UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BAYER SCHERA PHARMA AG and BAYER HEALTHCARE PHARMACEUTICALS INC.,

Plaintiffs,

–v. –

SANDOZ, INC., WATSON PHARMACEUTICALS, INC., and WATSON LABORATORIES, INC.,

Defendants.

08 Civ. 03710 (PGG)

MEMORANDUM OPINION AND ORDER

PAUL G. GARDEPHE, U.S.D.J.

In this action, Bayer Schera Pharma AG and Bayer Healthcare Pharmaceuticals Inc. (collectively "Bayer") allege that Defendants' proposed generic production of Bayer's brand-name oral contraceptive Yasmin will infringe on Bayer's patent rights. Bayer initiated this litigation after Watson filed an abbreviated new drug application ("ANDA") to market a generic version of Yasmin. (See Cmplt. ¶¶ 14, 15)

Pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc (2003); 35 U.S.C. §§ 156 (2002), 271 (2003)) (collectively the "Hatch-Waxman Act"), a thirty-month stay is currently in place preventing Defendants Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. (collectively "Watson") from obtaining final approval from the Food and Drug Administration for their marketing of a generic version of Yasmin. See 21 U.S.C. § 355(j)(5)(B)(iii). The thirty-month stay expires on September 4, 2010. (Bayer Br. 3) Before the Court is Bayer's motion to extend the statutory thirty-month stay pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). (Docket No. 79)

For the reasons set forth below, Bayer's motion to extend the statutory thirty-month stay will be DENIED.

BACKGROUND

A. Procedural History

Bayer has filed multiple patent infringement suits against Watson and Sandoz in both the Southern District of New York and the District of Nevada relating to their proposed generic production of the oral contraceptive Yasmin and the related oral contraceptive Yaz.

On November 5, 2007, Bayer sued Watson in the District of Nevada for infringement of U.S. Patent No. 6,787, 531 ("the '531 patent"), U.S. Reissue Patent No. 37,564 ("the '564 patent"), and U.S. Reissue Patent No. 37, 838 ("the '838 patent"), all relating to Yaz. (Jansen Decl. ¶ 3, Id., Ex. 1 ("Nevada Yaz Cmplt.") ¶¶ 16-18)

On April 17, 2008, Bayer filed the instant action against Watson and Sandoz in the Southern District of New York for infringement of U.S. Patent No. 5,569,652 ("the '652 patent") in connection with Yasmin. (Cmplt. ¶¶ 20, 21) The case was assigned to Judge Crotty. On July 21, 2008, Watson sent a letter to the Court seeking a pre-motion conference. Watson's letter indicated that it intended to contest in personam jurisdiction. (Bayer Br., Ex. 2, July 21, 2008 Meister Ltr.) Judge Crotty held an initial conference on August 20, 2008. At that time, he informed the parties that he might be required to recuse himself. (Cooklin Decl ¶ 4) Judge Crotty subsequently recused himself, and this matter was reassigned to this Court on September 10, 2008. (Docket No. 20)

On August 1, 2008, Bayer sued Sandoz in the District of Nevada alleging infringement of the '564 patent and the '838 patent in connection with Yaz. (Jansen Decl. ¶ 4) Sandoz answered the complaint on September 19, 2008, and asserted a counterclaim for a declaratory judgment that the '652 patent is invalid. (Id.) On November 24, 2008, the Nevada District Court consolidated the two Yaz actions. (Id.; Letter from Delphine W. Knight Brown dated January 14, 2009 (Docket No. 41))

On September 18, 2008, Bayer sued Sandoz and Watson in the Southern District of New York alleging infringement of the '652 patent in connection with Yaz ("New York Yaz action"). (08 Civ. 08112 Cmplt. ¶¶ 24, 25)

On September 22, 2008, Sandoz filed a motion to transfer the instant action to the District of Nevada pursuant to 28 U.S.C. § 1404(a). (Docket No. 22) Bayer subsequently joined that motion. (See Transcript of Initial Conference dated Oct. 1, 2008 ("Oct. 1 Tr.") at 7:5-6; Sept. 25, 2008 Bensinger Ltr. (Docket No. 37)) Sandoz and Bayer later requested that the New York Yaz action also be transferred to the District of Nevada. (See Oct. 1 Tr. at 4:15-17; Sept. 25, 2008 Bensinger Ltr. (Docket No. 37))

This Court held its first conference in this matter on October 1, 2008. At that conference, Bayer argued that this Court should defer consideration of Watson's proposed jurisdictional motion and resolve the transfer issue. (Oct. 1 Tr. 8:10-17, 11:14-18) The Court accepted Bayer's argument, and announced that it would address Sandoz and Bayer's motion to transfer before considering any other contemplated motions. (Id. at 30:10-14) On February 17, 2009, this Court denied the motion to transfer the instant action and the New York Yaz action to the District of Nevada. Bayer Schera Pharma AG

v. Sandoz, Inc., No. 08 Civ. 03710 (PGG), 08 Civ. 08112 (PGG), 2009 WL 440381 (S.D.N.Y. Feb. 18, 2009).

After this Court's decision denying the motion to transfer, Bayer and Watson entered into a stipulation regarding jurisdictional discovery and a schedule for briefing on Watson's motion to dismiss. (Docket No. 45) On April 27, 2009, Watson filed its motion to dismiss. (Docket No. 55) Approximately three months later, on July 28, 2009, Watson withdrew its motion to dismiss. (July 28, 2009 Cooklin Ltr. (Docket No. 68; 08 Civ. 08112, Docket No. 25))

On December 21, 2009, Watson and Sandoz filed a motion for judgment on the pleadings arguing that the '652 patent is invalid. (Docket No. 78) That same day, Bayer filed the instant motion to extend the statutory thirty-month stay with respect to the FDA's approval of Watson's proposed generic Yasmin product. (Docket No. 79)

DISCUSSION

I. THE ANDA FRAMEWORK

"The Hatch-Waxman Act strikes a balance between two potentially competing policy interests – inducing pioneering development of pharmaceutical formulations and methods and facilitating efficient transition to a market with low-cost, generic copies of those pioneering inventions at the close of a patent term." Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd., 601 F.3d 1359, 1360 (Fed. Cir. 2010) (citing Andrx Pharms., Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002)).

"The Hatch-Waxman Act . . . requires a pioneer drug manufacturer to notify the FDA of all patents that 'claim [ ] the drug for which the [NDA] applicant submitted the application.'" Eli Lilly & Co. v. Teva Pharm. USA, Inc., 557 F.3d 1346,

1348 (Fed. Cir. 2009) (quoting 21 U.S.C. §§ 355(b)(1) & (c)(2)). "The FDA lists such patents in its Approved Drug Products With Therapeutic Equivalence Evaluations, known as the 'Orange Book.'" Id. Pursuant to the Hatch-Waxman Act, "a generic manufacturer infringes a patent . . . by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent." Id. (citing 35 U.S.C. § 271(e)(2)).

"A manufacturer that seeks to market a generic drug may submit an ANDA for approval by the United States Food and Drug Administration ('FDA'), rather than submitting a full New Drug Application ('NDA') showing the safety and efficacy of the generic drug." Eli Lilly & Co., 557 F.3d at 1348. "The ANDA process streamlines FDA approval by allowing the generic manufacturer to rely on the safety and efficacy studies of a drug already in the Orange Book upon a showing of bioequivalence." Novo Nordisk A/S, 601 F.3d at 1361.

"As part of the approval process, an ANDA applicant must make a certification addressing each patent listed in the Orange Book that claims the drug." Eli Lilly & Co., 557 F.3d at 1348. More specifically, "the generic manufacturer must select one of four alternatives permitting use of the patented product or process: (I) no such patent information has been submitted to the FDA; (II) the patent has expired; (III) the patent is set to expire on a certain date; or (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug." Novo Nordisk A/S, 601 F.3d at 1361 (citing 21 U.S.C. § 355(j)(2)(A)(vii)). "These are commonly referred to as paragraph I, II, III, and IV certifications." Eli Lilly & Co., 557 F.3d at 1348.

"When an ANDA certifies under paragraph IV, the applicant must provide the patentee a detailed basis for its belief that the patent is not infringed, that it is invalid, or that it is unenforceable." Eli Lilly & Co., 557 F.3d at 1348 (citing 21 U.S.C. § 355(j)(2)(B)). "The patentee then has forty-five days to sue the ANDA applicant for patent infringement," after which time the FDA is able to "proceed to approve the ANDA." Id. (citing 21 U.S.C. § 355(j)(5)(B)(iii)). If the patentee does file suit within the forty-five day period, "the FDA may not approve the ANDA until expiration of the patent, resolution of the suit, or thirty months after the patentee's receipt of notice, whichever is earlier." Id. (citing 21 U.S.C. § 355(j)(5)(B)(iii)). However, "[t]he court entertaining this suit has discretion to order a shorter or longer stay if 'either party to the action fail[s] to reasonably cooperate in expediting the action.'" Novo Nordisk A/S, 601 F.3d at 1362 (quoting 21 U.S.C. § 355(j)(5)(B)(iii)). The House Report accompanying 21 U.S.C. § 355(j)(5)(B)(iii) states that "'[f]ailure by either party to cooperate in a reasonable manner may be used by the court to reduce or lengthen the time, as appropriate, before an ANDA approval becomes effective.'" Eli Lilly & Co., 557 F.3d at 1350 (quoting H.R. Rep. No. 98-857, at 16 (1984), as reprinted in 1984 U.S.C.C.A.N. 2686, 2700).

Extension of the thirty-month stay is not automatic. Congress was aware that in many cases the thirty-month stay provided in Section 355(j)(5)(B)(iii) would expire before the merits of an underlying patent infringement suit were resolved. See Zeneca Ltd. v. Pharmachemie B.V., No. 96 Civ. 12413 (RCL), 1998 U.S. Dist. LEXIS 12842, at *12 (D. Mass. Jul. 8, 1998) (Report and Recommendation adopted by District Court) ("Plainly legislators were aware of the potential length of time it takes to resolve

patent litigation, yet a stay intended to coincide precisely with that period was rejected. . . . That the statutory bar might expire prior to a ruling on the validity of the patent was anticipated and accepted by legislators as part of the compromise measure."). Indeed, Congress rejected a proposed amendment that "would have required that either the patent expire before [FDA] approval [of a generic substitute for marketing], or that there be a final decision by a Federal District Court that the patent in question was not valid." H.R. Rep. No. 98-857, Part. II at 9 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2693. The House Report notes that "a requirement that FDA defer generic approval until after a court decision of patent invalidity would substantially delay FDA approvals," and comments that the patent holder is nonetheless protected, because "in the event that the FDA approves a generic because of the expiration [of the stay] without a court decision, and it is later determined that the patent is valid, the patent owner may still recover damages from the generic [manufacturer]." H.R. Rep. No. 98-857, Part II at 9 (1984), reprinted at 1984 U.S.C.C.A.N. 2647, 2694 (citation and footnote omitted).

Here, Watson filed an ANDA seeking permission to market a generic version of Yasmin (Cmplt. ¶ 15) and submitted a Paragraph IV certification alleging that Bayer's patents are invalid or will not be infringed by the use, manufacture, or sale of a generic version of Yasmin. (Id. ¶ 19) Watson sent the statutorily-required ANDA notice letter to Bayer on or about March 4, 2008. (Id. ¶ 19) On April 17, 2008 – within the 45-day statutory period – Bayer filed the instant action against Watson and Sandoz in the Southern District of New York. Accordingly, FDA's approval of Watson's ANDA has been stayed since that time. The thirty-month statutory stay expires on September 4, 2010.

On December 21, 2009, Bayer moved to extend the statutory thirty-month stay pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), arguing that Watson delayed these proceedings by filing a frivolous motion to dismiss for lack of personal jurisdiction.

II. WATSON HAS NOT DELAYED THESE PROCEEDINGS

Section 355(j)(5)(B)(iii) authorizes this Court to extend the thirty-month statutory stay period where a party has "failed to reasonably cooperate in expediting the [underlying patent infringement] action." 21 U.S.C. § 355(j)(5)(B)(iii). Here, Bayer argues that the statutory stay period should be extended "until resolution of this case on the merits," because Watson delayed this action by filing a frivolous motion to dismiss for lack of personal jurisdiction. (Bayer Br. 8) Bayer notes that Watson withdrew its motion to dismiss three months after it was filed, and two days before its answers to Bayer's second set of jurisdictional interrogatories was due. (Id.) As discussed below, however, Bayer has not demonstrated that Watson's filing of the jurisdictional motion caused any delay in these proceedings.

A. Applicable Law

"'Statutory stay adjustments [under Section 355(J)(5)(B)(iii) have not been frequent.'" Eli Lilly & Co., 557 F.3d at 1354 & n.2 (Prost, J., dissenting) (quoting Gerald Sobel et al., Hatch-Waxman Litigation from the Perspective of Pioneer Pharmaceutical Companies, in Patent Litigation Strategies Handbook 183, 196-97 (Barry L. Grossman & Gary M. Hoffman eds., 2d ed. 2005)); see also Claire Comfort, Will the Federal Circuit's Eli Lilly v. Teva Decision Lead to Efforts to Abuse the Modification Provision of the Hatch-Waxman Act?, 16 Rich. J.L. & Tech. 1, 1 (2009) ("The federal district courts have on the whole been very conservative in their interpretation of the

modification provision. . . . The district courts have, to date, seldom exercised their power to alter the obligatory thirty-month stay.").

In the few cases in which courts have extended the statutory thirty-month stay, the record has included evidence that a party obstructed discovery, sought a stay of the underlying action, or otherwise interfered with the expeditious resolution of the infringement action. See Eli Lilly & Co. v. Teva Pharm. USA, Inc., No. 06 Civ. 1017 (SEB), 2008 U.S. Dist. LEXIS 88554, at *3 (S.D. Ind. Oct. 29, 2008), aff'd, 557 F.3d 1346 (Fed. Cir. 2009) (extending thirty-month stay where defendant amended its ANDA near the discovery deadline in order to defeat infringement claims and did not disclose its plan to amend for eight months); Dey, L.P. v. Ivax Pharms., Inc., 233 F.R.D. 567 (C.D. Cal. 2005) (granting motion to extend thirty-month stay where plaintiff had "unreasonably drawn out discovery . . . by repeatedly changing its position on inventorship – a key issue in any patent case" and "failed to produce in discovery documents relating to a study it conducted" comparing its product to a prior art drug); Novartis Corp. v. Dr. Reddy's Labs., Ltd., No. 04 Civ. 0757 (SAS), 2004 U.S. Dist. LEXIS 21094, at *13 (S.D.N.Y. Oct. 21, 2004) (tolling thirty-month period during a stay of the proceedings because the defendant could not "feasibly argue that it is reasonably cooperating in expediting the action when it asked the court to stay the proceedings"); Eli Lilly & Co. v. Zenith Goldline Pharm., Inc., No. 99-38-C, 2001 U.S. Dist. LEXIS 2728, at *2-3 (S.D. Ind. Mar. 8, 2001) (extending thirty-month stay after defendant failed to provide expert witness reports on "the central issue of the case -- invalidity" by the deadline set by the case management plan).

Conversely, courts have denied motions to extend the statutory stay period where there is not clear evidence that a party has failed to reasonably cooperate in expediting the infringement action. See In re Brimonidine Patent Litig., No. 07-md-1866, 2008 U.S. Dist. LEXIS 92405, at *10 (D. Del. Oct. 31, 2008) (allegations that the defendant "failed to respond promptly to the FDA's call for bioequivalence data," "suppressed relevant information," and "engaged in dilatory discovery tactics" were insufficient to warrant the tolling of the thirty-month stay because "[t]he record simply does not reflect the type of dilatory conduct and discovery antics that necessitate such a finding"); Minn. Mining & Mfg. Co. v. Alphapharm Pty. Ltd., No. 99 Civ. 13, 2002 WL 1299996, at *3 (D. Minn. Mar. 8, 2002) (denying motion to extend thirty-month stay despite defendant's late submission of expert reports and other discovery materials; "[b]ased on the procedural history of [the] case, and the timeline by which documents and reports were exchanged," the defendant "has not unreasonably prolonged the litigation"); Minn. Mining & Mfg. Co. v. Alphapharm Pty. Ltd., No.99 Civ. 13, slip op. at 3, 4, 8, 9 (D. Minn. Apr. 2, 2001) (Report and Recommendation adopted by District Court) (denying motion to extend stay period where defendant had "not timely respond[ed] to discovery requests" and had amended its ANDA; court ruled that there were "insufficient grounds to conclude that [defendant] took these actions for the improper purpose of delaying the litigation"); see also Glaxo v. Torpharm, Inc., No. 95 C 4686 (WTH), 1997 U.S. Dist. LEXIS 12816, at *8-9 (N.D. Ill. Aug. 20, 1997) (denying motion to shorten the thirty-month stay where the plaintiff was, inter alia, "untimely in its document productions," because the court had the "overall impression . . . that both

parties conducted a tremendous amount of discovery within a relatively short period of time" and because the plaintiff had "cooperated in moving along this litigation").

As several courts have noted, "[i]n deciding whether to grant or deny a motion to extend the 30-month stay in an ANDA case," the ultimate question is "whether the generic defendant 'unreasonably prolonged the litigation.'" In re Brimonidine Patent Litig., 2008 U.S. Dist. LEXIS 92405, at *9 (quoting Minn. Mining & Mfg. Co., 2002 WL 1299996, at *3).

B. Watson's Motion to Dismiss Did Not Prolong or Delay this Litigation

Bayer argues that Watson's motion to dismiss caused more than a year of delay, running from July 21, 2008 – when Watson first requested permission from Judge Crotty to file a motion to dismiss – to July 23, 2009, when Watson withdrew its motion. A review of the procedural history of this action, however, makes clear that Watson's motion to dismiss caused no delay whatsoever.

Bayer filed this case on April 17, 2008, and it was assigned to Judge Crotty at that time. On July 21, 2008, Watson sent a letter to Judge Crotty seeking a pre-motion conference. Watson's letter requested permission to file a motion to dismiss on grounds of lack of in personam jurisdiction. Judge Crotty held an initial conference on August 20, 2008. At that time, he informed the parties that he might be required to recuse himself. (Cooklin Decl ¶ 4) Judge Crotty subsequently recused himself, and this matter was reassigned to this Court on September 10, 2008. (Docket No. 20) No portion of the delay from April 17 to September 10, 2008 is attributable to Watson. Instead, that period of delay arose solely from the recusal and reassignment process.

On September 22, 2008, Sandoz, Bayer's co-defendant, filed a motion to transfer, which Bayer subsequently joined. (Bayer Br., Ex. 5 (Sept. 25, 2008 Bensinger Ltr.))

This Court held its first conference in this matter on October 1, 2008. At that conference, Bayer argued that this Court should defer any consideration of a motion to dismiss from Watson until after the transfer issue was resolved. (Oct. 1 Tr. 8:10-17, 11:14-18) The Court accepted Bayer's argument, and announced that it would address Sandoz and Bayer's motion to transfer before considering any other contemplated motions. (Id. at 30:10-14) Briefing on the motion to transfer then proceeded. Watson did not file a motion to dismiss.

Bayer argues, however, that "Sandoz's motion to transfer resulted from [Watson's] baseless motion [to dismiss]." (Bayer Repl. Br. 10) Watson had not filed a motion to dismiss as of the date of Sandoz's transfer motion, however, and a review of the parties' submissions and statements in connection with the motion to transfer reveals that the factors motivating the transfer motion were primarily a belief that the action would proceed more rapidly in Nevada, the convenience of the parties, the convenience of witnesses, judicial economy concerns, and concerns about the possibility of inconsistent judgments.

In its brief in support of its motion to transfer, Sandoz argued that "[t]o have the parties conduct duplicative discovery, and this Court to undertake the identical claims analysis several months after the court in Nevada, would be a waste of judicial resources and could potentially lead to inconsistent results." (Sandoz Memorandum of Law in Support of its Motion to Transfer Venue to the District of Nevada, at 1-2 (Docket

No. 23)) Sandoz's submission in support of the motion to transfer does not suggest that it filed the motion because of concern that Watson might contest personal jurisdiction.[1]

In joining Sandoz's motion, Bayer echoed its arguments about efficiency and judicial economy:

> Transfer will enable Judge Dawson in the District of Nevada to adjudicate efficiently all the Watson and Sandoz, Yasmin and YAZ cases.
>
> Bayer's guiding principle has been to keep its '652 patent cases together before one judge rather than see its '652 litigation split between New York and Nevada. Transfer serves this goal.
>
> . . . .
>
> Transfer serves the interests of justice and conserves judicial resources because it keeps all '652 litigation together in one court and efficiently moves all the cases along on the merits.

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[1] While at the October 1 conference Sandoz mentioned that there was a "question about" jurisdiction in New York, Sandoz reiterated that its transfer motion was driven "primarily" by efficiency, judicial economy, the convenience of the parties and of witnesses, and concerns about possible inconsistent judgments:

> We moved to transfer from this venue to Nevada primarily because the patents that Sandoz was sued on in this jurisdiction are related to the patents that at that point we were sued on in Nevada. . . . So since the District of Nevada first took jurisdiction over this body of patents in the YAZ case against Watson and has the prescheduling order in that case, it envisions close of discovery in January and moving the case forward in a timely fashion next year, we would rather have the validity of the patents, the infringement of the patents, any declaratory judgments on related patents decided as quickly as possible. It seemed to us that the best strategy for that would be to have all the cases heard, moved to Nevada, and consolidated with the Bayer v. Watson action in Nevada. There will be identical witnesses in the cases; some will be from foreign jurisdictions. All of the parties, there is jurisdiction over them in Nevada, there is a question about New York. And we feel that the timely resolution, we would like to avoid any inconsistent judgments on the related patents to get the entire decision made quickly for the defendants so that we can move forward with bringing our product to market. So it's more a timely argument, it's a convenience to the parties argument, also judicial economy because we want to have all discovery take place once in one jurisdiction and on all the patents.

(Oct. 1 Tr. 4:1-5:3)

(Bayer Br., Ex. 5 (Sept. 25, 2008 Bensinger Ltr.))

In sum, no portion of the period between September 20, 2008 – when Sandoz's transfer motion was filed – and February 17, 2009 – when the transfer motion was denied – is properly attributable to Watson.

After the Court denied the motion to transfer, the parties consulted as to an appropriate schedule for jurisdictional discovery and briefing on Watson's proposed motion to dismiss. Watson proposed a forty-day period for jurisdictional discovery (Cooklin Decl. ¶19, Ex. 10 (Email from Cedric Tan to Paul Skiermont dated Mar. 11, 2009)), but Bayer argued that 120 days was necessary. (Cooklin Decl. ¶ 20) Watson revised the joint stipulation and incorporated Bayer's request for a 120-day jurisdictional discovery period. (Cooklin Decl., Ex. 11 (Email from Cedric Tan to Adam K. Mortara dated Mar. 13, 2009)) On March 20, 2009, this Court issued a scheduling order providing for a ninety-day discovery period (Docket No. 45), and on April 27, 2009, Watson filed its motion to dismiss. (Docket No. 55) Nothing about Watson's conduct in setting a schedule for jurisdictional discovery and briefing suggests any effort to delay these proceedings. Indeed, Watson consistently advocated a more expedited schedule than did Bayer. On July 28, 2009 – before Bayer's opposition papers were due – Watson withdrew its motion to dismiss.

While Watson's motion to dismiss was pending for three months before its withdrawal, Bayer has offered no evidence that the mere submission of this motion – or the limited jurisdictional discovery that the parties conducted – caused any significant delay in these proceedings. Bayer – the plaintiff in this matter – has not sought to expedite this litigation. Bayer did not make Rule 26(a) initial disclosures until November

2, 2009 (Jansen Decl., Ex. 8 (Bayer's Rule 26(a)(1) Disclosures)) and never sought a Rule 26(f) conference with Watson,[2] which is the predicate for a discovery plan. This Court did not impose any stay on merits discovery while jurisdictional discovery and briefing was taking place, but Bayer never sought to take merits discovery. In short, there is no reason to believe that this litigation would be any further advanced if Watson's jurisdictional motion had never been filed. Because there is no evidence that Watson "failed to reasonably cooperate in expediting the action," there is no basis for extending the thirty-month stay under 21 U.S.C. § 355(j)(5)(B)(iii).

CONCLUSION

For the reasons stated above, Bayer's motion to extend the statutory thirty-month stay pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) is DENIED. The Clerk of the Court is directed to terminate the motion. (Docket No. 79)

Dated: New York, New York
September 2, 2010

SO ORDERED.

Paul G. Gardephe
United States District Judge

[2] The Rule 26(f) conference took place on October 5, 2009, and was scheduled at Watson's volition. (See Jansen Decl. ¶ 10 ("Bayer's counsel never initiated the Rule 26(f) conference of counsel that is a pre-requisite to serving document requests. As counsel for Watson, I initiated the conference, scheduling it for Monday, October 5, 2009."))