IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS, INC., and SCHERING CORPORATION, Plaintiffs, v. TEVA PARENTERAL MEDICINES, INC., and TEVA PHARMACEUTICALS USA, INC., Defendants.	C.A. No. 09-105-JCJ
MILLENNIUM PHARMACEUTICALS, INC., and SCHERING CORPORATION, Plaintiffs, v. TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	C.A. No. 09-204-JCJ
MILLENNIUM PHARMACEUTICALS, INC., and SCHERING CORPORATION, Plaintiffs, v. TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	C.A. No. 10-137-JCJ **REDACTED – PUBLIC VERSION**

PLAINTIFFS' OPPOSITION TO TEVA'S MOTION TO STAY

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I. INTRODUCTION

Defendants come to this Court asking to be rescued from a dilemma entirely of their own making. Despite having complete control over the timing and scope of these actions, Defendants [redacted]. Having made that choice, Teva now asks this Court to bail it out from the entirely predictable [redacted] by staying both these actions and the FDA approval process, such that final resolution of this matter is unlikely to be achieved for five years or more.

As a threshold matter, Teva's proposed stay would delay the administrative proceedings in the FDA by a total of forty-five months—*fifteen months* longer than the thirty-months provided by Congress in the Hatch-Waxman Act.[1] Teva's proposed stay is thus unauthorized by the Hatch-Waxman Act, which only allows a district court to extend the statutory thirty-month stay if "either party to the action failed to reasonably cooperate in expediting the action." Teva has most assuredly failed to meet that standard. The Court should reject the stay request on that basis alone.

Even if Teva's proposed stay were authorized under the Hatch-Waxman Act (which it is not), Teva has not met its burden of demonstrating that a stay is warranted. ***First***, Teva has not shown that it would suffer undue prejudice without a stay. [redacted] *Teva* controlled

[1] Teva's motion seeks an order both (1) "staying the present actions until May 11, 1012 (subject to a showing of good cause by any party that the stay should be lifted earlier)," and (2) tolling the FDA's thirty-month stay of approval of Teva's ANDA. (Mot. at 1.)

when these actions would commence and *what* patents would be at issue. [redacted]

Second, Plaintiffs will suffer substantial prejudice if forced to wait an additional two and a half years to litigate this case. Although the case is indeed in its early stages, Plaintiffs filed this action seeking declaratory judgment for the express purpose of obtaining a prompt resolution of Teva's invalidity assertions against the three challenged INTEGRILIN® patents. A two and one-half year stay would delay final resolution of these claims for at least five years—thereby depriving Plaintiffs of the timely resolution of their claims. In addition, such delay could jeopardize the availability of key evidence, much of which is already years old and will likely include testimony from individuals not employed by Plaintiffs.

Third, contrary to Teva's assertion, a stay would not encourage settlement. Far from it. Plaintiffs have significant motivation to remove any uncertainty regarding their INTEGRILIN® product – either by litigation or settlement. In contrast, a stay would only postpone any attention by Teva to this case, thereby eliminating whatever motivation Teva might have to engage in settlement discussions. As such, the stay requested by Teva would unfairly provide Teva a tactical advantage that it would not otherwise enjoy without the stay.

For these reasons, the Court should deny Teva's motion to stay.

II. BACKGROUND

Plaintiffs Millennium Pharmaceuticals, Inc. ("Millennium") and Schering Corporation ("Schering") are pharmaceutical companies dedicated to the discovery and development of new drug therapies.

Schering is the holder of an approved New Drug Application ("NDA") for INTEGRILIN® injection, a drug used in hospitals to treat patients suffering from heart attacks. Five patents pertaining to INTEGRILIN® and the use of INTEGRILIN® are listed in the FDA's "Orange Book." The three later expiring patents (all expiring in 2015) are the subject of these actions: (1) U.S. Patent No. 5,807,825 ("the '825 patent"); (2) U.S. Patent No. 5,747,447 ("the '447 patent"); and (3) U.S. Patent No. 5,968,902 ("the '902 patent"). Two earlier expiring patents (both expiring in 2014) are not at issue: (4) U.S. Patent No. 5,686,570 ("the '570 patent"); and (5) U.S. Patent No. 5,756,451 ("the '451 patent").

A. Congress's Statutory Framework Governing ANDA Submissions.

1. The Generic Manufacturer Decides Which Patents to Challenge.

Under the Hatch-Waxman Act, a generic manufacturer may submit an ANDA to market a generic copy of an FDA-approved pharmaceutical product. In connection with such an ANDA, the generic manufacturer must make a certification with respect to each Orange Book-listed patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii). [redacted]

A PIV Certification is based on a challenge to the validity of the listed patent or an assertion that the proposed generic product does not infringe the listed patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). By filing a PIII Certification, the generic manufacturer does not challenge the infringement or validity of the manufacturer's patent, but instead certifies that it

will not market its generic product before expiration of that patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(III). When the generic manufacturer submits a PIII Certification, the FDA may not grant approval of the generic product until after expiration of the patent. The generic manufacturer can later amend its ANDA to convert a PIII Certification to a PIV Certification. *See* 21 C.F.R. § 314.94(a)(12)(viii).

2. The Generic Manufacturer Controls The Timing Of Litigation.

The submission of a PIV is an act of patent infringement under 35 U.S.C. § 271(e) that triggers the right of the patent owner to bring an infringement action. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (the submission of a PIV Certification is an "artificial act of infringement" created by statute).

To trigger section 271(e), the ANDA filer must provide notice to the pioneer drug company of the factual and legal bases for the PIV Certification. *See* 21 U.S.C. § 355(j)(2)(B). Upon such notice, the pioneer company has the option of suing on all, some, or none of the patents included in the PIV Certification. If the pioneer company does not bring suit within forty-five days of receiving notice, the FDA may issue final approval of the ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

3. The Thirty-Month Stay.

If the pioneer company brings suit within forty-five days, the FDA typically may not approve the ANDA for thirty-months. *See id.* This period is known as the "thirty-month stay" and is the period which Teva proposes to extend here.

The FDA may approve the ANDA after the thirty-month stay expires, or earlier if a court has decided the patents-in-suit are invalid or not infringed. *See id.* Importantly for the issue currently pending before the Court, the thirty-month stay can only be extended by the

district court if "either party to the action failed to reasonably cooperate in expediting the action." *Id*. The statute does not provide any other grounds for extending the 30-month stay.

4. Forfeiture.

The Hatch-Waxman Act also grants the first company to submit a PIV Certification a 180-day period of generic marketing exclusivity. *See* 21 U.S.C. § 355(j)(5)(B)(iv). The generic manufacturer can forfeit the 180-day exclusivity period on certain "forfeiture events." 21 U.S.C. § 355(j)(5)(D). Most relevantly here, Teva will forfeit its claimed exclusivity if it fails to market a generic copy of INTEGRILIN® within seventy-five days after a final decision in these patent infringement actions from which no appeal can be taken. *See id.*

B. [redacted] Which It Now Seeks To Avoid With Its Proposed Extension Of The Thirty-Month Stay.

[redacted]

- By letter dated January 8, 2009, Plaintiffs received notification that Teva had filed ANDA No. 90-854 [redacted] the '825 patent and seeking to bring to market a generic version of INTEGRILIN® some six years before expiration of the November 11, 2014 patents.

- Forty-five days later, by letter dated February 13, 2009, Plaintiffs received notification that Teva also sought to challenge the '447 and '902 patents with ANDA No. 90-854.
- Nearly a year later, by letter dated January 5, 2010, Plaintiffs received a third notification that Teva had filed yet another ANDA for INTEGRILIN®. This most recent submission once again challenges the three later expiring patents (the '825, '447 and '902 patents), but seeks to bring to market a different dose of a generic version of INTEGRILIN® .

III. ARGUMENT

A. Teva's Proposed Extension Of The Thirty-Month Stay Is Not Authorized By The Hatch-Waxman Act.

Teva's motion is grounded in the incorrect assertion that this Court has complete discretion to extend the FDA's thirty-month stay. (Mot. at 6.) Although a district court often has broad discretion to stay litigation to control *its own docket*, there is no such discretion here because Teva is asking this Court to extend the *FDA's* statutory thirty-month stay. Congress has expressly limited the circumstances in which such an extension can be granted. Where Congress has prescribed a particular standard for the grant of stays, the district court must adhere to it strictly. *See Williams v. U.S. Merit Systems Protection Bd.*, 15 F.3d 46, 49 (4th Cir. 1994) (vacating district court's stay order on interlocutory appeal where the statute only allowed for the grant of stays under particular circumstances); *see also Melkonyan v. Sullivan*, 501 U.S. 89, 100 (1991) (although a district court has discretionary authority to remand cases under judicial review, "Congress's explicit delineation in § 405(g) regarding the circumstances under which remands are authorized . . . limt[ed] the district court's authority to enter remand orders" under the statute).

Here, Congress has expressly provided that the thirty-month stay can not be altered unless a "party to the action failed to reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii). The Federal Circuit has made it clear that failure to reasonably

cooperate in expediting litigation is the ***sole*** ground for which a court may extend the thirty-month stay in an ANDA litigation. *See Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, 557 F.3d 1346, 1350 (Fed. Cir. 2009) (explaining that enlargements of the thirty-month stay are determined "based on the parties' *uncooperative discovery practices*" (emphasis added)); *see also Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1376 (Fed. Cir. 2002) (vacating order shortening thirty-month stay because the district court "exceeded its authority" in altering the period for reasons other than that specified in the Hatch Waxman Act: "We find no such authority in the statute, which is *addressed only to delay* related to the particular infringement action. Thus, the district court exceeded its authority in shortening the thirty-month stay." (emphasis added)).

Consistent with that mandate, this district has refused to grant an extension of the thirty-month stay where the record was devoid of "the type of dilatory conduct and discovery antics that necessitate such a finding." *In re Brimonidine Patent Litig.*, No. 07-md-1866-GMS, 2008 WL 4809037, at *3 (D. Del. Oct. 31, 2008) (Sleet, J.) ("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.'").[2]

Teva does not contend that Plaintiffs have engaged in uncooperative discovery practices. Nor can it. Rather, the entire basis for Teva's claim that this Court may extend the thirty-month stay in the absence of a showing of delay caused by Plaintiffs is a lone, unpublished

[2] *See also Minn. Mining & Mfg. Co. v. Alphapharm Pty. Ltd.*, No. CIV-99-13, 2002 WL 1299996, at *3 (D. Minn. Mar. 8, 2002) (declining to extend the thirty-month stay because the nonmoving party "has not unreasonably prolonged the litigation"); *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, No. IP99-0038-C-H/G, 2001 WL 238090, at *1 (S.D. Ind. Mar. 8, 2001) (granting request to extend the thirty-month stay where the non moving party failed to meet the case management deadline for serving its expert witness reports, thereby delaying trial)

decision by the Northern District of Illinois in *Abbott Labs. v. Matrix Labs., Inc.*, No. 09-cv-1586, 2009 WL 3719214 (N.D. Ill. Nov. 5, 2009).

Even apart from the fact that a decision from a district court in Illinois is not binding in the District of Delaware, *Abbott Labs* does not justify Teva's proposed stay. Most critically, the *Abbott Labs* court improperly did not recognize that the "failed to reasonably cooperate" restriction in section 355(j)(5)(B)(iii) limits the court's discretion to enlarge the thirty-month period. *See Abbott Labs*, 2009 WL 3719214, at *3. As such, the *Abbott Labs* decision plainly runs afoul of the Federal Circuit's holdings in *Eli Lilly* and *Andrx* and Chief Judge Sleet's decision in *Brimonidine*. *See Eli Lilly*, 557 F.3d at 1350 (to extend the statutory thirty-month stay the district court must make "factual findings" based on "sufficient evidence" that the non-moving party "failed to reasonably cooperate in expediting the litigation"); *Andrx*, 276 F.3d at 1380 (remanding to the district court with specific directions to alter the thirty-month period "on the ground that the parties are not complying with the statutory requirement to 'reasonably cooperate in expedite the action.'"); *Brimonidine*, 2008 WL 4809037, at *3 (extension of the thirty-month stay is not warranted absent findings that the non-moving party employed "dilatory discovery tactics in an effort to try to 'run the clock'"). Accordingly, the *Abbott Labs* decision provides no basis for this Court to extend the thirty-month stay, and Teva's reliance on that flawed decision is an invitation to this Court to commit error.

B. Teva Cannot Demonstrate A Clear Case Of Hardship Or Inequity Absent A Stay.

Even if Teva could meet the Hatch-Waxman Act standard for enlarging the thirty-month period—which it cannot—Teva is not entitled to a stay unless it can demonstrate a "clear case of hardship or inequity." *St. Clair Intellectual Prop. Consultants, Inc. v. Fujifilm Holdings Corp.*, No. 08-373-JJF-LPS, 2009 WL 192457, at *2 (D. Del. Jan. 27, 2009); *see also Gold v.*

Johns-Manville Sales Corp., 723 F.2d 1068, 1075-1076 (3d Cir. 1983) ("It is well settled that before a stay may be issued, the petitioner must demonstrate 'a clear case of hardship or inequity,' if there is 'even a fair possibility' that the stay would work damage on another party") (quoting *Landis v. North American Co.*, 299 U.S. 248, 255 (1936)). Teva cannot meet that difficult burden here because (1) any harm to Teva is of its own doing, (2) the proposed stay would in fact harm Plaintiffs, and (3) the proposed stay would provide Teva an undeserved tactical advantage.

1. Any Harm To Teva In The Absence Of A Stay Was Completely Preventable And Is Entirely Of Teva's Own Doing.

Teva cannot credibly claim prejudice because any harm caused by litigating these actions now was of Teva's own doing. This Court has recognized that a party cannot establish prejudice where the source of the harm from which it seeks relief was its own fault. *See Cognex Corp. v. National Instruments Corp.*, No. 00-442-JJF, 2001 WL 34368283, at *2 (D. Del. June 29, 2001) (finding that a party could not establish a "clear case of hardship or inequity" where the circumstances giving rise to the stay request were "a result of [the party's] own making").

Teva controlled when these actions would be brought and what patents would be at issue. [redacted] a strategy the Hatch-Waxman Act was designed to discourage.

2. The Proposed Stay Would Prejudice Plaintiffs.

On the other hand, Plaintiffs will suffer substantial prejudice if forced to wait for an additional two and half years to continue litigating this case. Although the actions are in their early stages, Plaintiffs filed these actions seeking a prompt resolution of the Teva-generated cloud that has been hovering over its INTEGRILIN® business as a result of the allegations made by Teva challenging the validity of the three patents-in-suit. By staying the actions for an additional two and a half years, Plaintiffs would be prejudiced in several critical respects:

First, Plaintiffs seek a declaratory judgment that the patents-in-suit are valid and enforceable, not only to defeat Teva, but to ward off any additional potential generic challengers. The very purpose of such declaratory judgment actions is to permit a threatened party to obtain prompt resolution of the uncertainty hanging over its business activities. Here, however, a stay would unfairly deprive Plaintiffs of that right by allowing Teva to escape a timely resolution of Plaintiffs' claims. *See, e.g., Am. Ceramicraft, Inc. v. Eisenbraun Reiss, Inc.*, No. 92-2851, 1993 WL 498863, at *10 (D.N.J. June 16, 1993) (denying stay because "Plaintiffs' need for declaratory relief remains very much alive. As along as the validity of the [patent-in-suit] remains in doubt, none of the parties here can put this matter behind them and go about the business of manufacturing and selling"); *see also Artic Cat, Inc. v. Injection Research Specialists, Inc.*, No. 01-00543, 2003 WL 22047872, at *2 (D. Minn. Aug. 29, 2003) (denying motion to stay declaratory judgment action).

Second, although Plaintiffs have taken the appropriate steps to preserve documents under their custody and control, the two- to three-year delay that would accompany the stay requested by Teva could subject Plaintiffs to the needless risk of potential evidentiary issues. Some of the underlying evidence relating to the discovery of INTEGRILIN® was created years ago. The additional passage of time may lead to faded memories and the potential loss of

useful testimonial evidence. For example, one of the named inventors of the patents-in-suit, Robert Scarborough, passed away in 2006. In such circumstances, a stay is not appropriate. *See BarTex Research, LLC v. FedEx Corp.*, 611 F. Supp. 2d 647, 652 (E.D. Tex. 2009) (no stay where "witnesses could become unavailable, their memories may fade, and evidence may be lost"); *Anascape, Ltd. v. Microsoft Corp.*, 475 F. Supp. 2d 612, 616 (E.D. Tex. 2007) (no complete stay because of the prejudice posed based on stale evidence); *see also Alltech, Inc. v. Cenzone Tech., Inc.*, No. 06-0153-JM-RBB, 2007 WL 935516, at *2 (S.D. Cal. Mar. 21, 2007) (no stay where approximately two year stay "could result in loss of evidence and the fading of witness memory"); *Gladish v. Tyco Toys, Inc.*, No. 92-01666-WBS-JFM, 1993 WL 625509, at *2 (C.D. Cal. Sept. 15, 1993) (no stay where "witnesses may become available . . . and memories may fade").

Teva cannot overcome the resulting prejudice to Plaintiffs simply by pointing to the early procedural posture of this case. (Mot. at 8-9.) Otherwise, every motion to stay brought early in a litigation would be automatically granted. Of course, that is not the law. *See, e.g.*, *Robbins v. H.H. Brown Shoe Co.*, No. 08-06885-WHP, 2009 WL 2170174, at *2 (S.D.N.Y. June 30, 2009) (denying motion to stay action in its "early stages"); *IMAX Corp. v. In-Three, Inc.*, 385 F. Supp. 2d 1030, 1032 (C.D. Cal. 2005) (denying stay motion filed just three months into the litigation).

3. A Stay Would Eliminate A Significant Motivation For Teva To Settle And Provide Teva With An Undeserved Tactical Advantage

Finally, contrary to Teva's argument, a stay would not encourage settlement. (Mot. at 7-8.) Indeed, the proposed stay would remove from the table any motivation for Teva to amicably resolve this case.

In the end, Teva's request for a stay is antithetical to the interests of the Hatch-Waxman Act and the careful framework that Congress crafted when it provided for a 180-day exclusivity period. For this reason, it is not surprising that Teva has only found a single, unpublished case extending the thirty-month stay [redacted]. Although Teva points out that the primary purpose underlying the 180-day exclusivity period is to encourage generic manufacturers to enter the marketplace, that grant is designed to reward the generic manufacturer for engaging in the risks and costs associated with actively litigating against a pioneer drug company to bring a generic drug to market as early as possible. *See Hi-Tech Pharmacal Co., Inc. v. FDA*, 587 F. Supp. 2d 1, 4 (D.D.C. 2008) (explaining that the statutory purpose of the 180-day exclusivity period is to incentivize the "first-filing" generic company to "undertake the risk of litigation"). [redacted] Granting a stay in such a situation would do harm to the balance struck by Congress when it crafted the Hatch-Waxman Act, essentially rendering meaningless the forfeiture events that Congress drafted to "ensure that the 180-day exclusivity period enjoyed by the first generic to challenge a patent cannot be used as a bottleneck to prevent additional generic competition." *Id.* (quoting 149 Cong. Rec. S15746 (daily ed. Nov. 24, 2003) (statement of Sen. Schumer)). Teva's proposed stay seeks to do just that.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court deny Teva's motion to stay.

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CERTIFICATE OF SERVICE

I hereby certify that on April 5, 2010, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to:

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I further certify that I caused copies of the foregoing document to be served on April 5, 2010, upon the following in the manner indicated:

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