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Paper No. 34
Entered: December 28, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AUROBINDO PHARMA USA, INC.
Petitioner,

v.

ANDRX CORPORATION,
ANDRX LABORATORIES, INC.
ANDRX LABORATORIES (NJ), INC.
ANDRX EU LTD.
ANDRX PHARMACEUTICALS, LLC,
TEVA PHARMACEUTICAL INDUSTRIES LTD.
Patent Owner(s)

Case IPR2017-01648
Patent 6,866,866 B1

Before SUSAN L.C. MITCHELL, JO-ANNE M. KOKOSKI, and DEVON ZASTROW NEWMAN, *Administrative Patent Judges*.

NEWMAN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a); 37 C.F.R. § 42.73

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–25 of U.S. Patent No. 6,866,866 B1 (Ex. 1001, "the '866 patent"). We have jurisdiction under 35 U.S.C. § 6. The evidentiary standard is a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

Having reviewed the arguments of the parties and the supporting evidence, we determine that Petitioner has not demonstrated by a preponderance of the evidence that the challenged claims are unpatentable.

A. Procedural History

Aurobindo Pharma USA, Inc. ("Petitioner") filed a Corrected Petition requesting an *inter partes* review of claims 1–25 of the '866 patent. Paper 8 ("Pet."). The Petition relies upon the Declaration of Dr. Fatemeh Akhlaghi. Ex. 1019 ("Akhlaghi Decl.").

Andrx, LLC ("Patent Owner") filed a Preliminary Response to the Petition.[1] Paper 11 ("Prelim. Resp."). We instituted an *inter partes* review of challenged claims 1–25 on one ground of unpatentability, pursuant to 35 U.S.C. § 314. Paper 12 ("Inst. Dec."), 21–22.

After institution and before the due date for Patent Owner's Response, however, the U.S. Supreme Court issued its decision in *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018). *See* Paper 20. Pursuant to *SAS Institute*, a decision to institute an *inter partes* review under 35 U.S.C. § 314 may not

[1] No other party named in the Petition entered an appearance on behalf of Patent Owner in this matter.

institute trial on fewer than all claims challenged in the petition. *SAS Institute*, 138 S. Ct. at 1355–56, 1358. In this proceeding, we had instituted only on Petitioner's ground based on § 103. *See* Inst. Dec. 22. Accordingly, we modified our Decision on Institution to include review of all challenged claims on all grounds presented in the Petition. Paper 20, 2–3. The parties subsequently submitted a Joint Motion to Limit the Petition, requesting that the Petition be limited to the ground based on § 103, for obviousness of claims 1–25 over Timmins[2] and Cheng.[3] Joint Motion 2. We granted the motion. Paper 23.

Patent Owner filed a Response (Paper 25, "PO Resp."), which relies upon the Declaration of Dr. Jennifer Dressman ("Dressman Decl.," Ex. 2010). Petitioner filed a Reply (Paper 26, "Reply").

An oral hearing was held on September 24, 2018, and a transcript of the hearing is included in the record. Paper 33 ("Tr.").

B. Related Proceedings

Petitioner identifies a currently pending district court action filed by Patent Owner against the Petitioner, asserting infringement of the '866 patent, *Shionogi Inc. v. Aurobindo Pharma Ltd.*, Civ. Act. No. 1:17-cv-00072-UNA (D. Del. 1-25-17), and identifies multiple previous litigations in the District of Delaware, the Federal Circuit (Ex. 1006), and in the District of New Jersey. Pet. 7–8. Patent Owner identifies five prior individual or

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[2] Timmins, Peter et al., WO 99/47128, published September 23, 1999 ("Timmins" Ex. 1003).
[3] Cheng, Xiu, Xiu et al., WO 99/47125, published September 23, 1999 ("Cheng" Ex. 1002).

consolidated actions that were filed and dismissed, including some by settlement. Paper 6, 3–4.

C. The '866 and Relevant Background

The '866 patent relates to "controlled release unit dose formulations containing an antihyperglycemic drug. . . . [specifically] an oral dosage form comprising a biguanide such as metformin." Ex. 1001, 1:6–11. Metformin is used to manage non-insulin dependent diabetes mellitus (NIDDM). *Id.* at 1:56–58.

According to the Specification, various techniques have been used to provide controlled and extended-release pharmaceutical dosage forms that provide stable therapeutic serum levels of the drug, thereby minimizing the effect of missed doses. *Id.* at 1:14–18. Because metformin is a short-acting drug, it requires twice- or thrice-daily doses. *Id.* at 2:4–6. The '866 patent states that, due to adverse events associated with use of metformin, reducing the dosage or using an extended-release form would provide a benefit, in addition to reducing the frequency of administration and improving the drug's safety profile. *Id.* at 2:6–16.

The '866 patent discloses a controlled release dosage form of metformin that is suitable for once-a-day dosing in the "fed" state, preferably at dinner. *Id.* at 8:54–56. The '866 patent states that, when administered in this manner, the bioavailability of the drug is improved relative to the fasted state, which is opposite of the commercially available form of metformin, GLUCOPHAGE®. *Id.* at 8:56–59. In addition, when dosed at dinnertime, the controlled release formulations provide a T_{max} between 5.5 and 7.5 hours after oral administration (which is delayed relative to the T_{max} provided by GLUCOPHAGE®), "such that the level of

the drug is greatest at the time when human patients are manufacturing glucose at highest levels." *Id.* at 8:66–9:6.

D. Challenged Claims and Reviewed Ground of Unpatentability

As discussed above, the sole ground of review at issue is whether claims 1–25 are unpatentable under 35 U.S.C. § 103 based on the combination of Timmins and Cheng. *See* Inst. Dec. 22; Paper 23 (granting Parties' Joint Motion to Limit Petition).

Claim 1 of the '866 patent, the only independent claim, is representative and is reproduced below, with the limitation at issue italicized:

> 1. A controlled release oral dosage form for the reduction of serum glucose levels in human patients with NIDDM, comprising an effective dose of metformin or a pharmaceutically acceptable salt thereof and a controlled-release carrier to control the release of said metformin or pharmaceutically acceptable salt thereof from said dosage form, said dosage form being suitable for providing once-a-day oral administration of the metformin or pharmaceutically acceptable salt thereof, wherein following oral administration of a single dose, *the dosage form provides a mean time to maximum plasma concentration (T_{max}) of the metformin from 5.5 to 7.5 hours after administration* following dinner.

Dependent claims 2–25 recite additional or more restricted limitations with respect to those in claim 1, including narrower T_{max} ranges (claims 2, 3, 23, and 24), specified dissolution profiles (claims 4 and 5), specified heights of the mean plasma concentration/time curve at specific hours after dosing (claims 6 and 7), and specified C_{max}, $AUC_{0–24}$, $AUC_{0–\infty}$, and/or $t_{1/2}$ values when certain dosing parameters are followed (claims 8–22). Claim 25 additionally recites

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