NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IMPAX LABORATORIES, INC.., Plaintiff, v. ACTAVIS LABORATORIES FL, INC. and ACTAVIS PHARMA INC., Defendants.	:	**Civil Action No. 15-cv-6934 (SRC)(CLW)** **OPINION AND ORDER**

CHESLER, District Judge

This matter comes before the Court upon the motion filed by Plaintiff Impax Laboratories, Inc. ("Impax") to stay proceedings in this case related to U.S. Patent No. 7,094,427 ("the '427 patent"), pending the outcome of ongoing United States Patent and Trademark Office ("PTO") reexamination proceedings [Docket Entry 43]. Defendants Actavis Laboratories FL, Inc. and Actavis Pharma Inc. ("Actavis") oppose this motion. The Court has considered the parties' submissions and proceeds to rule without oral argument, pursuant to Federal Rule of Civil Procedure 78. For the reasons set forth below, the Court will grant in part and deny in part Impax's motion.

I. BACKGROUND

a. DISTRICT OF NEW JERSEY LITIGATION

Impax filed the Complaint on September 17, 2015, based on Actavis's submission of Abbreviated New Drug Application ("ANDA") No. 208522 to the Food and Drug Administration ("FDA"), seeking approval for a generic version of Impax's Rytary®

(Levodopa/Carbidopa) capsule drug. (Compl. ¶ 1.) Impax asserts six patents in this suit.[1] (Compl. ¶¶ 1, 29-97.) Of relevance to this motion, Impax is the holder of the '427 patent, issued on August 22, 2006. (Compl. ¶ 20.) Impax also holds New Drug Application ("NDA") No. 203312 for carbidopa and levodopa capsules for oral use in various dosages, sold under the tradename Rytary®. (Compl. ¶ 26.)

The 30-month stay on final approval of Actavis's ANDA in this case, pursuant to the provisions of the Hatch-Waxman Act, expires on February 5, 2018 [Docket Entry 33]. Actavis served preliminary non-infringement and invalidity contentions on March 10, 2016 [Docket Entry 42]. Impax's responses to Actavis's contentions, as well as Impax's infringement contentions, are due June 3, 2016 [Docket Entry 42]. Claim construction is scheduled to be completed on August 19, 2016, and the Court has not yet set a date for a *Markman* hearing [Docket Entry 33]. The deadline for fact discovery is scheduled for February 14, 2017 [Docket Entry 33]. No depositions have been taken, no expert reports have been filed, and a trial date has not been set. Finally, Impax filed this motion to stay April 19, 2016 [Docket Entry 43].

b. PTO REEXAMINATION OF THE '427 PATENT

A third party filed a request for an *ex parte* reexamination of the '427 patent on May 11, 2012. (Reexam No. 90/012293). Pursuant to this request, on May 3, 2013, the PTO issued a non-final office action rejecting all claims of the '427 patent as anticipated or obvious based on prior art. Impax has amended its claims twice, but the PTO still issued a final rejection of all amended claims on July 25, 2014. Impax responded to the final rejection by submitting a further set of amendments to the PTO on September 25, 2014, but the PTO declined to enter these

[1] The six patents asserted in this suit are U.S. Patent Nos. 7,094,427, 8,377,474, 8,454,998, 8,557,283, 9,089,607, and 9,089,608. (Compl. ¶ 1.)

suggested amendments on November 24, 2014. Impax filed a notice of appeal to the Patent Trial and Appeal Board ("PTAB") the next day, based on further amended claims. The final argument in the reexamination appeal is set before the PTAB for June 1, 2016. Impax acknowledges that it has abandoned pursuit of all original claims in the '427 patent.

Impax seeks a stay with respect to the '427 patent, until completion of the reexamination proceedings; furthermore, Impax acknowledges that there is no definite schedule for when these proceedings will be completed. Actavis contends that Impax is seeking a stay of all proceedings on this patent until the appeals process is completed, which could take several years, and that such a stay would cause undue prejudice to Actavis.

II. LEGAL STANDARD TO STAY A PROCEEDING

"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." *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936). "How this can best be done calls for the exercise of judgment, which must weigh competing interests and maintain an even balance." *Id.* at 254-55. Therefore, district courts have broad powers to stay proceedings. *Bechtel v. Laborers' Int'l Union*, 544 F.2d 1207, 1215 (3d Cir. 1976). "In the exercise of its sound discretion, a court may hold one lawsuit in abeyance to abide the outcome of another which may substantially affect it or be dispositive of the issues." *Id.*; *see also Am. Life Ins. Co. v. Stewart*, 300 U.S. 203, 215 (1937). The party seeking a stay of civil litigation bears the burden to show that the stay would be appropriate. *Landis*, 299 U.S. at 255.

Courts have "consistently recognized the inherent power of the district courts to grant a stay pending reexamination of a patent." *Procter & Gamble v. Kraft Foods Global, Inc.*, 549 F.3d 842, 849 (Fed. Cir. 2008); *see also Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426-27 (Fed.

Cir. 1988); *Viskase Corp. v. Am. Nat'l Can Co.*, 261 F.3d 1316 (Fed. Cir. 2001). There is no conflict between a challenge to a patent in federal court and a reexamination at the PTO, despite the fact that the two forums may come to different legal conclusions on the same patent given the different legal standards applied. *Ethicon*, 849 F.2d at 1428-29, n.3.

Courts in this District have noted a generally liberal policy toward granting stays pending patent reexamination by the PTO. *See, e.g., Brass Smith, LLC v. RPI Indus., Inc.*, No. 09-6344, 2011 WL 4444717, at *6 (D.N.J. Nov. 1, 2010) (listing relevant cases); *Sabert Corp. v. Waddington N. Am., Inc.*, No. 06-5423, 2007 WL 2705157, at *5-6 (D.N.J. Sept. 14, 2007); *Cima Labs., Inc. v. Actavis Grp. HF*, No. 07-893, 2007 WL 1672229, at *9 (D.N.J. June 7, 2007). When courts have denied a stay pending reexamination proceedings at the PTO, it has most often been because the case was in a "late stage of litigation, [] discovery was or would be almost completed, or the matter had been marked for trial." *GPAC, Inc. v. D.W.W. Enters., Inc.*, 144 F.R.D. 60, 64 (1992). District courts seek to avoid the potential for waste of a court's time and resources when a PTO decision could "drastically alter" the nature of a case. *WABCO Holdings v. Bendix Commercial Vehicle Sys.*, No. 09-3179, 2010 WL 2628335, at *2 n.2 (D.N.J. June 28, 2010). But stays pending PTO reexamination of one or more asserted patents in a case are not automatic, as a "stay in litigation inevitably causes further delay in an already lengthy process, and could potentially harm [the opposing party]." *Brass Smith*, No. 09-6344, 2011 WL 4444717, at *2 (quoting *Eberle v. Harris*, No. 03-5809, 2005 WL 6192865, at *2 (D.N.J. Dec. 8, 2005)). Furthermore, the PTO cannot stay the reexamination once a request has been granted, and thus the district court is the only forum in which a party can seek a stay in a case with parallel proceedings. *Ethicon*, 849 F.2d at 1422.

III. DISCUSSION

Typically, courts consider the following three factors in determining whether to stay a case pending reexamination of a patent: "(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 and the trial of the case; and (3) whether discovery is complete and a trial date has been set." *Stryker Trauma S.A. v. Synthes (USA),* No. 01–3879, 2008 WL 877848, at *1 (D.N.J. Mar. 28, 2008) (quoting *Xerox Corp. v. 3Com Corp.*, 69 F. Supp. 2d 404, 406 (W.D.N.Y. Feb. 18, 1999)). In analyzing these factors, courts "weigh[ ] the benefits of the stay against the costs." *Id.*

a. Potential Prejudice to Actavis

The first factor for consideration in analyzing Impax's request for a stay is "whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party." *Id.* The court weighs whether disadvantages from delay are outweighed by advantages from allowing the PTO to complete the reexamination process before further consideration of the district court case, on a case-by-case basis. *ICI Uniqema v. Kobo Prods., Inc.*, No. 06-2943, 2009 WL 4034829, at *2 (D.N.J. Nov. 20, 2009). Furthermore, the Federal Circuit has made clear that district courts are not required to stay judicial resolution of a case pending reexamination. *Viskase*, 261 F.3d at 1328. But "[t]he delay inherent to the reexamination process does not constitute, by itself, undue prejudice." *CCP Sys. AG v. Samsung Elecs. Corp.*, No. 09-4354, 2010 WL 5080570, at *3 (D.N.J. Dec. 7, 2010).

Given the facts underlying its suit, Impax has not made an ordinary request for a stay pending a reexamination. Impax filed suit and asserted the '427 patent more than a year after the PTO had issued a final rejection on all amended claims in the '427 patent; in fact, the reexamination had proceeded well into the appeal process at the time of Impax's filing. Impax

has not established that moving forward with litigation on the ’427 patent would be particularly unfair or burdensome, since Impax asserted claims that it knew could not be enforced in their asserted forms, given the PTO’s rejection and Impax’s subsequent amendment of these claims in the reexamination process.

Actavis faces potentially significant prejudice from a stay, however. First, Actavis made its invalidity and non-infringement disclosures on March 10, 2016. A stay at this time would allow Impax to avoid making its infringement and validity disclosures for an unknown period of time. Granting a stay would provide an unfair tactical advantage to Impax in this litigation, since the Complaint does not allege specific facts that make clear what the basis of Impax’s allegations against Actavis are with respect to the ’427 patent.

The unknown duration of Impax’s requested stay increases the risk of prejudice to Actavis. Should Impax not succeed in its current appeal before the PTAB, it has the right to appeal the decision at the PTAB and then the Federal Circuit. These appeals could take years, therein prejudicing Actavis’s ability to enter the market following the end of the 30-month stay, should it prevail on the merits. *See Nippon Steel & Sumito Metal Corp. v. POSCO*, No. 12-2429, 2013 WL 1867042, at *6 (D.N.J. May 2, 2013). Should Impax prevail at some point during the appeals process, the Court will be forced to litigate the ’427 patent on a separate track, therein potentially delaying Actavis’s entry onto the market even further. Furthermore, Impax gains a tactical advantage, should litigation be delayed in this case. Delaying the date on which Actavis could enter the market by granting a long stay in this case may, in effect, extend the 30-month stay in place on the final approval of Actavis’s ANDA. Impax offers no reasonable justification as to why Actavis should have to potentially enter the market at risk when the 30-month stay concludes, if this Court grants a stay on the ’427 patent. For these reasons, the Court finds that

this factor weighs against granting a stay.

b. Potential Simplification of the Case

The second factor for consideration "whether a stay will simplify the issues in question and trial of the case." *Stryker Trauma,* 2008 WL 877848, at *1. Reexamination proceedings may simplify litigation by the "cancellation, clarification, or limitation of claims" that may eliminate the court's need to litigate whether Actavis has infringed one or more of the asserted claims. *Ethicon*, 849 F.2d at 1428. At this point, all claims in the original '427 patent have been finally rejected by the PTO. If the '427 patent does emerge from reexamination in any form, it will do so with amended claims. Expending significant effort now in the litigation of this patent at this time may be illogical, given that *Markman* proceedings and expert reports at this time would analyze the original '427 claims Impax has already abandoned. That being said, Actavis asserts that the '427 patent is prior art to the other patents in the suit, and thus some discovery about this patent may be relevant to the case even if the patent is cancelled. Given these facts, this factor weighs in favor of at least a partial stay.

c. Status of Case

The third and final factor for consideration is "whether discovery is complete and whether a trial date has been set." *Stryker Trauma,* 2008 WL 877848, at *1. Courts emphasize that a stay should be sought early in the litigation process. *Sabert Corp.*, 2007 WL 2705157, at *7 (D.N.J. Sept. 14, 2007). The third factor often weighs against a stay in situations with a "late stage of litigation, [where] discovery was or would be almost completed, or [when] the matter had been marked for trial." *GPAC*, 144 F.R.D. at 64. This case is in its early stages. Fact discovery in this case is not scheduled to end until February 14, 2017 [Docket Entry 33]. *Markman* hearing and trial dates have not been set by this Court. No depositions have been

taken, no expert reports have been filed, and no dispositive motions have been filed with the Court. Discovery in this case is certainly not complete. The Court finds that this factor weighs in favor of granting a stay.

d. Weighing the Factors

The Court finds that Impax has not met its burden to justify the grant of a total stay on proceedings on the ’427 patent. Actavis faces significant potential prejudice from a complete stay, given the potential length of the stay, the current state of the reexamination, and the procedural posture of the case. The risk of prejudice to Actavis outweighs the possibility that a stay may simplify the case, and the relatively early stage of the case.

Actavis concedes that proceeding to a *Markman* hearing and expert reports on the ’427 patent at this time may not be logical, since the claims Impax is currently asserting before the PTAB are not the claims asserted before this Court, and the Court agrees. (Opp. Br. at 14.) That being said, requiring Impax to serve its validity and infringement contentions with respect to the ’427 patent, and permitting some fact discovery on the ’427 patent will help to mitigate the prejudice to Actavis from a stay, while conserving the Court’s resources. Therefore, the Court will order Impax to proceed according to the Scheduling Order with respect to the submission of its Local Patent Rule 3.1, 3.4A and 3.6 validity and infringement contentions. Furthermore, fact discovery may proceed with respect to the ’427 patent. Specifically, fact discovery is permitted with respect to the history, conception, reduction to practice, use and/or sale of any embodiments or alleged inventions disclosed or claimed in the ‘427 patent, any support for disclosures made in and inventions claimed in the ’427 patent, and information and factual materials disclosed in the specification or used in the prosecution and reexamination history, pertaining to the ’427 patent and related patents.

IT IS THEREFORE, on this 26th day of May, 2016,

ORDERED that Impax's motion to stay proceedings in this case related to U.S. Patent No. 7,094,427 [Docket Entry 43] is **GRANTED IN PART** and **DENIED IN PART**; and it is further

ORDERED that Impax shall proceed according to the Amended Scheduling Order [Docket Entry 42] with respect to its required disclosures on U.S. Patent No. 7,094,427; and it is further

ORDERED that fact discovery shall proceed with respect to U.S. Patent No. 7,094,427 as detailed in this Opinion and Order; and it is further

ORDERED that the remainder of this case, with respect to U.S. Patent No. 7,094,427, is **STAYED** pending completion of the reexamination process; and it is further

ORDERED that Impax shall provide the Court with status updates regarding the *ex parte* reexamination of U.S. Patent No. 7,094,427, every sixty (60) days starting June 17, 2016; and it is further

ORDERED that Impax shall notify the Court within ten (10) days of any disposition of the *ex parte* reexamination of U.S. Patent No. 7,094,427.

s/ Stanley R. Chesler
STANLEY R. CHESLER
United States District Judge