

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALTAIRE PHARMACEUTICALS, INC.,
Petitioner,

v.

PARAGON BIOTECK, INC.,
Patent Owner.

Case PGR2015-00011
Patent 8,859,623

**PARAGON'S IDENTIFICATION OF
IMPROPER NEW REPLY MATERIALS THAT
SHOULD BE STRUCK FROM THE RECORD**

I. STATEMENT OF THE PRECISE RELIEF REQUESTED

Petitioner's Reply advances new argument and evidence exceeding the proper scope of reply. See 37 CFR §42.23; 77 Fed. Reg. 48,756, 48,767. The new evidence and argument is an improper attempt to cure (1) the lack of any expert testimony submitted with the Petition; and (2) the 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). Ex. 2042. Pursuant to the Board's authorization (Paper 38), Paragon submits this paper identifying materials that are untimely and/or outside the scope of a proper reply. These materials should be struck and expunged from the record pursuant to 37 CFR § 42.12.

II. STATEMENT OF THE REASONS FOR THE RELIEF REQUESTED

Assad Sawaya Newly Appearing as an Expert Witness: The entirety of **Ex. 1025** (Declaration No. 3 of Assad Sawaya) and **Paper 35, § II** purport to qualify Assad Sawaya as an expert witness. Assad Sawaya was not previously presented or qualified as an expert witness under FRE 702. The Board already assessed this issue and agreed. See Paper 14 at 14 (Assad Sawaya "is not shown to be an expert witness" and the Board "accord[ed] no weight to his opinion in that capacity."). Accordingly, the materials represent a departure from the Petition.

New Experimental Protocols and Test Data: The entirety of **Exs. 1027** (TMQC# 247-01), **1028** (TMQC# 247-00), and **1030** (STU0346) present details of

HPLC methods and validation experiments never previously submitted by Petitioner. The **entirety of Ex. 1029** (Declaration of Rashid Zaman) presents testimony regarding the method and validation experiments. The **entirety of Exs. 1031, 1032** (Declaration No. 2 of Michael Sawaya), and **1033** allegedly show that a Paragon employee was mailed a paper copy of some version of STU-0346. **Paper 35, §§ III.A-B** presents arguments regarding this new evidence.

It is undeniable that, prior to the Reply, *no HPLC method or validation experiments had ever been submitted by Petitioner*—either in the petition materials or by motion under 37 C.F.R. 42.123. Paragon’s Response pointed out that the test data provided with the Petition did not comply with 37 C.F.R. § 42.65(b). *See* Paper 20 at 31-36. The petition materials were confusing at best as to methodologies utilized, making different references to “proprietary” materials with no corresponding detail (*see* Ex. 1003 ¶¶ 21, 47; Pet. at 20, 49-50, 61), as well as USP standard protocol methods (*see* Ex. 1003 p. 21, n.5). Paragon and the Board reasonably concluded that the test method in the Petition presumably corresponded to “the USP standard HPLC method.” Paper 14 at 12; Paper 7 at 12-13. Petitioner now alleges it used a “proprietary” method (not the USP method), which the newly submitted exhibits present for the first time. The methodologies are unquestionably new to the case, and represent a departure from the Petition.

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Respectfully submitted,

Date: May 20, 2016

/ Michael T. Rosato /

Michael T. Rosato, Lead Counsel

Reg. No. 52,182

UPDATED LIST OF EXHIBITS

EXHIBIT NO.	DESCRIPTION
2001	Declaration of Assad Sawaya in Support of Altaire Pharmaceuticals, Inc. and Sawaya Aquebogue, LLC's Motion to Dismiss or, in the Alternative, for Transfer of Venue; Paragon BioTeck, Inc. v. Altaire Pharmaceuticals, Inc. and Sawaya Aquebogue, LLC. (Case 3:15-cv-00189-PK; Document 21; Filed 3/23/15; U.S. District Court of OR)
2002	Proof of Service Summons and Complaint; Paragon BioTeck, Inc. v. Altaire Pharmaceuticals, Inc., et al (Case 3:15-cv-00189-PK; Document 17; Filed 3/20/15; U.S. District Court of OR)
2003	Proof of Service Summons and Complaint; Paragon BioTeck, Inc. v. Altaire Pharmaceuticals, Inc., et al (Case 3:15-cv-00189-PK; Document 18; Filed 3/20/15; U.S. District Court of OR)
2004	Paragon's Response to Defendants' Motion to Dismiss or for Transfer of Venue; Paragon BioTeck, Inc. v. Altaire Pharmaceuticals, Inc. and Sawaya Aquebogue, LLC. (Case 3:15-cv-00189-PK; Document 27; Filed 4/15/15; U.S. District Court of OR)
2005	Air State Facility Permit Under the Environmental Conservation Law Issued to Sawaya Aquebogue, LLC for an Altaire Pharmaceuticals Facility on behalf of Michael Sawaya, Altaire Pharmaceuticals; New York State Department of Environmental Conservation (Effective Date April 27, 2010)
2006	Altaire Pharmaceuticals, Inc. and Sawaya Aquebogue, LLC's Motion to Dismiss or, in the Alternative, for Transfer of Venue. Paragon BioTeck, Inc. v. Altaire Pharmaceuticals, Inc. and Sawaya Aquebogue, LLC. (Case 3:15-cv-00189-PK; Document 20; Filed 3/23/15; U.S. District Court of OR)
2007	Letter from Michael Sawaya, General Counsel of Altaire Pharmaceuticals, Inc. to Travis Sydow of Paragon BioTeck, Inc. Dated June 12, 2015

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