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Paper 91
Entered: May 7, 2021

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[1]
Patent 7,326,708 B2

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

MAJORS, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)
Denying Patent Owner's Motion to Exclude
37 C.F.R. § 42.64

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[1] Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. were joined as parties to this proceeding via Motion for Joinder in IPR2020-01060; and Sun Pharmaceuticals Industries Ltd. was joined as a party to this proceeding via Motion for Joinder in IPR2020-01072.

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I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner" or "Mylan"),[2] 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"). On May 12, 2020, based on the preliminary record, we instituted *inter partes* review of the challenged claims on all asserted grounds. Paper 21 ("Inst. Dec.").

After institution, Patent Owner Merck Sharp & Dohme Corp. ("Patent Owner" or "Merck") filed a Response. Paper 41 ("PO Resp."). Petitioner filed a Reply. Paper 65 ("Reply"). Patent Owner filed a Sur-reply. Paper 74 ("Sur-reply"). Also before us is Patent Owner's Motion to Exclude (*see* Papers 81, 85). We held an oral hearing on February 11, 2021, and the transcript is on file. Paper 90 ("Tr.").

As a brief overview, the claims here relate to a compound called "sitagliptin" and, specifically, to particular dihydrogenphosphate ("DHP") salt forms of it that have a 1-to-1 ratio, or stoichiometry, between the relevant phosphate anion and the corresponding sitagliptin cation. Pet. 1–2; PO Resp. 1 (discussing "1:1 sitagliptin DHP"); Ex. 1001, 2:44–65, 15:64–16:15 (claim 1). Sitagliptin is among a class of compounds known as dipeptidyl peptidase-IV inhibitors, which can inhibit an enzyme implicated in the etiology of non-insulin dependent diabetes mellitus (i.e., Type 2 diabetes). *Id.* at 1:3–36. Indeed, Merck developed and sells its drug

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

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product, Januvia, which is indicated for treatment of Type 2 diabetes and includes a 1:1 sitagliptin DHP salt. PO Resp. 1, 25–26; Ex. 2003 ¶ 2.[3]

The dispute in this case focuses, in large part, on whether an earlier-filed international patent application, which Merck also owns, expressly or inherently discloses the 1:1 sitagliptin DHP salt claimed in the '708 patent.[4] At institution, and despite our determination that this prior art included no explicit disclosure of a phosphate salt of sitagliptin having the 1:1 stoichiometry, we nevertheless instituted trial based, *inter alia*, on testimony from Petitioner's expert that sitagliptin can only be mono-protonated and reacting sitagliptin with phosphoric acid forms the 1:1 DHP salt "every time" and is, thus, inherent. Inst. Dec. 52–53 (noting preliminary record "suggest[s] the 1:1 salt is the necessary byproduct of contacting phosphoric acid and sitagliptin"). Because it is undisputed that the prior art does not expressly disclose the specific 1:1 DHP salt of sitagliptin,[5] and the evidence through trial now shows that sitagliptin can form phosphate salts in non-1:1 ratios without necessarily forming the 1:1 salt (i.e., no inherency), Merck argues that Petitioner's anticipation challenge fails. PO Resp. 6–19.

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[3] Merck has indicated that "the crystalline monohydrate form of the DHP salt . . . is the solid form of sitagliptin used today in Merck's products." Paper 10, 4–5.

[4] The published international patent application (WO 03/004498) and a U.S. counterpart patent (US 6,699,871; also asserted here as anticipating art) contain materially "identical" disclosures. *See* Pet. 33; Tr. 7:8–13.

[5] *See* Tr. 15:7–19 (Petitioner's counsel agreeing that "there's no express disclosure of a 1:1 DHP salt of sitagliptin in the WO ['498] reference or the '871 reference"); Ex. 2103 ¶ 67.

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If anticipation fails, Petitioner is left with obviousness. But, in Merck's telling, the obviousness challenge fares no better because Merck's inventors reduced to practice the subject matter of almost all the challenged claims before the key prior art published, thus disqualifying that art as a § 102(a) reference; and, even if that art still qualifies under § 102(e), Merck's common ownership of the art eliminates it from the obviousness analysis under § 103(c)(1).[6] PO Resp. 22–28. For the two dependent claims for which Merck does not argue an earlier reduction to practice, Merck contends those claims are not obvious because, among other things, that claimed subject matter was highly unpredictable and Petitioner failed to show a reason why it would have been made by an ordinarily skilled person with a reasonable expectation of success. *Id.* at 38–59.

We address in detail the parties' arguments on anticipation and obviousness in the sections below. On this trial record, however, we find Petitioner has failed to show by a preponderance of the evidence that claims 1–4, 17, 19, and 21–21 are unpatentable. Petitioner has, thus, not met its burden and proved unpatentability of the challenged claims. 35 U.S.C. § 316(e). Our reasoning is detailed in Section II below.

We also deny Patent Owner's Motion to Exclude. *Infra* Section III.

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[6] Under the pre-AIA § 103(c)(1) exception, subject matter developed by "another person" that qualifies as prior art under § 102(e) can be eliminated from use in an obviousness analysis if that subject matter and the claimed invention are commonly owned or under obligation of assignment to the same person or entity at the time of the invention. 35 U.S.C. § 103(c)(1).

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A. Related Patents and Proceedings

"[T]here are no related United States patents or pending applications" and "this is the first IPR directed to the '708 patent." Pet. 7, 67.

Petitioner identifies several related cases before the courts including, without limitation: *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). Patent Owner states that it "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." Paper 10, 10. 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.)).

There are also related matters filed with the Board. After institution, other petitioners filed substantially identical petitions challenging claims of the '708 patent and requested joinder with Mylan in this proceeding. *See* IPR2020-01045 ("Teva" matter); IPR2020-01060 ("Dr. Reddy's" matter); IPR2020-01072 ("Sun" matter). We instituted trial in those other matters and joined the petitioners as parties here. IPR2020-00040, Papers 44–46. The Dr. Reddy's and Sun parties remain joined. The Teva parties (Teva Pharmaceuticals USA, Inc. and Watson Laboratories, Inc.) have settled with Merck and IPR2020-01045 is terminated. IPR2020-01045, Paper 25. The Teva parties are no longer joined. IPR2020-00040, Paper 73, 2–3.

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