Paper No. ____
Filed: January 24, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AUROBINDO PHARMA USA INC.,
Petitioner,

v.

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

Case No. IPR 2018-_____
Patent No. 6,790,459

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 6,790,459 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

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I. PAYMENT OF FEES

Pursuant to 37 C.F.R. §§ 42.15(A) AND 42.103 the fee paid at the time of filing this petition, is charged to Deposit Account 506744. Should any further fees be required by the present Petition, the Patent Trial and Appeal Board ("PTAB") is hereby authorized to charge the above referenced Deposit Account.

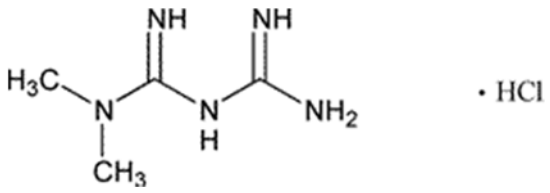
II. INTRODUCTION

Pursuant to the provisions of 35 U.S.C. § 311 and § 6 of the Leahy-Smith America Invents Act ("AIA"), and to 37 C.F.R. Part 42, Aurobindo Pharma Inc., ("Petitioner") hereby requests inter partes review of United States Patent No. 6,790,459 to Xiu Cheng *et al.*, ("the '459 patent," Ex. 1001), which issued on Sept. 14, 2004, and is currently assigned to Andrx Labs LLC., which is owned by Teva Pharmaceutical Industries Inc. (collectively "Patent Owner(s)").

A. Commercial Product Said to Be Covered by the '459 Patent

FORTAMET® (metformin hydrochloride) Extended-Release Tablets contain an oral antihyperglycemic drug used in the management of type 2 diabetes. Metformin hydrochloride (N,N-dimethylimidodicarbonimidicdiamide hydrochloride) is a member of the biguanide class of oral antihyperglycemics and is not chemically or pharmacologically related to any other class of oral

antihyperglycemic agents. The empirical formula of metformin hydrochloride is $C_4H_{11}N_5$.HCl and its molecular weight is 165.63. Its structural formula is:



B. Brief Overview of the '459 Patent.

U.S. Patent No. 6,790,459 (the '459 patent") issued with 21 claims of which claim 1 is the sole independent claim. Claim 1 of the '459 patent is directed to a method for lowering blood glucose levels in human patients needing treatment for non-insulin-dependent diabetes mellitus (NIDDM), comprising orally administering to human patients on a once-a-day basis at least one oral controlled release dosage form comprising an effective dose of metformin, or a pharmaceutically acceptable salt thereof, and an effective amount of a controlled release carrier to control the release of said metformin, or pharmaceutically acceptable salt thereof, from the dosage form within specified pharmacokinetic (PK) parameters. The pharmacokinetic parameters of the once a day dosage include a mean time to maximum plasma concentration (T_{max}) of metformin at from 5.5 to 7.5 hours after administration following dinner; a mean AUC_{0-24} of 22590±3626 ng·hr/ml and a

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