UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Taro Pharmaceuticals U.S.A., Inc.,

v.

Apotex Technologies, Inc.

Patent No. 7,049,328 B2

Title: USE FOR DEFERIPRONE

DECLARATION OF JAYESH MEHTA, M.D., IN SUPPORT OF THE PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,049,328 B2

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I, Jayesh Mehta, M.D., declare as follows:

I. INTRODUCTION

1. I have been retained by Taro Pharmaceuticals U.S.A., Inc., in connection with its petition for *inter partes* review of U.S. Patent No. 7,049,328 (Ex. 1001) ("the '328 Patent"). The statements set forth in this declaration are based on my own personal knowledge. Although I am being compensated for the time spent preparing this declaration, my compensation is not contingent on the outcome of this proceeding, the related litigation, or on any of the opinions provided below. I have no financial interest in these proceedings.

2. The opinions set forth in this declaration are my own. My opinions are based on many years of experience in the field of hematology and oncology, teaching medical students, residents and fellows, and treating patients with malignant and non-malignant hematologic diseases. In forming my opinions, I also relied on the documents discussed in this declaration.

II. BACKGROUND AND QUALIFICATIONS

3. I hold an M.D. and I am a Professor of Medicine and Director of the Hematopoietic Stem Cell Transplant Program at the Northwestern University Feinberg School of Medicine, a position I have held since 2000. I am also Deputy Director of the Northwestern University Comprehensive Transplant Center and have held this position since 2010. I have extensive experience as a hematologist

working with patients who have a range of blood disorders, and I have experience with the use of iron chelators.

4. Prior to joining Northwestern University, from 1999–2000, I was a Professor of Medicine and Clinical Director of the Division of Transplantation Medicine, and Director of the Myeloma and Lymphoma Program, at the South Carolina Cancer Center and Palmetto Richland Memorial Hospital, University of South Carolina. From 1996–1999, I was an Associate Professor of Medicine and Chief of the Section of Allogeneic Stem Cell Transplantation (1998–1999) in the Myeloma and Transplantation Research Center at the University of Arkansas for Medical Sciences.

5. I performed fellowships in the Department of Bone Marrow Transplantation and Cancer Immunobiology at the Hadassah University Hospital in Jerusalem, Israel, from 1991–1992, and in the Leukemia and Myeloma Units in the Department of Medical Oncology at the Royal Marsden Hospital in London, England, from 1992–1996. I was also a lecturer in Hematology at the Seth GS Medical College and King Edward VII Memorial Hospital, in Mumbai, India, in 1990.

6. I received an M.B.B.S. (a first medical degree) from Bombay University, India, in 1985 and an M.D. in internal medicine from Bombay University in 1990. I practiced clinical hematology in India from 1989-1991.

7. I am board certified in internal medicine and hematology and licensed to practice medicine in Illinois.

8. I currently treat patients for various blood disorders and also conduct research in the areas of hematopoietic stem cell transplantation, use of hematopoietic stem cells for experimental and clinical tissue repair, multiple myeloma, and opportunistic infections in immunocompromised patients. While practicing in India from 1989-1991, I was directly involved with the care of several transfusion-dependent patients who received deferiprone. These patients were treated with a regimen of deferiprone at a dose range of 75 to 99 mg/kg of body weight per day. Some of my work from this time period has been published. *See*, for example, Mehta J. et al., *Autoantibodies in Thalassaemia Major: Relationship with Oral Iron Chelator L1*, J. ASSOC. PHYSICIANS INDIA, 1993, 41(6):339–41 (Ex. 1031). Even after leaving India to practice in Jerusalem, Israel, and London, UK, I continued to collaborate with my Indian colleagues and thus continued be involved with the treatment of these patients through 1995. Since 1995, I have treated many additional patients with iron chelators including deferiprone, and continued to follow the clinical literature describing treatment of blood transfusion-dependent patients with deferiprone. I have always prescribed deferiprone to transfusion-dependent patients in a dose range of 75 to 99 mg/kg of body weight per day.

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