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

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

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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 80 peer-reviewed articles, I have published at least 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, College 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

and considered various other documents in arriving at my opinions, and I cite them in this declaration. For convenience, documents cited in this declaration are listed in the Appendix in Section XIII.

10. I am being compensated by the petitioner at the rate of $450/hour for my work. I have no financial interest in the outcome of this matter.

III. OVERVIEW OF THE '459 PATENT

11. The '459 patent is titled "Methods for Treating Diabetes via Administration of Controlled Release Metformin." The '459 patent issued on September 14, 2004 claiming priority through U.S. Application No. 09/705,625 to a filing date of November 3, 2000.

12. As noted in the Abstract, the '459 patent discloses a "[a] method for treating patients having noninsulin-dependent diabetes mellitus (NIDDM) by administering a controlled release oral solid dosage form containing preferably a biguanide drug, such as metformin, on a once-a-day basis. The dosage form provides a mean time to maximum plasma-concentration (T_{max}) of the drug which occurs at 5.5 to 7.5 hours after oral administration on a once-a-day basis to human patients. Preferably, the dose of drug is administered at dinnertime to a patient in the fed state."

13. The "Summary of the Invention," notes that: "In preferred embodiments, the controlled release oral dosage form of the present invention is a tablet consisting of (a) a core comprising: (i) the antihyperglycemic drug; (ii) optionally a binding agent, and (iii) optionally an absorption enhancer; (b) a membrane coating surrounding the

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