

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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STEADYMED LTD.,

Petitioner,

v.

UNITED THERAPEUTICS CORPORATION

Patent Owner.

Case IPR2016-00006

Patent No. 8,497,393

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**PETITIONER'S OPPOSITION TO PATENT OWNER'S  
MOTION TO EXCLUDE**

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Petitioner, SteadyMed Ltd. ("Petitioner"), respectfully submits this response in opposition to Patent Owner's Motion to Exclude Petitioner's Evidence Pursuant to 37 C.F.R. § 42.64(c) ("Motion" or "Mot.").

## I. INTRODUCTION

Patent Owner's Motion seeks to expunge relevant evidence from the record simply because it is not favorable to Patent Owner's positions in this *inter partes* review proceeding. This is not the standard, nor is this permissible. Patent Owner seeks to exclude *nearly every position* that Petitioner has taken in this proceeding:

- Exhibits 1009 (Winkler Declaration) and Exhibit 1017: Dr. Winkler's conclusions that the '393 Patent is invalid for anticipation and obviousness based on prior art references Moriarty, Phares, and Kawakami and his underlying support for the precision of HPLC instrumentation;
- Exhibit 1022 (Rogers Declaration): Dr. Rogers' opinions responding to Patent Owner's challenge on melting point, specifically, why the melting point of treprostinil diethanolamine salt Form B can be compared between the '393 Patent and the Phares reference; and
- Exhibit 2059 and Petitioner's Reply: Portions of Petitioner's Reply and Dr. Williams' deposition that support the fact that the Moriarty method produces *the same product as the product of the '393 Patent*, a product with a purity of ██████, and that Petitioner and its counsel cherry-picked 10 batches of

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