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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

ASTRAZENECA AB,
Patent Owner

Case No. IPR2015-01340
Patent No. RE44,186

PETITION FOR INTER PARTES REVIEW

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I. 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, Mylan Pharmaceuticals Inc. ("Petitioner") hereby requests review of United States Reissue Patent No. RE44,186 to Robl (hereinafter "the '186 patent," Ex. 1001) that issued on April 30, 2013, and is currently assigned to AstraZeneca AB ("Patent Owner"). This Petition demonstrates, by a preponderance of the evidence, that there is a reasonable likelihood that claims 1, 2, 4, 6-22, 25-30, 32-37 and 39-42 of the '186 patent are unpatentable for failing to distinguish over prior art. Thus, claims 1, 2, 4, 6-22, 25-30, 32-37 and 39-42 of the '186 patent should be found unpatentable and canceled.

A. Brief Overview of the '186 Patent

The '186 patent is entitled "Cyclopropyl-Fused Pyrrolidine-Based Inhibitors of Dipeptidyl Peptidase IV and Method." Ex. 1001. In a general sense, the '186 patent discloses compounds said to inhibit the enzyme dipeptidyl peptidase IV ("DP-IV" also referred to in the claims as "DP4). This enzyme is responsible for the metabolic cleavage of certain peptides found in the body, including glucagon, a peptide of 29 amino acids. *Id.*, at col. 1, l. 30-34. The glucagon peptide has multiple actions *in vivo*, including the stimulation of insulin secretion, inhibition of glucagon secretion, promotion of satiety, and the slowing of gastric emptying. *Id.*, at col. 1, l. 40-44. Glucagon is rapidly degraded in the body, and the DP-IV enzyme has been shown to be the primary degrader of glucagon. Id., at col. 1, l. 49-54. Thus, inhibitors of DP-IV *in vivo* should increase endogenous levels of

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