

U.S. Patent No.: 8,859,623
Reply to Patent Owner's Preliminary Statement

Paper No. ____

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Altaire Pharmaceuticals, Inc.

Petitioner

v.

Paragon BioTeck, Inc.

Patent Owner

U.S. Patent No. 8,859,623
Issue Date: October 14, 2014

Entitled: METHODS AND COMPOSITIONS OF STABLE PHENYLEPHRINE
FORMULATIONS

Post-Grant Review No.: Case PGR2015-00011

REPLY TO PATENT OWNER'S PRELIMINARY STATEMENT

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Petitioner hereby timely files this Reply Brief to address Patent Owner's Preliminary Statement ("Statement"). Petitioner anticipated and therefore addressed many of Patent Owner's arguments in its Statement (and is prepared to address all of the arguments in the full proceedings), and limits this Reply Brief to Patent Owner's allegations that Sawaya Aquebogue ("Saw Aque") should have been identified as a real party-in-interest under 35 U.S.C. § 322(a)(2).

In an attempt to avoid addressing the merits of the Petition in this PGR proceeding, Patent Owner purposefully misleads this Board by alleging that Saw Aque and Petitioner "are closely intertwined entities" and therefore Saw Aque should have been identified as a "real party-in-interest." *See* Statement at 3. Patent Owner's sole basis for that assertion is its own allegation in an opposition to a motion to dismiss for lack of personal jurisdiction in a district court litigation. *See id.* (citing Ex. 2004 (Paragon's Opposition to Motion to Dismiss)). In that same paper, Patent Owner requested jurisdictional discovery¹ because "[Patent Owner] Paragon *anticipates* that any such limited and focused discovery would demonstrate that [Petitioner] Altaire and Sawaya Aquebogue are not separate and distinct entities" (*see* Ex. 2004 at 14 (emphasis added)). Patent Owner has no basis

¹ Patent Owner's request for jurisdictional discovery was denied as moot since the underlying motion to dismiss was granted.

for its representations to this Board that Saw Aque and Altaire are “closely intertwined” such that the Board should consider Saw Aque a real party-in-interest. Indeed, the facts demonstrate that Saw Aque is a separate and distinct entity that has no control over Petitioner Altaire Pharmaceuticals, Inc. or the Petition.

I. LEGAL FRAMEWORK

The Board “generally accept[s] a petitioner’s identification of real parties in interest at the time of filing the petition.” *Kapsch Trafficcom IVHS Inc. v. Neology, Inc.*, IPR2015-00808, at 4 (Paper No. 13) (P.T.A.B. Sept. 14, 2015) (Exhibit 1021). “A patent owner challenging a petitioner’s RPI disclosure *must* provide sufficient evidence to show the disclosure is inadequate.” *Id.* (citing *Intellectual Ventures Mgmt., LLC v. Xilinx, Inc.*, IPR2012-00018 at 3 (Paper 12)) (emphasis added).

“[W]hether a party who is not a named participant in a given proceeding is a ‘real party-in-interest’ to that proceeding is a highly fact-dependent question.” *Id.* (quoting Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,759 (2012)) (citations omitted). “In general, a ‘real party-in-interest’ is ‘the party that desires review of the patent,’ and ‘may be the petitioner itself, and/or it may be the party or parties at whose behest the petition has been filed.’” *Id.*

Factors considered in determining whether an unnamed party is a real party-in-interest are set forth in *Kapsch supra*. *See id.* at 5-6. These factors include: 1)

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whether the “non-party exercised or could have exercised control over a party’s participation in a proceeding” and 2) whether a non-party “funds and directs and controls’ a[PGR] petition or proceeding; the non-party’s relationship with the petitioner; the non-party’s relationship to the petition itself[;] and the nature of the entity filing the petition.” *Id.*

Moreover, a bedrock principal of corporate law is to respect corporate distinctions. *See, e.g., U.S. v. Bestfoods*, 524 U.S. 51, 69 (1998) (“*Bestfoods*”).

There, the Supreme Court recognized:

[C]ontrol through the ownership of shares does not fuse the corporations, even when the directors are common to each

...

This recognition that the corporate personalities remain distinct has its corollary in the “well established principle [of corporate law] that directors and officers holding positions with a parent and its subsidiary can and do ‘change hats’ to represent the two corporations separately, despite their common ownership.” Since courts generally presume “that the directors are wearing their ‘subsidiary hats’ and not their ‘parent hats’ when acting for the subsidiary.”

Id. (internal citations omitted). *See also Kapsch supra* at 5 (“A party does not become a [real party-in-interest] merely through an association with another party in an endeavor unrelated to the IPR proceeding.”) (citations omitted).

In this case, Patent Owner has failed to submit or cite to any factual evidence to show that any of the required factors is present and thus fails to meet the Board's threshold showing that the Petition fails to identify any real party-in-interest. As such, Patent Owner's arguments should be dismissed and the merits of this PGR proceeding should be heard.

II. STATEMENT OF FACTS

After years of Petitioner selling its Phenylephrine Hydrochloride Ophthalmic Solution, Petitioner and Patent Owner entered into an agreement dated May 15, 2011 ("Agreement") whereby Petitioner became Patent Owner's exclusive supplier, and Patent Owner became Petitioner's exclusive distributor. *See* Ex. 2001, Exhibit A at 1. Saw Aque has no obligations to either Petitioner or Patent Owner under the Agreement. *See* Sawaya Declaration, ¶ 15 (Exhibit 1022). Indeed, Patent Owner admits that Saw Aque is a "non-party to the contract." *See* Letter at 1, *Altaire Pharms., Inc. v. Paragon BioTeck, Inc.*, No. 2:15-cv-02416 (E.D.N.Y. Sept. 18, 2015) (Exhibit 1023). Accordingly, Saw Aque does not receive any portion of the proceeds from the purchases by Patent Owner. Exhibit 1022, ¶ 10.

Contrary to the Patent Owner's representations, Petitioner and Saw Aque are separate and distinct entities that have no ownership interest in one another. *See* *Id.* at ¶ 6. Further, Petitioner and Saw Aque are *not* under common control or run

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