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

TEVA'S REPLY IN SUPPORT OF ITS MOTION TO STAY

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I. INTRODUCTION.

These actions should be stayed. Schering does not dispute that Teva would be greatly prejudiced without a stay. Nor does Schering dispute that granting a stay would conserve the Court's resources and simplify the issues for trial. Still further, Schering does not dispute that these actions are still in their infancy and ripe for a stay.

These undisputed facts well justify a stay. Schering ignores them, however, and spends most of its efforts arguing that these actions should not be stayed because the Court allegedly lacks authority to toll the 30-month stays at the FDA. But this argument misses the point. These actions should be stayed regardless of whether the Court also tolls the stays at the FDA. Schering's remaining arguments regarding alleged prejudice to Schering and Teva's motivation to settle are equally unavailing, as discussed below. Teva's Motion should be granted.

II. ARGUMENT.

A. Plaintiffs Do Not Dispute What Really Counts.

Schering's Opposition is significant for what it does *not* say. Schering does not even attempt to dispute the following:

- [redacted] (*See* Mot. at 6).
- [redacted] (*See id.*).
- Teva will be greatly prejudiced if the requested stay is not granted. (*See id.*).
- A stay of the present actions could simplify the issues for trial. (*See* Mot. at 7-8).
- 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] (*See* Mot. at 6).
- The Court's resources will be conserved with a stay. (*See* Mot. at 8).

- These actions are still in their infancy and are ripe for a stay. (*See* Mot. at 8-9).

These undisputed facts fit squarely within the factors considered by the Court in assessing a possible stay, (*see* Mot. at 6), and they more than justify a stay here.

Schering cites only one Hatch-Waxman case where a stay was denied: *In re Brominidine*. There, however, the plaintiffs requested the stay, not the generic defendant, [redacted] [redacted] *See In re Brimonidine Patent Litigation,* No. 07-1866 (GMS), 2008 WL 4809037, at *2 (D. Del. Nov. 3, 2008). The same result can only be achieved here by granting a stay.

B. These Actions Should Be Stayed Regardless Of Whether The Court Also Tolls the 30-Month Stays at the FDA.

Schering argues that these actions should not be stayed because the Court allegedly lacks authority to toll the 30-month stays at the FDA. But these actions should be stayed *regardless* of whether the Court also tolls the stays at the FDA. Tolling at the FDA is not a prerequisite to a stay here.

Teva requested a tolling of the 30-month stays at the FDA as an accommodation to Schering – to preempt any alleged prejudice arguments by Schering. Schering's Opposition brief, however, makes it clear that Teva's proposed accommodation is unwanted. Teva will accept either alternative – tolling or not tolling – as long as these actions are stayed.

[redacted] To be clear, the stays at the FDA relate to final approval of the ANDAs, not FDA activities towards approval. The FDA may continue to work on the ANDAs during the 30-month stays, but it is not permitted to approve them during the stay periods. [redacted]

[redacted]

Should the Court decide that tolling is appropriate, it has the authority to do so in the present circumstances. Indeed [redacted] the court ordered a stay of the action while tolling the 30-month stay at the FDA. *See Abbott Labs. v. Matrix Labs., Inc.*, No. 09-1586, 2009 WL 3719214, at *5 (N.D. Ill. Nov. 5, 2009). Plaintiffs make a big deal out of the fact that Teva cited only one case in support of the Court's authority to toll the 30-month stay (*Abbott Labs.*), but [redacted] Plaintiffs have cited *zero* cases that have [redacted] and held otherwise. Indeed, the *Abbott* court acknowledged – and apparently rejected – the very argument raised by Schering that courts lack authority to toll the 30-month stay [redacted] *See id.* (acknowledging the *Andrx Pharm., Inc. v. Biovail Corp.* case relied upon by Schering in support of its position here).

C. Schering's Remaining Arguments Are Equally Unavailing.

1. Schering's attempt to blame Teva for these actions is unfounded.

Schering tries to blame Teva for these actions and argues that [redacted] (Opp. at 9). But Schering filed these actions, not Teva, and Schering itself acknowledges that it had "the option of suing on all, some, or none of the patents included in the

PIV Certification." (Opp. at 4). Schering chose the option of suing Teva – if Teva had its way, none of these actions would have been filed.

[redacted] In any event, [redacted] there is no dispute that Teva was simply following the Hatch-Waxman framework, that Teva would be significantly prejudiced without a stay, and that a stay could cure such prejudice.[1]

2. Schering's alleged prejudice arguments are unsupported.

Schering would not be prejudiced by a stay. Schering argues in the abstract that a "cloud" is "hovering" over its eptifibatide business that requires "prompt resolution," but Schering did not provide any support for this argument. (Opp. at 10). Indeed, this argument is directly at odds with Schering's own conduct in these actions. If Schering truly sought to erase a "cloud" over its business, it surely would pursue these actions with at least a modicum of haste. But Schering has not produced *any* documents, served *any* interrogatories, or sought *any* depositions. In addition, Schering has granted repeated extensions (spanning almost 4 months) for Teva's responses to the lone set of document requests served by Schering in these actions.

[1] The *Cognex Corp.* case cited by Plaintiffs did not hold, as Plaintiffs suggest, that a party cannot establish prejudice where the source of harm is its own doing. Rather, the Court held that, under the specific circumstances of the case, any potential waste that might be avoided by a stay was insufficient in comparison with the waste already inflicted on the defendant and the Court by the plaintiff's failure to seek an earlier reexamination. *Cognex Corp. v. National Instruments Corp.*, 2001 WL 34368283, at **1-3 (D. Del. Jun. 29, 2001).

Schering's unsupported allegations of business prejudice are also at odds with the reality of the present circumstances. [redacted] *See Novartis Corp. v. Dr. Reddy's Labs., Ltd.*, 2004 WL 2368007, *3 (S.D.N.Y. Oct. 21, 2004) (rejecting argument that alleged "cloud" over patent was sufficient to establish prejudice [redacted]

Schering also argues in the abstract that a stay would subject them to a needless risk of potential evidentiary issues. (Opp. at 10-11). But Schering again failed to provide any support for this argument, and it failed to show that such abstract concerns differ from every other case in which a stay is granted. General unsupported allegations about the potential loss of evidence are insufficient to deny a stay. *See Abbott Labs.*, 2009 WL 3719214, *4 ("Abbott suggests that a lengthy or indeterminate stay may create evidentiary problems. While the proposition may be true in the abstract, a court must have some specific basis for determining that harm to a party would result if a stay issues."). Moreover, the primary focus of these actions is the invalidity of the patents-in-suit based on prior art references. These prior art references are in the public domain and will not be going anywhere during the proposed stay.

3. A stay would not provide Teva with a tactical advantage.

Schering alleges that a stay would remove Teva's motivation to settle these actions, but this does not make sense. With a stay, [redacted] Plus, a stay means that Teva has these actions hanging over its head during the pendency of the stay, while Schering gets to enjoy the benefit of formally asserting legal claims without needing to prove

them. If anything, Teva would have a greater motivation to settle during a stay. Schering, in any event, has failed to show how an alleged decrease in Teva's motivation to settle results in a tactical disadvantage for Schering in pursuing these actions on the merits.

Schering's remaining argument – that "Teva's request for a stay is antithetical to the interests of the Hatch-Waxman Act" – also has nothing to do with whether a stay would result in a tactical disadvantage for Schering. (Opp. at 12). Besides, Schering is simply wrong. For example, Schering suggests that Teva would be avoiding the "risks and costs" of litigation with a stay, but Teva still faces the same "risks and costs" – they are just delayed. In addition, Schering alleges that a stay "would not result in the earliest possible entry of a generic into the marketplace," [redacted] We can litigate these actions now or later, [redacted]

III. CONCLUSION

For the foregoing reasons, Teva's Motion to Stay these actions until May 11, 2012 (subject to a showing of good cause by any party that the stay should be lifted earlier) should be granted.

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Respectfully submitted,

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