

Paper No. _____
Filed: August 9, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC,
Petitioner

v.

ALKERMES PHARMA IRELAND LIMITED,
Patent Owner

Case IPR2018-00943
Patent 7,919,499

**Patent Owner's Preliminary Response
to Petition for *Inter Partes* Review
of U.S. Patent No. 7,919,499**

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. BACKGROUND	2
A. Naltrexone Is Unlike Other Treatments for Substance Use Disorder	3
B. The Need for a Better Alternative Lasted Decades.....	5
C. Vivitrol Is the Only FDA-Approved Depot Injection Product that Solves the Problems Associated With Oral Naltrexone.....	9
III. AMNEAL’S ALLEGED INVALIDITY GROUNDS.....	12
A. The ’499 Patent Claims Methods of Treating with Novel Formulations of Naltrexone That Are Capable of Achieving an Unexpected AUC Profile.....	12
B. The Prior Art Fails to Teach Naltrexone Formulations Having the Claimed Dose and AUC Profile	13
C. Grounds 1 and 2: Disguised as Anticipation Grounds, Amneal’s Arguments Are Improper, Unsupported, and Lack Requisite Disclosures of Key Elements.....	15
1. Amneal’s Anticipation Arguments Are Flawed Because They Rely on Multiple References	16
2. Ground 1: The Comer Ground Is Flawed	17
a. Comer Fails to Teach Treating a Patient in Need of Naltrexone	18
b. Comer Fails to Teach the Claimed Serum AUC Profile.....	19
c. Comer’s Reference to Depotrex is Insufficient to Teach the Claimed Formulation	26
3. Ground 2: The Nuwayser Ground Is Flawed.....	30

TABLE OF CONTENTS

(continued)

	Page
a. Amneal’s Ground 2 Suffers from the Same Deficiencies as Ground 1	30
b. Nuwayser Fails to Teach the Claimed Dose and AUC Profile.....	31
4. Amneal’s Argument Regarding Use of a Secondary Reference Contravenes the Law on Anticipation	32
5. Conclusion.....	33
D. Grounds 3 and 4: As the Obviousness-Equivalents of Grounds 1 and 2, Amneal’s Arguments Incorrectly Rely on Hindsight and Lack Support	33
1. Even Combined, Comer and Nuwayser Still Suffer from Striking Deficiencies	34
2. There Is No Motivation or Reasonable Expectation of Success.....	35
3. Amneal’s Arguments Rely on Hindsight	38
4. Comer Teaches Away from the Claimed Invention	40
5. Amneal Has Not Shown that the Dependent Claims Are Obvious	42
6. Conclusion.....	44
E. Ground 5: Amneal’s Arguments Rely on Questionable Analysis and Ignore Key Results that Teach Away from the Claimed Invention.....	44
F. Ground 6: Amneal’s Arguments Are Flawed Because They Are Hindsight Driven and Not Based on References Shown to be Printed Publications	47

TABLE OF CONTENTS

(continued)

	Page
1. Amneal Has Not Established that the Alkermes 10-K and the Vivitrex Specimen Qualify as Printed Publications Under 35 U.S.C. § 311(b).....	47
a. Amneal Has Failed to Establish that the Alkermes 10-K Is a Printed Publication	48
b. Amneal Has Failed to Establish that the Vivitrex Specimen Is a Printed Publication	51
2. Amneal Has Not Established that a POSA Would Have Combined the Alkermes 10-K, the Vivitrex Specimen, and Wright	53
3. The Asserted Combination of References Does Not Teach or Suggest All Claim Features	54
IV. SECONDARY INDICIA OF NONOBVIOUSNESS.....	55
A. The Claimed Invention Provided Unexpected Results	56
B. Others Failed and There Was a Long-Felt, But Unsolved, Need	58
C. There Was Skepticism in the Industry.....	59
D. Commercial Success	60
V. THE BOARD SHOULD EXERCISE ITS DISCRETION TO DENY THE PETITION UNDER 35 U.S.C. § 325(D)	61
VI. AMNEAL’S CLAIM CONSTRUCTIONS ARE UNNECESSARY OR INCORRECT	62
VII. CONCLUSION	63

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>A.R.M., Inc. v. Cottingham Agencies Ltd.</i> , IPR2014-00671, Paper 10 (Oct. 3, 2014)	48
<i>Actavis, Inc. v. Research Corp. Techs., Inc.</i> , IPR2014-01126, Paper 21 (Jan. 9, 2015).....	48
<i>Apple Inc. v. ITC</i> , 725 F.3d 1356 (Fed. Cir. 2013)	55
<i>Arendi S.A.R.L. v. Apple Inc.</i> , 832 F.3d 1355 (Fed. Cir. 2016)	46
<i>Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.</i> , 776 F.2d 281 (Fed. Cir. 1985)	23
<i>In re Baxter Travenol Labs.</i> , 952 F.2d 388 (Fed. Cir. 1991)	32
<i>Brown & Williamson Tobacco Corp. v. Philip Morris Inc.</i> , 229 F.3d 1120 (Fed. Cir. 2000)	60
<i>Celltrion, Inc. v. Biogen, Inc.</i> , IPR2017-01095, Paper 12 (Oct. 6, 2017)	50
<i>Cheese Sys., Inc. v. Tetra Pak Cheese & Powder Sys., Inc.</i> , 725 F.3d 1342 (Fed. Cir. 2013)	33
<i>Coal. For Affordable Drugs III LLC v. Jazz Pharms., Inc.</i> , IPR2015-01018, Paper 17 (Oct. 15, 2015)	48
<i>Coal. For Affordable Drugs IV LLC v. Pharmacyclics, Inc.</i> , IPR2015-01076, Paper 33 (Oct. 19, 2015)	48
<i>Coal. For Affordable Drugs XI LLC v. Insys Pharma, Inc.</i> , IPR2015-01797, Paper 9 (Mar. 10, 2016)	2, 21
<i>Coal. For Affordable Drugs XI LLC v. Insys Pharma, Inc.</i> , IPR2015-01799, Paper 9 (Mar. 10, 2016)	2, 21, 23

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.