IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

HOSPIRA, INC.,	)	
Plaintiff-Appellant,	)	
v.	)	No. 14-1920
SYLVIA M. BURWELL, et al.,	)	
Defendants-Appellees.	)	

OPPOSITION OF FEDERAL APPELLEES TO APPELLANT'S EMERGENCY MOTION FOR INJUNCTION PENDING APPEAL

INTRODUCTION

This Court should deny Hospira, Inc.'s request to enjoin the marketing of its competitors' generic drugs during the pendency of this appeal. The district court correctly held that the FDA acted lawfully in rejecting Hospira's efforts to delay the approval of the competitors' abbreviated new drug applications ("ANDAs"). The FDA's approval of the ANDAs rests on a carefully reasoned and consistent interpretation of the governing statutory provisions and regulations, one that permits generic drug manufacturers to obtain approval of ANDAs for drugs covered by method-of-use patents if – but only if – the indications and other information in the proposed ANDA labeling omit references to patented uses of the drug. The district court's opinion gives appropriate deference to that considered administrative interpretation, and it is unlikely to be reversed on appeal. Hospira's

claim that it will suffer irreparable harm in the absence of an injunction is misconceived, and any financial harm to Hospira is offset by the corresponding financial harm that will accrue to its competitors if they are kept off the market during the pendency of the appeal. At the same time, an injunction pending appeal would cause significant harm to the public interest, by depriving patients of the benefits of increased competition in the market for Hospira's drug – benefits that the provisions of the Hatch-Waxman Amendments at issue in this case are specifically designed to promote. For all of these reasons, Hospira has not satisfied the stringent standards for an injunction pending appeal, and its motion for such relief should be denied.[1]

STATEMENT

A. Statutory and Regulatory Background

1. New Drug Applications

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), pharmaceutical companies seeking to market the initial version of a new drug (also known as the "innovator" or "pioneer" drug) must first obtain FDA approval by filing a new drug application ("NDA") containing extensive scientific data demonstrating the safety and effectiveness of the drug. 21 U.S.C. § 355(a), (b). An NDA applicant

[1] We note that Intervenor Sandoz, Inc. filed for leave to file a response to Hospira's emergency motion for an injunction pending appeal at 2:00PM on Sept. 7, 2014. Sandoz' filing comes too late for the Federal Appellees to respond, and as a matter of fairness, Sandoz' filing should not be entertained by the Court.

must also submit information on any patent that claims the drug, or a method of using the drug, for which a claim of patent infringement could reasonably be asserted against an unauthorized party. 21 U.S.C. § 355(b)(1), (c)(2). FDA's implementing regulation, 21 C.F.R. § 314.53, requires NDA applicants to submit relevant patent numbers and expiration dates, as well as a description of any method of using the drug covered by a patent and identification of the labeling that corresponds to the patented method of use. The narrative description of the method of use is known as the "use code;" FDA assigns a unique "use code" to each description submitted. *See* 68 Fed. Reg. 36676, 36683 (June 18, 2003).

FDA does not have expertise in patent law and does not evaluate the accuracy of the use codes. *See Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1677 (2012). Instead, FDA plays a ministerial role, publishing the patent information it receives, including use codes, in "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the "Orange Book." 21 U.S.C. § 355(b)(1), (c)(2); *see also* 21 C.F.R.§ 314.53(e).

2. Abbreviated New Drug Applications

The Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Amendments), codified in relevant part at 21 U.S.C. § 355, permits a manufacturer to submit an ANDA requesting approval of a generic version of an approved drug product. 21 U.S.C. § 355(j). ANDA applicants need

not submit clinical data to demonstrate the safety and efficacy of the generic product, as with an NDA. *See id.* Rather, an ANDA relies on FDA's previous findings that the product approved under the NDA is safe and effective. Among other information, an ANDA must include data showing that the generic drug product is bioequivalent to the innovator product. 21 U.S.C. § 355(j)(2)(A)(iv), (j)(4)(F); 21 C.F.R. § 314.127(a)(6)(i), 314.94(a)(7).

a. Paragraph IV Certification

The timing for approval of ANDAs depends, in part, on whether any patents claim the innovator drug or particular uses of the drug. If the Orange Book lists such a patent, and an ANDA applicant asserts that the patent is invalid or that the patent would not be infringed by the drug covered by the ANDA, the applicant must provide the FDA with a certification to that effect, known as a "paragraph IV certification." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The applicant must also provide notice of its paragraph IV certification to the NDA holder and the patent owner, explaining the factual and legal basis for the applicant's opinion that the patent is invalid or not infringed. *Id.* § 355(j)(2)(B).

The filing of a paragraph IV certification is deemed an act of infringement, 35 U.S.C. § 271(e)(2)(A), that enables the NDA holder and patent owner to sue the ANDA applicant. If the NDA holder does not sue the ANDA applicant within 45 days, FDA may approve the ANDA if it is otherwise approvable. 21 C.F.R.

§ 314.107(f)(2). If the NDA holder does sue the ANDA applicant within 45 days, FDA must stay approval of the ANDA for 30 months, unless a court issues a final order that the patent is invalid, unenforceable, or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3).

b. Section viii Statement

When a patent is listed only for a method of use, an ANDA applicant may instead submit a "section viii statement" acknowledging that a given method-of-use patent has been listed, but stating that the patent at issue "does not claim a use for which the applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(viii). In order to make a section viii statement, the ANDA applicant must omit from its proposed labeling information pertaining to the protected use. *See* 21 C.F.R. §§ 314.92(a)(1), 314.94(a)(l2)(iii). If an ANDA applicant files a section viii statement and carves out the labeling sections that have been identified as corresponding to the patented use, the patent claiming the protected method of use will not serve as a barrier to ANDA approval.

The FDCA generally mandates that generic drug labeling be the same as the reference listed drug's labeling, but it allows for exceptions if "the new [ANDA] drug and the listed drug are produced or distributed by different manufacturers." 21 U.S.C. §355(j)(2)(A)(v). One of the permissible labeling differences is the "omission [from the generic drug's labeling] of an indication or other aspect of

labeling protected by patent." 21 C.F.R. § 314.94(a)(8)(iv). In order to approve an ANDA containing proposed labeling that omits such protected information, FDA must find that the "differences do not render the proposed drug product less safe and effective than the listed drug for all remaining non-protected conditions of use." 21 C.F.R. § 314.127(a)(7). The courts have confirmed an ANDA applicant's ability to carve out protected labeling, *see, e.g.*, *Sigma-Tau Pharms., Inc. v. Schwetz*, 288 F.3d 141, 148 n.3 (4th Cir. 2002); *Bristol-Myers Squibb v. Shalala*, 91 F.3d 1493, 1500 (D.C. Cir. 1996).

B. Factual Background

1. Hospira's NDA for Precedex

Hospira holds NDA 21-038 for Precedex, which was first approved on December 17, 1999, and has been marketed without generic competition since that time. Precedex is currently approved for the following indications:

1. Sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting. Administer Precedex by continuous infusion not to exceed 24 hours.

2. Sedation of non-intubated patients prior to and/or during surgical and other procedures.

Ex. A at 1.

Hospira originally listed U.S. Patent No. 6,716,867 (the '867 patent), a method-of-use patent, on May 6, 2004, with the following use code (U-572):

"Intensive care unit sedation." *Id.* at 2. At that time, Precedex was approved for only the first of the two indications above.

Precedex was approved for the second procedural indication, and Hospira submitted one additional method-of-use patent for the second indication to be included in the Orange Book: U.S. Patent No. 5,344,840 (the '840 patent) with the following use code (U-912) for that indication: "Sedation of non-intubated patients prior to and/or during surgical and other procedures." *Id.* The '840 method-of-use patent expired on September 6, 2011. *Id.* A pediatric exclusivity period associated with an unrelated patent expired on January 15, 2014. Mem. Op., Ex. A to App. Mot. (Sept. 5, 2014) ("Mem. Op."), at 10. Thus, the last remaining patent now protecting Precedex is the '867 method-of-use patent. *Id.*

Defendants Mylan Institutional LLC ("Mylan") and Par Sterile Products Inc. ("Par"), submitted ANDAs to market generic versions of Precedex. Mylan and Par both submitted section viii statements with respect to the '867 method-of-use patent. In connection with those statements, Mylan and Par carved out of their proposed labeling all references to the "Intensive Care Unit Sedation" use claimed by Hospira's '867 use code, and sought approval only to market the drug for procedural sedation. *See* Ex. B.

On January 6, 2014, in an effort to block the approval of any ANDAs, Hospira sought to amend the '867 use code to cover "intensive care unit sedation,

including sedation of non-intubated patients prior to and/or during surgical and other procedures." Mem. Op. at 11. Hospira argued that this new use code was meant to "clarif[y] – without expanding" the original use code, and that it had "exactly the same scope." *Id.* Hospira contended that the use code covered the first indication for ICU sedation "in its entirety," and that it also partially overlapped with the second indication for procedural sedation "to the extent such sedation occurred in an ICU." Ex. E to App. Mot., at 5, 8. Hospira submitted evidence that doctors had used Precedex for procedures in the ICU, and argued that such use meant that ANDA sponsors could not submit section viii statements to carve out the second indication. *Id.* at 5.

2. FDA's Decision and ANDA Approvals

In accordance with its ministerial role in accepting patent use code information, FDA changed the use code on January 8, 2014 (U-1472). Ex. A at 2. But after carefully reviewing Hospira's arguments as well as other comments made to a public docket, FDA determined that under either the original or amended use code, it could approve an ANDA with a section viii statement carving out the first indication for ICU sedation, as well as other references to ICU sedation in other portions of the labeling. *Id.* at 10. FDA scientific reviewers determined that an ANDA with such carved-out labeling would not be less safe or effective than Precedex for the remaining, unprotected procedural indication. *Id.* at 14.

FDA observed that it had previously allowed similar carve-outs over innovator objections for the drugs repaglinide, tramadol, and oxandrolone. *Id.* at 10-13. In addition, FDA rejected Hospira's argument that *Caraco*'s reference to "overlap" between proposed ANDA labeling and the brand drug's use code precludes any ANDA approvals for the procedural indication. The FDA noted that the broad use code at issue in *Caraco* covered all three approved methods of using the drug at issue in their entirety. Here, in contrast, Hospira's use code was limited to use in the ICU, and "[u]se in an intensive care setting is not expressly disclosed in the any proposed ANDA labeling." *Id.* at 12.

Accordingly, on August 18, 2014, FDA issued a decision approving ANDAs for the procedural indication for Mylan and Par. Mem. Op. at 14. Neither applicant sought approval for the ICU indication, and there are no references to the ICU or ICU sedation in their labeling. *See, e.g.*, Ex. B (Mylan draft labeling). The district court sustained that decision.

STANDARD OF REVIEW

Hospira seeks an injunction to stay FDA's decision and block the marketing of its competitors' generic drugs during the pendency of this appeal. It has not made the showing necessary to justify "the extraordinary remedy of injunction." *See Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008) (quotation omitted). As we now show, Hospira has failed to demonstrate any of

the factors required for injunctive relief under *Winter*: (1) likelihood of success on the merits, (2) likelihood of irreparable harm without a stay, (3) that the balance of equities is in its favor, and (4) that an injunction prohibiting the marketing of approved generic versions of Precedex would be in the public interest. *See id.; see also Real Truth About Obama, Inc. v. FEC*, 575 F.3d 342, 346-47 (4th Cir. 2009), *vacated on other grounds*, *Citizens United v. FEC*, 558 U.S. 310 (2010), *aff'd*, *The Real Truth About Obama, Inc. v. FEC*, 607 F.3d 355 (4th Cir. 2010) (per curiam) (following the preliminary injunction standards in *Winter*).[2]

ARGUMENT

I. Hospira Has Not Established A Likelihood of Success on the Merits

A showing of likelihood of success on the merits "is far stricter than the [previous] requirement that the plaintiff demonstrate only a grave or serious question for litigation." *Real Truth*, 575 F.3d at 346-47. Hospira has failed to make any such showing. The FDA decision at issue is subject to review under the Administrative Procedure Act ("APA"), and may be disturbed only if "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This standard is highly deferential to the agency. *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Moreover,

[2] Hospira asserts that it remains an open question whether an independent showing must be made for each factor under *Winter*. App. Mot. at 9 n.2. But even if this Court were to apply a balancing test based on *Long v. Robinson*, 432 F.2d 977 (4th Cir. 1970), Hospira has failed to show that it meets any of the factors.

because this case implicates the FDA's statutory interpretation, it is governed by the familiar framework of *Chevron*, under which a court must uphold an agency's permissible construction of its own statute.

A. The District Court Properly Deferred to FDA's Interpretation and Decision

As the district court held, FDA has reasonably interpreted both the statute and its implementing regulations to allow approvals of ANDAs that carve out information regarding protected methods of use. *See* Mem. Op. at 19-25. The statute requires FDA to determine whether the patent "claim[s] a use for which the [ANDA] applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(viii); *see also* 68 Fed. Reg. 36682 (requiring NDA holders to describe their patents with specificity to "permit ANDA [] applicants, and [FDA], to assess whether the ANDA [] applicant is seeking approval for a use the sponsor states is claimed in the listed patent, and thus determine whether the applicant must submit a patent certification or may submit a section viii statement"). Although FDA accepts the use code from the brand company, FDA must compare the use code to the proposed ANDA labeling to assess whether the applicant is "seeking approval" for a claimed use.

Here, the use code is limited to ICU sedation. If the proposed ANDA labeling identified ICU sedation as an indicated use, or discussed use of the drug for procedural sedation in the ICU setting, the applicant would be seeking approval

for the claimed use and could not rely on a section viii statement. But the ANDAs here have instead entirely carved out that protected use from their proposed labeling.[3] Ex. B. The statutory question is therefore whether an applicant is "seeking approval" for a claimed use if the indication and other information in the labeling make no reference whatsoever to that use, but it is theoretically possible for a physician to use the drug in circumstances that involve the claimed use. The district court correctly determined that Congress has not spoken specifically to that precise question, and that the FDA reasonably construed the statute and regulation not to preclude approval of an ANDA in this situation.

Contrary to Hospira's suggestion, the outcome here is not dictated by what Hospira characterizes as the "overlap" between its use code and the procedural sedation indication on the ANDA labeling. The district court properly rejected Hospira's attempted reliance on the reference to "overlap" in *Caraco*, finding that "*Caraco* actually supports the FDA's actions here." Mem. Op. at 26. It was only after the brand company in *Caraco* had expanded the scope of its use code to completely cover the approved indication that FDA determined that no ANDA could be approved with carved-out labeling. *Id.* at 27-28. For Precedex, by contrast, Hospira limited its use code to "intensive care unit sedation," a use that

[3] Hospira asserts without any basis that its patent "claimed a use (procedural sedation in the ICU) for which the ANDAs were seeking approval." App. Mot. at 10. The ANDA proposed labeling does *not* seek approval for any use in the ICU. *See* Ex. B.

does not subsume the approved indication for procedural sedation, and the revised use code did not enlarge the scope of the claimed use. *Id.* at 28. Thus, this case does not present the kind of "overlap" that was before the Supreme Court in *Caraco*, and here, unlike there, the use code leaves "sufficient space" for approval of ANDAs that omit all references to the protected use. *Id.*[4]

Hospira's position is that the bare possibility that a physician may use the drug for procedural sedation in an ICU setting is enough, without more, to prevent the FDA from approving the ANDA, even if the labeling scrupulously avoids any reference to ICU sedation. Nothing in the statute and nothing in *Caraco* requires FDA to interpret and apply subsection viii in this tail-wagging-the-dog fashion.

The court also properly rejected Hospira's arguments that FDA had been inconsistent, pointing out that FDA's approval of the ANDAs here is entirely consistent with its past practice regarding other ANDAs involving similar carveouts. *Id.* at 25. The district court recognized that mere foreseeability of particular uses by physicians does not matter to FDA's carve-out analysis, relying on *Sigma Tau*, 288 F.3d at 146-48, which "reject[ed] as 'profoundly anti-

[4] *Caraco*'s use of "overlap," and the corresponding use of that term in the government's amicus brief in *Caraco*, was meant to summarize a portion of a preamble to a prior FDA rulemaking proceeding. *See* 132 S. Ct. at 1677 (citing 68 Fed. Reg. 36682-36683 (2003)). The preamble does not itself refer to "overlap," and it was focused on the patent information that must be provided by an NDA applicant, rather than on the requirements of section viii statements. Nowhere in the preamble did FDA address the situation at issue here, much less suggest that a different disposition would be called for.

competitive' the argument that if there is 'foreseeable off-label use' FDA must 'bar the approval of generic drugs, even for unprotected indications.'" *Id.* at 30.[5]

B. FDA Did Not Violate APA Rulemaking Requirements

The district court also properly rejected Hospira's claim that FDA has announced a new "rule" in its Precedex decision. As the court explained, the decision "was entirely consistent with the FDA's past practice" and did not effect any change in existing law. *Id.* at 31. As such, "FDA was therefore not required to follow the formal rulemaking procedures required by the APA when the FDA promulgates a new rule." *Id.* Far from establishing a new rule, FDA reasonably interpreted and applied the *existing* regulations to the facts of this case, and did so in conformity with its past practices. Hospira's claim that FDA should have conducted additional rulemaking in these circumstances is therefore wholly without merit.

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[5] Hospira attempts to distinguish *Sigma Tau* on the ground that here, the use is "on label." *Id.* at 10-11; *see also id.* at 4 ("the second indication relating to surgical and other procedures instructs use both in and out of the ICU"). But the ANDA labeling does not "instruct" use in the ICU; it *omits* use in the ICU. *See* Ex. B. The labeling's silence on setting, and the possibility of use in that setting, does not make use in the ICU "on label." In fact, if the ANDA applicants were to market their products for ICU sedation, the products would be considered misbranded for lacking adequate instructions for use for that indication, which is omitted from the labeling. *See* 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.5 (defining "adequate directions for use" as "directions under which the layman can use a drug safely and for the purposes for which it is intended").

II. Hospira's Claims of Prospective Lost Revenues and the Balance of Equities Do Not Support an Injunction

Hospira asserts that FDA's approval of Mylan's and Par's ANDAs will result in lost sales and lost revenues for Hospira. But the magnitude of those anticipated losses is highly speculative, and Hospira has offered no evidence that lost sales would amount to the kind of grave financial injury that courts ordinarily require as a predicate for injunctive relief. Moreover, to the extent that an injunction would protect Hospira's revenues, it would do so by depriving Mylan and Par of the revenues that they would be earning through the marketing of their generic versions of Precedex. Thus, even if Hospira's anticipated loss of revenues qualified as irreparable harm, the corresponding financial harm that an injunction would visit on the generic manufacturers would leave the balance of equities in equipoise.

Hospira speculates that, with a "premature" generic entry, it could lose "tens of millions of dollars, if not more than a hundred million dollars, in profits . . . ." Ex. C to App. Mot., ¶ 22. But Hospira greatly overstates the significance of Precedex in its overall business. Hospira is a large, diversified company that generated approximately $4 billion in net sales in 2013.[6] While Hospira claims that Precedex accounts for almost all of Hospira's branded pharmaceutical

[6] *See* Hospira Investor Relations, *available at* http://www.hospirainvestor.com/phoenix.zhtml?c=175550&p=irol-irhome.

business (App. Mot. at 14), the district court pointed out that the branded pharmaceutical business "is a relatively small portion of its overall company." *See* Ex. B. to App. Mot. (Letter Order), at 2. Precedex accounts for only about 11% of Hospira's net global sales, and about 17 % of its sales of specialty injectable pharmaceuticals in the Americas.[7] Thus, by the admission of Hospira's own CEO, Precedex is not a "strategic driver" of the company's finances.[8] The company has long recognized that Precedex "will go generic at some point," and when it does so, in the CEO's words, "we'll get over that product." *Id.* A loss to a single product line as a result of competition from generic manufacturers would not cause "extreme hardship" to Hospira overall, much less threaten its existence. *See Astellas Pharma U.S., Inc. v. FDA*, 642 F. Supp. 2d 10, 21-23 (D.D.C. 2009) (concluding that plaintiff pioneer drug company had not established irreparable injury even where sales of the brand drug constituted "approximately half of its total U.S. revenue for [a given] fiscal year" (collecting cases)); *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 532 F. Supp. 2d 666, 682 (D.N.J. 2007) (rejecting claims of irreparable injury because, although the brand drug made up a "large portion" of the plaintiff's sales, plaintiff had known that its period of exclusivity

[7] *See* Hospira Annual Report (2013), *available at* http://nasdaqomx.mobular.net/nasdaqomx/7/3396/4848/.

[8] Hospira at JPMorgan Healthcare Conference Breakout Session - Final FD (Fair Disclosure) Wire (Jan. 15, 2014) (available in LEXIS Current News file).

would be ending, and "[i]t is difficult to accept that [plaintiff] does not have a business plan in place to deal with the introduction of a generic version of [the RLD]").[9]

Moreover, any financial harm that Hospira might incur in the absence of an injunction pending appeal will be matched, if not exceeded, by the financial harm that lawfully approved ANDA holders will suffer if they are deprived of their right to market during the period that an injunction is in effect. The D.C. Circuit has found in similar circumstances that the balance of harms "results roughly in a draw." *Serono Labs. Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998).

III. The Public Interest Strongly Weighs Against An Injunction

As this Court has noted, "in *Winter*, the Supreme Court emphasized the public interest requirement [governing equitable relief], stating, '[i]n exercising their sound discretion, courts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction.'" *Real Truth*,

[9] Hospira also argues that, absent an injunction pending appeal, any victory on appeal would be "hollow" because Sandoz will enter the market in December 2014. App. Mot. at 9. Having voluntarily agreed to allow Sandoz to begin marketing in December, Hospira is poorly situated to complain about the effect of that timing on this litigation. In any event, if the Court grants Hospira's motion to expedite this appeal, the Court can issue a decision before Sandoz enters the market, meaning that even from Hospira's perspective, denial of an injunction pending appeal would not deprive the appeal of value to Hospira.

575 F.3d at 347 (quoting *Winter*, 555 U.S. at 24). Here, the potential harm to the public interest weighs decisively against an injunction.

Hospira wrongly asserts that "FDA has no stake in the immediate implementation of its decision." App. Mot. at 15. Although FDA has no commercial stake in the outcome of this litigation, FDA and the public share a vital interest in generic drug approvals. *See Serono*, 158 F.3d at 1326 (determining that the public interest is "inextricably linked" to Congress's purpose in passing the Hatch-Waxman Amendments). FDA is charged with implementing the statutory scheme governing the approval of generic drugs in the manner prescribed by Congress in the FDCA. Section viii allows generic applicants to obtain approval for unprotected indications, which furthers the goal of the Hatch-Waxman Amendments to facilitate approval of generic drugs. *See Bristol-Myers Squibb Co.*, 91 F.3d at 1500 ("The Report accompanying the House bill expressly noted that it 'permits an ANDA to be approved for less than all of the indications for which the listed drug has been approved.'") (quoting H.R. Rep. No. 857 (Part I), 98th Cong., 2d Sess. 21-22, reprinted in 1984 U.S.C.C.A.N. 2654-55)); *Teva Pharms., USA, Inc. v. Leavitt*, 548 F.3d 103, 104 (D.C. Cir. 2008) ("The Hatch-Waxman Amendments help to expedite the marketing of generic drugs.") (citing Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1585 (1984)). All of this inures to the benefit of

America's patients, who gain timely access to less expensive prescription drugs, and who will be deprived of that access by the injunction sought by Hospira.

In denying Hospira's motion for a stay pending appeal, the district court stated, "the public interest would not be served by a stay as consumers benefit from safe and effective generic drug products on the market." *See* Letter Order, Dkt. No. 125, at 2 (Sept. 5, 2014). Hospira has already delayed the lawful marketing of these drugs for nearly three weeks. The public deserves access to them now.

IV. This Court Has Jurisdiction Under 28 U.S.C. § 1291.

The federal appellees agree with Hospira that appellate jurisdiction lies in this Court under 28 U.S.C. § 1291. The jurisdiction of the Federal Circuit under 28 U.S.C. § 1295(a)(1) is confined to appeals from civil actions that "aris[e] under * * * any Act of Congress relating to patents." Under the Supreme Court's settled approach to "arising under" jurisdiction, a claim arises under the federal patent laws only if the plaintiff's well pleaded complaint "'establish[es] either that federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law'" *Holmes Group, Inc. v. Vornado Air Circulation Sys.*, 535 U.S. 826, 830 (2002).

That is plainly not true here. Hospira's complaint presents claims arising under the FDCA and the APA, and it invokes the subject matter jurisdiction under 28 U.S.C. § 1331 rather than 28 U.S.C. § 1338. *See* Compl. ¶ 8. Hospira is

challenging FDA's interpretation of 21 U.S.C. § 355(j)(2)(A)(viii), which is a part of the FDCA and relates to FDA's regulatory authority over generic drugs. The district court's decision was based on the administrative record and the deferential standards of review under *Chevron*, 467 U.S. 837, and the APA – not on a dispute about the scope of the patent, which Hospira concedes is limited to ICU sedation. And Hospira's claim that the ANDA applicants are seeking approval for a use claimed by a patent does not implicate any issues of patent law or require claim construction. Similar cases involving patent information and ANDA approvals have been adjudicated by other circuit courts of appeals under 28 U.S.C. § 1291. *See, e.g.*, *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 238 (4th Cir. 2002); *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 883 (D.C. Cir. 2004). Like those cases, this case does not arise under federal patent laws and therefore does not belong with the Federal Circuit.

CONCLUSION

For these reasons, this Court should deny Hospira's motion for an injunction pending appeal.

Respectfully submitted,

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Dated: September 7, 2014

CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of September 2014, a copy of the foregoing Opposition of Federal Appellees to Appellant's Emergency Motion for Injunction Pending Appeal was delivered to the clerk, and further, 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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