Trials@uspto.gov
571.272.7822

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AUROBINDO PHARMA USA INC.,
Petitioner,

v.

ANDRX LABS, LLC,
Patent Owner.

Case IPR2017-01673
Patent 6,790,459 B1

Before SUSAN L.C. MITCHELL, TINA E. HULSE, and DEVON ZASTROW NEWMAN, *Administrative Patent Judges*.

HULSE, *Administrative Patent Judge*.

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

I. INTRODUCTION

Aurobindo Pharma USA Inc. ("Petitioner") filed a Corrected Petition requesting an *inter partes* review of claims 1–21 of U.S. Patent No. 6,790,459 B1 (Ex. 1001, "the '459 patent"). Paper 8 ("Pet."). Andrx Labs, LLC ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp.").

We have 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." 35 U.S.C. § 314(a). Upon considering the Petition and Preliminary Response, we determine that Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–21 of the '459 patent. Accordingly, we decline to institute an *inter partes* review of those claims.

A. Related Proceedings

The '459 patent has been asserted against Petitioner in pending district court case *Shionogi Inc. v. Aurobindo Pharma Ltd.*, No. 1:17-cv-00072-UNA (D. Del.). Pet. 11–12; Paper 6, 4.

B. The '459 Patent

The '459 patent relates to a method for treating patients with non-insulin-dependent diabetes mellitus (NIDDM) by administering a controlled release oral dosage form containing preferably a biguanide drug such as metformin on a once daily basis. Ex. 1001, Abstract. Metformin is an oral antihyperglycemic drug that improves glucose tolerance in NIDDM patients by lowering both basal and postprandial plasma glucose. *Id.* at 1:57–62. Metformin hydrochloride is marketed as Glucophage, for which there is no fixed dosage regimen for managing hyperglycemia in diabetes mellitus. *Id.*

at 1:62–67. Glucophage dosing is individualized based on both effectiveness and tolerance, while not exceeding the maximum recommended dose of 2550 mg per day. *Id.* at 1:67–2:3.

Metformin is a short acting drug that requires dosing two or three times a day. *Id.* at 2:5–7. Metformin use, however, is often associated with gastrointestinal adverse side effects, which may be partially avoided by either reducing the initial and/or maintenance dose or using an extended release dosage form. *Id.* at 2:7–12. An advantage of using an extended release dosage form is reducing the frequency of administration. *Id.* at 2:12–14.

The '459 patent states that vast amounts of research have been performed on controlled or sustained release compositions, but very little research has been performed on controlled or sustained release compositions that employ antihyperglycemic drugs. *Id.* at 1:51–55. Thus, according to the specification, "an extended-release dosage form of metformin may improve the quality of therapy in patients with N[I]DDM and the safety profile relative to a conventional dosage form." *Id.* at 2:15–17.

C. Illustrative Claim

Petitioner challenges claims 1–21 of the '459 patent, of which claim 1 is the only independent claim. Claim 1 is representative and is reproduced below:

> 1. A method for lowering blood glucose levels in human patients needing treatment for non-insulin-dependent diabetes mellitus (NIDDM), comprising orally administering to human patients on a once-a-day basis at least one oral controlled release dosage form comprising an effective dose of metformin or a pharmaceutically acceptable salt thereof and an effective amount of a controlled release carrier to control the release of said metformin or pharmaceutically acceptable salt thereof from said

> dosage form, wherein following oral administration of a single dose, the dosage form provides a mean time to maximum plasma concentration (T_{max}) of metformin at from 5.5 to 7.5 hours after administration following dinner; and the administration of the at least one metformin dosage form provides a mean AUC_{0-24} of 22590±3626 ng·hr/ml and a mean C_{max} of 2435±630 ng/ml on the first day of administration and a mean AUC_{0-24} of 24136±7996 ng·hr /ml and a mean C_{max} of 2288±736 n[g]/ml on the 14th day of administration, for administration of a 2000 mg once-a-day dose of metformin.

Ex. 1001, 22:13–30.

Dependent claims 2–10, 12, and 13 further limit the pharmacokinetic parameters of claim 1. Dependent claims 11 and 17–21 further limit the dose of metformin. Dependent claims 14 and 15 further recite administering at least one additional pharmaceutically active ingredient for treatment of NIDDM. And dependent claim 16 requires that the dose of metformin comprises metformin hydrochloride. *Id.* at 22:31–24:32.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–21 of the '459 patent on the following grounds:

Reference(s)	Basis	Claims challenged
Chen[1]	§ 102	1–21
Cheng,[2] Timmins,[3] Tucker,[4] and Lewis[5]	§ 103	1–21

Petitioner also relies on the Declaration of Dr. Fatemah Akhlaghi, Pharm.D., Ph.D. Ex. 1009.

II. ANALYSIS

A. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art as of November 3, 2000, would have had "experience in the research or development of pharmaceuticals and have the ability to gather and interpret pharmacokinetic data, as well as understand the relationship between drug release from a dosage form and its effect on pharmacokinetic parameters." Pet. 15; Ex. 1009 ¶ 70. Petitioner further asserts that a person of ordinary skill in the art would include "an individual with a Pharm.D. and/or Ph.D. with experience in pharmaceutical sciences, dosage form design, clinical pharmacology or related fields such as pharmacology." Pet. 15; Ex. 1009

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[1] Chen et al., WO 00/12097, published Mar. 9, 2000 ("Chen," Ex. 1011).
[2] Cheng et al., WO 99/47125, published Sept. 23, 1999 ("Cheng," Ex. 1002).
[3] Timmins et al., WO 99/47128, published Sept. 23, 1999 ("Timmins," Ex. 1013).
[4] Tucker et al., *Metformin Kinetics in Healthy Subjects and in Patients with Diabetes Mellitus*, 12 BR. J. CLIN. PHARMAC. 235–46 (1981) ("Tucker," Ex. 1005).
[5] Lewis et al., WO 00/28989, published May 25, 2000 ("Lewis," Ex. 1003).

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