

IN THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF WEST VIRGINIA

ENTERED
MAR 31 2003
U.S. DISTRICT COURT
CLARKSBURG, WV 26301

ORTHO-MCNEIL PHARMACEUTICAL,
INC., JOHNSON & JOHNSON
PHARMACEUTICAL RESEARCH &
DEVELOPMENT, LLC, and DAIICHI
PHARMACEUTICAL CO., LTD.,

Plaintiffs,

v.

Civil Action No. 1:02CV32

(Judge Keeley)

MYLAN LABORATORIES, INC. and MYLAN
PHARMACEUTICALS, INC.,

Defendants.

ORDER DENYING PLAINTIFFS' MOTION TO AMEND

This matter comes before the Court on Plaintiffs' Motion for Leave to File Amended Complaint. The motion is fully briefed and ripe for review. For the following reasons, Plaintiffs' motion is **DENIED**.

BACKGROUND.

This is a pharmaceutical drug patent infringement action. Plaintiffs Daiichi Pharmaceutical Company, Ltd. (Daiichi), Ortho-McNeil Pharmaceutical, Inc. (Ortho), and Johnson & Johnson Research & Development, LLC (J&J) are brand-name pharmaceutical manufacturers. Defendants Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (together, Mylan) are generic pharmaceutical

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manufacturers seeking to market a drug similar to the one produced by Plaintiffs. At the heart of this case is United States Letters Patent No. 5,053,407 (the '407 patent) for a drug compound called levofloxacin, issued to Daiichi and licensed to Ortho and J&J. Plaintiffs claim that Mylan has willfully infringed the '407 patent.

Plaintiffs now seek to amend their complaint to add a claim against Quimica Sintetica, S.A. (Quimica), Mylan's manufacturer and supplier of bulk levofloxacin, and Quimica's U.S. agent, Betachem, Inc. (Betachem), for inducement of patent infringement pursuant to 35 U.S.C. § 371(b). Mylan vigorously opposes this motion.

Analysis.

The United States Supreme Court set forth the guidelines concerning a district court's consideration of motions to amend under Federal Rule of Civil Procedure 15(a) in Foman v. Davis, 371 U.S. 178 (1962):

Rule 15(a) declares that leave to amend "shall be freely given when justice so requires"; this mandate is to be heeded. If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits. In the absence of any apparent or declared reason--such as 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 allowance of the

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amendment, futility of amendment, etc.--the leave sought should, as the rules require, be "freely given." Of course, the grant or denial of an opportunity to amend is within the discretion of the District Court, but outright refusal to grant the leave without any justifying reason appearing for the denial is not an exercise of discretion; it is merely abuse of that discretion and inconsistent with the spirit of the Federal Rules.

Id. at 182.

Plaintiffs argue that they have properly pled a claim for inducement of patent infringement against Quimica and Betachem and, therefore, the Court should grant the motion to amend. Without question, plaintiffs very clearly allege that Quimica and Betachem knowingly and intentionally "assist[ed] with, participat[ed] in, contribut[ed] to, and or support[ed] the submission of an ANDA to the FDA seeking approval for the commercial manufacture of levofloxacin tablets before the expiration of the '407 patent." Further, they allege that Quimica and Betachem knowingly urged Mylan to file the ANDA.¹ Thus, Plaintiffs have successfully alleged that Quimica and Betachem induced Mylan to commit an act of infringement. See Water Technologies Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988) (noting that a party induces infringement by "knowingly aiding and abetting another's direct

¹Despite Mylan's arguments to the contrary, filing an ANDA is an act of infringement that technically fulfills the requirement that a claim of inducement recite a predicate act of infringement.

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infringement"; but analyzing only the requirement of intent and not setting forth any specific pleading requirements).

Plaintiffs urge the Court to adopt the reasoning in Smithkline Beecham Corp. v. Pentech Pharm., Inc., 2001 WL 184804 (N.D. Ill. Feb. 20, 2001), on the present motion. Indeed, Smithkline is strikingly similar to the present case; there, the district court granted a motion to amend where the plaintiffs had simply alleged that the inducers knowingly aided and abetted the direct infringer in filing its ANDA. The court in Smithkline, however, ended its analysis without addressing all of the requirements of Rule 8 of the Federal Rules of Civil Procedure.

Federal Rule of Civil Procedure 8(a) requires a "short and plain statement of the claim **showing that the pleader is entitled to relief.**" (emphasis added). See Burns v. AAF-McQuay, Inc., 980 F. Supp. 175, 179 (W.D. Va. 1997) (proper standard of review when amendment is challenged on grounds of futility is whether the proposed amendment states a claim upon which relief can be granted). If relief cannot be granted, the amendment is futile. See Hutsell v. Sayre, 5 F.3d 996 (6th Cir. 1993) (where court already determined that police officer was protected from liability under qualified immunity, amendment to add police officer as defendant in a § 1983 action would be futile).

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Plaintiffs seek the following relief against Quimica and Betachem:

1. A judgment that Quimica Sintetica and Betachem, Inc. have induced Mylan Pharmaceuticals, Inc. and Mylan Laboratories, Inc. to infringe the '407 Patent under 35 U.S.C. § 271(b).
2. A judgment declaring that the making, using, selling, offering to sell, or importing of bulk levofloxacin for use in manufacturing levofloxacin tablets would constitute infringement of the '407 patent, or inducing or contributing to such conduct, by Quimica Sintetica and Betachem, Inc. pursuant to 35 U.S.C. § 271(a), (b) and/or (c);
3. A judgment permanently enjoining Quimica Sintetica and Betachem, Inc. and each of their officers, agents, servants, and employees, and those persons in active concert or participation with any of them from manufacturing, using, selling, or offering to sell bulk levofloxacin in the U.S., or importing bulk levofloxacin into the U.S.

35 U.S.C. § 271(e)(4) states, however:

(4) For an act of infringement described in paragraph (2)--

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or

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veterinary biological product, and
(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285. [emphasis added]

Section (e)(4)(A) allows the Court to forestall FDA approval of the pharmaceutical that is the subject of the lawsuit until the valid patent expires. Plaintiffs do not ask for such relief against Quimica and Betachem, so this provision is not applicable here. The Court notes, however, that an attempt to include such a prayer for relief would be needlessly duplicative, as Plaintiffs have sought such relief in their pending claims against Mylan.

Section (e)(4)(B) permits the Court to enjoin a defendant from manufacturing, using, or selling an "approved drug"--not the "patented invention"--in the United States. Plaintiffs request that Quimica and Betachem be enjoined from selling bulk levofloxacin in the United States for commercial gain. There are two problems with this request. First, bulk levofloxacin is not the drug for which Mylan's ANDA seeks approval; therefore this remedy does not apply. Second, Plaintiffs seek to enjoin Quimica

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and Betachem from doing something they are not accused of doing--making commercial sales of bulk levofloxacin. The proposed Amended Complaint only alleges that Quimica and Betachem provided Mylan with raw materials for its ANDA preparations. This activity is excepted from infringement by 35 U.S.C. § 271(e)(1). Moreover, 35 U.S.C. § 271(e)(3) prevents the Court from crafting a narrower injunction to prevent such activity. Any possible equitable relief against Quimica and Betachem is therefore either speculative or barred by the statute.

Finally, because the parties agree that there have been no commercial sales of the alleged infringing levofloxacin tablets, the remedy of 35 U.S.C. § 271(e)(4)(C) is unavailable.

Conclusion.

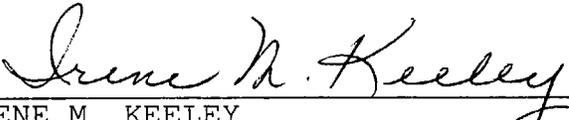
Because Plaintiffs' Amended Complaint does not, and cannot, state a ground for relief against Quimica Sintetica, S.A. and Betachem, Inc., as inducers under 35 U.S.C. § 271(b) for an act of infringement committed under 35 U.S.C. § 271(e)(2), their Motion to Amend is **DENIED**.

It is so **ORDERED**.

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The Clerk is directed to transmit copies of this Order to counsel of record herein.

DATED: March 31, 2003.



IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE