UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

APOTEX TECHNOLOGIES, INC.,
Patent Owner.

Case IPR2017-01446
U.S. Patent No. 7,049,328 B2

Title: USE FOR DEFERIPRONE

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

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

Table of Contents

I. INTRODUCTION 1

II. INSTITUTED GROUNDS 1

III. BACKGROUND OF THE TECHNOLOGY 2

A. Methods to Assess Cardiac Function 2

B. Iron Chelation Therapy in Blood Transfusion Dependent Thalassemia Patients 3

IV. THE '328 PATENT 4

V. LEVEL OF ORDINARY SKILL IN THE ART 4

VI. CLAIM CONSTRUCTION 4

VII. THE PRIOR ART 6

A. Hoffbrand 1998 (Ex. 1007) 6

B. Olivieri Abstract 1995 (Ex. 1010) 6

C. Olivieri 1995 (Ex. 1012) 7

VIII. THE PRIMARY REFERENCES FAIL TO DISCLOSE EACH ELEMENT OF CLAIMS 1, 2, 4-10, AND DEPENDENT CLAIMS THEREFROM 7

A. Hoffbrand 1998 does not explicitly or inherently disclose or teach or suggest each and every claim limitation 8

1. Hoffbrand 1998 does not disclose or teach or suggest treating a blood transfusion dependent patient having a condition on the spectrum of cardiac disease due to iron overload 8

2. Hoffbrand 1998 does not disclose or teach or suggest administering a therapeutically effective amount of deferiprone such that the methods of treatment required by claims 1, 2, and 4-10 were successfully practiced 9

B. Olivieri Abstract 1995 does not explicitly or inherently disclose or teach or suggest each and every claim limitation 12

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

1. Olivieri Abstract 1995 does not disclose treating a blood transfusion dependent patient having a condition on the spectrum of cardiac disease due to iron overload 12

2. Olivieri Abstract 1995 does not disclose administering a therapeutically effective amount of deferiprone such that the methods of treatment required by claims 1, 2, and 4-10 are practiced 13

C. Olivieri 1995 does not explicitly or inherently disclose or teach or suggest each and every claim limitation 14

1. Olivieri 1995 does not disclose or suggest treating a blood transfusion dependent patient having a condition on the spectrum of cardiac disease due to iron overload 14

2. Olivieri 1995 does not disclose or suggest administering a therapeutically effective amount of deferiprone such that the methods of treatment required by claims 1, 2, and 4-10 are practiced 16

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

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

I. INTRODUCTION

1. I previously provided a declaration (Ex. 2001) dated September 8, 2017 in these proceedings in support of Patent Owner's Preliminary Response ("First Coates Decl."). In it, I expressed my opinion that the subject matter claimed in U.S. Patent 7,049,328 ("the '328 patent") is novel and non-obvious, as those concepts have been explained to me, over the prior art references cited by Taro Pharmaceuticals USA, Inc. ("Taro" or "Petitioner").

2. My background and qualifications, set forth in paragraphs 1-7 of the First Coates Decl. (Ex. 2001), remain unchanged. Further, my *curriculum vitae* ("CV"), previously submitted as Ex. 2002, remains unchanged.

3. The opinions I expressed in the First Coates Decl. (Ex. 2001) also remain unchanged. Thus, the opinions I express in this Second Declaration are in addition to those expressed in the First Coates Decl. (Ex. 2001.)

II. INSTITUTED GROUNDS

4. The following table summarizes the claims of the '328 patent challenged by Taro and the bases and references providing grounds for institution of this *Inter Partes* Review ("IPR"):

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

Reference(s)	Basis	Claims Challenged
Hoffbrand 1998	§ 102(b)	1, 2, 4-11, 13-17, 19
Olivieri Abstract 1995	§ 102(b)	1, 2, 4-11, 13-17, 19
Olivieri 1995	§ 102(b)	1, 2, 4-11, 13-17, 19
Hoffbrand 1998	§ 103(a)	1, 2, 4-17, 19
Olivieri Abstract 1995	§ 103(a)	1, 2, 4-17, 19
Olivieri 1995	§ 103(a)	1, 2, 4-17, 19

(Institution Decision at 41.)

5. It has been explained to me that "§ 102(b)" stands for the section of the patent statute pertaining to anticipation. My understanding of the legal standards for anticipation are the same as set forth in the First Coates Decl. (Ex. 2001 at ¶¶ 9-11.)

6. It has been explained to me that "§ 103(a)" stands for the section of the patent statute pertaining to obviousness. My understanding of the legal standards for obviousness are the same as set forth in the First Coates Decl. (Ex. 2001 at ¶¶ 12-15.)

III. BACKGROUND OF THE TECHNOLOGY

7. The background of the technology, set forth in paragraphs 16-24 of the First Coates Decl. (Ex. 2001), remains unchanged. I further supplement the background of the technology as follows.

A. Methods to Assess Cardiac Function

8. As a hematologist, in order to evaluate cardiac function in blood transfusion dependent patients, I rely on and work in concert with cardiologists,

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

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.