**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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| MYLAN LABORATORIES, INC. *et al.*,[1] | | |
| Plaintiffs, | Civil Action No.: | 07-579 (RMU) |
| v. | | |
| MICHAEL LEAVITT *et al.*, | Document No.: | 79 |
| Defendants, | | |
| and | | |
| TEVA PHARMACEUTICALS USA., | | |
| APOTEX, INC., | | |
| MUTUAL PHARMACEUTICALS CO., | | |
| Intervenors. | | |

## MEMORANDUM OPINION

**DENYING MYLAN'S EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER**

## I. INTRODUCTION

This matter comes before the court on the plaintiff's emergency motion for a temporary restraining order. Plaintiff Mylan Laboratories asks the court to order the FDA to relist Pfizer's patent for Norvasc on its patent register. Currently, the plaintiff is one of only two generic drug manufacturers who market their generic version of this drug to the public. A prior ruling from this court recognized that Mylan would enjoy generic market exclusivity as to this drug until such time as the patent expired[2] or was otherwise removed from the official patent register.

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[1] The plaintiffs in this case are Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. For ease of reference, the court refers to the plaintiffs throughout this Memorandum Opinion in the singular.

[2] The patent expired on March 25, 2007.

Mylan's generic market exclusivity was set to expire in September of 2007. However, on June 22, 2007, the FDA delisted Pfizer's patent for Norvasc from its register,[3] opening a legal freeway for as many as eight other generic manufacturers to enter the market. Facing this large and unexpected potential diminution of its market share for the generic version of Norvasc, Mylan asks the court to direct the FDA to relist the patent, thereby restoring the status quo pending appeal. Because the plaintiff fails to demonstrate sufficiently changed circumstances warranting immediate action by this district court, the court denies the plaintiff's motion for immediate injunctive relief.

## II. BACKGROUND

These matters last came before the court in earnest on a motion for a preliminary injunction filed by the plaintiff on April 23, 2007. At that time, the plaintiff objected to numerous rulings of the FDA affecting the barriers-to-entry in the generic drug market for amlodipine besylate. Pl.'s Mot. for Prel. Inj. (Apr. 23, 2007) ("Pl.'s Mot. for Inj."). Of relevance here, Mylan challenged the FDA's conclusion that, under the Hatch Waxman Act, Mylan's 180-day period of market exclusivity for amlodipine besylate does not survive the expiration of Pfizer's patent for Norvasc. Pl.'s Mot. for Inj. at 12. On April 30, 2007, the court ruled, *inter alia*, that the FDA's interpretation regarding Mylan's market exclusivity constituted a reasonable interpretation of the law. Mem. Op. (Apr. 30, 2007) at 19. Objecting to this ruling, the plaintiff sought reconsideration, which the court denied on May 14, 2007. Order (May 14, 2007). Immediately following this court's denial of Mylan's motion for reconsideration, the plaintiff

[3] The FDA took this action pursuant to Pfizer's request that the FDA delist its patent. Pl.'s Application for a TRO ("Pl.'s Mot. for TRO") at 1.

filed a notice of appeal with the D.C. Circuit. Explaining that the plaintiff had "not satisfied the stringent standards required for an injunction pending appeal, the D.C. Circuit denied relief." Order, *Mylan v. Leavitt*, No. 07-5156 (D.C. Cir. May 23, 2007) at 1. The plaintiff knocked again at the D.C. Circuit's door, this time with an emergency motion for an expedited appeal. The D.C. Circuit refused this request. Order, *Mylan v. Leavitt*, No. 07-5156 (D.C. Cir. May 29, 2007) at 1. During the course of these procedural maneuvers, Pfizer's pediatric exclusivity privilege (which was set to expire on September 25, 2007) prevented new generic manufacturers from entering the market. This changed on June 22, 2007, when the FDA delisted Pfizer's patent. Pl.'s Mot. for TRO, Ex. A.

Suddenly, the plaintiff was faced with the prospect that numerous generic drug manufacturers would soon enter the market,[4] thus diluting the plaintiff's almost exclusive market share for the generic version of Norvasc.

## III. ANALYSIS

### A. Legal Standard for Injunctive Relief Pending Appeal

When a party appeals the court's interlocutory or final judgment granting, dissolving, or denying an injunction, the court, in its discretion, "may suspend, modify, restore, or grant an injunction during the pendency of the appeal[.]" FED. R. CIV. P. 62(c). The court analyzes motions for a stay pending appeal under the same factors that it considers for motions for a preliminary injunction. *Wash. Metro. Area Transit Comm'n v. Holiday Tours*, 559 F.2d 841,

[4] Prior to entering the market, each of these generic drug manufacturers must receive FDA approval for their drug. 21 U.S.C. § 355(a); *Mead Johnson Pharm. Group v. Bowen*, 838 F.2d 1332-33 (D.C. Cir. 1988).

842-43 (D.C. Cir. 1977). Thus, the court may issue a stay pending appeal of an order on interim injunctive relief only when the movant demonstrates:

> (1) a substantial likelihood of success on the merits, (2) that it would suffer irreparable injury if the injunction is not granted, (3) that an injunction would not substantially injure other interested parties, and (4) that the public interest would be furthered by the injunction.

*Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (internal citations omitted). Because the plaintiff seeks a mandatory injunction, rather than to merely maintain the status quo, the plaintiff must demonstrate (beyond the familiar four-part test for injunctive relief) that it is "clearly" entitled to the relief it seeks or "extreme or very serious damage will result."[5] *Farris v. Rice*, 453 F. Supp. 2d 76, 79 (D.D.C. 2006); *see also King v. Leavitt*, 475 F. Supp. 2d 67, 71 (D.D.C. 2007) (quoting *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 36 (D.D.C. 2000)).

The court observes that because it has previously considered the precise legal issue on appeal, the movant's showing of likelihood of success must be impressive. *Fullmer v. Mich. Dept of State Police*, 207 F. Supp. 2d 663, 664 (E.D. Mich. 2002) (noting that the movant must demonstrate a likelihood of reversal on appeal). The law-of-the-case doctrine, which prevents a court from revisiting an issue it has already decided, reinforces this conclusion. *LaShawn v. Barry*, 87 F.3d 1389, 1393 (D.C. Cir. 1996) (declaring that "[t]he same issue presented a second time in the same case in the same court should lead to the same result . . . in the absence of

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[5] The D.C. Circuit has neither adopted nor rejected this rule. *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 834 n31 (D.C. Cir. 1984) (explaining that "[i]n this circuit, however, no case seems to squarely require a heightened showing, and we express no view as to whether a heightened showing should in fact be required").

extraordinary circumstances such as where the initial decision was 'clearly erroneous and would work a manifest injustice'") (citations omitted).

To justify a stay pending appeal, a movant need not always establish a high probability of success on the merits, as a particularly strong showing of irreparable injury or some other combination of factors may warrant a stay. *Cuomo v. U.S. Nuclear Regulatory Comm'n*, 772 F.2d 972, 974 (D.C. Cir. 1985) (per curium); *United States v. Phillip Morris Inc.*, 314 F.3d 612, 617 (D.C. Cir. 2003).

As for burdens, it is "the movant's obligation to justify the court's exercise of such an extraordinary remedy." *Cuomo*, 772 F.2d at 978; *see also Twelve John Does v. District of Columbia*, No. 80-2136, 1988 WL 90106, at *1 (D.D.C. Aug. 4, 1988) (cautioning that "[a]n indefinite stay pending appeal is an extraordinary remedy, and is to be granted only after careful deliberation has persuaded the Court of the necessity of the relief") (citations omitted); *Judicial Watch, Inc. v. Nat'l Energy Policy Dev. Group*, 230 F. Supp. 2d 12, 14 (D.D.C. 2002) (noting that "the applicant must satisfy 'stringent standards required for a stay pending appeal'") (*citing Summers v. Howard Univ.*, No. 02-7069, 2002 WL 31269623 (D.C. Cir. Oct. 10, 2002)). When a moving party fails to establish a substantial case on the merits, and further fails to "demonstrate that the balance of equities or the public interest strongly favors the granting of a stay," a motion for stay is properly denied. *Cuomo*, 772 F.2d at 972.

**B. The Plaintiff Fails to Demonstrate that a Stay Pending Appeal is Justified**

Mylan's current arguments for a stay pending appeal are substantially similar to the arguments it made in its first request for a preliminary injunction. That is, the plaintiff again argues that the FDA's conclusion regarding Mylan's exclusivity is not reasonable, and that Mylan will suffer irreparable harm if other manufacturers enter the market. *Compare* Pl.'s Mot.

for Inj. at 12 (arguing that "nothing in the text or legislative history of the Hatch-Waxman Act indicates that generic exclusivity is forfeited upon patent expiration") *with* Pl.'s Mot. for TRO (June 26, 2007) at 9 (arguing that "vested 180-day generic exclusivity extends beyond patent expiration"); *compare* Pl.'s Mot. for Inj. at 15 (asserting that "[l]oss of such exclusivity would impair its access to customers and diminish its ability to establish and retain market share") *with* Pl.'s Mot. for TRO at 21 (asserting that "Mylan will irrevocably lose a portion of [anticipated] revenues").

Since the court issued its April 30, 2007 Memorandum Opinion, the FDA has delisted Pfizer's patent and, consequently, eight rival generic manufacturers are mobilized to enter the generic market.[6] Pl.'s Mot. for TRO at 1; Notice (June 28, 2007). The plaintiff argues that this elevates the probability and extent of irreparable injury, as "now eight other generics are poised to flood the market during the pendency of Mylan's appeal." Pl.'s Reply at 9.

The changed circumstances alleged by the plaintiff do not warrant a reexamination of the court's appraisal of the four factors guiding issuance of a preliminary injunction. As to the plaintiff's likelihood of success on the merits (properly cast as its likelihood of obtaining a reversal, *Fullmer*, 207 F. Supp. 2d at 664), the court remains confident in its prior determination that "the FDA's conclusion that Mylan's 180-day exclusivity does not survive patent expiration constitutes a reasonable interpretation of the statute." Mem. Op. (Apr. 30, 2007) at 19. The plaintiff fails to argue that an intervening change of law or some other circumstance compels this court to revisit its prior conclusion.

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[6] According to Mylan, the FDA has just approved the Abbreviated New Drug Application for one of the generic drug manufacturers, clearing the final regulatory hurdle for that company to enter the market. Notice (June 28, 2007).

As to irreparable injury, the court previously ruled that the plaintiff had not demonstrated that market competition constitutes irreparable harm. Mem. Op. (Apr. 30, 2007) at 20 (noting that the plaintiff's injury does not "cause extreme hardship to [its] business or threaten its very existence"). The potential entry of numerous competitors raises the stakes but differs from past alleged injury only in degree not kind. *See Lightfoot v. District of Columbia*, No. 01-1484, 2006 WL 175222, *8 (D.D.C. Jan. 24, 2006) (holding that losses must threaten the survival of a business); *see also Varicon Int'l v. Office of Personnel Mgmt.*, 934 F. Supp. 440, 447-48 (D.D.C. 1996) (finding no irreparable harm due to a lost contract where the movant's revenue would decline by ten percent); *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 220-21 (D.D.C. 1996) (finding no irreparable harm where the movant would lose eighty million dollars–less than one percent of its total sales); *TGS Tech., Inc. v. United States*, No. 92-0062, 1992 U.S. Dist. LEXIS 195, at *10 (D.D.C. Jan. 14, 1992) (finding no irreparable harm where a lost contract constituted twenty percent of the movant's business). The court's conclusion that Mylan's speculative, prospective losses do not constitute irreparable injury remains undisturbed.[7]

Turning to the question of substantial injury to other interested parties, the court can discern no shift in the weight of equities since its prior ruling. Assuming a stable demand for the drug in question, the entry of more competitors into the market will simply redistribute a portion of revenues from the plaintiff to new manufacturers in an ultimately zero-sum transfer. In any

[7] Perhaps a showing that the financial wherewithal of the plaintiff had changed to such a degree that a dilution of its market share would likely lead to financial collapse would constitute a sufficient change in circumstances for the court to revisit (for the second time) its prior ruling. And perhaps such a showing would constitute a sufficient emergency for the court to issue a stay, though the D.C. Circuit denied that precise request. But here, Mylan makes no claims that upset the court's prior conclusion that no irreparable injury exists.

case, the harm to other interested parties is equivalent to the harm to Mylan–prospective, speculative, and financial.

This brings the court to the final factor: the public interest. The plaintiff challenges the FDA's interpretation of a statute that it is charged with implementing faithfully. No superceding circumstances warrant re-examining the court's conclusion that the public interest "does not favor a distortion of the principles of the Hatch-Waxman Act." Mem. Op. (April 30, 2007) at 21.

Injunctive relief emanating from this court is wholly inappropriate. The plaintiff has made no showing of irreparable harm. The court maintains confidence in its substantive legal ruling regarding the 180-day exclusivity and its prior conclusion regarding the balance of harms to other parties and the public. Moreover, its ruling is presently before the Circuit. *See McCowan v. Sears, Roebuck and Co.*, 908 F.2d 1099, 1103 (2d Cir. 1990) (recognizing the pitfalls of "duplicative substantive review in two different courts"); *see also Griggs v. Provident Consumer Disc. Co*., 459 U.S. 56, 58 (1982) (noting that "a federal district court and a federal court of appeals should not attempt to assert jurisdiction over a case simultaneously"). Accordingly, the court denies the plaintiff's request for a TRO and a stay pending appeal.

## IV. CONCLUSION

For the foregoing reasons, the court denies the plaintiff's motion for injunctive relief. An order consistent with this Memorandum Opinion is separately and contemporaneously issues this 29th day of June, 2007.

RICARDO M. URBINA
United States District Judge