

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: CYCLOBENZAPRINE)
HYDROCHLORIDE EXTENDED-) Civ. No. 09-MD-2118-SLR
RELEASE CAPSULE PATENT)
LITIGATION)
)

MEMORANDUM ORDER

At Wilmington this 24th day of May, 2011, having reviewed the motion for reconsideration filed by defendants Mylan Pharmaceuticals, Inc. and Mylan Inc. (collectively, "Mylan"), whereby Mylan seeks reconsideration of the court's order granting plaintiffs' motion for a temporary restraining order ("TRO") (D.I. 273);

IT IS ORDERED that said motion (D.I. 275) is denied, as follows:

1. **Background.** I incorporate by reference the background section of my memorandum order of May 20, 2011. In that order, I granted plaintiffs' motion to enjoin Mylan from manufacturing, using, offering to sell, or selling generic extended release cyclobenzaprine products, on the conditions that plaintiffs seek an expedited appeal and remove their authorized generic from the market. (D.I. 256) Plaintiffs agreed to these conditions in a letter to the court that same day. (D.I. 274) The parties were further ordered to submit to the court a proposed form of order by Monday, May 23, 2011. (*Id.*)

2. **Legal standard.** The purpose of a motion for reargument or reconsideration is to correct manifest errors of law or fact or to present newly discovered evidence. *Max's Seafood Café ex rel. Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir.

1999). Accordingly, a court should alter or amend its judgment only if the movant demonstrates at least one of the following: (1) a change in the controlling law; (2) availability of new evidence not available when the court issued its order; or (3) a need to correct a clear error of law or fact or to prevent manifest injustice. *See Id.*; *see also*, *Schering Corp. v. Amgen, Inc.*, 25 F. Supp. 2d 293, 295 (D. Del. 1998).

3. A motion for reargument is not properly premised on a request that a court rethink a decision already made. *Glendon Energy Co. v. Borough of Glendon*, 836 F. Supp. 1109, 1122 (E.D. Pa. 1993). Motions for reargument may not be used “to argue new facts or issues that inexcusably were not presented to the court in the matter previously decided.” *Brambles USA, Inc., v. Blocker*, 735 F. Supp. 1239, 1240 (D. Del. 1990). Reargument, however, may be appropriate where “the court has patently misunderstood a party, or has made a decision outside the adversarial issues presented to the court by the parties, or has made an error not of reasoning but of apprehension.” *Id.* at 1241.

4. **Discussion.** In its motion for reconsideration, Mylan argues that the court erroneously granted plaintiffs’ motion for a TRO despite the fact that the court did not find that plaintiffs had shown a likelihood of success on the merits, and that the court had given too little weight to defendants’ irreparable harm. (D.I. 275)

5. **Likelihood of success on the merits.** I credited plaintiffs with this factor, as it was “just as likely as not” that plaintiffs would prevail on appeal. Defendants argue that I erred in so concluding, in that a showing of a likelihood of success on the merits is a prerequisite for issuing a TRO. (*Id.* at 1-2) I agree with defendants’ argument in the

normal course, i.e., when I am asked at the commencement of a case to evaluate its merits, to predict what its outcome might be after adjudication before me, and to grant relief before the non-moving party has had the opportunity to fully explore its defenses.

6. Under the circumstances at bar, however, I conclude that this factor switches from having a gate-keeping function to simply being one of the four factors to be considered when granting or denying an injunction. First, a grant of a TRO post-trial merely preserves the status quo pending appeal; it does not change the status quo as it would at the commencement of a case. Moreover, now that a trial record has been created wherein each party has presented substantial evidence, to evaluate the likelihood of success on appeal would require me to predict how my analysis of the record will play in the Federal Circuit. From a realistic standpoint, the record on appeal looks very different from the record during its creation: The lawyers have refined their arguments; there are multiple eyes scouring the record for error; the Federal Circuit is reviewing *de novo*, as a matter of law, many of the issues presented. Indeed, it makes no sense to me to give this factor more weight than the other factors which can be ascertained and evaluated with some degree of certainty.

7. The above view of the likelihood of success on the merits tracks with Federal Circuit case law. In *Eli Lilly and Co. v. Actavis Elizabeth LLC*, Civ. No. 2010-1500, 2010 WL 3374123, at *1 (Fed. Cir. Aug. 31, 2010), a case in which plaintiffs sought to obtain an injunction pending appeal, the Federal Circuit reasoned that “[t]o obtain a stay or injunction, **pending appeal**, a movant must establish a strong likelihood of success on the merits, or **failing that**, nonetheless demonstrate a substantial case on the merits

provided that the **harm factors militate in its favor.**" While I stand by my decision, plaintiffs certainly presented a substantial case.

8. In contrast, instances where the Federal Circuit required a movant to establish a likelihood of success on the merits occurred at a very early stage of litigation. In *PHG Techs., LLC v. St. John Cos.*, 469 F.3d 1361, 1364 (Fed. Cir. 2007), the defendant appealed a district court's grant of an injunction that was filed by plaintiff only two weeks after initiating suit. The Federal Circuit held that "[o]ur case law and logic both require that a movant cannot be granted a preliminary injunction unless it establishes both of the first two factors, *i.e.*, likelihood of success on the merits and irreparable harm." *Id.* (citations omitted).

9. **Balancing harms.** Mylan will suffer harm from the issuance of a TRO. However, Mylan's harm is not as substantial as the harm to plaintiffs if the court denies said order, for the reasons stated in my earlier order. Compounding this issue is the fact that Mylan brought the harm on itself. Mylan did not need to launch its generic upon the issuance of the court's opinion, and could have preserved its 180 day exclusivity period throughout the appeal to the Federal Circuit.¹ I am sympathetic to Mylan but, ultimately, this factor favors plaintiffs and will be further addressed through

¹With respect to the forfeiture of the 180 day exclusivity, 35 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(A) states that the 75 day window in which a generic must market its product or it will forfeit exclusivity does not apply until,

[i]n an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

the conditions of the TRO, including the aforementioned and the posting of a bond should Mylan prevail on appeal.

10. **Conclusion.** For the reasons stated herein, as well as in the court's order dated May 20, 2011, Mylan's motion for reconsideration (D.I. 275) is denied. Plaintiffs' motion for a TRO (D.I. 256) is granted. Plaintiffs' motion to alter judgment (D.I. 270) is denied, in order to expedite the appeal process.



United States District Judge