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

Case IPR2018-00530
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
35 U.S.C. § 314(a)

I. INTRODUCTION

Aurobindo Pharma USA Inc. ("Petitioner") filed a 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 1 ("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 arguments and evidence, we determine that it is appropriate to exercise our discretion to deny institution under 35 U.S.C. § 314(a). Accordingly, we decline to institute an *inter partes* review of the challenged claims of the '459 patent.

A. Related Proceedings

Patent Owner has asserted the '459 patent against Petitioner in a pending lawsuit, *Shionogi Inc. v. Aurobindo Pharma Ltd.*, Case No. 1.17-cv-00072 (D. Del., filed Jan. 25, 2017). Pet. 11; Paper 7, 3. Patent Owner also identifies the pending lawsuit, *Shionogi Inc. v. Qingdao Baheal Pharmaceutical Co.*, Civ. No. 1:17-cv-1347-MSG (D. Del., filed Sept. 22, 2017). Paper 7, 4.

The parties also note that we denied institution in IPR2017-01673, which challenged the same claims of the '459 patent. Paper 7, 1. Additionally, Patent Owner notes Petitioner has filed a petition in IPR2017-01648, which challenges the claims of U.S. Patent No. 6,866,866. *Id.* We instituted *inter partes* review in that proceeding, which is currently pending.

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 ground:

References	Basis	Claims challenged
Cheng,[1] Timmins,[2] Wagner,[3] Lewis,[4] Gibaldi,[5] and DeFronzo[6]	§ 103	1–21

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

II. ANALYSIS

A. IPR2017-01673

On June 23, 2017, Petitioner filed a petition seeking *inter partes* review of claims 1–21 of the '459 patent on the following grounds:

[1] Cheng et al., WO 99/47125, published Sept. 23, 1999 ("Cheng," Ex. 1002).
[2] Timmins et al., WO 99/47128, published Sept. 23, 1999 ("Timmins," Ex. 1013).
[3] John G. Wagner, *Fundamentals of Clinical Pharmacokinetics* (1st ed. 1975) ("Wagner," Ex. 1019).
[4] Lewis et al., WO 00/28989, published May 25, 2000 ("Lewis," Ex. 1003).
[5] Gibaldi et al., *Pharmacokinetics* (2d ed. 2007) ("Gibaldi," Ex. 1018).
[6] DeFronzo et al., *Efficacy of Metformin in Patients with Non-Insulin-Dependent Diabetes Mellitus*, 333 NEW ENGLAND J. MED. 541–49 (1995) ("DeFronzo," Ex. 1020).

Reference(s)	Basis	Claims challenged
Chen[7]	§ 102	1–21
Cheng, Timmins, Tucker,[8] and Lewis	§ 103	1–21

Aurobindo Pharma USA Inc. v. Andrx Labs, LLC, Case IPR2017-01673 ("the First IPR"), Paper 1 at 14 ("the First Petition"). Petitioner also relied on the same declarant, Dr. Akhlaghi, to support its petition. *Id.*, Ex. 1009. Patent Owner filed a preliminary response on October 11, 2017. *Id.*, Paper 10. We entered our decision denying institution on both grounds on December 29, 2017. *Id.*, Paper 11.

B. Application of Our Discretion Under 35 U.S.C. § 314(a)

Institution of an *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a) (authorizing institution of an *inter partes* review under particular circumstances, but not requiring institution under any circumstances); *see also Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (explaining that under § 314(a) "the PTO is permitted, but never compelled, to institute an IPR proceeding"). When determining whether to exercise our discretion under § 314(a), we consider the following non-exhaustive factors:

1. whether the same petitioner previously filed a petition directed to the same claims of the same patent;

2. whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it;

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[7] Chen et al., WO 00/12097, published Mar. 9, 2000 ("Chen," Ex. 1011).
[8] 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).

3. whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response to the first petition or received the Board's decision on whether to institute review in the first petition;

4. the length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition;

5. whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent;

6. the finite resources of the Board; and

7. the requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.

Gen. Plastic Indus. Co. v. Canon Kabushiki Kaisha, Case IPR2016-01357, slip op. at 15–16 (PTAB Sept. 6, 2017) (Paper 19) (precedential) (hereinafter, "*General Plastic*") (citing *NVIDIA Corp. v. Samsung Elecs. Co.*, Case IPR2016-00134, slip op. at 6–7 (PTAB May 4, 2016) (Paper 9)). We address each of these factors in turn.

1. Whether the Same Petitioner Previously Filed a Petition Directed to the Same Claims of the Same Patent

Petitioner filed the First Petition in the First IPR challenging the same claims of the same patent as the instant case. *See* First Petition, 14. We, therefore, find this factor weighs in favor of denying institution.

2. Whether at the Time of Filing of the First Petition the Petitioner Knew of the Prior Art Asserted in the Second Petition or Should Have Known of It

The First Petition challenged the patentability of the claims as obvious over Cheng, Timmins, Tucker, and Lewis. *Id.* Here, Petitioner challenges the claims over Cheng, Timmins, Wagner, Lewis, Gibaldi, and DeFronzo.

Pet. 14. Thus, Petitioner clearly knew of at least Cheng, Timmins, and Lewis at the time of filing the First Petition.

Whether Petitioner knew of Wagner, Gibaldi, and DeFronzo at the time of filing the First Petition, however, is unclear. But, as Patent Owner notes, Wagner was published in 1975, Gibaldi in 2007, and DeFronzo in 1995. Prelim. Resp. 29. Thus, all three of the additional references were available well before the filing of the First Petition on June 23, 2017. Absent an explanation from Petitioner, we are persuaded that it is reasonable to assume that Petitioner could have found the newly asserted prior art through the exercise of reasonable diligence in its prior searches. *See Gen. Plastic*, slip op. at 20.

On this record, we find that this factor weighs in favor of denying institution.

3. Whether at the Time of Filing of the Second Petition the Petitioner Already Received the Patent Owner's Preliminary Response to the First Petition or Received the Board's Decision on Whether to Institute Review in the First Petition

Patent Owner filed its Preliminary Response in the First IPR on October 11, 2017. First IPR, Paper 10. We entered our decision denying institution in the First IPR on December 28, 2017. First IPR, Paper 11. Thus, Petitioner had both the Preliminary Response and our decision on whether to institute review in the First IPR when it filed the Petition in this case on January 24, 2018. Pet., cover.

Indeed, Petitioner notes that the Petition in this case "is an attempt to address the deficiencies noted by the panel in [the decision denying institution in the First IPR], and entails new references in the obviousness assertion to address the concerns of the panel in respect of the Tucker reference." Pet. 11. Similarly, Petitioner states that Dr. Akhlaghi's

declaration in this proceeding is "a revised (from IPR2017-016[7]3) declaration . . . addressing the concerns of the panel in IPR2017-016[7]3." Pet. 13.

Thus, by admission, Petitioner used our decision in the First IPR as a roadmap to shift its strategy and reformulate its challenge to the claims of the '459 patent. As stated in *General Plastic*, "this is unfair to patent owners and is an inefficient use of the *inter partes* review process." *Id.*, at 17–18. Accordingly, we find that this factor weighs heavily in favor of denying institution.

4. The Length of Time that Elapsed Between the Time the Petitioner Learned of the Prior Art Asserted in the Second Petition and the Filing of the Second Petition

As explained above, Petitioner was aware of Cheng, Timmins, and Lewis at the time of filing the First Petition, but it is unclear when Petitioner became aware of Wagner, Gibaldi, and DeFronzo. Nevertheless, in the absence of an explanation from Petitioner as to why it could not have found the newly asserted references earlier, we agree with Patent Owner that it is reasonable to assume that Petitioner was aware of—or should have been aware of—the new references at the time it filed the First Petition.

We, therefore, find that this factor weighs in favor of denying institution.

5. Whether the Petitioner Provides Adequate Explanation for the Time Elapsed Between the Filings of Multiple Petitions Directed to the Same Claims of the Same Patent

6. The Finite Resources of the Board

We address Factors 5 and 6 together. Other than to assert that the instant Petition "is an attempt to address the deficiencies" of the First Petition (Pet. 11), Petitioner does not explain why it filed the second follow-

on petition approximately seven months after the First Petition. Petitioner's explanation is insufficient because, as explained above, allowing a petitioner to use our decisions as a roadmap to cure the deficiencies in a first, failed petition is unfair to patent owners and an inefficient use of our resources. *See Gen. Plastic*, slip op. at 21 ("[M]ultiple, staggered petition filings, such as those here, are an inefficient use of the *inter partes* review process and the Board's resources.").

Accordingly, we find Factors 5 and 6 weigh heavily in favor of denying institution.

7. The Requirement Under 35 U.S.C. § 316(a)(11) to Issue a Final Determination Not Later than 1 Year After the Date on Which the Director Notices Institution of Review

Because the First Petition was denied, whether we can issue a final determination no later than one year after institution does not apply to our analysis here. This factor is therefore neutral.

8. Applying the General Plastic *Factors*

As explained above, six of the seven *General Plastic* factors weigh in favor of denying institution, with several weighing heavily in favor of denial. Moreover, we note that Petitioner was silent in response to Patent Owner's *General Plastic* arguments in the Preliminary Response, despite our invitation to request authorization to file a Reply to the Preliminary Response. *See* Paper 9. Specifically, Petitioner attempted to address the *General Plastic* factors in an updated mandatory notice, which we subsequently expunged as an improperly filed paper. *Id.* at 1–2. During the telephone conference to discuss that paper, Petitioner sought guidance regarding where it could make arguments to address the *General Plastic* factors. *Id.* at 1. We explained to Petitioner that it "could request

authorization to file a reply after Patent Owner files its Patent Owner Preliminary Response (assuming the Preliminary Response addresses the *General Plastic* factors)." *Id.* Petitioner, however, never made such a request.

Although there is no *per se* rule precluding follow-on petitions after a denial of a first petition, we are persuaded that exercising our discretion under § 314(a) to deny institution is appropriate under the facts and circumstances of this case.

III. CONCLUSION

For the foregoing reasons, we exercise our discretion under 35 U.S.C. § 314(a) and decline to institute an *inter partes* review of the '459 patent claims.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied* as to all challenged claims of the '459 patent and no trial is instituted.

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