IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: CYCLOBENZAPRINE HYDROCHLORIDE EXTENDED-RELEASE CAPSULE PATENT LITIGATION	)	C.A. No. 09-md-2118-SLR
	)	**JURY TRIAL DEMANDED**
EURAND, INC., CEPHALON, INC. and ANESTA AG, Plaintiffs, v. MYLAN PHARMACEUTICALS INC., MYLAN INC., and BARR LABORATORIES, INC., Defendants.	)	C.A. No. 08-889-SLR

MYLAN'S EMERGENCY MOTION FOR
RECONSIDERATION OF MAY 20 MEMORANDUM ORDER

Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. ("Mylan") respectfully seek emergency reconsideration of the Court's May 20, 2011 Memorandum Order (D.I. 273) conditionally granting Plaintiffs' motion for a temporary restraining order because the Court committed fundamental, material errors of law in that Order.

As the Court recognized, plaintiffs must demonstrate four elements – including "a likelihood of success on the merits" – to obtain a TRO. D.I. 273 at 2. The Court also correctly recognized that "'[f]ailure to establish any element in [plaintiffs'] favor renders a preliminary injunction inappropriate.'" D.I. 273 at 2 (quoting *NutraSweet Co. v. Tiv-Mar Enters., Inc.*, 176 F.3d 151, 153 (3d Cir. 1999) (emphasis added)). The Court, however, did not find that Plaintiffs were likely to succeed on the merits but rather that "plaintiffs' success on appeal is just as likely

as not." D.I. 273 at 6. As a matter of law, this sort of 50-50 assessment is insufficient to establish a likelihood of success and destroys the basis for the TRO.[1]

This legal error is particularly fundamental given that the Court addressed and rejected in its Order every single attack that Plaintiffs leveled on its invalidity opinion as grounds for reversal. D.I. 273 at 3-6. Given the Court's previous comprehensive Opinion finding by clear and convincing evidence that Plaintiffs' patents are invalid, coupled with the clarifications in its May 20 Order and the Court's determination that the points raised were immaterial, Plaintiffs simply cannot establish – and this Court cannot, consistent with its decision, find – that they are more likely than not to reverse this invalidity determination on appeal.

The Court also fundamentally erred in characterizing the harm to Mylan from the loss of its 180-day exclusivity period as "minimal." D.I. 273 at 6. This is a highly valuable statutory right the loss of which courts have repeatedly recognized is irreparable. For example, one decision described that harm as follows:

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[1] *See, e.g., Am. Republic Ins. Co. v. Great-West Life & Annuity Ins. Co.*, No. 09-2857, 2010 U.S. Dist. LEXIS 21885, at *10-11 (D. Colo. Feb. 17, 2010) (finding where "[i]t is at least equally likely" that defendants will prevail on claim, "plaintiff has failed to show a substantial likelihood of success" on that claim (emphasis added)). *See also Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1364 (Fed. Cir. 1997) ("In order to demonstrate that it has a likelihood of success, Genentech must show that, in light of the presumptions and burdens that will inhere at trial on the merits . . . its infringement claim will likely withstand Novo's challenges to the validity and enforceability of the '199 patent."); *Greenwich Collieries v. Dir., Office of Workers' Comp. Programs*, 990 F.2d 730, 736 (3d Cir. 1993) ("Allowing a claimant, who bears the ultimate burden of persuasion, to prevail when the evidence is in equipoise is tantamount to allowing that claimant to prevail despite having failed to carry his burden by a preponderance of the evidence." (emphasis added)); *Precision Med., Inc. v. Genstar Techs. Co.*, No. 10-5161, 2011 U.S. Dist. LEXIS 48406, at *7-8 (E.D. Pa. May 3, 2011) ("To demonstrate a likelihood of success on the merits, the patentee must show that it . . . will likely survive a validity challenge posed by the alleged infringer." (emphasis added)); *Research Found. of State Univ. of N.Y. v. Mylan Pharms., Inc.*, 723 F. Supp. 2d 638, 652 (D. Del. 2010) ("[I]t is the patentee, the movant, who must persuade the court that, despite the challenge presented to validity, the patentee nevertheless is likely to succeed at trial on the validity issue." (citing *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1377 (Fed. Cir. 2009))).

> [Intervenor-defendants] Teva and Ranbaxy are . . . entitled to enjoy a 180-day period of generic marketing exclusivity. . . . [U]nlike the harm that Apotex allegedly faces, the potential injury that the intervenor-defendants [Teva and Ranbaxy] face is not "merely economic." Rather, they stand to lose a statutory entitlement [to 180-day generic exclusivity], which is a harm that has been recognized as sufficiently irreparable. Once the statutory entitlement has been lost, it cannot be recaptured.

Apotex, Inc. v. FDA, No. Civ. A. 06-0627 JDB, 2006 WL 1030151, at *17 (D.D.C. Apr. 19, 2006) (emphasis added; citation omitted). Another decision similarly recognizes the irreparable harm that results from loss of the 180-day exclusivity period:

> [E]ntry of an injunction would deprive Ivax of the exclusivity to which it is entitled and millions of dollars a day. Once the statutory entitlement has been lost, it cannot be recaptured. Moreover, entry of an order barring intervenor-defendants from marketing their generic simvastatin product would preclude them from fulfilling the contracts they have negotiated with major simvastatin purchasers, and which they have begun to fulfill. That would not only undercut intervenor-defendants' ability to negotiate additional long-term contracts, but could also potentially harm intervenor-defendants by destroying goodwill and impairing their future access to major customers.

Sandoz, Inc. v. FDA, 439 F. Supp. 2d 26, 32-33 (D.D.C. 2006) (citations omitted); *accord Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 n.6 (D.C. Cir. 1998) ("Here, however, the district court found that Mova would be harmed by the loss of its 'officially sanctioned heard start' . . . ."); *see also Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 29 (D.D.C. 1997) ("[T]here is a significant economic advantage to receiving first approval and being the first company to enter the market, an advantage that can never be fully recouped through money damages or by 'playing catch-up.'"). At a bare minimum, it is erroneous to conclude that the alleged harm to Plaintiffs – after they voluntarily authorized the launch of an authorized generic by a third party – somehow outweighs the harm to Mylan in a manner that would justify the extraordinary relief provided by a TRO.

Moreover, Mylan should not be penalized for deciding to lawfully launch when it did. Unlike cases such as the *AstraZeneca* case so heavily relied upon by Plaintiffs, Mylan did not launch until after this Court ruled that Plaintiffs' patents were invalid by clear and convincing evidence, thus automatically extinguishing the previously entered injunction. Significantly, Plaintiffs filed no pre-decision request to extend that injunction. There can be no infringement of invalid patents.

Finally, the Court's Order reverses – rather than preserves – the status quo expressly permitted by its invalidity Opinion with no explanation of how Plaintiffs demonstrated any right to a TRO under the much more difficult standard applicable to mandatory (rather than prohibitory) injunctive relief.

Mylan urgently requests a telephonic hearing this afternoon to address this matter.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on May 20, 2011, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on May 20, 2011, the attached document was Electronically Mailed to the following person(s):

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