

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS KABI USA LLC,
Petitioner,
v.

CUBIST PHARMACEUTICALS, INC.
Patent Owner.

U.S. Patent No. 8,129,342

Cases IPR2015-01566, IPR2015-01570, IPR2015-01571, IPR2015-01572

EXPERT DECLARATION OF RALPH TARANTINO, PH.D.

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1. My name is Ralph Tarantino, Ph.D. I have been retained by counsel for Fresenius Kabi USA LLC (Fresenius). I understand that Fresenius intends to petition for *inter partes* review of U.S. Patent No. 8,129,342 (the ‘342 patent) [Ex. 1002], which is assigned to Cubist Pharmaceuticals, Inc. I also understand that Fresenius intends to petition for *inter partes* review of U.S. Patent No. 8,058,238 (the ‘238 patent) [Ex. 1001], which is also assigned to Cubist Pharmaceuticals, Inc. I further understand that Fresenius will request that the United States Patent and Trademark Office cancel the claims of the ‘342 patent and the ‘238 patent as unpatentable in the *Inter Partes* Review petitions. I submit this expert declaration, which addresses and supports Fresenius’s *Inter Partes* Review petition for the ‘342 patent. I have prepared and submitted a separate declaration which addresses and supports Fresenius’s *Inter Partes* Review petition for the ‘238 patent.

I. Qualifications and Background

A. Education and Experience; Prior Testimony

2. I am currently a Pharmaceutical Consultant and Principal of Steritech Solutions, LLC. I have an undergraduate degree in Pharmacy from Long Island University and a Ph.D. in Pharmaceutical Sciences from St. John’s University. I am a registered pharmacist in the State of New York.

3. After receiving my doctorate in 1989, I joined Hoffmann-La Roche, Inc. in Nutley, New Jersey. Since its founding in 1896, Hoffmann-La Roche has

grown into one of the world's leading healthcare companies with a focus on pharmaceutical and biotechnology therapies. Roche has identified and developed leading cancer therapies and other significant treatments including, for example, Roferon-A®, Valium®, Bactrim®, Hivid® and Accutane®. I worked at Hoffmann La Roche until 2011, when I founded Steritech Solutions, LLC.

4. Since its incorporation in 2011, I have been the Principal of Steritech Solutions, LLC. Steritech provides consulting services directly to the pharmaceutical industry and other businesses involved with pharmaceuticals such as investment or legal firms. I have consulted on peptide/protein formulations and processing, quality assurance, manufacturing, drug delivery devices and primary packaging issues. My work at Steritech has focused on injectable drug products.

5. At Hoffmann-La Roche, I primarily worked in the areas of peptide/protein preformulation, formulation development, and the manufacture of toxicology and clinical supplies for injectable products. I was the head of sterile clinical manufacturing for 17 years. In this capacity, I managed two Good Manufacturing Practice ("GMP") sterile suites and one Good Laboratory Practice ("GLP") sterile suite.

6. In my role at Hoffmann-La Roche, I was responsible for the sterilization processes for equipment, facilities and drug products, as well as the validation of these processes for both GLP and GMP sterile products. I developed

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