IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC., Plaintiff, v. ALKEM LABORATORIES Ltd. Defendant.	)	C.A. No. 17-CV-815-GMS LEAD CASE
AMGEN INC., Plaintiff, v. MACLEODS PHARMACEUTICALS, LTD., and MACLEODS PHARMA USA, INC., Defendant.	)	C.A. No. 17-CV-817-GMS CONSOLIDATED **Contains Confidential Information Pursuant to L.R. 26.2**

MEMORANDUM

I. INTRODUCTION

The plaintiff Amgen, Inc. ("Amgen"), pursuant to the Hatch-Waxman Act, filed a patent infringement action against Macleods Pharmaceuticals LTD and Macleods Pharma USA, Inc. ("Macleods") for infringement of one or more claims of U.S. Patent No. 9,375,405 ("the '405 patent") by the filing of its Abbreviated New Drug Applications ("ANDA") No. 209362 with the FDA. Presently before the court is Macleods's Motion for Judgment on the Pleadings and Motion for Sanctions with respect to Amgen's claims for infringement of the '405 patent. (D.I. 18, D.I. 20 in C.A. No. 17-817-GMS) For the reasons that follow, the court will deny both motions.

II. BACKGROUND

Macleods triggered this lawsuit by filing its ANDA, seeking FDA approval to manufacture, use and/or sell a generic version of Amgen's Sensipar® product prior to the expiration of the '405 patent. The '405 patent is assigned to Amgen and is listed in the FDA's Orange Book as covering Sensipar®. The '405 patent claims a binder composition that requires one of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carbonxymethylcellulose, or a mixture thereof as a binder present in a pharmaceutical composition. Macleods's alleges that its ANDA products do not contain any of the listed excipients.[1] therefore the Amgen could only assert a claim under the doctrine of equivalents. (D.I. 18 at 1 in C.A. No. 17-817-GMS.) Macleods argues that Amgen's potential claim under the doctrine of equivalents is barred by the doctrine of prosecution history estoppel. (*Id.*) Additionally, currently pending before the court is Macleods's motion for sanctions under Fed. R. Civ. P. 11 arguing that Amgen failed to conduct any inquiry into the details of the accused products and, as a result, has no legal or factual basis for its suit. (D.I. 20 in C.A. No. 17-817-GMS.)

III. MOTION FOR JUDGMENT ON THE PLEADINGS

A. STANDARD OF REVIEW

When deciding a motion for judgment on the pleadings, the court must view the facts and inferences drawn from the pleadings in the light most favorable to the non-moving party. *Revell v. Port Auth.*, 598 F.3d 128, 134 (3d Cir. 2010); *See also Green v. Fund Asset Mgmt., L.P.*, 245 F.3d 213, 220 (3d Cir. 2001). The court is "not compelled to accept unsupported conclusions and unwarranted inferences, or a legal conclusion couched as a factual allegation." *Baraka v.*

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[1] In support of this assertion, Macleods points to Amgen's answer to Macleods's counterclaims where Amgen acknowledged that—according to the documents produced by Macleods at the time—the generic products did not contain any of the binders recited in the '405 patent. (D.I. 27 at 3; D.I. 14 at ¶ 26.) At this stage in the litigation, the court will not rule on whether Macleods has directly infringed.

McGreevey, 481 F.3d 187 (3d Cir. 2007) (internal citations and quotation marks omitted). The issue for the court is "not whether the plaintiff will ultimately prevail, but whether the claimant is entitled to offer evidence to support the claims." *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974).

B. DISCUSSION

Macleods argues that Amgen's claim for infringement under the doctrine of equivalents is barred by the doctrine of prosecution history estoppel. (D.I. 18 at 8 in C.A. No. 17-817-GMS.) Amgen asserts that Macleods's motion should be denied for two reasons. First, Amgen argues that Macleods's motion should be converted into a motion for summary judgment because it requires resolving factual issues[2] and, if converted, should be denied because there are material facts in dispute. (D.I. 27 at 7-11 in C.A. No. 17-817-GMS.) Second, Amgen insists that if the court does consider Macleods's motion for judgment on the pleadings, the court should find that prosecution history estoppel does not apply. (D.I. 27 at 11-18 in C.A. No. 17-817-GMS.) Thus, the underlying issue before the court is whether, at the pleadings stage in this ANDA case where the file history is highly technical and hotly disputed by the parties, the court should non-suit the plaintiff.

The application and scope of prosecution history estoppel is ultimately a matter of law for the court to decide. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1368 (Fed. Cir. 2003). Where the patentee has narrowed a claim through amendment, the court must consider a three-part, fact intensive framework to determine whether amendment-based

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[2] Amgen attacks Macleods's process in filing this motion and asserts that its reliance on the prosecution history requires that this motion be treated as one for summary judgment under Rule 56. Fed. R. Civ. P. 12(d); (D.I. 27 at 4.) The facts in the '405 patent's prosecution history, unlike those in *In re Bendamustine*, are disputed by the parties. The court agrees with Amgen that as a result of the presence of material factual disputes, this motion should have been brought as a summary judgment motion—if at all. The court will not convert the instant motion for judgment on the pleadings into a motion for summary judgment motion for two reasons. First, as Amgen correctly points out, the court typically does not permit summary judgment practice in ANDA cases. Second, initial disclosures started an entire month after this Rule 12(c) was first filed on September 11, 2017 which makes both summary judgment and, frankly, the instant motion, premature.

prosecution history estoppel exists and the scope of such estoppel. *Festo Corp.*, 344 F.3d at 1366-67. First, the court must determine if the amendment was narrowing. *Id.* at 1366. If so, the court must then determine if the amendment was made for reasons substantially related to patentability. *Id.* at 1366. If there is no clear reason for the amendment, a rebuttable presumption is created that the patentee had a substantial reasons relating to patentability. *Id.* at 1366. The patentee must rebut the presumption using facts from the prosecution history to show that the amendment was not made for reasons relating to patentability. *Id.* at 1366-67. This step necessarily requires the analysis of underlying facts. *See Festo Corp.*, 344 F.3d at 1368 n.3 ("We recognize that rebuttal of the presumption may be subject to underlying facts . . . [n]onetheless, the resolution of factual issues underlying a legal question may properly be decided by the court."). Finally, if the court determines that the amendment was made for reasons substantially related to patentability, then the court must determine the scope of the surrender resulting from the narrowing amendment. *Id.* at 1367.

Here, there are material disputes of fact between the parties concerning the prosecution history of the '405 patent. Thus, the court must first resolve these disputes and that resolution will inform the first two steps of the *Festo* analysis. Moving on to the scope of the surrender, absent an understanding of which equivalents are in question and the equivalents of the listed binder excipients, neither of which is discussed by either party in its briefing, the court is unable to do its job.

This case is still in the early stages of litigation. Discovery did not begin in this case until one month after the filing of this motion. At the time of the filing of this initial motion and Amgen's response, Amgen had not been provided any information regarding Macleods's generic product except for its public ANDA filing and Macleods's June 9, 2017 Notice Letter. (D.I. 27 at

20 in C.A. No. 17-817-GMS.) Further, none of the cases cited by Macleods in its briefing support its contention that on this record the court should grant its motion for judgment on the pleadings or convert the motion into one for summary judgment. Therefore, the court will deny Macleods's motion for judgment on the pleadings.

IV. MOTION FOR SANCTIONS

Rule 11 of the Federal Rules of Civil Procedure allows a court to sanction a party or attorneys under limited circumstances. "Rule 11(b) requires an attorney to conduct a reasonable inquiry into the law and facts before filing a pleading in a court and to certify that the claims contained therein are not frivolous, legally unreasonable, without factual foundation, or asserted for an improper purpose." *Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1300 (Fed. Cir. 2004). On September 15, 2017, six days after filing its motion for judgment on the pleadings, Macleods filed a motion for sanctions arguing that there is no possibility of infringement of the '405 patent by Macleods, either literally or under the doctrine of equivalents—the same argument advanced in its motion for judgment on the pleadings. (D.I. 20 in C.A. No. 17-817-GMS.) With due regard for Macleods views and thoughts on the matter, its motion for sanctions is as premature as its pleadings motion, and not well taken.

CONCLUSION

For the foregoing reasons the court will deny the both Macleods's Motion for Judgment on the Pleadings with respect to Amgen's claims for infringement of the '405 patent and Macleods's Motion for Sanctions. (D.I. 18, D.I. 20 in C.A. No. 17-817-GMS.)

Dated: December 19, 2017

UNITED STATES DISTRICT COURT