

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**

Table of Contents

I.	INTRODUCTION	1
II.	BACKGROUND AND QUALIFICATIONS	1
III.	LEGAL STANDARDS	4
	A. Anticipation	4
	B. Obviousness.....	5
IV.	BACKGROUND OF THE TECHNOLOGY	6
	A. Thalassemia	6
	B. Iron Overload	7
	C. Iron Chelation Therapy	7
V.	THE '328 PATENT	10
VI.	LEVEL OF ORDINARY SKILL IN THE ART	13
VII.	CLAIM CONSTRUCTION	14
VIII.	THE ALLEGED PRIOR ART	15
	A. MIMS (Ex. 1009)	15
	B. Hoffbrand 1998 (Ex. 1007)	16
	C. Olivieri Abstract 1995 (Ex. 1010).....	17
	D. Agarwal (Ex. 1011)	17
	E. Olivieri 1995 (Ex. 1012)	18
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

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

X. Claims 1, 2, 4-17, and 19 Are Not Obvious Over the Primary References in View of the Knowledge of a POSA32

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

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.