IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

ABBOTT LABORATORIES,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Civil Action No. 09 CV 1586
	)	
MATRIX LABORATORIES, INC.	)	Hon. Judge Robert M. Dow, Jr.
MATRIX LABORATORIES, LTD.	)	Hon. Magistrate Judge Jeffrey Cole
MYLAN INC.	)	
	)	
Defendants.	)	

REPLY MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO STAY

I. Introduction

Defendants Matrix Laboratories, Inc., Matrix Laboratories, Ltd., and Mylan Inc. (collectively, "Defendants") submit this reply memorandum in support of their Motion to Stay this action (the "Motion").

As Defendants explained in their Opening Memorandum, a stay of this action until July 2014 is entirely appropriate. It would conserve judicial resources for at least five years, reduce the risk of piecemeal litigation that would arise if, as is likely, other generic drug manufacturers seek to challenge the patents at issue, and achieve these laudable goals without altering Abbott's protections under the Hatch-Waxman Act or causing Abbott to suffer any prejudice.

In its Response, Abbott does not genuinely contest any of these factors that weigh in favor of a stay. Instead, Abbott poses concerns about the Court's authority to issue the requested stay, the likelihood of judicial economies, and possible prejudice or tactical disadvantage arising from a delay.

These concerns are unfounded. As Defendants explain below, the proposed stay is

consistent with both the letter and underlying policies of the Hatch-Waxman Act. Indeed, the leading case that Abbott cites in its Response actually grants the Defendants a stay in circumstances substantially similar to those at issue here. Furthermore, Abbott's concerns that judicial resources may not be conserved by a stay simply fail to recognize the realities of Hatch-Waxman litigation, which typically involves multiple lawsuits that are most efficiently addressed together, rather than in piecemeal fashion. Finally, Abbott's concerns about inadequate protections against potential prejudice or tactical disadvantage hold no water. With the proposed, flexible "good cause" basis to lift the stay, all parties are fully protected if future events arise that militate in favor of recommencing this action sooner than July 2014.

II. Argument

1. *A Stay Is Not Contrary To The Statute*

Although Abbott accurately quotes the Hatch-Waxman Act, which directs the parties to "reasonably cooperate in expediting the action," 21 U.S.C. § 355(j)(5)(B)(iii), it goes too far in arguing that this language precludes entry of the stay that Defendants have requested. To the contrary, this provision of the statute is merely a mechanism to address a situation in which the parties are not moving quickly enough, giving the Court discretion to lengthen or shorten the 30-month period in response. *See* Allan M. Fox & Alan R. Bennett, The Legislative History of the Drug Price competition and Patent Term Restoration Act of 1984 40 (1987).

Abbott has not cited a single case, and Defendants are not aware of any, in which a court has denied a stay as contrary to the Hatch-Waxman Act. Indeed, the leading case Abbott cites in support of its stated concern about the Court's authority to enter a stay -- *Novartis Corp. v. Dr. Reddy's Labs., Ltd.*, No. 04 Civ. 0757, 2004 WL 2368007 (S.D.N.Y. Oct. 21, 2004) -- addressed the same issue presented here and granted a stay. *Novartis* specifically addressed the

"cooperation" clause on which Abbott's argument rests, noting that the party moving for the stay (the ANDA filer, as here) could not feasibly argue that it was in compliance with the "cooperation" clause. *Id*. at *3. As a result, the court followed the mechanism provided in the statute, tolling the 30-month period along with granting a stay. *Id*.

Not only does Defendants' proposal comply with the letter of the Hatch-Waxman Act, it is also consistent with the spirit of the law. A primary goal of the Act is to promote speedy entry of generics into the market. *See* 21 U.S.C. § 355(j). The "cooperation" clause can most reasonably be read as a mechanism intended to serve this purpose. For the drug at issue here, however, Defendants have certified to the FDA that they will not launch a generic version of Kaletra prior to 2016. (Opening Mem. at 4.) Therefore, granting a stay will not slow down the market entry of generic Kaletra and therefore is not, as Abbott argues, inconsistent with the statute.

In addition, Abbot's analysis on the question of the Court's authority fails to address at all the inherent power of the district court to manage its docket. *See* Opening Mem. at 5 (citing cases); *see also Novartis Corp. v. Dr. Reddy's Labs., Ltd.*, No. 04 Civ. 0757, 2004 WL 2368007, at *3 (S.D.N.Y. Oct. 21, 2004). As the *Novartis* court states,

> [T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants. How this can best be done calls for the exercise of judgment, which must weigh competing interests and maintain an even balance.

Id. at *3 (quoting *Landis v. North Am. Co.*, 299 U.S. 248, 254 (1936)). In this case, the Court may properly exercise this inherent power because, as Defendants have demonstrated in their Opening Memorandum, all the relevant factors that courts typically consider weigh in favor of entry of a stay. *See* Opening Mem. at 6-10.

2. *The Stay Will Not Alter Abbott's Protections Under The Statute*

Abbott also argues that there is no precedent addressing how Defendants' proposed stay could affect "the 30-month stay or other rights under the Hatch-Waxman Act," but nevertheless speculates that an administrative stay or closure could be treated as a dismissal, thus extinguishing Abbott's rights under Hatch-Waxman or prompting the FDA to prematurely approve Defendants' ANDA. (Resp. Br. at 5.) This concern is wholly without legal basis. Indeed, as noted in the cases cited by Abbott, a "substantial body of persuasive precedent" has established that "an order merely directing that a case be marked closed constitutes an administrative closing that has no legal consequence other than to remove that case from the district court's active docket."[1] *See Dees v. Billy*, 394 F.3d 1290 (9th Cir. 2005) (citing *Penn West Assocs., Inc. v. Cohen*, 371 F.3d 118, 128 (3d Cir.2004)).

Further, by statutory mandate, the FDA *cannot* finally approve Defendants' ANDA until the end of the automatic 30-month stay (which would be tolled under Defendants' proposal) or until a judgment by this Court that the patents-in-suit are invalid or not infringed. 21 U.S.C. 355(j)(5)(B)(iii). Indeed, Abbott recognizes that the purpose of the 30-month stay is "to protect the NDA holder from the threat that an ANDA filer will begin selling its product before the patentee has a chance to prove in court that the proposed generic product infringes a valid patent." (Resp. Br. at 3.) Since the terms of Defendants' proposed stay plainly meet this statutory purpose, there is no basis for Abbott's suggestion that a stay might alter Abbott's

[1] Abbott cites only one case ostensibly in support of its concern that a stay might be treated as a dismissal. *See SP Techs., LLC v. HTC Corp.*, No. 08 c 3760, 2009 U.S. Dist. LEXIS 38076, at *9-10 (N.D. Ill. May 6, 2009). *SP Technologies*, however, merely shows one possible way to craft an administrative stay, and in fact distinguishes a stay from a dismissal. *See id.* ("[T]he court finds that a stay pending reexamination of the patent would best serve the interests of justice. However, . . . the court will entertain appropriate motions or, on its own, make further ruling if it would best serve the interests of justice, including, as HTC has suggested, dismissing the action with leave to reinstate after the resolution of the patent issue.").

protections under the Act.

3. *A Stay Would Promote Judicial Economy*

Although Abbott argues that Defendants have not identified specifically how a stay would promote judicial economy (Resp. Br. at 6-7), Defendants' Opening Memorandum noted that prescription drug litigation typically involves multiple generic challengers and multiple ANDA filers. (Opening Mem. at 6.) *See* Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study 26 (2002) ("A substantial portion of the total number of ANDAs . . . relate to the same brandname product or NDA."). Abbott does not dispute the likelihood of multiple generic challengers. Indeed, it worries about the possibility of having to bring suit in multiple forums. Although one cannot predict with certainty whether and where these cases may arise, or what issues of infringement and invalidity will arise in them, it is difficult to imagine a scenario in which there would not be significant overlap between any later-filed case and this one. If this case were to proceed now, the Court's holdings and factual finding related to dispositive briefing and trial would not be binding on the later ANDA filers who are not parties in this case. *See, e.g.*, *Universal Guaranty Life Ins. Co. v. Coughlin*, 481 F.3d 458, 462 (7th Cir. 2007) (noting that collateral estoppel requires, among other things, that "the party against whom collateral estoppel is invoked must be fully represented in the prior action"). This Court, or other courts, would have to address those issues for a second time, with a risk of inconsistent rulings and a certainty of wasteful duplication. Staying this action is therefore likely to promote efficient expenditure of judicial resources and justice.

Abbott also argues that the stay would not promote judicial economy because "there is no guarantee that [lawsuits against later ANDA filers] could be properly brought in this jurisdiction." (Resp. Br. at 7.) But if suits by other ANDA filers cannot properly be brought

here, that is all the more reason to stay the case. Co-pending cases in different district courts would be exactly the situation that would constitute a wasteful duplication of judicial efforts. Accordingly, for the benefit of the judicial system as a whole, it makes sense for all the litigations to be addressed (for pretrial purposes at the very least, *see* 28 U.S.C. 1407(a)) in a single forum, and granting a stay in the litigation now is the only realistic way to preserve that option.

A stay also preserves judicial resources and the resources of the parties. Defendants' motion, if granted, would avoid expending judicial resources on this case until a point in time more proximate to the date when Abbott could conceivably suffer any alleged injury from a product launch, and it would also allow the parties to forego the substantial expense and burden of discovery and trial in a complex patent case for the next five years. The parties will be in a better position to evaluate the costs and benefits of this litigation at a time much closer to 2016 when a generic product may launch.

Given the seven-year interval before Defendants can market a generic version of Kaletra®, other intervening events are possible as well. Although one cannot say with certainty what these events might be, it is not difficult to imagine that in seven years there would be an event that could affect the issues in this litigation. This possibility further underscores the prudence of staying this litigation.

4. *Abbott's Concerns About the Adequacy of Protections Against Alleged Prejudice And Tactical Disadvantages Are Unfounded.*

Finally, although Abbott expresses concerns about the adequacy of protections in the proposed stay, it does not actually identify any tactical disadvantage or cognizable prejudice that it would suffer as a result of the stay. For example, Abbott argues that the stay does not protect its interests because the "good cause" necessary to lift the stay is not sufficiently defined. To be

sure, the proposed stay is lengthy and it is not possible to predict all the scenarios that may result in a party wishing to lift the stay, but that is exactly the attraction of the "good cause" standard. It has the benefit of providing flexibility for the Court to deal with unforeseen future events. As courts in this district and other circuits have recognized, "good cause" is well understood to signify a "sound basis or legitimate need to take judicial action." *Hollinger Inter. Inc. v. Hollinger Inc.*, 2005 WL 3177880, at *1 (N.D. Ill. Jan. 19, 2005) (quoting *In re Alexander Grant & Co. Litig.*, 820 F.2d 352, 356 (11th Cir. 1987)). There is no reason to believe this well-established, flexible standard will not serve the Court and parties well in this case.[2]

Abbott also argues that a lengthy stay could create evidentiary problems, but this expressed concern about lost documents or unavailability of witnesses is misplaced. Defendants, and presumably Abbott, have issued litigation hold memos to the relevant employees so that documentary evidence related to this matter should be preserved during the stay. Lost recollection of witnesses is likewise a low risk for Abbott because its burden of proof is limited to infringement, and the question of infringement is governed by the ANDA product likely to be marketed. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). To determine the nature of the product at issue, the parties and the Court will look to the ANDA itself, which describes the product in detail. *See Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248-49 (Fed. Cir. 2000) ("Since the compound for which approval is sought is that which is

[2] As a clarification of Abbott's statement about the date on which Defendants may launch their generic product (Resp. Br. at 7), Defendants reiterate that its current Paragraph III certifications prevent it from launching before 2016. (Opening Mem. at 4-5.) Defendants currently have no plan to convert a Paragraph III to a Paragraph IV certification, and do not anticipate such a conversion, but do not intend to convey to the Court or Abbott that a conversion is impossible in the event it is warranted by any change in circumstance. In that case, however, Abbott would receive notice of the conversion, and Abbott or Defendants could then bring a motion to lift the stay, and the Court would then determine whether that conversion constitutes "good cause."

expected to be marketed, the purpose of the submission of the ANDA is to sell that well-defined compound and the ultimate question of infringement is usually straightforward."). And to the extent that evidence regarding facts and circumstances relating to the production, sale and distribution of the product is necessary, such evidence would most appropriately come from persons employed by Defendants closer in time to the actual product launch.

III. Conclusion

For the reasons set forth above, Defendants respectfully request the Court grant their motion and enter an order staying this action until July 1, 2014, but providing that the stay may be lifted at an earlier date upon a showing of good cause by any party to this action. Further, Defendants request the Court to issue an order tolling the remaining period of the thirty-month automatic stay of FDA approval of ANDA No. 91-202 during the pendency of the Court's stay of these proceedings.

Defendants respectfully suggest that the issues presented by the motion have been amply covered by the parties' briefs and that no oral argument should be necessary to resolve the stay issue.

Dated: June 18, 2009

By: s/ Amethyst C. Smith

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