**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE FOURTH CIRCUIT**

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| Hospira, Inc. | * | |
| Appellant, | * | |
| v. | * | |
| Sylvia Mathews Burwell, et al. | * | Case No. 14-1920 |
| Appellees. | * | |
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**APPELLANT'S EMERGENCY MOTION FOR INJUNCTION PENDING APPEAL, MEMORANDUM IN SUPPORT AND REQUEST FOR EXPEDITED CONSIDERATION**

## INTRODUCTION

Pursuant to Fed. R. App. P. 8(a)(2), appellant Hospira, Inc. respectfully moves the Court for entry of an injunction pending the hearing and disposition of this appeal. This appeal arises from a final judgment of the United States District Court for District of Maryland (Hon. George Jarrod Hazel.) entered on the evening of September 5, 2014. (ECF No. 123). Immediately prior to the entry of that judgment, the lower court held a telephone conference to announce its decision. Following the Court's announcement of its holding, Hospira, through counsel, made an oral motion for a stay and/or for an injunction pending appeal. That motion was denied. Ex. B (ECF No. 125).

Hospira urgently needs an injunction pending the disposition of this appeal. In the absence of injunctive relief, Hospira will suffer irreparable harm, harm which will not and cannot be undone even if Hospira prevails in this appeal. Hospira has strong grounds for obtaining reversal of the lower court's decision, and the balance of the equities and the public interest strongly favor granting the requested injunctive relief.

Hospira's complaint challenges a final agency decision of the defendant (now appellee) United States Food and Drug Administration ("FDA"). That decision authorizes FDA to approve generic versions of a Hospira prescription drug. Hospira's position is that FDA's decision is unlawful both substantively and procedurally, and thus any generic drug approvals which FDA grants based on that decision are similarly unlawful. FDA's decision is substantively unlawful because it violates the 1984 Hatch-Waxman Amendments to the federal Food, Drug, and Cosmetic Act ("FDCA"), specifically 21 U.S.C. § 355(j)(2)(A)(viii), as interpreted by FDA and the Supreme Court in *Caraco Pharm. Labs. Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012); FDA's decision is procedurally unlawful because it violates the rulemaking requirements of the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 553(b)-(d). The court below rejected both of Hospira's claims. *See* Ex. A (District Court's Memorandum Opinion, ECF No. 122). For the reasons set forth below, there is a substantial likelihood that Hospira will prevail in this Court on one or both of its claims, either of which is a sufficient basis for a judgment in Hospira's favor.

The immediate undeniably urgent consequence of the lower court's decision is that it dissolves the district court's temporary restraining order (entered on August 19, 2014, ECF No. 20, and modified on August 26, 2014, ECF No. 75) which order preserved the status quo while this action was pending in the lower court. That order stayed any further approvals of generic versions of Hospira's drug and stayed the further sale and distribution of generic versions of the drug by the two generic manufacturers which had obtained FDA approvals as the immediate consequence of and on the same day as FDA's decision, Mylan Institutional LLC ("Mylan") and Par Sterile Products LLC ("Par"), both intervenor defendants below (now appellees). In the absence of an injunction pending appeal, generic versions of Hospira's drug, starting first with a

flood of product from Mylan and Par and likely followed by others as FDA grants further approvals, will be on the market in large volumes in violation of Hospira's market exclusivity rights and, as a consequence, Hospira will be irreparably harmed.

The narrow relief which Hospira seeks is the relief the court below granted in its modified temporary restraining order. Pending the outcome of this appeal, this Court should stay the effectiveness of FDA's decision, including prohibiting FDA from granting any further generic drug approvals based upon the decision which Hospira challenges in this case, and prohibiting Mylan and Par from the further sale and distribution of their respective generic versions of Hospira's drug. A proposed form of order is attached.

In conjunction with the present motion for an injunction, Hospira moves separately to expedite proceedings in this matter. That motion seeks the establishment of a briefing schedule so that the Court may hear oral argument in this matter during the October 2014 argument session. This case proceeded on a very expedited basis in the court below (from filing on August 19, 2014, to final disposition on September 5, 2014). Hospira respectfully submits that comparable expedited proceedings are appropriate here. Further, expediting the matter blunts the anticipated arguments in opposition to the present motion for an injunction of Mylan and Par, if not FDA, of alleged harm and prejudice if the Court grants the requested injunction pending appeal.

Further grounds and arguments in support of Hospira's motion are set forth below.

## FACTUAL AND LEGAL BACKGROUND

Hospira is the New Drug Application ("NDA") holder for dexmedetomidine hydrochloride, which it markets under the brand name Precedex. Hospira obtained FDA's approval for two indications (*i.e.*, FDA-approved uses) for Precedex: (1) "sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting,

[administered] by continuous infusion not to exceed 24 hours," and (2) "sedation of non-intubated patients prior to and/or during surgical and other procedures." Ex. A at 7-8. While the first indication only instructs use in the ICU, the second indication relating to surgical and other procedures instructs use both in and out of the ICU. FDA has acknowledged that some uses under the second indication will take place in the ICU.

Hospira is an owner of U.S. Patent No. 6,716,867 ("the '867 patent"). The '867 patent gives Hospira exclusive rights over the claimed "method of use" of Precedex. The '867 patent contains two independent use claims directed to methods of "sedating a patient in an intensive care unit." *Id.* Hospira timely filed the '867 patent with FDA on May 6, 2004, along with the patent's expiration date and a description of the method-of-use protected by the patent (the patent "use code"). In line with FDA's self-described "ministerial" role with respect to patent matters, FDA published Hospira's use code, "intensive care unit sedation," in FDA's comprehensive listing of all drug products (commonly referred to as the "Orange Book"). *Id.* Hospira subsequently filed a clarification, but not broadening, of its use code.

Companies seeking to bring a generic version of a brand drug product to market may submit an Abbreviated New Drug Application ("ANDA"). ANDA applicants may rely on the safety and efficacy studies contained in the NDA (in this case, Hospira's NDA for Precedex), as long as the generic version of the drug has the same active ingredients and routes of administration as, and is "bioequivalent" to, the innovator (brand) drug. *See* § 21 U.S.C. 355(j)(2)(A)(ii)-(v).

The FDCA requires that an ANDA file one of four certifications with respect to each patent listed in the Orange Book: (i) patent information has not been submitted; (ii) the patent has expired; (iii) the ANDA applicant will not seek final FDA approval before the date the patent

expires; or (iv) the brand's patent is invalid, unenforceable, or will not be infringed by the ANDA applicant's product ("paragraph IV"). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). The FDCA and FDA regulations provide clear mechanisms for timely and expeditious judicial review and resolution of any patent disputes if an ANDA files a paragraph IV certification. An ANDA applicant that submits a paragraph IV certification must give notice to the holder of the patent, which then has a 45-day period in which to bring an action for patent infringement, and the bringing of this action automatically stays final FDA approval of the ANDA application until the court rules that the patent is not infringed, or until 30 months have passed, whichever occurs first. *See* 21 U.S.C. § 355(j)(5)(B). In this case, Sandoz, Inc. pursued the proper paragraph IV process and obtained its statutory 180-day exclusivity rights.

In limited circumstances, an ANDA applicant is permitted to bypass the paragraph IV certification and notice requirements and seek immediate review and then approval for its generic drug. An ANDA applicant seeking to bypass the paragraph IV certification procedure must state in its application that it is not seeking approval for an approved indication (an FDA approved use for the drug) covered by the patented method of use, but, instead, is seeking approval only for an approved indication that is *not* covered by any unexpired method-of-use patent. 21 U.S.C. § 355(j)(2)(A)(viii). This statement is commonly referred to as a "section viii statement." FDA, for its part, can approve an ANDA that relies on a section viii statement *only* if the generic's label (approved use) does not overlap with the brand's (Hospira's) patent use code. *See Caraco*, 132 S. Ct. at 1677 (citing 68 Fed. Reg. 36682-36683 (2003)) (FDA's statements). In that limited situation, a generic applicant will propose labeling (proposed use) for the generic drug that redacts or "carves-out" from the brand drug's approved labeling the patented methods of use. *See* 21 C.F.R. § 314.94(a)(8)(iv). Section viii statements are very

much the exception, and FDA may approve a modified "carve-out" label only if the applicant satisfies the section viii conditions. *See* 21 C.F.R. § 314.127(a)(7).

FDA's clear position and practice for years has been that it would not approve an ANDA that relies on a section viii statement if that statement overlaps *in any way* with the brand's use code as published in the Orange Book. *See* 68 Fed. Reg. at 36682-36683. As the Supreme Court has noted, "whether section viii is available to a generic manufacturer depends on how the brand describes its patent. Only if the [innovator's] use code provides sufficient space for the generic's proposed label will the FDA approve an ANDA with a section viii statement." *Caraco*, 132 S. Ct. at 1677. Thus, if the NDA holder's use code and related narrative for its method-of-use patent overlaps "at all" with all approved indications, the FDA has to reject a section viii statement. *See id.* ("[T]he FDA will not approve such an ANDA if the generic's proposed carve-out label *overlaps at all* with the brand's use code." (emphasis added)). The Supreme Court's understanding of FDA's position came directly from the amicus brief the Federal Government (FDA) submitted. Brief for the United States as Amicus Curiae Supporting Petitioners, *Caraco Pharm. Labs. Ltd. v. Novo Nordisk A/S*, 2011 WL 3919720, at *5 (2011).

## PROCEEDINGS AT FDA AND FDA'S DECISION

Hospira wrote to FDA's Chief Counsel in January 2014 requesting that FDA confirm that it would not grant final approval to any ANDA for generic Precedex based on a section viii statement. Rather than doing so, FDA sent a letter to Hospira (as the NDA holder) and a limited pool of others ("all applicants who submitted Abbreviated New Drug Applications (ANDAs) to the [FDA] referencing Precedex") soliciting comments in a public online docket (Docket No. FDA-2014-N-0087) which it labeled "rulemaking." *See* Ex. A at 11-12. FDA sought comments "on certain legal and regulatory issues that pertain to Precedex." The comments are in the Administrative Record. One of the reasons that FDA gave for opening the docket was to

"establish an administrative record on which the agency may base future decisions." Administrative Record 000864.

On August 18, 2014, nearly a full 7 months after the docket was closed to further comments, FDA issued its decision. Ex. A at 13-14. In its decision, FDA stated that FDA "can approve ANDAs for broad, general indications that may partially overlap with a protected method of us." *Id*. at 14. FDA acknowledged the overlap between Hospira's use code and the procedural indication. *Id.* at 14. FDA's decision was the predicate for FDA to grant final approval to generic versions of Precedex (Mylan and Par) based upon a section viii statement. Almost immediately Par, by its own admission, released a 6-week supply of generic Precedex into the market. ECF No. 40. Mylan, too, admitted that in the 36-hour period between the FDA docket decision and the district court's TRO, it had transferred "tens of millions" of dollars' worth of generic Precedex to wholesalers and customers. ECF No. 39-3 ¶ 8.

## PROCEEDINGS BELOW

This action was filed in the early morning hours on August 19, 2014, about 12 hours after FDA posted its final decision in Docket No. FDA-2014-N-0087. Hospira filed a two-count complaint challenging FDA's decision on substantive grounds (the decision violates the section viii provision of the statute) and procedural grounds (the decision violates the rulemaking requirements of the APA) and a motion for a temporary restraining order. The district court held a hearing on that motion on the afternoon of August 19 and at that hearing it granted the motions to intervene of Mylan (as an intervenor defendant) and Sandoz Inc. (as an intervenor plaintiff) (Par sought and was granted intervention subsequently). At the conclusion of the hearing, the court took the matter under advisement and later that evening issued a Memorandum Opinion and Order granting Hospira's motion for a temporary restraining order. ECF No. 19-20. The court found that there was a substantial likelihood that Hospira would prevail on both of its

claims, that Hospira would suffer irreparable injury in the absence of a temporary restraining order, and that the balance of the equities and the public interest weighed in favor of Hospira. *Id.*

The following day, August 20, during a telephone conference with counsel, the court granted Mylan's motion to stay a portion of the temporary restraining order pending the filing of a motion for reconsideration. Mylan and Par sought reconsideration and rescission of the entire order and, following a hearing, the court denied full reconsideration while issuing a modified temporary restraining order which, among other things, preserved the stay of FDA's docket decision and prohibited any additional shipments of generic Precedex by Par and Mylan. ECF No. 75.

The court advanced final proceedings on the merits and consolidated them with the hearing on Hospira's motion for a preliminary injunction. Following briefing and a hearing on September 4, the Court issued its Memorandum Opinion and Order on September 5 denying Hospira's motion for summary judgment and granting the cross-motions of FDA, Mylan, and Par. Ex. A. The court also denied Hospira's motion for a stay/injunction pending appeal, including the limited request for a stay/injunction for a few days, until September 10, pending application to this Court. Ex. B. Hospira's appeal was noted on September 5.

## ARGUMENT

### A. Standard

In determining whether to grant the requested injunctive relief a stay under Fed. R. App. P. 8(a)(2), the Court considers: (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether the issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies. *Hilton v. Braunskill*, 481 U.S. 770, 776

(1987); *accord Long v. Robinson*, 432 F.2d 977 (4th Cir. 1970).[1] The four factors are balanced, such that a stronger showing on some of the prongs outweighs a weaker showing on others. 16A Wright & Miller, *Federal Practice and Procedure* § 3954 (4th ed. Apr. 2014); *Brady v. Nat'l Football League*, 640 F.3d 785, 789 (8th Cir. 2011) ("Ultimately, we must consider the relative strength of the four factors, 'balancing them all.'"). Absent a stay of the district court's decision and an injunction, if the district court is later reversed when the Court rules on the merits of the appeal, a victory would be hollow; Hospira's remaining period of exclusivity (until Sandoz comes to market in December pursuant to the parties' settlement agreement) would be eliminated.[2]

**B. The Court Should Enter An Injunction Pending Appeal.**

**1. Hospira Is Likely To Succeed On The Merits Of The Appeal.**

Hospira need not show that its "ultimate success . . . is a mathematical probability"; it is sufficient if the appellant "has raised questions going to the merits so serious, substantial, difficult and doubtful, as to make them a fair ground for . . . more deliberative investigation." *Wash. Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 843-44 (D.C. Cir.

[1] The Administrative Procedure Act also provides that, "[o]n such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court . . . may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705. The "test" for stay of an agency action pending judicial review is the same as that applied to a request for preliminary injunction, *Wash. Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841 (D.C. Cir. 1977), which is similar to the present test. *See, e.g., Apotex v. FDA*, No. 04-5211 (D.C. Cir. July 26, 2004) (ordering that FDA's final approval of ANDA be stayed pending resolution of the appeal).

[2] This Court has not decided whether, under *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7 (2008), an independent showing must be made for each factor. *See Rose v. Logan*, No. RDB-13-3592, 2014 U.S. Dist. LEXIS 98404, at *2-6 (D. Md. July 21, 2014). If the Court decides to apply *Winter* here, Hospira makes the requisite showing under each factor. This case demonstrates why, as to appeals, *Winter* should not apply; regardless of what the Court thinks about the other three factors, if the Court does not grant a stay of the district court's order and order an injunction and a few months from now decides that Hospira is entitled to win on the merits, a victory will be meaningless. *See infra*.

1977) (affirming district court's order staying its permanent injunction where court "ruled on an admittedly difficult legal question and when the equities of the case suggest[ed] that the status quo should be maintained"). The Court must weigh the likelihood of success in a case presenting "an admittedly difficult legal question" against the other factors (the public interest and the balance of equities) and determine whether a stay is appropriate. *Id.* Hospira makes the necessary strong showing on both of its counts.

*First*, FDA violated the FDCA by deciding that it could approve a generic drug pursuant to a section viii statement. The statute is clear that a section viii approval is only available if Hospira's "method-of-use patent . . . does not claim a use for which the applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(viii). Hospira's method-of-use patent (as determined by Hospira's use code description) claimed a use (procedural sedation in the ICU) for which the ANDAs were seeking approval. The significance of the issues which Hospira raises is confirmed by FDA's own lengthy deliberations here. FDA opened a docket, received comments, and considered the matter for almost seven months. An assertion that Hospira's substantive Hatch-Waxman claim is not significant and substantial is undercut entirely by this history.

Further, the strength of Hospira's position is confirmed by the fact that it is, as the district court noted in granting a temporary restraining order, a position "embraced" by the Supreme Court in *Caraco* (ECF No. 19): "the FDA will not approve such an ANDA [pursuant to a section viii statement] if the generic's proposed carve-out label overlaps at all with the brand's use code." 132 S. Ct. at 1677. Here, there is FDA acknowledged "overlap" and yet FDA's decision authorizes generic approvals (and approvals have been granted with more to follow) notwithstanding this overlap. The district court misapplied this Court's decision in *Sigma-Tau Pharmaceuticals v. Schwetz*, 288 F.3d 141 (4th Cir. 2002). This case, unlike *Sigma-Tau*, is not

about "foreseeable" or "off-label" use; rather, the improper FDA approval here authorizes "on-label" protected use. There is a substantial likelihood of reversal on this ground.

*Second*, Hospira is also likely to prevail on its procedural claim. FDA acted contrary to the APA by promulgating a new "rule" without following the notice-and-comment procedures of the APA. FDA improperly used a "rulemaking lite" docket to "establish an administrative record on which the agency may base future decisions." Administrative Record 000864. FDA's decision sets forth a rule as that term is defined in the APA ("an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy," 5 U.S.C. § 551(4)), and yet – and this not in dispute – it was not adopted in accordance with the APA's rulemaking requirements. FDA's decision-adopted rule "has the force of law," *Molycorp v. EPA*, 197 F.3d 543, 545 (D.C. Cir. 1999), it will "affect[] individual rights and obligations," *Morton v. Ruiz*, 415 U.S. 199, 232 (1974), and represents a sharp departure from FDA's previously oft stated "no overlap at all" position, *N.C. Growers' Ass'n v. United Farm Workers*, 702 F.3d 755, 765-66 (4th Cir. 2012). FDA's not properly adopted rule has all the indicia of being a "rule" squarely within the contemplation of and subject to the rulemaking requirements of the APA and, accordingly, it is invalid because it was not lawfully adopted. There is a substantial likelihood of reversal on this ground.

In ruling on Hospira's motion for temporary restraining order/preliminary injunction, the court below found that Hospira was likely to succeed on the merits of both counts of the complaint. (ECF No. 19, at 5-6). After Mylan moved to reconsider the temporary restraining order in total, the district court denied Mylan's request, amending the order only in part. (ECF No. 75). The lower court in denying a stay/injunction pending appeal acknowledged that, notwithstanding the court's decision on the merits, Hospira satisfied the "substantial likelihood

prong" for purposes of an injunction pending appeal. This case involves serious and substantial questions. The district court's decision reflects the weight and difficulty of the issues at hand and demonstrates the importance of maintaining the status quo until the Fourth Circuit has an opportunity to rule on the matter.

**2. Hospira Will Be Irreparably Harmed Absent A Stay.**

Without this Court's immediate intervention, Hospira will be irreparably harmed. The district court twice recognized the importance of maintaining the status quo; the district court record, including affidavits submitted by defendant intervenor Par, *see, e.g.*, (ECF No. 40 Pera Decl.), demonstrate that even one day can be – and has been – used by Par and defendant intervenor Mylan to radically change the status quo. If the Court ultimately agrees with Hospira on the merits of either of its claims in a few months, that victory will be a hollow one if this Court rules against Hospira without a stay.

Irreparable harm is demonstrated where any calculation of damages is "'difficult to ascertain or are inadequate'" or where "the failure to grant preliminary relief creates the possibility of permanent loss of customers to a competitor or the loss of goodwill." *Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 551-52 (4th Cir. 1994); *see also Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Bradley*, 756 F.2d 1048, 1055 (4th Cir. 1985) ("irreparable, noncompensable harm in the loss of . . . customers"); *Signature Flight Support Corp. v. Landow Aviation Ltd. P'ship*, 442 F. App'x 776, 785 (4th Cir. 2011) (irreparable harm met in permanent injunction case where evidence demonstrated harm in fact by losing customer base and loss of goodwill). Price erosion and diminished market share also constitute irreparable harm, particularly in the context of generic drug entry. *Bayer Healthcare, LLC v. FDA*, 942 F. Supp. 2d 17, 26 (D.D.C. 2013). The entry of a generic to market inevitably results in a decline in the brand's price and a loss of good will to customers, who will buy the

less expensive drug. *Id.*; *see also AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1063 (Fed. Cir. 2010) (affirming grant of injunctive relief where damage from layoffs caused by generic entry would be significant and unquantifiable).

If the Court denies a stay and Hospira ultimately wins on appeal, Hospira will be irreparably harmed. For one, Hospira will have been deprived of its statutory right to exclusivity. Generic manufacturers commonly place at least six months' worth of generic product into the wholesale distribution channel within days of final approval in an effort to secure the most favorable position vis-à-vis other generic entrants. Ex. C ¶ 18. FDA approved two generic drugs in its August 18 Decision, and it is undisputed that Par and Mylan shipped their product immediately upon receiving approval from FDA. (ECF No. 40 Para Decl. ¶ 13; ECF No. 39-3 ¶¶ 8-9; ECF No. 65-6 ¶¶ 3, 7). And undoubtedly, very soon after the district court issued its final judgment and denied Hospira's motion to stay, Mylan and Par resumed shipping their generic product. Mylan and Par will continue to do so until the Court issues a stay and orders an injunction or Hospira ultimately wins on the merits. If Hospira wins a few months from now, absent a stay and injunction, that victory will be hollow.

As an almost immediate consequence of premature generic entry, Hospira will be forced to terminate its U.S. brand drug sales force of approximately 130 persons. Ex. C. ¶ 20; *see also Par Pharms. v. TWi Pharms.* No. CCB-11-2466, 2014 U.S. Dist. LEXIS 110963, at *10-11 (D. Md. Aug. 12, 2014) (finding that Par demonstrated irreparable harm by presenting evidence that lost revenue would likely force entire branded division to shut down, which was an alleged "small portion of Par's overall business"). Precedex sales will immediately and significantly erode; rapid sales and price erosion are common upon entry of multiple generics due to the generic practices of pricing at a discount to the brand to ensure uptake and placing multiple

months of the generic product in the wholesale distribution channel immediately on FDA approval. Ex. C ¶ 21. Significant price erosion is used to acquire market share; this is in contrast to a situation in which there is one generic during a 180-day exclusivity period (*i.e.*, Sandoz). *Id.* That price erosion and market share will not be recoverable. *Id.* Significant lost profits will hinder Hospira's ability to fund research and development on new drug products and will eliminate Hospira's ability to fund clinical trials for Precedex. *Id.* ¶¶ 23, 24. Moreover, as Sandoz argued below, "[n]o party seriously disputes the irreparable statutory injury Sandoz faces if [it loses the exclusivity period for which it fought]." ECF No. 108, at 15. Absent an injunction, the current two generics on the market are certain to be joined soon by additional ones as FDA grants approvals pursuant to the decision challenged here. The administrative record shows at least two other potential section viii filers are in queue for ANDA approval, and and the prospect of their entry in the market will further irreparably erode Hospira's market position. The harm to Hospira will grow as new generics enter the market.

In granting the temporary restraining order, the district court found that Hospira would be irreparably harmed by the flood of generics to market given erosion of market share and price, possible termination of Hospira's U.S. brand drug sales force, and possible permanent loss of customers. ECF No. 6-8 (citing *Multi-Channel TV Cable Co.*, 22 F.3d at 551-552). Precedex represents roughly 98.4% of Hospira's U.S. branded pharmaceutical business. Ex. C ¶ 16. The district court, in denying Hospira's motion for stay, dismissed the importance of this number because "this is a relatively small portion of its overall company." Ex. B. This, however, does not diminish the irreparable harm to Hospira. The irreparable injury is that, as a result of generic entry, Hospira will suffer irreparable loss of customers, loss of market share and price erosion, and be forced to terminate its U.S. brand drug sales force. Ex. C. The sales force exists only for

the brand business, Ex. C ¶ 20, for which Precedex is 98.4%. Though the posture of the case has changed, the harm (and possibility for more as more generics are approved) remains no only unchanged but increases.

**3. The Issuance Of An Injunction Will Not Substantially Injure Other Parties.**

Absent action by the Court, Hospira will be severely and irreparably injured. Hospira will lose the advantages it enjoys from the rights it has in the '867 patent while it waits for a resolution of the underlying question of the illegality of FDA's action. FDA will suffer no harm if the Court grants the requested injunction. FDA has no stake in the immediate implementation of its decision. Hospira, however, has no monetary recovery remedy against FDA to recover Hospira's losses in the absence of an injunction. *See FDIC v. Meyer*, 510 U.S. 471, 475 (1994) ("Absent a waiver, sovereign immunity shields the Federal Government and its agencies from suit."); *e.g.*, *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 77 n.19 (D.D.C. 2010) (claimed economic injury is irreparable because plaintiffs cannot recover damages against FDA because it is shielded by sovereign immunity), *aff'd sub nom. Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010). And Hospira has no remedy at law – monetary damages or otherwise – to compensate it for the loss that it was denied its procedural rights under the APA.

If this Court rules in Hospira's favor, Mylan and Par will have benefitted tremendously (and not have been harmed) by flooding the market and eliminating Hospira's statutory right to patent exclusivity. An ultimate decision in this case will occur, even on an expedited schedule, not for a number of months. Under any time frame, a victory will be hollow. Mylan and Par will have placed enough generic product onto the market to eliminate Hospira's statutory right to exclusivity if the Court ultimately rules in Hospira's favor.

Granting the limited interim relief requested will not substantially injure the other parties. It will maintain the status quo while the appeal is pending. Hospira fully supports expediting

proceedings on the merits of this case. This matter should proceed very quickly to the merits, with Hospira filing its Opening Brief very soon, followed by the Appellee's Response Brief, and then Hospira's Reply Brief very soon thereafter. With the schedule Hospira is proposing, this case will have gone from complaint to final appellate argument in approximately two months, compared to the seven months it took FDA to make its docket decision.

**4. The Public Interest Favors Entering An Injunction.**

As the district court found in granting the temporary restraining order, the public certainly "has an interest in an agency's compliance with its governing statute." ECF No. 19, at 8. Here, Sandoz followed the law, litigated the patent issues, and obtained the right to come to market five years prior to patent expiration. The process worked as Congress intended, but FDA's decision and Mylan's and Par's entry into the market has upset the balance Congress set in the Hatch-Waxman Amendments. "[I]t is generally in the public interest to uphold patent rights." *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 704 (Fed. Cir. 2008). "[T]he patent system provides incentive to the innovative drug companies to continue costly development efforts," and thus, there is a "significant 'public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents." *Sanofi-Synthelabo v. Apotex*, 470 F.3d 1368, 1383 (Fed. Cir. 2006). Hatch-Waxman does not encourage generic entry by disregarding the law.

The public interest is also served by requiring FDA to comply with the law, not by allowing it to act outside the bounds of its authority and without the notice and full participation the APA requires for promulgating rules. *See N.C. Growers' Ass'n*, 702 F.3d at 765-66 (notice and comment procedures ensure the agency "benefits from the experience and input of comments by the public" and are "designed to encourage public participation in the

administrative process"). FDA proceeded at a stately pace in its deliberations of this matter; all parties respected that process and awaited the agency's outcome; the public interest is not served by rushed (further) implementation of FDA's decision.

In anticipation of arguments that the public has an interest in immediate access to low-cost generic versions of generic Precedex, Hospira notes that no such sense of urgency was evidenced by FDA, which took 7 months to issue its docket decision that led to the approval of Mylan's and Par's ANDAs.

**C. The Court Should Waive the Bond Requirement.**

The Court has the discretion whether to require a bond to secure the opposing parties' rights. *See* Fed. R. App. P. 8(a)(2)(E) ("The court may condition relief on a party's filing a bond or other appropriate security in the district court."). Hospira respectfully requests that the Court waive a bond here. Hospira will move expeditiously to have this case heard and decided on the merits. It is undisputed that Mylan and Par have already supplied their wholesalers with a significant supply of generic product. (ECF No. 40 Para Decl. ¶ 13; ECF No. 39-3 ¶¶ 8-9; ECF No. 65-6 ¶¶ 3, 7). In arguing below that they should not be required to recall product, Mylan and Par argued that they had distributed a high volume – months – of product to their distributors; any supposed harm will be more than compensated by the fact that Mylan and Par have already profited from a head start in the market place. In addition, the stay Hospira is requesting will preserve Mylan's and Par's market position by preventing other section viii filers from coming on the market while the stay is in place.

## CONCLUSION

For the reasons stated, the Court should grant Hospira's motion for immediate stay of the district court's decision and for an injunction pending appeal. A proposed form of order is attached.

Respectfully submitted,

Dated: September 6, 2014

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*Attorneys for Appellant Hospira, Inc.*

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE FOURTH CIRCUIT**

| | | |
|---|---|---|
| Hospira, Inc. | * | |
| Appellant, | * | |
| v. | * | |
| Sylvia Mathews Burwell, et al. | * | Docket No. 14-1920 |
| Appellees. | * | |
| | * | |

* * * * * * * * * * * * *

**[Proposed] Order**

Pending before the Court is the motion of Appellant Hospira, Inc. ("Hospira") for an injunction pending the disposition of this Court's review of the final judgment of the United States District Court for the District of Maryland entered on September 5, 2014, in Case No. GJH-14-02662 (ECF No. 123) ("the Judgment"). Having reviewed the motion and any opposition thereto, the Court finds that Hospira has made the necessary showing for relief under Fed. R. App. P. 8(a). The Court finds that (1) Hospira has made a strong showing that it is likely to succeed on the merits; (2) Hospira will be irreparably injured absent a stay and the injunctive relief requested; (3) the issuance of the stay and an injunction during the pendency of this appeal will not substantially injure the other parties interested in the proceeding; and (4) the public interest lies in favor of a stay of the district court's judgment and injunction pending appeal.

For the reasons stated and for good cause shown, the motion is hereby GRANTED this _____ day of September, 2014 at _____. Therefore, the Judgment is hereby STAYED.

It is further ORDERED that:

1. The August 18, 2014 decision of Appellee U.S. Food and Drug Administration ("FDA") in Docket No. FDA-2014-N-0087 is hereby STAYED, and any additional action which FDA is proposing to take in reliance upon that decision, including issuing any further approvals of abbreviated new drug applications allowing the sale, marketing and distribution of a generic version of Precedex® is similarly STAYED and ENJOINED;
2. Appellees Mylan Institutional LLC and Par Sterile Products, LLC shall not sell, market or distribute generic versions of Precedex® during the pendency of this Order.

This Order shall remain in effect pending this Court's disposition of the appeal of the Judgment, or until further order of the Court.

Dated: September ___, 2014

_____

Judge
United States Court of Appeals
for the Fourth Circuit

**CERTIFICATE OF SERVICE**

I hereby certify that on this 6th day of September 2014, a copy of the foregoing Corporate Disclosure Statement was delivered, via electronic filing, to George Brian Busey, gbusey@mofo.com; Steven M. Klepper, sklepper@kg-law.com; Michael Randolph Shebelskie, mshebelskie@hunton.com; and julwick@kg-law.com. I further certify that the following were served by electronic mail:

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/s/

Ralph S. Tyler