

**UNITED STATES PATENT AND TRADEMARK OFFICE**  
**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

*Aurobindo Pharma USA Inc.*  
Petitioner

v.

*Andrx Corporation,*  
*Andrx Laboratories, Inc.*  
*Andrx Laboratories (NJ), Inc.*  
*Andrx EU Ltd.*  
*Andrx Pharmaceuticals, LLC,*  
*Teva Pharmaceutical Industries Ltd.*  
Patent Owner(s)

U.S. Patent No. 6,866,866 to Chen  
Issue Date: March 15, 2005  
Title: Controlled Release Metformin Compositions

**CORRECTED PETITION FOR *INTER PARTES* REVIEW OF U.S.  
PATENT NO. 6,866,866 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §§  
42.1-.80, 42.100-.123**

*Mail Stop* "PATENT BOARD"  
Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O Box 1450  
Alexandria, VA 22313-1450

TABLE OF CONTENTS

Petitioners' Exhibit List..... v

I. PAYMENT OF FEES ..... 1

II. INTRODUCTION ..... 1

    A. Brief Overview Of The '866 Patent..... 1

    B. Critical Date..... 6

III. STANDING (37 C.F.R. 42.104(A)); PROCEDURAL STATEMENTS.. 7

IV. MANDATORY NOTICES (37 C.F.R. 42.8(A)(1))..... 7

    A. Each Real Party In Interest (37 c.f.r. § 42.8 (b)(1)) ..... 7

    B. Notice Of Related Matters (37 c.f.r. § 42.8(b)(2)) ..... 7

        1. Judicial Matters Involving The '866 Patent..... 7

        2. Administrative Matters..... 8

    C. Designation Of Lead And Back-Up Counsel (37 c.f.r. § 42.8(b)(3) ..... 8

    D. Notice Of Service Information (37 c.f.r. § 42.8(b)(4))..... 9

V. IDENTIFICATION OF CHALLENGE (37 C.F.R. § 42.104(b)) ..... 10

VI. STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR IN RESPECT OF EACH CHALLENGED CLAIMS (37 C.F.R. § 42.22(a)) ..... 10

VII. PERSON OF ORDINARY SKILL IN THE ART IN RESPECT OF '866 PATENT ..... 11

VIII. BACKGROUND OF TECHNOLOGY AND PRIOR ART.....	12
A. Claims 1-25 of the '866 Patent are Unpatentable Under 35 U.S.C. 102(a) Over Chen, WO 00/12097 (EX1007).....	14
B. At Least Claims 1-3 of the '866 patent Are Unpatentable As Anticipated Under 102(a) Over Timmins, WO 99/47128 (EX1003).....	17
C. Claims 1-25 Of The '866 Patent Are Unpatentable As Obvious Under 103 Over Cheng WO 99/47125 (EX1002) In Light Of Timmins WO 99/47128 (EX1003) .....	19
IX. CLAIM CONSTRUCTION IN LIGHT OF A POSA.....	23
A. Claim Construction Standard.....	23
1. "metformin" .....	23
5. "therapeutically effective reduction" .....	23
7. "C <sub>max</sub> " .....	24
8. "C <sub>min</sub> " .....	24
9. "C <sub>avg</sub> " .....	24
10. "T <sub>max</sub> " .....	24
12. "AUC" .....	24
19. "Degree of Fluctuation".....	25
21. "the membrane" .....	25
22. "passageway".....	25
X. DETAILED ANALYSIS OF GROUNDS FOR TRIAL .....	25
A. Ground 1: Claims 1-25 Are Unpatentable Under 35 U.S.C. § 102 Over Chen WO 00/12097 (EX1007) As Being Anticipated .....	25
B. Ground 2: At Least Claims 1-3 Are Unpatentable Under 35 U.S.C. § 102 Over Timmins WO 00/47128 (EX1003) As Being	

Anticipated .....	38
C. Ground 3: Claims 1-25 Are Unpatentable Under 35 U.S.C. § 103(a) as Being Obvious Over Cheng WO 99/47125 (EX1002) In View Of WO Timmins 99/47128 (EX1003) .....	40
D. Objective Indicia Of Non-Obviousness .....	53
XI. CONCLUSION.....	54

## PETITIONERS' EXHIBIT LIST

Exhibit No.	Description
1001	U.S. Patent 6,866,866
1002	WO 99/47125 (" <i>Cheng et al.</i> ")
1003	WO 99/47128 (" <i>Timmins et al.</i> ")
1004	U.S. Patent 6,099,859
1005	Prosecution File History of U.S. Patent 6,866,866 (Application No. 09/705,630)
1006	Fed. Cir. [2012-1228] (July 2, 2012)
1007	WO 00/12097 (" <i>Chen et al.</i> ")
1008	Lupin Settlement
1009	Mylan Settlement
1010	Amendment Under 37 C.F.R. 1.111 (dated February 24, 2003), Application No. 09/705,630.
1011	U.S. Patent No. 6,475,521
1012	Labelling NDA 21202 (GLUCOPHAGE® and GLUCOPHAGE XR®)
1013	U.S. Patent 5,955,106 (" <i>Moeckel</i> ")
1014	WO 00/28989 (" <i>Lewis et al.</i> ")
1015	U.S. Patent 6,284,275
1016	U.S. Patent 6,099,862
1017	U.S. Patent 3,845,770
1018	Remington, 1995 (" <i>Chiao</i> ")
1019	Declaration of Dr. Fatemeh Akhlaghi
1020	CV of Dr. Fatemeh Akhlaghi

# 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.