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

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

PLAINTIFF'S RESPONSE TO DEFENDANTS' MOTION TO STAY

I. INTRODUCTION

Defendants Matrix Laboratories, Inc., Matrix Laboratories Ltd., and Mylan Inc. (collectively "Defendants") knowingly provoked this lawsuit by submitting Paragraph IV Certifications to the Federal Food and Drug Administration ("FDA"), challenging two of the patents that cover Abbott's important HIV treatment, Kaletra® tablets. Defendants now seek to stay this litigation for a period of five years, or until one of the parties requests to lift the stay upon a showing of "good cause." While staying this litigation may provide some benefit to both parties, Abbott nevertheless cannot consent to Defendants' motion for a stay for two reasons:

(1) Defendants' request for a five-year stay is contrary to the affirmative, statutory duty mandated by the Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98-417 (Sept. 24, 1984) 98 Stat. 1603 ("Hatch-Waxman Act") to reasonably cooperate to expedite the pending litigation; and

(2) Defendants' proposed stay is not sufficiently tailored to protect against potential prejudice and harm to Abbott.

Because of the significant interests at stake, Abbott Laboratories requests oral argument on Defendants' Motion to Stay.

II. BACKGROUND

Abbott Laboratories ("Abbott"), a pharmaceutical company dedicated to the discovery and development of new drug products, is the holder of an approved New Drug Application ("NDA") for Kaletra® tablets, an innovative drug product containing two antiretroviral drugs used to treat patients suffering from HIV infection. As part of its NDA, Abbott was required to submit the results of clinical trials regarding the safety and efficacy of Kaletra® tablets and to identify all patents that "could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §§ 355(b)(1), 355(c)(2) (2008); *see Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1355 (Fed. Cir. 2008). Accordingly, Abbott listed eleven patents pertaining to Kaletra® tablets and their use, including the patents at issue in this litigation. The FDA publishes the list of patents for each pharmaceutical product in what is known as the "Orange Book."

A. The Hatch-Waxman Act

Under the Hatch-Waxman Act, generic drug companies wishing to develop generic copies of an FDA-approved pharmaceutical product can file an Abbreviated New Drug Application ("ANDA"), which relies upon the research conducted by the innovator pharmaceutical company. *Janssen*, 540 F.3d at 1355-56. An ANDA filer must, for each unexpired Orange Book-listed patent, file a Paragraph III Certification (if it does not challenge the patent's validity or infringement) or a Paragraph IV Certification (if it decides to challenge the patent's validity or assert it does not infringe). 21 U.S.C. § 355(j)(2)(A)(vii); *Janssen*, 540 F.3d at 1356; 21 C.F.R. § 314.94(a)(12). The ANDA applicant can submit a Paragraph IV Certification when it originally files its ANDA, or it can opt to file a Paragraph III Certification initially, and later amend its ANDA to convert to a Paragraph IV Certification. 21 C.F.R. § 314.94(a)(12)(viii)(A).

The Hatch-Waxman Act provides that the patent owner cannot bring suit for patent infringement against ANDA filers that do not submit Paragraph IV Certifications. *See* 35 U.S.C. § 271(e)(1). The act of filing the Paragraph IV Certification, however, is an act of infringement under 35 U.S.C. § 271(e)(2)(A). *Janssen*, 540 F.3d at 1356. Thus, a generic company that prepares and files an ANDA that does not contain a Paragraph IV Certification does not risk being sued for patent infringement under 35 U.S.C. § 271(e); it is only the submission of a Paragraph IV Certification that provides subject matter jurisdiction under the Hatch-Waxman Act.

The ANDA applicant must provide notice of the Paragraph IV Certification to the NDA holder and the patent owner. 21 U.S.C. § 355(j)(2)(B); *Janssen*, 540 F.3d at 1356; 21 C.F.R. § 314.95. If the NDA holder/patent owner brings suit within 45 days of receipt of such notice, the FDA may not approve the ANDA for 30 months or the date of a court decision holding the patents at issue not infringed or invalid (whichever is sooner). 21 U.S.C. § 355(j)(5)(B)(iii); *Janssen*, 540 F.3d at 1356. The purpose of this 30-month stay is to protect the NDA holder from the threat that the 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.

To ensure that both the ANDA filer and the NDA holder work diligently toward a resolution of the case on its merits, Congress imposed an affirmative duty on both parties to "reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3)(i)(A). If either party fails to do so, the 30-month stay could be extended or shortened accordingly, and FDA approval may be granted sooner or later than would otherwise be possible. 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3)(i)(A).

B. Defendants Controlled the Timing of This Lawsuit

The Defendants chose when to submit their Paragraph IV Certifications and

which of the eleven Orange Book-listed patents pertaining to Kaletra® tablets they would challenge. Defendants were well aware of the Hatch-Waxman Act provisions governing lawsuits brought under 35 U.S.C. § 271(e)(2), and therefore knowingly controlled the timing of this lawsuit when they submitted and notified Abbott of their Paragraph IV Certifications.

Prior to these acts, Abbott had neither incentive nor any statutory basis to bring suit against the Defendants based on the filing of their ANDA for generic Kaletra® tablets. *See* 35 U.S.C. § 271(e)(1). Had Defendants waited five years to submit their Paragraph IV Certifications, Abbott would not have suffered any harm. When viewed from this perspective, Abbott has no objection, in theory, to a five year hiatus from litigating the two patents in suit, provided Abbott would not be prejudiced or otherwise harmed by Defendants' strategy of filing the Paragraph IV Certifications prematurely. Indeed, such a hiatus may confer tangible benefits to both parties, including avoiding the cost and burden of litigation at this time. But Defendants' request for a stay runs contrary to the letter and intent of the Hatch-Waxman Act and, as currently formulated, does not provide Abbott with sufficient protection against potential prejudice and tactical disadvantage. For these reasons, as explained in more detail below, Abbott cannot join Defendants' motion to stay.

III. ARGUMENT

A. A Five Year Stay Is Inconsistent With the Statutory Duty To Expedite the Action.

The Hatch-Waxman Act imposes an affirmative duty to "reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3)(i)(A). Abbott's consent to Defendants' proposed stay would not constitute "reasonably cooperat[ing] in expediting the action." *See Novartis Corp. v. Dr. Reddy's Labs., Ltd.*, No. 04 Civ.0757, 2004 WL 2368007, at *3 (S.D.N.Y. Oct. 21, 2004) (A party "cannot feasibly argue that it is

reasonably cooperating in expediting the action when it has asked the court to stay the proceedings."). Indeed, Defendants' request to stay the litigation amounts to a *failure* to cooperate to expedite. Under these circumstances, the Hatch-Waxman Act authorizes the Court to extend, or toll, the 30-month stay. *Id.*; *see also* 21 U.S.C. § 355(j)(5)(B)(iii); *Eli Lilly and Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1350 (Fed. Cir. 2009); 21 C.F.R. § 314.107(b)(3)(i)(A). Defendants apparently acknowledge and accept this consequence of their request to stay the case, voluntarily proposing a tolling of the 30-month stay. [Defendant's Memorandum in Support of Defendants' Motion to Stay ("Deft. Mem.") at 1, 7]. However, Defendants' offer to toll the 30-month stay does not absolve Abbott's statutory duty to expedite.

B. There is No Clear Precedent For a Five-Year Stay Under the Present Circumstances.

Defendants claim their proposal for a five-year stay is "conceptually rooted" in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104 (D. Mass. 1998) [Deft. Mem. at 8], notwithstanding the fact that *Amgen* did not involve the 180-day exclusivity period or 30-month stay Hatch Waxman Act provisions. Defendants also rely on *Novartis v. Dr. Reddy's Labs., Ltd.*, 2004 WL 2368007, at *3 (S.D.N.Y. Oct. 21, 2004) to support their motion to stay. [Deft. Mem. at 7-8]. But *Amgen, Novartis* and the other cases Defendants rely on are not directly on point, and it is not clear how those case holdings should be applied in the context of the stay requested in this case, which is based merely on Defendants' Paragraph IV Certification filing strategy.

Indeed, to Abbott's knowledge, neither the Federal Circuit nor the FDA has addressed whether or how such a lengthy "administrative stay" could affect the 30-month stay or other rights under the Hatch-Waxman Act. Dismissal could extinguish Abbott's rights under the

Hatch-Waxman Act; it is not clear what effect administrative closure would have.[1] Some Circuits have acknowledged there are significant differences between an "administrative stay/closure" and a dismissal in other contexts. *See Dees v. Billy*, 394 F.3d 1290, 1293-94 (9th Cir. 2005); *Penn-America Ins. Co. v. Mapp,* 521 F.3d 290, 295-96 (4th Cir. 2008). However, since the issue has not been addressed directly by the Federal Circuit or this Court in the context of a Hatch-Waxman Act litigation, Abbott is justifiably cautious about any action that could potentially cause the FDA to prematurely approve an ANDA before Abbott has the opportunity to litigate the infringement and validity of U.S. Patent Nos. 7,148,359 and 7,364,752 ("the '359 and '752 patents").

C. Defendants Have Not Shown That the Proposed Stay Would Promote Judicial Economy or Simplify Issues For Trial.

Defendants argue that a stay would promote judicial economy "by avoiding premature litigation," and simplify issues for trial by allowing this Court to "address[] the patents-in-suit only once" and reduce the risk of "piecemeal litigation" regarding the validity of the '359 and '752 patents. [Deft. Mem. at 2, 6]. But Defendants do not explain what infringement or validity issues this Court would need to decide more than once or why "the Court would be obliged to decide some of the same issues all over again" if the litigation proceeds. [*See* Deft. Mem. at 6, 10]. To the extent Defendants might be referring to additional

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1 *See, e.g.*, *Stampley v. LVNV Funding, LLC*, 583 F. Supp. 2d 960, 966 (N.D. Ill. 2008) (administratively closing a non-patent case pending appeal in another matter, "with full leave to reinstate," and stating "[a] stay has multiple advantages over a dismissal, including allowing the federal court to retain jurisdiction…[and] protecting the plaintiff from any statute of limitations problems…"); *but 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) (granting stay pending reexamination in a non-ANDA case, but expressly maintaining its prerogative to end the stay and dismiss the case *sua sponte* if doing so would "best serve the interests of justice, including…dismissing the action with leave to reinstate after the resolution of the patent issue.").

ANDA filers that opt to file Paragraph IV Certifications regarding the '359 and/or '752 patents and thus provoke additional lawsuits, there is no guarantee that such lawsuits could be properly brought in this jurisdiction. At best, this scenario is speculative.

In addition, Defendants contend there is "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." [Deft. Mem. at 6]. However, Defendants fail to identify any such potential "intervening events" that could have that effect. Thus, Defendants have not shown that a five-year stay would realistically promote judicial economy or simplify any issues in this particular case.

D. Defendants' Proposal Does Not Adequately Protect Abbott Against Prejudice or Tactical Disadvantage.

Defendants propose tolling the 30-month statutory stay in order to give Abbott sufficient time to litigate this case free from the threat that Defendants will launch their proposed generic Kaletra® tablets. However, tolling the 30-month stay does not alleviate Abbott's valid concerns regarding the stay's possible negative impact on Abbott's interests.

First, little value can be placed on Defendants' "reassurances" that this stay conveniently postpones litigating this action until December 2016, because Defendants may lift the stay at any time for "good cause." [*See* Deft. Mem. at 1, 11]. Despite the significance of a "good cause" event, Defendants completely fail to articulate what types of events Defendants consider "good cause" to resume the litigation. Defendants have unequivocally assured this Court that it will not market its proposed generic tablets before December 26, 2016, which means it will not convert any of its nine Paragraph III Certifications to Paragraph IV Certifications. [*See* Deft. Mem. at 1, 4, 7, 10; 5/14/2009 Status Hearing Transcript at 8, 9]. However, Defendants also admit that it is "likely" and "expected" that another ANDA filer will

submit a Paragraph IV Certification before 2014. Defendants do not indicate whether such an event would be considered "good cause" sufficient to lift the stay. Nor do they identify any other event that would constitute "good cause," or the standard that would govern whether the stay should be lifted.

Second, courts recognize that a lengthy or indeterminate stay creates evidentiary problems. *See, e.g., Clinton v. Jones*, 520 U.S. 681, 707-08 (1997) (a stay "increase[s] the danger of prejudice resulting from the loss of evidence, including the inability of witnesses to recall specific facts"). Defendants' stay proposal contains no provisions for what categories of evidence/documents the parties would need to retain for the next five years, as initial disclosures have not been exchanged and fact discovery has not begun in this case. In addition, there is no guarantee that Defendants' employees, including employees of Matrix Laboratories, Ltd. who reside in India and have relevant information regarding Defendants' proposed products, will remain employed by Defendants over the next five to seven years during which this case remains pending. This could make potential witnesses (and their documents) much more difficult to locate and/or depose, and could potentially deprive Abbott of important evidence.

For at least these reasons, a five-year stay could create problems for Abbott. Yet Defendants' proposed stay, as outlined in its Memorandum and Proposed Order, addresses none of these types of problems. As such, it is not sufficiently tailored to adequately protect Abbott's interests.

IV. CONCLUSION

Abbott cannot consent to Defendants' proposed five-year stay because the proposed stay does not provide sufficient protection of Abbott's interests, as explained above. Given the novel character of Defendants' proposed stay and the complex issues it implicates,

Abbott respectfully requests oral argument on this motion, to assist the Court in rendering its decision.

DATE: June 12, 2009.

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CERTIFICATE OF SERVICE

I, Elizabeth S. Elmore, hereby certify that on June 12, 2009, Plaintiff's Response to Defendants' Motion to Stay was filed electronically with the Clerk of the Court using CM/ECF which will send notification to the following registered attorney(s) of record that the document has been filed and is available for viewing and downloading:

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