UNITED STATES PAENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Mr. J. Kyle and Mr. Erich Spangenbergh
Petitioner

v.

ALPEX PHARMA
Patent Owner

Patent No. 8,440,170
Issued: May 14, 2013
Filed: PCT January 30, 2009
Inventors: F. Stroppolo and S. Ardalan
Title: "Orally Disintegrating Tablets with Speckled Appearance"

Inter Partes Review: No. IPR2016-00245

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Patent Trial and Appeal Board
United States Patent and Trademark Office
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PRELIMINARY RESPONSE BY PATENT OWNER
UNDER 37 C.F.R. § 42.107

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I. INTRODUCTION

Pursuant to 35 U.S.C. § 313 and 37 C.F.R. § 47.107(a), Patent Owner Alpex ("Alpex") presents this Preliminary Response ("Preliminary Response") to the Petition for Inter Partes Review ("Petition") of U.S. Patent No. 8,440,170 ("the '170 Patent") which was filed November 24, 2015 by Bass and Spangenberg ("Petitioners").

Petitioners have not argued that any of claims 1-9 of the '170 Patent defines subject matter anticipated by the prior art. Rather, Petitioners have patched together combination of reference teachings which putatively would have made Alpex's claimed invention unpatentable. The Petition contends two grounds for deciding against the '170 Patent, namely: ground 1 to the effect that '170 Patent claims 1-9 are unpatentable for obviousness on a combination of teachings from two references Petitioners call "the *Prevacid Label*" and "Stawski"; and ground 2 to the effect that '170 Patent claims 1-3, 5, 6, 8 and 9 are unpatentable for obviousness on a combination of teachings from "the *Prevacid Label*" and another reference Petitioners call "Serpelloni".

However, grounds 1 and 2 are fatally defective because Petitioners have simply not established a case of *prima facie* obviousness over either the *Prevacid Label* in view of Stawski, or the *Prevacid Label* in view of Serpelloni. Alpex submits that the attempted reference combinations are unavailing because (i) neither involves references which in the aggregate describe all the elements of the '170 Patent claims, (ii) in any event, even if combined, the references would have led away from the '170 Patent invention as claimed, and (iii) in reality, the references cannot be properly combined under the law because the modifications to the *Prevacid Label* which Petitioners propose in both instances results in making the *Prevacid Label* unsatisfactory for its intended purpose.

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