**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| MILLENNIUM PHARMACEUTICALS, INC. and SCHERING CORPORATION,<br><br>Plaintiffs,<br><br>v.<br><br>TEVA PARENTERAL MEDICINES, INC. and TEVA PHARMACEUTICALS USA, INC.,<br><br>Defendants. | Civil Action No. 1:09-cv-105-JCJ<br><br>Judge J. Curtis Joyner<br><br>PUBLIC VERSION |
| MILLENNIUM PHARMACEUTICALS, INC. and SCHERING CORPORATION,<br><br>Plaintiffs,<br><br>v.<br><br>TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD.,<br><br>Defendants. | Civil Action No. 1:09-cv-204-JCJ<br><br>Judge J. Curtis Joyner<br><br>PUBLIC VERSION |
| MILLENNIUM PHARMACEUTICALS, INC. and SCHERING CORPORATION,<br><br>Plaintiffs,<br><br>v.<br><br>TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD.,<br><br>Defendants. | Civil Action No. 1:10-cv-137-JCJ<br><br>Judge J. Curtis Joyner<br><br>PUBLIC VERSION |

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**TEVA'S MOTION TO STAY**

Defendants, Teva Parenteral Medicines, Inc. and Teva Pharmaceuticals USA, Inc. (collectively "Teva"), hereby move for an order (1) staying the present actions until May 11, 2012 (subject to a showing of good cause by any party that the stay should be lifted earlier), and (2) tolling the Food & Drug Administration's ("FDA") thirty-month stays of approval of Teva's Abbreviated New Drug Applications ("ANDAs") for the drug at issue here, eptifibatide.

## I. NATURE AND STAGE OF THE PROCEEDINGS

Plaintiffs, Millennium Pharmaceuticals, Inc. and Schering Corp. (collectively "Schering"), filed the present actions on February 18, 2009 (Civil Action No. 09-105), March 27, 2009 (Civil Action No. 09-204), and February 19, 2010 (Civil Action No. 10-137). All three of the actions involve roughly the same allegations. Schering alleges that Teva's act of filing certain ANDAs with the FDA constitutes infringement of three patents. (*See* D.I. 9 at 5-7 (No. 09-105); D.I. 1 at 6-9 (No. 09-204); D.I. 1 at 6-11 (No. 10-137)). Teva contends that the asserted patents are invalid, not infringed, and/or are otherwise unenforceable. (*See* D.I. 10 at 13-14 (No. 09-105); D.I. 8 at 18-19 (No. 09-204)).

No scheduling order has been entered in any of the actions. Likewise, no discovery has been exchanged by the parties. Indeed, the most recent action (Civil Action No. 10-137) was filed only a few weeks ago and Teva has not yet answered.

## II. BACKGROUND

### A. Overview of ANDA Litigation

A pharmaceutical company ("brand company") seeking approval to market a new drug product must file a New Drug Application ("NDA") with the FDA. *See* 21 U.S.C. § 355(a). In connection with the NDA, the brand company must report certain patents relating to the drug to

the FDA so that they can be included in the so-called "Orange Book."[1] Specifically, the brand company must list the patent number(s) and expiration date(s) of any patent that claims the drug or claims a method of using the drug. Patents listed in the Orange Book are commonly referred to as "Orange Book patents."

A generic pharmaceutical company ("generic company") seeking approval to market a generic version of the same drug product may file an ANDA. In connection with the ANDA, the generic company must certify that:

I. no patents have been filed with the FDA;
II. certain patents listed in the Orange Book have expired;
III. FDA approval of the ANDA should be delayed until the expiration of certain patents listed in the Orange Book; and/or
IV. certain patents listed in the Orange Book are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the generic drug.

*See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)–(IV). These certifications are known as Paragraph I, Paragraph II, Paragraph III, and Paragraph IV certifications, respectively. The generic company must ordinarily provide one of these certifications for each Orange Book patent.

[redacted] When a Paragraph III certification is made with respect to an Orange Book patent, the FDA may not approve the ANDA until the expiration of the patent, which sometimes may be many years off in the future. When a Paragraph IV certification is made, on the other hand, the FDA may approve the ANDA before the expiration of the patent, but only in certain circumstances highlighted below and, especially relevant here, only if other Orange Book patents do not present an obstacle to approval (*i.e.*, only if there are no other Orange Book patents that were certified under Paragraph III that have not yet expired). Since the generic company may not market a generic version of the drug

[1] The FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," is commonly known as the Orange Book and is available online at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.

without approval of the ANDA, any delay in approval has the effect of keeping the generic company off the market.

Pursuant to 35 U.S.C. § 271(e)(2)(A), submitting a Paragraph IV certification to the FDA constitutes an "artificial" act of patent infringement. *See* 35 U.S.C. § 271(e)(2)(A); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1365 (Fed. Cir. 2003). A generic company that files a Paragraph IV certification must give notice of this certification to the brand company. If the brand company files a patent infringement lawsuit against the generic company within 45 days of this notice, the Hatch-Waxman Act provides for a "30-month stay" that prohibits the FDA from approving the ANDA until thirty months after the notice. 21 U.S.C. § 355(j)(5)(B)(iii). If, however, before the thirty months expire, a court finds the patent(s) subject to the Paragraph IV certification are invalid, unenforceable, or not infringed, or the court enters a settlement order or consent decree to the same effect, then the FDA may approve the ANDA before the termination of the thirty-month period (but, again, only if other Orange Book patents do not present an obstacle). 21 U.S.C. § 355(j)(5)(B)(iii)(I).

The Hatch-Waxman Act was enacted, in part, to encourage generic companies to file ANDAs, thereby increasing the volume of low-cost generic drugs on the market. To this end, the Act provides the incentive of a 180-day period of market exclusivity for the first company to file a Paragraph IV certification for a particular drug (sometimes referred to as the "first filer"). 21 U.S.C. § 355(j)(5)(B)(iv). Ordinarily, this means that, once the ANDA is approved by the FDA, the first filer is entitled to market a generic version of the drug for 180 days without competition from other generic companies. This exclusivity period can be very valuable to the generic company.

To obtain this benefit, however, the generic company must begin marketing the drug within 75 days after a final un-appealed, or non-appealable, judgment is made that the patent(s) subject to the Paragraph IV certification is/are invalid, unenforceable, and/or not infringed. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA). If the first-filer fails to comply with this "Failure to Market" provision of the Act, it forfeits the 180-day exclusivity period. *Id.*

**B. The Present ANDA Litigations**

The present actions were filed pursuant to the procedures discussed above. Schering filed NDA No. 20-7018 for its eptifibatide drug product (commercially known as INTEGRILIN®), and listed the following five patents in the Orange Book:

| PATENT | EXPIRATION DATE | TEVA'S CERTIFICATION |
|---|---|---|
| U.S. Patent No. 5,686,570 | November 11, 2014 | [redacted] |
| U.S. Patent No. 5,756,451 | November 11, 2014 | [redacted] |
| U.S. Patent No. 5,747,447 | May 5, 2015 | [redacted] |
| U.S. Patent No. 5,968,902 | June 2, 2015 | [redacted] |
| U.S. Patent No. 5,807,825 | September 15, 2015 | [redacted] |

Teva filed two ANDAs relevant here: ANDA Nos. 90-854 and 91-555.[2] These ANDAs requested approval from the FDA to market generic versions of eptifibatide (each ANDA addresses different dosage strengths of eptifibatide). Pursuant to the Hatch-Waxman Act, Teva made certain certifications for each of the Orange Book patents listed above. [redacted]

[redacted]

[2] The ANDAs and corresponding certifications were filed by Teva Parenteral Medicines, Inc., not Teva Pharmaceuticals USA, Inc. This distinction is not material for purposes of this motion so, for simplicity, the designation "Teva" is used generically.

[redacted]

After receiving notice [redacted] Schering filed the present actions for infringement [redacted] These actions were filed within the 45-day window and, therefore, Schering triggered automatic 30-month stays of approval of Teva's ANDAs.

[redacted]

Herein lies the problem. [redacted]

[redacted]

If these actions proceed on the current track, [redacted] Teva believes that these actions may take roughly 2½ years to litigate to a final conclusion. Accordingly, Teva requests a stay of these actions until May 11, 2012, or 2½ years before the expiration of the 2014 patents.

## III. ARGUMENT

### A. Legal Standard for Evaluating Whether a Stay is Appropriate

The decision to grant a stay is firmly within the discretion of the Court. *Abbott Diabetes Care, Inc. v. DexCom, Inc.*, No. 06-514 (GMS), 2007 WL 2892707, at *4 (D. Del. Sept. 30, 2007) (citing *Cost Bros., Inc. v. Travelers Indemnity Co.*, 760 F.2d 58, 60 (3d Cir. 1985)); *In re Brimonidine Patent Litigation*, No. 07-1866 (GMS), 2008 WL 4809037, at *1 (D. Del. Nov. 3, 2008) (citing *Cost Bros.*). The following three factors are considered: (1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-movant, (2) whether a stay would simplify the issues in question and the trial in the case, and (3) whether discovery has been completed and whether a trial date has been set. *Id.* Each of these factors weighs in favor of a stay here.

### B. A Stay is Appropriate Here

#### 1. Prejudice Concerns Support a Stay

Teva will be greatly prejudiced if the requested stay is not granted. As explained above, [redacted] *See In re Brimonidine*, 2008 WL 4809037, at *2 (refusing to grant a stay because, *inter alia,* the delay would likely result in a generic company forfeiting its 180-day market exclusivity); *Janssen Pharmaceutica N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1361 (Fed. Cir. 2008) ("The 180-day exclusivity period is important to generic pharmaceutical companies as it promotes patent challenges by enabling a generic company to recover its investment in these challenges."). Moreover, without a stay, the Court may spend significant time and effort to resolve these actions (they are bench trials, not jury trials) when, in the end, the resolution is not meaningful [redacted]

On the other hand, a stay would not prejudice Schering. Teva cannot market generic eptifibatide in the United States until the FDA approves its ANDAs. [redacted] he FDA presently remains unable to approve Teva's ANDA as a result of the thirty-month stays triggered by these actions. Although Schering may have argued that a stay of these actions would prejudice it with respect to the 30-month stays at the FDA, Teva has eliminated this argument by concurrently requesting an order tolling the FDA's 30-month stays of approval.

The Northern District of Illinois recently granted a stay [redacted] *Abbott Labs. v. Matrix Labs., Inc.*, No. 09-cv-1586, 2009 WL 3719214, at *5 (N.D. Ill. Nov. 5, 2009). In *Abbott*, the defendants filed an ANDA containing both Paragraph III and Paragraph IV certifications. Based on the Orange Book patents at issue, the defendants could not possibly market their generic product until at least 2016. *Id.* at *1-2. [redacted] the defendants argued that "without a stay they could lose out on Hatch-Waxman's 180-day market exclusivity period." *Id.* at *1. The court stated:

> [T]he Court concludes that the combination of its inherent authority to exercise control over cases pending on its docket and the statutory authority to adjust the thirty-month period to take into account the particular circumstances of "the particular infringement action" – here, that Defendants have recognized that they may not launch their generic products until at least 2016 – weigh in favor of entering a stay.

*Id.* at *3. The court granted the defendants' motion to stay the action until July 1, 2014. *Id.* at *5. Likewise here, a stay should be entered.

**2. A Stay Could Simplify The Issues or Render Litigation Unnecessary**

A stay of the present actions could simplify the issues in the present litigations. [redacted]

[redacted]

In addition, intervening events could occur during the stay that would simplify the issues for trial. For example, one of Teva's affirmative defenses is that the asserted patents are invalid as obvious under 35 U.S.C. § 103. In evaluating such a defense, the Court may consider, among other things, whether the alleged invention is commercially successful. *See generally KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (setting forth obviousness test). By delaying these actions, additional data regarding whether the alleged invention is commercially successful will be generated. This additional data may limit, or possibly eliminate, the need for both parties to address the issue of commercial success at trial.

Still further, the status of the patents-in-suit could change during the proposed stay. For example, Schering could request that the FDA de-list one or more of the 2015 patents from the Orange Book pursuant to 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC). This would certainly narrow the issues in these actions.

Moreover, the Court's resources may be conserved with a stay. Not only would proceeding with the actions result in a premature use of judicial resources, but as the *Abbott* court recognized, "no speculation is required to support the conclusion that granting a stay will preserve the Court's resources." *See Abbott Labs.*, 2009 WL 3719214, at *5.

**3. The Present Litigations Are Still In Their Infancy**

These actions are still in their infancy. No documents have been produced, no interrogatories have been served, and no depositions have been taken. The most recent action, for example, was filed only a few weeks ago, and Teva has yet to answer. No scheduling order

has been entered in any of the actions. In these circumstances, a stay is appropriate. *See, e.g.*, *Abbott Diabetes Care*, 2007 WL 2892707, at *5 (granting a stay where "no scheduling Order is in place, no discovery has taken place, and little time has yet to be invested in the litigation"); *United Sweetener USA, Inc. v. NutraSweet Co.*, 766 F. Supp. 212, 216-17 (D. Del. 1991) (granting a stay where the litigation was at an early stage); *Abbott Labs*, 2009 WL 3719214, at *4 (granting a stay where the case was "at an early stage - no discovery has taken place, and the only issue in the case thus far has been whether a stay is appropriate").

## IV. CONCLUSION

For the foregoing reasons, Teva requests an order (1) staying the present actions until May 11, 2012 (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 stays of approval of Teva's ANDA Nos. 90-854 and 91-555.

Dated: March 12, 2010

Respectfully submitted,

By: /s/ Mary B. Matterer

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**TEVA'S RULE 7.1.1 STATEMENT**

Counsel for Defendants, Teva Parenteral Medicines, Inc. and Teva Pharmaceuticals USA, Inc. (collectively "Teva"), hereby states that it made a reasonable effort to reach agreement with counsel for Plaintiffs on the matters set forth in this Motion, but as of today, Plaintiffs were not willing to agree with the Motion.

Respectfully submitted,

Dated: March 12, 2010

By: /s/ Mary B. Matterer

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| MILLENNIUM PHARMACEUTICALS, INC. and SCHERING CORPORATION,<br><br>Plaintiffs,<br><br>v.<br><br>TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD.,<br><br>Defendants. | Civil Action No. 1:10-cv-137-JCJ<br><br>Judge J. Curtis Joyner |

**[PROPOSED] ORDER**

Having considered Teva's Motion to Stay and all related briefing and argument,

**IT IS HEREBY ORDERED** this _____ day of _____, 2010 that the Motion is GRANTED. These three actions (C.A. Nos. 09-105-JCJ, 09-204-JCJ and 10-137-JCJ) are hereby stayed until May 11, 2012, subject to a showing of good cause by any party that the stay should be lifted earlier. Additionally, the Food & Drug Administration's thirty-month stays of approval of Teva Parenteral Medicines, Inc.'s Abbreviated New Drug Application Nos. 90-854 and 91-555 are hereby tolled.

_____
J. CURTIS JOYNER
United States District Court Judge