

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STEADYMED LTD.

Petitioner,

v.

UNITED THERAPEUTICS CORPORATION

Patent Owner.

Case IPR 2016-00006

Patent No. 8,497,393B2

**PETITIONER'S OBJECTIONS TO EVIDENCE
PURSUANT TO 37 C.F.R. § 42.64**

Mail Stop "Patent Board"
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Petitioner SteadyMed Ltd. (“Petitioner”) hereby files its objections to the exhibits submitted with Patent Owner United Therapeutics’ Response to Petition for *Inter Partes* Review, Paper 31, in Case No. IPR2016-00006 (the “Response”). Petitioner’s objections to the below identified exhibits include the following:

Exhibit	Objection(s)
Ex. 2020 (Declaration of Robert M. Williams, Ph.D) ¹	This exhibit is objected to as irrelevant to the grounds upon which trial has been instituted (FRE 401-402), and as more prejudicial than probative (FRE 403). Petitioner further objects to Ex. 2020, under FRE 701, because the opinion testimony contained in this exhibit reaches legal conclusions for which the declarant has not established that he is credible for providing, as shown in Paragraphs 73 and 76, among others.
Ex. 2021 (Curriculum Vitae of Robert M. Williams, Ph.D)	This exhibit is objected to as irrelevant to the grounds upon which trial has been

¹ Patent Owner has filed certain exhibits under seal, including portions of Exs. 2020 and 2022, and 2052-2054 in their entirety. Petitioner sets forth all of its objections to both Patent Owner’s sealed and non-sealed evidence in the foregoing objections.

Exhibit	Objection(s)
	instituted (FRE 401-402), and as more prejudicial than probative (FRE 403).
Ex. 2022 (Declaration of Robert R. Ruffolo, Jr., Ph.D)	<p>This exhibit is objected to as irrelevant to the grounds upon which trial has been instituted (FRE 401-402), and as more prejudicial than probative (FRE 403).</p> <p>Petitioner further objects to Ex. 2022, under FRE 701, because the opinion testimony contained in this exhibit reaches legal conclusions for which the declarant has not established that he is credible for providing, as shown in Paragraphs 64, 67, 69, and 74, among others. Petitioner further objects to Ex. 2022 under FRE 702 (improper expert testimony) and <i>Daubert v. Merrell Dow Pharmaceuticals, Inc.</i>, 509 U.S. 579 (1993). Indeed, Dr. Ruffolo does not possess the requisite credentials or</p>

Exhibit	Objection(s)
	<p>expertise to render opinions in this trial, as he has no background in analytical chemistry/HPLC, medicinal chemistry, or organic chemistry, nor does he have any experience working for the FDA (yet opines as to what would be “significant and clinically meaningful to the FDA”, Ex. 2022 at Para. 67).</p> <p>Additionally, Dr. Ruffolo’s declaration is used to support Patent Owner’s claim regarding an alleged long-felt unmet need for the ‘393 Patent, but does not, for example, contain sufficient evidence of a nexus between the claimed invention and Patent Owner’s commercial success. <i>See</i> Decision, Paper 28, at 51; Ex. 2022, at Para. 31.</p>
<p>Ex. 2023 (Curriculum Vitae of Robert R. Ruffolo, Jr., Ph.D)</p>	<p>This exhibit is objected to as irrelevant to the grounds upon which trial has been</p>

Exhibit	Objection(s)
	instituted (FRE 401-402), and as more prejudicial than probative (FRE 403).
Ex. 2025 (Prosecution History of U.S. Patent No. 6,209,259)	This exhibit is objected to as irrelevant to the grounds upon which trial has been instituted (FRE 401-402), and as unduly prejudicial (FRE 403). Ex. 2025 concerns statements from the prosecution history of unrelated patent, and is used solely to buttress the claim that the Board should overturn its previous claim construction ruling. It has no relevance to any issue in this proceeding.
Ex. 2026 (Williams, et.al., <i>Asymmetric, Stereocontrolled Total Synthesis of Paraherquamide A</i> , J. Am. Chem. Soc. 2003, 125, 12172-12178.)	This exhibit is objected to as irrelevant to the grounds upon which trial has been instituted (FRE 401-402), and as more prejudicial than probative (FRE 403). It is not substantively relied upon by Patent Owner in its Response.

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