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,	)	C.A. No. 08-889-SLR
v.	)	
MYLAN PHARMACEUTICALS INC., MYLAN INC., and BARR LABORATORIES, INC.,	)	
Defendants.	)	

MYLAN'S SUPPLEMENTAL MEMORANDUM
FOLLOWING THE MAY 23, 2011 HEARING

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Dated: May 24, 2011
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Defendants Mylan Pharmaceutical Inc. and Mylan Inc. ("Mylan") respectfully submit this supplemental memorandum following the May 23, 2011 hearing to address the following points:

- It is reversible error to enter an injunction absent a finding that Plaintiffs are more likely than not to succeed in overturning this Court's invalidity determination.
- Given the U.S. Court of Appeals for the Federal Circuit's high affirmance rate on obviousness determinations, it is highly unlikely that this Court's well-reasoned Opinion will get reversed on appeal.
- An injunction against Mylan would thwart the Hatch-Waxman Act's goal of accelerating consumer access to lower-priced, high-quality generic drug products.
- Even if the Federal Circuit agrees to expedite an appeal of any injunction, the appeal would likely outlast Mylan's entire 180-day exclusivity period.

I. PLAINTIFFS' FAILURE TO ESTABLISH A LIKELIHOOD OF SUCCESS IN REVERSING THE COURT'S INVALIDITY DETERMINATION DESTROYS THE BASIS FOR ANY INJUNCTION AGAINST MYLAN – REGARDLESS OF THE BALANCE OF HARMS.

Despite Plaintiffs' attempt to "mush up" the preliminary injunction factors,[1] the Court may not simply balance harms in considering the extraordinary remedy of injunctive relief. Rather, it must first find that Plaintiffs have shown that they are more likely than not to obtain a reversal of this Court's invalidity determination on appeal. Absent this critical showing – which Plaintiffs have not made – the requested injunction must be denied before harm to the parties is even considered.[2] Indeed, any other outcome would be reversible error.

[1] In this regard, Plaintiffs rely on the partially reversed *Union Carbide Chemicals & Plastics Tech. Corp. v. Shell Oil Co.* decision, No. Civ. 99-CV-274-SLR, Civ. 99-846-SLR, 2004 WL 1305849, at *21 (D. Del. June 9, 2004), *rev'd in part & vacated in part*, 425 F.3d 1366 (Fed. Cir. 2005). That case, however, cited the test for determining whether a stay of an injunction pending appeal – rather than an injunction itself – is proper. *See id.* at *21 ("Shell seeks a stay of this injunction pending resolution of Shell's anticipated appeal to the Federal Circuit.").

[2] Plaintiffs fault Mylan for not reciting the standard for reconsideration, but even Plaintiffs acknowledge that reconsideration is appropriate where there is "[a] need to correct a clear error of law or fact or to prevent manifest injustice." D.I. 277 at 3 (citing *Max's Seafood Cafe v.*

In both the Federal and Third Circuits, case law is uniform that without proof of a likelihood of success, a district court must deny an injunction request – no matter how the other factors are weighed. For example, in a particularly explicit admonition, the Federal Circuit has cautioned that:

> A movant seeking a preliminary injunction must establish a reasonable likelihood of success on the merits both with respect to validity and infringement of its patent. . . . . [A] movant cannot be granted a preliminary injunction without findings by the district court that the movant carried its burden on both factors.
>
> . . . [I]rrespective of relative or public harms, a movant must establish both a likelihood of success on the merits and irreparable harm . . . .

Reebok Int'l Ltd. v. J. Baker, Inc., 32 F.3d 1552, 1555-56 (Fed. Cir. 1994) (emphasis added).

Other decisions repeatedly have affirmed this bedrock principle. *See, e.g.*, *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001) ("Our 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."); *PHG Techs., LLC v. St. John Cos., Inc.*, 469 F.3d 1361, 1369 (Fed. Cir. 2007) ("Because PHG has not established that at least the first preliminary injunction factor – likelihood of success on the merits – weighs in its favor, the district court abused its discretion in granting PHG's motion for a preliminary injunction." (citation omitted)); *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009) ("With regard to the first factor-establishing a likelihood of success on the merits-the patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement, and that it will likely withstand challenges, if any, to the validity of the patent."); *id.* at 1380 (observing that injunction "test places the burden

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Quinteros, 176 F.3d 669, 677 (3d Cir. 1999)). Mylan identified precisely such clear errors of law, including the grant of injunctive relief in the absence of a finding that Plaintiffs were more likely than not to succeed in reversing this Court's invalidity determination.

on the plaintiff to prove likelihood of success."); *NutraSweet Co. v. Tiv-Mar Enters., Inc.*, 176 F.3d 151, 153 (3d Cir. 1999) ("[F]ailure to establish any element in [plaintiffs'] favor renders a preliminary injunction inappropriate.").

Of course, "likelihood of success" in a patent case encompasses validity. *See Amazon.com*, 239 F.3d at 1359 ("When moving for the extraordinary relief of a preliminary injunction," a "patentee must . . . present a clear case supporting the validity of the patent in suit."); *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1351 (Fed. Cir. 2000) ("A patent holder seeking a preliminary injunction bears the burden of establishing a likelihood of success on the merits with respect to the patent's validity." (emphasis added)).

Importantly, the court need not even reach the other factors if it finds that the movant has not established a likelihood of success:

> While a district court must consider all four factors before granting a preliminary injunction to determine whether the moving party has carried its burden of establishing each of the four, we specifically decline today to require a district court to articulate findings on the third and fourth factors when the court denies a preliminary injunction because a party fails to either of the two critical factors.

Reebok Int'l, 32 F.3d at 1556; *see also id.* ("[A] district court may properly deny a motion for preliminary injunction simply based on the movant's failure to establish a reasonable likelihood of success on the merits . . . .").

Even in the preliminary injunction context – where patents are presumed valid[3] and no validity determination has been made – courts routinely deny preliminary injunctions where the non-movant raises even a substantial question regarding the patent's invalidity that the patentee cannot prove lacks substantial merit:

[3] *See, e.g.*, *Titan Tire*, 566 F.3d at 1377 ("[T]he patent enjoys the same presumption of validity during preliminary injunction proceedings as at other stages of litigation.").

> If [an accused infringer] raises a substantial question concerning either infringement or validity, *i.e.*, asserts an infringement or invalidity defense that the patentee cannot prove 'lacks substantial merit,' the preliminary injunction should not issue.

Amazon.com, 239 F.3d at 1351; *accord id.* at 1360 (finding that accused infringer had "cast enough doubt on the validity of the [asserted] patent to avoid a preliminary injunction"); *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1005-06 (Fed. Cir. 2009) ("A patent holder seeking a preliminary injunction bears the ultimate burden of establishing a likelihood of success on the merits with respect to the patent's validity. If the alleged infringer raises a 'substantial question' of invalidity, the preliminary injunction should not issue."); *PHG Techs.*, 469 F.3d at 1365 ("[I]n order to defeat the injunction on grounds of potential invalidity, St. John, as the party bearing the burden of proof on the issue at trial, must establish a substantial question of invalidity."). As the Federal Circuit has observed, the trial court:

> must determine whether it is more likely than not that the challenger will be able to prove at trial, by clear and convincing evidence, that the patent is invalid. … <u>If the trial court is persuaded, then it follows that the patentee by definition has not been able to show a likelihood of success at trial on the merits of the validity issue, at least not at this stage</u>.

Titan Tire, 566 F.3d at 1379-80 (emphasis added).

Significantly, this case is no longer in its preliminary stages, where patent validity has not yet been fully considered. Rather, the Court has held a 7-day bench trial, issued a 42-page Opinion invalidating Plaintiffs' asserted patented claims (D.I. 254), and confirmed that Opinion – rejecting every challenge brought by Plaintiffs – in a supplemental clarification issued in its May 20, 2011 Memorandum Order (D.I. 273). Thus, Mylan has shown far more than a "substantial question" of patent invalidity – it has actually succeeded at trial in obtaining a final invalidity determination. *See Altana Pharma*, 566 F.3d at 1006 ("The burden on the accused

infringer to show a substantial question of invalidity at this stage is lower than what is required to prove invalidity at trial." (emphasis added)).

In a particularly revealing case, where, as here, a final invalidity determination had been reached, a district court granted summary judgment of invalidity in favor of the accused infringer and then denied the patentee's motion for a preliminary injunction pending appeal. *See Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1341 (Fed. Cir. 2000). On appeal, the Federal Circuit reversed the court's invalidity determination but nonetheless affirmed the court's denial of a preliminary injunction, specifically explaining that:

> [A]lthough the record before us does not support the district court's grant of summary judgment, it does raise a substantial question of patent invalidity. For that reason, we see no clear error in the finding of the district court that, in the face of Blok-Lok's challenge to the validity of the '801 patent, Helifix could not establish a likelihood of success on the merits.

Id. at 1352. Thus, even in the unlikely event that the Federal Circuit reverses this Court's invalidity determination, Mylan has demonstrated far more than a "substantial question" of patent validity, which suffices as a matter of law to defeat Plaintiffs' proposed injunction.

It would be reversible error for this Court to enter an injunction despite having found that Mylan had established invalidity by clear and convincing evidence at trial when the law clearly provides that the far lower standard of merely raising a "substantial question" of invalidity suffices – without more – to defeat an injunction. This is particularly true given that the only challenges leveled by Plaintiffs are factual, not legal, so a much more deferential review standard applies. *Compare Natron Corp. v. Schkura U.S.A., Inc.*, 558 F.3d 1352, 1355 (Fed. Cir. 2009) ("We review summary judgment determinations *de novo*.") *with Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004) (explaining that the obviousness determination rests on "various factual findings that this court reviews for clear error following a bench trial" (citations omitted)).

The Court's invalidity determination was comprehensive and sound, and the Court clarified that Opinion in its May 20, 2011 Memorandum Order. D.I. 273. Especially in light of the almost non-existent reversal rate of obviousness determinations discussed in Part II below, the Court's invalidity decision is highly likely to be affirmed. Respectfully, it would simply not be plausible for the Court, having invalidated those patents scarcely two weeks ago, now to conclude that Plaintiffs have shown that they are likely to succeed on the merits on appeal based on the same law and facts that led to the Court's original invalidity decision in the first place.

Plaintiffs simply cannot demonstrate a likelihood of success in this case given its posture.[4] That failure defeats their requested injunction as a matter of law.

II. TRIAL DECISIONS REGARDING OBVIOUSNESS ARE RARELY OVERTURNED.

Actual recent appeal statistics in cases involving obviousness determinations further establish that reversal of the Court's obviousness determination is highly unlikely. To the contrary, there have been at least 35 reported Federal Circuit decisions since 2009 addressing trial decisions related to obviousness, and the Federal Circuit affirmed the trial decision finding either obviousness[5] or nonobviousness[6] in 26 of them.[7] In another six cases, the Federal Circuit

[4] Plaintiffs' reliance on the nonprecedential *Eli Lilly* case does not help them. *See Eli Lilly & Co. v. Actavis Elizabeth LLC*, No. 2010-1500, 2010 WL 3374123, at *1 (Fed. Cir. Aug. 26, 2010). Unlike this case, the *Eli Lilly* court ruled that: (i) the asserted claims were infringed; (ii) the asserted claims were novel, nonobvious, and enabled; and (iii) the patent was not unenforceable due to inequitable conduct. *See Eli Lilly and Co. v. Actavis Elizabeth LLC*, 731 F. Supp. 2d 348 (D.N.J. 2010). The district court rested its invalidity decision on one aspect of the utility requirement, for which the district court thought "[t]here was little guidance in the case law" on the issue. *Id.* at 380. In the present case, there is a wealth of precedential guidance concerning obviousness.

[5] *See, e.g., Purdue Pharma Prods v. Par Pharm., Inc.*, 377 F. App'x 978 (Fed. Cir. 2010) (affirming bench trial determination of obviousness); *Verizon Servs. Corp. v. Cox Fibernet Virginia, Inc.*, 602 F.3d 1325 (Fed. Cir. 2010) (affirming jury verdict of obviousness); *Siemens AG v. Seagate Tech.*, 369 F. App'x, 118 (Fed. Cir. 2010) (affirming jury verdict of nonobviousness); *Alloc., Inc. v. Pergo, Inc.*, 366 F. App'x 173 (Fed. Cir. 2010) (affirming jury

overturned a nonobviousness verdict and held the claims to be obvious.[8] Only in three cases (8.5%) did the Federal Circuit overturn a trial court's determination that claims were obvious.[9]

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verdict of obviousness); *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1289 (Fed. Cir. 2010) (affirming bench trial of obviousness); *Therasense, Inc., v. Becton, Dickinson & Co.*, 593 F.3d 1325 (Fed. Cir. 2010) (affirming jury verdict on obviousness grounds), *vacated on other grounds*, 374 F. App'x 35 (Fed. Cir. 2010); *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288 (Fed. Cir. 2009) (affirming jury verdict of obviousness for 7 claims, affirming district court JMOL on obviousness verdict for 6 claims); *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341 (Fed. Cir. 2009) (affirming bench trial of obviousness); *Monolithic Power Sys., Inc. v. O2 Micro Int'l Ltd.*, 558 F.3d 1341 (Fed. Cir. 2009) (affirming jury verdict of obviousness); *Rothman v. Target Corp.*, 556 F.3d 1310 (Fed. Cir. 2009) (affirming jury verdict of obviousness).

[6] *See, e.g., In re Brimonidine Patent Litig.*, No. 2010-1102, 2011 WL 1898206 (Fed. Cir. May 19, 2011) (after bench trial, Federal Circuit overturned nonobviousness on 1 patent, affirmed nonobviousness on 4 patents); *Hynix Semiconductor, Inc. v. Rambus Inc.*, No. 2009-1299, 2011 WL 1815978 (Fed. Cir. May 13, 2011) (affirming jury verdict of nonobviousness); *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1323 (Fed. Cir. 2011) (affirming jury verdict of nonobviousness); *Daiichi Sankyo Co., v. Mylan Inc.*, 619 F.3d 1346 (Fed. Cir. 2010) (affirming bench trial of nonobviousness); *Spine Solutions, Inc., v. Medtronic Sofamore Danek USA, Inc.*, 620 F.3d 1305 (Fed. Cir. 2010) (affirming jury verdict of nonobviousness); *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 619 F.3d 1329 (Fed. Cir. 2010) (affirming bench trial of nonobviousness); *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357 (Fed. Cir. 2010) (affirming jury verdict of nonobviousness); *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343 (Fed. Cir. 2010) (affirming jury verdict of nonobviousness); *Applera Corp.-Applied Biosystems Group v. Illumina, Inc.*, 375 F. App'x 12 (Fed. Cir. 2010) (affirming jury verdict of nonobviousness); *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831 (Fed. Cir. 2010) (affirming jury verdict of nonobviousness); *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860 (Fed. Cir. 2010) (affirming jury verdict of nonobviousness); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301 (Fed. Cir. 2009) (affirming jury verdict of nonobviousness); *Gemtron Corp. v. Saint-Gobain Corp.*, 572 F.3d 1371 (Fed. Cir. 2009) (affirming jury verdict of non-obviousness); *Procter & Gamble Co. v. Teva Pharms., USA, Inc.*, 566 F.3d 989 (Fed. Cir. 2009) (affirming bench trial of nonobviousness); *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319 (Fed. Cir. 2009) (affirming jury verdict of nonobviousness); *Kinetic Concepts, Inc. v. Blue Sky Med. Group, Inc.*, 554 F.3d 1010 (Fed. Cir. 2009) (affirming jury verdict of nonobviousness).

[7] These decisions include bench trials reviewed under clear error and jury trials reviewed under substantial evidence standards. Summary judgment decisions were not included.

[8] *See, e.g., Western Union Co. v. Moneygram Payment Sys., Inc.*, 626 F.3d 1361 (Fed. Cir. 2010) (overturning jury determination of nonobviousness); *Wyers v. Master Lock Co.*, 616 F.3d 1231 (Fed. Cir. 2010) (reversing jury determination of nonobviousness); *Ritchie v. Vast Resources, Inc.*, 563 F.3d 1334 (Fed. Cir. 2009) (reversing bench trial of nonobviousness); *Boston Scientific Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982 (Fed. Cir. 2009) (reversing jury determination of

Two of those cases were overturned because the Federal Circuit modified the district court's claim construction – a concern not at issue here. Mylan located only a single case since 2009 in which the Federal Circuit overturned a trial decision on the basis of factual determinations. This overwhelming affirmance track record further confirms that Plaintiffs will be highly unlikely to succeed in reversing the Court's invalidity determination.[10]

III. ENJOINING MYLAN WOULD THWART THE HATCH-WAXMAN ACT'S GOALS OF ENCOURAGING CHALLENGES TO INVALID PATENTS AND ACCELERATING ACCESS TO LOWER-PRICED GENERIC DRUGS.

Above and beyond Plaintiffs' failure to establish a likelihood of success, they have wholly failed to explain how the irreparable harm that Mylan would suffer from an injunction by the loss of some or all of its statutory 180-day exclusivity period is at all consistent with Congress's objectives in enacting the Hatch-Waxman Act.[11] To the contrary, such an injunction at this stage in the case would contravene the Act's objective of encouraging the development – and availability – of lower-cost pharmaceuticals when related patents are shown to be invalid.

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nonobviousness); *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331 (Fed. Cir. 2009) (overturning jury nonobviousness verdict based on purported inconsistencies); *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335 (Fed. Cir. 2009) (overturning jury verdict of nonobviousness).

[9] *See, e.g.*, *Hologic, Inc. v. Senorx, Inc.*, No. 2010-1235, 2011 WL 651791 (Fed. Cir. Feb. 24, 2011) (jury verdict of obviousness overturned due to improper claim construction); *Honeywell Int'l, Inc. v. United States*, 609 F.3d 1292 (Fed. Cir. 2010) (overturning obviousness bench trial determination on claim construction grounds); *Crocs, Inc. v. ITC*, 598 F.3d 1294 (Fed. Cir. 2010) (overturning obviousness bench trial).

[10] This review did not include any cases in which the Federal Circuit summarily affirmed under Fed. R. App. Proc. 36. Inclusion of any such cases would make the affirmance rate even higher.

[11] "Hatch-Waxman Act" refers collectively to the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271), as amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

With the Hatch-Waxman Act, "Congress sought to get generic drugs into the hands of patients at reasonable prices-fast." *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). Courts recognize the value of the 180-day exclusivity period earned by the first generic company to file an Abbreviated New Drug Application ("ANDA") challenging the applicability of the branded company's patents. *See Apotex, Inc. v. FDA*, No. Civ. A. 06-0627 JDB, 2006 WL 1030151, at *17 (D.D.C. Apr. 19, 2006) ("[ANDA applicants] 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" (emphasis added; citation omitted)); *Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26, 32-33 (D.D.C. 2006) ("[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." (citations omitted)); *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 131 (D.D.C. 1997) (finding irreparable harm where FDA deprives a party of its "180-day statutory grant of exclusivity. . . . All parties recognize that the earliest generic drug manufacturer in a specific market has a distinct advantage over later entrants."), *aff'd by* 140 F.3d 1060, 1067, n.6 (D.C. Cir. 1998) (confirming that Mova's loss of its "officially sanctioned head start . . . suffices to show a severe economic impact to Mova," for purposes of satisfying the irreparable harm standard); *Mylan Pharms. v. Shalala*, 81 F. Supp. 2d 30, 44 (D.D.C. 2000) (denying requested injunctive relief where the balance of harms weighed in favor of Geneva, who would otherwise be "depriv[ed] . . . of the full benefits of exclusivity"); *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 29 (D.D.C. 1997) (granting preliminary injunction and acknowledging that "there 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'").

In view of the significant and irreparable harm associated with the generic company's loss of the 180-day exclusivity period, courts have frequently issued injunctions to prevent the loss of this exclusivity. *See TorPharm, Inc. v. Shalala*, No. Civ. A. 97-1925, 1997 WL 333472411, at *4 (D.D.C. Sept. 15, 1997) (issuing injunction where, among other things, generic company was improperly denied timely access to market, which the brand company acknowledged to be "critical for success in [the] marketplace"); *see also Bracco Diagnostics*, 963 F. Supp. at 29 (issuing an injunction in favor of generic company that faced wrongful deprivation of the "significant economic advantage" that would have resulted from its ability to enter the market with 180-day exclusivity); *Mova Pharm.*, 955 F. Supp. at 131 (issuing injunction in light of threatened deprivation of 180-day exclusivity period).

A core purpose of the Hatch-Waxman Act is to encourage generic companies to undertake the cost and risk of challenging invalid patents. Each time a generic company does so, the company assumes significant cost and risk. Suggesting that a generic company is somehow at fault for lawfully entering the market after successfully undertaking that cost and risk thwarts Congress's objectives in enacting the statute. Once a generic company obtains a post-trial, federal court opinion confirming the invalidity of a patent, it is even more incentivized to act as Congress intended by making its lower-cost, high-quality, FDA-approved generic pharmaceutical product immediately available to the public.[12] If a court permitted a losing

[12] In calculating Mylan's estimated damages in the event that the Court issues an injunction, Mylan assumed a market with two generic companies, Mylan and an authorized generic. While Mylan recognizes that it is at least theoretically possible for other generic companies such as Anchen or Barr to enter the market during the damages period, Mylan made this assumption to ensure that the bond amount would be sufficient to cover its losses under a two-generic-company

branded company nonetheless to obtain an injunction simply because the Federal Circuit "might" reverse the district court's decision on appeal, the statutory incentives would be destroyed. Simply put, there is no basis in law to reach such an absurd conclusion.

Although this case might appear to present the Court with a Sophie's choice between two harms, Congress accepted that the potential harm to Cephalon is precisely what is contemplated by the Hatch-Waxman scheme – indeed, it is the harm that a losing party in any litigation must reasonably expect. If the injunction issues here, Mylan will be harmed; if the injunction does not issue, Cephalon will be harmed. But the so-called "harm" to Cephalon is the natural and logical consequence from the invalidation of its asserted patent claims. Indeed, that purported harm to the patent holder is the public's gain from their newfound ability to purchase a lower-priced, high-quality generic alternative to Cephalon's product. Mylan has every right to immediately offer its cyclobenzaprine ER products after a decision invalidating Plaintiffs' asserted patent claims – indeed, the Hatch-Waxman statutory scheme encourages Mylan to do so – given that there can be no infringement of an invalid patent. *See, e.g.*, *Simmons Co. v. A. Brandwein & Co.*, 250 F.2d 440, 447 (7th Cir. 1957) ("It is obvious that there could be no infringement of an invalid patent.").[13]

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market scenario. Given that the bond amount provides a damages cap against an injunction later found to be improper, this Court should follow the judicial practice of erring on the high side to the extent that there is any uncertainty regarding the amount of the bond.

[13] Mylan notes that launching a generic version after a district court ruling of invalidity is not unusual practice. That is precisely what happened after this court found the asserted patent covering the Alzheimer's drug galantamine to be invalid for lack of enablement. *See In re '318 Patent Infringement Litig.*, 578 F. Supp. 2d 711 (D. Del. 2008), *aff'd*, 583 F.3d 1317 (Fed. Cir. 2009).

IV. EVEN AN EXPEDITED APPEAL WOULD LIKELY CONSUME MYLAN'S ENTIRE 180-DAY EXCLUSIVITY PERIOD.

During the hearing, the Court inquired about the expedited appeal process at the Federal Circuit. May 23, 2011 Tr. 11:10-14. Mylan submits the following comments to address this point.

The Federal Circuit does, under appropriate circumstances, grant a motion to expedite an appeal. Even under with an expedited appeal, however, there is an overwhelming likelihood that Mylan will lose all – or at least most – of its 180-day exclusivity period. Indeed, the Federal Circuit's own internal statistics confirm that most appeals from district court cases take approximately 11 months from the docketing date to the disposition date.[14]

Examples of two recent accelerated appeals illustrate how Mylan will suffer irreparable harm under an injunction even with an expedited appeal.

In *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 601 F.3d 1359 (Fed. Cir. 2010), the Federal Circuit granted the appellants' motion to expedite appeal. Under the expedited schedule, it still took just over six months from the filing of the notice of appeal to the issuance of the Federal Circuit's opinion. Including the petitions for rehearing, the expedited appeal lasted ten months.

In *i4i Limited Partnership v. Microsoft Corp.*, 598 F.3d 831 (Fed. Cir. 2009), the notice of appeal was filed on August 18, 2009, together with a motion to expedite the appeal. The court issued its initial opinion on December 22, 2009, and then issued a revised opinion on March 10, 2009, some six months after the notice of appeal was filed.

[14] http://www.cafc.uscourts.gov/images/stories/the-court/statistics/Median_Dispositon_Time_for_Cases_Terminated_after_Hearing_or_Submission_Detailed_Table_of_Data_2001-2010.pdf (Ex. A hereto).

As the above examples illustrate, even under an expedited schedule, if Mylan is enjoined, all or most of its 180-day exclusivity period would be consumed during the appeal.

CONCLUSION

For the foregoing reasons, and for the reasons stated in Mylan's previous submissions regarding this matter, the Court should refrain from entering an injunction against Mylan. Mylan further reserves its rights to present additional support and arguments to its position.

Respectfully submitted,

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Dated: May 24, 2011
1014040 / 33695 (MDL)