IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK; NEW YORK UNIVERSITY; GALDERMA LABORATORIES INC.; AND GALDERMA LABORATORIES, L.P.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 09-184-GMS-LPS
MYLAN PHARMACEUTICALS INC.,	:	
Defendant.	:	

MEMORANDUM ORDER ON DEFENDANT'S MOTION TO AMEND

Plaintiffs – The Research Foundation of State University of New York, New York University, Galderma Laboratories, Inc. ("Galderma"), and Galderma Laboratories L.P. – filed this patent infringement action on March 19, 2009. (D.I. 1) On April 16, 2009, Defendant Mylan Pharmaceuticals Inc. ("Mylan") answered and counterclaimed for a declaratory judgment that the patents-in-suit are both invalid and not infringed. (D.I. 14) The Court-scheduled deadline to amend the pleadings was November 23, 2009 and the deadline for completion of fact discovery was June 9, 2010. (D.I. 85)

On April 9, 2010, Mylan filed a Motion For Leave To File An Amended Answer and Counterclaims (the "Motion"). (D.I. 96) For the reasons set forth below, the Court will grant Mylan's Motion.

I. THE PARTIES' CONTENTIONS

By its Motion, Mylan requests leave to amend its answer and counterclaims (collectively, "Answer") to assert an additional affirmative defense and corresponding counterclaim pertaining to unenforceability of two of the patents-in-suit – Nos. 7,211,267 and 7,232,572 (collectively, the "Ashley patents") due to inequitable conduct. Mylan's proposed amended Answer also reformats its previously alleged counterclaims concerning invalidity and noninfringement, and modifies the verb tense of certain responses to Plaintiffs' "exceptional case" allegations.[1]

In response, Plaintiffs contend that, by seeking to amend its pleadings more than four months after the deadline set forth in the Scheduling Order (D.I. 26; D.I. 85), Mylan seeks not only leave to file its amended pleadings, but also seeks modification of that Scheduling Order. To Plaintiffs, Mylan has not demonstrated "good cause" to amend under Federal Rule of Civil Procedure 16. Moreover, Mylan's untimely amendment would prejudice Plaintiffs and is futile under Federal Rule of Civil Procedure 15 and, thus, should be denied.

II. LEGAL STANDARDS

In pertinent part, Rule 15(a) of the Federal Rules of Civil Procedure provides that after a responsive pleading has been filed a party may amend its pleading "only with the opposing party's written consent or the court's leave," and "[t]he court should freely give leave when justice so requires. The decision to grant or deny leave to amend lies within the discretion of the Court, and factors the Court should consider in exercising its discretion include "undue delay, bad faith, dilatory motive, prejudice, and futility." *In re Burlington Coat Factory Secs. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997) (internal citations omitted). An amendment is futile if it is

[1]Plaintiffs do not appear to oppose this portion of Mylan's Motion.

frivolous, fails to state a claim upon which relief can be granted, or "advances a claim or defense that is legally insufficient on its face." *Koken v. GPC Int'l, Inc.*, 443 F. Supp. 2d 631, 634 (D. Del. 2006). Delay alone is an insufficient reason to deny leave to amend, but there are grounds to deny amendment if the delay is coupled with either an unwarranted burden on the Court or undue prejudice to the non-moving party (as a result of the amendment). *See Cureton v. Nat'l Collegiate Athletic Ass'n*, 252 F.3d 267, 273 (3d Cir. 2001). A party may suffer undue prejudice if the proposed amendment causes surprise, results in additional discovery, or adds costs to the litigation in defending against the new facts or theories alleged. *See id.* "Thus, while bearing in mind the liberal pleading philosophy of the federal rules, the question of undue delay requires that we focus on the movant's reasons for not amending sooner. . . . [Moreover,] [t]he issue of prejudice requires that we focus on the hardship to the [non-movant] if the amendment were permitted." *Id.* (internal citations omitted).

Further, "[i]f a party moves for leave to amend the pleadings after a deadline imposed by a Scheduling Order, Rule 16 of the Federal Rules of Civil Procedure is implicated." *WebXchange Inc. v. Dell Inc.*, 2010 WL 256547, at *2 (D. Del. Jan. 20, 2010). Pursuant to Federal Rule of Civil Procedure 16(b), "[a] schedule may be modified only for good cause and with the judge's consent." Fed. R. Civ. P. 16(b)(4). After passage of a pleading deadline, the Third Circuit mandates that good cause be shown in order to amend. *See WebXchange*, 2010 WL 256547, at *2. "Good cause" exists when the imposed schedule "cannot reasonably be met despite the diligence of the party seeking the extension." *ICU Med., Inc. v. Rymed Techs., Inc.*, 674 F. Supp. 2d 574, 577 (D. Del. Dec. 16, 2009) (citing Fed. R. Civ. P. 16(b)(4) Advisory Committee Notes (1983 Amendments)). "In contrast to Rule 15(a), the good cause standard

under Rule 16(b) hinges on diligence of the movant, and not on prejudice to the non-moving party." *Raquette Freres v. SPI Pharma, Inc.*, 2009 WL 1444835, at *4 (D. Del. May 21, 2009).

III. ANALYSIS

Mylan summarizes its allegations of unenforceability as follows:

> Mylan's unenforceability allegations arise from the FDA's determination in September 2003 that Galderma's product Periostat® contains an amount of doxycycline (20 mg twice daily) sufficient to inhibit bacteria. The FDA specifically concluded that "at the approved dose of 20 mg twice daily, "**Periostat has the capacity to inhibit micro-organisms**" and "**Periostat . . . has the capacity to inhibit or destroy strains of bacteria** . . . ." *See* Mylan's Proposed Amended Answer and Counterclaims ("Amended Pleading") ¶ 45. That determination is highly material to the patentability of the Ashley patents because both patents identify Periostat as "an especially preferred embodiment" and all claims in both patents are limited to an amount of a tetracycline compound (*e.g.*, doxycycline) that will **not** substantially inhibit the growth of bacteria.

(D.I. 144 at 1) These allegations are not futile.

Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). In addition, when alleging inequitable conduct, the Federal Circuit "requires that the pleadings allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009). While Rule 9(b) allows "[m]alice, intent, knowledge, and other conditions of a person's mind [to] be alleged generally, . . . 'generally' is a relative term. In the context of Rule 9, it is to be compared to the particularity requirement applicable to fraud or mistake." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1954 (2009). "Although 'knowledge' and 'intent' may be averred generally, [Federal Circuit] precedent . . . requires that the pleadings allege sufficient underlying facts from

which a court may reasonably infer that a party acted with the requisite state of mind." *Exergen*, 575 F.3d at 1327. "In sum, to plead the 'circumstances' of inequitable conduct with the requisite 'particularity' under Rule 9(b), the pleading must identify the specific *who, what, when, where and how* of the material misrepresentation or omission committed before the PTO." *Id.* (emphasis added).

Mylan's amended Answer meets these standards. It expressly alleges that Ashley, the inventor, and Feit, a prosecuting attorney, knew of a 2003 FDA Memo which concluded that the same daily dosage of doxycycline that is claimed in the patents-in-suit as a sub-antibacterial amount (i.e., an amount that does not significantly inhibit micro-organisms) in fact has the capacity to inhibit micro-organisms (i.e., is an antibiotic). Ashley and Feit withheld the FDA Memo during prosecution despite knowing of its existence from their participation in litigation between the FDA and CollaGenex, Plaintiff Galderma's predecessor as assignee of the Ashley patents. *See CollaGenex Pharms., Inc. v. Thompson*, 2005 WL 256561, at *6 (D.D.C. Jan. 19, 2005). Ashley participated in the litigation in his capacity as Senior Vice President of Commercial Development for CollaGenex; Feit's law firm, Hoffman & Baron, represented CollaGenex in other litigation involving Periostat®. Deceptive intent may be inferred from the alleged materiality of the FDA Memo, Ashley and Feit's knowledge and withholding of it, and the lack of any reasonable explanation for withholding it.

Nor is there evidence of bad faith or dilatory motive on the part of Mylan. Mylan served timely document requests to which the FDA Memo would have been responsive. Specifically, in July 2009, Mylan served a document request seeking: "All documents and things relating to the oral administration of 40mg or less of any form of doxycycline, prior to April 5, 2001." (D.I. 144

at 3-4) (quoting Request for Production No. 38) On November 18, 2009, at a time when the Court's Scheduling Order imposed a November 23, 2009 deadline for amended pleadings, Mylan served another document request, this time seeking all documents "'relating to any legal proceeding, including but not limited to [an Eastern District of New York case], concerning Periostat®.'" (D.I. 144 at 4) (quoting Request for Production No. 56) Plaintiffs, as of the date of Mylan's Motion, had not produced the FDA Memo to Mylan.

Mylan explains that it did not discover the litigation between CollaGenex and the FDA earlier because when it conducted a search of publicly available litigation documents it limited its search to patent infringement actions. (D.I. 145 ¶¶ 2, 10) With hindsight, it is clear that a search of all federal court decisions (on Westlaw or Lexis, for example) for "Periostat" would have retrieved the FDA action. Whatever one thinks of Mylan's failure to conduct such a search sooner, Mylan's failure is not evidence of bad faith or dilatory motive.

Nor is there undue prejudice to Plaintiffs. In order to prove undue prejudice, the non-movant "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). Here, Plaintiffs include the successor to CollaGenex; undoubtedly they have had the FDA Memo, among other materials relating to the prosecution of Periostat® and the *CollaGenex* litigation, for quite some time. To the extent Mylan's amended Answer necessitates any additional discovery from either side, there was at the time Mylan filed its Motion sufficient time in the Scheduling Order for such discovery to be conducted. Mylan filed its Motion on April 9, 2010, at a time fact when discovery was due to conclude on June 9, 2010.

For the same reasons already explained in connection with the Rule 15 analysis above, good cause exists under Rule 16 to amend the Scheduling Order to permit Mylan's amended pleading.

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. The Motion For Leave To File An Amended Answer and Counterclaims (D.I. 96) filed by Defendant Mylan Pharmaceuticals Inc. is **GRANTED**.

2. The Clerk shall docket the proposed First Amended Answer And Counterclaims attached as Exhibit A to the Motion, and the First Amended Answer And Counterclaims shall be deemed filed and served as of the date of this Order.

Dated: June 28, 2010

Leonard P. Stark
UNITED STATES MAGISTRATE JUDGE