

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

ABBOTT LABORATORIES)	
)	
Plaintiff,)	Case No.: 09-cv-1586
)	
v.)	Judge Robert M. Dow, Jr.
)	
MATRIX LABORATORIES, INC.,)	
MATRIX LABORATORIES, LTD., and)	
MYLAN, INC.)	
)	
Defendants.)	

MEMORANDUM OPINION AND ORDER

Plaintiff, Abbott Laboratories (“Abbott”), filed this lawsuit on March 13, 2009. The case is based on the Hatch-Waxman amendments to the Food, Drug, and Cosmetic Act. Abbott’s complaint [1] alleges that Defendants infringed two of Abbott’s patents when Defendants filed an Abbreviated New Drug Application (“ANDA”) with the Food and Drug Administration (“FDA”). Defendants’ ANDA included certifications asserting that two of Abbott’s patents are invalid. Those certifications constitute acts of infringement under the Patent Act.

Before the Court is Defendants’ motion to stay [39]. In that motion, Defendants ask the Court to: (i) stay this action for five years, (ii) toll the running of the 30-month limitations in 21 U.S.C. § 355(j)(5)(B)(iii), and (iii) provide that the stay be lifted upon a showing of good cause. As the parties have recognized [see 44], Defendants essentially request an “administrative stay.” In addition to citing concerns about the premature use of judicial resources, Defendants argue in their memorandum of law [41] that without a stay they could lose out on Hatch-Waxman’s 180-day market exclusivity period, which Congress included to provide an incentive to challenge suspect patents. Moreover, because of another aspect of their ANDA application, the earliest

that Defendants could market their generic drug is 2016. In its response [45], Abbott argues that the harms that Defendants foresee are speculative and that delaying the action may make it more difficult to litigate the disputed patents' validity in the future.

For the reasons set forth below, Defendants' stay motion [39] is granted. The action is stayed until July 1, 2014; the limitations period under 21 U.S.C. § 355(j)(5)(B)(iii) will be tolled during the pendency of the stay; and the stay may be lifted or modified at any time, upon a showing of good cause.

I. Background on the FDCA and the Hatch-Waxman Act

Protecting the public health was Congress's "overriding purpose" in enacting the Food, Drug, and Cosmetic Act (21 U.S.C. § 301 *et seq.*) (the "FDCA"). *United States v. An Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 798 (1969). Before a new drug can be introduced into interstate commerce, a person must gain the approval of the Secretary of Health and Human Services. 21 U.S.C. § 355(a). To gain the Secretary's approval, a New Drug Application ("NDA") must include safety and efficacy studies. 21 U.S.C. § 355(b)(1). The Hatch-Waxman Act can speed up the process because it permits a generic manufacturer in certain circumstances to use a pioneer drug manufacturer's safety and efficacy studies as part of an Abbreviated New Drug Application ("ANDA"), rather than requiring the generic manufacturer to submit an NDA.

As part of the statutory scheme, Hatch-Waxman requires a pioneer drug manufacturer to notify the FDA of all patents that claim an NDA drug. 21 U.S.C. §§ 355(b)(1) & (c)(2). The FDA lists these patents in its "Orange Book." *Eli Lilly & Co. v. Teva Pharm.*, 557 F.3d 1346, 1348 (Fed. Cir. 2009). When a generic manufacturer files an ANDA, it must make one of four certifications with respect to the pertinent patents: "(I) that such patent information has not been filed, (II) that such patent has expired, (III) [a certification] of the date on which such patent will

expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of [the generic drug].” 21 U.S.C. § 355(j)(2)(A)(vii) (providing that the certifications must be made “in the opinion of the applicant and to the best of his knowledge[] with respect to each patent which claims the listed drug”).

The only two types of certifications that are at issue here are Paragraph III certifications and Paragraph IV certifications. If an ANDA filer makes a Paragraph III certification, the earliest that the ANDA application can be approved is the date on which the Paragraph III patent expires. 21 U.S.C. § 355(j)(5)(B)(ii). If an ANDA filer makes a Paragraph IV certification, it is deemed to have engaged in an act of patent infringement. 35 U.S.C. § 271(e)(2). However, if the patent holder does not bring suit for patent infringement within 45 days, then the ANDA approval is effective immediately (unless, as is the case here, there also are Paragraph III certifications whose dates have not yet been reached). See 21 U.S.C. §§ 355(j)(5)(B), (j)(5)(B)(iii). If an ANDA filer makes a Paragraph IV certification and the patent holder does bring suit for infringement, then the ANDA generally will not be approved for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii).

II. Legal Standard on a Motion to Stay

District courts have the inherent power to manage their dockets, including the authority to stay proceedings. “[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.” See, e.g., *Tex. Independent Producers & Royalty Owners Ass’n v. EPA*, 410 F.3d 964, 980 (7th Cir. 2004) (quoting *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936)). Courts often consider the following factors when deciding whether to stay an action: (i) whether a stay will unduly prejudice or tactically disadvantage the non-moving party,

(ii) whether a stay will simplify the issues in question and streamline the trial, and (iii) whether a stay will reduce the burden of litigation on the parties and on the court. *Tap Pharm. Prods., Inc. v. Atrix Labs., Inc.*, 2004 WL 422697, at *1 (N.D. Ill. Mar. 3, 2004). “[I]f there is even a fair possibility that the stay * * * will work damage to some one else,” the party seeking the stay “must make out a clear case of hardship or inequity in being required to go forward.” *Landis*, 299 U.S. at 255. The interest of all parties must be weighed, and the decision to stay an action is not made lightly. *Home Ins. Co. v. Coastal Lumber Co.*, 575 F.Supp. 1081, 1083 (N.D. Ga. 1983). The nature of the inquiry dictates that, although factors are useful, mechanical application of factors is not. *Cf. Landis*, 299 U.S. at 255 (rejecting one “formula” as “too mechanical and narrow”).

III. Analysis

A. Undue Prejudice or Tactical Disadvantage

Consideration of the appropriate factors weighs in favor of issuing a stay in this case. First, there is no evidence that delaying the litigation will unduly prejudice or tactically disadvantage Abbott. Under Hatch-Waxman, initiating a patent suit generally bars approval of an ANDA application for 30 months. 21 U.S.C. § 355(j)(5)(B)(iii). In other words, by filing a patent lawsuit, the pioneer drug manufacturer can maintain its hold over the market for the pioneer drug. Therefore, Abbott *could* suffer prejudice if any motion for a stay were not accompanied by an order tolling the 30-month limitations period. But for tolling, the 30-month period could run during the pendency of the stay. However, Defendants’ motion to stay the action has been accompanied by a request that the Court toll the limitations period.

Abbot suggests that Defendants’ stay request is contrary to the duty imposed by the Hatch-Waxman Act “to reasonably cooperate in expediting” the pending litigation. See 21

U.S.C. § 355(j)(5)(B)(iii). To be sure, as another court has observed, Defendants “cannot feasibly argue that [they are] reasonably cooperating in expediting the action when [they have] asked the court to stay the proceedings.” *Novartis Corp. v. Dr. Reddy’s Labs., Ltd.*, 2004 WL 2368007, at *3 (S.D.N.Y. Oct. 21, 2004). However, as the *Novartis* Court recognized, Hatch-Waxman provides a remedy: in its discretion the Court may extend the thirty-month period or, as in *Novartis*, toll that period during the stay. *Id.* at *3-4; *cf. Andrx Pharm., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1374-74 (Fed. Cir. 2002) (holding that the district court erred in adjusting the thirty-month period set forth in Section 355(j)(5)(B)(iii) on the basis of allegedly infringing conduct before the FDA and explaining that the statutory authority to shorten or lengthen the thirty-month period “is addressed only to delay related to the particular infringement action”). In short, the Court concludes that the combination of its inherent authority to exercise control over cases pending on its docket and the statutory authority to adjust the thirty-month period to take into account the particular circumstances of “the particular infringement action” – here, that Defendants have recognized that they may not launch their generic products until at least 2016 – weigh in favor of entering a stay.

Abbott also raises a concern about the effect that an administrative stay and the transfer of this matter to the Court’s suspense calendar may have on the parties’ rights under Hatch-Waxman. The Court appreciates Abbott’s concern, but is persuaded that the concern is adequately addressed by the “substantial body of persuasive precedent” establishing 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.” *Dees v. Billy*, 394 F.3d 1290, 1294 (9th Cir. 2005); *Penn West Assocs., Inc. v. Cohen*, 371 F.3d 118, 128 (3d Cir. 2004). As the courts have explained, there is no material difference between a

“simple stay” and an “administrative closure.” *Dees*, 394 F.3d at 1294 (citing *Mire v. Full Spectrum Lending, Inc.*, 389 F.3d 163, 167 (5th Cir. 2004)). An administrative closure is simply a “case management tool” (*Dees*, 394 F.3d at 1294) that various courts of appeals have endorsed “in circumstances in which a case, though not dead, is likely to remain moribund for an appreciable period of time,” subject to being reopened at the request of any party or on the Court’s own motion. *Penn West*, 371 F.3d at 127. The bottom line in all of these cases is that an administrative closing “has no legal consequence other than to remove that case from the district court’s active docket.” *Id.* at 128. Although it appears that Abbott is correct that the Seventh Circuit has not weighed in specifically on this subject, the “substantial body of persuasive precedent” identified by the other circuits is so uniform that the Court is confident that our court of appeals would view the issue in the same way as its sister circuits. Accordingly, consistent with the principles articulated above, the stay entered in this case and the transfer of the case to the Court’s suspense calendar is not intended to have any effect on any party’s procedural or substantive rights, including Abbott’s rights under the Hatch-Waxman Act. See *Novartis*, 2004 WL 2368007, at *4 (issuing stay of proceedings in similar circumstances and directing the clerk of the court to “transfer the action to the suspense docket pending further order of the Court.”).

Finally, 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. *Clinton v. Jones*, 520 U.S. 681, 707-08 (1997) (concluding that the district court should not have issued a stay where the movant had failed to demonstrate that it would be “hamper[ed]” without a stay). And although Defendants bear the burden of establishing that a stay is warranted (*id.*), Abbott refutes Defendants’ arguments only with the general concern that litigating the case in the future may

prove difficult. Moreover, its response acknowledges that the problem is not insoluble: rather, Abbott complains that the order “is not sufficiently tailored” to address its concerns. While Abbott has not offered specific language to address its general concerns, the proviso that the stay order can be modified or lifted at any time upon a showing of good cause offers an avenue for specific, and even targeted, relief should concrete evidentiary problems arise.¹

B. Simplification of Issues

The second factor that courts commonly consider as part of the stay inquiry is whether a stay would simplify the issues and streamline the trial. This factor provides only weak support for a stay. Defendants contend that “intervening events” could simplify trial and eliminate issues; and failing to issue a stay may force the Court to decide the same issue multiple times because “prescription drugs tend to attract multiple generic challenges.” [41, at 6]. Abbott’s response, however, correctly notes that Defendants have failed to explain what these intervening events might be and how issuing a stay would protect the Court from deciding the same issue multiple times. [45, at 6-7]. In the event that multiple actions are filed, it may be appropriate to transfer such actions to this Court or it may be appropriate to stay the subsequent actions. *GE Business Fin. Svcs. Inc. v. Spratt*, 2009 WL 1064608, at *2 n.1 (N.D. Ill. Apr. 20, 2009) (“[D]istrict courts normally stay or transfer a federal suit for reasons of wise judicial administration whenever it is duplicative of a parallel action already pending in another federal

¹ Defendants, too, raise an argument about the purposes of Hatch-Waxman. Specifically, they argue that the Act’s purpose of spurring generics through a 180-day exclusivity period could be frustrated without a stay. The Court’s decision to grant a stay rests on traditional factors such as docket control and the efficient use of the Court’s and the parties’ resources. Legislation serves many purposes, particularly when as here the legislation was part of a carefully crafted, comprehensive scheme. Although “a thing may be within the letter of the statute and yet not * * * within its spirit” (*Church of the Holy Trinity v. United States*, 143 U.S. 457, 459 (1892)) that conclusion should not be reached lightly. Cf. *Jaskolski v. Daniels*, 427 F.3d 456, 462 (7th Cir. 2005) (suggesting that *Holy Trinity* “has no modern traction”). The Court is not prepared, on the record and briefing before it, to conclude that one among many purposes furnishes the authority to avoid an implication that arises as a result of the language that Congress chose to enact. Nor is it self-evident that such an outcome would frustrate Congress’s intent.

court.”). In fact, the federal courts have various mechanisms for coordination and/or consolidation of cases for pre-trial or for all purposes. Yet, the appropriateness of granting a stay in a future, yet-to-be-filed case does not support the argument that a stay is appropriate now, in *this* case. Thus, the Court agrees that this factor does not weigh heavily in favor of granting a stay in this case.

C. Burdens of Litigation on the Parties and the Court

The third factor, whether a stay might reduce the burdens of litigation on the parties and on the court, weighs more decidedly in favor of a stay. Abbott acknowledges that “staying this litigation may provide some benefit to both parties.” [45, at 1]. Moreover, the case is at an early stage – no discovery has taken place, and the only issue in the case thus far has been whether a stay is appropriate. In short, no party will have wasted resources if a stay is entered. See *Arrivalstar S.S. v. Canadian Nat’l Ry. Co.*, 2008 WL 2940807, at *2 (N.D. Ill. July 25, 2008) (collecting cases in which the early phase of litigation weighed in favor of issuing a stay). Again, and despite conceding that staying the action may benefit both parties, Abbott argues only in general terms that it could be harder to litigate this case in the future. However, as discussed above, it also implicitly acknowledges that a more narrowly tailored stay – one that addressed its concerns about discovery in the future – would address its concerns. Were Plaintiff to identify specific concerns and explain how they could be addressed, it might furnish the Court with good cause to lift or modify the order staying the action.

* * * *

In sum, the Court concludes that Abbott’s interests will not be harmed by issuing a stay because the Court also orders the tolling of the limitations period in 21 U.S.C. § 355(j)(5)(B)(iii). Although it is questionable whether a delay will simplify any subsequent trial, weak support for a

single factor is not dispositive. And no speculation is required to support the conclusion that granting a stay will preserve the Court's resources, and Abbott acknowledges that a stay may preserve the parties' resources as well. On balance, then, the pertinent factors favor a stay.

IV. Conclusion

For the reasons set forth above, Defendants' motion to stay the action until July 1, 2014 [39] is granted. The limitations period under 21 U.S.C. § 355(j)(5)(B)(iii) will be tolled during the pendency of the stay. The stay may be lifted or modified upon a showing of good cause.



Dated: November 5, 2009

Robert M. Dow, Jr.
United States District Judge