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

PAR STERILE PRODUCTS, LLC'S OPPOSITION TO HOSPIRA'S MOTION FOR AN INJUNCTION PENDING APPEAL

Par Sterile Products, LLC ("Par") opposes Hospira, Inc.'s ("Hospira") motion for an injunction pending appeal (Doc. 5). The district court acted well within its discretion under Fed. R. Civ. P. 62(c) to deny an injunction pending appeal. (ECF 125.)[1]

Hospira's motion reflects its latest tactic to delay generic competition for its Precedex® product. This time, Hospira asks this Court to enjoin Par and Mylan Institutional, LLC ("Mylan") for almost eight weeks, until an October 28–30, 2014 argument date.

The Food and Drug Administration ("FDA") approved Par's generic Precedex product on August 18, 2014. The next day, Hospira—without naming Par or giving it notice—filed this suit challenging the approval of Par's product and moved for a TRO. Hospira's TRO motion was based on self-serving and misleading facts.

It only took the district court a few weeks to see through Hospira's contentions. The district court resolved the simple issue before it: Was the FDA's decision approving Par's generic Precedex arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law? 5 U.S.C. § 706(2)(A). The issue was not even close. Despite

[1] "ECF" references are to the district court's docket. Par has attached the evidence it submitted below.

Hospira's efforts to obfuscate the issues, the FDA's decision approving Par's product was unremarkable and similar to its approvals of numerous other products in the past.

When the district court denied Hospira's request for an injunction pending appeal (ECF 125), the district court noted how Hospira had misled it in claiming irreparable harm. The FDA's approval for Par's generic product was unremarkable, and the district court's decision granting summary judgment against Hospira is unremarkable. Hospira cannot complain about suffering "irreparable" harm when its whole lawsuit was an unlawful attempt to prolong a monopoly.

Par, on the other hand, suffers disproportionately from any further injunction against its sale of generic Precedex. Before Hospira sued the FDA, Hospira had already improperly caused the FDA to delay the approval of Par's product. Par has waited for almost eight months to sell its generic Precedex product. If this injunction is granted, Par would not merely lose sales and an opportunity to be one of the first generic products on the market; Par will soon have to start destroying its existing stock made nearly a year ago. Par's interests and the

public's interests align with Congress' interest in getting less expensive generic drugs on the market faster.

The Court should deny Hospira's motion. Hospira, which does not use the word "discretion" in its motion, cannot establish that the district court abused its Rule 62(c) discretion when it denied Hospira's request for a stay pending appeal.

I. Relevant Factual Background

The district court's opinion details the background facts on the products at stake, the Hatch-Waxman Act, and the generic regulatory scheme including "little viii carve-outs." (ECF 122 at 3–15.)

A. Hospira's Precedex and Its Invalid '867 Patent

Hospira owns the Precedex drug, which was originally approved for intensive care unit ("ICU") sedation (1999), and additionally approved for procedural sedation (2008). (*See* ECF 97-24.) Over the years, Hospira also obtained three patents allegedly covering methods of using Precedex, including U.S. Patent No. 6,716,867 ("the '867 patent"), which is limited to ICU sedation. (ECF 97-19.)

This lawsuit against the FDA is entirely based on Hospira's inconsistent identification of the '867 patent as now covering some aspect of procedural sedation. At least one district court has already

found the '867 patent invalid. Back in 2009, Sandoz, Inc. ("Sandoz"), an intervenor-plaintiff in this case, challenged the validity of the '867 patent and won. (ECF 97-8, *Hospira, Inc. v. Sandoz Int'l GmbH*, No. 09-cv-4591 (D.N.J. April 30, 2012).)[2] During that litigation, Hospira repeatedly acknowledged that the '867 patent does not cover procedural sedation—the exact opposite of what Hospira told the district court in this case. (ECF 97-14; ECF 97-15.)

B. Par's Abbreviated New Drug Application, and Its "Little viii Carve Out"

On February 2, 2012, Par submitted its Abbreviated New Drug Application ("ANDA") No. 20-3972, seeking FDA approval to market its generic Precedex product for procedural sedation.[3] (ECF 97-23 ¶ 8.) Under the Hatch-Waxman Act, Par could seek FDA approval for less than all of a branded drug's approved indications of use in order to avoid a patent. *See* 21 U.S.C. § 355(j)(2)(A)(viii). Because Hospira's

[2] In a private settlement during the appeal of that case, Hospira and Sandoz cut a deal allowing Sandoz to launch its generic Precedex on December 26, 2014, if Sandoz agreed to completely reverse its position on the '867 patent, go back to the New Jersey district court, and ask the district court to vacate its prior judgment of invalidity of the '867 patent. (ECF 97-17.) After months of deliberation, the district court finally granted the plea to vacate on February 27, 2014. (ECF 97-18.)

[3] The ANDA was submitted by JHP Pharmaceuticals, LLC, which changed its name to Par Sterile Products, LLC on February 26, 2014.

Precedex is approved for ICU sedation and procedural sedation, and because the invalid '867 patent was limited to ICU sedation, Par carved out ICU sedation from its ANDA, leaving only procedural sedation. This is called a "little viii carve-out." Even though Par carved out ICU sedation, Par had to wait until January 15, 2014 to launch its product because Hospira had another patent for procedural sedation that was expiring on January 15, 2014. (ECF 97-2 at 1 n.1.)

Nine days before the FDA was set to approve Par's product, Hospira contrived an obstacle to approval: On January 6, 2014, it changed its FDA "use code"—an abridged description of a patent for FDA purposes—for the '867 patent. Essentially, Hospira revised its "use code" to create the impression that it somehow overlapped, covered, or claimed Par's carved-out procedural indication. (ECF 97-12.) This maneuver cost Par seven months of delay and millions of dollars. By Hospira's own admission, the revised use code did not substantively alter the original use code, which begs the question: Why change it at all? The reason is obvious: It did this just to stall the FDA's approval of

Par's product.[4] Immediately after filing its use code amendment on January 6, 2014, Hospira wrote to the FDA requesting that the FDA refuse to grant final approval to any ANDA for generic Precedex based on a section viii statement. (ECF 97-22 ¶ 9.)

C. The Seven-Month Delay in the Approval of Par's Product

On January 15, 2014, Par expected a letter from the FDA approving its product. Instead, Par received a letter from the FDA soliciting comments on whether the FDA should still approve any ANDAs containing section viii carve-outs. (ECF 97-2.) Seven months later, on August 18, 2014, the FDA approved Par's ANDA, for the same reasons it originally intended to approve Par's product. (ECF 97-23 ¶ 9.) Par had manufactured batches of its product almost a year earlier, in September 2013. (ECF 117 ¶ 4.) Par therefore needed to get its product to its customers immediately, and Par began shipping its product to wholesale distributor customers on August 19, 2014. (ECF 117 ¶ 7.)

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[4] Par filed a lawsuit against Hospira for violating the Sherman Act. *Par Sterile Products, LLC v. Hospira, Inc. et al.*, No. 14-cv-5343, D.I. 1 (D.N.J. Aug. 25, 2014). Par seeks money damages for the harm caused by Hospira's false statements to the FDA and its manipulation of the FDA to delay the FDA approval of Par's product.

The FDA's decision approving Par's product turned out to be unremarkable; despite Hospira's efforts to obfuscate the issue, the FDA's decision is no different from other approvals for generic drug products with a section viii carve-outs like Par's. (ECF 122 at 24–25 (citing ECF 2-3 at 10, 12–13).)

D. Hospira's Baseless Lawsuit Against the FDA

The morning after the FDA approved Par's ANDA, Hospira sued the FDA and moved for a TRO to stop the FDA's approval of Par's product. Hospira sought a TRO with unprecedented remedies, including a request for a recall. (ECF 2.) Hospira did not join Par, even as it sought a nationwide recall of Par's product. (ECF 1.)

Without the benefit of all the relevant facts, the district court granted the TRO (ECF 20), "relying heavily" on Hospira's representation "that 98.4% of Hospira's U.S. branded sales are of Precedex®"—a representation that the district court would come to realize was highly misleading. (ECF 125; *see* ECF 2-4 ¶ 16.) As soon as Par became aware of the TRO on August 19, 2014, Par halted all sales. (ECF 117 ¶ 8.) Hospira was gaming the federal courts and the FDA to unlawfully prolong its monopoly on Precedex. If Hospira had an honest

patent infringement dispute with Par, Hospira should have sued Par for old-fashioned patent infringement. 35 U.S.C. §§ 271(a)–(c). But because Par's product is not directed to ICU sedation and Hospira's '867 patent is limited to ICU sedation, Hospira could not sue Par in good faith. Instead, Hospira brought this baseless lawsuit against the FDA to stall the FDA's approval of Par's product.

After Par intervened in the lawsuit, the district court stayed its recall to allow the defendants to move for reconsideration. On August 26, the district heard oral argument on its TRO. It vacated the recall, but it ordered the FDA to suspend its approval of Par's generic Precedex until the court could decide the case on the merits. (ECF 75.).

Once the FDA produced the administrative record, all parties filed cross-motions for summary judgment. Par and the FDA also opposed Hospira's original motion for a TRO and/or preliminary injunction. (ECF 91, 97.) On September 4, the district court heard oral argument on the merits.

The district court entered summary judgment in favor of FDA, Par, and Mylan. (ECF 123.) It issued a 31-page opinion explaining why the FDA's ruling deserved deference under Supreme Court decision in

Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984). The FDA's approval of Par's ANDA was not arbitrary, capricious, or contrary to law: It was an unremarkable approval by the FDA under its existing rules and regulations. (ECF 122.)

The district court granted Hospira's last minute request that it announce its decision on a telephonic hearing at 5:15 p.m (ECF 121 (granted by paperless order)), allowing Hospira time to obtain an appeal docketed on Friday evening for Saturday and Sunday motions practice. Hospira made an oral motion to stay the decision pending appeal, and the Court heard oral argument by the parties. At 6:55 p.m., the district court denied the request for the stay pending appeal. (ECF 125.)

II. Jurisdiction in this Court

Hospira invoked the district court's 28 U.S.C. § 1331 jurisdiction over claims arising under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301-399, and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–706. (ECF 1 at 17–21.) Hospira never attempted to invoke the district court's 28 U.S.C. § 1338 jurisdiction over "civil action[s] arising under any Act of Congress relating to patents." *Goldstein v. Moatz*, 364 F.3d 205, 210 n.8 (4th Cir. 2004) (a "'well-

pleaded complaint establishes 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.' ") (quoting *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 808–09 (1988)). This appeal falls outside 28 U.S.C. § 1295(a) and, therefore, this Court is the proper venue for appeal.

III. Standard of Review for a Request for Injunction Pending Appeal

An appellant's request for an injunction pending appeal essentially requests review of the district court's denial of injunctive relief pending appeal. Fed. R. Civ. P. 62(c) ("While an appeal is pending from an interlocutory order or final judgment that grants, dissolves, or denies an injunction, the court may suspend, modify, restore, or grant an injunction[.]") A district court's denial of such an injunction is reviewable for an abuse of discretion,[5] at least so long as "the motion for a stay has received full consideration by the trial judge," and does not turn on evidence developed after the trial court's ruling. *Long v. Robinson*, 432 F.2d 977, 979 (4th Cir. 1970) (Winter, J., in chambers).

[5] *Middle Rio Grande Conservancy Dist. v. Norton*, 294 F.3d 1220, 1225 (10th Cir. 2002); *Natural Res. Def. Council, Inc. v. Sw. Marine Inc.*, 242 F.3d 1163, 1168 (9th Cir. 2001); *Sierra Club, Lone Star Chapter v. Cedar Point Oil Co. Inc.*, 73 F.3d 546, 579 (5th Cir. 1996).

The showings required for a Rule 62(c) request for an injunction pending appeal are the same showings required for a Rule 65(a) request for a preliminary injunction pending trial: (i) that the movant is likely to succeed on the merits; (ii) that the movant is likely to suffer irreparable harm without the injunctive relief, (iii) that the adverse parties will not sustain substantial harm; and (iv) the injunction is in the public interest. *Long*, 432 F.2d at 979 (Winter, J., in chambers); *see Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).

Ignoring the abuse-of-discretion standard, *Aggarao v. MOL Ship Mgmt. Co.*, 675 F.3d 355, 366 (4th Cir. 2012), Hospira argues as though *de novo* review controlled. Factual findings are reviewed for clear error; legal conclusions, de novo. *WV Ass'n of Club Owners & Fraternal Servs., Inc. v. Musgrave*, 553 F.3d 292, 298 (4th Cir. 2009). The district court's rulings were primarily factual. (ECF 125.)

IV. The District Court Did Not Abuse Its Discretion in Denying Hospira's Motion to Stay the Decision Pending Appeal

The district court heard oral argument on Hospira's motion, considered the factors for an injunction, and concluded: "Taken together, the relevant four factors weigh against granting a stay of the Court's denial of Hospira's motion for preliminary injunction." (ECF 125

at 2.) That ruling, which made specific factual findings based on the knowledge of the case Judge Hazel gain over the course of 17 intensive days of litigation, was a wise exercise of discretion.

A. Hospira Will Not Succeed on Appeal

Hospira asked the district court to review the FDA's August 18 decision approving Par's ANDA pursuant to the APA. *See* 5 U.S.C. § 706(2)(A). Despite Hospira's efforts to obfuscate the issues, the district court rejected Hospira's arguments, which are the same arguments made again here on appeal. The district court's opinion was unremarkable, and nothing will change on this appeal. *Family Furniture, Inc. v. Brown*, 9 F.3d 1075, 1076 (4th Cir. 1993) (movant must make a strong showing of probability of success on the appeal.)

First, Hospira incorrectly insists Congress unequivocally prohibited any overlap at all between a generic drug label and a corresponding patent use code. 21 U.S.C. § 355(j)(2)(A)(viii); *see Chevron*, 467 U.S. 837.[6] The district court held: "the statute [FDCA] does not speak to the 'precise question at issue' before this Court," and

[6] Hospira's motion does not cite *Chevron*. Hospira can hardly claim a likelihood of success on the merits in this administrative dispute without addressing the district court's actual *Chevron* analysis.

therefore the FDA's approval of Par's ANDA was not contrary to law. (ECF 122 at 19.) The FDCA does not even speak to "use codes," "overlap," or generic "labels." (*Id.*) The district court recognized Hospira's inconsistency: "Despite Hospira's acknowledgement at the hearing on the temporary restraining order that the language of section viii is 'not the greatest language in the world,' . . . Hospira now contends . . . '[t]here is no ambiguity in the statute.'" (*Id.* at 19.)

Second, after finding that Congress had not "directly spoken to the precise question at issue," the district court rejected Hospira's insistence that the FDA's decision should be accorded no deference. *Chevron*, 467 U.S. at 842. Hospira argued that the FDA had been inconsistent, but the district court rejected Hospira's argument for three reasons: the FDA has been consistent all along; Hospira merely relied on dicta to support its accusation[7]; and Hospira was wrong to assert Par's label overlapped with Hospira's use code. Because the FDA's approval of Par's ANDA was simply a routine, unremarkable, and sound application of old rules, "[t]he Court cannot find that the FDA's

[7] "Hospira relies principally on one sentence made by the government on behalf of the FDA in a Supreme Court *amicus curiae* brief purporting to interpret the Federal Register." (ECF 122 at 22.)

decision was 'arbitrary, capricious, or manifestly contrary to the statute." (ECF 122 at 30 (citing *Chevron*, 476 U.S. at 844–45).)

Third, Hospira still incorrectly argues that the FDA created a new rule to approve Par's ANDA, which demanded the full notice and comment rulemaking requirements under the APA. *See* 5 U.S.C. § 702. The district court recognized, however, that the FDA did nothing new when it approved Par's ANDA. There was no "new" rule. Hospira's contentions depend on a figment of its imagination.

B. Hospira Will Not be Irreparably Harmed Because Any Harm Is Measured in Dollars Alone, and Its Precedex Product Is Going Generic in December 2014

Finding no irreparable harm to Hospira, the district court noted that it granted the TRO based on Hospira's misleading information.:

> [T]he Court is not satisfied that Hospira will suffer irreparable harm absent a stay. In finding irreparable harm for purpose of the temporary restraining order, the Court relied heavily on the fact that 98.4% of Hospira's U.S. branded sales are of Precedex® but has since learned this is a relatively small portion of its overall company.

(ECF 125 at 2.) This factual ruling deserves great deference.[8]

[8] Hospira contended that 98.4 percent of its U.S. brand product business came from the sale of Precedex in 2013. (ECF 97-22 ¶ 16.) This is misleading. (ECF 118 ¶ 8.) Hospira is a huge pharmaceutical company with sales not confined to U.S. brand pharmaceuticals, but

In the highly unlikely event Hospira prevails on some portion of its appeal, Hospira cannot be irreparably harmed because any loss reduces to a calculable sum of money. *See Sampson v. Murray*, 415 U.S. 61, 90 (1974) ("The key word in this consideration is irreparable. Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay, are not enough.") (internal quotation marks and citation omitted); *Hughes Network Sys., Inc. v. InterDigital Comm. Corp.*, 17 F.3d 691, 694 (4th Cir. 1994) ("Where the harm suffered by the moving party may be compensated by an award of money damages at judgment, courts generally have refused to find that harm irreparable.").

Par submitted opinions from a third-party expert economist testimony to dispel Hospira's self-serving declarations. (*See* ECF 97-27, 111-1, and 118.) Neither Hospira nor Sandoz rebutted the objective

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which also include branded generic and generic drugs sold in the U.S. and worldwide. (ECF 97-28 at 53; ECF 118 ¶ 8.) Out of Hospira's total $4 billion in net pharmaceutical product sales, Precedex contributes only 7.8 percent. (*Id.*) Even these percentages are overstated because they include sales for both the original Precedex and the new Precedex Premix. (*Id.* at ¶ 9.) Precedex sales likely represent less than 5% of Hospira's net product sales. (*Id.*)

opinions of Par's expert with its own expert, but instead responded with attorney argument.

As explained in opinions from Par's expert, any harm to Hospira by denying it injunctive relief can be calculated: Every unit Par sells would go to Hospira at Hospira's current prices for Precedex. (ECF 118 ¶ 7.) One simply multiplies Par's unit sales by the price at which Hospira typically sells its product.[9] *See Altana Pharma AG v. Teva Pharm. USA, Inc.*, 532 F. Supp. 2d 666, 683 (D.N.J. 2007), *aff'd*, 566 F.3d 999, 1011 (Fed. Cir. 2009). As Chief Justice Roberts held in denying a brand-name manufacturer's motion to stay the mandate following the grant of certiorari: "Given 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 2014)

[9] Par's sales are not expected to have a significant impact on the price of Precedex, i.e., price erosion. (ECF 97-27 ¶¶ 4–6.) A branded drug generally has no desire to compete with the price of a generic drug. (*Id.*) To extract as much revenue as possible from the remaining audience, brands even raise the drug price. (*Id.*) In this instance, any price erosion would be minimized because the market will convert to generics in less than four months irrespective of an injunction. (ECF 97-28 at 52, ECF 97-27 ¶ 7.)

Hospira has already itself calculated the economic impact of generic entry into the Precedex market. Its CEO, Michael Ball, stated that Hospira had already forecasted an earnings guidance range of $2.30 and $2.50 a share due to "FDA's ability to approve generic versions of Precedex" under a "carve-out process" resulting in "an ealier-than-planned introduction of the generic version of" Precedex. (ECF 39-2 at 261–65.) *See Novartis Corp. v. Teva Pharm. USA, Inc.*, CIV 04-4473 HAA ES, 2007 WL 1695689, at *28 (D.N.J. June 11, 2007) (finding no irreparable harm in the context of a preliminary injunction, in part, because Novartis's own expert's was able "to calculate (preliminarily) the potential pecuniary harm to Novartis"); *Altana Pharma AG*, 532 F. Supp. 2d at 683; *Mike's Train House, Inc. v. Broadway Ltd. Imps., LLC*, 708 F. Supp. 2d 527, 532 (D. Md. 2010).

Furthermore, any "harm" to Hospira cannot be irreparable because Hospira admits that such harm is inevitable due to other forces: "In December 2013, Hospira entered into a settlement in its patent litigation over Precedex . . . provid[ing] for a market entry date for Sandoz to sell a generic version of Precedex no later than December 26, 2014." (ECF 97-28; *see also* ECF 118 ¶ 7.) Beginning in December

2014, Hospira will likely lose the vast majority of its Precedex sales to generic competition regardless of whether Par is precluded from the market by an injunction. (ECF 118 ¶ 10.)

Because Precedex is going generic on December 26, 2014, Hospira is already replacing it with another version of Precedex, a ready-to-use version ("Precedex Premix"), which obtained FDA approval in March 2013. Since the launch of Precedex Premix, Hospira's sales volumes for Precedex have fallen by approximately half. (ECF 118 ¶¶ 5, 9.) Hospira cannot be irreparably harmed by the loss of sales of Precedex when it is currently cannibalizing its own sales. (*Id.* ¶¶ 9, 11, 15.)

Despite the growth of Precedex Premix, Hospira incredibly states that it will lay off its entire sales staff unless Par and Mylan's products are enjoined. (Doc. 5-1 at 3.) Even if it did, severance payments are calculable for the 130 people it specifically identified. (ECF 97-27 ¶ 8.) Hospira pleads that it will not be able to "fund research and development on new drug products" without its monopoly (Doc. 5-1 at 14), but Sandoz is entering the market in four months as a generic. (ECF 97-27 ¶ 9). "If a claim of lost opportunity to conduct research were sufficient to compel a finding of irreparable harm, it is hard to imagine

any manufacturer with a research and development program that could not make that same claim[.]" *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1578 (Fed. Cir. 1996) Par too develops, manufactures, and markets generic and biosimilar drugs that are equally as important to the FDA's mission.

Any argument by Hospira that it cannot recoup any loss from the FDA due to its sovereign immunity rings hollow. Hospira made the decision to sue the FDA instead of Par. Moreover, at this point, Par and Mylan are involved as intervenor-defendants.[10]

C. The Balance of the Equities Strongly Disfavors any Injunction, and Would Irreparably Harm Par

The district court found, as a factual matter, that "Mylan and Par Sterile would suffer continued harm if they were forced to continue to turn away customers." (ECF 125 at 2.) Hospira's conduct has already hurt Par's reputation as one of the most reliable pharmaceutical companies in the world. Par sold its product on August 19; Par had to stop selling later that evening; and now, Hospira again asks this Court

[10] This case is different from *Par Pharm., Inc. v. TWi Pharm., Inc.*, No. 11-2466 (D. Md.), where Par Pharmaceutical, Inc. sought an injunction pending appeal because in that case, Strativa is an entirely separate division with only a few products, and wherein Megace®, the drug at issue, was basically that entire division.

to cast an indefinite legal cloud over Par's future sales. *Winter*, 555 U.S. at 24 (holding that courts "must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief"); *Viropharma, Inc. v. Hamburg*, 898 F. Supp. 2d 1, 28 (D.D.C. 2012).

Enjoining Par again closes Par's short window to competitively sell its product, and Par loses any advantage to being a first entrant. Par turned down at least five customers during the course of the district court's TRO. (ECF 111-2 ¶ 3.) If the Court grants an injunction, Par expects to lose existing contracts with large purchasers, and Par's customers will also be forced to purchase Precedex at Hospira's inflated, monopolistic prices. (ECF 117 ¶ 12; ECF 118 ¶ 14.) Every day that Par's approved product is kept off the market costs Par substantial sums of money. (ECF 117 ¶ 10; ECF 118 ¶ 12.) Moreover, Par's opportunity to sell its product is fleeting because of Sandoz's expected launch in December 2014, and because Hospira is increasingly cannibalizing its own Precedex sales with its Precedex Premix. (ECF 118 ¶¶ 5, 9, 11, 15.)

An injunction for another two months would cause Par to lose any advantage to being one of the first approved generic products on the

market, and there is no recompense available for that loss. (ECF 118 ¶ 12) An injunction causes Par to suffer significant non-economic harms, including the loss of good will and relationships Par developed with its customers; the loss of business opportunities; and a substantial loss of market share. (ECF 118 ¶¶ 7–10.)

D. The Public Wants Less Expensive Drugs; Public Interest Is Hurt by a Preliminary Injunction Against the Generics

The district court correctly found the "the public interest would not be served by a stay as consumers benefit from safe and effective generic products on the market." (ECF 125 at 2.) Keeping generics off the market contravenes the purpose of the Hatch-Waxman Act.

> The public interest favors denying the preliminary injunction. . . . If this Court enters the injunction requested by Sandoz . . . it will effectively take . . . low-cost generic [versions of the] product out of the hands of consumers. Thus, Sandoz's proposed injunction would not only harm hundreds of thousands of patients, it would also go against the **clear purpose of the Hatch–Waxman Act, which is to 'get generic drugs into the hands of patients at reasonable prices—fast.**'

Sandoz, Inc. v. FDA, 439 F. Supp. 2d 26, 33 (D.D.C. 2006) (quoting legislative history) (emphasis added). It also cannot be in the public's interest to protect Hospira's unlawful monopoly over Precedex. *Cf.* 15

U.S.C. § 16(e) (requiring courts to consider the public interest when considering consent decrees resolving antitrust enforcement actions).

V. Hospira Must Post a Bond

Hospira asks, at the conclusion of its motion, that the Court waive any requirement for a bond. Hospira contends that a bond is unnecessary because Par already sold some product and therefore, the market has adequate supply of Par's product. This is untrue, and Par had to turn down customers during the TRO. (ECF 111-2 ¶ 3.) Hospira also states that an injunction preserves the status quo, which to Hospira, is a monopoly over Precedex. (*Id.*) Hospira only wants to extend its monopoly.

The amount of a bond depends on the duration of the proceedings. The district court denied Par's request for a bond on September 4, 2014, because the district court intended to issue its final decision the next day. This appeal is not expected to be decided in one day. As it stands, there is no case schedule. Hospira should provide a $34,164,352 bond to protect Par's interests through June 2015. Par reserves the right to supplement its bond amount once this Court issues a briefing schedule.

WHEREFORE, Par requests that the Court deny Hospira's motion for an injunction pending its appeal.

Respectfully submitted:

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CERTIFICATE OF SERVICE

I hereby certify that, on September 7, 2014, I filed the foregoing with the Court's CM/ECF system, which will send electronic notice to:

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