# 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 Patent No. 7,049,328 B2 Title: USE FOR DEFERIPRONE Inter Partes Review No. IPR2017-01446

PETITIONER'S REPLY



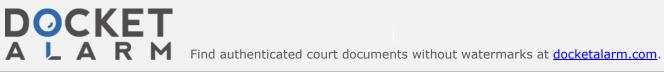
# **TABLE OF CONTENTS**

I.	INTRO	TRODUCTION			
II.	CLAIN	M CONSTRUCTION	2		
	A.	The Claims Require a "Therapeutically Effective Amount of Deferiprone" and 75 mg/kg/day Meets This Limitation	3		
	В.	Some Claims Are Drawn to Treating Iron Loading in the Heart; Some Claims Are Drawn to Treating Cardiac Disease	4		
	C.	Because the Intended Results Are Not Limiting, the Claims Do Not Require "Successful Practice" of the Claimed Methods			
		Claim Differentiation Does Not Transform the Intended     Results into Limitations	6		
		2. The Successful Achievement of the Claimed Results Is Not Relevant to Patentability	8		
III.	THE CLAIMS ARE ANTICIPATED BY THE PRIOR ART				
	A.	Olivieri Abstract 1995 Anticipates the Challenged Claims	11		
	B.	Olivieri 1995 Anticipates the Challenged Claims	14		
	C.	Hoffbrand 1998 Anticipates the Challenged Claims	16		
IV.	THE	CLAIMS ARE OBVIOUS OVER THE PRIOR ART	19		
	A.	The Prior Art Does Not Teach Away from Treating Iron-Induced Cardiac Disease with Deferiprone	21		
	B.	The Other Secondary Considerations Do Not Support	23		



# TABLE OF AUTHORITIES

	Page(s)
Cases	
Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368 (Fed. Cir. 2001)	2, 7, 8
Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc., 752 F.3d 967 (Fed. Cir. 2013)	24
Connell v. Sears, Roebuck & Co., 722 F.2d 1542 (Fed. Cir. 1983)	19
Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560 (Fed. Cir. 1988)	12
<i>In re Huai-Hung Kao</i> , 639 F.3d 1057 (Fed. Cir. 2011)	24
King Pharms., Inc. v. Eon Labs., Inc., 616 F.3d 1267 (Fed. Cir. 2010)	8
Wi-Lan USA, Inc. v. Apple Inc., 830 F.3d 1374 (Fed. Cir. 2016)	6



### I. INTRODUCTION

Cardiac health was of central importance to doctors treating blood-transfusion-dependent patients. Cardiac disease was the main cause of death for these patients prior to the introduction of chelation therapy; it was a concern when patients were treated with the original iron chelator, deferoxamine, and continued to be a concern with deferiprone. Doctors understood that cardiac iron was the culprit, and the prior art studied this issue. For example, the '328 patent cites Dr. Olivieri's early work, which recognized that "deferiprone induced reduction of iron in the liver and the heart." (Ex. 1001, 7:47–54.) Doctors, including Dr. Olivieri and Dr. Hoffbrand, administered deferiprone to blood-transfusion-dependent patients in order to reduce iron overload, which they understood would reduce their cardiac iron, which would in turn improve heart function and treat cardiac disease.

Patent Owner ("PO") defends its patent by claiming that the named inventors came up with a "new use" for the admittedly old drug deferiprone. But the prior art not only taught the administration of 75 mg/kg/day deferiprone to blood-transfusion-dependent patients, it also taught administering that amount of deferiprone to such patients (i) with cardiac iron overload and (ii) with iron-induced cardiac disease, (iii) with positive results. "Newly discovered results of known processes directed to the same purpose are not patentable, because such



results are inherent." *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.,* 246 F.3d 1368,1376 (Fed. Cir. 2001). Because the claimed methods of treatment are directed to the same patient populations with the same drug in the same amount as in the prior art, the Board should find that the claims are unpatentable and cancel the challenged claims.

### II. CLAIM CONSTRUCTION

All of the claims are directed to treating blood-transfusion-dependent patients by administering a therapeutically effective amount of deferiprone. The preambles identify the method and the type of patient; the independent claims (and claim 19) each recite an intended result:

Claim	Method of	Type of Patient	Intended Result
1	treating iron induced cardiac disease	experiencing an iron overload condition of the heart	to stabilize/reduce iron accumulation in the heart
2	treating iron loading in the heart	experiencing an iron overload condition of the heart	to reduce further iron overload in the heart
4	stabilizing iron induced heart disease	having iron overload	to treat the iron burden in the heart
5	reducing the iron burden in the heart	having iron overload	to reduce the iron burden of the heart



# DOCKET

# 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.

