

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS V LLC;
HAYMAN CREDES MASTER FUND, L.P.;
HAYMAN ORANGE FUND SPC – PORTFOLIO A;
HAYMAN CAPITAL MASTER FUND, L.P.;
HAYMAN CAPITAL MANAGEMENT, L.P.;
HAYMAN OFFSHORE MANAGEMENT, INC.;
HAYMAN INVESTMENTS, LLC;
NXN PARTNERS, LLC;
IP NAVIGATION GROUP, LLC;
J KYLE BASS; and ERICH SPANGENBERG,
Petitioner,

v.

BIOGEN MA INC.,
Patent Owner.

Case: IPR2015-01993
U.S. Patent No. 8,399,514

BIOGEN'S MOTION FOR OBSERVATIONS ON CROSS-EXAMINATION

As authorized by the March 22, 2016 Scheduling Order (Paper No. 21) and modified by the August 2, 2016 Notice of Joint Stipulation to Modify Due Dates 2-4 (Paper 44), Patent Owner Biogen MA Inc. respectfully submits the following motion for observations regarding the cross-examination of Petitioner's reply expert, Dr. Samuel J. Pleasure, and requests that the Board enter this motion. Office Patent Trial Practice Guide, 77 Fed. Reg. 48756 at 48767-68 (August 14, 2012).

Observation 1.

In **Exhibit 2384**, page 27, line 16 through page 28, line 18, Dr. Pleasure testified that he did not know the substance of Biogen's Patent Owner Response (Paper 38) nor was he asked to substantively consider it in preparing his declaration. This testimony is relevant to whether Dr. Pleasure's declaration contains arguments or evidence outside the scope of a proper reply in violation of 37 C.F.R. § 42.23(b), as raised in **Exhibit 3001**. This testimony is relevant because it shows that Dr. Pleasure's declaration was not intended to reply to Biogen's evidence and arguments relating to non-obviousness in its Patent Owner response. (**Ex. 3001.**)

Observation 2.

In **Exhibit 2384**, page 18, line 6 through page 22, line 7, Dr. Pleasure testified that he could not recall reviewing the declarations of Drs. Brundage,

Rudick, Thisted, O'Neill, or Dawson; he did not know the substance of their opinions; he had no specific knowledge of the declaration and opinions of Dr. Wynn; and he did not review the deposition testimony of Drs. Wynn, Rudick, or O'Neill. This testimony is relevant to whether Dr. Pleasure's declaration contains arguments or evidence outside the scope of a proper reply in violation of 37 C.F.R. § 42.23(b), as raised in **Exhibit 3001**. This testimony is relevant because it shows that Dr. Pleasure's declaration does not reply to any of Biogen's expert declarations. (**Ex. 3001**.)

Observation 3.

In **Exhibit 2384**, page 26, line 7 through page 27, line 1, Dr. Pleasure testified that he had no specific knowledge of the substance of the Petition (Paper 1), did not know whether he agreed or disagreed with it, and did not rely on it as a basis for the opinions in his declaration. This testimony is relevant to whether Dr. Pleasure's declaration contains arguments or evidence outside the scope of a proper reply in violation of 37 C.F.R. § 42.23(b), as raised in **Exhibit 3001**. This testimony is relevant because it shows that Dr. Pleasure has no specific knowledge of the Petition's theories of unpatentability and supports Biogen's position that Dr. Pleasure's declaration contains new obviousness positions that were not raised in the Petition. (**Ex. 3001**.)

Observation 4.

In **Exhibit 2384**, page 22, line 18 through page 26, line 6, Dr. Pleasure testified that he had no specific knowledge of the substance of Dr. Linberg’s declaration (**Ex. 1005**) and did not review Dr. Linberg’s deposition testimony (**Ex. 2071**), stating that instead he “was trying to come at this with [his] own thinking.” This testimony is relevant to whether Dr. Pleasure’s declaration contains arguments or evidence outside the scope of a proper reply in violation of 37 C.F.R. § 42.23(b), as raised in **Exhibit 3001**. This testimony is relevant because it shows that Dr. Pleasure has no specific knowledge of Dr. Linberg’s original theories of obviousness (**Ex. 1005**; **Ex. 2071**) and supports Biogen’s position that Dr. Pleasure’s declaration contains new obviousness positions that were not raised in the Petition. (**Ex. 3001**.)

Observation 5.

In **Exhibit 2384**, page 20, line 25 through page 21, line 15, Dr. Pleasure testified that he did not recall reviewing Dr. Rudick’s declaration or deposition testimony. In **Exhibit 2384**, page 22, lines 8 to 17, Dr. Pleasure further testified that he did not review the prosecution history of the ’514 patent “in its full form.” This testimony is relevant to the issues of unexpected results and long-felt but unmet need, as raised in Biogen’s Opposition to the Petition (Paper 38 at pages 43 to 52), Dr. Rudick’s declaration submitted during prosecution (**Ex. 2011** at ¶¶ 7 to

28), and Dr. Rudick's declaration submitted with Biogen's Opposition to the Petition (**Ex. 2044** at ¶¶ 37 to 55). The testimony is relevant because it shows that Dr. Pleasure was unaware of arguments to which he was supposed to be responding and supports Biogen's position that Dr. Pleasure's declaration does not reply to Biogen's evidence of unexpected results. (**Ex. 3001**; Paper 38 at pages 43-52.)

Observation 6.

In **Exhibit 2384**, page 21, lines 18 to 22, Dr. Pleasure testified that he did not review Dr. Thisted's declaration. In **Exhibit 2384**, page 53, lines 21 to 23, Dr. Pleasure further testified that he is not an expert in biostatistics. In **Exhibit 2384**, page 172, line 17 through page 173, line 15, Dr. Pleasure also testified that he has not conducted any formal statistical analyses of any of the clinical trial results reported in the DEFINE or CONFIRM phase 3 studies. This testimony is relevant to the issue of unexpected results, as raised in Biogen's Opposition to the Petition (Paper 38 at pages 43 to 52) and Dr. Thisted's declaration (**Ex. 2038**). This testimony is relevant because it demonstrates that Dr. Pleasure was unaware of evidence to which he was supposed to be responding and supports Biogen's position that Dr. Pleasure's declaration does not reply to Biogen's evidence of unexpected results. (**Ex. 3001**; Paper 38 at pages 43-52.)

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