

Hill, Kyle

From: Rosato, Michael
Sent: Thursday, May 12, 2016 11:22 AM
To: Trials
Cc: Parmelee, Steve; Brown, Andrew; Doshi, Dipu; England, Jonathan; Thronson, Mark
Subject: PGR2015-00011

Follow Up Flag: Follow up
Flag Status: Completed

Dear Trials,

On May 6, 2016, Petitioner (Altaire) filed its Reply brief to the Patent Owner's Response. Patent Owner (Paragon Biotech) respectfully requests a conference call with the Board to discuss the issues identified below.

[Issue 1] New argument and evidence in Reply

Petitioner's reply advances new argument and evidence exceeding the proper scope of reply, per 37 CFR §42.23 and the Trial Practice Guide (e.g., 77 Fed. Reg. 48,756, 48,767). The new evidence includes the following:

- Three newly submitted witness declarations: Exhibit 1025 (Third Declaration of Assad Sawaya), Exhibit 1029 (Zaman Declaration), Exhibit 1032 (Second Declaration of M. Sawaya)
- Three newly submitted test reports with experimental protocols and data not previously made of record: Exhibit 1027 (TMQC-247-01), Exhibit 1028 (TMQC-247-00), Exhibit 1030 (STU0346)

The new argument and evidence is believed an untimely attempt to cure (1) the lack of any expert testimony submitted with the petition; and (2) failure to disclose test methodology and information corresponding to the original test data submitted with the petition, as required per 37 CFR 42.65(b). Paragon is concerned that the remaining schedule in this proceeding lacks the requisite time and opportunity for Paragon to address the insufficiency of the new material. As such, Paragon seeks the following corresponding relief from the Board:

- Motion to Strike: Because the new argument/evidence effectively amounts to a new petition, all materials (Reply brief and corresponding exhibits) should be struck and expunged from the record. If a motion is deemed necessary, Paragon requests authorization to file a motion to strike, which may be decided on an expedited basis.
- Surreply: As an alternative to striking the new argument/evidence, Paragon requests authorization to file a surreply together with new testimonial evidence and/or experimental evidence.
- Extension of the Board's deadline to issue a Final Written Decision: If new argument/evidence is not struck, Paragon requests extending the Board's deadline for issuing a Final Written Decision for up to 6 months per 35 USC §316(a)(11). Such an extension would be critical to accommodating briefing and discovery related to addressing the new argument/evidence.

[Issue 2] Motion to Terminate for Failure to Name all Real Parties-In-Interest

Following post-institution discovery, Paragon again raised the issue of unnamed real parties-in-interest in its Patent Owner's Response. Paper 20 at 14-27. In its Reply brief, Petitioner asserts that the proper vehicle for raising this issue is a motion to terminate, not the Patent Owner's Response. Paper 36 at 17-18. Paragon respectfully disagrees. However, to the extent the Board deems a motion to terminate to be the proper vehicle in this instance, Paragon seeks authorization to present such a motion.

Counsel for the parties have conferred. Parties are mutually available for a conference call with the Board during the following times:

- Friday 5/13/2016: Noon to 3:30 EST
- Monday 5/16/2016: Noon to 1pm EST; 2-5pm EST

Sincerely,

Michael T Rosato (Lead Counsel for Patent Owner)

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