UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
ARGENTUM PHARMACEUTICALS LLC Petitioners,
V.
CIPLA LTD.
Patent Owner and Licensee
Case: IPR2017-00807
U.S. Patent No. 8,168,620

## DECLARATION OF JOHN C. STAINES, JR. IN SUPPORT OF PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

**MARCH 6, 2018** 



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### I. **QUALIFICATIONS**

- 1. I am a Director and Principal in the Washington, DC office of Navigant Economics LLC ("Navigant Economics"), a subsidiary of Navigant Consulting, Inc., an international consulting firm. Navigant Economics provides expertise primarily in economics, finance, public policy, and business strategy. I am knowledgeable in the fields of microeconomics, industrial organization, financial economics, and statistics, and have particular expertise in applying the tools of these disciplines to legal disputes arising in the pharmaceutical and related industries.
- 2. My educational background includes a B.A. in Economics and M.P.M. in Public Policy from the University of Maryland and an M.B.A. in Business Economics and Finance from the University of Chicago. Since 1984, I have worked as a consultant on economic, financial, statistical, and general business issues arising in commercial litigation disputes. My work primarily has involved analyzing competitive issues and estimating commercial damages associated with various types of legal and regulatory matters, most often relating to the pharmaceutical industry. I have been accepted as an expert witness in Federal Court to opine on economic issues arising in pharmaceutical-related patent and antitrust litigation. A copy of my curriculum vitae is included as Appendix A to this report.



3. Navigant Economics is being compensated for the work I perform in connection with this case at my standard hourly rate of \$535. Part of the work underlying this report was performed by staff of Navigant Economics working under my direction. Payment of fees to Navigant Economics associated with work performed on this matter is not contingent upon or in any way affected by the nature of my opinions or the outcome of this litigation.

### II. <u>OBJECTIVES</u>

4. I have been retained by the Petitioners in this matter, Argentum Pharmaceuticals LLC. ("Argentum") to render independent expert opinions concerning the existence and sources of any commercial success that may be associated with the allergic rhinitis ("AR") treatments, Dymista® and Duonase (and certain Duonase "imitator" products), as they may relate to the obviousness of the technology claimed by U.S. Patent Number 8,168,620 (the "'620 patent"), entitled "Combination of Azelastine and Steroids." Dymista® was marketed in the United States as an AR treatment by Meda AB ("Meda"), <sup>2</sup> and currently is marketed by Mylan, Inc.



 $<sup>\</sup>frac{1}{2}$  Exhibit 1001.

Exhibit 2068, p. 2.

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