IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: BRIMONIDINE PATENT LITIGATION	)	MDL Docket No. 07-md-1866 GMS

MEMORANDUM

I. INTRODUCTION

Presently pending before the court is plaintiff, Allergan, Inc.'s ("Allergan") motion to stay the action against defendants, Exela PharmSci, Inc. ("Exela"), Exela PharmSci Pvt., Ltd. ("Exela India"), Paddock Laboratories, Inc. ("Paddock"), and PharmaForce, Inc. ("PharmaForce") (collectively, the "Exela Defendants").[1] Plaintiff further requests that the court toll the 30-month stay under the Hatch-Waxman Act, and grant it leave to use information produced under the protective order in this case in a citizen's petition to be filed with the FDA. For the reasons that follow, the court will deny the plaintiff's motion to stay the action against the Exela Defendants, and its requests to toll the 30-month stay, and for leave to use information produced under the protective order in this case in its citizen's petition.

II. BACKGROUND

Allergan is a drug company that markets the medication ALPHAGAN P® 0.15% for use in the treatment of glaucoma. According to the Orange Book, ALPHAGAN P® 0.15% is covered by United States Patent No. 6,641,834 (the "'834 patent"). Allergan is the owner of the '834 patent. On November 1, 2006, Exela submitted an Abbreviated New Drug Application

[1] Plaintiff, however, is not seeking to stay the action against defendants, Apotex Corp. and Apotex, Inc.

("ANDA") to the FDA seeking approval to market a generic version of ALPHAGAN P® 0.15%.[2] Exela certified in its ANDA submission that it intended to market a generic version of ALPHAGAN P® 0.15% before the '834 patent expires, and that the '834 patent was invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Exela's generic version. On February 8, 2007, Exela sent a notice letter to Allergan informing Allergan that Exela's ANDA had been filed and stating the legal and factual bases for Exela's opinion that the '834 patent was invalid, unenforceable, and/or will not be infringed by the Exela product.

On March 28, 2007, Allergan filed suit against Exela for patent infringement in the Central District of California. On April 27, 2007, Allergan added defendants, Paddock and PharmaForce to that suit. By an order entered August 21, 2007, Allergan's suit against Exela, Paddock, and PharmaForce was transferred to this court and consolidated with another action by Allergan. Trial of this consolidated matter is set to begin in March 2009.

III. DISCUSSION

Allergan requests that the court: (a) stay the action against the Exela Defendants, (b) toll the 30-month stay, and (c) grant it leave to use information produced under the protective order in its citizen's petition. The court will consider each of these requests in turn.

A. Staying the Case Against Exela

The decision to stay a case is firmly within the discretion of the court. *See Cost Bros., Inc. v. Travelers Indem. Co.*, 760 F.2d 58, 60 (3d Cir. 1985). In considering a motion to stay, the

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[2] On January 29, 2007, the FDA acknowledged receipt of Exela's ANDA and advised Exela that the ANDA was assigned number 78-590.

court is guided by the following factors: "(i) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (ii) whether a stay will simplify the issues in question and trial of the case; and (iii) whether discovery is complete and whether a trial date has been set." *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, No. 06-514-GMS, 2007 U.S. Dist. LEXIS 73198, at *13 (D. Del. Sept. 30, 2007); *Zoetics, Inc. v. Yahoo!, Inc.*, No. 06-108-JJF, 2006 U.S. Dist. LEXIS 46910, at *4 (D. Del. July 6, 2006) (same).

Allergan contends that this case should be stayed against the Exela Defendants because (1) Paddock and PharmaForce are no longer in partnership with Exela,[3] and (2) Exela has not provided the FDA with certain bioequivalence testing information that is required to proceed with the ANDA process.[4] Exela argues that this case should not be stayed. Specifically, Exela contends that, to its detriment, a stay will only serve to delay market entry of Exela's generic alternative to Allergan's brand name drug. Exela further contends that it would be severely prejudiced if this case were stayed because it could lose the 180-day exclusivity period associated with its ANDA first filer status.

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[3] Specifically, Allergan argues that because Paddock's and PharmaForce's relationships with Exela are now terminated, the action against Exela should be stayed -- especially since Paddock (not Exela) was the designated manufacturer of the product described in the ANDA, and PharmaForce (not Exela) is the entity that actually supplied nearly all of the required information to the FDA for the ANDA. D.I. 86 at 1. Allergan insists that, without Paddock and PharmaForce, Exela's ANDA is "effectively a hollow shell" and that the ANDA submission process will need to be essentially re-started "from square one." *Id.* at 2.

[4] Allergan further contends that Exela's ANDA "is and was a sham filing" and that the FDA review staff "prematurely accepted the ANDA for filing." D.I. 86 at 19. This contention, however, is rebutted, at least in part, by the September 24, 2008 facsimile (D.I. 123) that Exela received from the FDA. In that facsimile, the FDA poses to Exela a series of questions relating to the FDA's ongoing review of Exela's ANDA. *Id.* In the court's view, the facsimile does not seem to indicate or suggest that Exela's ANDA is either a sham or in some way premature; or that for some reason it is not being considered substantively by the FDA.

The court concludes that this action against the Exela Defendants should not be stayed. The court is persuaded that a stay of this action will, indeed, be unduly prejudicial to Exela. First, it is clear to the court that a stay would likely cause Exela to lose its first filer status. As Exela correctly notes, the Hatch-Waxman Act grants the first ANDA filer a 180-day period during which it has the exclusive right to market a generic version of the brand name drug. *See* 21 U.S.C. § 355(j)(5)(B)(iv). If this case were stayed, Exela risks losing the180-day exclusivity period associated with its ANDA first filer status. Second, the court agrees that staying this action against Exela will delay market entry of any Exela generic product covered by the ANDA at issue in this litigation. In the court's view, these potential consequences for Exela are not insignificant. The court, therefore, finds that Exela will be unduly prejudiced if this action were stayed.

Further, the court is not persuaded that staying the case against the Exela Defendants will necessarily simplify the issues in question and trial of this case. As it stands, this case is fairly straightforward -- involving a Hatch-Waxman patent infringement case with only one patent at issue. Specifically, in this case, Allergan has accused Exela's 0.15% brimonidine formulation of infringing certain claims of its '834 patent. Exela, on the other hand, has filed an ANDA covering the product at issue, and maintains that its product does not infringe any of Allergan's patents.

Nonetheless, Allergan contends that since the partnership between Exela, Paddock and PharmaForce has ended, there is no "real" ANDA to litigate in this case,[5] and that staying the

[5] The court notes, however, that there is an actual ANDA on file with the FDA in this case, *i.e.*, ANDA 78-590.

case, while Exela finds new partners to assist with its ANDA, is the "only way" to ensure that the trial addresses the correct product. D.I. 86 at 12, 16. The court is not convinced. As Exela correctly notes, any injunctive relief awarded in this case could very well be styled to cover the possibility of future manufacturers posed by Allergan. Furthermore, in ANDA cases like this, the customary relief when there has been an unsuccessful Paragraph IV challenge[6] is for the court to order the generic company to stay off the market until the patent expires, and for the FDA to refrain from final approval of the ANDA until the patent expires. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A). Thus, without approval of Exela's ANDA, no product described in Exela's ANDA could be marketed -- regardless of Exela's partnership with Paddock or PharmaForce, its manufacturer, or the existence (or non-existence) of other Exela partners. Allergan has not demonstrated that staying this case until Exela finds new partners to assist with its ANDA will simplify the issues in question and trial in this case. Likewise, Allergan has not convinced the court that staying this case until Exela provides the FDA with bioequivalence testing information will simplify the issues presented here either.

Additionally, the court is not persuaded that staying the action at this late stage in the proceedings is warranted -- especially since discovery in this matter is nearing completion and a trial date is firmly set. First, fact discovery in this case ended on October 15, 2008. D.I. 131. Second, the court has already conducted a *Markman* hearing in this case and entered an order construing those patent claims at issue. D.I. 138. Third, expert discovery in this case is scheduled to close on December 12, 2008. D.I. 131. Finally, trial in this matter is set to begin on

[6] Under the Hatch-Waxman Act, a Paragraph IV certification begins the process in which the question of whether the listed patent is valid or will be infringed by the proposed generic product may be answered by the courts prior to the expiration of the patent.

March 9, 2009. D.I. 28. Indeed, this case is quite far along. Moreover, the court is not convinced (and Allergan has not demonstrated) that granting a stay at this late juncture in the case -- with less than six months to go before trial -- is justified.

Accordingly, the court denies Allergan's motion to stay the action against the Exela Defendants.

B. Tolling the 30-Month Stay

In ANDA cases, the 30-month stay prevents the FDA from approving an ANDA for 30 months after the patentee files an infringement action. *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1328 (Fed. Cir. 2005). Courts, nonetheless, are permitted to either lengthen or shorten the 30-month stay period when a "party to the action fails to reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(2)(B)(iii). In deciding whether to grant or deny a motion to extend the 30-month stay in an ANDA case, the court examines whether the generic defendant "unreasonably prolonged the litigation." *See, e.g., Minnesota Mining & Mfg. Co. v. Alphapharm Pty. Ltd.*, No. 99-13, 2002 WL 1299996, at *3 (D. Minn. Mar. 8, 2002).

Here, Allergan contends that the 30-month stay should be tolled because Exela has not reasonably cooperated in expediting this litigation. Specifically, Allergan contends that Exela has: (1) failed to respond promptly to the FDA's call for bioequivalence data; (2) suppressed relevant information; and (3) engaged in dilatory discovery tactics, all in an effort to try to "run the clock" on Allergan. Exela contends, however, that Allergan's claims are without merit, and that it has not prolonged this case in any way. Exela further contends that it has actually attempted to expedite this case by, among other ways, providing Allergan access to the 0.15% brimonidine formulation at issue and described in Exela's ANDA.

After reviewing the record and considering the parties' contentions, the court finds that tolling the 30-month stay in this case is not warranted. Specifically, the court is not persuaded that, on this record, there has been a sufficient showing to support a finding that Exela has not reasonably cooperated in expediting this litigation. The record simply does not reflect the type of dilatory conduct and discovery antics that necessitate such a finding.[7] Furthermore, the court is not satisfied that Exela's need to identify a new manufacturer, or conduct certain bioequivalence studies, or submit supplemental product information to the FDA, is necessarily indicative of Exela's failure to reasonably cooperate in expediting this litigation. In fact, it strikes the court that, as Exela suggests, these types of issues "are, and should be, a normal part of the give-and-take associated with the drug approval process." D.I. 116 at 8. Absent more, the court concludes that tolling the 30-month stay in this case is not warranted.

C. Granting Allergan Leave to Use Protected Information in a Citizen's Petition

Allergan requests leave of the court to use information produced in this case to file a citizen's petition with the FDA. Exela contends that, in the first instance, Allergan does not need the court's permission to file a citizen's petition. Exela further contends that this request is really a tactic for delay, and represents an attempt by Allergan to disclose Exela's confidential information to the public. Although the court does not necessarily agree with Exela's characterization of Allergan's motives in this regard, the court is, nonetheless, not inclined to grant Allergan's request. The court notes that both parties agree that Allergan does not actually need the court's permission the file a citizen's petition with the FDA. That said, the rub,

[7] The court notes that there has been only one discovery conference requested in this matter. D.I. 111.

however, is whether the court should permit Allergan to use information produced under the protective order in this case, *i.e.*, Exela's confidential information, in its citizen's petition. The court concludes that it should not. First, the court is unwilling to, at least without ample justification, insert itself into the FDA's drug approval process. Second, Allergan has not sufficiently demonstrated to the court why it needs to use Exela's confidential information in its petition. It is just not apparent to the court why use of Exela's confidential information is necessary. Allergan's request for leave to use information produced under the protective order in this case in its citizen's petition is, therefore, denied.

IV. CONCLUSION

For the foregoing reasons, the court denies Allergan's motion to stay the action against the Exela Defendants, and its requests to toll the 30-month stay, and for leave to use information produced under the protective order in this case in its citizen's petition to the FDA.

Dated: October 31, 2008

CHIEF, UNITED STATES DISTRICT JUDGE

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ORDER

For the reasons stated in the court's Memorandum of this same date, IT IS HEREBY ORDERED THAT:

1. Plaintiff's motion to stay the action against the Exela Defendants, toll the 30-month stay, and for leave to use information produced under the protective order in this case in its citizen's petition to the FDA (D.I. 85) is DENIED.

Dated: October 31, 2008

CHIEF, UNITED STATES DISTRICT JUDGE