UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ALTAIRE PHARMACEUTICALS, INC.,
Petitioner,

v.

PARAGON BIOTECK, INC.,
Patent Owner.

_____

Case PGR 2015-00011
Patent 8,859,623 B1

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PETITIONER'S REPLY TO
PATENT OWNER'S RESPONSE

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Exhibit No.	Exhibit Name
Exhibit 1025:	Declaration No. 3 of Assad Sawaya (May 4, 2016)
Exhibit 1026:	Deposition Transcript of Gojko Lalic, Ph.D. (April 12, 2016)
Exhibit 1027:	TMQC# 247-01 (March 17, 2015)
Exhibit 1028:	TMQC# 247-00 (May 31, 2013)
Exhibit 1029:	Declaration of Rashid Zaman (May 5, 2016)
Exhibit 1030:	STU0346 (May 29, 2013)
Exhibit 1031:	Transmittal letter from M. Sawaya to L. McBluett (March 26, 2014)
Exhibit 1032:	Declaration No. 2 of Michael Sawaya (May 4, 2016)
Exhibit 1033:	Email from L. McBluett to M. Sawaya (March 25, 2014)
Exhibit 1034:	Deposition Transcript of Sailaja Machiraju (April 29, 2016)
Exhibit 1035:	Orange Book listing for U.S. Patent No. 8, 859,623 (Accessed May 4, 2016)
Exhibit 1036:	Email from A. Brown to D. Doshi et al. (April 8, 2016)

I. INTRODUCTION

Patent Owner's Response (Paper 20) fails to provide any evidence that Petitioner's products sold prior to the earliest effective filing date were not chirally pure. Nor does Patent Owner provide any evidence that Lots 11578 and 11581 were not tested after cold storage at 2-8°C. Patent Owner also fails to provide any rebuttal to Petitioner's position that the claimed invention would have been obvious under 35 U.S.C. § 103.

Patent Owner only argues that Petitioner has failed to meet its burden (a preponderance of the evidence). In support, Patent Owner provides tests to show that the USP standard HPLC test cannot distinguish R-phenylephrine from S-phenylephrine. But Petitioner did not rely on the USP standard HPLC test; instead, Petitioner relied on its proprietary HPLC test that can distinguish between R-phenylephrine from S-phenylephrine—this is the same proprietary test that Patent Owner relies on in its dealings with Petitioner, the Food & Drug Administration (FDA), and its customers.

Patent Owner also attempts to discredit Petitioner's optical rotation tests notwithstanding Patent Owner's reliance on the optical rotation tests in support of its New Drug Application (NDA) to the FDA. And while it calls into question the chiral purity of the R-phenylephrine standard used in the optical rotation tests, Patent Owner fails to provide any evidence to show that the representation of the

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