

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.

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2.	Cheng <i>et al.</i> , WO1999/047125 (the "125 publication") with an International publication date of Sept. 23, 1999 claiming priority from provisional application no. 90/045,330 filed on March 20, 1998. Thus, 'the '125 publication, qualifies as prior art to the '459 patent claims under 35 U.S.C. §102(b). (<i>Ex. 1002</i>)	46

3.	Timmins <i>et al.</i> , WO 99/47128 was published on September 23, 1999. The '128 publication, therefore qualifies as prior art to the '459 patent claims under 35 U.S.C. §102(a) (<i>Ex. 1013</i>)	49
4.	Tucker <i>et al.</i> , "Metformin kinetics in healthy subjects and in patients with diabetes mellitus." University Department of Therapeutics: The Royal Hallamshire Hospital, Sheffield, S10 2JF. <i>Br. J. Clin. Pharmac.</i> (1981), 12, 235-246. The 'G.T. TUCKER <i>et al.</i> , publication, therefore qualifies as prior art to the '459 patent claims under 35 U.S.C. §102(b) (<i>Ex. 1005</i>)	50
5.	Lewis <i>et al.</i> , WO 00/28989 A1 was published on 25 May 2000. The '989 publication, therefore qualifies as prior art to the '459 patent claims under 35 U.S.C. §102(a) (<i>Ex. 1003</i>).	51
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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 position 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 Mail 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

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