

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC. and CIMA LABS,)
INC.,)
)
Plaintiffs,)
)
v.) Civ. No. 11-1152-SLR
)
IMPAX LABORATORIES, INC.,)
)
Defendant.)

MEMORANDUM ORDER

At Wilmington this 6th day of September, 2012, having considered defendant Impax Labs., Inc.’s (“Impax’s”) motion to dismiss and the papers submitted therewith; IT IS ORDERED that said motion (D.I. 9) is granted, as follows.

1. **Background.** On November 18, 2011, plaintiffs Cephalon, Inc. (“Cephalon”) and CIMA Labs., Inc. (“CIMA”) (collectively, “plaintiffs”) filed the present lawsuit alleging infringement of U.S. Patent Nos. 6,200,604 (“the ‘604 patent”), 6,974,590 (“the ‘590 patent”), 7,862,832 (“the ‘832 patent”) and 7,862,833 (“the ‘833 patent”) by Impax. (D.I. 1) Plaintiffs’ action arises out of the filing of an Abbreviated New Drug Application (“ANDA”)¹ by Impax in 2011² for a generic version of Fentora® (fentanyl buccal tablets), used to treat breakthrough pain in cancer patients. The ‘604 and ‘590 patents, assigned to CIMA and exclusively licensed to Cephalon, have been addressed in previous ANDA litigation in this court, wherein the court found both patents invalid for

¹No. 203357.

²Plaintiffs received notice of Impax’s ANDA on October 7, 2011. (D.I. 4)

lack of enablement. See *Cephalon, Inc. v. Watson Pharma., Inc.*, Civ. No. 08-330, 769 F. Supp. 2d 729 (D. Del. 2011) (hereinafter, “*Watson*”).³

2. Plaintiffs allege that Impax infringes each of the patents in suit by virtue of its filing of an ANDA containing a paragraph IV certification⁴ as to the ‘604, ‘590, ‘832 and ‘833 patents (hereinafter, “the patents-in-suit”).⁵ “Count I” through “Count IV” of plaintiffs’ complaint are directed to the ‘604 and ‘590 patents, and are the subject of Impax’s currently-pending motion to dismiss. (D.I. 9) Therein, Impax argues that there is no reason to litigate any issues involving the invalid ‘604 and ‘590 patents, as validity was actually litigated in the *Watson* litigation, culminating with a final judgment of invalidity against plaintiffs. (D.I. 10)

3. **Standard.** In *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, 402 U.S. 313 (1971), the Supreme Court held that, in the patent context, defensive collateral estoppel may be used if the accused infringer shows: “(1) that a patent was found invalid in a prior case that had proceeded through final judgment and in which all procedural opportunities were available to the patentee; (2) that the issues litigated were identical; and (3) that the party against whom estoppel is applied had a full and fair opportunity to litigate.” *Abbott Labs. v. Andrx Pharma., Inc.*, 473 F.3d 1196,

³The court incorporates its prior opinion by reference here and henceforth presumes familiarity with that decision.

⁴See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

⁵See 35 U.S.C. § 271(e)(2)(A) (“(2) It shall be an act of infringement to submit – (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent[.]”).

1203 (Fed. Cir. 2007). Regional Circuit law controls the determination of whether prior findings invoke collateral estoppel pursuant to these guidelines. *Id.* at 1202-03.

4. In this regard, the Third Circuit has held that collateral estoppel applies when “(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action.” *Jean Alexander Cosmetics, Inc. v. L’Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006) (citations omitted). The Third Circuit has also considered whether the party being precluded had “a full and fair opportunity to litigate the issue in question in the prior litigation” and, in addition, whether the issue was determined by final judgment. *Id.* (citations omitted).

5. **Discussion.** Plaintiffs’ response to Impax’s motion is two-fold. First, plaintiffs argue that collateral estoppel does not apply to bar its claims on the ‘604 and ‘590 patents because it did not have a “full and fair opportunity” to litigate enablement defenses in the *Watson* action. (D.I. 23 at 5-9) Specifically, plaintiffs assert that the court improperly supplemented the trial evidence (i.e., the testimony of Watson’s expert, Dr. Mumper) with party briefing and attorney argument in order to arrive at its non-enablement conclusion post-trial. (*Id.* at 8) “[W]hile Cephalon was able to address – and rebut – Watson’s inadequate trial evidence, it had no opportunity to answer the attorney argument back-filled by the court into the evidentiary holes in Watson’s enablement case.” (*Id.*) Plaintiffs also argue that the court improperly applied the reasoning from Watson’s failed non-adopted claim construction position to the

enablement inquiry. (*Id.* at 8-9)

6. The court does not agree with plaintiffs' characterizations of the *Watson* decision and, upon review, is not inclined to find that plaintiffs did not have an opportunity to address enablement. The court took into consideration plaintiffs' enablement arguments in the *Watson* opinion, with accompanying citations to the record. See *Watson*, 769 F. Supp. 2d at 752-54. Pursuant to *Blonder-Tongue*, collateral estoppel applies to bar the re-litigation of the invalid '604 and '590 patents. Therefore, the court grants Impax's motion to dismiss the related claims.

7. Alternatively, plaintiffs request that the court stay this litigation pending the Federal Circuit's review of the court's *Watson* decision on appeal.⁶ (D.I. 23 at 9-10) Impax opposes a stay on the basis that the '832 and '833 patents "issued from unrelated patent applications, name entirely different inventors, and will be unaffected by the *Watson* appeal."⁷ (D.I. 27 at 6)

8. Motions to stay invoke the broad discretionary powers of the court. *Dentsply Int'l, Inc. v. Kerr Mfg. Co.*, 734 F.Supp. 656, 658 (D. Del. 1990) (citing *Bechtel Corp. v. Laborers' Int'l Union*, 544 F.2d 1207, 1215 (3d Cir. 1976)). Three general factors inform the court in this regard:

- (1) whether the granting of a stay would cause the non-moving party to suffer undue prejudice from any delay or allow the moving party to gain a clear tactical

⁶According to the Federal Circuit's PACER site, the *Watson* case was appealed to the Federal Circuit on April 18, 2011. Plaintiffs filed several extensions of time to file its opening brief between May 19, 2011 and May 4, 2012; briefing commenced in the appeal on May 18, 2012 and has only recently been completed. Oral argument does not appear to have been scheduled.

⁷Impax also lists the "'981 patent" in this regard, which appears to be in error.

advantage over the non-moving party; (2) whether a stay will simplify the issues for trial; and (3) whether discovery is complete and a trial date set.

Enhanced Security Research, LLC v. Cisco Sys., Inc., Civ. No. 09–571, 2010 WL 2573925, at *3 (D. Del. June 25, 2010) (citing *St. Clair Intellectual Prop. Consultants v. Sony Corp.*, Civ. No. 01–557, 2003 WL 25283239, at *1 (D. Del. Jan. 30, 2003)).

9. The court has entered a schedule in this case with a trial date of June 24, 2013. (D.I. 26) Plaintiffs have stated that the 30-month stay deadline is April 7, 2014. (D.I. 4) The court is currently scheduling trials in October 2014. Thus, the court could not resolve the present dispute within thirty months if the remaining claims are stayed. Given the public interest at stake, the court declines plaintiffs' request for a stay.


United States District Judge