Paper No. ___
Filed: October 28, 2016

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 IPR2016-00712
Patent No. 8,927,592

PETITIONER'S MOTION TO FILE SUPPLEMENTAL INFORMATION PURSUANT TO 37. C.F.R. § 42.123(a)

I. INTRODUCTION

Pursuant to 37 C.F.R. § 42.123(a), Petitioner Mylan Laboratories Limited ("Petitioner") moves to submit as supplemental information:

1. An October 7, 2016, district court claim construction memorandum opinion ("Claim Construction Order," Ex. 1039) that construes the very same claims for which *inter partes* review has been instituted in this proceeding ("the instituted claims") and that supports and confirms the Board's claim constructions from the institution decision (Paper 9).
2. A June 9, 2016, Final Office Action (Ex. 1040) for a continuation application of the '592 patent in which the same Examiner who originally allowed the instituted claims has finally rejected claims that are even narrower than the instituted claims.

Petitioner respectfully requests permission to file these documents as supplemental information under 37 C.F.R. § 42.123(a) because each of these documents is "relevant to a claim for which the trial has been instituted" and because the request for authorization to file the motion was made on October 21, 2016, "within one month after the date the trial [was] instituted" on September 22, 2016.

II. STATEMENT OF MATERIAL FACTS

On March 15, 2016, Mylan filed a petition for *inter partes* review (paper 3) of claims 1-5 and 7-30 of U.S. Patent No. 8,927,592 ("the '592 patent", Ex. 1001). Petitioner also submitted an expert declaration (Ex. 1002) by Dr. Rahul Seth.

On June 9, 2016, the same Examiner who allowed the instituted claims of the '592 patent issued a Final Office Action rejecting all pending claims in U.S. Patent Application No. 14/575,566 (the '566 application). The '566 application is a continuation of the application that led to the '592 patent. The Office Action referredthe Petition in this IPR and stated that the "Seth Declaration is directly applicable to the instant claims and refutes points raised in the Sartor Declaration." Ex. 1040 at 3. The Office Action also characterized the claims undergoing examination as follows:

> The instant claims recite methods for treating a patient with castration resistant or hormone refractory, metastatic prostate cancer that has progressed during or after treatment with docetaxel, comprising administering to said patient a dose of 20 to 25 mg/m2 of cabazitaxel, or a hydrate or solvate thereof, as a one-hour infusion, in combination with 10 mg/day of prednisone or prednisolone, wherein the administration of cabazitaxel, or hydrate or solvate thereof, is repeated as a new cycle every 3 weeks.

Id. at 5. The Examiner determined that the claims were unpatentable in view of prior art references asserted in this IPR proceeding, including Beardsley, Mita, and Pivot. For example, the Office Action states:

> The indicia of obviousness in the instant case are many and strong, as the prior art teaches all of the limitations of the instant claims. Cabazitaxel was known in the art and taught to be useful in treating cancer, particularly docetaxel-resistant cancer. Clinically effective doses of cabazitaxel were known in the art and are the same doses presently claimed. Taxanes, including cabazitaxel, were known in the art to be administered in combination with prednisone in the dose presently claimed.

Id. at 16-18. The Examiner also concluded that the skilled artisan would have had a reasonable expectation of success, stating:

> The skilled artisan would have been imbued with more than a reasonable expectation that cabazitaxel, in the dosing regimen presently claimed, administered in combination with 10mg/day prednisone, would be effective in treating castration resistant or hormone refractory metastatic prostate cancer that has progressed during or after treatment with docetaxel. This is particularly true because the cited prior art teaches that in a Phase II trial, cabazitaxel is **clinically effective in treating docetaxel-resistant metastatic breast cancer** (Beardsley *et al.* and Pivot *et al.*), *which led* to cabazitaxel being investigated in a phase III multi-center, randomized superiority trial comparing 3-weekly XRP6258 with prednisone to mitoxantrone with prednisone in patients with castrate resistant metastatic prostate

> cancer previously treated with docetaxel-containing treatment (Beardsley *et al.*, Rodrigues *et al.*, and NHSC). Those skilled in the art would not administer a drug in a Phase III clinical trial if they did not have at least a reasonable expectation that treatment would be successful.

Id. at 20 (all emphasis in original). The Examiner also rejected Dr. Sartor's arguments regarding likelihood of success of the Phase III trial:

> It is the position of the Examiner that the Sartor declaration incorrectly assumes that positive results of Phase III clinical trials were necessary to demonstrate a reasonable likelihood of success for administering 20-25 mg/m^2 of cabazitaxel with prednisone to patients with mCRPC that had progressed during or after treatment docetaxel

Id. at 28-29. The Examiner similarly rejected Dr. Sartor's testimony that there was no reasonable likelihood of success in obtaining statistically significant results:

> The Examiner is thus not persuaded by Applicants' argument that a person of ordinary skill in the art would not have had a reasonable expectation that the Phase III study of cabazitaxel for treating prostate cancer referred to in Beardsley et al., Rodriguez [*sic*] et al., and NHSC would succeed in returning statistically significant results over the reference treatment.

Id. at 30-31.

On June 24, 2016, Patent Owner filed a preliminary response along with another declaration from Dr. Sartor (Ex. 2001). In its preliminary response, Patent Owner asked the Board to defer to the Examiner's original decision to allow the

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