UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC. AND APOTEX CORP.
Petitioners

v.

CELGENE CORPORATION
Patent Owner

Case IPR2018-00685
Patent 8,741,929 B2
Issued: June 3, 2014

Title: METHODS OF USING 3-(4-AMINO-1-OXO-1,3-DIHYDRO-ISOINDOL-2-YL)-PIPERIDINE-2,6-DIONE FOR TREATMENT OF MANTLE CELL LYMPHOMAS

PETITIONERS' REQUEST FOR REHEARING

Case No. IPR2018-00685

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Pursuant to 37 C.F.R. § 42.71(d), Apotex Inc. and Apotex Corp. ("Petitioners") submit this Request for Rehearing of the Board's Decision Denying Institution of *Inter Partes* Review of U.S. Patent No. 8,741,929 (Paper No. 8) ("Decision").

I. INTRODUCTION

The Board should grant rehearing of its Decision not to institute based on three crucial errors in its analysis.

First, with respect to Grounds 1 and 2, the Board overlooked or disregarded that the Drach reference, a review article synthesizing relevant prior art for mantle cell lymphoma ("MCL") treatment, discloses substantially more than what was substantively considered by the Examiner. Specifically, the Board determined that Drach, which discloses the clinical use of ***lenalidomide*** and was not substantively considered by the Examiner, was cumulative of references the Examiner considered that focused only on the use of ***thalidomide*** to treat MCL. The Board also disregarded its own finding that Drach was "stronger evidence" than the thalidomide references because Drach disclosed that lenalidomide was "a new treatment paradigm" for MCL. Drach's unique teachings were lynchpins of Petitioners' argument and the declaration of Petitioners' expert, Dr. Thirman, with respect to reasonable expectation of success and of lack unexpected results.

Second, with respect to Ground 2, the Board misapprehended that the Querfeld reference, which was not considered during prosecution, was cumulative of the Zeldis reference, despite Querfeld disclosing a Phase II lenalidomide clinical study not disclosed by Zeldis. Querfeld's additional teachings are relevant to the issues of reasonable expectation of success and lack of unexpected results, and were relied upon by Dr. Thirman and Petitioners.

Lastly, the Board should have instituted trial in light of numerous disputed issues of material fact present here. Indeed, Dr. Thirman squarely disagreed with the declaration of Dr. Zhang, which was submitted by Patent Owner during prosecution, on the issue of unexpected results. Likewise, Dr. Thirman disagreed with many factual assertions of Patent Owner in its Preliminary Response regarding reasonable expectation of success and unexpected results. Such factual disputes should have been viewed in a light most favorable to the Petitioner and should ultimately be resolved at trial.

II. LEGAL STANDARD

Requests for rehearing are governed by 37 C.F.R. § 42.71(d), which provides in pertinent part that a party's "request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply." *Id.* When rehearing a decision on petition, a panel reviews the decision for

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