IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS, INC. and SCHERING CORP.,	:	
Plaintiffs,	:	CIVIL ACTION
v.	:	NO. 09-cv-105
TEVA PARENTERAL MEDICINES, INC. and TEVA PHARMACEUTICALS USA, INC.,	:	
Defendants.	:	
MILLENNIUM PHARMACEUTICALS, INC. and SCHERING CORP.,	:	
Plaintiffs,	:	CIVIL ACTION
v.	:	NO. 09-cv-204
TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	:	
Defendants.	:	
MILLENNIUM PHARMACEUTICALS, INC. and SCHERING CORP.,	:	
Plaintiffs,	:	CIVIL ACTION
v.	:	NO. 10-cv-137
TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	:	
Defendants.	:	

MEMORANDUM AND ORDER

Joyner, J. **April 13, 2010**

This case is now before the Court on Defendants' Motion to Stay (Doc. No. 13). For the reasons set forth below, the Motion is DENIED.

Factual Background

Plaintiffs in this case are pharmaceutical companies that develop new drugs, including Integrelin, which is an injection used to treat individuals suffering heart attacks. Plaintiffs hold five patents relating to Integrelin: U.S. Patent No. 5,686,570; U.S. Patent No. 5,756,451; U.S. Patent No. 5,807,825; U.S. Patent No. 5,747,447; and U.S. Patent No. 5,968,902. Patents No. 5,686,570 and 5,756,451 ("the 2014 patents") both expire in 2014, while Patents No. 5,807,825, 5,747,447, and 5,968,902 ("the 2015 patents") all expire in 2015.

Defendants produce and market generic pharmaceutical drugs, and have filed Abbreviated New Drug Applications ("ANDAs") for generic versions of Integrelin in two different dosage strengths. One of these ANDAs relates only to the 2014 patents and is not relevant to the present litigation. The other ANDA, however, implicates both the 2014 and the 2015 patents, and is the focus of the present litigation.

In an effort to decrease the distortion on patent rights caused by the extensive regulatory process through which

pharmaceutical drugs must pass prior to reaching the market, Congress established a special framework for approval of generic drug applications before the relevant patents have expired. Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 670-71 (1990). Under this framework, the developer of a generic drug may file an ANDA to begin the process of developing and receiving approval of its generic drug before the relevant patent has expired.

When filing an ANDA, the generic company must address any patents listed in the New Drug Application ("NDA") that was filed by the patent holder with the Food and Drug Administration ("FDA") before the patent holder began marketing and distributing its drug. The company filing the ANDA must certify one of the following: I. no patents were listed in the NDA; II. the listed patents have expired; III. valid patents still exist, and FDA approval should be delayed until these patents have expired; or IV. the patents listed in the NDA application are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). If the ANDA filer chooses to submit a Paragraph IV certification, the patent holder must be given notice, and has 45 days to bring suit to establish the validity of its patent. If this happens, the ANDA is stayed for a 30-month period. If this does not happen, or if a court determines that the Paragraph IV certification was proper, the FDA can approve the ANDA before the

expiration of the patent.

As noted above, Defendants filed two ANDAs related to Integrelin. The one that related solely to Plaintiffs' 2014 patents had only Paragraph III certifications. The other, however, was covered both by the 2014 and 2015 patents, and had Paragraph III and Paragraph IV certifications; the 2014 patents again received a Paragraph III certification, while the 2015 patents were certified under Paragraph IV. Following receipt of notice of the Paragraph IV certifications, Plaintiffs timely brought suit, seeking a declaratory judgment to establish the validity of their patents and their applicability to Defendants' ANDA.

Defendants now seek a stay, both of the proceedings before this Court and of the FDA's resolution of Defendants' ANDA. Defendants' reason for seeking this stay is related to the expected benefits that come from having an ANDA approved. The first company to file a Paragraph IV certification of a drug is entitled to a 180-day period of market exclusivity once the ANDA is approved by the FDA. This exclusivity period, however, is forfeited if the filer does not begin marketing its generic drug within 75 days of a final judgment that the patents given a Paragraph IV certification are invalid, unenforceable, or not infringed. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA). In the present case, the drug that is the subject of Defendants' ANDA is

covered by patents that were certified under both Paragraph III and Paragraph IV, and the Paragraph III certifications are on patents that do not expire until 2014. Because of this, even if Defendants were successful in this litigation and their Paragraph IV certifications of the 2015 patents were approved, Defendants would be unable to market their generic version of the drug until the 2014 patents expired. As any such favorable adjudication of the 2015 patents would almost certainly occur more than 75 days before the 2014 patents expire, Defendants could be forced to forfeit their 180-day exclusivity period, even if they are ultimately successful in this litigation.

Defendants, therefore, seek a stay in this Court so that they can take advantage of the statutory incentive provided if they are ultimately successful in their Paragraph IV certifications. Plaintiffs, however, assert that Defendants have chosen the timing of the certification process, and assert that it is inappropriate to prejudice Plaintiffs for Defendants' actions.

Standard

It is well established that any decision whether to grant a stay is within the discretion of the court. Cost Bros., Inc. v. Travelers Indem. Co., 760 F.2d 58, 60 (3d Cir. 1985). In exercising such discretion, the court should consider the possible damage caused to each party, whether granting the stay

will cause any hardship or inequity for a party, and whether the stay will help simplify the issues that need to be tried. United Sweetener USA, Inc. v. Nutrasweet Co., 766 F. Supp. 212, 217 (D. Del. 1991). More recently, courts have stated that this discretion should be guided by considerations of whether the non-moving party will be unduly prejudiced, whether a stay will help simplify the issues for trial, and whether discovery has been completed and a trial date has been set. In re Brimonidine Patent Litig., No. 07-md-1866, 2008 WL 4809037, at *1 (D. Del. Oct. 31, 2008). The party seeking a stay, however, must demonstrate a "clear case of hardship or inequity" if there is "even a fair possibility" that a stay will cause harm to the non-moving party. Gold v. Johns-Manville Sales Corp., 723 F.2d 1068, 1075-76 (3d Cir. 1983) (quoting Landis v. N. American Co., 299 U.S. 248, 255 (1936)).

Discussion

We will begin by addressing the potential hardships that each side would suffer if we were to grant or deny the stay. Defendants assert that if we deny a stay, they will almost certainly lose their 180-day exclusivity period. Plaintiffs first contest the validity of this consideration. Second, Plaintiffs assert that they would be harmed by not being able to clear the cloud that Defendants have placed around Plaintiffs' patents and by the inevitable decline or possible loss of

evidence necessary to support their patents' validity that would accompany the proposed multi-year delay.

Beginning with Plaintiffs' alleged injuries, we believe that Plaintiffs would be prejudiced in not being able to timely "clear the cloud" that has been cast over the validity of their patents. Congress clearly intended to allow for a prompt adjudication of these disputes by making the filing of an ANDA with a Paragraph IV certification an "artificial act of infringement." Eli Lilly, 496 U.S. at 678. By doing so, patent holders were able, and, in fact, required, to promptly bring suit. To prevent Plaintiffs from doing so in this case would alter the clearly established statutory time line, and would force Plaintiffs to wait for several years to have an opportunity to establish their patents' validity. Any such delay only increases the prejudice suffered; by forcing Plaintiffs to wait an additional two years to establish the validity of their patents, the granting of a stay would only make it more difficult for Plaintiffs to successfully do so as memories fade and documents may be lost. It is clear, therefore, that Plaintiffs would be harmed by this stay. Plaintiffs would be greatly delayed in availing themselves of a statutorily provided path that was meant to expedite the consideration of patent validity, and would be forced to let several more years pass before presenting their evidence.

Given that Plaintiffs have demonstrated more than "a fair

possibility" that they will be harmed by the entry of a stay, Defendants must show that they have a "clear case of hardship or inequity" in order to justify the granting of a stay. Gold, 723 F.2d at 1075-76. Admittedly, Defendants have shown that they will be harmed if a stay is not entered, as they will likely forfeit their 180-day exclusivity period. Defendants, however, have only themselves to blame for this result. Defendants were aware of the statutory preconditions necessary for them to obtain the 180-day exclusivity period, and were aware of the potential that this could be forfeited given the timing of the filing of their ANDAs. Although Defendants did not file this suit, they were well aware that their ANDA triggered the start of a 45-day period for Plaintiffs to defend the validity of their patents, and, in this sense, did control the timing of the present litigation. Rather than wait until they could fully take advantage of their position as first filer, however, Defendants sought to prematurely reserve their place at the front of the line, and now seek an order from this Court that allows them to preserve that position. This is not the type of hardship or balance of inequities that can appropriately convince this Court to issue a stay in the present proceedings. Although Defendants may suffer a hardship, it is one of their own creation and, therefore, we do not think that it can outweigh the harm caused to Plaintiffs by granting this stay. Having examined the

possible damages to the parties, this factor weighs against granting a stay in the present case.

Turning to the second factor to be considered, we also do not think that a stay would be likely to simplify the issues for trial. Although Defendants assert that a stay could result in a settlement or in Plaintiffs deciding to de-list one or more of their patents, given the current juncture of the case these appear to be possibilities more than likelihoods. There is simply no indication from Plaintiffs that they plan on doing anything other than actively defending their patents. Plaintiffs, on the other hand, note that granting a stay would remove any incentive for Defendants to settle, as they could simply wait for this Court to adjudicate the validity of Plaintiffs' patents at a later date without threat of any damage. We agree with Plaintiffs on this matter, and believe that there is no legitimate likelihood of simplifying the issues for trial if a stay is granted.

Finally, we must address the stage of litigation at which the stay was requested. In the present case, discovery has not begun and no trial date, or even scheduling order, has been set. While this factor, therefore, makes it appropriate to grant a stay, we do not think that it independently supports granting a stay.

Conclusion

Although it would be permissible to grant a stay at this stage of the proceedings, given the balancing of the other factors discussed above, we do not believe that it would be appropriate to exercise our discretion to do so at this time. Granting a stay would cause a hardship to Plaintiffs and any hardship caused to Defendants was the foreseeable result of Defendants' choice to file their ANDAs when they did. As granting a stay would also not be likely to simplify the issues for trial, Defendants' request shall be denied. Finally, although the parties extensively briefed the issue of whether this Court has the authority to extend the FDA's 30-month stay, we do not find it necessary to address these arguments as we have decided against staying the present action, and, therefore, there is no reason to extend the FDA's stay.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS, INC. and SCHERING CORP.,	:	
Plaintiffs,	:	CIVIL ACTION
v.	:	NO. 09-cv-105
TEVA PARENTERAL MEDICINES, INC. and TEVA PHARMACEUTICALS USA, INC.,	:	
Defendants.	:	
MILLENNIUM PHARMACEUTICALS, INC. and SCHERING CORP.,	:	
Plaintiffs,	:	CIVIL ACTION
v.	:	NO. 09-cv-204
TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	:	
Defendants.	:	
MILLENNIUM PHARMACEUTICALS, INC. and SCHERING CORP.,	:	
Plaintiffs,	:	CIVIL ACTION
v.	:	NO. 10-cv-137
TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	:	
Defendants.	:	

ORDER

AND NOW, this 13th day of April, 2010, upon consideration

of Defendants' Motion to Stay (Doc. No. 13) and responses thereto, it is hereby ORDERED, for the reasons set forth in the attached Memorandum, that the Motion is DENIED.

BY THE COURT:

s/J. Curtis Joyner
J. Curtis Joyner, J.