IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SANOFI-AVENTIS, *et al.*, Plaintiffs,	
v.	Civ. No. 09-1495 (RMU)
FOOD AND DRUG ADMINISTRATION, *et al.* Defendants.	

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Federal Rules of Civil Procedure 56 and 57 and Local Civil Rules 7 and 56.1, Plaintiffs hereby move this Court to enter summary judgment in their favor, declare all approvals of generic oxaliplatin products granted by FDA to date unlawful, and issue a permanent injunction ordering FDA to rescind all such approvals and refrain from granting any further such approvals until expiration of the automatic 30-month stay.

As set forth in more detail in the accompanying memorandum of points and authorities in support of this motion, the approvals are based on FDA's legally incorrect position that a stayed judgment is a "judgment" within the meaning of 21 U.S.C. § 355(c)(3)(C)(i) and (j)(5)(B)(iii)(I)(aa). FDA's position violates the core principles of inherent Judicial Branch power recently reaffirmed by the Supreme Court in *Nken v. Holder*, 129 S. Ct. 1749 (Apr. 22, 2009). The Federal Circuit's decision on September 10, 2009, vacating the judgment at issue further confirms that FDA committed legal error in granting the approvals despite the stay of the judgment. FDA thus abused its discretion in granting the approvals, which are not in accordance

with 21 U.S.C. § 355(c)(3)(C)(i) and (j)(5)(B)(iii)(I)(aa). FDA therefore violated the Administrative Procedure Act, 5 U.S.C. § 706(2), and Plaintiffs are entitled to judgment as a matter of law.

Because the infringing products' unlawful presence on the market is causing ongoing and grave harm, Sanofi and Debiopharm are separately moving for expedited resolution of their motion for summary judgment.

In addition to the supporting memorandum of points and authorities, a statement of undisputed material facts and a proposed order accompany this motion.

Respectfully submitted,

/s/

Anthony Herman (D.C. Bar No. 424643)
Peter O. Safir (D.C. Bar No. 217612)
Emily Johnson Henn (D.C. Bar No. 471077)
Joshua D. Greenberg (D.C. Bar No. 480534)
COVINGTON & BURLING LLP
1201 Pennsylvania Ave., N.W.
Washington, DC 20004
(202) 662-6000 (Telephone)
(202) 662-6291 (Fax)

Attorneys for Plaintiffs sanofi-aventis, sanofi-aventis U.S. LLC, and Debiopharm S.A.

September 14, 2009

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SANOFI-AVENTIS, *et al.*, Plaintiffs,	
v.	Civ. No. 09-1495
FOOD AND DRUG ADMINISTRATION, *et al.* Defendants.	

STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Local Civil Rule 7(h), Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively, "Sanofi") and Debiopharm S.A. ("Debiopharm") hereby submit this statement of material facts as to which there is no genuine issue:

1. Eloxatin is a platinum-based anti-cancer agent with oxaliplatin as its active ingredient. FDA-Approved Label for Eloxatin (Rev. Nov. 2004), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/021759lbl.pdf.

2. FDA approved the current solution formulation of Eloxatin on January 31, 2005. Letter from Richard Pazdur, M.D., Director, Division of Oncology Drug Products, Office of Drug Evaluation I, Center for Drug Evaluation & Research, FDA, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2005/021759ltr.pdf.

3. Sanofi and Debiopharm filed their pending patent lawsuits in June and July 2007 against Intervenors and other manufacturers seeking to market generic oxaliplatin products in the

U.S. District Court for the District of New Jersey. (*E.g.*, No. 07-2837 (filed against Teva on June 18, 2007) and Nos. 07-cv-3409 & 07-cv-4550 (filed against Mayne on July 23, 2007), all of which are consolidated in *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 07-cv-2762 (JAP).)

4. Debiopharm owns the patent in suit, U.S. Patent No. 5,338,874 ("the '874 patent"). (Ex. E, Harrington Decl. ¶ 5 n.1.[1]) Sanofi is the exclusive licensee of the '874 patent in the United States. (*Id.*)

5. On June 18, 2009, the District of New Jersey ruled that the '874 patent was not infringed, and a judgment reflecting that ruling was entered on June 30, 2009. (*Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 07-cv-2762 (JAP), Docs. 378 & 411 (D.N.J. June 18 & 30, 2009).)

6. On June 30, 2009, Sanofi and Debiopharm moved the U.S. Court of Appeals for the Federal Circuit to stay the judgment and petitioned for a writ of mandamus. (*Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 2009-1427 (Fed. Cir. filed June 30, 2009); *In re Sanofi-Aventis U.S. LLC*, Misc. No. 905 (Fed. Cir. filed June 30, 2009).)

7. On July 1, 2009, the Federal Circuit temporarily stayed the judgment pending its receipt of the generic manufacturers' responses to the stay motion and mandamus petition. (Ex. A, Order, *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 2009-1427 (Fed. Cir. July 1, 2009).)

8. On July 10, 2009, the Federal Circuit stayed the judgment pending appeal. (Ex. B, Order, *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 2009-1427 (Fed. Cir. July 10, 2009).)

---

[1] The declaration bears the caption of the pending patent litigation because it was originally submitted in that litigation.

The exhibit letters used in this statement of undisputed material facts are the same as those used in the exhibits to the memorandum of points and authorities in support of the motion.

9. On August 7, 2009, FDA approved Teva's Section 505(b)(2) application and Mayne's ANDA. (Doc. 7, Teva's Mot. to Intervene at 2 ¶ 1; Doc. 13-2, Mem. in Supp. of Mayne's Mot. to Intervene at 3.)

10. Beginning on August 11, 2009, generic drug manufacturers including Intervenors Teva Parenteral Medicines, Inc. ("Teva") and Mayne Pharma Limited ("Mayne") launched their oxaliplatin products. *See, e.g.,* The Wall Street Journal, *Teva Announces Approval and Launch of Oxaliplatin Injection,* Aug. 11, 2009, *available at* http://online.wsj.com/article/PR-CO-20090811-908177.html?mod=wsjcrmain; Press Release, *Hospira* [Mayne's Parent Company] *Launches Generic Oxaliplatin Injection: Key Cancer Drug Offered In Solution Form,* Aug. 11, 2009, *available at* http://www.reuters.com/article/pressRelease/idUS182278+11-Aug-2009+PRN20090811.

11. On September 2, 2009, the Federal Circuit heard oral argument in Sanofi and Debiopharm's expedited appeal of the District of New Jersey's judgment. (Ex. C, *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 2009-1427, slip op. at 4 (Fed. Cir. Sept. 10, 2009).)

12. On September 10, 2009, the Federal Circuit unanimously vacated the judgment and remanded the case to the District of New Jersey. (*Id.* at 3, 8.)

Respectfully submitted,

/s/

Anthony Herman (D.C. Bar No. 424643)
Peter O. Safir (D.C. Bar No. 217612)
Emily Johnson Henn (D.C. Bar No. 471077)
Joshua D. Greenberg (D.C. Bar No. 480534)
COVINGTON & BURLING LLP
1201 Pennsylvania Ave., N.W.
Washington, DC 20004
(202) 662-6000 (Telephone)
(202) 662-6291 (Fax)

Attorneys for Plaintiffs sanofi-aventis, sanofi-aventis U.S. LLC, and Debiopharm S.A.

September 14, 2009

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SANOFI-AVENTIS, *et al.*, Plaintiffs,	)	
v.	)	Civ. No. 09-1495 (RMU)
FOOD AND DRUG ADMINISTRATION, *et al.* Defendants.	)	

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Anthony Herman (D.C. Bar No. 424643)
Peter O. Safir (D.C. Bar No. 217612)
Emily Johnson Henn (D.C. Bar No. 471077)
Joshua D. Greenberg (D.C. Bar No. 480534)
COVINGTON & BURLING LLP
1201 Pennsylvania Ave., N.W.
Washington, DC 20004
(202) 662-6000 (Telephone)
(202) 662-6291 (Fax)

Attorneys for Plaintiffs sanofi-aventis, sanofi-aventis U.S. LLC, and Debiopharm S.A.

September 14, 2009

INTRODUCTION

This case stems from FDA's unlawful approvals of generic drugs based on a district court decision of non-infringement that was immediately stayed – and has now been overturned and vacated – by the Federal Circuit. FDA's unlawful approvals rest on the agency's misapprehension of the Hatch-Waxman Act, upset the carefully crafted balance struck by Congress in that Act, and cannot be squared with the Supreme Court's recent decision in *Nken v. Holder*, 129 S. Ct. 1749 (Apr. 22, 2009).

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC (collectively, "Sanofi") and Debiopharm S.A. ("Debiopharm"), respectively, are the exclusive licensee in the United States and the owner of patents covering the drug oxaliplatin. Oxaliplatin is approved by FDA to treat colon cancer, and is marketed as Eloxatin®. In mid-2007, Sanofi and Debiopharm filed patent lawsuits in the U.S. District Court for the District of New Jersey against generic manufacturers seeking to market copycat oxaliplatin products. Under the Hatch-Waxman Act amendments to the Food, Drug and Cosmetic Act (the "Hatch-Waxman Act"), the timely filed patent lawsuits automatically stay FDA approval of the generic products for 30 months – until August 9, 2010. 21 U.S.C. § 355(c)(3)(C), (j)(5)(B)(iii).

One day after the New Jersey court entered a judgment of non-infringement in the patent litigation, the Federal Circuit exercised its inherent judicial authority and stayed the judgment pending resolution of Sanofi and Debiopharm's expedited appeal. (Exs. A & B, Orders, *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 2009-1427 (Fed. Cir. July 1 & 10, 2009).) Under *Nken*,, the stay is a "temporary setting aside of the source of [FDA's] authority to" approve generic oxaliplatin products. 129 S. Ct. at 1756-58 (emphasis added). The stay thus preserved (or

should have preserved) "the status quo – the state of affairs before the [judgment] was entered" – while the Federal Circuit "assesse[d] the legality of the [judgment]." *Id.* (emphasis added).

Despite the stay, FDA approved applications for generic oxaliplatin products submitted by some of the defendants in the patent litigation, including Intervenors. Immediately thereafter, generic drug manufacturers including Intervenors Teva Parenteral Medicines, Inc. ("Teva") and Mayne Pharma Limited ("Mayne") shipped large amounts of their copycat oxaliplatin products for commercial sales.[2]

Following expedited briefing and argument, on September 10, 2009, the Federal Circuit vacated the New Jersey court's judgment. (Ex. C, *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 2009-1427, slip op. at 3, 8 (Fed. Cir. Sept. 10, 2009).) The vacatur makes permanent the stay's "temporary setting aside" of the judgment. *Nken*, 129 S. Ct. at 1758. As a matter of law, the vacatur means that the judgment underlying FDA's approvals never existed. *See* 47 Am. Jur. 2d *Judgments* § 714 (2009) ("When a judgment has been rendered and later set aside or vacated, the matter stands precisely as if there had been no judgment.") (emphasis added).

FDA's approvals violate the Hatch-Waxman Act, under which the stay on such approvals may be lifted before the end of the 30-month period only where "the district court decides that the patent is invalid or not infringed" and "enters judgment reflecting the decision." 21 U.S.C. § 355(c)(3)(C)(i), (j)(5)(B)(iii)(I)(aa). As Judge Moore – who authored the Federal Circuit's opinion vacating the New Jersey court's judgment (Ex. C at 3) – explained, the Federal Circuit's

---

[2] *See, e.g.*, The Wall Street Journal, *Teva Announces Approval and Launch of Oxaliplatin Injection*, Aug. 11, 2009, *available at* http://online.wsj.com/article/PR-CO-20090811-908177.html?mod=wsjcrmain; Press Release, *Hospira* [Mayne's Parent Company] *Launches Generic Oxaliplatin Injection: Key Cancer Drug Offered In Solution Form*, Aug. 11, 2009, *available at* http://www.reuters.com/article/pressRelease/idUS182278+11-Aug-2009+PRN20090811.

"obvious intention" in staying the judgment was "to suspend alteration of the status quo," *i.e.*, to maintain "the imposition of the 30-month hold and abeyance of the approval of the [generic oxaliplatin] applications." (Ex. D at 4, *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, Nos. 2009-1427 & -1444 (Fed. Cir. Aug. 13, 2009) (Moore, J., concurring in the denial of reconsideration).) FDA's decision to approve those applications despite the stay "is plainly contrary to *Nken*, which voids any legal effect from the stayed judgment, including the effect of triggering provisions of Hatch-Waxman." (*Id.* at 5.) That the Federal Circuit has now vacated the judgment further confirms that FDA's approvals must be set aside: The approvals are now based on a "judgment" that never existed. Because there is no "judgment" under 21 U.S.C. § 355(c)(3)(C)(i) and (j)(5)(B)(iii)(I)(aa), the approvals are an abuse of discretion and not in accordance with law, in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2).

Accordingly, Sanofi and Debiopharm respectfully request that this Court enter summary judgment in their favor, declare all generic oxaliplatin approvals granted to date unlawful, and issue a permanent injunction ordering FDA to rescind all such approvals and refrain from granting any further such approvals until expiration of the automatic 30-month stay.[3]

BACKGROUND

A. The Hatch-Waxman Act and the Critical Role of the Automatic 30-Month Stay Provision in Maintaining the Delicate Balance Created By Congress

Companies that develop new prescription drugs ("innovators"), such as Sanofi and Debiopharm, must file new drug applications ("NDAs") demonstrating that their drugs are safe and effective before they can market new drugs. 21 U.S.C. § 355(b)(1). NDAs are extensive

[3] Because the infringing products' unlawful presence on the market is causing ongoing and grave harm, Sanofi and Debiopharm are separately moving for expedited resolution of their motion for summary judgment.

and heavily detailed applications that typically require innovators to engage in expensive pre-clinical and clinical research, including clinical trials. NDAs must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." *Id.*

In contrast, companies seeking to market generic copies of an innovator drug, such as Intervenors, "piggyback" on the innovator's prior showings of safety and effectiveness, and may obtain expedited FDA approval by submitting Section 505(b)(2) applications or ANDAs. *See Teva Pharm., USA, Inc. v. Leavitt*, 548 F.3d 103, 104 (D.C. Cir. 2008) ("A manufacturer preparing to market a generic bioequivalent of a branded drug can take a short-cut: filing an Abbreviated New Drug Application (ANDA) that piggybacks on the original manufacturer's evidence of safety and efficacy."); *Mylan Labs., Inc. v. Leavitt*, 484 F. Supp. 2d 109, 114 (D.D.C. 2007) (Urbina, J.) ("The generic manufacturer is allowed to essentially piggyback its ANDA on the FDA's previous findings that the pioneer drug is safe and effective.").

Congress created this abbreviated pathway to market for generic products in 1984 when it enacted the Hatch-Waxman Act. As this Court has recognized, in doing so Congress struck a delicate balance: "The overarching purpose of this abbreviated drug approval mechanism is to strike a 'balance encouraging innovation in drug development with accelerating the availability of lower cost alternatives to approved brand-name drugs.'" *Mylan Labs.*, 484 F. Supp. 2d at 114 (quoting H.R. Rep. No. 98-857 (Part I), at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. at 2647-48). Congress designed the Hatch-Waxman Act not only to increase access to generic drug products, but also to "strive[ ] to induce name-brand pharmaceutical firms to develop new drug products" by "promoting industry incentives to research and develop new drug treatments." 484 F. Supp. 2d at 124; *see also Abbott Labs. v. Young*, 920 F.2d 984, 985 (D.C. Cir. 1990) ("Facing

the classic question of the appropriate trade-off between greater incentives for the invention of new products and greater affordability of those products, Congress struck a balance between expediting generic drug applications and protecting the interests of the original drug manufacturers."). Congress carefully balanced these "multi-faceted" objectives, *Mylan Labs.*, 484 F. Supp. 2d at 124, by giving innovators like Sanofi and Debiopharm a "30-month stay in the approval of [generic applications] within which to litigate [their] case," *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1366 (Fed. Cir. 2008).

The delicate balance created by Congress rests on a detailed regime for adjudicating patent disputes before generic drugs enter the market. NDAs must include information on eligible patents that claim the drug substance, drug product, or method of use of the drug covered by the NDA. 21 U.S.C. § 355(b)(1), (c)(2). When an applicant submits a Section 505(b)(2) application or an ANDA, it must include one of four certifications to each patent listed for the innovator drug referenced in the ANDA. *Id.* § 355(b)(2)(A), (j)(2)(A)(vii). The certification relevant here is a "paragraph IV certification," which asserts that the pertinent listed patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* § 355(b)(2)(A)(iv), (j)(2)(A)(vii)(IV).

A section 505(b)(2) or ANDA applicant must promptly notify each NDA and patent holder of a paragraph IV certification. *Id.* § 355(b)(3), (j)(2)(B)(ii). Filing a paragraph IV certification is deemed an act of patent infringement. 35 U.S.C. § 271(e)(2)(A). Upon receipt of notice of the paragraph IV certification, the patent holder may bring an infringement action.

In the Hatch-Waxman Act, Congress provided that, if a patent holder files an infringement action within 45 days after it receives notification of a paragraph IV certification, FDA is automatically stayed from approving the section 505(b)(2) application or ANDA for up

to 30 months from the patent holder's receipt of the notification. 21 U.S.C. § 355(c)(3)(C); *id.* § 355(j)(5)(B)(iii). The purpose of this 30-month stay provision is to allow the innovator to litigate its patent claims: "When a generic manufacturer files an ANDA with a paragraph IV certification, Hatch-Waxman grants the brand name pharmaceutical manufacturer a 30-month stay in the approval of that ANDA within which to litigate its case." *Ortho-McNeil Pharm.*, 520 F.3d at 1366 (citing 21 U.S.C. § 355(j)(5)(B)(iii)). A 2003 amendment to the statute provides that the stay ends when "the district court decides that the patent is invalid or not infringed" and "enters judgment reflecting the decision." 21 U.S.C. § 355(c)(3)(C)(i), (j)(5)(B)(iii)(I)(aa).

The statute is silent regarding what happens where a court of appeals (i) stays the district court's judgment immediately following entry and (ii) vacates the district court's judgment on an expedited appeal. There is nothing in the Hatch-Waxman Act or its legislative history to suggest that Congress intended to deprive courts of their inherent authority to stay (or vacate) judgments and thereby restore the status quo ante.

B. Eloxatin

Eloxatin is a platinum-based anti-cancer agent with oxaliplatin as its active ingredient.[4] On January 31, 2005, FDA approved the current solution formulation of Eloxatin, when administered with two other chemotherapy drugs, for adjuvant treatment of patients with stage III colon cancer who have had their primary (original) tumors surgically removed and for treatment of advanced colon cancer.[5] FDA's approval of Eloxatin is based on evidence of

---

[4] FDA-Approved Label for Eloxatin (Rev. Nov. 2004), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/021759lbl.pdf.

[5] Letter from Richard Pazdur, M.D., Director, Division of Oncology Drug Products, Office of Drug Evaluation I, Center for Drug Evaluation & Research, FDA, to Mark Moyer, V.P., Drug Regulatory Affairs, Sanofi-Synthlabo, Inc. 1 (Jan. 31, 2005), *available at* http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2005/021759ltr.pdf.

improvement in patients' disease-free survival after a median period of four years.[6] Sanofi has listed four patents in the Orange Book for Eloxatin, including United States Patent Nos. 5,290,961 (exp. Jan. 12, 2013), 5,338,874 (exp. Apr. 7, 2013), 5,420,319 (exp. Aug. 9, 2016), and 5,716,988 (exp. Aug. 7, 2015). Sales of Eloxatin in 2008 totaled approximately $1.3 billion. *See, e.g.*, The Wall Street Journal, *Teva Announces Approval and Launch of Oxaliplatin Injection*, Aug. 11, 2009, *available at* http://online.wsj.com/article/PR-CO-20090811-908177.html?mod=wsjcrmain.

Under the Hatch-Waxman Act, because Sanofi and Debiopharm timely sued the generic manufacturers, FDA approval of those manufacturers' generic versions of Eloxatin is stayed until August 9, 2010, unless a "judgment" is entered earlier and is not stayed or vacated. *See* 21 U.S.C. § 355(c)(3)(C)(i), (j)(5)(B)(iii)(I)(aa).

C. The Patent Litigation and the Federal Circuit's Stay and Vacatur

Debiopharm owns the patent in suit, U.S. Patent No. 5,338,874 ("the '874 patent"). (Ex. E, Harrington Decl. ¶ 5 n.1.) (The declaration bears the caption of the pending patent litigation because it was originally submitted in that litigation.) Sanofi is the exclusive licensee of the '874 patent in the United States. (*Id.*)

Sanofi and Debiopharm filed their pending patent lawsuits in June and July 2007 against Intervenors and other generic manufacturers seeking to market copycat oxaliplatin products in the District of New Jersey. On June 18, 2009, the court ruled that the '874 patent was not infringed, and it entered judgment on June 30. (*Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 07-cv-2762 (JAP), Docs. 378 & 411 (D.N.J. June 18 & 30, 2009).) Later on June 30, Sanofi and

---

6 *Id.*

Debiopharm moved the Federal Circuit to stay the judgment and petitioned for a writ of mandamus. (*Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 2009-1427 (Fed. Cir. filed June 30, 2009); *In re Sanofi-Aventis U.S. LLC*, Misc. No. 905 (Fed. Cir. filed June 30, 2009).[7])

On July 1 – the very next day – the Federal Circuit temporarily stayed the judgment pending its receipt of the generic manufacturers' responses to the stay motion and mandamus petition. (Ex. A, Order, *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 2009-1427 (Fed. Cir. July 1, 2009).) On July 10, the Federal Circuit stayed the judgment pending resolution of Sanofi and Debiopharm's appeal. (Ex. B, Order, *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 2009-1427 (Fed. Cir. July 10, 2009).) Nevertheless, "[o]n the evening of" Friday, August 7, FDA approved Teva's Section 505(b)(2) application (Doc. 7 at 2 ¶ 1) and Mayne's ANDA (Doc. 13-2 at 3). Teva, Mayne, and other generic manufacturers launched their oxaliplatin products within days, and ever since have earned windfall profits by marketing their infringing products.

On Monday, August 10, Sanofi and Debiopharm moved for a temporary restraining order and preliminary injunction.[8] This Court denied the motions at a hearing that day attended by counsel for Defendants, and on August 11 entered an order reflecting its ruling. Teva

---

[7] In seeking mandamus as an alternate means of preserving the status quo ante, Sanofi and Debiopharm were simply acting out of concern, which proved prescient, that FDA would overlook that a stay preserves "the status quo – the state of affairs before the [judgment] was entered" – while the court of appeals "assesses the legality of the [judgment]." *Nken*, 129 S. Ct. at 1756-58 (emphasis added).

[8] Sanofi and Debiopharm moved for interim injunctive relief ordering FDA to rescind final approval of section 505(b)(2) new drug application ("505(b)(2) application") No. 022160 submitted by Intervenor Teva, and to withhold or rescind (as applicable) final approval of abbreviated new drug application ("ANDA") Nos. 078820 and 078822 submitted by Teva and Pharmachemie BV, Nos. 078813 and 078815 submitted by Intervenor Mayne, No. 078818 submitted by Sun Pharmaceutical Industries, Ltd. ("Sun"), No. 078810 submitted by Fresenius Kabi Oncology Plc ("Fresenius"), No. 078803 submitted by Actavis, Inc., No. 078943 submitted by Barr Laboratories, Inc. and Pliva-Lachema A.S., and No. 078819 submitted by APP Pharmaceuticals Inc., all for generic versions of oxaliplatin.

subsequently moved to intervene (Doc. 7), and its order was granted. Mayne later moved to intervene as well (Doc. 13); that motion is pending.[9] On August 18, the Court issued a memorandum opinion explaining its rulings. (Doc. 21.)

Sanofi and Debiopharm filed a notice of emergency appeal on August 11 and moved for emergency injunctive relief the following day. On August 18, a panel of the D.C. Circuit denied the emergency motion. Sanofi and Debiopharm's subsequent emergency petition for *en banc* reconsideration was denied on August 20.

On September 2, the Federal Circuit heard oral argument in Sanofi and Debiopharm's expedited appeal of the New Jersey court's judgment. (Ex. C, *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 2009-1427, slip op. at 4 (Fed. Cir. Sept. 10, 2009).) Five business days later, the Federal Circuit "vacate[d] and remand[ed]" the New Jersey court's judgment. (*Id.* at 3, 8 (emphases in original).) The Federal Circuit observed that "despite the stay of judgment, the FDA granted final approval of the [applications submitted] by certain defendants" in the patent litigation." (*Id.* at 3 (emphasis added).) With regard to the patent decision, the court of appeals held that the New Jersey court "erred" by violating a well-settled principle about which the Federal Circuit had "repeatedly warned," including in an *en banc* decision in 2005. (*Id.* at 3, 5 (citing *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc)) (emphasis added).)

ARGUMENT

Summary judgment is appropriate where, as here, "there is no genuine issue as to any material fact" and "the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). Here, the material facts are all undisputed, and the only contested issue is a purely legal one:

---

[9] For simplicity, because no party opposes intervention by Mayne, this motion refers to Teva and Mayne collectively as "Intervenors.")

whether FDA acted unlawfully in approving applications to market generic oxaliplatin products despite the Federal Circuit's stay, and subsequent vacatur, of the judgment that FDA misperceived as a source of authority for its action. The Court can and should resolve this legal issue now.

Sanofi and Debiopharm respectfully submit that *Nken* "address[es] the central issue in the instant case" because the Supreme Court's opinion holds that a stay restores the legal state of affairs that existed before "the date of the entry of judgment." *Sanofi-Aventis v. FDA*, Civ. No. 09-1495 (RMU), --- F. Supp. 2d ---, 2009 WL 2498686, at *3 (D.D.C. Aug. 11, 2009). *Nken* holds that the decision by a court of appeals to stay a judgment pending review restores the state of affairs that existed "before" entry of the judgment and is a "temporary setting aside of the source of the Government's authority" conferred by the judgment. 129 S. Ct. at 1758.

The Hatch-Waxman Act expressly provides that a "judgment" is the source of FDA's authority to approve generic drugs. 21 U.S.C. § 355(c)(3)(C), (j)(5)(B)(iii). Under *Nken*, because the Federal Circuit stayed the judgment, which was subsequently vacated, FDA never had authority to approve generic oxaliplatin products. FDA's approvals of such products are therefore unlawful and should be set aside.

I. UNDER *NKEN*, FDA'S APPROVALS ARE UNLAWFUL BECAUSE THE FEDERAL CIRCUIT'S PRIOR STAY ORDER PRESERVED THE STATE OF AFFAIRS THAT EXISTED BEFORE ENTRY OF THE JUDGMENT.

The Supreme Court's decision in *Nken* holds that "Congress's failure expressly to confer the authority [of a court of appeals to stay a district court's judgment pending appeal] in a statute allowing appellate review should not be taken as an implicit denial of that power." 129 S. Ct. at 1756. *Nken* instructs that courts must be "loath to conclude that Congress would, 'without clearly expressing such a purpose, deprive the Court of Appeals of its customary power to stay

orders under review.'" *Id.* at 1760 (quoting *Scripps-Howard Radio, Inc. v. FCC*, 316 U.S. 4, 11 (1942)).

As in *Nken*, here the statute says nothing about the power of a court of appeals to stay a district court's judgment, much less "clearly express[]" a "purpose" to deprive courts of appeals of their traditional authority to preserve the status quo ante. *Id.* *Nken* instructs that such Congressional silence "should not be taken as an implicit denial of" the power of a court of appeals to preserve the state of affairs that existed before entry of a district court's judgment pending appeal. *Id.* at 1756 (emphasis added). FDA and Intervenors cannot overcome "the 'presumption favoring the retention of long-established and familiar principles, except when a statutory purpose to the contrary is evident.'" *Id.* at 1760 (quoting *Isbrandtsen Co. v. Johnson*, 343 U.S. 779, 783 (1952)).

Under *Nken*, the statute's silence is dispositive: The Federal Circuit retained its inherent power to stay the district court's judgment and thereby restore "the status quo—the state of affairs before the [judgment] was entered." *Id.* at 1758. As FDA correctly acknowledged at the hearing on August 10, 2009, the statute could not be written more plainly and means what it says: That the applicable provisions "say[ ] nothing about stays" means that FDA cannot approve generic drugs based on a district court judgment stayed before approval. *Nken*, 129 S. Ct. at 1759.[10]

[10] Both in the prior hearing in this Court and in the D.C. Circuit, FDA expressly disclaimed any reliance on *Chevron*. The agency's decision therefore cannot be given deference. *See Peter Pan Bus. Lines, Inc. v. Fed. Motor Carrier Safety Admin.*, 471 F.3d 1350, 1354 (D.C. Cir. 2006) ("*Chevron* step 2 deference is reserved for those instances where an agency recognizes that the Congress's intent is not plain from the statute's face.").

The Federal Circuit's "obvious intention" in staying the district court's judgment was "to suspend alteration of the status quo" – "the imposition of the 30-month hold and abeyance of the approval of the [generic oxaliplatin] applications." (Ex. D at 4.) Because the applicable Hatch-Waxman Act provisions say nothing about a stay, the Federal Circuit's stay order preserved – or at least should have maintained – the status quo ante: "Congress's failure expressly to confer the authority [of a court of appeals to stay a district court's judgment pending appeal] in a statute allowing appellate review should not be taken as an implicit denial of that power." *Nken*, 129 S. Ct. at 1756.

Under the circumstances presented here, the 2003 amendment of the applicable Hatch-Waxman Act provisions does not affect FDA's authority to approve generic products. Before the 2003 amendment, those provisions stated that a generic drug approval "shall be made effective on the date of the court decision" if "the court" decides before the end of the 30-month period that the patent in suit is invalid or not infringed by the generic products. 21 U.S.C. § 355(j)(5)(B)(iii) (2002). The 2003 amendment clarified that a judgment of invalidity or non-infringement entered by "a district court" authorizes FDA approval, and that an appeal – standing alone – does not preserve the automatic 30-month stay. Conf. Report on H.R. 1, Medicare Prescription Drug & Modernization Act of 2003, Sec. 1101 ("30-Month Stay-Of-Effectiveness Period"), 149 Cong. Rec. H11877-03, at *H11976-77 (daily ed. Nov. 20, 2003). The 2003 amendment thus prevents innovators from filing unwarranted appeals to delay generic entry.

But this case is far removed from what concerned Congress in that amendment. It is not about the effect of an appeal of a judgment, but rather it concerns the effect of an immediate stay and subsequent vacatur of that judgment by the court of appeals. In enacting the 2003

amendment, Congress chose not to disturb the inherent power of a court of appeals to stay a district court's judgment pending review. To the contrary, as modified by the 2003 amendment, the statute still "says nothing about stays." *Nken*, 129 S. Ct. at 1759. Under *Nken*, therefore, the Federal Circuit's stay and vacatur of the District of New Jersey's judgment render FDA's approvals unwarranted and unlawful.

A separate provision in the statute, 21 U.S.C. § 355(h), further demonstrates that Congress did not intend to deprive courts of appeals of their traditional stay authority. Enacted in 1962, Section 355(h) authorizes review by a court of appeals of an FDA decision "refusing or withdrawing approval of an application." Section 355(h) provides: "The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order." Thus, when Congress enacted the Hatch-Waxman Act in 1984, it was well aware of the power of a court of appeals to issue stays. That Congress had such awareness and did not "clearly express[ ]" a purpose to deprive courts of appeals of that power, *Nken*, 129 S. Ct. at 1760, is dispositive. In Section 355, as with the statute at issue in *Nken*, "when Congress wanted to refer to a stay . . . it used the word 'stay.'" 129 S. Ct. at 1759.

Sanofi and Debiopharm respectfully submit that in this case there is no "difference . . . between the date of entry of judgment and the date of enforceability of that judgment." *Sanofi-Aventis*, 2009 WL 2498686, at *3. As FDA and Intervenors have acknowledged, entry of the judgment is the source of FDA's authority to enforce or give effect to the judgment by granting final approval. Under *Nken*, the Federal Circuit's stay order effectively "un-entered" the judgment – because the stay restored the legal state of affairs that existed before entry of the

judgment – and FDA therefore lacked authority to enforce or take any action grounded on the judgment.

Moreover, FDA has never read the applicable Hatch-Waxman Act provisions to require immediate approval of generic drug applications on the date a district court judgment was entered – as the very approvals at issue make clear. FDA's approvals of generic oxaliplatin products followed more than a month after the district court entered its judgment on June 30 – and after the Federal Circuit had stayed that judgment. If FDA believed that entry of the judgment immediately triggers its statutory duty to provide approval, FDA would have approved the applications on June 30 (or as soon thereafter as possible).

But FDA does not hold such a belief. To the contrary, as a general matter, FDA does not grant final approval of a generic drug application at the conclusion of patent litigation until it has subsequently reexamined the application "to determine whether there have been any changes in the conditions under which the application was tentatively approved.'" *Mylan Labs., Inc. v. Thompson*, 332 F. Supp. 2d 106, 112 (D.D.C. 2004) (citing 21 U.S.C. § 355(j)(4)(A)-(K) and quoting 59 Fed. Reg. 50338, 50352 (Oct. 3, 1994)), *aff'd*, 389 F.3d 1272 (D.C. Cir. 2004). "Changes in conditions that could delay final approval of a tentatively approved generic drug" include, among other things, "a change in standards governing impurity levels" and "a material change to the formulation or labeling of the pioneering drug." *Mylan Labs.*, 332 F. Supp. 2d at 112.

II. THE VACATUR OF THE STAYED JUDGMENT CONFIRMS THAT FDA ACTED UNLAWFULLY IN ALLOWING INFRINGERS ON THE MARKET.

The Federal Circuit's vacatur of the New Jersey court's judgment makes permanent the "temporary setting aside" of that judgment effected by the stay. *Nken*, 129 S. Ct. at 1758. The D.C. Circuit has recognized that vacating a judgment permanently sets it aside. *See Alabama*

Power Co. v. E.P.A., 40 F.3d 450, 456 (D.C. Cir. 1994) ("To 'vacate' . . . means 'to annul; to cancel or rescind; to declare, to make, or to render, void; to defeat; to deprive of force; to make of no authority or validity; to set aside.'") (quoting *Action on Smoking & Health v. Civil Aeronautics Bd.*, 713 F.2d 795, 797 (D.C. Cir. 1983)) (omission in original).

As a matter of law, the judgment cannot support FDA's approvals because a vacated judgment "'ha[s] no legal effect whatever.'" *Friends of the Everglades v. S. Fla. Water Mgmt. Dist.*, 570 F.3d 1210, 1218 (11th Cir. 2009) (quoting *United States v. Sigma Int'l, Inc.*, 300 F.3d 1278, 1280 (11th Cir. 2002) (*en banc*); *see also* Black's Law Dictionary 1546 (7th ed. 1999) (to "vacate" is "to nullify or cancel; make void; invalidate"). The vacatur means that the judgment never existed: "When a judgment has been rendered and later set aside or vacated, the matter stands precisely as if there had been no judgment. The vacated judgment lacks force or effect and places the parties in the position they occupied before entry of the judgment." 47 Am. Jur. 2d *Judgments* § 714 (2009) (footnote omitted).

The Federal Circuit's decision to vacate the judgment further confirms that FDA acted unlawfully in approving generic oxaliplatin products despite the stay's temporary "setting aside of the source of [FDA's] authority to" approve those products, *Nken*, 129 S. Ct. at 1758, because the vacatur nullifies any effect of the district court's judgment.

CONCLUSION

The Federal Circuit exercised its inherent power to stay the District of New Jersey's judgment, thereby preserving the preexisting legal state of affairs pending resolution of Sanofi and Debiopharm's expedited appeal. By approving copycat oxaliplatin products despite the stay, FDA violated the Hatch-Waxman Act under the principles of Judicial Branch power that the Supreme Court reaffirmed in *Nken*. Now that the Federal Circuit has vacated the District of New Jersey's judgment, the approvals are *a fortiori* unlawful. Only this Court can ensure that the stay

entered by the Federal Circuit has the effect that the court of appeals intended. Because FDA was not a party to the patent litigation pending in the Federal Circuit, "the stay d[id] not empower [the Federal Circuit] to direct FDA's conduct." "[T]hat is the business of the District of Columbia." (Ex. D at 5, *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 2009-1427 & -1444 (Fed. Cir. Aug. 13, 2009) (Moore, J., concurring in the denial of reconsideration) (emphasis added).)

This Court should enter summary judgment in favor of Sanofi and Debiopharm, declare all generic oxaliplatin approvals granted by FDA to date unlawful, and issue a permanent injunction ordering FDA to rescind all such approvals and refrain from granting any further approvals for such products until expiration of the automatic 30-month stay that Congress mandated when it enacted the Hatch-Waxman Act.

Respectfully submitted,

/s/

Anthony Herman (D.C. Bar No. 424643)
Peter O. Safir (D.C. Bar No. 217612)
Emily Johnson Henn (D.C. Bar No. 471077)
Joshua D. Greenberg (D.C. Bar No. 480534)
COVINGTON & BURLING LLP
1201 Pennsylvania Ave., N.W.
Washington, DC 20004
(202) 662-6000 (Telephone)
(202) 662-6291 (Fax)

Attorneys for Plaintiffs sanofi-aventis, sanofi-aventis U.S. LLC, and Debiopharm S.A.

September 14, 2009

CERTIFICATE OF SERVICE

I hereby certify that on September 14, 2009, I caused the foregoing documents and the exhibits thereto to be filed by Electronic Case Filing (ECF) with the U.S. District Court for the District of Columbia. This system caused an electronic notification and link to be sent to the following:

Gerald C. Kell
Senior Trial Counsel
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044
(202) 514-1586
gerald.kell@usdoj.gov

Counsel for Defendants

Charles B. Klein
Winston & Strawn LLP
1700 K Street, NW
Washington DC 20006
cklein@winston.com

Gail J. Standish
Winston & Strawn LLP
333 South Grand Avenue
Los Angeles, CA 90071
gstandish@winston.com

James F. Hurst
Winston & Strawn LLP
35 W. Wacker Drive
Chicago, IL 60601
jhurst@winston.com

Counsel for Intervenor Mayne Pharma Ltd., Mayne Pharma (USA) Inc., Hospira Australia Pty Ltd., and Hospira, Inc.

William F. Sheehan
Goodwin Procter LLP
901 New York Avenue, NW
Washington, DC 20001
wsheehan@goodwinprocter.com

David Hashmall
Goodwin Procter LLP
620 Eighth Avenue
New York, NY 10018
dhashmall@goodwinprocter.com

Henry Dinger
Goodwin Procter LLP
53 State Street
Boston, MA 02109
hdinger@goodwinprocter.com

Counsel for Intervenor Teva Parenteral Medicines, Inc.

/s/
Joshua D. Greenberg