Paper No. ____
Filed: November 19, 2015

Filed on behalf of: Mylan Pharmaceuticals Inc.
By: Steven W. Parmelee
Michael T. Rosato
WILSON SONSINI GOODRICH & ROSATI
701 Fifth Avenue
Suite 5100
Seattle, WA 98104-7036
Tel.: 206-883-2542
Fax: 206-883-2699
Email: sparmelee@wsgr.com
Email: mrosato@wsgr.com

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.

IPR2016-00217

Patent No. 6,310,094

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 6,310,094

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

TABLE OF CONTENTS

Page

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

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. 6,310,094 to Liu *et al*. (hereinafter "the '094 patent," Ex. 1001) that issued on October 30, 2001, and is assigned to Baxter International Inc. ("Patent Owner"). This Petition demonstrates there is a reasonable likelihood that claims 1-9 of the '094 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 1-9 of the '094 patent should be found unpatentable and canceled.

A. Brief Overview of the '094 Patent

Esmolol hydrochloride, a beta-blocker for treating 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. 13-15.

The '094 patent is entitled "Ready-To-Use Esmolol Solution," and has an earliest claimed priority date of January 12, 2001. Claims of the '094 are directed to pharmaceutical compositions of esmolol hydrochloride (claims 1-3), and to methods of making the pharmaceutical composition sterile by autoclaving (claims 4-9). Claim 1 simply recites an aqueous pharmaceutical composition comprising

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

esmolol hydrochloride, buffering agent, and osmotic-adjusting agent within specified concentrations, and having a pH value within a specified range. Ex. 1001, col. 5, ll. 9-16. Claims 2 and 3 depend from claim 1 and list particular, well-known buffering agents and osmotic-adjusting agents, respectively. *Id*. at col. 5, ll. 17-25.

Claim 4 recites a method for preparing a pharmaceutical composition comprising esmolol hydrochloride, buffering agent, and osmotic-adjusting agent, but further recites that the composition is in a sealed container, which is autoclaved for a period of time sufficient to render the composition sterile. *Id*. at col. 6, ll. 1-9. Dependent claims refer to specific ranges of concentrations of esmolol hydrochloride, buffering agent, and osmotic-adjusting agent in the composition (claim 5), to the autoclaving being at 115 to 130 °C for 5 to 40 minutes (claim 6), to the container being a flexible, polymeric container free from polyvinyl chloride, (claim 7), and to the container having a moisture barrier (claim 8), in which the barrier is an aluminum overpouch (claim 9). *Id.* at col. 6, ll. 10-23.

The Background of the Invention of the ’094 patent acknowledges that esmolol hydrochloride is a well-known pharmaceutical treatment for cardiac disorders. *Id*. at col. 1, ll. 14-16. The ’094 Background further states, without citation to a scientific reference or other source, that esmolol hydrochloride is unstable in aqueous solutions due to the susceptibility of its ester moiety to hydrolytic degradation. *Id*. at col. 1, ll. 24-33. According to the ’094, “[i]n the past, the rate of degradation of esmolol hydrochloride has been reduced by the use of acetate as a buffer, maintaining the pH as close to 5.0 as possible, minimizing

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.