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 Inc.
Patent Owner(s).

U.S. Patent No. 6,790,459 to Cheng et al.
Issue Date: September 14, 2004
Title: Methods for Treating Diabetes via Administration of Controlled Release Metformin

---

Declaration of Dr. Fatemeh Akhlaghi, Pharm.D., Ph.D.

TABLE OF CONTENTS

I, Fatemeh Akhlaghi, declare as follows:

I. QUALIFICATIONS

1. My name is Fatemeh Akhlaghi. I have been working in the areas of pharmacokinetics, clinical pharmacology and drug metabolism since 1990. In particular, I have worked for the past 15 years on the clinical pharmacology of oral hypoglycemic agents, including metformin, to treat type 2 diabetes mellitus. I have in-depth understanding to the physiological and pathological factors affecting drug deposition in patients with type 2 diabetes. In addition to 70 peer-reviewed articles, I have published 15 articles on the pharmacokinetics of various drugs in patients with type 2 diabetes.

2. I am presently a full Professor (since 2011) at the University of Rhode Island, School of Pharmacy and an Adjunct Professor of Medicine at Brown University Medical School (since July 2014). I am currently Professor of Pharmacokinetics and the Ernest Mario Distinguished Chair of Pharmaceutics in the College of Pharmacy, University of Rhode Island.

3. I received my Pharm.D. Degree from the University of Mashhad, Iran, in 1990, and my Ph.D. degree in Pharmaceutical Sciences from the University of Sydney Australia in 1997. I undertook a post-doctorate positon at the University of Sydney until 1998, followed by a position as Senior Clinical Scientist, at the University of Cambridge, U.K. until January 2001.

4. In February 2001, I was employed as an Assistant Professor at the University of Rhode Island. I received tenure in 2006, being appointed as an Associate Professor.

5. I have received numerous honors and award, including the Levy Maill Pattison Award at the University of Sydney, the Paul-Ehrlich Magic Bullet Award, Nurnberg, Germany, and the Outstanding Intellectual Property Award from the University of Rhode Island.

6. I have extensive experience in pharmacokinetic and pharmacodynamics, drug development, and design and execution of bioequivalence and drug interaction studies.

7. A summary of my experience, education, publications and other qualifications is provided in my CV, a copy of which is submitted separately. (Ex. 1010).

II. SCOPE OF WORK

8. I understand that a petition is being filed with the United States Patent and Trademark Office ("USPTO") to challenge the validity of all of the claims of U.S. Patent No. 6,790,459 to Cheng et al, ("the '459 patent", Ex. 1001) through the USPTO procedure known as *Inter Partes Review*. I have been retained by Aurobindo Pharma U.S.A. to provide my opinion as to the validity of the claims of the '459 patent.

9. I have reviewed the '459 patent and its prosecution history generated at the United States Patent and Trademark Office in full (Ex. 1006). I have also reviewed

DOCKET ALARM

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.