

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Aurobindo Pharma USA Inc.
Petitioners,

v.

Andrx Labs, LLC
Patent Owner

Case IPR2017-01673
U.S. Patent No. 6,790,459

**PATENT OWNER'S PRELIMINARY RESPONSE
UNDER 37 C.F.R. § 42.107**

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I. Introduction

Aurobindo petitions to institute *inter partes* review of U.S. Patent No. 6,760,459 (“the ’459 patent”) (Ex. 1001) based on legally deficient grounds and on references already considered and rejected by the Patent Office over the course of a rigorous examination. The Petition and the accompanying Declaration of Dr. Fatemeh Akhlaghi (hereinafter “the Akhlaghi Declaration”) (Ex. 1009) not only reargue positions that the Patent Office previously considered and rejected before issuing the challenged claims, but also assert a reference that does not even qualify as prior art to the ’459 patent. As such, the Petition fails to establish that Petitioner is reasonably likely to prevail in establishing the unpatentability of any challenged claim. Accordingly, the Board should decline to institute *inter partes* review. *See* 35 U.S.C. § 314; 37 C.F.R. § 42.108.

Petitioner has challenged claims 1-21 of the ’459 patent. The challenged claims describe the important discovery of a method for lowering blood glucose levels in human patients with non-insulin-dependent diabetes mellitus (“NIDDM,” also known as type 2 diabetes) using a controlled release once-a-day dosage form of metformin that provides effective control of blood glucose levels, and that is superior to prior methods. More specifically, the challenged claims recite, *inter*

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