

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 NON-SEALED EVIDENCE
PURSUANT TO 37 C.F.R. § 42.64**

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U.S. Patent and Trademark Office
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Alexandria, VA 22313-1450

Petitioner SteadyMed Ltd. (“Petitioner”) hereby files its objections to the non-sealed evidence¹ submitted with Patent Owner United Therapeutics’ Preliminary Response to Petition for *Inter Partes* Review, Paper 8, in Case No. IPR2016-00006 (the “Response”). Petitioner’s objections to the below identified evidence include the following:

Evidence	Objection(s)
Ex. 2002 (Remodulin Label)	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. 2002 was not substantively relied upon in the Response. Ex. 2002 is cited only for the statement that “Remodulin® was the second drug to receive FDA approval for the treatment of PAH” (p. 1), which is not relevant to any issue in this proceeding.

¹ Petitioner will submit its objections to Patent Owner’s sealed evidence (Exs. 2003, 2004, 2005, and 2006) on or before April 29, 2016. *See* (Paper 16).

<p>Ex. 2009 (U.S. Patent No. 8,748,657; the '657 patent)</p>	<p>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. 2009 concerns a continuation application of the '393 Patent, which is not relevant to any issue in this proceeding.</p>
<p>Ex. 2010 (The '657 patent prosecution history)</p>	<p>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. 2010 concerns statements from the prosecution history of a continuation application of the '393 Patent, which is not relevant to any issue in this proceeding.</p>

<p>Ex. 2013 (Trial testimony of Dr. Williams and Dr. Aristoff)</p>	<p>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. 2013 was not substantively relied upon in Patent Owner's Response. Petitioner further objects to Ex. 2013 to the extent such testimony offers improper expert opinions in violation of 37 C.F.R. § 42.65(a) and/or FRE 702. Dr. Williams and Dr. Aristoff have not been designated as experts in this proceeding, in the form of an expert declaration or otherwise, and thus, are shielded from cross-examination. Their testimony from a prior litigation – <i>involving a patent not at issue in this proceeding</i> – is accordingly improper. Petitioner further objects to Ex. 2013 as constituting hearsay for which no exception has been established (FRE 801/802).</p>
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Ex. 2015 (U.S. Patent No. 4,668,814; the '814 patent)	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. 2016 (UTC Form 10K 2014 Annual Report)	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. 2016 was not substantively relied upon in the Response. Patent Owner cites Ex. 2016 only to discuss revenues for its Remodulin® product (p. 56), which is not relevant to any issue in this proceeding.

Petitioner reserves the right to further object to this and other evidence based on Patent Owner's subsequent use of and arguments based on such evidence.

Date: April 22, 2016

Respectfully submitted,

/s/ Stuart E. Pollack /
 Stuart E. Pollack, J.D. Ph.D.
 Reg. No. 43,862
 DLA Piper LLP (US)

/s/ Lisa A. Haile /
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