitioner filed the proposed supplemental information as Exhibits 1170–1172 for our consideration with the Motion. Mot. 2. Patent Owner filed an Opposition to the Motion (Paper 30 (“Opposition” or “Opp.”)) supported by Exhibits 2201–2204.

¹ There are slight differences in the numbering of Papers and Exhibits in IPR2017-01621 and IPR2017-01622. Notwithstanding these differences, the papers relating to the motion addressed herein are substantively identical. Unless otherwise noted, for the convenience of the Board, citations to Papers and Exhibits referenced herein are only to IPR2017-01621, with the understanding that there exists a corresponding, substantively identical, Paper or Exhibit in IPR2017-01622.

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Petitioner contends that the “proposed supplemental information speaks directly to the inventive entity of the challenged claims and thus is plainly relevant to the prior art status of Ghofrani,” a reference relied upon in connection with the instituted ground. Mot. 4. Patent Owner asserts that “none of the proposed exhibits even mention, much less address, Ghofrani or its authorship” and that “none of the proposed exhibits even mention, much less address, the challenged claims, their specific limitations, or the inventorship thereof.” Opp. 2. For the reasons expressed below, Petitioner’s Motion is *granted*.

II. ANALYSIS

37 C.F.R. § 42.123(a) concerns supplemental information and states:

(a) *Motion to submit supplemental information*. Once a trial has been instituted, a party may file a motion to submit supplemental information in accordance with the following requirements:

(1) A request for the authorization to file a motion to submit supplemental information is made within one month of the date the trial is instituted.

(2) The supplemental information must be relevant to a claim for which the trial has been instituted.

Satisfaction of the above-listed requirements for filing the motion, however, does not mean the Board will grant the motion. *Redline Detection, LLC v. Star Envirotech, Inc.*, 811 F.3d 435, 445 (Fed. Cir. 2015). Instead, the “guiding principle” for the Board is to “ensure efficient administration of the Office and the ability of the Office to complete IPR proceedings in a timely manner.” *Id.* Under this “guiding principle,” the Board has broad discretion in granting or denying motions to submit supplemental information. *Id.*

There is no question that Patent Owner made its request within one

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month of the date trial was instituted. The relevance of proffered Exhibits, however, is disputed.

Exhibit 1170 is a complaint from a Maryland state court litigation between Dr. Lewis J. Rubin, a named inventor, and the Patent Owner over ownership of the patents at issue in this proceeding. The complaint states, in relevant part:

23. During [a] Mid-September 2003 Luncheon, Dr. Rubin mentioned that he had conceived a new PAH [pulmonary arterial hypertension] treatment program using an inhalation methodology for the administration of the drug treprostinil, which he believed offered distinct advantages over known intravenous and subcutaneous PAH treatments. Dr. Rubin's proposed program was of great interest to Rothblatt and the social luncheon turned to a discussion of a proposed UTC development program, relating to Dr. Rubin's new PAH treatment methodology.

24. The Mid-September 2003 Luncheon lasted for no less than 4 hours. Dr. Rubin fully outlined a program to develop his new PAH treatment, providing Rothblatt with full particulars concerning his inventions which later became the subject of the claims in the '507 and '240 patents. . . .

25. As more fully discussed at the Mid-September 2003 Luncheon, Dr. Rubin proposed the administration of treprostinil by a metered dose inhaler or pulsed nebulizer that would effectively deliver the medication in a single event consisting of fewer than 18 breaths. This disclosure provided the approach for UTC's program to develop Dr. Rubin's inventions . . .

Ex. 1170, 8.

Exhibit 1171 is an affidavit from Dr. Rubin submitted in connection with the Maryland state court litigation. In it, Dr. Rubin states, in relevant part:

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I conceptualized the invention which is the subject of the patent rights at issue in this case – the treatment of PAH by administration of treprostinil by a metered dose inhaler or pulsed nebulizer. An aspect of the invention, which I believe is critical is the delivery of the medication in a single even consisting of fewer than 18 breaths.

Ex. 1171, 2.

Exhibit 1172 is the Declaration of Rachel Turow (“the Turow Declaration”), which was submitted in U.S. Application No. 11/748,205 (“the ’205 application”), a parent of the applications that ultimately issued as the patents at issue in these proceedings. It was submitted under 37 C.F.R. § 1.47(a) to request that the Patent Office accept inventors’ oaths in without the signatures of Horst Olschewski, Thomas Schmehl, Werner Seeger, and Robert Voswinckel, all four of whom are identified as inventors on the patents at issue. Ex. 1172, 2. The Turow Declaration attaches a number of exhibits, including email correspondence with the non-signing inventors. In one of the emails attached to the Turow Declaration, Dr. Seegar states:

Should, against this background, you and our further Lung Rx partners insist on the views expressed in Paul’s email [that UTC owned intellectual property rights to the non-signing inventors’ work], I would like to clarify that we are willing to withdraw from the patent, giving you absolute freedom for the further promotion of the patent, independent of our group.

Ex. 1072, 25. In another email attached to the Turow Declaration, Dr. Seegar states:

Sorry, this is a misunderstanding. Our suggestion is that (in case Lung RX insists on the view you expressed in your emails, what apparently is the case) our names (Olschewski, Voswinckel, Schmehl, and Seeger) are removed from the patent.

Ex. 1072, 27.

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