UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TARO PHARMACEUTICALS U.S.A., INC.,
Petitioners,

v.

APOTEX TECHNOLOGIES, INC.,
Patent Owner.

Case IPR2017-01446
U.S. Patent No. 7,049,328

Title: USE FOR DEFERIPRONE

DECLARATION OF THOMAS D. COATES, M.D.,
IN SUPPORT OF PATENT OWNER'S PRELIMINARY RESPONSE

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IX. THE PRIMARY REFERENCES OF GROUNDS 1-5 FAIL TO DISCLOSE EACH ELEMENT OF CLAIMS 1, 2, 4-10, AND DEPENDENT CLAIMS THEREFROM 19

A. MIMS does not anticipate claims 1, 2, and 4-10 or dependent claims therefrom (Ground 1) 20

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1. MIMS does not disclose treating a patient having an iron overload condition of the heart 20

2. MIMS does not disclose the therapeutically effective amount of deferiprone required by claims 1, 2, and 4-10 as defined by the specific claimed results of claims 1, 2, 4-10, and 19.....21

B. Hoffbrand 1998 (Ground 2) does not disclose the therapeutically effective amount of deferiprone required by claims 1, 2, and 4-10 as defined by the specific claimed results of claims 1, 2, 4-10, and 19 ..23

C. Olivieri Abstract 1995 does not anticipate claims 1, 2, and 4-10 or dependent claims therefrom (Ground 3) 25

1. Olivieri Abstract 1995 does not disclose treating a patient having an iron overload condition of the heart.....25

2. Olivieri Abstract 1995 does not disclose the therapeutically effective amount of deferiprone required by claims 1, 2, and 4-10 as defined by the specific claimed results of claims 1, 2, 4-10, and 19.....26

D. Agarwal does not anticipate claims 1, 2, and 4-10 or dependent claims therefrom (Ground 4) 28

1. Agarwal does not disclose treating a patient having an iron overload condition of the heart 28

2. Agarwal does not disclose the therapeutically effective amount of deferiprone required by claims 1, 2, and 4-10 as defined by the specific claimed results of claims 1, 2, 4-10, and 19.....29

E. Olivieri 1995 does not anticipate claims 1, 2, 4-10 or dependent claims therefrom (Ground 5).....30

1. Olivieri 1995 does not disclose treating a patient having an iron overload condition of the heart 30

2. Olivieri 1995 does not disclose the therapeutically effective amount of deferiprone required by claims 1, 2, and 4-10 as defined by the specific claimed results of claims 1, 2, 4-10, and 19.....31

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X. Claims 1, 2, 4-17, and 19 Are Not Obvious Over the Primary References in View of the Knowledge of a POSA 32

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I, Thomas D. Coates, M.D., declare as follows:

I. INTRODUCTION

1. I have been retained by Cozen O'Connor LLP, counsel for Apotex Technologies, Inc. ("Apotex"), to provide my expert testimony in this proceeding.

2. Although I am being compensated for my work on this matter, my compensation does not in any way depend on the outcome of this *inter partes* review or any related proceeding.

3. The opinions set forth in this declaration are based on my education, knowledge, and experience in hematology, particularly the diagnosis and management of transfusion related iron overload, as well as my review of relevant materials discussed herein.

II. BACKGROUND AND QUALIFICATIONS

1. The following is a brief summary of my background and qualifications, the full extent of which can be found in my *curriculum vitae*. (Ex. 2002.)

2. I am a recognized leader in hematology, particularly the diagnosis and management of transfusion-related iron overload. Since 1991, I have been the Section Head of the Hematology-Division of Pediatric Hematology-Oncology at Children's Hospital Los Angeles ("CHLA"). Since 1992, I have held the positions of tenured Associate and tenured (since 2005) full Professor of Pediatrics and

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