Post Grant Review No. PGR 2016-00008
Patent No. 9,173,942
Petitioner's Request for Partial Rehearing Regarding
Decision Denying Institution of Post Grant Review
Attorney Docket No. REDDY 7.2R-022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, LTD. and
DR. REDDY'S LABORATORIES, INC.,
Petitioners

v.

HELSINN HEALTHCARE S.A. and ROCHE PALO ALTO LLC,
Patent Owners.

U.S. Patent No. 9,173,942 to Giorgio Calderari *et al.*
Issue Date: November 3, 2015
Title: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

Post Grant Review No. PGR2016-00008

PETITIONERS' REQUEST FOR PARTIAL REHEARING REGARDING DECISION DENYING INSTITUTION OF POST GRANT REVIEW

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I. INTRODUCTION AND SUMMARY OF ARGUMENT

Pursuant to 37 C.F.R. § 42.71(c) and (d), Petitioner respectfully requests rehearing with regard to only Part C of the Board's August 17, 2016 Decision denying institution of post grant review ("Decision"), appearing at pages 10-13 thereof and addressing written description under 35 U.S.C. § 112(a). This request is timely filed within 30 days of the entry of the Board's Decision, as set forth in 37 C.F.R. § 42.71(d)(2).

Petitioner respectfully submits that the Board misapplied the law, as set forth at pages 24-30 of the Petition, requiring that the "entirety of the specification" be used to determine whether, to one skilled in the art, the invention described in the specification is of a much narrower scope than that later claimed in U.S. Patent No. 9,173,942 ("the '942 Patent").

In fact, the Board is believed to have overlooked the vast majority of the specification of the '942 Patent which demonstrates that the "entirety of the specification" is directed to palonosetron formulations having enhanced stability, as set forth at pages 10-14 of the Petition, whereas the claims omit any requirement of stability. Even the portions of the specification the Board cited at pages 3-5 of the Decision support Petitioner's position. Collectively, *all* of these portions

demonstrate the narrow invention of stable palonosetron formulations described in the specification as a whole, which is in stark contrast to the claims.

The Board also misapprehended the Patent Owner's argument discussed at page 10 of the Decision, which actually confirms Petitioner's contention that increased stability was and is the central purpose of the '942 Patent as a whole.

Still further, the Board is believed to have overlooked the Declaration of Dr. Christopher A. Fausel (Exh. 1038 (cited in the Petition at 25, 27, 30)), which provided the only direct evidence in this record as to how a person of ordinary skill would have viewed the entirety of the specification: the specification limits the proper scope of the claims to *stable* formulations.

Petitioner also respectfully submits that the Board overlooked the Patent Owner's numerous prior patents having the same specification as the '942 Patent, discussed at pages 16-18 of the Petition. Those prior patents contradict the Board's conclusion (Decision 12) that recitation of certain selected ingredients and concentrations in the '942 claims make it unnecessary for the '942 claims to recite stability.

Under 37 C.F.R. § 42.71(c), "[w]hen rehearing a decision on petition, a panel will review the decision for an abuse of discretion." An abuse of discretion

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