

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC. AND APOTEX CORP.,
Petitioners,

v.

AUSPEX PHARMACEUTICALS, INC.,
Patent Owner.

Case No. IPR2021-01507
U.S. Patent No. 8,524,733

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

TABLE OF AUTHORITIES iii

PATENT OWNER’S EXHIBIT LIST v

INTRODUCTION 1

BACKGROUND 3

I. Tetrabenazine..... 3

II. Deuteration. 7

III. The ’733 Patent..... 13

 A. The Challenged Claims. 13

 B. Summary of Relevant Prosecution History..... 14

ARGUMENT 15

IV. The Board Should Exercise its Discretion Under §§ 325(d) and 314(a)
to Deny Institution. 15

 A. The Office Substantively Considered the Same Prior Art and
Arguments Raised in the Petition..... 16

 1. Petitioners’ Tetrabenazine References Were Before the
Examiner. 17

 2. Petitioners’ Deuteration References Are Cumulative..... 18

 3. Petitioners’ Arguments Overlap with the Arguments
Made During Prosecution. 22

 B. The Petitioners Cannot Demonstrate that the Office Erred in a
Manner Material to the Patentability of the Challenged Claims..... 24

 1. Petitioners’ Art and Arguments Were Closely Evaluated. 25

 2. Petitioners Fail to Identify Any Material Error that
Warrants Reconsideration..... 25

C.	The Board Should Exercise its Discretion to Deny Institution Due to Petitioners’ Attempted Extortion.....	33
V.	Petitioners Have Not Established a Reasonable Likelihood of Prevailing on Any Ground.....	34
A.	Petitioners’ Reference Provides a Blueprint for Solving Tetrabenazine’s Alleged Problems.	35
B.	The POSA Would Not Have Been Motivated to Deuterate Tetrabenazine with a Reasonable Expectation of Success.....	41
1.	Side Effects.	41
2.	Duration of Action.	45
3.	Physicochemical Properties.	61
C.	Petitioners’ Arguments About the Sites of Deuteration Are Predicated on Hindsight.	64
D.	Objective Indicia of Nonobviousness.	72
1.	Unexpected Properties.	72
2.	Other Objective Indicia.....	74
	CONCLUSION.....	75

TABLE OF AUTHORITIES

CASES

Advanced Bionics, IPR2019-01469, Paper 6 (Feb. 13, 2020)16, 24, 25

Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586,
Paper 8 (Dec. 15, 2017)16, 20, 24

Canon Inc. v. Papst Licensing GmbH & Co. KG, IPR2016-01202, Paper 15
(Dec. 15, 2016)19

Cosmax Co. v. AmorePacific Corp., IPR2018-01516, Paper 8
(Feb. 20, 2019).....20

CSL Behring GmbH v. Shire Viropharma Inc. IPR2019-00459, Paper 8 (Jul.
2, 2019)30

Ex parte Allen, Appeal No. 2018-008208 (Application No. 14/712,101,
July 1, 2020).....40

In re Rouffet, 149 F.3d 1350 (Fed. Cir. 1998)75

Kinetic Concepts, Inc. v. Smith & Nephew, Inc., 688 F.3d 1342
(Fed. Cir. 2012).....40

Leo Pharm. Prods. v. Rea, 726 F.3d 1346 (Fed. Cir. 2013).....7, 74

Microsoft Corp. v. Koninklijke Philips N.V., IPR2018-00277, Paper 11 (Jun.
8, 2018)19

Neptune Generic v. Auspex Pharmaceuticals, IPR2015-01313, Paper 25
(Dec. 9, 2015)13

Puma, Inc. v. Nike Inc., IPR2019-01042, Paper 10 (Oct. 31, 2019)18, 25

Regeneron Pharms. v. Merus N.V., 864 F.3d 1343 (Fed. Cir. 2017)22

Roku Inc. v. Universal Electronics, Inc. IPR2019-01619, Paper 11 (Apr. 2,
2020)21

Unified Patents Inc. v. Berman, IPR2016-01571, Paper 10 (Dec. 14, 2016)....21, 24

Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044 (Fed. Cir. 1988).....74
Winner Int’l Royalty Corp. v. Wang, 202 F. 3d 1340 (Fed. Cir. 2000).....40

OTHER AUTHORITIES

37 C.F.R. § 42.6(a)(3).....68
35 U.S.C. § 103(c)15
35 U.S.C. § 314(a)33, 34
35 U.S.C. § 325(d) 2, 14, 15, 19, 20, 28, 34

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.