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Paper 8
Entered: April 18, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMERIGEN PHARMACEUTICALS LIMITED,
Petitioner,

v.

SHIRE LLC,
Patent Owner.

Case IPR2015-02009
Patent RE42,096 E

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

SCHEINER, *Administrative Patent Judge*.

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

I. INTRODUCTION

Amerigen Pharmaceuticals Limited ("Petitioner") filed a Petition (Paper 1, "Pet.") on October 1, 2015, requesting an *inter partes* review of claims 1–3, 5, 8, 9, 11, 18–21, 23, and 25 of U.S. Patent No. RE42,096 E (Ex. 1001, "the '096 patent"). Shire LLC ("Shire" or "Patent Owner") filed a Preliminary Response (Paper 7, "Prelim. Resp.") on January 19, 2016. We have jurisdiction 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 information presented in the Petition and the Preliminary Response, we are persuaded that Petitioner has established a reasonable likelihood that it would prevail in its challenges to claims 18–21, 23, and 25 of the '096 patent. Accordingly, we institute an *inter partes* review of those claims.

A. Related Proceedings

Petitioner informs us of the following related judicial matters: *Shire LLC v. Amerigen Pharms. Ltd.*, 14-cv-6095 (D.N.J. Oct. 1, 2014); *Shire LLC v. Corepharma LLC*, 14-05694 (D.N.J. Sept. 12, 2014); *Shire LLC v. Par Pharm. Inc.*, 15-cv-01454 (D.N.J. Feb. 26, 2015). Pet. 1. Patent Owner

identifies the same related matters in its Mandatory Notices under 37 C.F.R. § 42.8(a)(2).[1] Paper 6, 1.

B. The Asserted Grounds of Unpatentability

Petitioner asserts the challenged claims are unpatentable on the following grounds. Pet. 4–8, 17–60.[2]

References	**Basis**	**Claims Challenged**
Mehta[3]	§ 102(e)	1–3, 5, 8, 9, 11, 18–21, 23, and 25
Mehta and Adderall PDR[4]	§ 103(a)	1–3, 5, 18–21, 23, and 25
Mehta, Adderall PDR, and Rosen[5]	§ 103(a)	8, 9, and 11

[1] Patent Owner informs us of a number of additional related judicial and administrative matters. Prelim. Resp. 2–7. We are not persuaded that Petitioner's failure to include those matters in its mandatory notices warrants dismissal of the Petition, and decline to do so on that basis.

[2] Petitioner supports its challenges with the Declaration of Edmund J. Elder, Jr., Ph.D., R.Ph., executed September 30, 2015 ("Elder Declaration") (Ex. 1006).

[3] U.S. Patent No. 5,837,284, issued November 17, 1998, to Mehta et al. ("Mehta") (Ex. 1003).

[4] PHYSICIANS' DESK REFERENCE 331, 2209–11 (51st ed. 1997) ("Adderall PDR") (Ex. 1004).

[5] Earl Rosen et al., *Absorption and Excretion of Radioactively Tagged Dextroamphetamine Sulfate from a Sustained-Release Preparation*, 194 JAMA 145–147 (1965). ("Rosen") (Ex. 1015).

C. The '096 Patent (Ex. 1001)

The '096 patent, titled "ORAL PULSED DOSE DRUG DELIVERY SYSTEM," is a reissue of U.S. Patent 6,322,819,[6] and "is listed in the FDA's 'Orange Book' of approved drug products for Adderall XR®, which is indicated for Attention Deficit Hyperactivity Disorder (ADHD)." Prelim. Resp. 1.

The '096 patent teaches that 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." Ex. 1001, 3:20–13. Administering two separate doses, however, "is time consuming, inconvenient, and may be problematic for those children having difficulties in swallowing tablet formulations." *Id.* at 3:14–17.

The '096 patent, thus, discloses a pharmaceutical composition comprising "an oral multiple pulsed dose delivery system for amphetamine salts and mixtures thereof" (*id.* at 3:22–24), "in which there is immediate release of drug and enteric release of drug wherein the enteric release is a pulsed release and wherein the drug includes one or more amphetamine salts and mixtures thereof" (*id.* at 3:53–57). In other words, "[t]he immediate release component releases the pharmaceutical agent in a pulsed dose upon oral administration of the delivery system" (*id.* at 3:58–60), while "[t]he

[6] U.S. Patent No. 6,322,819, issued November 7, 2001 to Burnside et al. ("the '819 patent") (Ex. 1017).

enteric release coating layer retards or delays the release of the pharmaceutical active or drug for a specified time period ("lag time") until a predetermined time, at which time the release of the drug is rapid and complete" (*id.* at 3:61–64).

> In accordance with a preferred embodiment . . . there is provided a pharmaceutical composition for delivering one or more pharmaceutically active amphetamine salts that includes:
>
> (a) one or more pharmaceutically active amphetamine salts that are covered with an immediate release coating, and
>
> (b) one or more pharmaceutically active amphetamine salts that are covered with an enteric release coating wherein (1) the enteric release coating has a defined minimum thickness and/or (2) there is a protective layer between the at least one pharmaceutically active amphetamine salt and the enteric release coating and/or (3) there is a protective layer over the enteric release coating.

Id. at 3:28–42.

According to the '096 patent, plasma levels of the pharmaceutically active amphetamine salts "will reach a peak fairly rapidly after about 2 hours, and after about 4 hours a second pulse dose is released, wherein a second fairly rapid additive increase of plasma drug levels occurs which slowly decreases over the course of the next 12 hours." *Id.* at 10:4–9. Thus, "the multiple dosage form of the . . . invention can deliver rapid and complete dosages of pharmaceutically active amphetamine salts to achieve the desired levels of the drug in a recipient over the course of about 8 hours with a single oral administration." *Id.* at 9:66–10:3.

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