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Paper 11
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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 PGR2016-00008
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 2; "Pet.") requesting post-grant review of claims 1–19 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 9 ("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

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[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 8 (Updated Mandatory Notices, filed May 18, 2016), 2.

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 7, 2.

In addition, several parents 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 7, 2–3.

Finally, Petitioner filed concurrently a Petition for post-grant review of claims 1–6, 10, and 11 of the '942 patent, on obviousness grounds. PGR2016-00007.

B. The '942 Patent (Ex. 1001)

The '942 patent is directed to formulations "for the treatment and prevention of emesis using palonosetron," where the formulations "are shelf stable for periods greater than 24 months at room temperature." Ex. 1001, 2:65–3:1. According to the specification, "palonosetron can be formulated

in some instances at concentrations of only about 1/10th 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 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,

[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.

> 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.

C. Illustrative Claim

Of the challenged claims, claims 1 and 12 are independent. Claim 1, reproduced below, is illustrative.

> 1. A formulation comprising a pharmaceutical sterile aqueous intravenous solution, wherein said pharmaceutical sterile aqueous intravenous solution comprises:

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