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Paper 15
Date: September 1, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SUN PHARMACEUTICAL INDUSTRIES LTD.,
Petitioner,

v.

MERCK SHARP & DOHME CORP.,
Patent Owner.

IPR2020-01060
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

Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively "Petitioner"),[1] on June 11, 2020, filed a Petition for *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 2 ("Pet." or "Petition"). Petitioner also filed a Motion for Joinder (Paper 3, "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 10, 2020, Merck Sharp & Dohme Corp. ("Patent Owner" or "Merck") filed an Opposition ("Opp." or "Opposition") to Petitioner's Motion for Joinder. Paper 7. Petitioner filed a Reply in support of the Motion. Paper 9 ("Mot. Reply"). And, on August 20, 2020, Patent Owner filed a Preliminary Response to the Petition. Paper 13 ("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. Sun Pharmaceutical Industries Ltd.*, 1:19-cv-00319 (D. Del); *Merck Sharp & Dohme Corp. v. Watson Pharmaceuticals, Inc.*, 1:19-cv-00317 (D.

[1] Petitioner identifies Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. as the real parties-in-interest. Pet. 6.

Del.), *Merck Sharp & Dohme Corp. v. Teva Pharmaceuticals USA, Inc.*, 1:19-cv-00318 (D. Del.); and *Merck Sharp & Dohme Corp. v. Dr. Reddy's Laboratories Ltd.*, 1:20-cv-00847 (D. Del.). Pet. 6–7 (listing cases); Paper 5, 2–3 (Patent Owner's Mandatory Notices). As Merck has explained, its lawsuits against several generic drug companies related to the '708 patent, including 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 pending before the Patent Office: *Teva Pharmaceuticals USA, Inc. v. Merck Sharp & Dohme Corp.*, IPR2020-01045; and *Sun Pharmaceuticals Industries, Ltd. v. Merck Sharp & Dohme Corp.*, IPR2020-01072. Paper 5, 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.*, IPR2020-1072, Papers 2 and 3.

B. *Asserted Grounds of Unpatentability*

Petitioner asserts six grounds of unpatentability (Pet. 12) 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]

[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").

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
4	103	WO '498, Brittain

Petitioner also cites the declaration of Dr. Joseph M. Fortunak (Ex. 1017), but has indicated that it will withdraw Dr. Baldwin's declaration, and will rely instead on the testimony of Mylan's declarant, Dr. Mukund Chorghade (Ex. 1002), in the Mylan IPR if permitted.[8] Mot. 4.

II. INSTITUTION OF INTER PARTES REVIEW

The Petition advances the same grounds of unpatentability that are included in the instituted Mylan IPR. *Compare* Pet. 12–69, *with* Mylan IPR, Paper 1, 12–69; *see also* Mylan IPR, Paper 21, 4–5, 64 (Institution Decision). Indeed, Petitioner asserts that its Petition is "substantially the same as" the petition in the Mylan IPR—relating to the same patent, claims, grounds of unpatentability, and evidence, including the same prior art and combinations. Mot. 1; *see also id.* at 3–4 (explaining that the petitions are substantially identical, except for, different real parties-in-interest listings and other minor updates). We conclude the Petition is, in effect, a "me-too" challenge relative to the petition in the Mylan IPR.

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.

[8] Petitioner cites these declarations in tandem as "EXS1002/1017." *See, e.g.*, Pet. 12 n.5 (explaining that Dr. Fortunak's declaration is "identical" to Dr. Chorghade's declaration).

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