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Paper 21
Date: September 1, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC. AND WATSON LABORATORIES, INC.,
Petitioner,

v.

MERCK SHARP & DOHME CORP.,
Patent Owner.

IPR2020-01045
Patent 7,326,708 B2

Before SHERIDAN K. SNEDDEN, ROBERT A. POLLOCK, and TIMOTHY G. MAJORS, *Administrative Patent Judges.*

MAJORS, *Administrative Patent Judge.*

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. §314
Granting Motion for Joinder
35 U.S.C. § 315(c); 37 C.F.R. § 42.122

I. INTRODUCTION

Teva Pharmaceuticals USA, Inc. and Watson Laboratories, Inc. (collectively "Petitioner"),[1] on June 10, 2020, filed a Petition to institute *inter partes* review of claims 1–4, 17, 19, and 21–23 of U.S. Patent No. 7,326,708 B2 (Ex. 1001, "the '708 patent"). Paper 3 ("Pet." or "Petition"). Petitioner also filed a Motion for Joinder (Paper 4, "Mot." or "Motion") with *Mylan Pharmaceuticals Inc. v. Merck Sharp & Dohme Corp.*, IPR2020-00040, in which Mylan is challenging the patentability of those same claims of the '708 patent ("Mylan IPR"). We instituted *inter partes* review of the Mylan IPR on May 12, 2020. Mylan IPR, Paper 21.

On July 7, 2020, Merck Sharp & Dohme Corp. ("Patent Owner" or "Merck") filed an Opposition ("Opp." or "Opposition") to Petitioner's Motion for Joinder. Paper 9. Petitioner filed a Reply in support of the Motion. Paper 13 ("Mot. Reply"). And, on August 14, 2020, Patent Owner filed a Preliminary Response to the Petition. Paper 16 ("Prelim. Resp.").

A. Related Proceedings

The parties identify several proceedings where the '708 patent is being asserted, including: *Merck Sharp & Dohme Corp. v. Mylan Pharm. Inc. et al.*, 1:19:-cv-00101 (N.D. W. Va); *Merck Sharp & Dohme Corp. v. Mylan Pharm. Inc. et al.*, 1:19-cv-01489 (D. Del.); *Merck Sharp & Dohme Corp. v. Watson Pharmaceuticals, Inc.*, 1:19-cv-00317 (D. Del.), and *Merck Sharp & Dohme Corp. v. Teva Pharmaceuticals USA, Inc.*, 1:19-cv-00318 (D. Del.). Pet. 6–7 (listing cases); Paper 7, 2–3 (Patent Owner's Mandatory

[1] Petitioner identifies Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Watson Laboratories, Inc. as the real parties-in-interest. Pet. 6.

Notices). As Merck has explained, its lawsuits against several generic drug companies related to the '708 patent, including those suits identified above, have been consolidated for pretrial purposes in a multidistrict litigation. *See* Mylan IPR, Paper 10, 10 (identifying *In re Sitagliptin Phosphate ('708 & '921) Patent Litig.* C.A. No. 19-md-2902-RGA (D. Del.)).

In addition to the Mylan IPR, Patent Owner identifies the following related administrative matters before the Patent Office: *Dr. Reddy's Laboratories, Inc. v. Merck Sharp & Dohme Corp.*, IPR2020-01060; and *Sun Pharmaceuticals Industries, Ltd. v. Merck Sharp & Dohme Corp.*, IPR2020-01072. Paper 7, 3.[2]

[2] Petitioners in these related matters filed their petitions at or about the same time as the present Petition. Those other petitioners similarly move for joinder with the Mylan IPR. *See, e.g.*, IPR2020-1060, Paper 3.

B. Asserted Grounds

Petitioner asserts six grounds of unpatentability (Pet. 13) as set forth in the table below:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–3, 17, 19, 21–23	102[3]	WO '498[4]
1–3, 17, 19, 21–23	102	the '871 patent[5]
3, 17, 19, 21–23	103	WO '498
1–3, 17, 19, 21–23	103	WO '498, Bastin[6]
4	103	WO '498, Bastin, Brittain[7]
4	103	WO '498, Brittain

[3] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Because the challenged claims of the '708 patent have an effective filing date before the effective date of the applicable AIA amendments, we refer to the pre-AIA versions of 35 U.S.C. §§ 102 and 103 in this Decision.

[4] Edmondson et al., WO 03/004498 A1, published Jan. 16, 2003 (Ex. 1004, "WO '498"). WO '498 published from Application No. PCT/US02/21349, filed July 5, 2002, which claims priority to US Provisional Application No. 60/303,474, filed July 6, 2001 (Ex. 1012).

[5] Edmondson et al., US 6,699,871 B2, issued Mar. 2, 2004 (Ex. 1007, "the '871 patent"). The '871 patent issued from an application filed July 5, 2002, and claims priority to US Provisional Application No. 60/303,474, filed July 6, 2001 (Ex. 1012).

[6] Richard J. Bastin et al., *Salt Selection and Optimisation Procedures for Pharmaceutical New Chemical Entities*, 4 ORGANIC PROCESS RESEARCH & DEVELOPMENT 427–435, 2000 (Ex. 1006, "Bastin").

[7] Polymorphism in Pharmaceutical Solids, Harry G. Brittain ed., 1999 (Ex. 1005, "Brittain").

Petitioner also cites the declaration of Dr. Leonard Chyall (Ex. 1002), but has indicated that it will withdraw Dr. Chyall's declaration, and will rely instead on the testimony of Mylan's declarant, Dr. Mukund Chorghade, in the Mylan IPR if permitted. Pet. 13; Mot. 5.

II. INSTITUTION OF INTER PARTES REVIEW

The Petition advances the same grounds of unpatentability that are included in the instituted Mylan IPR. *Compare* Pet. 13–71, *with* Mylan IPR, Paper 1, 12–69; *see also* Mylan IPR, Paper 21, 4–5, 64 (Institution Decision). Indeed, Petitioner asserts that "Teva's Petition is a 'Me-Too' petition filed within one month of the Board's May 12, 2020 Order instituting trial" in the Mylan IPR, that "Teva's Petition raises no issues which are not raised in Mylan's petition," and that the only differences between the petitions are minor and non-substantive. Pet. 1 n.1 (noting, for example, differences in party names and typographical changes).

Merck filed a Preliminary Response, agreeing that "[t]he Petition at issue is a 'Me-Too' petition," that was filed with a timely motion for joinder. Prelim. Resp. 1.[8] Merck notes the preliminary arguments it raised in response to the petition in the Mylan IPR. *Id.* But, recognizing that the Board granted institution in the Mylan IPR notwithstanding those arguments, Merck, "[f]or efficiency and to conserve judicial resources," does not specifically raise or restate those arguments at this time. *Id.* at 2

[8] Patent Owner's Preliminary Response does not include page numbers, but we treat as though it includes pages 1–4, with page 1 beginning after the caption page.

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