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Paper No. 12
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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, TINA E. HULSE, and
DEVON ZASTROW NEWMAN, *Administrative Patent Judges*.

NEWMAN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Aurobindo Pharma USA, Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–25 of U.S. Patent No. 6,866,866 B1 (Ex. 1001, "the '866 patent"). Paper 1. Petitioner subsequently filed a Corrected Petition seeking the same relief. Paper 8 ("Pet."). Andrx, LLC ("Patent Owner") filed a Preliminary Response to the Petition. Paper 11 ("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 established a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–25 of the '866 patent. Accordingly, we institute an *inter partes* review of those claims.

A. 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. and Andrx Labs. L.L.C. v. Aurobindo Pharma Ltd. et al.*, Civ. Act. No. 1:17-cv-00072-UNA (D. Del. 1-25-17). Pet. 7. Petitioner also states that the "'866 patent has been the subject of extensive previous litigation, both in the District of Delaware, the Federal Circuit (EX1006), and in the District of New Jersey, all of which has settled." Pet. 7–8. Patent Owner identifies several additional individual or consolidated actions involving the '866 patent that were filed and dismissed, including by settlement. Prelim. Resp. 11–12.

B. The '866 Patent

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 pharmaceutical dosage forms that are controlled or as extended-release forms to permit stable therapeutic serum levels of the drug, thereby minimizing missed doses. *Id.* at 1:14–18. Because metformin is a short-acting drug, it required 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 disclosed metformin dosage is a controlled release dosage form 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 the opposite result 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} from 5.5 to 7.5 hours after oral administration, which is delayed relative to the T_{max} provided by Glucophage. With the delayed T_{max} of the disclosed controlled release formulation, the level of the drug peaks coincident with when the subject

manufactures the highest levels of glucose, i.e. at night, while also lowering insulin levels. *Id.* at 8:66–9:14.

C. Illustrative Claim

Petitioner challenges claims 1–25 of the '866 patent, of which claim 1 is the only independent claim. Claim 1 is representative and is reproduced below:

> 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.

D. Real Parties in Interest

Petitioner identifies the real parties in interest for itself as Aurobindo Pharma USA, Inc., and Aurobindo Pharma Ltd. Pet. 7. Patent Owner does not identify a real party in interest but responds on behalf of Andrx Labs, LLC, as Patent Owner. Prelim. Resp., cover page.

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–25 of the '866 patent on the following grounds:

Reference(s)	Basis	Claims challenged
Chen[1]	§ 102(a)	1–25
Timmins[2]	§ 102(a)	1–3
Cheng[3] and Timmins	§ 103	1–25

Petitioner also relies on the Declaration of Dr. Fatemeh Akhlaghi, Pharm.D., Ph.D. (Ex. 1019) (hereinafter, "Akhlaghi Dec.")

II. ANALYSIS

A. Person of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art would have had "a Pharm.D. and/or Ph.D. with experience in pharmaceutical sciences, dosage forms, clinical pharmacology or related fields, such as pharmacology." Pet. 11; Ex. 1019 ¶¶ 91–96. Petitioner further asserts that a person of ordinary skill in the art would have had "experience in the research or development of pharmaceuticals and have the ability to gather and interpret pharmacokinetic data and the relationship between drug release from a dosage form and its effect on pharmacokinetic parameters." *Id.* Moreover, Petitioner contends that "pharmaceutical development is an inherently collaborative process" and that the skilled artisan would have had "access to, or be part of a team including, other skilled individuals, such as an M.D. with experience in the field of diabetes treatment." *Id.*

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[1] Chen, Chi-Ming, et al., WO 00/12097, published March 9, 2000 ("Chen" Ex. 1007).
[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).

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