UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

BAYER HEALTHCARE LLC,

Plaintiff-
Counterclaim Defendant,

Case No. 08-C-0953
(Consolidated With
Case No. 09-C-0108)

-vs-

NORBROOK LABORATORIES, LTD.,
and NORBROOK, INC. USA,

Defendants-
Counterclaimants.

DECISION AND ORDER

This matter comes before the Court upon the motion of the Plaintiff, Bayer Healthcare LLC ("Bayer"), for an extension through the February 6, 2012, trial date of the 30-month stay of the Food and Drug Administration's ("FDA") approval of the Abbreviated New Animal Drug Application ("ANADA") No. 200-495[1] filed by the Defendants, Norbrook Laboratories, Ltd., and Norbrook, Inc. USA (collectively "Norbrook").

In seeking the extension, Bayer argues that, because Norbrook has failed to reasonably cooperate in expediting this action, the Court should extend the stay. Norbrook, contests Bayer's assertion, contending that it has reasonably cooperated in expediting this

[1] The Court notes that Bayer and Norbrook have cited two different ANADA numbers – 011-557 and 200-495 respectively.

litigation and that the motion should be denied. For the reasons stated herein, Bayer's motion to extend the stay through the trial is granted.

Factual Background

The Generic Animal Drug and Patent Term Restoration Act ("GADAPTRA"), codified in 21 U.S.C. § 360b, provides generic manufacturers with a method to facilitate early entry of generic drugs into the market while protecting the patent rights of pioneering drug companies. Under GADAPTRA, pioneering drug companies with animal drug patents may file a New Animal Drug Application ("NADA") with the FDA and upon approval, their patent will be listed in the Green Book, *see* 21 U.S.C. §§ 360b(c)(3). Once the patent is listed in the Green Book, a generic manufacturer seeking to market a generic version of a pioneering drug may file an ANADA with the FDA. The ANADA may rely upon tests and studies done by the original pioneering drug company and its NADA.

However, a generic drug manufacturer must include in its ANADA a "certification" that addresses the relationship of the generic drug to the pioneering drug patent. *See* 21 U.S.C. § 360b(n)(1)(H). The generic manufacturer must assert that either (i) the patent holder has not filed any information with the FDA; (ii) the patent has expired; (iii) the patent will expire on a certain date; or, (iv) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new animal drug for which the application is filed. *Id*.

If the generic drug manufacturer makes a Paragraph IV certification, a notification must be sent to each owner of the patent which is the subject of the certification.

21 U.S.C. § 360b(n)(2)(A)(i).[2] Upon receiving notice, the pioneering drug company, who owns the patent in question, has 45 days to file suit under 35 U.S.C. § 271(e)(2) in order to trigger an automatic 30-month stay on FDA approval of the generic drug manufacturer's ANADA. 21 U.S.C. § 360b(c)(2)(D)(iii). A district court may shorten or extend the stay depending upon whether either party has failed to reasonably cooperate in expediting the action. *Id.*

Bayer alleges that it owns United States Patent No. 5,756,506 ("the '506 patent), entitled"Single High Dose Fluoroquinolone." (Compl. ¶¶ 17, 19.) The '506 patent covers the use of antibiotic enrofloxacin in a single, high dose to treat sick cattle. (Compl., Ex. A.) Bayer alleges that Norbrook has infringed the '506 patent. (Compl. ¶¶ 24, 25.)

On September 29, 2008, Bayer received notice that Norbrook filed an ANADA, No. 011-557, seeking approval for a generic animal drug product which contains enrofloxacin to treat cattle with bovine respiratory disease. (Compl. ¶ 21.) The notice also stated that Norbrook had submitted to the FDA a "Paragraph IV certification" with respect to the '506 patent. (*Id.*)

On November 7, 2008, Bayer commenced this lawsuit by filing a one-count Complaint alleging that Norbrook's filing of its ANADA prior to expiration of the '506 patent is an act of infringement in violation of 35 U.S.C. § 271(e)(2). (Compl. ¶ 24.) Since Norbrook's ANADA asserted a Paragraph IV certification and Bayer filed suit within the

[2] Although the subsection is not specifically addressed in this decision, the Court notes that 21 U.S.C. § 360b(n)(2)(A) should cite 21 U.S.C. § 360b(n)(1)(H)(iv), not 21 U.S.C. § 360b(n)(1)(G)(iv). Notably, 21 U.S.C. § 360b (n)(1)(G) does not contain *any* subsections.

statutorily prescribed time, an automatic 30-month stay on approval of Norbrook's ANADA was triggered. *See* 21 U.S.C. §§ 360b(n)(2)(A)-(B); 21 U.S.C. § 360b(c)(2)(D)(iii).

On December 1, 2008, Norbrook submitted an amendment to the FDA withdrawing its Paragraph IV certification and substituting a Section I patent certification.[3] (Third Am. Answer & Countercl. ¶ 21.)

Fact discovery opened on May 1, 2009. (Scheduling Order, Feb. 24, 2009.) The deadline, as amended, for fact discovery was August 13, 2010. (Third Am. Scheduling Order, Jul. 20, 2010.) The trial was initially set for March 21, 2011, within the 30-month stay period that would expire on March 29, 2011. (Scheduling Order, Feb. 24, 2009.)

Norbrook filed an unopposed motion to amend the scheduling order, requesting a May 2011 trial date. (Norbrook's May 21, 2010, Mot. Am.) The Court granted Norbrook's motion to amend and rescheduled the trial for May 2, 2011. (Am. Scheduling Order, May 22, 2010.) Expert discovery was set to close on January 28, 2011. (Fourth Am. Scheduling Order, Nov. 17, 2010.)

On December 6, 2010, five months before the scheduled trial date, Norbrook informed Bayer that it was making changes to its ANADA. (Fisher Decl. ¶ 16, Ex. N.) On December 23, 2010, Norbrook produced a number of documents relating to the ANADA, including an amended label for its ANADA. (Fisher Decl. ¶¶ 17-19, Exs. O-Q.)

[3] Previously, this Court held that Norbrook failed to show that the FDA will approve the amendment. *Bayer Healthcare, LLC. v. Norbrook Labs., Ltd.*, No. 08-C-0953, 2009 WL 6337911, at *7 (E.D. Wis. Sept. 24, 2009). Based on that determination, the Court declines to accept Norbrook's contention that that the Paragraph IV certification and 30-month stay are invalid.

On January 6, 2011, Bayer served Norbrook with a second set of interrogatories, a Rule 30(b)(6) deposition notice for a January 24, 2010, deposition, and a request that Norbrook supplement its earlier responses to interrogatories and production of documents with information regarding Norbrook's December 2010 amendments to its ANADA. (Fisher Decl. ¶¶ 20-22, Exs. R-T.) Norbrook responded to Bayer's second set of interrogatories on April 5, 2011. (Fisher Decl. ¶ 32, Ex. FF.)

On March 29, 2011, the Court issued a fifth amended scheduling order that reopened fact discovery on issues relating to the changes in Norbrook's ANADA until August 26, 2011, and rescheduled the trial to February 6, 2012. The stay continues through June 30, 2011, to afford this Court the opportunity to resolve the instant motion. (Court's Mar. 24, 2011, Decision and Order, 7.)

Motion to Extend Stay

As the basis for requesting an extension of the stay on the FDA approval of Norbrook's ANADA through the February 6, 2012, trial, Bayer asserts that Norbrook has failed to reasonably cooperate in expediting this action. More specifically, Bayer asserts that "Norbrook changed its [ANADA] application *after* the close of fact discovery and *after* the submission of expert reports, just months before trial." (Bayer's Mem. Supp. Mot. Extend Stay, 12.) Bayer argues that these changes were made deliberately – as a part of Norbrook's strategy – to delay the litigation and that this warrants an extension under *Eli Lilly and Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346 (Fed. Cir. 2009). (Bayer's Reply Supp. Mot. Extend Stay, 5.)

In addition, Bayer asserts that Norbrook failed to serve "discovery responses for more than three months, not withstanding that the Federal Rules [of Civil Procedure] mandate a response within 30 days." (*Id.* at 6.) Furthermore, Bayer asserts that Norbrook has advanced a 35 U.S.C. § 112 defense in violation of an agreement to forego that defense, and used its late amendment to its ANADA to insert the § 112 defense after the Court had stricken it. (*Id.*) Bayer argues that Norbrook's actions, when taken collectively, "[were] unreasonable and delayed [the] trial in this case beyond the date of stay expiry." (*Id.*) Thus, Bayer asks this Court to extend the stay of FDA approval of Norbrook's ANADA through the February 6, 2012, trial.

Norbrook, however, asserts that it has reasonably cooperated in expediting this litigation and even hints that no stay exists. (Norbrook's Mem. Opp'n Mot. Extend Stay, 8-10.) Norbrook contends that the 30-month stay is not intended to enable the parties to fully resolve their patent disputes before its expiration and that Bayer should file for preliminary injunctive relief if it wants to prevent the FDA from approving Norbrook's ANADA. (*Id.* at 6, 11.) Further, Norbrook argues that it was trying to expedite this litigation when it decided to forego asserting inequitable conduct and obviousness claims against Bayer. (*Id.* at 8.) Norbrook also disputes Bayer's characterization of the agreement to forego § 112 defenses and counterclaims as applying to all possible § 112 enablement defenses and asserts that this Court found Norbrook was not dilatory or playing games in later asserting its § 112 enablement defense. (*Id.* at 8-9.)

Additionally, Norbrook argues that *Eli Lilly* does not apply because Norbrook's ANADA amendment does not change the method for which it seeks FDA approval, whereas in *Eli Lilly*, the ANADA amendment materially changed the product in question. (*Id.* at 9.) Norbrook states that its ANADA amendment is not comparable to those addressed in *Eli Lilly*. (*Id.*) Norbrook also argues that Bayer's arguments to extend the stay are irrelevant because Bayer's patent is invalid and Norbrook is not infringing on that patent.[4] (*Id.* at 17.) Norbrook asks this Court to deny Bayer's motion to extend the 30-month stay.

Analysis

In considering Bayer's request to extend the stay, the questions before the Court are (1) whether Norbrook has failed to reasonably cooperate in expediting this action; and, (2) if so, whether the stay should be extended through the February 6, 2012, trial date pursuant to 21 U.S.C. § 360b(c)(2)(D)(iii).

Section 360b(c)(2)(D)(iii) of Title 21 of the United States Code states:

> If . . . an action is brought before the expiration of [45 days from the date the notice provided under subsection (n)(2)(B)(i)[5]], the approval shall be made effective upon the expiration of the 30 month period. . . or such shorter or longer period as the court may order because either party to the action [has] failed to reasonably cooperate in expediting the action . . . .

[4] This Court will not address Norbrook's patent invalidity argument because it pertains to issues for trial. In this Decision and Order, the Court will only address the issue of whether to extend the statutorily prescribed 30-month stay.

[5] Although the subsections are not addressed in this decision, the Court notes that 21 U.S.C. § 360b(c)(2)(D)(iii) should cite subsection (n)(2)(A)(i) not (n)(2)(B)(i) because (n)(2)(B) does not contain any subsections.

Bayer filed this action within 45 days after receiving notice of Norbrook's ANADA and Paragraph IV certification, thus, triggering the automatic 30-month stay and giving subject matter jurisdiction to this Court to determine the period of the stay.

A district court has the discretion to adjust the 30-month stay if it finds either party has failed to reasonably cooperate in expediting this action. *Eli Lilly*, 557 F.3d at 1350. In *Eli Lilly*, Teva Pharmaceuticals ("Teva") changed a manufacturing specification eight months before the trial date. *Id.* The district court reasoned that "because Teva provided Lilly with its altered [product] just eight months before trial, [the stay would be extended] to provide Lilly with a reasonable amount of time to allow its expert to test and report [on the altered product] . . . and for Lilly to assess and utilize that information and analysis in preparation for trial." *Id*. The federal circuit court of appeals upheld the extension finding that the record contained sufficient evidence upon which the district court rationally based its decision. *Id*.

In this case, Norbrook changed its ANADA in December 2010 – leaving Bayer with only five months to reassess and prepare its infringement case before the May 2, 2011, trial date. No doubt, Norbrook's actions – in waiting four months after the close of discovery and only five months before trial to change its ANADA – provide a strong basis for this Court to extend the stay, compared to those of *Eli Lilly*.

Additionally, Bayer asserts that the stay should be extended because Norbrook failed to comply with Bayer's discovery requests. The assertion is somewhat misleading. Bayer served its second set of interrogatories on January 6, 2011. Pursuant to Rule 33(b)(2)

of the Federal Rules of Civil Procedure, Norbrook had 30 days, or until February 10, 2011,[6] to respond to them. However, the Fourth Amended Scheduling Order, provided "[a]ll requests for expert discovery must be served by a date sufficiently early so that all expert discovery in this case can be completed no later than *January 28, 2011*." (Fourth Am. Scheduling Order ¶ 1, Nov. 17, 2010.)

Bayer served its second set of interrogatories too late. Under the time allowed by Rule 33, the date Bayer served its interrogatories did not allow for the completion of expert discovery on January 28, 2011. Norbrook's delay in responding was not proper – Norbrook should have objected to the interrogatories as too late. Since the timing of Bayer's January 2011 interrogatories violated the Court's scheduling order, Norbrook's untimely responses to them does not provide a reasonable basis for finding that Norbrook failed to reasonably cooperate in expediting this action.

Norbrook cites *Bayer Schera Pharma AG v. Sandoz, Inc.*, No. 08 Civ. 03710, 2010 WL 3447906 (S.D.N.Y. Sept. 2, 2010), in contending that the stay should not be extended. However, the situation in that case is not analogous. In *Bayer Schera*, 2010 WL 3447906, at *6, Bayer contended that a motion to dismiss for lack of personal jurisdiction, which had been pending three months until it was withdrawn, established that the movant had failed to reasonably cooperate in expediting the action. However, the district court held

[6] Rule 6 of the Federal Rules of Civil Procedure was used to calculate the February 10, 2011, date. Pursuant to Rule 6(a)(1), January 6, 2011, the day on which the requests were served was excluded and every intermediate day was included, bringing the date to February 6, 2011. Since February 6, 2011, fell on a Sunday, the period continued to run until Monday, February 7, 2011. *See* Fed. R. Civ. P. 6(a)(1)(C). Then, pursuant to Rule 6(d), three days were added resulting in a February 10, 2011, date for Norbrook to respond to Bayer's discovery requests.

that Bayer had "offered no evidence that the mere submission of this motion – or the limited jurisdictional discovery that the parties conducted – caused any significant delay in [the] proceedings." *Id*. at * 7. Instead, the court held that Bayer – the plaintiff – had not sought to expedite the litigation *Id*. In this case, however, Norbrook's December 2010 ANADA amendment has resulted in a delay of the litigation.

In sum, because Norbrook changed its ANADA application so late in litigation – much later than in *Eli Lilly* – this Court finds that Norbrook failed to reasonably cooperate in expediting this action. Therefore, Bayer's motion to extend the stay through the February 6, 2012, trial date is granted. Based on the foregoing, the Court need not address Norbrook's contention that Bayer should be required to seek a preliminary injunction to prevent the FDA from approving Norbrook's ANADA.

NOW, THEREFORE, BASED ON THE FOREGOING, IT IS HEREBY ORDERED THAT:

1. Bayer's motion (Docket No. 179) to extend the stay of FDA approval of Norbrook's ANADA No. 200-495 through the trial is **GRANTED**;and,

2. The stay is **EXTENDED** through the February 6, 2012, trial.

Dated at Milwaukee, Wisconsin, this 7th day of June, 2011.

BY THE COURT

s/ Rudolph T. Randa
HON. RUDOLPH T. RANDA
U.S. District Judge