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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. & MYLAN LABORATORIES LIMITED,
Petitioners,

v.

BAXTER INTERNATIONAL INC.,
Patent Owner.

IPR2016-00218

Patent No. 6,528,540

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 6,528,540

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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. and Mylan Laboratories Limited (collectively referred to herein as "Petitioner"), request review of United States Patent No. 6,528,540 to Liu *et al*. (hereinafter "the '540 patent," Ex. 1001) that issued on March 4, 2003, and is currently assigned to Baxter International Inc. ("Patent Owner"). This Petition demonstrates there is a reasonable likelihood that claims 1-6, 8-10, and 12-16 of the '540 patent are unpatentable based on a preponderance of the evidence for failing to distinguish over prior art. Thus, trial should be instituted by the Patent Trial and Appeal Board and claims 1-6, 8-10, and 12-16 of the '540 patent should be found unpatentable and canceled.

A. Brief Overview of the '540 Patent

Esmolol hydrochloride, a beta-blocker for cardiac disorders, was originally approved by the United States Food and Drug Administration (FDA) in 1988. This prior formulation of esmolol hydrochloride is well-described in the art. *See*, *e.g*., L. Blanski *et al*., *Esmolol*, *the first ultra-short-acting intravenous beta blocker for use in critically ill patients*, 17 HEART LUNG 80 (1988) (hereinafter "Blanski," Ex. 1010); *see also*, Ex. 1001, col. 1, ll. 10-12.

The '540 patent is entitled "Esmolol Formulation." The '540 patent, with an earliest claimed priority date of January 12, 2001, is directed to pharmaceutical compositions of the drug esmolol hydrochloride, and methods of making the drug composition sterile by autoclaving. Claim 1 recites an aqueous, sterile

pharmaceutical composition comprising esmolol hydrochloride, buffering agent, and osmotic-adjusting agent within specified concentrations, and having a pH value within a specified range. Ex. 1001, col. 5, l. 61 – col. 6, l. 28. Dependent claims refer to a narrower range of pH values for the composition (claim 2), to buffering agents (claim 3), to osmotic-adjusting agents (claims 4 and 5), to ranges of concentrations (claim 6), to a heat sterilized container (claim 8), which container is a vial, ampul, bag, bottle, or syringe (claim 9), and which container is from 1 to 500 mL in volume (claim 10).

Claim 12 is an independent claim, and is similar to claim 1, differing in the recited pH value and the recited concentrations of esmolol hydrochloride, buffering agent, and osmotic-adjusting agent. *Id*. at col. 6, l. 65 – col. 7, l. 6.

Claim 13 is an independent claim, and recites a method for preparing an aqueous, sterile pharmaceutical composition comprising esmolol hydrochloride, buffering agent, osmotic-adjusting agent, having a pH within a specified range, and further recites forming the composition in a sealed container, which is autoclaved for a period of time sufficient to render the composition sterile. *Id*. at col. 7, l. 7 - col. 8, l. 3. Dependent claims refer to a narrower range of pH values for the composition (claim 14), and to the autoclaving being at 115 °C to 130 °C for 5 to 40 minutes (claims 15 and 16).

The Background of the Invention of the ’540 patent acknowledges that esmolol hydrochloride is a well known pharmaceutical treatment for cardiac disorders. *Id*. at col. 1, ll. 10-12. The ’540 further states, without citation to a scientific reference or other source, that esmolol hydrochloride is unstable in

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