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Paper 7
Entered: April 14, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC,
Petitioner,

v.

SHIRE LABORATORIES, INC.,[1]
Patent Owner.

Case IPR2017-00011
Patent RE41,148 E

Before TONI R. SCHEINER, LORA M. GREEN, and SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

[1] The Petition, as filed, identifies Shire Laboratories, Inc. as the Patent Owner. According to Patent Owner, "[t]he real parties-in-interest are Shire Laboratories, Inc. and Shire LLC." Paper 4, 1. We note that Patent Owner has filed Papers 4 and 5 as "Shire Laboratories, Inc.," but filed its Preliminary Response (Paper 6) as "Shire LLC."

SHIRE EX. 2008

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Mylan" or "Petitioner") filed a Petition (Paper 1, "Pet.") on October 4, 2016, requesting an *inter partes* review of claims 1–20 of U.S. Patent No. RE41,148 E (Ex. 1001, "the '148 patent"). Shire LLC ("Shire" or "Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp.") on January 17, 2017. We have statutory authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Upon consideration of the arguments and evidence presented in the Petition and the Preliminary Response, we are not persuaded that Petitioner has established a reasonable likelihood that it would prevail in its challenges to claims 1–20 of the '148 patent. Accordingly, we do not institute an *inter partes* review of claims 1–20.

A. Related Proceedings

Petitioner informs us that "[t]he '148 patent is currently the subject, as the parent patent[2] or current reissue form," of the following proceedings: *Shire LLC v. Amerigen Pharmaceuticals Ltd.*, No. 1:14-cv-06095-RMB-JS (D.N.J.); *Shire LLC v. Abhai LLC*, No. 1:15-cv-13909-WGY (D. Mass.);

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[2] U.S. Patent No. 6,605,300, issued August 12, 2003 to Beth A. Burnside et al. ("the '300 patent").

Shire LLC v. Par Pharmaceutical, Inc., No. 1-14-cv-01454 (D.N.J.); *Shire LLC v. CorePharma, LLC*, No. 1-14-cv-05694 (D.N.J.); *Shire LLC v. Neos Therapeutics, Inc.*, No. 3-13-cv-01452 (N.D. Tex.); *Shire LLC v. Watson Pharmaceuticals, Inc.*, No. 1-11-cv-02340 (S.D.N.Y.). Patent Owner identifies, for the most part, the same related matters in its Mandatory Notices under 37 C.F.R. § 42.8(a)(2). Paper 4, 1.

The parties further inform us that U.S. Patent RE42,096,[3] a related patent, is currently the subject of IPR2016-01033—*Mylan Pharmaceuticals, Inc. v. Shire Labs, Inc.* Pet. 5; Paper 4, 2.

Finally, Patent Owner represents that Petitioner "Mylan . . . has no litigation with Shire over [the '148 and '096] patents." Prelim. Resp. 1.

[3] U.S. Patent RE42,096, reissued February 1, 2011 to Beth A. Burnside et al. ("the '096 patent").

B. The Asserted Ground of Unpatentability

Petitioner asserts that claims 1–20 are unpatentable under 35 U.S.C. § 103 as obvious over Mehta,[4] PDR 1997,[5] Brown,[6] Amidon,[7] and Slattum.[8] Pet. 8–58.

Petitioner supports its challenges with the Declaration of David E. Auslander, Ph.D., executed September 17, 2016 (Ex. 1002, "Auslander Declaration"), and the Declaration of Anthony Palmieri, Ph.D., R.Ph., executed August 26, 2016 (Ex. 1029, "Palmieri Declaration"). Patent Owner supports its position with the Declaration of Bernhardt L. Trout, Ph.D., executed January 10, 2017 (Ex. 2001, "Trout Declaration").

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[4] U.S. Patent No. 5,837,284, issued November 17, 1998, to Atul M. Mehta et al. ("Mehta") (Ex. 1005).

[5] PHYSICIANS' DESK REFERENCE 331, 2209–2211 (51st ed. 1997) ("PDR 1997") (Ex. 1009).

[6] Gerald L. Brown et al., *Behavior and Motor Activity Response in Hyperactive Children and Plasma Amphetamine Levels Following a Sustained Release Preparation*, 19 JOURNAL OF THE AMERICAN ACADEMY OF CHILD PSYCHIATRY 225–239 (1980) ("Brown") (Ex. 1011).

[7] U.S. Patent 5,229,131, issued July 20, 1993, to Gordon L. Amidon et al. ("Amidon") (Ex. 1004).

[8] Patricia W. Slattum et al., *Comparison of Methods for the Assessment of Central Nervous System Stimulant Response after Dextroamphetamine Administration to Healthy Male Volunteers*, 36 J. CLIN. PHARMACOL. 1039–1050 (1996) ("Slattum") (Ex. 1031).

C. The '148 Patent (Ex. 1001)

The '148 patent, titled "ORAL PULSED DOSE DRUG DELIVERY SYSTEM," is a reissue of U.S. Patent 6,605,300, and a continuation-in-part of U.S. Patent RE42,096 ("the '096 patent").[9] Ex. 1001 (51), (63).

The '148 patent teaches that Adderall® "comprises a mixture of four amphetamine salts, dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate and amphetamine sulfate, which in combination, are indicated for treatment of Attention Deficit[] Hyperactivity Disorder [ADHD] in children from 3–10 years if age." *Id.* at 3:16–21. According to the '148 patent, ADHD in children conventionally is treated by administering two separate doses of medication, "one in the morning, and one approximately 4–6 hours later, commonly away from home under other than parental supervision." *Id.* at 3:25–27. Administering two separate doses, however, "is time consuming, inconvenient, and may be problematic for those children having difficulties in swallowing tablet formulations." *Id.* at 3:28–30.

In order to avoid these disadvantages, the '148 patent discloses a "pulsed dose delivery system for amphetamine salts and mixtures thereof" that includes: "one or more pharmaceutically active amphetamine salts that are covered with an immediate release coating," and "one or more

[9] The '096 patent is a reissue of U.S. Patent No. 6,322,819, issued November 7, 2001 to Beth A. Burnside et al. ("the '819 patent"). Ex. 1001 (63).

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