UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MYLAN LABORATORIES, INC., *et al.*, Plaintiffs/Cross-Defendants, and MUTUAL PHARMACEUTICAL CO., INC., Intervenor-Plaintiff/Cross-Defendant, v. MICHAEL LEAVITT, *et al.*, Defendants/Cross-Defendants, TEVA PHARMACEUTICALS USA, INC., Intervenor-Defendant/Cross-Claimant, and APOTEX INC., Intervenor-Defendant/Cross-Defendant.	Case No. 07-579 (RMU)

BRIEF OF TEVA PHARMACEUTICALS USA, INC. IN OPPOSITION TO MYLAN'S RENEWED MOTION FOR TEMPORARY INJUNCTIVE RELIEF

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INTRODUCTION

Mylan's renewed motion for temporary injunctive relief comes before this Court with a strong sense of déjà vu. After all, Mylan raised these precise issues in its earlier motions for temporary injunctive relief, and this Court squarely rejected them. With respect to the effect of patent delisting on FDA's authority to approve additional ANDAs, this Court held that Teva would be entitled to final approval once "administrative or legal action completely de-lists Pfizer's patent from the Orange Book." Opinion at 18. And with respect to Mylan's eligibility for 180-day exclusivity, this Court held that "FDA's conclusion that Mylan's 180-exclusivity does not survive patent expiration constitutes a reasonable interpretation of the statute. And for this reason, Mylan fails to convince the court that it has a substantial likelihood of success on this claim." *Id*. at 19. FDA now has taken final action to completely delist Pfizer's patent from the Orange Book, and Teva is thus—as this Court previously recognized—entitled to immediate final approval from the Agency, unblocked by any period of marketing exclusivity.

But that is not all. Beyond the fact that Mylan's motion merely reiterates the same discredited arguments that this Court previously considered and rejected, its motion asks this Court to exercise jurisdiction it plainly does not possess. That is so because Mylan has appealed this Court's prior decision holding that Mylan is not entitled to 180-day exclusivity to the D.C. Circuit, and "[t]he filing of a notice of appeal, including an interlocutory appeal, 'confers jurisdiction on the court of appeals and divests the district court of control over those aspects of the case involved in the appeal.' The district court does not regain jurisdiction over those issues until the court of appeals issues its mandate." *United States v. DeFries*, 129 F.3d 1293, 1302 (D.C. Cir. 1997) (quoting *Griggs v. Provident Consumer Discount Co.*, 459 U.S. 56, 58 (1982) (per curiam); citing *Johnson v. Bechtel Associates Professional Corp.*, 801 F.2d 412, 415 (D.C. Cir. 1986) (per curiam). Thus, even if Mylan were right about the law (which it is not), and even

if it could make out a colorable claim of irreparable injury (based on claims this Court previously rejected as plainly insufficient to sustain its burden), this Court would be powerless to grant Mylan the relief it seeks.

Finally, there is no basis for entering any sort of a stay pending appeal. When Mylan appealed this Court's prior decision to the D.C. Circuit, it moved the D.C. Circuit for a stay pending appeal. The D.C. Circuit denied that motion. *See* Order, *Mylan v. Leavitt*, No. 07-5156, May 23, 2007, at 1 (attached as Exh. 1) (denying Mylan's emergency motion for a stay pending appeal). Mylan then moved the D.C. Circuit to expedite its consideration of the appeal. The D.C. Circuit denied that motion as well. *See* Order, *Mylan v. Leavitt*, No. 07-5156, May 29, 2007, at 1 (attached as Exh. 2) (denying Mylan's motion to expedite appeal). Given the D.C. Circuit's prior consideration and denial of Mylan's motion for a stay pending appeal—and of Mylan's motion simply to expedite proceedings in its appeal of this matter—this Court has no jurisdiction or basis for granting such relief.

At bottom, Mylan's motion is legally frivolous and jurisdictionally defective. This Court should summarily reject Mylan's application for injunctive relief.

ARGUMENT

I. MYLAN HAS NO CHANCE OF SUCCESS ON THE MERITS.

A. This Court Lacks Jurisdiction To Adjudicate Mylan's Motion.

As a threshold matter, Mylan's motion should be denied for the simple reason that this Court lacks jurisdiction to entertain it. When Mylan last sought temporary injunctive relief from this Court, it raised the same argument it presents here—namely, that it was entitled to injunctive relief in order to preserve its alleged right to 180-day marketing exclusivity. The parties fully briefed that issue, *see* Opinion at 18 n.9, and on April 30 this Court squarely rejected Mylan's claims after full consideration on the merits. *See id.* ("Because the issue is now fully briefed,

because the issue will be ripe when pediatric exclusivity ultimately expires, and to provide but one ruling on the pressing legal issues, the court proceeds with its analysis."); *id*. at 19 ("FDA's conclusion that Mylan's 180-exclusivity does not survive patent expiration constitutes a reasonable interpretation of the statute."); *see also id*. at 18 (holding that Teva would be entitled to final approval once "administrative or legal action completely de-lists Pfizer's patent from the Orange Book").

On May 14, 2007, Mylan filed a notice of appeal from—among other things—"the denial of Mylan's motion for a preliminary injunction dated April 23, 2007 (Dkt. No. 44), and Mylan's amended motion for a preliminary injunction dated April 16, 2007 (Dkt. No. 50), entered in this action by the Honorable Ricardo M. Urbina on April 30, 2007 (Dkt. No. 66), and all orders underlying the denial of Mylan's request for injunctive relief." *See* Mylan Notice of Appeal (Docket No. 76). There is no serious question that Mylan's appeal from this Court's opinion and order denying Mylan's assertion that it is entitled to 180-day exclusivity for its generic amlodipine drug products divests this Court of jurisdiction to revisit that issue.

As the Supreme Court has explained, "a federal district court and a federal court of appeals should not attempt to assert jurisdiction over a case simultaneously. The filing of a notice of appeal is an event of jurisdictional significance—it confers jurisdiction on the court of appeals and divests the district court of its control over those aspects of the case involved in the appeal." *Griggs*, 459 U.S. at 58. Indeed, "[s]o complete is the transfer of jurisdiction that any orders of the district court touching upon the substance of the matter on appeal are considered null and void if entered subsequent to the timely filing of the notice of appeal." Charles Alan Wright, Arthur R. Miller, & Edward H. Cooper, 16A *Federal Practice & Procedure Jurisdiction* §§ 3949.1 (3d ed.1999 and 2005 Pocket Part) (collecting cases).

Under these circumstances, then, this Court lacks jurisdiction to revisit the issues previously addressed in its opinion and order on Mylan's initial motion for preliminary injunctive relief. *See, e.g., Pro Sales, Inc. v. Texaco, U.S.A.*, 792 F.2d 1394, 1396 n.1 (9th Cir. 1986) (holding that district court erred by attempting to amend its prior opinion after notice of appeal was filed, and declining to consider the amended opinion on appeal); *Ced's Inc. v. U.S. E.P.A.*, 745 F.2d 1092, 1095 (7th Cir. 1984) (holding that district court erred by attempting to supplement its conclusions of law after appeal had been noticed; vacating the court's supplemental order; and explaining that "[t]he filing of a notice of appeal sets the appellate clock running, and the parties and the clerk of the court become subject to deadlines imposed by the rules. The parties to an appeal are entitled to have a stable set of conclusions of law on which they can rely in preparing their briefs.").[1]

B. Even If This Court Did Have Jurisdiction, Mylan's Argument That It Is Entitled To 180-Day Exclusivity Is Frivolous.

In any event, Mylan's renewed motion for temporary injunctive relief boils down to a single flawed proposition: that its "right to the 180-day generic exclusivity reward vested prior to the patent's expiration and under the plain language of 21 U.S.C. § 355(j)(5)(B)(iv), the FDA does not have authority to cut short Mylan's generic exclusivity period." *See* Renewed Motion

[1] To be sure, courts may take "certain actions serving to preserve the status quo pending the appeal." *Ced's Inc.*, 745 F.2d at 1095 (citing *U.S. v. El-O-Pathic Pharmacy*, 192 F.2d 62, 79 (9th Cir. 1951) (granting a stay pending appeal under Fed. R. Civ. P. 62(c)). But there is no basis for doing so here, since Mylan is seeking outright to prevent "FDA from approving any additional ANDAs on amlodipine in derogation of Mylan's right to 180-day exclusivity," Renewed Motion at 23, and there is no jurisdiction to do so, since the D.C. Circuit already has considered and denied both Mylan's motion for a stay pending appeal and Mylan's motion to expedite the appeal. *See* Exhs. 1 (denying Mylan's motion for an emergency injunction pending appeal) and 2 (denying Mylan's motion for expedited consideration of its appeal). This Court has no jurisdiction to second-guess the D.C. Circuit's actions on this matter.

at 8. The obvious problem with that argument—as this Court concluded last time it was raised—is that Mylan is not entitled to 180-day exclusivity under the plain language of the statute, so there is nothing for FDA's delisting to "cut short." *See* Opinion at 18 ("FDA's conclusion that Mylan's 180-exclusivity does not survive patent expiration constitutes a reasonable interpretation of the statute.").

That is so, as this Court recognized, because the plain language of the Hatch-Waxman Act distinguishes between cases where a patent has expired and cases where the patent has not, by tying the effective date of an applicant's final approval to the type of patent certification contained in the applicant's ANDA. To that end, the statute provides that the approval of an ANDA "shall be made effective" on the latest of four possible dates, and each of those dates depends on the applicant's patent certification at the time it seeks final approval from the Agency. 21 U.S.C. § 355(j)(5)(B).

- First, where an applicant has submitted a paragraph I or paragraph II certification, the statute provides that "the approval [of the applicant's ANDA] may be made effective immediately." 21 U.S.C. § 355(j)(5)(B)(i).

- Second, where an applicant has submitted a paragraph III certification, "the approval [of the applicant's ANDA] may be made effective on the [certified] date [of patent expiration]." *Id*. § 355(j)(5)(B)(ii).

- Third, where an applicant has submitted a paragraph IV certification and was sued by the brand manufacturer within 45 days, "the approval [of the applicant's ANDA] shall be made effective upon the expiration of the thirty-month [stay]" or, depending on the outcome of such litigation, upon the date of a court decision holding the patent invalid or not infringed, or the date a patent injunction is lifted following a court decision that the patent is valid and would be infringed. *Id*. § 355(j)(5)(B)(iii).

- Finally, where an applicant has submitted a paragraph IV certification and filed its ANDA subsequent to another manufacturer's ANDA containing a paragraph IV certification, "the application shall be made effective not earlier than one hundred and eighty days after" either the prior applicant's first commercial marketing or a court decision holding the patent invalid, not infringed, or otherwise unenforceable. *Id*. § 355(j)(5)(B)(iv).

Thus, where a blocking patent expires and a subsequent applicant is deemed to have a paragraph II certification to that patent or formally converts to a paragraph II certification—as unquestionably happened here, *see* Opinion at 15-16, 18-19 (citing *Ranbaxy Labs., Ltd. v. FDA*, 307 F. Supp. 2d 15, 21 (D.D.C. 2004), *aff'd*, 2004 U.S. App. LEXIS 8311 (D.C. Cir. Apr. 26, 2004); 21 C.F.R. § 314.94(a)(12)(viii)(C)); *see also Mylan v. Thompson*, 389 F.3d 1272, 1281-82 (D.C. Cir. 2004); FDA Letter Decision at 8, 10-11—the first-filer's exclusivity no longer bars final approval of the subsequent applicant's ANDA. Instead, under the plain terms of the statute, "the approval may be made effective immediately." *Id.* § 355(j)(5)(B)(i).

As both FDA and this Court thus recognized previously, that unambiguous statutory language controls the outcome here. Before the '303 patent expired, Teva filed a paragraph IV certification to that patent. After the '303 patent expired, and pursuant to the mandate of § 314.94(a)(12)(viii)(C)(1), Teva amended its ANDA to include a paragraph II certification to that patent. The plain language of the statute thus divests Mylan of any exclusivity it previously held against Teva and the other paragraph IV applicants, by requiring the Agency to grant any otherwise eligible ANDA final approval "effective immediately." 21 U.S.C. § 355(j)(5)(B)(i). That is precisely what this Court held in its earlier decision. *See* Opinion at 18.

Mylan's renewed motion for temporary injunctive relief does not address 21 U.S.C. § 355(j)(5)(B)(i), challenge FDA's longstanding regulations with respect to amended patent certifications, or take issue with this Court's prior conclusion that Teva's ANDA was converted to a paragraph II certification upon patent expiration. Nor could it: Mylan's earlier argument that Teva was barred by Pfizer's pediatric exclusivity for Norvasc® was based entirely on the claim that Teva's ANDA was converted to a paragraph II certification upon patent expiration. *See*

Mylan Supp. Br. at 5 ("all unapproved ANDAs containing a paragraph IV certification [including Teva's ANDA] become paragraph II certifications upon the patent's expiration.").

That should be the beginning and end of this matter. By its plain terms, 21 U.S.C. § 355(j)(5)(B)(iv) no longer bars the Agency from granting immediate final approval to ANDAs that, like Teva's, contain post-patent expiration paragraph II certifications. Instead, Mylan's entitlement to marketing exclusivity against those applicants is controlled by 21 U.S.C. § 355(j)(5)(B)(i), and that provision unambiguously requires FDA to approve those ANDAs "effective immediately." 21 U.S.C. § 355(j)(5)(B)(i). As this Court previously held, FDA did not remotely abuse its discretion by reaching that precise conclusion; indeed, that conclusion was compelled by the plain language of the statute.

Even if there were some ambiguity here—and there is not—the conclusions this Court and FDA reached about 180-day exclusivity are consistent with prior case law on 180-day exclusivity. Indeed, every court that has addressed the impact of patent expiration on a first-filer's 180-day exclusivity supports the view that patent expiration divests the first filer of its exclusivity period, even after that period has commenced. *See, e.g.*, *Ranbaxy Labs. Ltd. v. Leavitt* [*Simvastatin*], 469 F.3d 120, 126 n.* (D.C. Cir. 2006); *Dr. Reddy's Labs., Inc. v. Thompson*, 302 F. Supp. 2d 340, 354-55 (D.N.J. 2003). For instance, in *Dr. Reddy's*, the court specifically upheld FDA's determination that the expiration of a patent divests the first-filer of its eligibility for exclusivity as a reasonable interpretation of the statute. 302 F. Supp. 2d at 354-55.

To be sure, *Dr. Reddy's* involved a case where the underlying patent expired before the Agency granted final approval to the first filer, rather than after it did so. But the court's rationale applies equally on the facts of this case. As *Dr. Reddy's* explains, a rule maintaining exclusivity after patent expiration would lead to perverse results, because it would allow an

applicant to file the first paragraph IV certification immediately prior to patent expiration and then delay the onset of full market competition even after the only patent barrier to full generic competition has fallen. *Dr. Reddy's*, 302 F. Supp. 2d at 354.

As *Dr. Reddy's* explained, that would be inconsistent with the purpose of the statutory scheme, which is intended to encourage patent challenges in order to remove "listed patents that prevent final ANDA approval," *id.*, and thereby facilitate early generic market entry. Once there are no remaining listed patents that prevent final ANDA approval, however, there is no reason to erect another barrier to full generic market entry; all subsequent applicants should be permitted to enter the market without regard to their status as subsequent filers. *Id*. ("Once a listed patent expires, there is no longer a need to provide an incentive to challenge it in court. Consistent with this statutory purpose, the FDA construes the statute to award 180-day exclusivity based only upon paragraph IV certifications to unexpired patents.") (citing 59 Fed. Reg. 50338, 50348)). Moreover, *Dr. Reddy's* squarely upheld FDA's determination that all applicants (and not just first filers) must convert to paragraph II certifications following patent expiration. *Id*. at 354-55; *see also id*. at 355-56 (upholding FDA's interpretation of 21 C.F.R. § 314.94(a)(12)(viii)). That, of course, is precisely what Teva did, and (again) Mylan neither challenges Teva's conversion to a paragraph II certification nor addresses the consequences that flow from that conversion under the plain language of the statute.

More recently, the D.C. Circuit built on *Dr. Reddy's* holding by explaining that "the text and structure of the statute suggest … that the first generic applicant may no longer ***retain*** exclusivity when the patent has expired." *Ranbaxy*, 469 F.3d at 126 n.* (emphasis added). That is so, the court suggested, because of 21 U.S.C. § 355(j)(5)(B)(i), which provides that an application containing a paragraph II certification may be approved "effective immediately." *Id*.

As the D.C. Circuit thus has recognized, the statute plainly dictates that there is no basis for continuing first-filer exclusivity after patent expiration, because the statute unambiguously permits subsequent ANDAs to be approved as soon as they contain post-expiration paragraph II certifications. *See supra* at 6-7.

Finally, the result reached by FDA and this Court in its prior opinion comports with FDA's longstanding interpretation of the pre-MMA "court-decision trigger." At this late date, it is well-settled that a first filer effectively may be deprived of its exclusivity where a subsequent applicant prevails in its own paragraph IV litigation, and thereby triggers the first-filer's 180-day exclusivity period—even if that happens at a time when the first filer cannot market its product. *See, e.g., Minnesota Mining & Mfg. Co. v. Barr Labs.*, 289 F.3d 775, 780 (Fed. Cir. 2002) ("The District of Columbia Circuit has explicitly held that § 355(j)(5)(B)(iv)(II) [can be] triggered by the termination of an action commenced by the second ANDA filer, and we agree.") (citing *Teva Pharms. USA, Inc. v. FDA*, 182 F.3d 1003, 1010 (D.C. Cir. 1999)). Thus, if a subsequent applicant obtains a court decision of invalidity, non-infringement, or unenforceability through its own post-paragraph IV litigation with the patentee (as Apotex did here), the first filer's exclusivity will begin to run—whether or not the first filer is eligible to market its product at that time.

As a result, the first filer's 180-day exclusivity period may run out entirely before the first filer can market its product for a single day. *See, e.g., SmithKline Beecham Corp. v. Geneva Pharms., Inc.*, 210 F.R.D. 547, 553 (E.D. Pa. 2002). In such cases, all applicants—regardless of their patent certification—are entitled to market their drug products on the 181st day after the triggering court decision, and that is so whether or not the first applicant has enjoyed a moment of its exclusivity period. It goes without saying that if the first filer's exclusivity period can

begin and end before the first filer can ever use it, that period cannot be extended past the 180th day simply because the manufacturer began its commercial marketing at some point ***during*** the period. In other words, it is well-settled that the mere triggering of a 180-day exclusivity period does not necessarily entitle the first filer to its full 180 days of exclusive marketing.

The same is true of patent expiration: the mere fact that Mylan finally triggered its 180-day exclusivity period two days before patent expiration does not entitle Mylan to the full measure of its exclusivity now that the final patent obstacle has expired and the patent has been removed from the Orange Book. Instead, permitting Mylan to do so would be flatly inconsistent with the fundamental goal of the statutory scheme, which aims to "'get generic drugs into the hands of patients at reasonable prices—fast.'" *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 809 (D.C. Cir. 2001) (quoting *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991)). That policy assumes a paramount importance once the expiration of a listed patent opens the pathway to full generic market entry, and there is no basis for depriving consumers of broader competition and increased price relief now that the '303 patent has expired.

II. MYLAN HAS NOT SUSTAINED ITS BURDEN OF DEMONSTRATING THAT THE EQUITIES FAVOR INJUNCTIVE RELIEF.

Even if Mylan could demonstrate a likelihood of success on the merits—despite the fact that this Court lacks jurisdiction, and despite the fact that it already has rejected the very same arguments Mylan presents on the merits—Mylan still would not be entitled to injunctive relief. Without belaboring the point, this Court previously held that Mylan has not sustained its burden of demonstrating irreparable injury from its loss of anticipated sales. *See* Opinion at 19-20. That decision is the law of this case, and Mylan offers no basis for revisiting that conclusion. *See, e.g.*, *LaShawn A. v. Barry*, 87 F.3d 1389, 1393 (D.C. Cir. 1996) (*in banc*) (holding that "in the absence of extraordinary circumstances such as where the initial decision was clearly erroneous

and would work a manifest injustice," courts should be "be loathe to reconsider issues already decided" because the *same* issue presented a second time in the *same case* in the *same court* should lead to the *same result*") (emphasis in original; citations and quotations omitted). Likewise, Mylan offers no basis for revisiting this Court's prior determination that "the balance of harms and the public interest both favor denying … injunctive relief." *Id*. at 22. Again, Mylan identifies no "extraordinary circumstances" that would support a departure from those prior determinations, and there is therefore no basis for reversing course. The equities therefore weigh against entering the requested relief.

CONCLUSION

For the foregoing reasons, this Court should deny Mylan's renewed motion for temporary injunctive relief.

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Respectfully submitted,

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