

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

**PETITIONER'S RESPONSIVE LIST PURSUANT TO BOARD'S ORDER
(PAPER NO. 56)**

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Pursuant to Paper No. 56, Petitioner SteadyMed Ltd. ("Petitioner") submits its responsive itemized list:

(1) Portions that Respond to Patent Owner's Arguments Regarding Melting Point of Polymorphs, Including Form A and Form B:

a) Rogers Declaration (Ex. 1022), p. 21, line 4 from the end of the page through p. 24, last line: See Patent Owner Response, at 22-24;

Williams Declaration (Ex. 2020), at ¶¶ 72-78; *see also* Exs. 2030 and 2031. For example:

"It is known in the art that sample size, rate of heating, the recrystallization solvent(s) used, and the conditions under which the crystalline sample was obtained can significantly affect the DSC data. Dr. Winkler's conclusion based on this single vague and incompletely described DSC data is not scientifically sound."

Williams Declaration, Ex. 2020, at ¶ 76; Patent Owner Response at 24.

b) Rogers Declaration (Ex. 1022), p. 29, first line through p. 30, line 4:

See Response to (a), above.

(2) Portions that Teach the Meaning and Provide Background to the

Scientific Terminology Used in Dr. Rogers' Opinion:

- a) Petitioner's Reply, p. 13, line 8: *See* Petitioner's Reply at 14-15. For example:

"By contrast, Dr. Rogers' Declaration cites several literature sources explaining that melting point uniquely identifies a polymorph. (Ex. 1022, ¶¶ 49-52). Thus, for the same polymorph, if the melting point differs, it is due to impurities contained in the sample having a lower melting point. (*Id.*, ¶ 64.) Dr. Rogers concludes that Phares' higher melting point is necessarily due to higher or at least identical purity. (*Id.*, ¶ 74.). Moreover, the width of the DSC peak in the Phares reference is very narrow, consistent with a very pure material. (*Id.*, ¶ 84.)."

Petitioner's Reply at 15.

- b) Rogers Declaration (Ex. 1022), p. 9, line 8 through p. 24, last line: *See* Petitioner's Reply at 14-15, Exs. 1001 ('393 Patent) and 1005 (Phares prior art reference); *see also* Petition, at 27-28, and 55. Patent Owner elected not to depose Dr. Rogers.
- c) Rogers Declaration (Ex. 1022), p. 26, line 7 from the end of the page through p. 30, line 4: *See* Response to (b), above, and Ex. 1027.

- d) Rogers Declaration (Ex. 1022), p. 30, line 11 (beginning of Section VIII.A.) through p. 34, line 6 from the end of the page: See
Petitioner's Reply at 15: "Moreover, the width of the DSC peak in the Phares reference is very narrow, consistent with a very pure material."
- e) Rogers Declaration (Ex. 1022), p. 35, line 1 through p. 36, last line:
See Petitioner's Reply at 15.
- f) Rogers Declaration (Ex. 1022), p. 37, line 4 through p. 38, last line:
See Response to (b), above.

(3) Portions Quoting Patent Owner's Expert, and the Board's Statements

Prohibiting Introduction of New Evidence

Petitioner quotes the October 6, 2016 transcript (Ex. 2060):

"MR. MAEBIUS: Well, this listing of the new arguments in petitioner's reply, and the Rogers' declaration, and the instances of mischaracterized testimony from patent owner's expert, will that allow us to get a decision on the question of whether we can address at the final hearing the mischaracterized testimony of Dr. Williams by pointing out other parts of the Williams' deposition transcript?

[...]

JUDGE HARLOW: Thank you for holding. Just to clarify, the parties will not be permitted to introduce new evidence at the oral hearing.

You will be permitted to point out any alleged mischaracterization and to identify other parts of the transcript *if they are of record* that might be responsive, but *the parties will not be permitted to raise new arguments or present new evidence.*"

(Ex. 2060, at 25:5-26:6) (emphasis added).

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