

[Dkt. Ent. 47, 48, 50]

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

ALCON LABORATORIES, INC., et  
al.,

Plaintiffs,

v.

AKORN, INC.,

Defendant.

Civil No. 15-cv-285 (RMB/JS)

**OPINION**

On January 14, 2015, Plaintiffs in this matter<sup>1</sup> filed a complaint against Akorn, Inc. ("Defendant") alleging patent infringement in connection with Defendant's Abbreviated New Drug Application ("ANDA") No. 207284. The patent at issue is related to the manufacture of the drug DUREZOL®. [Dkt. No. 1 at ¶ 6.]

On December 3, 2015, Plaintiffs filed a letter on the docket indicating that the matter had been selected for inter partes review ("IPR") by the Patent Trial and Appeals Board. [Dkt. No. 46.] On December 4, 2015, this Court issued an order to show cause why the matter should not be stayed pending the outcome of IPR. [Dkt. No. 47.] The parties both submitted letters on the issue, with Defendant opposing a stay and

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<sup>1</sup> Plaintiffs are Alcon Laboratories, Inc., Alcon Pharmaceuticals Ltd., Senju Pharmaceutical Co., Ltd., and Mitsubishi Chemical Corporation (collectively, "Plaintiffs").

Plaintiffs favoring a stay, provided the 30-month regulatory stay would also be correspondingly extended.

"It is well-established that 'the power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants.'" Power Survey, LLC v. Premier Utility Services, LLC, Civ. No. 13-5670, 2015 WL 5037003, at \*1 (D.N.J. Mar. 18, 2015) (quoting Landis v. North Am. Co., 299 U.S. 248, 251 (1936)). In that light, staying a patent case in which an IPR request has been granted is within the discretion of the Court. Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1426-27 (Fed. Cir. 1988) (noting that "[c]ourts have inherent power to manage their dockets and stay proceedings, including the authority to order a stay pending conclusion of a PTO reexamination.") (internal citations omitted); see also Cima Labs, Inc. v. Actavis Grp. HF, Nos. 07-893, 06-1999, 2007 WL 1672229, \*9 (D.N.J. June 7, 2007) ("[T]here is a liberal policy in favor of granting motions to stay proceedings pending the outcome of USPTO reexamination or reissuance proceedings").

In determining whether a stay is proper, courts typically rely upon a three-part test. "Courts consider (1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will

simplify the issues in question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set.” Power Survey, LLC, 2015 WL 5037003, at \*1. While the parties both contend that some degree of prejudice may befall them if a stay is ordered, the Court finds that even if these arguments ring true, the second and third factors nonetheless warrant the issuance of a stay.

Regarding the second factor, a stay will clearly simplify the issues in question and during trial of the case. “[I]t is virtually undeniable that a stay followed by a PTO reexamination will simplify the issues in the case and streamline the proceedings.” Cook Inc. v. Endologix, Civ. No. 09-1248, 2010 WL 325960, at \*2 (S.D. Ind. Jan. 21, 2010) (quoting Lincoln Nat’l Life Ins. Co. v. Transamerica Fin. Life Ins. Co., No. 1:08-cv-135, 2009 WL 1108822, at \*4 (N.D. Ind. Apr. 24, 2009)).

Defendant admits that to the extent the IPR cancels all of the claims in the ’319 patent, the entirety of the infringement and invalidity issues will be resolved. [Dkt. No. 48 at 4-5.]

While the Court is aware that the IPR may not resolve all issues, the case will still be greatly simplified, if only because this Court may make use of the analysis of the PTO thereafter. Cima, Inc., 2007 WL 1672229, at \*10 (“[G]iven the expertise of the PTO, its findings would provide a valuable analysis to the [C]ourt.”). Finally, a stay will also avoid the

complicating peril of this Court issuing inconsistent decisions. Eli Lilly and Co. v. Accord Healthcare Inc., Civ. No. 14-389, 2015 WL 8675158, at \*2 (S.D. Ind. Dec. 11, 2015) (“Staying this litigation will avoid the possibility of obtaining a result that is inconsistent with any decision by the PTO . . . .”). The second factor cuts strongly in favor of a stay.

Regarding the third factor, the Court finds that the status of the case favors granting a stay. Opening Markman briefs have not yet been filed in the case and no Markman hearing date has been set by the Court. Furthermore, fact discovery is not due to be completed until 45 days after the entry of the Court’s Claim Construction Order. [Dkt. No. 29.] Expert reports are not due for another 30 days after that. Id. A trial date is not on the horizon. “[M]ost often, cases have been denied a stay due to the late stage of litigation, the fact that discovery was or would be almost completed, or the matter had been marked for trial.” Cima Inc., 2007 WL 1672229, at \*10. No similar situation is present here. Accordingly, because this factor also cuts in favor of stay, the Court will stay the matter until a written decision is issued on the IPR.

Finally, with regard to Plaintiffs’ contention that the stay during IPR should also extend or toll the running of the 30-month regulatory stay under the Hatch-Waxman Act, this Court is without the authority to do so. As Plaintiffs note, “[t]he

30-month regulatory stay is a critical provision of the Hatch-Waxman Act . . . .” [Dkt. No. 49 at 2.] A court has discretion to extend the 30-month regulatory stay, but only if a party has “failed to reasonably cooperate in expediting the action.” 21 U.S.C. § 355(j)(5)(B)(iii); see also Novartis Corp. v. Dr. Reddy’s Labs. Ltd., Civ. No. 04-757, 2004 WL 2368007, at \*3 (S.D.N.Y. Oct. 21, 2004) (“[T]he Court has the discretion to extend the thirty-month period if either party to the action failed to reasonably cooperate in expediting the action.”); Sunovion Pharms, Inc. v. Sandoz, Inc., Nos. 10-MD-1500, 08-cv-89, 2011 WL 3875397, at \*3 (E.D. N.C. Sept. 1, 2011) (“[A]djustments of the 30-month stay are the exception, not the norm”). Put simply, the Court is not prepared to hold—nor have Plaintiffs argued—that either party has failed to reasonably cooperate in expediting the action. This is in accord with District of New Jersey precedent holding extension of the 30-month window is improper under similar circumstances. Cima, Inc., 2007 WL 1672229, at \*10.

Plaintiffs’ argument that this Court does have authority to toll the 30-month regulatory stay absent a finding of either party failing to reasonably cooperate with expediting the proceedings is unavailing. Plaintiffs point to two cases in which they claim courts have extended the regulatory stay when failing to do so would prejudice a party. See Novartis Corp.,

2004 WL 2368007; Abbott Labs. V. Matrix Labs., Inc., Civ. No. 09-1586, 2009 WL 3719214 (N.D. Ill. Nov. 5, 2009). The Court disagrees with Plaintiffs' reading of these authorities. In Novartis Corp., the court in its discretion extended the 30-month regulatory stay in connection with a requested stay, but only after finding that the party requesting the stay could not "feasibly argue that it [was] reasonably cooperating with expediting the action when it [had] asked the court to stay the proceedings." Id. at \*3. The court in Abbott relied on Novartis to reach the same result. 2009 WL 3719214, at \*3 (N.D. Ill. Nov. 5, 2009) ("To be sure, as another court has observed [in Novartis], Defendants cannot feasibly argue that they are reasonably cooperating in expediting the action when they have asked the court to stay the proceedings" (quotation marks and alterations omitted)).

In this case, the issue of a stay has arisen sua sponte, and the Court does not believe any party has failed to reasonably cooperate with expediting the proceedings. Cima, Inc., 2007 WL 1672229, at \*11 (holding that 21 U.S.C. § 355(j)(5)(B)(iii) was inapplicable in extending the 30-month stay under similar circumstances); see also Eli Lilly and Co. v. Accord Healthcare Inc., 2015 WL 8675158, at \*2 (S.D. Ind. Dec. 11, 2015) (staying proceedings during IPR and finding 21 U.S.C. § 355(j)(5)(B)(iii) inapplicable). To the extent that prejudice

may arise if this stay results in the matter continuing beyond the 30-month stay, Plaintiffs will have the opportunity to seek an injunction to prevent an at-risk launch. Eli Lilly, 2015 WL 8675158, at \*2.

Accordingly, the case is stayed until the PTO issues a written decision regarding IPR of the '319 patent.<sup>2</sup> Furthermore, the Clerk of the Court shall administratively terminate the case until directed to reopen it by this Court. An appropriate Order follows.

**DATED:** January 8, 2016

s/Renée Marie Bumb  
**RENÉE MARIE BUMB**  
**UNITED STATES DISTRICT JUDGE**

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<sup>2</sup> This Court may revisit the issue of whether the stay should be extended through any appeal from the IPR decision. At this time, however, the stay will continue only through the issuance of a decision by the Patent Trial and Appeals Board.