IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, WARNER-LAMBERT COMPANY, and WARNER-LAMBERT COMPANY LLC,	)	Case No. 08 C 7231
Plaintiffs,	)	Consolidated for all purposes with Case No. 09-cv-6053
v.	)	
APOTEX INC., and APOTEX CORP.,	)	Judge Robert M. Dow, Jr.
Defendants.	)	

PLAINTIFF PFIZER'S MOTION FOR RECONSIDERATION OF THE DISMISSAL OF PFIZER'S MOTION TO DISMISS DEFENDANT APOTEX'S COUNTERCLAIMS FOR FAILURE TO PROVIDE A *BONA FIDE* OFFER OF CONFIDENTIAL ACCESS

I. INTRODUCTION

Plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, and Warner-Lambert Company LLC (collectively "Pfizer" or "Plaintiffs") hereby move for reconsideration of the Court's Memorandum Opinion and Order [D.I. 144] ("MemoOp") denying Pfizer's motion to dismiss [D.I. 113] Counts III-VIII of Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex" or "Defendants") counterclaims for lack of subject matter jurisdiction. Pfizer respectfully requests reconsideration of the Court's dismissal "without prejudice" based on Apotex's failure to make the statutorily-required *bona fide* offer of confidential access ("OCA").[1]

[1] While Pfizer limits the instant motion for reconsideration to only the issue of whether the Court has subject matter jurisdiction based on Apotex's failure to provide a *bona fide* OCA, Pfizer preserves its right to appeal the dismissal of its motion to dismiss [D.I. 113] on all grounds when appropriate.

II. ARGUMENT

The Seventh Circuit instructs that motions for reconsideration serve the limited function to correct manifest errors of law or fact or to present newly discovered evidence. *Publishers Resource, Inc. v. Walker-Davis Publications, Inc.*, 762 F.2d 557, 561 (7th Cir. 1985). Here, reconsideration is appropriate to correct two errors: (1) the Court's factual error in finding that Apotex's OCA "*preliminarily* satisfied the requirement to make its offer of confidential access," MemoOp at 24 (emphasis added); and (2) the Court's legal error in allowing this acknowledged jurisdictional prerequisite to be satisfied retroactively.

A. The Court erred in finding Apotex's OCA preliminarily satisfied the statutory OCA jurisdictional prerequisite.

To bring a declaratory judgment action under § 355(j)(5)(C)(i), Apotex had the burden to provide a *bona fide* OCA to Pfizer. At least one Court has recognized that permitting an ANDA filer to impose onerous restrictions in its OCA would frustrate the purpose of the Hatch-Waxman Act statutory scheme and give generics the ability to withhold information about their ANDAs to prevent the branded company from filing suit within 45 days.[2] Apotex has done exactly that here.

The Court found a "dearth of authority addressing the propriety of restrictions imposed in offers of confidential access in the specific context of the Hatch-Waxman framework." MemoOp at 24. This is not surprising as the adequacy of an OCA is an inherently factual inquiry. Here the Court stated that it was "not clear from the briefing which particular attorneys Pfizer believes should be permitted to access Apotex's ANDA... ." *Id.* at 25. As stated in Pfizer's opening brief [D.I. 56 at 15-16], Apotex's OCA was clearly intended to do two things: (1) exclude *all* of Pfizer's in-house counsel—a fact the Court found was improper, MemoOp at 24-25 (citing *Matsushita Elec. Indus. Co., Ltd. v. United States*, 929 F.2d 1577, 1579 (Fed. Cir. 1991)); and (2)

[2] *See In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, 693 F. Supp.2d 409, 416-17 (D. Del. 2010)

exclude the undersigned Lipitor® counsel due to the patent prosecution bar—a fact well-known to Apotex.[3] Thus, Pfizer's most knowledgeable attorneys were intentionally denied access to Apotex's ANDA. These restrictions were not made in good faith and are objectively unreasonable. Such onerous restrictions would not be included in a protective order agreed to and entered into by the parties in an ANDA litigation, which is the statutory requirement.

The OCA requirement was added to the Hatch-Waxman Act declaratory judgment provisions via the MMA to eliminate situations like this. The statutory framework crafted by Congress allows an ANDA applicant to bring a declaratory judgment action for non-infringement if the patent owner does not bring suit within the 45 day period after receipt of the Paragraph IV notice letter, but only if the ANDA notice letter is accompanied by a *bona fide* OCA. *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)-(III). By requiring the ANDA applicant to provide an OCA at the time of the ANDA notice to the patent owner, Congress intended that the patent owner have access to the ANDA in order to evaluate whether to bring a patent infringement action against the ANDA applicant within the 45-day period. The burden is on the ANDA applicant in the first instance to provide a *bona fide* objectively reasonable OCA.

Here, Apotex's onerous OCA restrictions prevented Pfizer's most knowledgeable counsel access to Apotex's ANDA (a fact well-known to Apotex) and the ability to provide advice regarding Apotex's infringement of Pfizer's patents. In such circumstances, the balance struck by Congress was to deny declaratory judgment jurisdiction.

B. The Court committed legal error in permitting Apotex to retroactively fix an acknowledged jurisdictional requirement.

[3] Apotex is well-aware that Connolly Bove Lodge & Hutz LLP is the lawfirm prosecuting the reissue patent applications of Pfizer's 5,273,995 patent that are at issue in this litigation, as this information is publicly available from the United States Patent and Trademark Office records.

Having ruled that Apotex's OCA "preliminarily" satisfied the statutory OCA requirement despite its intentional and unreasonable restrictions, the Court committed legal error in allowing Apotex to retroactively satisfy the acknowledged jurisdictional requirement by correcting acknowledged material deficiencies. While the Court correctly found that the OCA is a jurisdictional prerequisite, MemoOp at 23 (citing *Apotex, Inc. v. Novartis AG*, 2007 WL 5493499, at *3; 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc); and § 355(j)(5)(C)(i)(III)), the Court incorrectly concluded that the adequacy of Apotex's offer "does not provide grounds for the dismissal of Apotex's counterclaims, *at least in the first instance*", MemoOp at 25 (emphasis added). To the contrary, Apotex's failure to provide a *bona fide* OCA deprives the Court of jurisdiction to hear the counterclaims under the Hatch-Waxman Act. The Court's proposed remedy—entering a negotiated protective order—cannot correct this failure of jurisdiction at the relevant time.

First, it is well-settled that a failure of subject matter jurisdiction at the time an action is filed cannot be corrected afterwards. *See GAF Building Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479, 483 (Fed. Cir. 1996) (holding that later events may not create jurisdiction where none existed at the time of filing) (citations omitted). Congress defines the jurisdiction of the lower federal courts, *see Finley v. United States*, 490 U.S. 545, 548 (1989), and, once the lines are drawn, "limits upon federal jurisdiction ... must be neither disregarded nor evaded," *Owen Equipment & Erection Co. v. Kroger*, 437 U.S. 365, 374 (1978). Here, Congress defined the jurisdictional prerequisites for Apotex to bring a declaratory action against Pfizer in connection with Apotex's ANDA. The requirement was that Apotex provide a *bona fide* OCA to Pfizer *before* initiating its declaratory judgment action. *See* 21 U.S.C. § 355(j)(5)(C)(i)(I) (stating that no action may be brought under 28 U.S.C. § 2201 unless the ANDA applicant provides, *inter*

alia, an OCA). The Court's decision to grant Apotex a "do-over" with its deficient OCA while maintaining jurisdiction over Apotex's declaratory judgment claims is plainly contrary to the purpose and intent of the Hatch-Waxman statutory scheme.

Second, negotiating a protective order *after* Apotex has initiated its declaratory judgment action against Pfizer eviscerates the jurisdictional requirement of § 355(j)(5)(C)(i)(I)(cc). The Court found the statute to be a jurisdictional prerequisite. MemoOp at 23 (citations omitted). The Court's solution to order the parties to negotiate a protective order now, does not remedy the fact that Apotex's illusory OCA defeated the statutory requirement to offer Pfizer *bona fide* access to Apotex's ANDA *before* Apotex could be permitted to bring a declaratory action. The Court's own conclusion about what Apotex will now do—calling failure to craft an appropriate protective order an "unlikely event"—perfectly illustrates the inexcusable failure of Apotex to be reasonable in the OCA that actually accompanied their ANDA notice. Indeed, one can scarcely imagine Apotex failing now to come to terms on a protective order when failure to do so could cause dismissal of its counterclaims. But the statute does not require negotiation, it requires the ANDA filer unilaterally to provide a *bona fide* OCA with its ANDA notice letter, because the patent owner has only 45 days to obtain the ANDA, review it and come to a decision as to whether to bring suit. The Court's remedy is simply not part of the Hatch-Waxman Act statutory scheme. Accordingly, the Court's ruling was improper as a matter of law.

Further, if allowed to stand, this ruling will serve as precedent for future ANDA applicants to make illusory OCAs that deny patent holders their right to any effective counsel, yet still permit the ANDA applicants to bring declaratory judgment actions against patent holders. The potential for mischief by future ANDA applicants is self-evident. Thus, as a matter

of public policy and statutory construction, the Court should dismiss Apotex's declaratory judgment claims for failure to provide a *bona fide* offer of confidential access.

III. CONCLUSION

For all the above reasons, Pfizer respectfully requests reconsideration of Pfizer's motion to dismiss [D.I. 113]. For the reasons above, Apotex's declaratory judgment counterclaims should be dismissed.

RESPECTFULLY SUBMITTED,

/s/John S. Mortimer
John S. Mortimer
jsmortimer@woodphillips.com
Jeffrey M. Drake
jmdrake@woodphillips.com
WOOD PHILLIPS
500 West Madison Street
Suite 3800
Chicago, IL 60661-2562
(312) 876-1800

OF COUNSEL:
Rudolf E. Hutz
Jeffrey B. Bove
Mary W. Bourke
Daniel C. Mulveny
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street
Wilmington, DE 19899
(302) 658-9141

William E. McShane
CONNOLLY BOVE LODGE & HUTZ LLP
1875 Eye Street, NW
Suite 1100
Washington, DC 20006
(202) 572-0335

Attorneys for Plaintiffs Pfizer Inc., Pfizer Ireland Pharmaceuticals, and Warner-Lambert Company LLC, formerly Warner-Lambert Company

CERTIFICATE OF SERVICE

I, John S. Mortimer, caused to be served a copy of the foregoing:

PLAINTIFF PFIZER'S MOTION FOR RECONSIDERATION OF THE DISMISSAL OF PFIZER'S MOTION TO DISMISS DEFENDANT APOTEX'S COUNTERCLAIMS FOR FAILURE TO PROVIDE A *BONA FIDE* OFFER OF CONFIDENTIAL ACCESS

by filing same with the Clerk of the Court using the CM/ECF system which will send electronic notification of such filing to the following counsel of record:

William A. Rakoczy
Andrew M. Alul
Rakoczy Molino Mazzochi Siwik, LLP
6 West Hubbard Street
Suite 500
Chicago Illinois 60654

Attorneys for Defendants Apotex Inc. and Apotex Corp.

/s/John S. Mortimer