

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC.,
Plaintiff,
v.
MYLAN TECHNOLOGIES INC.,
MYLAN PHARMACEUTICALS INC.,
and MYLAN INC.,
Defendants.

Civil Action No. 11-220-GMS

MEMORANDUM

I. BACKGROUND

On January 28, 2011, Mylan Technologies Inc., Mylan Pharmaceuticals Inc., and Mylan Inc. (collectively "Mylan") served Endo Pharmaceuticals Inc. ("Endo") with a Paragraph IV Notice indicating that it would seek FDA approval for a generic Lidoderm patch and that it believed U.S. Patent No. 5,741,510 ("the '510 Patent") was either invalid or would not be infringed. (D.I. 20 at 2.) According to Endo, at the time of the Paragraph IV Notice, LecTec Corp. ("LecTec"), not Endo, was the owner of the '510 Patent. *Id.* On March 14, 2011, Endo filed a Complaint against Mylan, alleging: (1) that Mylan had failed to comply with the notice requirements of 21 U.S.C. § 355(j)(2)(B)(iii)(I) and 21 C.F.R. 314.95(a)¹ ("Count I") and (2) that

¹ Both 21 U.S.C. § 355(j)(2)(B)(iii)(I) and 21 C.F.R. 314.95(a) require Paragraph IV Certification to be given to each owner of the patent that is the subject of the certification.

“[i]f the [c]ourt determines now or at a future date that Mylan has complied with its obligations under the Hatch-Waxman Act to provide valid notice of a Paragraph IV Certification, Endo pleads in the alternative that Mylan has infringed the ’510 Patent by submitting an ANDA on the LIDODERM Patch containing a Paragraph IV certification with respect to that patent” (“Count II”). (D.I. 1 at ¶50.) Endo sought injunctive relief to prevent Mylan’s launch of a Lidoderm generic. *Id.* at 10.

On May 20, 2011, Mylan filed a Motion to Dismiss Endo’s Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). (D.I. 10.) On March 30, 2012, the court issued an order granting Mylan’s motion and dismissing without prejudice Endo’s Complaint. (D.I. 19.) The court concluded that Endo lacked standing to challenge Mylan’s compliance with 21 U.S.C. § 355(j)(2)(B)(iii)(I), citing *Minn. Mining and Mfg. Co. v. Barr Labs.*, 289 F.3d 775, 782 (Fed. Cir. 2002). (D.I. 19 at n.2.) The court further concluded that it was “unable to rule on the issues related to infringement as pled in Endo’s complaint” because Endo lacked standing to assert Count I, and its infringement claim, as pled, was conditioned on a determination of Count I. (*Id.* at 1 n.3.)

Presently before the court is Endo’s Motion to Amend Complaint Pursuant to Rule 15(a) and for Reconsideration Under Rule 59(e) of the Federal Rules of Civil Procedure and Local Rule 7.1.5. (D.I. 20.) Endo seeks to amend its Complaint to restate its infringement claim, arguing that the “[c]ourt dismissed the original claim (Complaint Count II) without prejudice because of a technical defect in pleading.”² (D.I. 20 at 1.) After having considered Endo’s

² More specifically, Endo contends that “had [it] phrased the ‘in the alternative’ language . . . slightly differently, instead stating for instance: ‘If Count I is dismissed for any reason, Endo pleads in the alternative that

proposed amendment, the parties' submissions on the issue, and the pertinent law, the court concludes that leave to amend should be granted for the reasons that follow.

II. STANDARD OF REVIEW

A. Motion to Amend

A party may amend its pleading once as a matter of course within twenty-one days after serving it or, if the pleading is one to which a responsive pleading is required, twenty-one days after service of a responsive pleading or twenty-one days after service of a motion under Rule 12(b), (e), or (f), whichever is earlier. Fed. R. Civ. P. 15(a)(1)(A–B). Otherwise, Rule 15 permits a party to amend its pleading only with the opposing party's written consent or with leave of the court. *See* Fed. R. Civ. P. 15(a)(2). Pursuant to Rule 15, “[t]he court should freely give leave [to amend] when justice so requires.” *Id.*

The Third Circuit has consistently emphasized the liberal approach to pleading embodied by Rule 15. *See Arthur v. Maersk*, 434 F.3d 196, 202 (3d Cir. 2006); *Dole v. Arco Chem. Co.*, 921 F.2d 484, 487 (3d Cir. 1990) (“This approach ensures that a particular claim will be decided on the merits rather than on technicalities.”). The opportunity to amend is not automatic, but should be granted absent a showing of “undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of the allowance of the amendment, futility of amendment, etc.” *Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also Oran v. Stafford*, 226 F.3d 275, 291 (3d Cir. 2000). “Only when these factors suggest that amendment would be ‘unjust’ should the court deny leave.” *Arthur*, 434 F.3d at 203 (citing *Foman v. Davis*, 371 U.S.

Mylan has infringed the '510 patent,' the Court's reasoning for the dismissal . . . would not have applied.” (D.I. 20 at 4–5.)

at 182). Futility of amendment occurs when the complaint, as amended, does not state a claim upon which relief can be granted, and is therefore governed by the same standard of legal sufficiency that applies under Federal Rule of Civil Procedure 12(b)(6).” *See Oran*, 226 F.3d at 291 (citations omitted).

III. DISCUSSION

Endo seeks leave to amend its Complaint pursuant to Rule 15(a), or, in the alternative, amendment of the court’s dismissal order under Rule 59(e). As discussed below, the court finds that Endo should be permitted to amend its Complaint and thus will not reach its alternative request.

Endo contends that its Motion to Amend meets the standards of Rule 15(a)(2), asserting that it merely seeks to correct a “technical pleading defect” and that no prejudice will result if the amendment is allowed because the original Complaint provided notice of Endo’s intention to pursue a claim of patent infringement against Mylan. (D.I. 20 at 3–4.) In response, Mylan contends that Endo’s Motion “does not seek to correct an inadvertent error,” but instead, seeks to correct Endo’s “failed strategy to extend the statutory 30 month stay . . . instead of bringing a claim for infringement.” (D.I. 21 at 1, 3.) Mylan further argues that “Endo had ample opportunity to amend its complaint” but failed to do so, and that such failure is “the result of undue delay and dilatory conduct.”³ (*Id.* at 3.)

³ Mylan has not made any argument suggesting that bad faith, repeated failure to cure deficiencies by amendments previously allowed, or futility would support denial of Endo’s motion, and the court will not discuss these considerations.

A. Undue Delay and Dilatory Motive

Endo's delay was neither unexplained or so flagrant as to warrant denial of its Motion to Amend. The original Complaint was filed in March 2011 and the proposed amendment was filed in April 2012, slightly more than a year later. Endo, however, filed its Motion to Amend within fourteen days of the court's dismissal order. "There is, of course, no presumptive period in which a motion for leave to amend is deemed 'timely' or in which delay becomes 'undue.'" *Arthur*, 434 F.3d at 205. Rather, "[t]he question of undue delay, as well as the question of bad faith, requires that [the court] focus on the plaintiff[']s motives for not amending their complaint to assert this claim earlier." *Adams v. Gould Inc.*, 739 F.2d 858, 868 (3d Cir. 1984).

Here, Endo asserts that its challenge to the sufficiency of Mylan's Paragraph IV Notice and the resulting delay was "based on a good-faith interpretation of existing case law,"⁴ and that before the court's order, "Endo believed in good faith that it had properly pleaded infringement."⁵ (D.I. 22 at 2.) In light of the circumstances and the explanation offered by

⁴ Endo relied upon case law from the United States District Court for the Eastern District of Pennsylvania. In the cited case, the district court made a determination that the timing of a Paragraph IV Notice under 21 U.S.C. § 355(j)(2)(B)(ii)(1) was untimely and improper. *SB Pharmco Puerto Rico, Inc. v. Mutual Pharmaceutical Co.*, 552 F.Supp. 499, 508 (E.D. Pa. 2008) ("We are satisfied that the December 21 Paragraph IV Notice was premature and improper under 21 U.S.C. § 355(j)(2)(B)(ii)(1) and 21 C.F.R. § 314.95(b)."). Mylan contends that Endo failed to amend its complaint "in the face of binding Federal Circuit authority," citing *Minn. Mining and Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 783 (Fed. Cir. 2002) ("3M"), which held that "appellants cannot seek a judicial determination of whether a private party's paragraph IV certification complies with 21 U.S.C. § 355(j)(2)(B)."

Contrary to Mylan's assertions, however, Endo addressed 3M at some length in its briefs to the court, and chose to advance an argument challenging the reach of the Federal Circuit's 3M holding on "factually distinguishable" grounds. (D.I. 14 at 9-10) ("Mylan is wrong, because 3M and the other cases Mylan cites are factually distinguishable. None of the cases Mylan cites involved a situation where, as here, the ANDA filer failed to serve a Paragraph IV Notice on one of required parties."). The court is not persuaded that an advocate narrowly arguing that the Federal Circuit's 3M precedent should not apply to the particular context or circumstances of this action amounts to undue delay or dilatory conduct.

⁵ In Count II of its original complaint, Endo explicitly pled infringement of the '510 Patent: "Mylan's submission of an ANDA seeking to obtain FDA approval to engage in the commercial manufacture, use, or sale of its generic copy of the LIDODERM Patch prior to expiration of the '510 Patent constitutes infringement of the '510 Patent under 35 U.S.C. § 271(e)(2)(A)." (D.I. 1 at ¶49.) Endo, however, then stated: "[i]f the Court determines now

Endo, the court is unable to discern any dilatory motive and concludes that the delay was not so excessive as to be unreasonable.

B. Prejudice

Mylan also contends that it will be severely prejudiced should the court grant Endo's Motion to Amend because "if Endo had timely asserted its cause of action for infringement . . . Mylan could have spent that last year litigating the claim and moving towards a final decision." (D.I. 21 at 4.) Mylan, however, "must do more than merely claim prejudice; 'it must show that it was unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered had the . . . amendments been timely.'" *Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir. 1989) (quoting *Heyl & Patterson Int'l, Inc. v. F.D. Rich Housing*, 663 F.2d 419, 425 (3d Cir. 1981)).

While the court is not unsympathetic to Mylan's concerns, it does not believe that Mylan will suffer undue prejudice. Mylan was clearly put on notice of Endo's infringement claim, *see* 6 Wright, Miller & Kane, *Federal Practice and Procedure* § 1487 (2010) ("[C]ourts have allowed amendments when it was established that doing so would not unduly increase discovery or delay the trial, and when the opponent could not claim surprise, but effectively should have recognized that the new matter included in the amendment would be at issue."), and the amendment does not substantially change the underlying theory of the case, *see Inline Connection Corp. v. AOL Time Warner Inc.*, 237 F.R.D. 361, 369 (D. Del. 2006). Since discovery was in its earliest stages at

or at a future date that Mylan has complied with its obligations under the Hatch-Waxman Act . . . Endo pleads in the alternative that Mylan has infringed the '510 Patent. (*Id.* at ¶50.) If Endo had simply couched its infringement claim in the more traditional "in the alternative" language, rather than making Count II dependent upon a determination of Count I, the court could have dismissed Count I and addressed the sufficiency of Endo's infringement claim.

the time of dismissal, amendment of the Complaint will not deprive Mylan of the opportunity to present facts or evidence or otherwise prepare and present its case. *See Trueposition, Inc. v. Allen Telecom, Inc.*, No. 01-823-GMS, 2002 WL 1558531, at *2 (D. Del. July 16, 2002). Furthermore, the amendment will not delay or unduly complicate trial, nor are the issues raised by the amendment so remote from the other issues in the case that they might confuse or mislead the finder of fact. As such, the court concludes that allowing Endo to amend its Complaint at this stage of the proceedings would not be untimely or result in undue prejudice to Mylan. “To rule otherwise would result in the filing of another lawsuit and would not promote the interests of judicial efficiency.” *LG Electronics U.S.A., Inc. v. Whirlpool Corp.*, C.A. No. 10-311-GMS, 2011 WL 4043394, at *2 (D. Del. Sept. 12, 2011).

C. Relation Back

Finally, Mylan raises the issue of “relation back.” (D.I. 21 at 4–5.) The issues of leave to amend under Rule 15(a) and relation back under Rule 15(c), “while obviously related, are conceptually distinct.” *Arthur*, 434 F.3d at 202–03. While leave to amend should be granted whenever “justice so requires,” “[t]he relation back inquiry is more circumscribed.” *Arthur*, 434 F.3d at 203. Rule 15(c) allows for an amendment to relate back to the original complaint when one of three conditions is met:

- (A) the law that provides the applicable statute of limitations allows relation back;
- (B) the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out—or attempted to be set out—in the original pleading; or
- (C) the amendment changes the party or the naming of the party against whom a claim is asserted, if Rule 15(c)(1)(B) is satisfied and if, within the period provided by Rule 4(m) for serving the summons and complaint, the party to be brought in by amendment:
 - (i) received such notice of the action that it will not be prejudiced in

defending on the merits; and
(ii) knew or should have known that the action would have been brought against it, but for a mistake concerning the proper party's identity.

Fed. R. Civ. P. 15(c)(1). It is well-settled, however, that “the dismissal of a complaint without prejudice after the statute of limitations has run forecloses the plaintiff’s ability to remedy the deficiency underlying the dismissal and refile the complaint.” *Brennan v. Kulick*, 407 F.3d 603, 606 (3d Cir. 2005) (citations omitted). The reason “[a] ‘statute of limitations is not tolled by the filing of a complaint subsequently dismissed without prejudice,’” is that ““the original complaint is treated as if it never existed.”” *Id.* (quoting *Cardio-Medical Assocs. v. Crozer-Chester Med. Ctr.*, 721 F.2d 68, 77 (3d Cir. 1983)).

Here, Mylan contends that “the 45 day time period under 21 U.S.C. § 355(j)(5)(B)(iii) to invoke the 30 month stay is effectively a statute of limitations” and appears to suggest that, under the logic of *Brennan*, *Cardio-Medical*, and related decisions, Endo should not be permitted to rely upon its dismissed Complaint to trigger the thirty month stay. (D.I. 21 at 5.) As an initial matter, the court notes that the forty-five day window is not properly characterized as a “statute of limitations.” The Federal Circuit has made clear that the Patent Act lacks an affirmative statute of limitations—while 35 U.S.C. § 286 restricts the time period for recovery, it does not bar a late-filed infringement suit directly. *Standard Oil Co. v. Nippon Shokubai Kagaku Kogyo Co.*, 754 F.2d 345, 348 (Fed. Cir. 1985). Like § 286, the forty-five day rule may have collateral consequences for some patent litigation, but failure to file within that timeframe does not bar an infringement action itself. Thus, the rule recited in *Brennan* does not preclude Endo from repeating its infringement claim in an amended complaint.

Indeed, Mylan seems to recognize that the forty-five day window is not a true statute of

limitations, and it makes no direct argument that Endo should be barred from reasserting its infringement claims. Rather, Mylan appears to rely upon the underlying logic of the *Cardio-Medical* decision—if an original complaint dismissed without prejudice is “treated as if it never existed,” perhaps Endo’s Complaint should not be allowed to anchor a thirty month stay. In a sense, Endo failed to file a (valid) suit within the forty-five day window.

Though Mylan’s position has some logical appeal, it falls short when confronted with the statutory and regulatory language actually governing the application of the thirty month stay. 21 U.S.C. § 355(j)(5)(B)(iii) provides:

If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification . . . If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i)

21 U.S.C. § 355(j)(5)(B)(iii). While Endo’s Complaint suffered from certain pleading defects, there is no dispute that it was brought within the forty-five day timeframe, and, despite its pleading defect, the court believes it represents “an action . . . brought for infringement of the patent that is the subject of the certification” within the meaning of the statutory language. *Id.* As such, the stay should have been triggered by the filing of the Complaint and would run from “the date of the receipt of the notice provided under paragraph (2)(B)(i).” *Id.*

The question then becomes whether the stay has since been terminated. While the parties’ briefing does not indicate the present status of the stay or the effect had by the court’s dismissal order, the statute indicates that termination will occur only in the following ways: (1) at

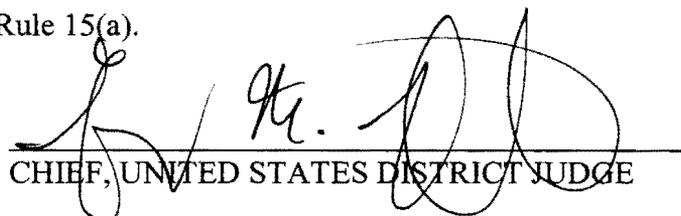
the expiration of the thirty month period; (2) at the expiration of “such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action;” (3) “if before the expiration of [the thirty month] period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity);” (4) “if before the expiration of [the thirty month] period the district court decides that the patent has been infringed;” and (5) “if before the expiration of [the thirty month] period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement.” Given this explicit language, the court does not view its dismissal order or its decision on the present motion as having any immediate effect on the thirty month stay. Mylan’s analogy to the statute of limitations context and suggestion that the Complaint be treated as if it never existed must fail in the face of such precise statutory guidance—the lengthy list recited above suggests that, if Congress had wished the thirty month stay to be extinguished upon a dismissal without prejudice, it would have said as much.

IV. CONCLUSION

In the absence of undue delay, bad faith, or dilatory motive on the part of the movant, repeated failure to cure deficiencies, undue prejudice to the opposing party, or futility of amendment, the court should exercise its discretion in favor of granting leave to amend. *See Foman*, 371 U.S. at 182. This liberal approach ensures that cases generally will be decided on the merits rather than on technicalities. *See Dole v. Arco Chem. Co.*, 921 F.2d 484, 487 (3d Cir.

1990); *Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir. 1989); *Heyl & Patterson Int'l, Inc. v. F.D. Rich Housing Virgin Islands*, 663 F.2d 419, 425 (3d Cir. 1981). For the reasons discussed above and having discovered no undue delay, dilatory motive, or undue prejudice, the court will grant Endo's Motion to Amend pursuant to Rule 15(a).

Dated: March 11, 2013


CHIEF, UNITED STATES DISTRICT JUDGE

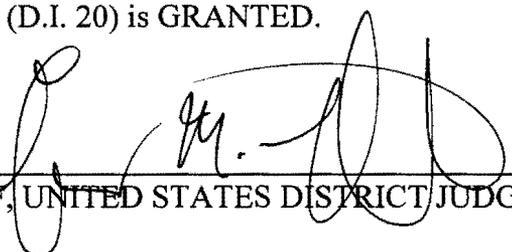
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 and MYLAN INC.,)
)
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 Defendants.)
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ORDER

At Wilmington this 11th day of March 2013, consistent with the memorandum opinion issued this same date, IT IS HEREBY ORDERED THAT:

The plaintiff's Motion to Amend Complaint (D.I. 20) is GRANTED.



CHIEF, UNITED STATES DISTRICT JUDGE