UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC., APOTEX CORP., ARGENTUM PHARMACEUTICALS LLC, ACTAVIS ELIZABETH LLC, TEVA PHARMACEUTICALS USA, INC., SUN PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMACEUTICAL INDUSTRIES, INC., AND SUN PHARMA GLOBAL FZE,

Petitioners,

V.

NOVARTIS AG,

Patent Owner.

Case IPR2017-00854[1]

U.S. Patent No. 9,187,405

SECOND DECLARATION OF WILLIAM J. JUSKO, PH.D.

Mail Stop Patent Board
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

[1] Cases IPR2017-01550, IPR2017-01946, and IPR2017-01929 have been joined with this proceeding.

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I, William J. Jusko, Ph.D., declare as follows:

I. Introduction

1. I previously submitted a May 2, 2017 declaration in this IPR, Exhibit 2005. I am a Professor of Pharmaceutical Sciences with over 50 years of experience and over 600 research articles in the area of pharmaceutical sciences. I have extensive experience in the design of pre-clinical and human clinical trials. My work has focused on the pharmacology of immunosuppressants and changes in cell trafficking that result. I have studied and published on the pharmacokinetics and pharmacodynamics of fingolimod in several animal species. My full qualifications and expertise are set out in my first declaration along with my *curriculum vitae* and publication list.

2. I understand that Apotex and now other companies have filed Petitions challenging the validity of U.S. Patent No. 9,187,405 ("'405 Patent"), owned by Novartis. The '405 Patent claims methods for ameliorating relapsing-remitting multiple sclerosis (RRMS) by administering 0.5 mg daily of fingolimod without a preceding loading dose. Since the submission of my first declaration, I understand the Board has instituted this IPR.

3. Counsel for Patent Owner Novartis asked me to review the Petitions in view of the Board's Institution Decision, focusing on the declaration from Dr. Barbara Giesser, Exhibit 1002. I understand Novartis filed an application for the

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