

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

UNITED THERAPEUTICS
CORPORATION,

Plaintiff,

v.

SANDOZ, INC.,

Defendant.

Civil Action No. 3:14-cv-5499
(PGS)(LHG)

DECLARATION OF ROBERT M. WILLIAMS, PH.D.

I, Robert M. Williams, Ph.D. declare as follows:

I. BACKGROUND

1. I am currently a tenured University Distinguished Professor of Chemistry at Colorado State University (CSU). I also serve as the Director for the Colorado Center for Drug Discovery. I am also co-Director (Experimental Therapeutics) for the Infectious Diseases Supercluster Initiative and co-Director for the Cancer Supercluster Initiative at CSU. I have been retained by United Therapeutics Corp. (“UTC”) as an expert in connection with the above-captioned matter.

2. I obtained my Bachelor of Arts degree in Chemistry from Syracuse University in 1975, and did laboratory research in the field of synthetic organic chemistry under the guidance of the Nobel Laureate Professor Ei-ichi Negishi. I obtained my Master’s degree and Ph.D. in Organic Chemistry in 1979 from the Massachusetts Institute of Technology (MIT). Upon graduating from MIT, I spent one year (1979-80) as a post-doctoral fellow at Harvard University in the laboratories of the Nobel Laureate, the late Professor Robert B. Woodward and Professor Yoshito Kishi. I have been a professor of chemistry since 1980.

3. I have extensive knowledge and experience in the area of synthetic organic chemistry and medicinal chemistry with an emphasis on biologically active compounds. My organic chemistry research interests include the total synthesis of

novel natural and synthetic products, heterocyclic chemistry, asymmetric synthesis, synthetic methodology, and reaction mechanisms. In addition to over 300 publications in the field, I have taught classes and conducted research in the area of synthetic organic chemistry and more specifically on prostaglandins, prostacyclins, thromboxanes, and related compounds. I also served as Principal Investigator (PI) on a research grant from the National Institutes of Health, to study the synthesis of thromboxane A₂, a member of the natural eicosanoids and researched the structure and function of this family of fatty acid derivatives including the prostaglandins.

4. I also have expertise in drug formulation for injectable, topical and oral medications. I have directed research programs for numerous therapeutic indications and I have consulted on many aspects of pharmaceutical drug discovery, development and manufacturing. This includes basic discovery and optimization, early process research, large-scale manufacturing and drug formulation.

5. I also currently serve on the Editorial board for *Chemistry & Biology*, and served as Editor for the *Organic Chemistry Series* published by Pergamon Press and Elsevier (1997-2012), and *Mini Reviews in Organic Chemistry* (Bentham Science). I have served as an editor for several other journals in the past, including *Tetrahedron: Asymmetry*, *Tetrahedron Publications*, *Amino Acids*, and the *Journal of the American Chemical Society*.

6. I am a member of the American Chemical Society, the Japan Antibiotics Research Association, and the International Society of Heterocyclic Chemistry. I have served as the Vice President of the International Society of Heterocyclic Chemistry, Chairing the 2003 International Congress of Heterocyclic Chemistry as organizer or co-organizer of numerous scientific meetings and symposia and.

7. I have been awarded numerous prizes and awards including the NIH Research Career Development Award (1984-89), the Eli Lilly Young Investigator Award (1986), the Merck, Sharp & Dohme Academic Development Award (1991), the Japanese Society for the Promotion of Science Fellowship (1999), the Arthur C. Cope Scholar Award sponsored by The American Chemical Society (2002), the Multiple Myeloma Research Foundation Senior Award (2010), the ACS Ernest Guenther Award in the Chemistry of Natural Products sponsored by Givoudan and The American Chemical Society (2011), the Japanese Society for the Promotion of Science Long-term Fellowship (2012-2013) and the local Rocky Mountain section of the American Chemical Society Organic Synthesis Award (2012).

8. My educational background, work experience, publications, and honors are set forth in my *curriculum vitae*, attached to this report as Exhibit A.

9. Below is a list of the cases where I have testified as an expert at trial or by deposition in the past four years: *Lundbeck v. Infosint.*, C.A. No. 1:06-cv-

02869-LAK-RLE (S.D.N.Y.); *Sanofi-Aventis v. Apotex and Hospira*; C.A. No. 1:07-cv-00721-GMS (D. Del.) (consolidated); *Johnson & Johnson, Cordis Corp., and Wyeth ("J&J") v. Abbott Laboratories, Abbott Cardiovascular Systems, Inc., Boston Scientific Corp., Boston Scientific SciMed, Inc., Medtronic, Inc., and Medtronic AVE, Inc.*, C.A. Nos. 3:08-cv-00230-JAP-TJB (D.N.J.) and 3:08-cv-01021-JAP-TJB (D.N.J.); *Allergan, Inc. v. Athena Cosmetics, Inc.*, C.A. Nos. 8:07-01316-JVS-RNB (C.D. Cal.) and 8:09-cv-00328-JVS-RNB (C.D. Cal.); *United Therapeutics Corp. v. Sandoz, Inc.*, C.A. Nos.: 12-cv-01617-PGS-LHG (D.N.J.) and 3:13-cv-00316-PGS-LHG (D.N.J.); *Gilead Sciences, Inc. and Emory University v. Cipla, Ltd.*, C.A. No.: 1:12-cv-06350-RJS (S.D.N.Y.); *Andrulis Pharmaceuticals v. Celgene Corp.*, C.A. No. 1:13-cv-01644-RGA (D. Del.); and *Genzyme Corp. v. Dr. Reddy's Laboratories, Ltd.*, C.A. No. 13-1506-GMS (D. Del.).

10. For this declaration, I have reviewed the '393 patent, its corresponding and related prosecution histories, certain documents referenced therein, and additional references that were part of the state of the art at the time of the invention, as listed in Exhibit B. In addition, I have reviewed the Joint Claim Construction and Pre-Hearing Statement. My opinions are also based on my knowledge, education, training, and experience, in addition to the materials I have relied upon.

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