UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, et al.,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	**Cause No. 1:16-cv-1512-WTL-DML**
	)	
APOTEX INC., et al.,	)	
	)	
Defendants.	)	

ENTRY ON MOTION TO STAY

This cause is before the Court on the Plaintiffs' Motion to Stay or Administratively Close Case Pending Resolution of Related Case on Appeal (Dkt. No. 37). The motion is fully briefed, and the Court, being duly advised, **GRANTS** the motion to the extent and for the reasons set forth below. The Court also **GRANTS** the Defendants' related motion for leave to file a surreply (Dkt. No. 66), and the Clerk is directed to docket the surreply, which is found at Dkt. No. 66-1. The Court has considered the surreply in making this ruling.

Plaintiff Eli Lilly and Company ("Lilly") is the holder of a New Drug Application for the manufacture and sale of a testosterone metered transdermal solution that it markets and sells under the trade name Axiron. This case arises out of an Abbreviated New Drug Application ("ANDA") filed by the Defendants seeking approval to market a generic version of the drug Axiron before the patents related to the drug expire. The Defendants' ANDA contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications") alleging that the claims of the patents are invalid, unenforceable, and/or would not be infringed by the generic drug for which the Defendants seek approval. The Plaintiffs have filed the instant action asserting various claims of patent infringement as to seven of the patents related to Axiron

(hereinafter referred to collectively as "the Patents"). The Patents are owned by Plaintiff Acrux DDS PTY Ltd.; Plaintiff Eli Lilly Export S.A. is the exclusive licensee of the Patents and has licensed its rights to Lilly.

As the title of the Plaintiffs' motion suggests, the Plaintiffs seek a stay of this case pending the Federal Circuit's ruling in a related case, *Eli Lilly and Company, et al. v. Perrigo Company, et al.*, Cause No. 1:13-cv-851-SEB-DKL (S.D. Ind.) (hereinafter referred to as "*Perrigo*"). *Perrigo* involved the filing of ANDAs relating to Axiron by four groups of defendants; the Plaintiffs alleged that those ANDAs infringed upon nine patents, including five of the seven patents at issue in this case.[1] After a trial, judgment was issued in *Perrigo* finding, *inter alia*, one claim in one of the Patents in this case ("the '944 Patent")[2] invalid and finding two claims in another of the Patents in this case ("the '861 Patent")[3] valid. The *Perrigo* court further found that those claims in the '861 Patent were infringed by the "spreading implement," or applicator, proposed to be used by one of the defendant groups in that case, but were not infringed by the applicators proposed by the other three.

The judgment in *Perrigo* was immediately appealed to the Federal Circuit. That appeal remains pending; the parties believe that a ruling is likely by the end of this calendar year.

The Plaintiffs argue in the instant motion that this case should be stayed in its entirety pending the Federal Circuit's ruling in *Perrigo*. Indeed, the parties jointly moved and received several extensions of the deadline for filing a case management plan in this case, representing

[1]The two remaining patents at issue in this case are continuations of patents that were at issue in *Perrigo*.

[2]The invention claimed in the '944 Patent "is directed to a transdermal drug delivery composition" and "extends to methods of administering such a composition to a subject and treatment of subjects using the composition." Dkt. No. 1-3 at 2.

[3]The invention claimed in the '861 Patent is a spreading implement that can be used for the transdermal delivery of solutions.

that the parties were contemplating an agreement to stay this action pending the *Perrigo* appeal in order to "streamline and expedite the resolution of disputed issues and to conserve party and judicial resources." Dkt. No. 37 at 4 (citing to various joint motions). Upon further contemplation, the Defendants decided that they would not agree to a complete stay of this case. Rather, the Defendants argue that discovery and motion practice should proceed as to the issue of whether their applicator infringes the four spreading implement patents at issue in this case (the '861 Patent and U.S. Patent Nos. 8,419,307; 8,177,449; and 9,289,586).

The Defendants correctly set forth the following relevant factors to be considered when deciding whether to enter a stay: whether the stay will unduly prejudice or tactically disadvantage the non-moving party; whether the stay will simplify the issues in question and streamline the trial; and whether the stay will reduce the burden of litigation on the parties and on the court. Dkt. No. 44 at 3-4 (citations omitted). As there is no question that the ruling by the Federal Circuit has the potential to streamline the issues to be resolved in this case, the task before the Court in considering the stay proposed by the Plaintiffs is to balance the potential judicial economy to be achieved by the stay (including both judicial resources and those of the parties) against the potential prejudice to the Defendants from any delay in the ultimate resolution of this case that a stay would cause.

The Defendants argue that they will suffer "extreme" prejudice in the form of irreparable loss of market share if they are unable to launch their generic Axiron at the same time as two of the *Perrigo* Defendants, which they believe will occur in August 2017. This belief is based upon the Defendants' "determin[ation] that Actavis' statutory 180-day exclusivity launch date begins in February 2017." Dkt. No. 44 at 3-4. In other words, the Defendants believe that Actavis (one of the *Perrigo* defendant groups) will launch its generic Axiron product this month, which they

believe will permit the two other defendant groups that were found non-infringing by the *Perrigo* court to launch their products 180 days later, in August 2017. The Defendants fail to explain what this belief is based on, and the Court lacks the necessary facts to assess its accuracy.

Even assuming that the Defendants' prediction is correct, however, any harm suffered by the Defendants entering the market later than its competitors would not be caused by the entry of a stay in this case. Rather, it would be caused by the fact that the Defendants filed their ANDA later than the *Perrigo* defendants filed theirs. It hardly seems inequitable that companies that filed ANDAs significantly earlier than the Defendants[4] would enter the market sooner.

Further, in order to accomplish their goal of entering the market by August 2017, the Defendants are not simply opposing a complete stay of this case, but are also seeking to expedite its resolution, proposing an extremely compressed discovery schedule and expedited briefing and consideration of dispositive motions. The Defendants' suggestion that the Plaintiffs and the Court should be required to expedite this case to such an extreme extent simply to enable the Defendants to enter the market at the same time as its competitors who initiated the ANDA process well before they did is not well-taken.[5]

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[4]The Defendants' notice letter to the Plaintiffs was dated May 12, 2016. The defendants whose applicators were found non-infringing by the *Perrigo* court sent notice letters dated September 2012, October 2013, and May 2015. The defendant who was found to infringe by the *Perrigo* court sent a notice letter dated October 2014.

[5]The Defendants also state that "[m]ost importantly, however, the grant of a stay against [them] would result in a drug product that is both less affordable and accessible to the public." Dkt. No. 44 at 6. Obviously there is a strong public interest in facilitating the availability of non-infringing generic drugs in the market. *See, e.g.*, *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) ("A central purpose of the Hatch-Waxman Act and the subsequent ANDA declaratory judgment amendment to that Act is 'to enable competitors to bring cheaper, generic . . . drugs to market as quickly as possible.'") (quoting 149 Cong. Rec. S15885 (Nov. 25. 2003)). This public interest is less compelling here, however, in light of the fact that under the scenario proposed by the Defendants, their product likely would be one of four generic versions of Axiron to enter the market in 2017.

That said, if, as the Defendants argue, this case reasonably can be resolved "within the next two to eight months" via dispositive motions, Dkt. No. 44 at 9, then it would seem that the prejudice to the Defendants that would be engendered by a stay could be considerable. (Of course, if the Defendants are ultimately unsuccessful and at least one of the Patents is found to be valid and infringed, then the Defendants would have suffered no prejudice at all.) However, the Defendants have failed to demonstrate that their goal of resolving this case quickly enough for them to enter the market in August 2017 (assuming, of course, that they prevail in this case) is feasible.

In fact, the Defendants are somewhat vague about their plan for resolving this case on such an expedited schedule. Their plan hinges on their assertion that "under the law, [they have] the right to seek dispositive relief on an expedited basis as a result of the *Perrigo* Court's findings." Dkt. 66-1 (citing *Galderma Labs., Inc. v. Ammeal Pharm., LLC*, 921 F. Supp. 2d 278, 282 (D. Del. 2012)). Dkt. No. 66-1 at 5. *Galderma* is not binding on this Court, of course,[6] and even if it were, neither *Galderma* nor the cases cited therein stand for the proposition that the Defendants are entitled to have their dispositive motions considered on such an expedited schedule.

Galderma was the second patent infringement case brought by the plaintiff relating to ANDAs filed by generic drug companies seeking to manufacture a "generic product containing 40 mg doxycycline administered once daily." The first action (the "Mylan action") ended in a

[6]The Court notes that the Defendants' actual citation is "*see, e.g. [Perrigo],*" both in this instance and in their initial response brief, suggesting that there are multiple authorities that support their argument. The Defendants do not identify any such authorities, however, and "[i]t is not this court's responsibility to research and construct the parties' arguments." *Draper v. Martin*, 664 F.3d 1110, 1114 (7th Cir. 2011).

judgment in favor of the defendants because the court found that the defendants' proposed product did not infringe on the patents at issue in that case (the "Ashley patents"). While the Mylan action was on appeal at the Federal Circuit, the defendants in *Galderma* moved for judgment on the pleadings with regard to the issue of infringement of the Ashley patents, arguing that collateral estoppel barred the plaintiffs from relitigating that issue. The court agreed, finding that the infringement issue was identical in the two cases and therefore the plaintiffs, having lost on that issue in the Mylan action, were bound by that ruling unless and until it was overturned on appeal.

The *Galderma* court recognized that "a claim of patent infringement will not often be defeated by an assertion of collateral estoppel." 921 F. Supp. 2d at 282. This Court agrees, because "[a]n infringement analysis involves the two-step process of 'construing the claims and comparing the properly construed claims to the accused product.'" *Tinnus Enterprises, LLC v. Telebrands Corp.*, ___ F.3d ___, 2017 WL 344324, at *6 (Fed. Cir. Jan. 24, 2017) (quoting *Advanced Steel Recovery, LLC v. X–Body Equip., Inc.*, 808 F.3d 1313, 1316 (Fed. Cir. 2015)). It may not often be the case that the second step of the analysis in one case will be dispositive of another case involving a different accused product. The Defendants have not attempted to explain why they believe this is such a case, beyond asserting, without support or explanation, that their applicator is "identical, or at least similar to," two of the applicators found to be non-infringing in *Perrigo*.[7] Neither do they explain how the "limited discovery and dispositive motion practice relating to the Applicator Patents only" that they propose, Dkt. No. 44 at 5, will lead to the final judgment of non-infringement with regard to all of the Patents such that they can

[7]A quick perusal of the *Perrigo* court's findings suggest that the two applicators in question are, in fact, quite different from one another.

avoid the thirty-month stay and receive the approval necessary to launch their product in August 2017. *See* 21 U.S.C.A. § 355(j)(5)(B)(iii)(I). They also fail to explain how they believe the issues of validity and infringement relating to the two patents that are at issue in this case but were not at issue in *Perrigo* can be resolved by August 2017.

The Defendants' entire prejudice argument is based upon their desire to enter the market by August 2017. Because the Defendants have not explained why they believe their competitors are likely to enter the market at that time, and because they have not explained how they believe the limited exception to the stay that they seek will enable them to reach that goal in any event, the Defendants have not shown that they will suffer undue prejudice if this case is stayed pending the appeal in *Perrigo*.

With regard to the final factor, whether the stay will reduce the burden of litigation on the parties and on the court, the Defendants argue that it will not because

> [i]f a stay is issued, the parties will be required to take discovery on the Defendants' spreading implement *after* all appeals in the *Perrigo* litigation have been exhausted. This is so regardless of the outcome of the *Perrigo* appeals regarding noninfringement and invalidity.

Dkt. No. 44 at 9. This is not necessarily true; if the Federal Circuit rules in *Perrigo* that the '861 Patent is invalid, and if that ruling is, as a matter of law, equally applicable to the other patents that relate to the spreading implement—which the Court assumes the Defendants believe to be the case—then there would be no need for a ruling on whether the Defendants' spreading implement infringes. The Defendants also argue:

> Moreover, if the Federal Circuit reverses the *Perrigo* Court's findings of invalidity (*i.e.*, the patents are found valid), but affirms the holding of noninfringement, Apotex will be required to litigate both infringement *and* validity. However, if this Court denies the stay and issues a final judgment of noninfringement in favor of Apotex after allowing limited, expedited discovery regarding Apotex's applicator, all future discovery will be rendered unnecessary if the Federal Circuit confirms the *Perrigo* Court's finding of noninfringement.

This argument is curious. If the Federal Circuit were to affirm the *Perrigo* court's finding that the '861 Patent is valid, nothing would force the Defendants to assert that it is invalid. The Defendants would be free to concede the validity of the '861 Patent and litigate only whether their product would infringe that patent, which is in essence what they are now proposing to do. If the Defendants believe they are entitled to an expedited judgment on the pleadings based on the collateral estoppel effect of the district court's ruling in *Perrigo*, it is unclear to the Court why they do not believe they would not be entitled to the same based upon the Federal Circuit's affirmance of that ruling.

Given the information currently before it, the Court determines that the likelihood that the Federal Circuit's ruling in *Perrigo* will streamline the issues to be decided in this case and lessen the burden on both the Court and the parties strongly militates in favor of the stay proposed by the Plaintiffs and that the stay would not unduly burden the Defendants. That said, the Court will expect the Plaintiffs to be prepared to expedite the resolution of this case once the *Perrigo* decision is rendered. To that end, the Court directs the parties to work together over the next few months to attempt to identify those issues that they can agree could be resolved by the *Perrigo* ruling; for example, the extent that certain invalidity findings in that case would apply to the Patents at issue in this case. In spite of the stay, if either party believes that the other party is not engaging in these discussions in good faith, they may request a status conference with the Court.

The Plaintiffs' motion to stay is **GRANTED** and this case is **STAYED** pending resolution of the Federal Circuit's ruling in *Perrigo*. The parties shall submit a joint case management plan within fourteen days of the date of the Federal Circuit's ruling in *Perrigo*. If the parties are unable to agree on a case management schedule, they shall file a motion for an

expedited status conference to resolve their differences. It is the Court's intention to resolve this matter as efficiently as possible once the stay is lifted.

SO ORDERED: 2/8/17

Hon. William T. Lawrence, Judge
United States District Court
Southern District of Indiana

Copies to all counsel of record via electronic notification