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.	)	

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO STAY

INTRODUCTION

Defendants Matrix Laboratories, Inc. ("Matrix, Inc."), Matrix Laboratories, Ltd. ("Matrix"), and Mylan Inc. ("Mylan") (collectively, "Defendants") submit this memorandum in support of their Motion to Stay this action (the "Motion"). The Motion seeks entry of an order (i) staying this action until July 1, 2014, (ii) providing that any party may move to lift the stay at an earlier date upon a showing of good cause, and (iii) during the pendency of the Court's stay, tolling the balance of the thirty-month period provided for in 21 U.S.C. § 355(j)(5)(B)(iii) with respect to approval by the U.S. Food and Drug Administration (the "FDA") of ANDA No. 91-202.

As Defendants explain in the Motion and below, they cannot market the lopinavir/ritonavir tablets that are the generic equivalent of Plaintiff's Kaletra® products until December 26, 2016, at the earliest. In other words, the risk for which Plaintiff seeks injunctive relief in this action cannot occur for over seven and a half years. Given the extraordinary length of time before any genuine injury can possibly arise, the stay of proceedings proposed by

Defendants is both appropriate and prudent. It conserves judicial resources by avoiding premature litigation. It reduces the risk of piecemeal litigation that would arise if, as is likely, other generic drug manufacturers seek to challenge the patents at issue. It preserves the Defendants' statutorily conferred right of market exclusivity in the event they succeed in challenging the patents at issue. And it achieves these results without causing Plaintiff to suffer any prejudice because Defendants cannot receive FDA approval to market the lopinavir/ritonavir tablets, either during the pendency of the requested stay or for a period of approximately 30 months thereafter.

BACKGROUND

To encourage the development of generic versions of new drugs, Congress passed the Hatch-Waxman Act, which creates an expedited approval mechanism permitting generic manufacturers to utilize an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j). Generic drug companies submitting an ANDA are not required to conduct their own independent clinical trials to prove safety and efficacy, but can instead rely on the evidence accumulated by the holder of an approved New Drug Application ("NDA") to show that the generic equivalent of the NDA holder's drug product is safe and effective. *See* 21 U.S.C. § 355(j)(2)(A)(iv), (j)(8)(B).

In filing an ANDA, the applicant must make one of four certifications with respect to any patents that the NDA holder has identified as covering its drug product.[1] These certifications are (I) that such patent information has not been filed with the FDA; (II) that such patent has expired; (III) that the patent will expire on a particular date and approval of the ANDA should be deferred until that date; or (IV) that the ANDA applicant believes the patent is invalid or will not

[1] The NDA holder lists these patents in the FDA's publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the "Orange Book."

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 options are respectively referred to as Paragraph I, II, III, and IV certifications.

If the applicant makes a Paragraph III certification with respect to a listed patent, FDA approval of its ANDA cannot become effective until the date that the patent expires. *See* 21 U.S.C. § 355(j)(5)(B)(ii). If an applicant makes a Paragraph IV certification with respect to a listed patent, the certification is considered an "artificial" act of patent infringement that creates a justiciable controversy and thereby enables a court to determine whether the patent at issue is either invalid or not infringed. *See Glaxo, Inc. v. Novopharm Ltd.*, 110 F.3d 1562, 1568-70 (Fed. Cir. 1997).

The ANDA filer must provide notice to the patentee and NDA holder of the factual and legal bases for its Paragraph IV certification. 21 U.S.C. § 355(j)(2)(B). If the patentee brings suit for infringement within 45 days of receipt of a Paragraph IV notice, the FDA is barred from approving the ANDA for 30 months ("the thirty-month automatic stay"), unless there is a determination prior to expiration of that 30-month period that the applicable patent(s) are invalid or not infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

As an incentive for generic pharmaceutical companies to challenge suspect Orange Book-listed patents, the Hatch-Waxman Act grants a 180-day period of marketing exclusivity to the first generic drug company to file a Paragraph IV certification on the particular drug. The exclusivity is enforced by the FDA, which is barred by statute from approving any later-filed ANDA based on the same NDA until the 180 day period of exclusivity has expired. *See* 21 U.S.C. § 355 (j)(5)(B)(iv); *Janssen Pharmaceutica N.V. v. Apotex, In*c., 540 F.3d 1353, 1356 (Fed. Cir. 2008). The 180-day exclusivity period starts to run once the first ANDA filer begins

to market the drug. *See* 21 U.S.C. § 355(j)(5)(B)(iv)(I). However, the Act requires marketing to be commenced within 75 days of a final, non-appealable judgment of patent non-infringement or invalidity. If the first ANDA applicant fails to market the drug within that 75-day window, it forfeits its right to the 180-day period of market exclusivity. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I).

Abbott is the holder of an approved NDA for lopinavir/ritonavir tablets, marketed as Kaletra®, for the treatment of human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS). In connection with filing its NDA, Abbott identified eleven patents purportedly covering Kaletra® that have been listed in the Orange Book. The listed patents included, among others: U.S. Patent No. 6,703,403 (the '403 Patent), which is set to expire on December 26, 2016; U.S. Patent No. 7,148,359 (the '359 Patent), which is set to expire on January 19, 2020; and U.S. Patent No. 7,364,752 (the '752 Patent), which is set to expire on May 10, 2021. *See* Electronic Orange Book Patent and Exclusivity Information, Lopinavir/Ritonavir 200mg/50mg.

On December 23, 2008, Matrix Inc. filed ANDA No. 91-202 seeking FDA approval to market two dosage strengths of generic lopinavir/ritonavir tablets. In connection with filing this ANDA, Matrix Inc. submitted Paragraph III certifications with respect to nine of the patents listed in the Orange Book for Kaletra®, including the '403 Patent, which was the latest of the nine patents to expire. As a result of this Paragraph III certification of the '403 Patent, Defendants cannot obtain final FDA approval to market the generic lopinavir/ritonavir tablets until at least December 26, 2016. *See* 21 U.S.C. § 355(j)(5)(B)(ii).

In filing ANDA No. 91-202, Matrix Inc. also submitted Paragraph IV certifications with respect to the '359 and '752 Patents. On or about January 30, 2009, Abbott received notice of these certifications, which included the factual and legal bases for the Defendants' claims that

the '359 and '752 Patents were invalid, unenforceable, and/or not infringed by the ANDA product. In response, Abbott filed this action on March 13, 2009, asserting infringement of these two patents.

Although the Defendants have appeared and answered the complaint, this action has not yet proceeded to the discovery stage, nor has the Court entered a scheduling order. Instead, at the initial status hearing in this case, the Court set a briefing schedule in order to take up Defendants' Stay Motion.

ARGUMENT

I. The Legal Standards Applicable to the Stay Motion

As this Court has recognized, a district court has the inherent power to manage its docket and to stay proceedings. *Arrivalstar S.S. v. Canadian Nat'l Railway Co.*, 2008 WL 2940807, at *2 (N.D. Ill. July 25, 2008) (granting stay of litigation pending reexamination of patents-in-suit); *see also Panduit Corp. v. Chatsworth Prods., Inc.*, 2005 WL 577099, at *1 (N.D. Ill. March 2, 2005) (granting alternative relief of a stay or dismissal without prejudice pending reexamination of patent-in-suit); *Novartis Corp. v. Dr. Reddy's Labs Ltd.*, 2004 WL 2368007 at *3 (SDNY 2004) (granting stay of patent infringement action pending the FDA's evaluation of defendant's new drug application).

In deciding whether to enter a stay, courts typically consider factors such as (i) whether a stay will simplify issues and promote judicial economy, (ii) whether a stay will reduce the burden of litigation on the parties and the court, and (iii) whether a stay will unduly prejudice or tactically disadvantage the non-moving party. *Arrivalstar*, 2008 WL 2940807 at *2. In this case, Defendants' request for a stay comfortably satisfies all of these considerations because the stay will conserve judicial resources, reduce the likelihood of piecemeal litigation regarding the

validity of the '359 and '752 Patents, avoid potentially unnecessary expense by the parties, cause no prejudice to the Plaintiff's interests, and ameliorate the risk that Defendants will suffer the loss of market exclusivity in the event that they prevail in the litigation before the date when their generic lopinavir/ritonavir tablets may be approved for marketing.

II. All Relevant Factors Favor Entry of a Stay

1. *Entry of a stay will promote judicial economy*

There can be no dispute that judicial economy will be promoted by a stay. As explained above, the earliest date on which FDA approval of ANDA No. 91-202 can become effective is December 26, 2016. There is simply no good reason to compel this Court to expend substantial judicial resources during the next thirty months (*e.g.*, resolving potential discovery disputes, conducting a Markman hearing, conducting a trial, etc.) to address Plaintiff's request for injunctive relief when there is no threat of genuine injury until so far into the future. Indeed, the significant passage of time before the earliest possible date of ANDA approval creates a genuine likelihood that intervening events may occur that could complicate, simplify, or even eliminate issues that the Court ultimately may be asked to decide.

For example, since prescription drugs tend to attract multiple generic challenges, other generic companies can be expected to file their own ANDAs for this drug in the future, precipitating additional lawsuits with the same or similar issues of non-infringement and invalidity. Such common issues would presumably be most efficiently litigated in a streamlined, consolidated action rather than piecemeal litigation before this or other courts. A stay promotes judicial economy because the Court need not commit itself now to piecemeal litigation over the same patents in the event that later generic drug challenges emerge. Rather, a stay now offers the realistic hope of promoting judicial economy by addressing the patents-in-suit only once.

2. *The very early stage of this case supports entry of a stay*

This case was filed approximately two months ago and the parties have not yet commenced discovery. Given the very early stage of the case, there is no issue with respect to a waste of resources or any of the other concerns that might arise if Defendants had requested a stay on the eve of trial. Indeed, courts frequently cite to the early stage of a case as a favorable factor in the decision to grant a stay. *See, e.g.*, *Arrivalstar*, 2008 WL 2940807, at *2; *Panduit*, 2005 WL 577099, at *1; *Aerotel, Ltd. v. IDT Corp*., 2003 WL 23100263, at *2 (S.D.N.Y. Dec. 30, 2003.

3. *The Proposed Stay Will Not Harm Plaintiff*

There is no tactical disadvantage or other harm to Plaintiff from a stay where, as Defendants propose, the stay occurs early in the litigation and is accompanied by tolling the thirty-month automatic stay of FDA approval of Matrix's ANDA until the case is re-opened. Absent FDA approval, Defendants are prohibited from marketing their generic lopinavir/ritonavir tablets, and based on Defendants' Paragraph III certifications, FDA approval cannot happen until December 2016 at the earliest.

This Court has the authority to toll the running of the 30-month automatic stay while the court action is dormant in order to insure Plaintiff is protected from harm. *See, e.g., Novartis v. Dr. Reddy's Labs., Ltd*., 2004 WL 2368007, at *3 (S.D.N.Y. Oct. 21, 2004). In *Novartis*, the court noted that the generic applicant did not object to tolling the thirty-month automatic stay during the pendency of the stay of the court proceedings. Likewise, Defendants here do not object to tolling the automatic stay. Under such circumstances, the court recognized that the tolling of the thirty-month stay was within its authority. *Id*. (citing 21 U.S.C. § 355(c)(3)(C)).

Importantly, the *Novartis* court also pointed out that the tolling of the 30-month stay prevented any economic harm to the patent holder:

> With an extension of the thirty-month period, Novartis will not be disadvantaged by a stay of these proceedings. Novartis argues that there is no evidence concerning when the FDA is likely to take action and that DRL's Paragraph (IV) Certification challenge to [the patent-in-suit] 'casts a cloud over [the] patent that Novartis is anxious to clear.' However, *DRL is prohibited from marketing any product containing amlodipine maleate during the FDA stay, thereby protecting Novartis from suffering economic harm during the pendency of a stay of these proceedings*. Also, it is in DRL's interest to obtain quick approval to market its product. Consequently, there is no justification for requiring the parties to move forward with discovery when the FDA's decision regarding its reevaluation of the drug may moot these proceedings.

Id. (emphasis added).

4. *Entry of a Stay Would Serve the Congressional Intent Underlying the 180-day Exclusivity Period in the Hatch-Waxman Act and Avoid the Prejudice to the Defendants If This Action Were Prematurely Decided in Their Favor.*

Defendants' proposal here is conceptually rooted in *Amgen, Inc. v. Hoechst Marion Roussel, Inc*., 3 F. Supp. 2d 104 (D. Mass. 1998). There, as here, a plaintiff-patentee sought a declaration of patent rights long before the defendants could reasonably expect to receive FDA approval of their product. While concluding that it possessed jurisdiction, because the controversy was sufficiently concrete and timely to be justiciable, the District Court of Massachusetts noted that the early timing of the litigation could interfere with an objective of the Hatch-Waxman Act. While the objective of the Act that was subject to frustration in *Amgen* differs from the present action, the concept of staying an action to avoid such frustration applies here.

In *Amgen*, the statutory purpose subjected to frustration was the freedom from accusations of patent infringement in connection with activities related to obtaining FDA approval, as codified in 35 U.S.C. §271(e)(1). *See* 3 F. Supp. 2d at 112-13. Here the statutory purpose subject to frustration is Congress' intent to encourage early challenges to patents that are unwarranted obstacles to generic competition for prescription drugs. So strong was that purpose

that, as described above, Congress specified that the first generic applicant challenging such patents would be entitled to a period of 180 days as the only generic marketer of the drug:

> [T]he Hatch-Waxman Act struck a careful balance between encouraging the development of new drugs and enabling the marketing of low-cost generic drugs. To this end, Congress decided to give generic pharmaceutical companies a 180-day exclusivity period as an incentive to challenge suspect Orange Book listed patents. The 180-day exclusivity period is important to generic pharmaceutical companies as it promotes patent challenges by enabling a generic company a period to recover its investment in these challenges.

Janssen Pharmaceutica N.V., 540 F.3d at 1361 (citation omitted).

As noted above, however, this exclusivity period can be forfeited if a generic applicant who is successful in the litigation does not bring its product to market within 75 days of the triggering court decision. This forfeiture provision is consistent with Congress' overall objective to bring generics to market as quickly as possible, because forfeiture discourages the first-filed generic from delaying the marketing of its own product, and thereby (because the first-filed applicant has exclusivity rights to market a generic drug for the first 180 days) delaying the entry of any other generic applicant at the same time.

In the present action, absent a stay, Defendants are in a Catch-22 situation in view of the forfeiture provision. If Defendants litigate now and win, their exclusivity will almost inevitably be forfeited because a final court decision would almost certainly occur more than 75 days prior to December 26, 2016. In that event, Defendants would have undertaken the expense of a successful challenge to the patent obstacle to generic entry, but would then compete with generic competitors who (especially if Defendants prevail on the basis that patent claims are invalid) would not have borne the competitive burden of the litigation expense. This is contrary to the Congressional purpose for granting the 180-day period of exclusivity, which is to encourage early challenges to patents by preventing free-riding by later generic applicants. If Defendants

lose, then they would presumably be enjoined under 35 U.S.C. §271(e)(4)(A) and unable to compete with later generic applicants until expiration of the patent(s) they would be found to infringe. In sum, if Defendants win soon, they lose in the marketplace, and if Defendants lose soon they lose in the marketplace. The only way to avoid the Catch-22 is to stay the action.

The underpinnings of Defendants' motion here are thus rooted in the same theoretical framework as *Amgen*, because in both cases a stay protects against the threat to a statutory objective of the Hatch-Waxman Act posed by the timing of the litigation. There, as here, a stay does no harm to the Plaintiff, but does good in terms of furthering a Congressional objective.

III. Conclusion

The Defendants' requested stay protects the interests of the parties and furthers Congress' policy choices with respect to both patentee and generic defendant. The tolling of the remaining balance of the 30-month automatic stay during the pendency of the Court's stay protects Abbott's interests, and allows Abbott to enjoy the exclusion of Defendants from the market for the full period to which it is entitled under the Hatch-Waxman framework. Meanwhile, the stay leaves open the possibility that Defendants may enjoy the benefit of the 180-day exclusivity period, thereby preserving the incentive that Congress intended to give to the first ANDA filer with a Paragraph IV certification.

In addition, a stay furthers the public interest in resolving disputes in a manner that is efficient in its consumption of scarce judicial resources. Granting the stay avoids resolving a dispute now that not only *could* be delayed (because the Paragraph III certifications extend out to the end of 2016), but also *should* be delayed (because it reduces the chances that the Court would be obliged to decide some of the same issues all over again).

Therefore, Defendants respectfully request that the Court 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.

Dated: May 22, 2009

By: s/ Amethyst C. Smith

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