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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN LABORATORIES LIMITED,
Petitioner,

v.

AVENTIS PHARMA S.A.,
Patent Owner.

Case No. IPR2016-00712
Patent No. 8,927,592

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 8,927,592

TABLE OF CONTENTS

Page

I. INTRODUCTION

Mylan Laboratories Limited ("Petitioner") requests review of U.S. Patent No. 8,927,592 to Gupta ("the '592 patent," Ex. 1001), that issued on January 6, 2015, and is currently assigned to Aventis Pharma S.A. ("Patent Owner"). This Petition demonstrates a reasonable likelihood that claims 1-5 and 7-30 of the '592 patent are unpatentable for failing to distinguish over prior art.

Independent claim 1 is to a method of treatment that requires:

- administering 20 to 25 mg/m^2 of cabazitaxel, or its hydrate or solvate;
- in combination with a corticoid;
- to a patient with prostate cancer; and
- that the cancer progressed during or after treatment with docetaxel (Taxotere®).

The claimed method administers a known drug, in a known dosage range, in a known combination, with known activity against a known indication, to patients with that indication. Independent claim 27 specifies metastatic "castration resistant or hormone refractory" prostate cancer, and a prednisone or prednisolone corticoid.

The claimed method was published more than one year before the earliest alleged priority date of the '592 patent. As just one example, Winquist discloses an ongoing Phase III clinical study ("the TROPIC study") in which 25 mg/m^2 of cabazitaxel (referenced as XRP-6258) was administered to patients in combination with prednisone (a corticoid) for treating hormone-refractory (castration-resistant) metastatic prostate cancer ("mCRPC") previously treated with docetaxel. Ex. 1009.

As another example, the TROPIC Listing describes the same TROPIC study

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