

In the United States Patent and Trademark Office

---

Before the Patent Trial and Appeal Board

---

AMERIGEN PHARMACEUTICALS LIMITED,

Petitioner,

v.

SHIRE LLC,

Patent Owner

---

U.S. Patent No. 8,846,100 to Shojaei *et al.*  
Appl. No. 11/383,066, filed May 12, 2006  
Issue Date: September 30, 2014

Title: CONTROLLED DOSE DRUG DELIVERY SYSTEM

---

Inter Partes Review No. Unassigned

---

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,846,100  
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §§ 42.100 *et. seq.***

## TABLE OF CONTENTS

<b>TABLE OF CONTENTS</b> .....	<b>i</b>
<b>TABLE OF AUTHORITIES</b> .....	<b>iv</b>
<b>EXHIBIT LIST</b> .....	<b>viii</b>
<b>I. INTRODUCTION</b> .....	<b>1</b>
<b>II. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)</b> .....	<b>2</b>
A. Real Party-In-Interest [37 C.F.R. § 42.8(b)(1)]:.....	2
B. Related Matters [37 C.F.R. § 42.8 (b)(2)]: .....	2
C. Designation of Lead and Back-Up Counsel [37 C.F.R. § 42.8 (b)(3)]: .....	2
D. Service Information [37 C.F.R. § 42.8(b)(4)]: .....	2
E. Fee Payment and Power of Attorney [37 C.F.R. §§ 42.10(b), 42.103]: .....	3
<b>III. REQUIREMENTS FOR <i>INTER PARTES</i> REVIEW</b> .....	<b>3</b>
A. Grounds for Standing [37 C.F.R. § 42.104(a)]:.....	3
B. Identification of the Challenge [37 C.F.R. § 42.104(b)]: .....	3
1. <i>Relevant Information Regarding the '100 Patent</i> .....	3
a. Specification.....	4
b. Claims. ....	5
c. Prosecution History. ....	6
d. Person of Ordinary Skill in the Art. ....	14
2. <i>Statement of Precise Relief Requested. [37 C.F.R. § 42.104(b)(1)]</i> 15	

3.	<i>Specific Statutory Grounds On Which The Challenge Is Based And Prior Art References Relied Upon. [37 C.F.R. §§ 42.104(b)(2) and (b)(4)]</i> .....	15
4.	<i>Challenged Claim Construction. [37 C.F.R. § 42.104(b)(3)]</i> .....	15
<b>IV.</b>	<b>DETAILED DESCRIPTION OF THE PRIOR ART UPON WHICH THE CHALLENGE IS BASED.</b> .....	<b>19</b>
A.	Technology Background.....	19
1.	<i>Amphetamine Was A Well-Known ADHD Treatment</i> .....	19
2.	<i>The Science of Drug Coatings, Release Timing, And Release Rates Was Well-Known.</i> .....	19
3.	<i>“Sculpting The Dose” Was Well-Known.</i> .....	21
B.	Printed Publications Relied Upon. ....	21
1.	<i>The ’819 Patent</i> .....	21
2.	<i>The ’300 Patent</i> .....	23
3.	<i>Kratochvil.</i> .....	25
4.	<i>Additional Prior Art Confirming the General Knowledge of the Ordinarily-Skilled Artisan.</i> .....	27
<b>V.</b>	<b>THE CONSTRUED CLAIMS ARE UNPATENTABLE, 37 C.F.R. § 42.104(b)(4).</b> .....	<b>28</b>
A.	Standard of Invalidity under 37 C.F.R. § 42.104(b)(4). ....	28
B.	Explanation Of Ground 1 For Unpatentability: The ’819 Patent Anticipates Each of the 31 Claims of the ’100 Patent. ....	32
1.	<i>The ’819 Patent Discloses Every Limitation of Independent Claim 1.</i> .....	33
2.	<i>The ’819 Patent Discloses the Modifications to the Pharmaceutical Composition of Claim 1 That Are Claimed by</i>	

*Dependent Claims 2-4, 13--21 and Claim 31.....37*

3. *Claims 5–12 are anticipated by the '819 patent.....43*

4. *The '819 Patent Anticipates Claims 22–30. ....46*

**VI. Conclusion.....60**

## TABLE OF AUTHORITIES

### FEDERAL CASES

<i>Allergan, Inc. v. Apotex Inc.</i> , 754 F.3d 925 (Fed. Cir 2014).....	28
<i>Bristol-Meyers Squibb Co. v. Ben Venue Labs., Inc.</i> , 246 F.3d 1368 (Fed. Cir. 2001) .....	29, 37
<i>Continental Can Co. U.S.A., Inc. v. Monsanto Co.</i> , 948 F.2d 1264 (Fed. Cir. 1991) .....	28, 46, 59
<i>Cuozzo Speed Techs., LLC v. Lee</i> , 136 S. Ct. 2131 (2016).....	16
<i>Dayco Prods. Inc. v. Total Containment, Inc.</i> , 329 F.3d 1358 (Fed. Cir. 2003).....	28
<i>Ex parte A</i> , 17 U.S.P.Q. 2d 1716 (B.P.A.I. 1990) .....	30, 43
<i>Graham v. John Deere Co.</i> , 383 U.S. 1 (1996).....	48
<i>Heartland Tanning, Inc. v. Sunless, Inc.</i> , IPR2014-00018, 2014 WL 1253151 (P.T.A.B., Mar. 13, 2014).....	31
<i>Hybritech Inc. v. Monoclonal Antibodies</i> , 802 F.2d 1367 (Fed. Cir. 1986) .....	29
<i>In re Aller</i> , 220 F.2d 454 (C.C.P.A. 1955) .....	8
<i>In re Applied Materials, Inc.</i> , 692 F.3d 1289 (Fed. Cir. 2012) .....	47, 60
<i>In re Best</i> , 562 F.2d 1252 (C.C.P.A. 1977) .....	28, 42, 45

# 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.