No. 14–1920

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

HOSPIRA, INC.,

Plaintiff-Appellant,

and

SANDOZ INC.

Intervenor-Plaintiff,

v.

SYLVIA 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-Appellees,

MYLAN INSTITUTIONAL LLC,

and

PAR STERILE PRODUCTS, LLC

Intervenor-Defendants-Appellees.

Appeal from the United States District Court for the District of Maryland
in case no. 8:14-cv-02662, Judge George J. Hazel

APPELLEE MYLAN INSTITUTIONAL LLC'S OPPOSITION TO APPELLANT HOSPIRA'S EMERGENCY MOTION FOR INJUNCTION

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INTRODUCTION

Hospira's unsuccessful suit in the district court asserted an Administrative Procedure Act ("APA") challenge under *Chevron* step one to FDA's approval of Mylan's generic drug application. Remarkably, Hospira never mentions *Chevron* once in its breathless motion seeking yet again to prevent Mylan from providing affordable, safe, and effective generic Precedex® to physicians and patients. This alone signals the weakness of Hospira's merits argument. As this Court will see, the district court painstakingly reviewed Hospira's arguments and concluded that the statute in question, 21 U.S.C. § 355(j)(2)(A)(viii), does not even mention the key terms at the center of this dispute, so Congress could hardly be said to have "directly spoken to the precise question at issue." Rather than relying on the statutory language, as is required under *Chevron* step one, Hospira hinges its claim on a piece of *dictum* ripped out of context from the Supreme Court's decision in *Caraco*. The district court explained why Hospira's reliance on *Caraco* fails. And as it explained, *Caraco* did not address the question under section viii posed by this appeal. The primary focus of *Caraco* involved providing a means for generic companies to challenge brand company "use codes," which the Court found were often abused by the brands to frustrate generic competition. It is the height of irony for Hospira to use *Caraco* to protect its own blatant use code abuse.

Hospira also misdirects in emphasizing the temporary restraining order it

obtained at the start of its case. But Hospira obtained that order largely because the district court had received only Hospira's lengthy brief when it issued the order after an oral hearing. Once the district court had the benefit of full briefing from FDA and Mylan, it carefully considered the merits, corrected its course, dismissed Hospira's complaint, and dissolved the injunction. The district court correctly determined that § 355(j)(2)(A)(viii) is silent on the precise question at issue here and then, under the highly deferential standard of review mandated by *Chevron* step two, held that FDA's approval of Mylan's application was sound. Additionally, because the district court found that FDA's decision was entirely consistent with its past practice, Hospira's procedural claim that FDA should have conducted a full rulemaking also fails. Indeed, fatal to Hospira's ability to show that it will succeed on this claim, the district court noted that, despite numerous requests that Hospira cite a contrary FDA decision, "Hospira's counsel was unable to provide any examples." Mem. Op., Dkt. No. 122, at 26 n.5.

Hospira's harm arguments fare no better, as they rely on the same hyperbole that characterize its merits arguments. For example, Hospira characterizes generic competition as a death blow, claiming that Precedex® accounts for 98.4% of its U.S. brand sales. Hospira fails to disclose that it has a robust generic business, such that Precedex® comprises only 17% of its total U.S. sales. Just as importantly, Hospira already faces generic competition as early as December 2014 (as a result

of settling patent litigation with Sandoz). Hospira has also prepared for earlier generic competition, telling investors that it has calculated the effect of this competition and that it will have a small impact on its earnings. Absent an injunction, Hospira faces only economic harm, which it admits it can quantify.

The harm faced by Mylan and the public, however, is all too real and irreparable. Hospira's use-code gamesmanship has already sidelined Mylan for over half a year, and the improper TRO that Hospira obtained has substantially hurt Mylan's ability to sell generic Precedex® due to market uncertainty and tainted Mylan's reputation for reliability. And keeping Mylan off the market is a key component of Hospira's efforts to switch the market to its new product, Precedex® Premix; if this happens, Mylan will never be able to recover its lost sales.

Moreover, the public is suffering a tremendous financial burden by having to pay Hospira's monopoly prices for Precedex®, and has no recourse for this harm. Moreover, the rule that Hospira wants in this case would dramatically impair FDA's ability to approve applications like Mylan's that seek to market a generic drug for a use not covered by a brand's patent, imposing huge costs on the American healthcare system. The primary public interest Hospira cites is vindication of the patent laws—left unsaid is that when Hospira sought to save the validity of the '867 patent, it told the exact opposite to the Federal Circuit: that the '867 patent *does not cover* the method of use that Hospira claims will be violated

under FDA's decision. Hospira does not seek to vindicate the patent laws—it has not even sued Mylan for patent infringement—it seeks to perpetuate improperly its monopoly. Mylan asks that this Court put a stop to Hospira's anti-competitive conduct and deny Hospira's demand for an injunction.

BACKGROUND

The Hatch-Waxman Act. Hatch-Waxman expressly permits a generic-drug company to submit to FDA an Abbreviated New Drug Application ("ANDA"). To inform ANDA applicants of which patents purportedly cover a brand drug, the brand company must submit to the FDA for publication in its "Orange Book" a "use code" for each listed method patent and certify to its accuracy within a specified timeframe. 21 U.S.C. § 355(b)(1), (i)(2); 21 C.F.R. § 314.53(c)(2)(ii); *Purepac Pharm. Co. v. Thompson* (*Purepac I*), 238 F. Supp. 2d 191, 208 (D.D.C. 2002). Courts repeatedly warn about abuse of the use code system by brand pharmaceutical companies. *Purepac I*, 238 F. Supp. 2d at 206-7, *aff'd*, 354 F.3d 877 (D.C. Cir. 2004) (*Purepac II*); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1678 (2012). For a patent listed in the Orange Book claiming a *method of use* of the listed drug product, Hatch-Waxman allows an ANDA applicant to file a section viii statement, which informs FDA that the listed patent "does not claim a use for which the [ANDA] applicant is seeking approval."

21 U.S.C. § 355(j)(2)(A)(viii) ("section viii"); *Purepac II*, 354 F.3d at 880.[1] To use a section viii statement, the ANDA applicant must remove from its ANDA label (or "carve out") the indication listed in the use code, creating a so-called "skinny label." *See* 59 Fed. Reg. 50347.

Submission and Tentative Approval of Mylan's ANDA. On February 28, 2011, Mylan submitted ANDA No. 202881 seeking FDA approval to sell Mylan's generic dexmedetomidine, branded by Hospira as Precedex®. AR[2] at 905-6. Precedex® is approved for two indications: "Sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting" (*i.e.*, Intensive Care Unit Sedation); and "Sedation of non-intubated patients prior to and/or during surgical and other procedures" (*i.e.*, Procedural Sedation).

As the district court found, these are distinct uses. Mem. Op. 28. Hospira's label describes "Intensive Care Unit Sedation" and "Procedural Sedation" as separate uses, with different dosages, administration instructions, withdrawal warnings, clinical trials and adverse event information. Mem. Op. at 8; AR at 866-90. The Drug Administration section of Hospira's label states that "Precedex should be administered only by persons skilled in the management of patients in

[1] Hospira contends (at 5-6) without citation that section viii statements "are very much the exception." Not true. Section viii is a congressionally sanctioned generic approval pathway, not some backdoor "exception."

[2] Cites to "AR" are to excerpts of the FDA's Administrative Record, filed below at Dkt. No. 76, and included as Exhibit 1 to the *Declaration of Shannon M. Bloodworth in Support of Mylan's Opposition to Hospira's Emergency Motion*.

the intensive care or operating room setting." AR at 870 (emphasis added).

U.S. Patent No. 6,716,867 ('867 patent) is a Hospira method patent, listed in the Orange Book with a use code. When Mylan submitted its ANDA, the Orange Book associated code U-572 ("Intensive Care Unit Sedation") with the '867 patent; Hospira separately listed U.S. Pat. No. 5,344,840 ("'840 patent," expired) as covering the Procedural Sedation Indication under a distinct use code. Mem. Op. at 8; AR at 899. Mylan did not seek to market its ANDA product for ICU Sedation, so Mylan submitted a section viii statement to the '867 patent and, as Hatch-Waxman permits, carved out of its ANDA label all references to ICU Sedation, *leaving only references to Procedural Sedation*. AR at 905-06. Mylan carved out of its label's Drug Administration section reference to the intensive care setting, stating that Mylan's product "should be administered *only* by persons skilled in the management of patients in the operating room setting." Dkt. No. 69-3 at 2.

Mylan's ANDA with its section viii statements was tentatively approved by FDA on March 4, 2013. *See* AR at 907-10. With this letter, Mylan's ANDA—with the section viii statement—was ready for final approval on January 15, 2014. Mem. Op. at 11.

Hospira's Change to the '867 Patent Use Code. On January 8, 2014, with the '840 patent (covering Procedural Sedation) having expired and approval of Mylan's ANDA imminent, Hospira belatedly revised its use code for the '867

patent, compelling FDA by law to change the Orange Book listing for that patent to U-1472, "Intensive Care Unit Sedation, Including Sedation Of Non-Intubated Patients Prior To And/Or During Surgical And Other Procedures." Mem. Op. at 11; AR at 855-858. Hospira offered no scientific or other substantive justification for this change; rather, it appears that Hospira simply grafted onto the use code for the '867 patent the use code that applied to its now-expired '840 patent. Nevertheless, Hospira assured FDA that the added language did *not* change the scope of the prior ICU Sedation use code. Mem. Op. at 11; AR at 858. In reliance on this statement, Mylan affirmed to the FDA that its section viii statement to the '867 patent remained correct. AR at 911.

Responding to Hospira's last-minute use-code change, FDA opened a docket and posted a Dear ANDA Applicant letter to gather input from parties potentially affected by the use code change. In its first filing to the docket, Hospira repeated its assurance to the FDA, saying that "Hospira did not in any way change the scope of the original use code, which was 'intensive care unit sedation.'" AR at 91; Mem. Op. at 11. Hospira further stated that the "old [ICU Sedation] and new use codes have exactly the same scope." AR at 101; Mem. Op. 11. FDA therefore determined that it could approve Mylan's ANDA with a carve out. Mem. Op. at 13; AR at 926.

As part of its deliberative process, FDA initiated a full labeling review and concluded that Mylan's label "carves out ICU sedation use," and is safe and

effective for the single Procedural Sedation indication. Mem. Op. at 12; AR at 959, 978. FDA also consulted with anesthesiologist Dr. Amelia Luckett, who found that "[n]one of the language explicitly related to intensive care unit (ICU) sedation was incorporated into the Mylan" ANDA label. Mem. Op. at 12.

FDA's determination is consistent with statements made by *Hospira itself* during prior litigation with Sandoz regarding the '867 patent. A year before submitting the revised use code, Hospira told the Federal Circuit that ICU Sedation and Procedural Sedation are distinct indications and that the '867 patent *does not* cover Procedural Sedation; the exact opposite of its position now. *Hospira, Inc. v. Sandoz Inc.*, No. 12-1426, 2013 WL 298230, at *76-77 (Fed. Cir. Jan. 11, 2013) (Hospira brief); Dkt. No. 39-2, Ex. 3 (Tr. from *Hospira, Inc. v. Sandoz Int'l*, No. 09-cv-4591, Dkt. No. 397 (D.N.J. Apr. 5, 2012)) at 147-148 (Dkt. No. 39-2 at 168-169). Hospira never informed FDA or the district court of these statements.

On August 18, 2014, FDA notified Mylan that its ANDA No. 202881 was approved. AR at 996-99. FDA also issued a decision letter in docket FDA-2014-N-0087, detailing its long-standing practice of approving ANDAs with appropriate section viii carve-outs. Mem. Op. at 13-14; AR at 804-19. The fifteen-page letter reviewed public comments, described the requirements for ANDA labeling, recounted FDA's previous and similar carve-out approvals, and determined that Mylan could carve out the ICU Sedation use. Mem. Op. at 13; AR at 804-19.

ARGUMENT

I. STANDARD OF REVIEW

In deciding whether to enter an injunction pending the disposition of this appeal, this Court must consider: "(1) whether the stay applicant has made a strong showing that [it] is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether 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). These factors track those required to obtain a preliminary injunction. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008) (listing factors). An applicant to this Court for such an injunction faces a "substantially greater" burden of persuasion than it faced before the district court. *Long v. Robinson*, 432 F.2d 977, 979 (4th Cir. 1970). Contrary to Hospira's suggestion (at 9 & n.2), this Circuit requires that each "factor be satisfied as articulated" and "separately consider[s] each *Winter* factor." *Pashby v. Delia*, 709 F.3d 307, 320-21 (4th Cir. 2013). Finally, a district court's factual findings in denying a stay are reviewed for abuse of discretion. *Maryland v. Universal Elections, Inc.*, 729 F.3d 370, 375 (4th Cir. 2013).

II. HOSPIRA FAILS TO SHOW LIKELY SUCCESS ON THE MERITS

Hospira's lawsuit advances two claims. *First*, it contends that in 21 U.S.C. § 355(j)(2)(A)(viii), Congress spoke directly to the precise questions at issue in this case and that FDA's approval of Mylan's ANDA transgressed that unambiguous

statutory command in violation of *Chevron* step one. *See, e.g.*, Hospira's Opp'n and Reply Mem. in Supp. of Mot. for Summ. J. (Dkt. No. 106) § II.A ("The Statute is Clear; This Is A *Chevron* Step One Case"). *Second*, Hospira contends that FDA's decision letter promulgated an entirely new rule, thereby requiring formal rulemaking procedures. Hospira is wrong on both counts and cannot show a strong likelihood of prevailing on either claim.[3]

Hospira's *Chevron* Argument Is Meritless. Remarkably, in its injunction motion in this Court, Hospira does not cite *Chevron*, much less explain why there is a strong likelihood it will prevail under the standards set forth in that seminal case. Nor does Hospira discuss the district court's *Chevron* analysis, much less attempt to demonstrate that it is wrong. "The objective of *Chevron* step one is not to interpret and apply the statute to resolve a claim, but to determine whether Congress's intent in enacting it was so clear as to foreclose any other interpretation." *King v. Burwell*, __ F.3d __, No. 14-1158, 2014 WL 3582800, at *5 (4th Cir. July 22, 2014) (quotations omitted). The question is not whether Hospira's "reading of [the statute] may be a plausible one," because "its burden is far higher than showing plausibility." *Philip Morris USA, Inc. v. Vilsack*, 736 F.3d

[3] Hospira says (at 11-12), without citation, that in denying a stay pending appeal, the district court "acknowledged that . . . Hospira satisfied the 'substantial likelihood prong' for purposes of an injunction pending appeal." That is nonsense. In denying a stay, the district court merely said that "this case presents complicated issues." Dkt. No. 125 at 2. That is *not* what Hospira says the district court said, and it is *not* the standard for showing likelihood of success on the merits.

284, 291 (4th Cir. 2013). Rather, "[t]o disturb [FDA's] decision at *Chevron* step one," Hospira "must persuade [the court] that [FDA's] decision is contrary to the unambiguously expressed intent of Congress." *Id*.

Hospira makes no effort to show that § 355(j)(2)(A)(viii) is "so clear" that FDA's hands are forever tied and any interpretation of section viii other than Hospira's reading is "foreclosed." In 21 U.S.C. § 355(j)(2)(A)(viii), Congress described the statement an ANDA applicant must give FDA when only an *unprotected* use is sought:

> [I]f with respect to the listed drug . . . information was filed [by the brand manufacturer] . . . for a method of use patent which does not claim a use for which the [ANDA] applicant is seeking approval under this subsection, [the applicant's ANDA shall contain] a statement that the method of use patent does not claim such a use.

Section viii thus requires only that an ANDA applicant state that a listed patent does not claim the use for which the ANDA applicant seeks approval. *See id*. As the district court found, the statute does not speak directly to the question posed by Hospira here: what constitutes "overlap" between an NDA holder's "use code" and an ANDA applicant's "carved-out label." Mem. Op. 19. The statute itself uses none of those terms, and it does not purport to prescribe ***how*** FDA is to determine whether a particular patent "does not claim a use for which the [ANDA] applicant is seeking approval." Mem. Op. 23-24. Congress left this to FDA's discretion.

Hospira would prefer that FDA approve section viii applications only where

the generic's label "does not overlap at all," even in theory, with the brand's use code. FDA concluded that Mylan's section viii statement was permissible because all "express references to the [patent] protected use are omitted from" Mylan's label. Mem. Op. at 13-14; AR at 813. Both methodologies assess whether Hospira's patent "claim[s] a use for which the [ANDA] applicant is seeking approval" under § 355(j)(2)(A)(viii); Hospira's methodology is decidedly *not* dictated or even supported by the text of the statute. *Philip Morris*, 736 F.3d at 292 (rejecting *Chevron* step one argument where the "minimal textual evidence is equally consistent with [two different] methodologies"). Use codes and labeling requirements are purely artifacts of FDA's own regulations; they are not statutory.

At *Chevron* step one, courts "should employ all the traditional tools of statutory construction in determining whether Congress has clearly expressed its intent regarding the issue in question," *King*, 2014 WL 3582800, at *5, but Hospira provided the court below, and now this Court, none of these tools. Hospira does not analyze statutory text, structure, context, purpose or legislative history. The statute alone merely states that an ANDA applicant proceeding under section viii must submit a statement that a listed method of use patent "does not claim a use for which the [ANDA] applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(viii). Hospira has never argued, as it must, that this language shows that "Congress's intent is so clear and unambiguous that it 'foreclose[s] any other interpretation'"

than the one advocated by Hospira, *King*, 2014 WL 3582800, at *7 (citation omitted). In contrast, the district court's opinion fully explains why Hospira's argument fails under *Chevron* step one. Mem. Op. at 17-21. That analysis comports with settled law under the *Chevron* doctrine.

Hospira failed to raise below a *Chevron* step two argument, and it effectively omits one here as well—most notably by failing to acknowledge, much less address, the deference due an agency when interpreting its organic statute under *Chevron*. At step two, "considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer" and accord "deference to administrative interpretations." *Chevron*, 467 U.S. at 844. As the district court recognized, review under *Chevron* step two is "highly deferential." Mem. Op. at 21. And when interpreting its own regulations, FDA's reading is "controlling unless plainly erroneous or inconsistent with the regulation." *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (quotation omitted).

Although Hospira did not address *Chevron* step two below, the district court thoroughly explained why FDA's decision was owed deference. *See* Mem. Op. at 21-29. Hospira relied primarily, as it does here, on a single sentence of *dictum* from *Caraco* and a similar snippet from the Solicitor General's brief in that case, *neither of which cite the statute*, and the district court explained why Hospira's reliance is misplaced. Mem. Op. at 21-30. Among other things, the "overlap" in

Caraco was different than what Hospira claims here, and Mylan's application did not seek approval for the use that Hospira claims is protected for Precedex®, because Mylan's approved label carves out all references to ICU Sedation and intensive care settings in general. As the district court found, "Hospira's argument boils down to what doctors *may* do with generic Precedex®," an inquiry squarely at odds with the Fourth Circuit's decision in *Sigma-Tau Pharms., Inc. v. Schwetz*, 288 F.3d 141, 146-48 (4th Cir. 2002); *see also* Mem. Op. 29-31; AR 813-15.

FDA Adopted No New Rule Requiring Notice and Comment. Hospira wrongly contends that FDA should have engaged in formal notice and comment rulemaking to approve Mylan's ANDA. FDA's approval of ANDAs are informal agency adjudications. *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001) (FDA approval of an ANDA is "informal adjudication"); *Apotex, Inc. v. Food & Drug Admin.*, 226 F. App'x 4, 5 (D.C. Cir. 2007) (FDA approval letters are informal adjudications). Indeed, if ANDA approvals and the decision letters that often accompany them required notice-and-comment rulemaking procedures, the approval process for generic drugs would grind to a virtual halt, frustrating Congress's intent to facilitate entry of generic competition. Hospira argued below that formal rulemaking was required because FDA's approval of Mylan's ANDA allegedly was a departure from the agency's past practices. That allegation is simply untrue. Critically, Hospira never provided the district court

with a *single* instance in which FDA interpreted section viii differently than here:

> It must also be noted that despite being asked on several occasions to provide the Court with examples of situations where the FDA interpreted section viii in a manner consistent with its preferred approach, and thus inconsistent with FDA's approach in the instant matter, Hospira's counsel was unable to provide any examples.

Mem. Op. at 26, n.5. Rather, the district court found that FDA has "consistently" interpreted section viii. *Id*. at 24, 30-31. FDA's August 18 decision letter identified numerous FDA approvals of generic drugs in circumstances comparable to Mylan's application. *Id*. at 24-25. In those instances, the district court explained, FDA approved generic drugs where their labels carved out and made no mention of the protected uses of the drugs, "notwithstanding the fact that a physician might conceivably use the generic drug for a protected method of use." *Id*. at 25.

III. HOSPIRA FACES NO IRREPARABLE HARM

Mylan has earned the right to provide generic Precedex® to physicians and patients, and the only harm Hospira will incur is loss of monopoly profits. As to the impact on its business, Hospira grossly exaggerates: Precedex® accounts for only 17% of its total generic and brand U.S. sales. Erick Decl. ¶ 37. Moreover, Hospira has been switching the market to a new formulation of Precedex® that Mylan does not have approval to sell, further retarding the impact of Mylan's entry on the market. *Id.* ¶¶ 14-19. Regardless, lost sales are a classic legal damage and cannot constitute irreparable harm. *Abbott Labs. v. Andrx Pharm., Inc.*, 452 F.3d

1331, 1348 (Fed. Cir. 2006).[4]

Hospira has a legal remedy to recoup those lost sales if there is validity to its assertion that Mylan's drug violates its method patent—Hospira can sue Mylan for patent infringement. The availability of such relief further derogates the need for an injunction pending appeal. Recently Chief Justice Roberts found there was no likelihood of irreparable harm in the Hatch-Waxman context where a branded manufacturer had the ability to recover damages for past patent infringement. The Chief Justice observed that "[g]iven the availability of that remedy, the extraordinary relief that [the brand manufacturer] seeks is unwarranted." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 134 S. Ct. 1621 (Roberts, Circuit Justice, Apr. 18, 2014). The same is true here. In arguing (at 13-14) that any future victory will be "hollow" and that its purported financial loses "will not be recoverable," Hospira tacitly concedes that it has no patent rights it can enforce against Mylan; otherwise Hospira could seek to recover its damages in a patent infringement suit. Yet Hospira has not done so, despite knowing about Mylan's ANDA since at least March 4, 2013, the date the ANDA received tentative approval. Having no valid patent rights over the Procedural Sedation use that Mylan seeks, Hospira's manipulation of FDA's use-code system constitutes an anti-competitive act of unclean hands, thereby precluding the equitable relief it seeks.

[4] *Hughes Network Sys., Inc. v. InterDigital Commc'ns Corp.*, 17 F.3d 691, 694 (4th Cir. 1994); *ViroPharma*, 898 F. Supp. 2d at 25.

Further, Hospira consented to generic competition starting in December 2014 to settle and vacate the District of New Jersey's finding that the '867 patent is invalid. Even taking Hospira's harms at face value, the two months of competition Hospira will face before the generic competition it expressly allowed cannot give rise to irreparable harm. Hospira's claim that it *may* fire 130 employees due to competition from Mylan and Par for the Procedural Sedation indication only is likely an exaggeration—it has not yet done so despite what Hospira characterizes as a market now flooded with generic product. Even if true, then this will be the inevitable result of Hospira's agreement allowing Sandoz to sell generic Precedex® for *both* of its indications in December 2014.

IV. AN INJUNCTION WILL SUBSTANTIALLY HARM MYLAN

In contrast, an injunction pending appeal would cause Mylan immediate, irreparable and unrecoverable harm. Mylan is a first entrant in the market for the generic version of Precedex®. Erick Decl. ¶ 11. As a first entrant in that generic market, Mylan has a significant first-entrant advantage, including the ability to establish contracts and relationships that persist even after its formal first-entrant advantage fades. *Id.* ¶¶ 11, 12. Offering the first generic product allows Mylan to gain a significant customer base, and provides Mylan the ability to enter into long-term contracts with distributors. *Id.* ¶ 11. Importantly, the window for Mylan to enjoy its first-entrant advantage is quickly closing, as Hospira continues to switch

the market to a formulation of Precedex®, Precedex® Premix, for which Mylan does not have FDA approval. *Id*. ¶¶ 29-34.

If Mylan's final approval is withdrawn or suspended, even temporarily, Mylan is expected to lose existing contracts with large purchasers and other first-to-market advantages, including the opportunity to supply major customers with other, non-exclusive products. *Id.* ¶ 13. In addition to losing tens of millions of dollars as an immediate result of these lost contracts (*id.* ¶ 10) and to losing sales opportunities because of Hospira's aggressive move to shift the market to Precedex® Premix, Mylan will also suffer significant and irreparable non-economic harms. These harms include the loss of goodwill and relationships Mylan developed with its customers and the loss of business opportunities. *Id.* Mylan has already seen a slower than expected uptake of its products into the market as a result of the confusion engendered by Hospira's litigation. *Id.* In short, a ban on the sale of Mylan's generic product would have a dramatically negative impact on Mylan's reputation and goodwill with its customers who have purchased the product. *Id.* ¶¶ 25-27. These harms are substantial, cannot readily be calculated, and are of the kind that courts repeatedly have held to be irreparable. *Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 552 (4th Cir. 1994); *Patriot, Inc. v. HUD*, 963 F. Supp. 1, 5 (D.D.C. 1997).

In denying Hospira's motion for an injunction pending appeal, the district

court found that Hospira would not suffer irreparable harm but that an injunction would inflict irreparable injury on Mylan. The court stated: "Defendant-Intervenors Mylan and Par Sterile would suffer continued harm if they were forced to continue to turn away customers." Letter Order, Dkt. No. 125, at 2. That finding is not plainly erroneous, and the district court's denial of the Hospira's motion for that reason is not an abuse of discretion. *Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 272 (4th Cir. 2002).

Finally, Mylan suffers harm each day this suit continues, because Hospira is using this APA action to assert patent rights that it has not—and could not—otherwise use against Mylan. Hospira knows that a patent infringement action against Mylan would fail—Hospira admitted repeatedly in court that the '867 patent does not cover Procedural Sedation, the only indication in Mylan's label.

V. AN INJUNCTION WILL HARM THE PUBLIC

An injunction will harm the public by depriving patients and insurers of more affordable medicine in contravention of congressional intent behind Hatch-Waxman—lowering the nation's healthcare costs by "enabling competitors to bring low-cost, generic copies of . . . drugs to markets." *Andrx Pharms.*, 276 F.3d at 1371. In fact, the injunction Hospira seeks is estimated to impose $150 million in extra costs to the nation's healthcare system. Erick Decl. ¶ 31. Significantly, the public has no mechanism by which it can recover these unjustified costs from

Hospira. An injunction would thus harm the public interest. *See ViroPharma*, 898 F. Supp. 2d at 29 ("[t]he public 'has a well-recognized interest in receiving generic competition . . . and a delay in the marketing of [the generic] drug could easily be against the public interest") (citation omitted).

In addition, the public is being harmed every day that Hospira maintains this APA action to assert improperly rights under the '867 patent, which has been held invalid by a federal district court.[5] But for Hospira's continued misuse of FDA use-code regulations and the court system, the public would be enjoying, *right now*, full and free access to for generic Precedex®. Instead, for eight months and counting, the public continues to suffer from a lack of competition and the benefits thereof due to Hospira's use code games. *See Compton v. Metal Prods., Inc.*, 453 F.2d 38, 45 (4th Cir. 1971). This harm is particularly egregious in that Mylan used the very mechanism that Congress intended to *speed* the availability of generics: "FDA may approve a section viii application *immediately*." *Purepac II*, 354 F.3d at 880 (emphasis added). Hospira's scheme thus directly harms the public.

CONCLUSION

For the reasons stated above, Mylan asks this Court to deny the request for injunction pending appeal.

[5] This invalidity finding was later vacated after the parties settled their patent dispute.

Dated: September 7, 2014.

Respectfully submitted,

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