

For the Petitioner
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Paper No. ____

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 FUND, L.P.;
HAYMAN OFFSHORE MANAGEMENT, INC.;
HAYMAN INVESTMENTS, LLC;
NXN PARTNERS, LLC;
IP NAVIGATION GROUP, LLC;
J KYLE BASS, and ERICH SPANGENBERG,
Petitioners,
v.
BIOGEN MA INC.,
Patent Owner.

Case IPR2015-01993
Patent 8,399,514 B2

COALITION RESPONSE TO BIOGEN'S MOTION FOR OBSERVATIONS

As authorized by the 22 March 2016 Scheduling Order (Paper 21), Petitioner respectfully submits the following Response to Biogen's Motion for Observations on Cross-Examination of Petitioner's reply expert, Dr. Samuel J. Pleasure filed 2 November 2016 (Paper 59).

Biogen's Motion should be disregarded in its entirety. A motion for observations "is not an opportunity to raise new issues, reargue issues, or pursue objections." PTAB Trial Practice Guide 77 Fed. Reg. 48756, 48768. However, that is exactly what Biogen's Motion does.

For example, at least Observations 1 through 6 in Biogen's Motion improperly argue the procedural issue of whether Petitioner's Reply had a proper scope under 37 C.F.R. §42.23(b). But the Board already explicitly ordered Biogen *not* to file a motion addressing that issue:

There is no apparent reason why the matter cannot be adequately addressed as part of the oral argument. The Board can also determine *sua sponte* whether an inappropriate new issue has been raised. A motion and conference call are therefore unnecessary.

Paper No. 52 at 2. Biogen's defiance of that Order justifies disregarding the Motion for Observations in its entirety.

Likewise, at least Observations 14-15 and 18 misuse the Motion as a sur-reply to reargue obviousness. Observation 19 improperly raises a new issue about what scientists have not determined as of today.

If even a single observation is improper, the entire Motion for Observations may be disregarded. *See Medtronic v. Nuvasive*, IPR2013-00506, Paper 37 at 2-4 (entire Motion for Observations dismissed due to a single improper observation).

In the present case, as discussed above, there are at least ten improper Observations: Observations 1-6, 14-15, and 18-19. This more than justifies disregarding the entire Motion for Observations under *Medtronic*.

For the sake of completeness, if the Board were not to disregard Biogen's Motion for Observations, Petitioner provides the following responses to individual Observations.

Response to Observation # 1. In Observation 1, Patent Owner argues that Dr. Pleasure's inability at his deposition to recall specific arguments from Biogen's "Patent Owner Response" was somehow relevant to whether Dr. Pleasure's declaration was outside the scope of a proper reply. Petitioner Responds that the deposition questions about a "Patent Owner Response" were misleading and confusing; there was no paper filed in this IPR titled "Patent Owner Response." Biogen did not even favor Dr. Pleasure with a copy of its Opposition after Dr. Pleasure said he did not know what document he was being asked about. **Exhibit 2384**, page 27, lines 16-22. Dr. Pleasure said he did consider the issues discussed in such papers generally. **Exhibit 2384**, page 27, line 25, through page 28, line 10. As demonstrated in Petitioner's Reply, Dr. Pleasure's testimony is evidence

responsive to the Opposition. This is true regardless of whether Dr. Pleasure identified particular statements in the Opposition.

Response to Observation # 2. Petitioner responds that Biogen’s summary of the cited testimony is misleading and inaccurate. Dr. Pleasure testified that he “was provided with a couple of those [Patent Owner’s expert] declarations, that I did read at some point” (**Exhibit 2384**, page 17, lines 20-24) and that he “read Daniel Wynn’s expert declaration” but did not “recall whether – the names of any other ones of any people that I’ve read” (**Exhibit 2384**, page 18, lines 11-14). Dr. Pleasure was not favored with a copy of any of these declarations or depositions at his deposition. As demonstrated in Petitioner’s Reply, Dr. Pleasure’s testimony rebuts the Opposition evidence. This is true regardless of whether Dr. Pleasure could remember off the top of his head all of Biogen’s numerous declarations.

Response to Observation # 3. Petitioner responds that Biogen’s summary of the cited testimony is misleading and inaccurate. When asked about a petition, Dr. Pleasure testified he was unsure what document he was being asked about, and Biogen did not provide a copy. **Exhibit 2384**, page 26, lines 7-19. Dr. Pleasure further testified he viewed such pleadings as legalese, and that he applied his education, training, and experience to come up with his own thinking about the underlying evidence he reviewed, rather than relying on the pleadings. (*Id.* Page

26, line 7, through page 27, line 24, and page 23, line 18 through page 24, line 15.). This does not detract from the Reply's use of his testimony to rebut the Opposition.

Response to Observation # 4. Petitioner responds that Biogen's summary of the cited testimony is misleading and inaccurate. First, the testimony in **Ex. 2384**, at page 23, line 14 through page 24, line 15 relates to Dr. Pleasure's testimony concerning the declaration of Dr. Wynn, not Dr. Linberg. Second, Dr. Pleasure testified he agreed with Dr. Linberg "in some substance, in most substance I do, I believe, but I'm not a hundred percent sure because I didn't review his opinions in great detail" (Ex. 2384, p. 24, ll. 16-22). In any event, if Biogen is correct that Dr. Pleasure did not rely on Dr. Linberg's opinions, that does not make his testimony improper.

Response to Observation # 5. Petitioner responds that the cited testimony does not detract from Dr. Pleasure's reasoned testimony on the issues of unexpected results and long-felt need. (**Ex. 1045**, ¶¶69-72 and 74-76). Observation # 5 is another improper attempt to pursue the procedural issue of proper scope of reply under §42.23(b).

Response to Observation # 6. Petitioner responds that the cited testimony does not detract from Dr. Pleasure's reasoned testimony on unexpected results. (**Ex. 1045**, ¶¶69-72 and 75). Observation # 6 is another improper attempt to pursue the procedural issue of proper scope of reply under §42.23(b).

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