

CONTAINS PROTECTIVE ORDER MATERIAL

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STEADYMED LTD.

Petitioner,

v.

UNITED THERAPEUTICS CORPORATION

Patent Owner.

Case IPR2016-00006

Patent No. 8,497,393 B2

**PETITIONER'S MOTION TO EXCLUDE EVIDENCE
PURSUANT TO 37 C.F.R. § 42.64(C)**

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I. INTRODUCTION.

Petitioner SteadyMed Ltd. ("Petitioner") moves to exclude the opinions of Patent Owner United Therapeutics' expert Robert Ruffolo regarding secondary considerations, found in Ex. 2022 (the "Ruffolo Declaration"). The Ruffolo Declaration offers the conclusion that there was a long-felt need for the claimed inventions. But Dr. Ruffolo was unaware of the correct legal standard required to show a long-felt need for a claimed invention, and instead, applied a wrong standard. His opinions thus are not relevant to the question of long-felt need. For that reason, these opinions are unreliable, confusing, and not helpful to the trier of fact. They should be excluded under Federal Rules of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

Dr. Ruffolo was asked by United Therapeutics' counsel to opine that there was "a long-felt unmet need" that the "'393 patent satisfied ... by providing a commercial scale synthesis of treprostinil that results in a treprostinil product with higher overall purity and lower level of individual impurities." (Ex. 2022, ¶ 31.) But Dr. Ruffolo was not told that the "long-felt unmet need" must be one that is recognized in the art, such that others were trying to pursue it. He was not told that the need was one that was not being met by the prior art. He was not told that the long-felt need had to have a nexus to the patent claims. And he was not told that the long-felt need had to be commensurate in scope with the claims.

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