

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

KASHIV PHARMA, LLC,  
Petitioner,

v.

PURDUE PHARMA L.P.,  
THE P.F. LABORATORIES, INC., and  
PURDUE PHARMACEUTICALS L.P.,  
Patent Owners.

---

Case IPR2018-00717  
U.S. Patent No. 9,492,393

---

**PATENT OWNER PRELIMINARY RESPONSE**



# TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES .....	iii
TABLE OF ABBREVIATIONS .....	v
LIST OF EXHIBITS .....	vi
I. INTRODUCTION .....	1
II. BACKGROUND .....	3
A. OxyContin® .....	3
B. The '393 Patent and Prosecution History.....	4
C. Pending Litigations.....	6
D. The Impax Merger.....	7
III. PERSON OF ORDINARY SKILL IN THE ART (“POSA”).....	8
IV. CLAIM CONSTRUCTION .....	8
A. “Compression Shaped” And “Compression” .....	9
B. “Curing” .....	10
C. “Optionally” .....	11
D. “Total Combined Weight Of Said High And Low Molecular Weight PEO” .....	11
E. “Selected From The Group Consisting Of 4,000,0000; 7,000,000; And A Combination Thereof” .....	12
F. Product-By-Process Limitations .....	13
V. THE PETITION SHOULD BE DENIED BECAUSE PETITIONER HAS NOT IDENTIFIED AMNEAL AS A REAL PARTY-IN- INTEREST .....	16
A. Legal Standards Governing Real-Parties-In-Interest .....	16
1. Factors relevant to determining who is a real-party-in- interest.....	17
2. 35 U.S.C. § 315(b) Time Bar.....	18
B. Amneal Is A Real-Party-In-Interest .....	19

**TABLE OF CONTENTS**  
(continued)

	<b>Page</b>
1. [REDACTED].....	19
2. [REDACTED].....	22
3. Amneal and Kashiv were represented by the same counsel in prior IPRs, and are currently represented by the same counsel in a litigation involving the '393 patent .....	25
4. Kashiv equates itself with Amneal in its Petition.....	27
C. The Petition Should Be Time-Barred Under 35 U.S.C. § 315(b).....	28
<b>VI. THE PETITION SHOULD BE DENIED BECAUSE PETITIONER'S ASSERTED PRIOR ART AND ARGUMENTS HAVE ALREADY BEEN REJECTED BY THE EXAMINER.....</b>	<b>29</b>
A. The Examiner Determined That Purdue's Density Testing Results Were Unexpected .....	31
1. A POSA would have expected curing to increase the density .....	32
2. Purdue's data establishes an unexpected density decrease.....	34
3. Decreased density provides superior results .....	40
4. Decreased density is not a latent property .....	42
B. The Petition Presents Substantially The Same Prior Art Or Arguments Previously Considered By The Office .....	43
1. Ground 1 Presents Substantially The Same Prior Art Or Arguments Previously Considered By The Office .....	44
2. Ground 2 Presents Substantially The Same Prior Art Or Arguments Previously Considered By The Office .....	47
<b>VII. CONCLUSION.....</b>	<b>50</b>

**TABLE OF AUTHORITIES**

	<b>Page</b>
<b>CASES</b>	
<i>Apotex Inc. et al. v. Osi Pharms, Inc.</i> , IPR2016-01284, Paper 8 (P.T.A.B. Jan. 9, 2017) .....	30
<i>Atlanta Gas Light Co. v. Bennet Regulatory Guards, Inc.</i> , IPR2013-00453, Paper 88 (P.T.A.B. Jan. 6, 2015) .....	passim
<i>Becton, Dickinson and Company v. B. Braun Melsungen AG</i> , IPR2017-01586, Paper 8 (P.T.A.B. Dec. 15, 2017) .....	30
<i>Cisco Systems, Inc. v. C-Cation Tech., LLC</i> , IPR2014-00454, Paper 12 (P.T.A.B. Aug. 29, 2014).....	39
<i>Harmonic Inc. v. Avid Tech, Inc.</i> , 815 F.3d 1356 (Fed. Cir. 2016) .....	29
<i>In re Baxter Travenol, Labs.</i> , 952 F.2d 389392 (Fed. Cir. 1991) .....	43
<i>In re Garnero</i> , 412 F.2d 276 (CCPA 1979) .....	14
<i>Johnson Health v. ICON Health and Fitness</i> , IPR2014-01242, Paper 16 (P.T.A.B. Feb. 11, 2015).....	27
<i>Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.</i> , 831 F.3d 1350 (Fed. Cir. 2016) .....	13
<i>Petroleum Geo-Services, Inc. v. WesternGeco, L.L.C.</i> , IPR2014-00689, Paper 22 (P.T.A.B. Aug. 12, 2014).....	18
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005) .....	9

...

*Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals LLC*,  
17-cv-00210-RGA (D. Del. Mar. 1, 2017).....6, 26

*Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals LLC*,  
C.A. No. 15-1152-RGA (D. Del. Dec. 15, 2015).....19, 22

*Purdue Pharma L.P. v. Kashiv*,  
17-cv-210, D.I. 86 (D. Del. Mar. 23, 2018).....26

*Unified Patents Inc. v. John L. Berman*,  
IPR2016-01571, Paper 10 (P.T.A.B. Dec. 14, 2016).....50

*Zoll Lifecor Corp. v. Electronics N. Am. Corp. et al.*,  
IPR2013-00609, Paper 15 (P.T.A.B. Mar. 20, 2014).....passim

**STATUTES**

35 U.S.C. 315(d) .....2

35 U.S.C. § 312(a)(2).....16

35 U.S.C. § 315(b) .....1, 18, 28

35 U.S.C. § 325(d) .....29, 43

**OTHER AUTHORITIES**

37 C.F.R. 42.100(b) .....8

37 C.F.R. § 42.6(a)(3).....39

77 Fed. Reg. 48,759 (Aug. 14, 2012)..... 16-18, 21

77 Fed. Reg. 48,760 (Aug. 14, 2012).....25

# 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.