

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, LTD. and
DR. REDDY'S LABORATORY, INC.,
Petitioner,

v.

HELSINN HEALTHCARE S.A.,
Patent Owner.

Case PGR2016-00007
Patent 9,173,942 B2

Before TONI R. SCHEINER, LORA M. GREEN, and
JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION
Denying Institution of Post-Grant Review
35 U.S.C. § 324; 37 C.F.R. § 42.208

I. INTRODUCTION

Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Petitioner" or "DRL") filed a Petition on February 5, 2016 (Paper 1; "Pet.") requesting post-grant review of claims 1–6, 10, and 11 of U.S. Patent No. 9,173,942 B2 (Ex. 1001; "the '942 patent"). Helsinn Healthcare S.A. ("Patent Owner" or "Helsinn") filed a Patent Owner Preliminary Response. Paper 10 ("Prelim. Resp.").¹

We have authority to determine whether to institute a post-grant review. 35 U.S.C. § 324(c); 37 C.F.R. § 42.4(a). The standard is set forth in § 324(a), which provides that a post-grant review shall not be instituted unless "the Director determines that the information presented in the petition filed under section 321, if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the claims challenged in the petition is unpatentable."

After considering the Petition and the Preliminary Response, we determine that Petitioner has failed to demonstrate that it is more likely than

¹ Helsinn represents that

Roche Palo Alto LLC, which was previously a co-assignee of U.S. Patent No. 9,173,942 . . . and a real party-in-interest in this proceeding, has assigned to Helsinn all right, title, and interest in and to the '942 patent. Accordingly, for purposes of this proceeding, Helsinn is the only remaining real party-in-interest.

Paper 9 (Updated Mandatory Notices, filed May 18, 2016), 2.

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not that at least one claim of the '942 patent is unpatentable. Accordingly, we do not institute a post-grant review.

A. Related Proceedings

The '942 patent has been asserted against Petitioner in *Helsinn Healthcare S.A. v. Dr. Reddy's Labs., Ltd.*, Civil Action No. 15-8662 (D.N.J.), filed December 15, 2015. Pet. 2; Paper 8, 2.

In addition, several parent applications of the '942 patent and other related patents have been asserted by Patent Owner in a number of civil actions. For example, U.S. Patent No. 7,947,724 has been asserted in *Helsinn Healthcare S.A. v. Dr. Reddy's Labs., Ltd.*, Civil Action No. 12-2867 (D.N.J.); and U.S. Patent Nos. 7,947,724, 7,947,725, 8,518,981, 8,598,218, and 8,598,219 have been asserted in *Helsinn Healthcare S.A. v. Dr. Reddy's Labs., Ltd.*, Civil Action Nos. 11-3962, 11-5579, 13-5815 (consolidated) (D.N.J.). See Pet. 2–3; Paper 8, 2–3.

Finally, Petitioner filed concurrently a Petition for post-grant review of claims 1–19 of the '942 patent. PGR2016-00008.

B. The '942 Patent (Ex. 1001)

The '942 patent is directed to formulations “for the treatment and prevention of emesis using palonosetron,” a previously known 5-HT₃ (5-hydroxytryptamine) receptor antagonist. Ex. 1001, 1: 29, 57–58. The specification teaches that palonosetron “is an order of magnitude more potent than most existing 5-HT₃ receptor antagonists, has a surprising half-life of about 40 hours, and is effective to reduce delayed-onset nausea

induced by chemotherapeutic agents.” *Id.* at 1:59–62. The specification discloses formulations that “are shelf stable for periods greater than 24 months at room temperature.” *Id.* at 2:65–3:1. In addition, the specification discloses that “palonosetron can be formulated in some instances at concentrations of only about $1/10^{th}$ the amount of other previously known compounds for treating emesis, [which] surprisingly allows the use of concentrations of palonosetron far below those that would ordinarily be expected.” *Id.* at 4:54–58.

[I]n one embodiment . . . a pharmaceutically stable solution for preventing or reducing emesis compris[es] a) from about 0.01 mg/mL to about 5 mg/mL palonosetron or a pharmaceutically acceptable salt thereof; and b) a pharmaceutically acceptable carrier. . . . In alternative embodiments, the formulation includes palonosetron or a pharmaceutically acceptable salt thereof in a concentration from about 0.02 mg/mL to about 1.0 mg/mL, from about 0.03 mg/mL to about 0.2 mg/mL, and most optimally about 0.05 mg/ml.²

Id. at 4:58–5:6.

In one particular embodiment the palonosetron is supplied in vials that comprise 5 ml. of solution, which equates to about 0.25 mg of palonosetron at a concentration of about 0.05 mg/ml.

Id. at 5:12–15.

[F]urther . . . by adjusting the formulation’s pH and/or excipient concentrations it is possible to increase the stability of

² According to the specification of the ’942 patent, “[w]hen concentrations of palonosetron are given herein, the concentration is measured in terms of the weight of the free base. Concentrations of all other ingredients are given based on the weight of ingredient added to the solution.” Ex. 1001, 4:14–18.

palonosetron formulations. Therefore, in another embodiment, . . . a pharmaceutically stable solution for preventing or reducing emesis compris[es] a) palonosetron or a pharmaceutically active salt thereof; and b) a pharmaceutically acceptable carrier, at a pH from about 4.0 to about 6.0. . . . In alternative embodiments, the pH is from about 4.5 to about 5.5, and most optimally about 5.0.

Id. at 5:16–30.

[I]n another embodiment . . . a pharmaceutically stable solution of palonosetron compris[es] . . . from about 0.01 to about 5.0 mg/ml palonosetron or a pharmaceutically acceptable salt thereof and (i) from about 10 to about 100 millimoles citrate buffer, and/or (ii) from about 0.005 to about 1.0 mg/ml EDTA.

Id. at 5:40–46.

[I]n another embodiment . . . a pharmaceutically stable solution of palonosetron compris[es] . . . a) palonosetron or a pharmaceutically acceptable salt thereof and b) a pharmaceutically acceptable carrier . . . compris[ing] a chelating agent and mannitol. . . . In various embodiments the mannitol is present in a concentration of from about 10.0 mg/ml to about 80 mg/ml, from about 20 mg/mL to about 60.0 mg/ml, or from about 40.0 to about 45.0 mg/ml.

Id. at 6:4–18.

Finally, the specification teaches that “palonosetron concentration was also a critical factor in chemical stability, with greatest stability seen at the lowest palonosetron concentrations.” *Id.* at 7:40–43.

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