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Paper No. 21
Date: May 12, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

MERCK SHARP & DOHME CORP.,
Patent Owner.

IPR2020-00040
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

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner" or "Mylan"),[1] on October 30, 2019, 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 1 ("Pet." or "Petition"). Merck Sharp & Dohme Corp. ("Patent Owner" or "Merck") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp.").

We granted (Paper 11) Petitioner's request to file a pre-institution Reply to Patent Owner's Preliminary Response. Paper 13. We permitted Patent Owner to file a Sur-Reply to Petitioner's authorized Reply. Paper 14. We permitted the filing of a Joint Notice of Supplemental Authority so that the parties could each address recently designated precedential decisions from the Board related to discretionary denials under 35 U.S.C. §§ 314(a) or 325(d). Paper 15. And, we requested supplemental briefing on the potential applicability of the factors set forth in *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 at 5 (PTAB Mar. 20, 2020) (precedential), to § 314(a) discretionary denial here. Paper 17 (Order), Paper 18 (Mylan brief); Paper 19 (Merck brief).

Under 35 U.S.C. § 314(a), *inter partes* review may not be instituted unless the Petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." For reasons stated below, we determine that Petitioner has

[1] Petitioner identifies itself, Mylan Inc., and Mylan N.V. as the real parties-in-interest. Pet. 6.

established a reasonable likelihood that it would prevail with respect to at least one challenged claim. We do not deny institution on a discretionary basis as requested by Patent Owner. We, therefore, institute *inter partes* review of claims 1–4, 17, 19, and 21–23 of the '708 patent.

A. *Related Patents and Proceedings*

Petitioner states that, based on its search of Patent Office records, "there are no related United States patents or pending applications." Pet. 7. Petitioner further states that, "to the best of Petitioner's knowledge, this is the first IPR directed to the '708 patent." Pet. 67.

Petitioner identifies several related cases pending before the courts including, without limitation, the following: *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.); and *Merck Sharp & Dohme Corp. v. Sandoz, Inc.*, 1:19-cv-00312 (D. Del.). Pet. 6–7 (listing cases). As Patent Owner explains, it "has filed Hatch-Waxman suits alleging infringement of the '708 patent, among others, against fourteen generic drug companies including Mylan, Teva, Apotex, Par, Sun, and Sandoz." Prelim. Resp. 10. As Patent Owner also notes, the litigation against the generic drug companies "has been consolidated for pretrial proceedings in a multidistrict litigation ('MDL')" before the district court in Delaware. *Id.* (identifying *In re Sitagliptin Phosphate ('708 & '921) Patent Litig.* C.A. No. 19-md-2902-RGA (D. Del.)).

B. *Asserted Grounds of Unpatentability*

Petitioner asserts six grounds of unpatentability (Pet. 12) as set forth in the table below:

Claims Challenged	35 U.S.C. §	Basis
1–3, 17, 19, 21–23	102(a), 102(e)(2)[2]	WO '498[3]
1–3, 17, 19, 21–23	102(e)(2)	the '871 patent[4]
3, 17, 19, 21–23	103	WO '498
1–3, 17, 19, 21–23	103	WO '498, Bastin[5]
4	103	WO '498, Bastin, Brittain[6]

[2] 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.

[3] 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).

[4] 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).

[5] 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").

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

Claims Challenged	35 U.S.C. §	Basis
4	103	WO '498, Brittain

Petitioner also relies on the declaration of Mukund Chorghade, Ph.D. (Ex. 1002), among other evidence.

C. *The '708 Patent*

The '708 patent is titled "PHOSPHORIC ACID SALT OF A DIPEPTIDYL PEPTIDASE-IV INHIBITOR." Ex. 1001, (54).

According to the '708 patent, "[t]he present invention relates to a particular salt of a dipeptidyl peptidase-IV inhibitor," and specifically, the dihydrogenphosphate ("DHP") salt of 4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine. *Id.* at 1:13–17. The chemical,4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine, is also known as "sitagliptin." *See* Ex. 2003 ¶ 2; Pet. 1 n.1.[7] The formula for the DHP salt of sitagliptin is shown below as formula (I):

[7] Petitioner notes that sitagliptin is also known as the chemical: 7-[(3R)-3-amino-4-(2,4,5-trifluorophenyl)butanoyl]-3-(trifluoromethyl)-5,6,7,8-tetrahydro-1,2,4-triazolo[4,3-α]pyrazine. Pet. 1 n.1; Ex. 1004, 47 (Example 7); Ex. 1007, 32:1–16 (Example 7); Ex. 1002 ¶ 67 (discussing Example 7 of WO '498 as "the hydrochloride salt of sitagliptin in its (R)-configuration"). In citing to the asserted references and other exhibits in this Decision, we use the pagination added to the exhibit copies not the original pagination, except that, for US patents, we use the column and line format or other indicia in such patents.

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