

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 8,927,592 B2

Before BRIAN P. MURPHY, TINA E. HULSE, and
CHRISTOPHER M. KAISER, *Administrative Patent Judges*.

MURPHY, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a); 37 C.F.R. § 42.73(a)

I. INTRODUCTION

Mylan Laboratories Limited (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–5 and 7–30 of U.S. Patent No. 8,927,592 (Ex. 1001, “the ’592 patent”). Paper 3 (“Petition” or “Pet.”). Petitioner supported its challenge with the Declaration of Dr. Rahul Seth. Ex. 1002. Aventis Pharma S.A. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 7 (“Prelim. Resp.”). On September 22, 2016, we instituted an *inter partes* review of claims 1–5 and 7–30 of the ’592 patent. Paper 9 (“Institution Decision”).

After institution, Patent Owner filed a Response (Paper 21, “PO Resp.”) and a Contingent Motion to Amend claims 27–30 of the ’592 patent (Paper 22, “MTA”). Patent Owner supported its Response and MTA with the Declaration of Dr. Alton Oliver Sartor (Ex. 2176), the Declaration of Mr. Michael Tate (Ex. 2149), and the Declaration of Mr. Art Lathers (Ex. 2231).

Petitioner filed a Reply (Paper 42, “Reply”) and Opposition to Patent Owner’s MTA (Paper 43, “MTA Opp.”¹). Petitioner supported its Reply and MTA Opposition with the Reply Declaration of Dr. Seth (Ex. 1043), and the Declaration of Mr. Robert McSorley (Ex. 1044).²

¹ Petitioner filed the MTA Opposition under seal, subject to the Board’s ruling on Petitioner’s Motion to Seal (Paper 45). Petitioner filed a redacted public version of the MTA Opposition as Paper 44.

² Petitioner filed Dr. Seth’s Reply Declaration and Mr. McSorley’s Declaration under seal, subject to the Board’s ruling on Petitioner’s Motion to Seal (Paper 45). Petitioner filed redacted public versions of the declarations using the same respective exhibit numbers.

Patent Owner filed a Reply to Petitioner's Opposition to Patent Owner's MTA. Paper 53 ("MTA Reply").³ Patent Owner supported its MTA Reply with the Reply Declaration of Dr. Sartor (Ex. 2259) and the Declaration of Patricia Matthews, RN, BSN (Ex. 2234).

Patent Owner filed a Motion to Exclude Exhibits 1089–1090 (Paper 61), Petitioner filed an Opposition (Paper 77 (under seal), Paper 78 (public version)), and Patent Owner filed a Reply (Paper 86).

Petitioner filed a Motion to Exclude Exhibits 2170, 2171, and 2179 and certain paragraphs in Exhibits 2001, 2176, and 2149 (Paper 64 (under seal), Paper 68 (public version)), Patent Owner filed an Opposition (Paper 72 (under seal), Paper 73 (public version)), and Petitioner filed a Reply (Paper 89 (under seal), Paper 95 (public version)).

Patent Owner filed Observations (Paper 80) on the cross-examination testimony of Dr. Seth (Ex. 2258) regarding Petitioner's Reply (Paper 42), and Petitioner filed a response to Patent Owner's Observations (Paper 93). Patent Owner also filed Observations (Paper 81 (under seal), Paper 82 (public version)) on the cross-examination testimony of Mr. McSorley (Ex. 2261) regarding Petitioner's Reply (Paper 42), and Petitioner filed a response to Patent Owner's Observations (Paper 92 (under seal), Paper 94 (public version)).

Petitioner filed Observations (Paper 84) on the cross-examination testimony of Dr. Sartor (Ex. 1098) with respect to Patent Owner's MTA, and Patent Owner filed a Response (Paper 90).

³ Patent Owner filed the MTA Reply under seal, subject to the Board's ruling on Patent Owner's Motion to Seal (Paper 54). Patent Owner filed a redacted public version of the MTA Reply as Paper 52.

An oral hearing was held on June 13, 2017, and a transcript of the oral hearing is of record. Paper 98 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6. This is a Final Written Decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73(a) regarding the patentability of the challenged claims. In this case, the claimed treatment method, administering a 20 to 25 mg/m² dose of cabazitaxel in combination with prednisone to docetaxel-refractory metastatic prostate cancer patients, was disclosed more than one year before the earliest effective filing date to which the ’592 patent might be entitled.⁴ Therefore, for the reasons that follow and based on our review of the complete trial record, we determine Petitioner has shown by a preponderance of the evidence that claims 1–5 and 7–30 of the ’592 patent are unpatentable. We further determine that Patent Owner’s Contingent Motion to Amend claims 27–30 is *denied*.

A. Real Parties in Interest and Related Proceedings

Petitioner identifies (i) Mylan Laboratories Limited, the Petitioner and a wholly-owned subsidiary of Mylan Inc., (ii) Mylan Pharmaceuticals Inc., which is a wholly-owned subsidiary of Mylan Inc., (iii) Mylan Inc., which is an indirectly wholly owned subsidiary of Mylan N.V., and (iv) Mylan N.V. as real parties in interest. Pet. 11.

Patent Owner identifies Patent Owner, Aventis Pharma S.A., Sanofi, the ultimate parent company of Aventis Pharma S.A., and Sanofi-Aventis U.S. LLC, an affiliate of Aventis Pharma S.A., as real parties in interest. Paper 6, 2.

⁴ We do not make a determination of the earliest effective filing date, because the references qualify as prior art regardless of that date.

Petitioner and Patent Owner identify the following as related district court proceedings in the District of New Jersey regarding the '592 patent: *Sanofi-Aventis U.S. LLC v. Mylan Laboratories Limited*, No. 15-03392; *Sanofi-Aventis U.S. LLC v. Apotex Corp*, C. A. No. 15-01835; *Sanofi-Aventis U.S. LLC v. Breckenridge Pharmaceutical, Inc.*, C. A. No. 15-01836; *Sanofi-Aventis U.S. LLC v. Accord Healthcare, Inc.*, C. A. No. 15-02520; *Sanofi-Aventis U.S. LLC v. BPI Labs, LLC*, C. A. No. 15-02521; *Sanofi-Aventis U.S. LLC v. Dr. Reddy Laboratories, Inc.*, C. A. No. 15-02522; *Sanofi-Aventis U.S. LLC v. Glenmark Generics Inc.*, C. A. No. 15-02523; *Sanofi-Aventis U.S. LLC v. Fresenius Kabi USA, LLC*, C. A. No. 15-02631; *Sanofi-Aventis U.S. LLC v. Actavis LLC*, C. A. No. 15-03107; *Sanofi-Aventis U.S. LLC v. BPI Labs, LLC*, C. A. No. 15-02521. Pet. 12; Paper 6, 2–3.

Petitioner further identifies IPR2016-00627 as an earlier challenge to U.S. Patent No. 5,847,170 directed to the compound cabazitaxel. Pet. 12. We denied institution in IPR2016-00627 (Paper 10) and Petitioner's request for rehearing (Paper 12).

B. Grounds of Unpatentability

We instituted an *inter partes* review of claims 1–5 and 7–30 of the '592 patent on the following grounds of unpatentability under 35 U.S.C. § 103:

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