UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

HOSPIRA, INC.,

Plaintiff,

and

SANDOZ, INC.

Intervenor-Plaintiff

v.

SYLVIA MATHEWS BURWELL,
Secretary of Health and Human Services

MARGARET A. HAMBURG, M.D.,
Commissioner of Food and Drugs,

and

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Defendants,

MYLAN INSTITUTIONAL LLC
781 Chestnut Ridge Rd.
Morgantown, WV 26505

Intervenor-Defendant.

Civil Action No. 8:14-cv-02662-GJH

MYLAN INSTITUTIONAL LLC'S MOTION TO STAY THE ORDER (DKT. NO. 20) ENTERED AUGUST 19, 2014

Mylan Institutional LLC ("Mylan") moves the Court to stay entry of Paragraphs 3 & 4 of the Temporary Restraining Order (Dkt. No. 20) entered on August 19, 2014 ("the Order"), or, if

such relief is not granted, for a stay of the Order *in toto* pending Mylan's appeal of the Order to the U.S. Court of Appeals for the Fourth Circuit. This emergency relief is necessary due to the unprecedented breadth, severity, and impractical nature of the Order as well as the irreparable harm from its fall out. This is particularly true regarding Paragraphs 3 & 4 of the Order, which go far beyond the limited injunctive relief necessary to protect the status quo, and as such, Mylan seeks an immediate stay of those paragraphs at least until Mylan is afforded a full opportunity to be heard in this Court through expedited briefing and hearing. If this targeted relief is not granted, then Mylan seeks a stay of the entire Order so that appeal of may be taken in the United States Court of Appeals for the Fourth Circuit. The reasons for this motion follow:

I. The Court Should Stay Entry of Paragraphs 3 and 4 of the Order Until Mylan Can Be Heard on the Issues Created Thereby

The Court should stay entry of Paragraphs 3 and 4 of the Order to provide Mylan the opportunity to be heard on Plaintiffs' request. Indeed, while Mylan's objections to Paragraphs 1 & 2 of the Order can be addressed in the course of expedited proceedings in this Court, Paragraphs 3 & 4 not only go far beyond any need or authority cited by Hospira, they are unprecedented and would impact immediate and irreparable harm on Mylan and others in the distribution chain.

By way of background, on August 19, 2014, this Court conducted a hearing on a motion for temporary restraining order filed by Hospira, Inc., seeking to enjoin the United States Food and Drug Administration ("FDA") from, among other things, approving Abbreviated New Drug Applications ("ANDA") predicated on Docket No. FDA-2014-N-0087. Hospira supported its motion with nearly two-hundred pages of written submissions, which had been filed early in the morning of the 19th. After the hearing, but without any written submissions from either

defendant FDA or intervenor Mylan, the Court granted the relief requested by Hospira in all respects.

In particular, Paragraphs 3 & 4 of the Court's Order read as follows:

> 3. FDA is ORDERED to recall any product sold or distributed under such an approval [pursuant to FDA's decision in Docket No. FDA-2014-N-0087]; and
>
> 4. Any action which FDA has taken prior to the entry of this Order predicated upon the decision in Docket No. FDA-2014-N-0087 is hereby RESCINDED *ab initio*.

These two paragraphs should be stayed because they constitute an unprecedented and unwarranted exercise of the Court's authority that far exceeds Hospira's purported need to maintain the *status quo*. *First*, Hospira provided no authority for the proposition that FDA can recall a pharmaceutical product, like Mylan's ANDA DEX product, that FDA has found to be safe and efficacious. No statute, no regulation, no case provides such authority to Mylan's knowledge. To the contrary, FDA's recall policy indicates that recall is a "voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well being." 21 C.F.R. § 7.40; *see also id.* § 7.45 (detailing instances in which FDA may *request* a recall, none of which apply here). Mylan has more than met that responsibility by preparing and supporting an ANDA for DEX, which the FDA approved due to the product's demonstrated safety and efficacy, and Hospira has not suggested otherwise. *See* August 18, 2014, FDA Approval Letter for Mylan's ANDA No. 202881 ("We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling.").

Second, the commercial events of the last two days have proved that a recall is a remedy drastically broader than necessary to prevent Hospira from suffering irreparable harm. *Tuttle v.*

Arlington Cty. Sch. Bd., 195 F.3d 698, 708 (4th Cir. 1999) ("An injunction should be tailored to restrain no more than what is reasonably required to accomplish its ends ... Although injunctive relief should be designed to grant the full relief needed to remedy the injury to the prevailing party, it should not go beyond the extent of the established violation.") (quoting *Hayes v. N. State Law Enforcement Officers Ass'n,* 10 F.3d 207, 217 (4th Cir. 1993)). Mylan's approved DEX product went on the market on August 18 after Mylan received FDA approval. But Hospira still stands. If in fact Mylan's sales activities on August 18 had brought some irreparable ruin to Hospira, that harm would surely have been made known at the hearing on the 19th. A recall as mandated in Paragraph 3 is therefore an extraordinarily blunt and overbroad tool unsuited to the job of providing narrowly tailored relief, as required in this Circuit. *See Hoechst Diafoil Co. v. Nan Ya Plastics Corp.*, 174 F.3d 411, 423 (4th Cir. 1999) (holding that a remedy provided by injunctive relief must be narrowly tailored to "protect only against the particular, threatened injury").

Third, there is no mechanism for implementing Paragraph 3. As noted above, there has been no showing that FDA has any authority to order Mylan to recall a safe and efficacious product. Instead, FDA's power to withdraw approval is specifically set forth in statute and it is limited to instances where the ANDA applicant is given notice and an opportunity to be heard on issues such as safety and efficacy. *See* 21 U.S.C. § 355(e). Moreover, Fed. R. Civ. P. 65(d)(2) limits the reach of this Court's injunctive power to the parties before it. *See* Fed. R. Civ. Proc. 65(d)(2) (limiting injunctive relief to the parties, their agents, and those "who are in active concert or participation" with them). Thus, entities such as Mylan's customers would not be subject to an order to return product, and Mylan has no ready contractual mechanism to require customers to return safe and efficacious product. *See Golden State Bottling Co., Inc. v. N.L.R.B.*,

414 U.S. 168, 179 (1973) (holding that Rule 65(d) covers only nonparties "in interest," "in 'privity,'" "represented by," or "subject to the control" of the enjoined party). Additionally, other generic manufacturers who have sold generic Precedex but who did not elect to intervene in the current action would enjoy an unfair advantage over Mylan, as they too would be beyond the reach of the Court's injunctive power under Rule 65(d)(2). *Id.*

Finally, the command in Paragraph 4 that any action taken by FDA pursuant to Docket No. FDA-20140-N-0087 is rescinded *ab initio* is utterly without precedent and has far-reaching and extraordinary potential consequences. This Paragraph literally strips Mylan of the regulatory approval it enjoyed to market its DEX product, creating the real specter that Mylan and others in the distribution chain acted without the requisite legal authority. To Mylan's knowledge, this has never occurred before in a Hatch-Waxman case and raises profound questions as to the consequences of the Order. Mylan in good faith sold its ANDA DEX product based on a determination by FDA that the product was safe and efficacious, just like the product to which it is bioequivalent. *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 216 (D.D.C. 1996) ("The bioequivalence requirement [of 21 U.S.C. § 355(j)(2)(A)(iv)] 'acts as a market entry restriction to ensure that generic drugs will be as safe and effective as their pioneer drug counterparts.'") (quoting *Schering Corp. v. Food and Drug Admin.*, 51 F.3d 390, 396 (3rd Cir. 1995). Indeed, it would be unlawful for Mylan to market DEX without such approval. 21 U.S.C. 355(a) ("No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection…(j) of this section is effective with respect to such drug.").

Paragraph 4 thus works an unprecedented, extraordinary, and unknowable potential penalty on Mylan and others in the distribution chain, none of whom were before the Court to be

heard. Most significantly, the reputational harm alone that Mylan would suffer if it were found to have sold unapproved pharmaceutical products is incalculable and far exceeds any alleged monetary harm that Hospira incurred due to Mylan being on the market for a single day. See *Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 552 (4th Cir. 1994) ("[T]he threat of a permanent loss of customers and the potential loss of goodwill also support a finding of irreparable harm.")(citing *Blackwelder Furn. Co. v. Seilig Mfg. Co., Inc.*, 550 F.2d 189, 197 (4th Cir. 1977) ("Irreparability of harm includes the impossibility of ascertaining with any accuracy the extent of the loss.")). The breadth of the injunction is thus excessive and should be stayed or otherwise modified to address future conduct rather than conduct that was fully lawful at the time in which it was engaged.

II. In the Alternative, the Court Should Stay Entry of the Order Pending Mylan's Appeal to the Fourth Circuit

In the alternative, should the Court deny Mylan's request to stay entry of Paragraphs 3 and 4, Mylan will be forced to seek emergency relief from the U.S. Court of Appeals for the Fourth Circuit. To provide adequate time to make this request, Mylan respectfully asks for a short stay of the Court's Order so that an appeal may be filed. "'[T]he power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants.' Landis v. N. Am. Co., 299 U.S. 248, 254 (1936); *see also Air Line Pilots Ass'n v. Miller*, 523 U.S. 866, 879 n.6 (1998) (same)."

III. Conclusion

For all the reasons set forth above, Mylan asks that the Court stay Paragraphs 3 & 4 of the Order (Dkt. No. 20) entered on April 19, 2014, or, in the alternative, stay the Order in its entirety pending emergency appeal to the Fourth Circuit.

Dated: August 20, 2014

Respectfully Submitted,

/s/ *Shannon M. Bloodworth*

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that the above motion to stay was served the 20th day of August, 2014, by overnight mail, as follows:

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/S/ Shannon M. Bloodworth
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