UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SANOFI-AVENTIS, *et al.*, Plaintiffs, v. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants, and TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., PHARMACHEMIE B.V., BARR LABORATORIES, INC., and PLIVA-LACHEMA a.s., Intervenor-Defendants.	Case No. 09-cv-1495 (RMU)

TEVA INTERVENOR-DEFENDANTS'
CROSS-MOTION FOR SUMMARY JUDGMENT

Intervenor-Defendants Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc., Pharmachemie B.V., Barr Laboratories, Inc. and Pliva-Lachema a.s. (collectively, "Teva") hereby move under Federal Rule of Civil Procedure 56 and Local Civil Rule 7 for summary judgment in their favor and in favor of defendants.

As set forth in more detail in the accompanying memorandum of points and authorities in support of this motion, the question of the validity of the Food and Drug Administration's ("FDA") final approval of Teva's generic drug application presents a pure question of law. Upon the entry of judgment that U.S. Patent No. 5,338,874 was not infringed, FDA was authorized — indeed, obligated — by the Hatch-Waxman Act to issue final approval of Teva's

generic drug application. *See* 21 U.S.C § 355(C)(3)(i)(I). As a matter of law, the stay or vacatur of such judgment has no effect on that authority.

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

September 28, 2009

Respectfully submitted,

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OPPOSITION TO STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF TEVA INTERVENOR-DEFENDANTS' CROSS MOTION FOR SUMMARY JUDGMENT

Pursuant to Local Civil Rule 7(h), Intervenor-Defendants Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc., Pharmachemie B.V., Barr Laboratories, Inc., and Pliva-Lachema a.s. (collectively, "Teva") hereby submit this opposition to statement of undisputed material facts in support of plaintiffs' motion for summary judgment:

Plaintiffs' Statement No. 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.

Teva's Response: Undisputed.

Plaintiffs' Statement No. 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.

Teva's Response: Undisputed.

Plaintiffs' Statement No. 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).)

Teva's Response: Undisputed, as to Teva.

Plaintiffs' Statement No. 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.*)

Teva's Response: Undisputed.

Plaintiffs' Statement No. 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).)

Teva's Response: Undisputed. This ruling resolved all of Sanofi's claims against Teva.

Plaintiffs' Statement No. 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).)

Teva's Response: Undisputed. In these motions, Sanofi did not seek an injunction against Teva launching its oxaliplatin solution product pending appeal. Sanofi's mandamus petition is attached as Ex. 1.

Plaintiffs' Statement No. 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).)

Teva's Response: Undisputed.

Plaintiffs' Statement No. 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).)

Teva's Response: Undisputed.

Plaintiffs' Statement No. 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.)

Teva's Response: Undisputed, as to Teva.

Plaintiffs' Statement No. 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.

Teva's Response: Undisputed, as to Teva. Teva's launch occurred after the Federal Circuit both denied Teva's motion to clarify the Federal Circuit's July 10, 2009 stay of judgment (Ex. 2, July 24, 2009 Federal Circuit Order) and denied Sanofi's emergency motion to enforce the July 10, 2009 stay of judgment (Ex. 3, August 11, 2009 Federal Circuit Order).

Plaintiffs' Statement No. 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).)

Teva's Response: Undisputed.

Plaintiffs' Statement No. 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.)

Teva's Response: Undisputed.

Pursuant to Local Civil Rule 7(h), Intervenor-Defendants Teva hereby submit this statement of undisputed material facts in support of Teva Intervenor-Defendants' cross-motion for summary judgment:

Teva's Statement No. 13: In March of 2000, FDA released a "Guidance for Industry: Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Acts" (Ex. 4, FDA Guidance, *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatorylnformation/Guidances/ucm072868.pdf).

Teva's Statement No. 14: On October 30, 2007, Teva answered Sanofi's complaint in the District of New Jersey, denying infringement and pleading affirmative defenses challenging the validity of the '874 patent on several grounds (Ex. 5, October 30, 2007 Teva D.N.J. Answer at ¶¶ 17-26, affirmative defenses at ¶¶ 1-2). Other defendants raised additional defenses, including the defense of inequitable conduct.

Teva's Statement No. 15: In 2008, Sanofi's Eloxatin generated approximately $1.4 billion dollars in annual sales, or approximately $3.8 million dollars per day (Ex. 6, February 11, 2009 Press Release distributed by Sanofi-Aventis at 4) (*see also* Sanofi Ex. E at ¶ 11).

Teva's Statement No. 16: On July 10, 2009, the Federal Circuit denied Sanofi's petition for mandamus (Ex. 7, July 10, 2009 Federal Circuit Mandamus Order).

Teva's Statement No. 17: An August 7, 2009 internal memorandum by Martin Shimer, Branch Chief, Regulatory Support Branch FDA/Office of Generic Drug, entitled "Approval of ANDAs After Entry of Judgment by District Court and Stay of Judgment by Federal Circuit" (Ex. 8, August 7, 2009 FDA Memorandum) sets forth the FDA's rationale for approving Teva's generic drug application.

Teva's Statement No. 18: On August 11, 2009, the Federal Circuit denied Sanofi's motion to enforce the July 10, 2009 stay of judgment (*Supra*, Ex. 3), and, two days later, denied Sanofi's motion for reconsideration (Ex. 9, August 13, 2009 Federal Circuit Order).

Teva's Statement No. 19: On August 18, 2009, the D.C. Circuit denied Sanofi's motion for an injunction (Ex. 10, August 18, 2009 D.C. Circuit Order) and, two days later, denied *en banc* reconsideration (Ex. 11, August 20, 2009 D.C. Circuit Order).

Teva's Statement No. 23: On September 23, 2009, Sanofi filed a motion for preliminary injunction in the District Court of New Jersey (Ex. 12, September 23, 2009 Sanofi Notice of Motion for Preliminary Injunction at 1-2).

Teva's Statement No. 24: The '874 patent is the only patent presently asserted by Sanofi against Teva in connection with *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 07-cv-2762 (JAP).

September 28, 2009

Respectfully submitted,

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MEMORANDUM OF POINTS AND AUTHORITIES OF TEVA INTERVENOR-DEFENDANTS IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT

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September 28, 2009

Table of Contents

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

Intervenor-Defendants Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc., Pharmachemie B.V., Barr Laboratories, Inc., and Pliva-Lachema a.s. (collectively, "Teva") submit this memorandum in opposition to the motion of plaintiffs Sanofi-Aventis, Sanofi-Aventis U.S. LLC, and Debiopharm S.A. (collectively "Sanofi") for summary judgment and in support of Teva's cross-motion for summary judgment.

INTRODUCTION

Sanofi challenges the approval by the Food and Drug Administration ("FDA") of Teva's application to market a generic version of Sanofi's oxaliplatin-based chemotherapy drug, Eloxatin®. Sanofi does not dispute that Teva's application satisfied the substantive requirements for generic drug approval imposed by the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act (the "Hatch-Waxman Act"). Teva's drug is as safe and effective as Sanofi's own product, and less expensive for cancer patients and their insurers.

Rather, Sanofi challenges the *timing* of FDA approval. But Sanofi admits the facts that fatally undermine its challenge as a matter of law. Sanofi (i) acknowledges that the pertinent statute, 21 U.S.C. § 355(c)(3)(C)(i)(I), requires FDA approval on "the date on which the court enters judgment" reflecting the district court's decision that the pertinent patent is not infringed, Sanofi Br. at 2; (ii) admits that such a judgment was entered on June 30, 2009, Statement of Undisputed Material Facts in Support of Plaintiffs' Motion for Summary Judgment ¶ 5; and (iii) admits that FDA approved Teva's application after the entry of that judgment, *id*. ¶ 9. Under the plain language of the statute, therefore, FDA approval was proper, as this Court concluded in denying Sanofi's motion for a preliminary injunction. August 18, 2009 Memorandum Opinion Denying the Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction at 6-7.

Sanofi argues that the decision of the Federal Circuit to stay the June 30 judgment before FDA approved Teva's application somehow suspended FDA's power to approve, and that the Federal Circuit's decision on September 10, 2009 to vacate that judgment and remand the patent case to the district court for further proceedings "confirms" FDA's error. Nothing in the Hatch-Waxman Act, however, makes FDA's power and obligation to approve generic drug applications turn on the fate on appeal of the judgment whose entry triggers approval.[1] Unless and until Sanofi ultimately prevails on its patent infringement claim against Teva, FDA's approval of Teva's generic product remains final.

The Court should accept this interpretation of the Hatch-Waxman Act not only because it is the only plausible way to read the statute's plain language, but also because it reflects the consistent and long-held view of FDA, the agency charged with interpreting and applying the Hatch-Waxman Act. As the D.C. Circuit has frequently recognized, under *Chevron* principles if FDA's interpretation of the Act is permissible — as it plainly is here — it must be followed.[2] FDA's careful consideration and rejection of the very argument that Sanofi advances in its motion in connection with its decision to grant Teva final approval warrants this Court's deference under *Chevron.*

Sanofi's counterargument misses the point entirely. Sanofi says that FDA's approval after the stay of the patent judgment is inconsistent with the customary power of circuit courts to stay judgments recognized in *Nken v. Holder*, 129 S. Ct. 1749 (2009). But *Nken* has no bearing on this case because FDA's authority to approve generic drug applications does not derive from

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[1] The only litigation event that can "undo" FDA approval is the entry of judgment *in favor of the patentee*. As part of such a judgment, the district court is authorized to reset the date for FDA approval to coincide with patent expiration and to enjoin any sale of the generic drug product in the interim. 35 U.S.C. § 271(e)(4). No such judgment for Sanofi has entered.

[2] *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984).

the judgment whose entry triggers FDA approval. Rather, that authority derives from the Hatch-Waxman Act itself. Since FDA is not enforcing the judgment when it approves the generic drug application, a stay or vacatur of that judgment does not affect FDA's approval authority unless it is accompanied by final judgment for the patentee. The Supreme Court in *Nken* did not consider whether Congress could identify the entry of a judgment as a discrete event affecting the timing of collateral action by an administrative agency.

Sanofi also invokes the specter of altering the "delicate balance" struck by Congress when it enacted the Hatch-Waxman Act. But it is Sanofi's approach that would upset the statutory balance. Congress sought to encourage patentees such as Sanofi to initiate lawsuits to resolve patent disputes with generic drug companies. The incentive was an automatic stay of FDA approval of generic drugs for up to thirty months — the functional equivalent of a preliminary injunction, but one granted without the need to prove likelihood of success or irreparable harm and without any obligation to post a bond. This statutory stay is available even if the patent-in-suit is plainly invalid or not infringed. The resulting delay in generic competition is enormously valuable to companies selling products such as Eloxatin® that generate millions of dollars in sales *each day.*

Congress tempered this extraordinary benefit by providing that if a generic drug company persuades the district court hearing the patent case that the patent-in-suit is invalid or not infringed, the automatic stay of FDA approval would automatically dissolve upon the entry of judgment for the defendant. Patentees in such cases can still forestall generic competition, but only by establishing the predicate for a preliminary injunction, *i.e.* likelihood of success on the merits and a favorable balance of equities. This course remains available to Sanofi, and Sanofi

has requested a preliminary injunction from the district court in New Jersey where the patent litigation remains pending.

This case is about Sanofi's attempt to obtain the benefits of a preliminary injunction without shouldering the corresponding burden of proving likelihood of ultimate success. That result would truly upset the balance struck by Congress by extending the statutory stay of FDA approval well past the time specified by Congress for its automatic dissolution, and would do so principally in circumstances where the patentee cannot establish that it is likely to succeed on the merits of its infringement case. It would simply provide a windfall for owners of weak or narrow patents at the expense of the public.

The question of the validity of the FDA's final approval of Teva's generic drug application is a pure question of law. This Court's analysis of that legal issue in denying Sanofi's preliminary injunction motion was entirely correct, and Sanofi has offered no reason to reconsider it. Sanofi's summary judgment motion should be denied and Teva's cross-motion granted.

BACKGROUND

I. The regulatory framework

To accelerate the availability of less expensive generic drugs, Congress created in the Hatch-Waxman Act a streamlined process for FDA approval. The Act relieves the generic company of the need to replicate the clinical studies performed by the brand company, and authorizes FDA to rely on the safety and efficacy determinations that it made in approving the new drug application of the brand company. *See generally Mova Pharm. Corp. v. Shalala,* 140 F.3d 1060, 1063-65 (D.C. Cir. 1998).

The Hatch-Waxman Act's goal of getting generic drugs to market "as quickly as possible"[3] depends on the prompt resolution of disputes concerning the patents that are said to protect brand pharmaceutical products. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 677 (1990). To that end, the Act requires brand companies to list (in a government publication referred to as the "Orange Book") all patents covering approved drugs or methods of using them. 21 U.S.C. § 355(b)(1). A company seeking approval of a generic version of the drug must certify with respect to each Orange Book listed patent whether the company contends that the patent is invalid or not infringed by the proposed generic formulation. 21 U.S.C. §§ 355(b)(2)(A), 355(j)(2)(A)(vii).[4] A certification that the patent is invalid or not infringed constitutes an act of infringement that permits the patentee to bring an infringement action. 35 U.S.C. § 271(e)(2).

Congress recognized that simply creating this cause of action would not by itself force patentees to bring lawsuits if they deemed the maintenance of patent uncertainty advantageous. It therefore created an incentive for patentees to bring infringement actions promptly. If the patentee brings an infringement action under 35 U.S.C. § 271(e) within 45 days of receiving the generic company's certification that the patent is invalid or not infringed, FDA is directed to approve the generic application "upon the expiration of the thirty-month period" commencing with the receipt of the certification. 21 U.S.C. § 355(c)(3)(C). However, if in the meantime the district court decides that the patent is invalid or not infringed, FDA is directed to approve the

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[3] *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) (citing 149 Cong. Rec. S155885 (Nov. 25, 2003)).

[4] The Hatch-Waxman Act specifies two pathways for approval of generic drugs: abbreviated new drug applications ("ANDAs") under § 355(j), and so-called "paper NDAs" under § 355(b)(2). *See Eli Lilly*, 496 U.S. at 676. Teva filed a paper NDA and will cite the provisions applicable to such applications in this brief, but the statutory provisions governing the timing of ANDAs under 21 U.S.C. § 355(j) are essentially identical.

generic application on "the date on which the court enters judgment reflecting the decision." *Id.* § 355(c)(3)(C)(i)(I). As the Supreme Court observed in *Eli Lilly*, "[i]f the [patent] owner brings … a suit [within 45 days], then [FDA] approval may not be made effective until the court rules that the patent is not infringed or until the expiration of (in general) 30 months, whichever first occurs." 496 U.S. at 677.

This is a very lucrative incentive. Ordinarily in patent infringement litigation a patentee can prevent competition by the allegedly infringing product before final judgment only by satisfying the familiar four-factor test for a preliminary injunction: likelihood of success on the merits, irreparable harm, a favorable balance of hardship, and a favorable impact on the public interest. *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1005 (Fed. Cir. 2009). To establish likelihood of success, the patentee must show not only that the accused device likely infringes its patent, but also that the invalidity and other defenses raised by the defendant "lack substantial merit." *Id.* at 1006. Moreover, the patentee will generally be required to post a bond to compensate the defendant for any economic harm suffered from the injunction if the defendant ultimately prevails.

In Hatch-Waxman Act cases, however, the patentee obtains the functional equivalent of a preliminary injunction *automatically*, without having to establish likelihood of success or irreparable harm and without the need to post a bond. Even if the patentee's case is exceedingly weak and an award of damages for patent infringement constitutes a perfectly adequate remedy at law, the patentee can prevent generic competition for up to two and a half years. Where, as here, the brand company's drug generates billions of dollars in annual sales, delaying generic competition even for a single day will translate into millions of dollars of additional revenues. Staving off generic competition for up to two and a half years is a very powerful incentive.

As noted above, however, Congress directed that this statutory delay of FDA approval terminates upon the entry of a final judgment by the district court in favor of the generic drug company. No provision of the Hatch-Waxman Act directs the suspension or rescission of FDA approval if the judgment whose entry triggered the approval is stayed or vacated. The only provision of the Act that contemplates any "resetting" of the approval date is 35 U.S.C. § 271(e)(4)(A), which directs the district court to set the date of approval no earlier than the expiration of the patent upon the final determination that the patent is valid and infringed in this litigation.[5]

It has long been FDA's view that the subsequent stay or vacatur of a judgment triggering final approval by itself has no effect on that approval. In 2000, FDA published a "Guidance for Industry,"[6] in which it stated:

> Neither a stay nor reversal of a district court decision finding the patent invalid, unenforceable, or not infringed will have an effect on the approval of the [generic application].... Should the NDA holder or patent owner wish to prevent an applicant with an approved [generic application] from marketing its product during the course of an appeal, it must obtain an injunction from the court.

Ex. 4 at 4. FDA adhered to that Guidance in this case.[7]

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[5] If that occurs, the FDA converts the earlier final approval to a tentative approval. *See Mylan Labs, Inc. v. Thompson*, 389 F.3d 1272, 1281-82 (D.C. Cir. 2004).

[6] Ex. 4, Guidance for Industry: Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (2000) ("FDA Guidance"), *available at*: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatorylnformation/Guidances/ucm072868.pdf

[7] FDA's reasoning is set forth in an internal memorandum dated August 7, 2009 and submitted to this Court by FDA's counsel at the preliminary injunction hearing. A copy of that memorandum is attached. (Ex. 8, "FDA Memorandum")

II. Procedural history

A. New Jersey patent litigation

When Teva filed its generic application and certified that Sanofi's patent[8] was invalid and/or not infringed, Sanofi sued for infringement in the federal district court in New Jersey. Sanofi asserted the '874 patent (and others) against Teva and other generic companies, and these cases were consolidated before Judge Pisano. The defendants all denied infringement and pleaded a number of affirmative defenses that challenged the validity of the '874 patent on several grounds. Some defendants further asserted that Sanofi's inequitable conduct rendered the '874 patent unenforceable.

On June 18, 2009, the district court ruled that none of the defendants infringed the '874 patent. That ruling resolved none of the affirmative defenses. Sanofi initially requested that the district judge enter judgment under Fed. R. Civ. P. 54(b) so that it could take an immediate appeal. Sanofi quickly changed course, however, when it realized that the entry of that order would trigger FDA's obligation to approve Teva's generic application. It therefore filed a premature notice of appeal from the interlocutory summary judgment ruling and argued that that appeal deprived the district court of jurisdiction to enter final judgment. The district court rejected this ploy and entered final judgment of non-infringement under Rule 54(b) on June 30.

B. Federal Circuit litigation

Sanofi appealed to the Federal Circuit and petitioned for a writ of mandamus directing the district court to vacate the judgment, or, alternatively, for a stay of the district court judgment pending appeal. Sanofi did not seek an injunction against Teva's launching its product pending

[8] U.S. Patent No. 5,338,874 (the "'874 patent"). The '874 patent is the only remaining patent asserted against Teva and the Mayne intervenors. Sanofi asserted additional Orange Book patents against the other defendants.

appeal. In its mandamus petition, Sanofi told the Federal Circuit that it sought mandamus because in "these Hatch-Waxman cases, entry of judgment of non-infringement triggers final FDA approval" and therefore "a stay of such a judgment may not result in maintaining the status quo." Ex. 1 at 1, 3 n.2. A panel of the court (Rader, Clevenger, and Mayer, JJ.) unanimously denied the mandamus petition, but granted the stay without opinion, with Judge Mayer dissenting.

On August 7, FDA approved Teva's generic application. On August 10, Sanofi moved the Federal Circuit to enforce the July 10, 2009 stay of judgment. A single judge of the Federal Circuit denied the motion the next day, ruling that Sanofi had not addressed the legal requirements of an injunction. Sanofi's motion for reconsideration was denied two days later by a three-judge panel of the Court (Linn, Prost and Moore, JJ.).

The Federal Circuit's July 10 stay order also expedited the briefing of the appeal. The Court heard argument on September 2, 2009, and, on September 10, released a non-precedential opinion holding that the district court's non-infringement ruling was based on a misreading of the '874 patent. The court remanded the case for further proceedings. The court's mandate has not yet issued from the Federal Circuit.

The panel's decision did not resolve what the proper construction of the '874 patent is. Accordingly, on remand, the district court must (i) determine whether the patent's claims are susceptible to a proper construction and, if so, what the correct construction is, (ii) decide whether the defendants infringe under that new claim construction, and (iii) consider whether the patent is valid and enforceable under that claim construction. The patent case is far from over, and Sanofi has yet to undertake to demonstrate that its ultimate success on the merits is likely.

C. Proceedings in this Court and the D.C. Circuit

On August 10, Sanofi also sued FDA in this Court, challenging the decision to grant final approval to the generic application of the Teva and Mayne intervenors under the Administrative Procedure Act ("APA"). Sanofi requested an injunction directing the rescission of those approvals and prohibiting any further approvals until the expiration of the 30-month stay.

Sanofi sought a temporary restraining order and preliminary injunction. This Court denied both on August 10, and issued its opinion on August 18. Teva launched its oxaliplatin product on August 11 after the Federal Circuit also denied Sanofi's motion to enforce the stay.

Sanofi appealed this Court's denial of the preliminary injunction and moved the D.C. Circuit for an injunction pending appeal and for expedited briefing on the appeal. On August 13, the D.C. Circuit issued an administrative injunction that suspended the final approvals and ordered very expedited briefing on Sanofi's motion for injunction pending appeal. On August 18, the D.C. Circuit denied Sanofi's motion for an injunction and its request for expedition. The full D.C. Circuit denied Sanofi's motion for *en banc* reconsideration two days later.

ARGUMENT

I. Under the plain language of the Hatch-Waxman Act, as consistently interpreted by FDA, neither the stay nor the vacatur of the judgment that triggered FDA approval affects the propriety of that approval.

Because Sanofi's suit against FDA arises under the APA, Sanofi must show that FDA's approval was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the [law]." 5 U.S.C. § 706(2)(A). This is a highly deferential standard, especially so here because the agency's challenged decision rests on its interpretation of the Hatch-Waxman Act, a statutory scheme that FDA is charged with administering. *Novartis Pharms. Corp. v. Leavitt*, 435 F.3d 344, 349 (D.C. Cir. 2006). Hence, review here is governed by *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984), which requires the Court first to inquire

"whether Congress has directly spoken to the precise question at issue" (*id*. at 842), *i.e.* "whether the statute unambiguously forbids the Agency's interpretation." *Barnhart v. Walton*, 535 U.S. 212, 218 (2002).

A. The plain language of the Act required FDA's approval.

Far from being prohibited, FDA's interpretation of the Hatch-Waxman Act is compelled by the statute's plain language:

> (i) *if* before the expiration of [a thirty-month stay] *the district court decides that the patent is invalid or not infringed* (including any substantive determination that there is no cause of action for patent infringement or invalidity), *the approval shall be made effective on—*
>
> (I) the date on which the court enters judgment reflecting the decision.

21 U.S.C. § 355(c)(3)(C)(i) (emphasis added).[9]

There is no dispute that FDA granted final approval only after the entry of a final judgment of non-infringement. Under the plain language of the Act, FDA approval was proper. Indeed, FDA had no choice but to grant approval since the Act commands that final approval "*shall* be made effective on … the date on which the court enters judgment." *Id.* (emphasis added). The Supreme Court has stressed that "the word 'shall' is ordinarily the language of command" and "militates against an implicit exception." *Alabama v. Bozeman*, 533 U.S. 146, 153 (2001).

Sanofi points to no statutory language that directs or even permits FDA to forbear from granting final approval if the patentee either manages to get a stay of the judgment before final approval issues or persuades the Federal Circuit to vacate the judgment. No such language

[9] Section 355(j)(5)(B)(iii)(I)(aa) creates the same rule for ANDAs.

exists. Its absence is particularly significant because Congress knew how to make consequences for generic drug approval turn on the fate of district court judgments on appeal. *See* 21 U.S.C. §§ 355(c)(3)(C)(ii) (after district court finding of infringement, approval shall be effective when court of appeals decides the patent is invalid or not infringed); 355(j)(5)(D)(i)(I)(bb)(AA) (statutory exclusivity forfeited if generic company fails to market within certain period after final decision "from which no appeal … can be taken" that the patent is invalid or not infringed). "Where Congress includes particular language in one section of a statute but omits it in another section of the same Act … Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983).

The Act also enumerates several cases in which FDA may rescind (*i.e.*, withdraw) a final approval. *See, e.g.*, 21 U.S.C. § 335c(a) (withdrawal for fraud); 21 U.S.C. § 355(e) (withdrawal upon finding imminent hazard to public health); 21 U.S.C. § 355(j)(6) (withdrawal of the reference listed drug's approval). However, the Act makes no provision for rescission in these circumstances.

Accordingly, applying the plain and unambiguous language of the Hatch-Waxman Act, FDA approval was both proper and unaffected by the Federal Circuit's stay and vacatur of the judgment in the patent litigation.

B. Even if the statutory text were ambiguous, the FDA's consistent interpretation of the language is entitled to deference.

Sanofi argues that Congress could not have intended to abrogate the traditional powers of federal appellate courts to stay district court judgments, and that this Court should construe the absence of express authorization in the Hatch-Waxman Act to grant approval in the face of a stay as requiring FDA to forbear from granting final approval if the brand company gets the Federal Circuit to grant a stay before FDA acts. As explained in the next section of this memorandum,

Sanofi's argument fails because using the entry of judgment as a trigger for FDA approval does not abrogate the power of an appellate court to stay a judgment. However, even if its argument sufficed to create an ambiguity in the meaning of the Act, FDA has construed the Hatch-Waxman Act to make the entry of judgment a trigger and that construction is entitled to deference.

Chevron cautions that courts should not "impose [their] own construction on the statute," but instead must determine if the agency's interpretation is "permissible." *Chevron*, 467 U.S. at 843. In other words, if there is ambiguity in the Act, and the Agency reasonably resolves that ambiguity, this Court must defer to FDA's permissible interpretation of that statute.

In *Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006), for example, the Court deferred to FDA's reasoned interpretation of a question similar to the one presented here but under an earlier version of the statute, *i.e.*, what constitutes "the date of the court decision." Without reaching the question of irreparable harm, this Court affirmed a district court's refusal to grant a preliminary injunction because there was "little likelihood" that the appellant could show that FDA's interpretation of "court decision," reflected in a lengthy reasoned written decision, was unreasonable. *Id.* at 1251, 1253-54.

FDA's approval in this case hews to the position it announced nearly a decade ago in its 2000 Guidance for Industry. FDA issued that Guidance due to the "considerable uncertainty" engendered by the old version of the law, which did not specify *which* court's decision mattered, stating only that the 30-month stay dissolved when "the court" rules in favor of the generic company on "the date of the court decision." 21 U.S.C. § 355(j)(4)(B)(iii)(I) (1988) (emphasis added). FDA initially read this to require a decision from a "court that enters final judgment from which no appeal can be or has been taken." 21 C.F.R. § 314.107(e)(1)(1999). But courts

rejected this reading and directed approval of ANDAs immediately upon *district court* rulings. *E.g.*, *TorPharm, Inc. v. Shalala*, No. 97-1925, 1997 WL 33472411, at *3-4 (D.D.C. Sep. 15, 1997). FDA's subsequent guidance reflected those decisions and noted the statute had engendered "considerable uncertainty" under which "ANDA applicants have held products off the market even after a victory in the district court." Ex. 4 at 3-4.

To provide certainty for businesses and courts — a rationale this Court declared "perfectly reasonable" in *Apotex* — FDA addressed the precise question at issue in this case:

> Neither a stay nor reversal of a district court decision finding the patent invalid, unenforceable, or not infringed will have an effect on the approval of the [generic application]…. Should the NDA holder or *patent* owner wish to prevent an applicant with an approved [generic application] from marketing its product during the course of an appeal, it must obtain an injunction from the court.

Ex. 4 at 4. This interpretation, too, is perfectly reasonable. *Apotex*, 449 F.3d at 1252. The date the district court enters a final judgment provides a specific trigger that can be identified with relative ease, and by definition, that date does not change based on events that transpire in the appellate court.

Congress amended the statute three years later specifically to provide for approval when the district court "enters judgment." Congress may be deemed to have been aware of FDA's interpretation, and indeed to have confirmed it. *See Isaacs v. Bowen*, 865 F.2d 468, 472-73 (2d Cir. 1989). As FDA noted in its memorandum regarding the applications involved in this case, Congress revised "the somewhat ambiguous 'date of the court decision'" language "to the very specific 'date on which the court enters judgment reflecting the decision.'" FDA Memorandum at 4. And "while the 'decision' described in the [earlier version] could be reflected in a number of actions (*e.g.*, issuing an opinion, issuing an order, entering these documents in the docket, entry of judgment), the 'entry of judgment' phrase refers to a specific recognized act described in

the Federal Rules of Civil Procedure (Fed. R. Civ. P. 58) and not likely to vary among courts." *Id*.

Finally, FDA spent more than a month in this case considering whether the Federal Circuit's stay of the judgment pending appeal warranted forbearance from releasing final approval. At the end of that period FDA acknowledged that the Hatch-Waxman Act "is silent regarding the effect of a stay or appeal of the district court's judgment on the timing of approval of an ANDA." FDA Memorandum at 4. The agency considered the effect of the 2003 amendments to the Hatch-Waxman Act, and concluded that the policy judgments reflected in the 2000 FDA Guidance continued to apply. FDA's reasoning in this regard is unimpeachable and Sanofi does not even discuss it.[10]

Finally, Sanofi's contrary rule makes little sense as a matter of policy. Under Sanofi's view, FDA would be fully entitled to approve *before* an appellate stay, but not *after*. The timing of the entry of an appellate stay is itself arbitrary and unpredictable, and can range anywhere from hours to weeks after the entry of judgment by the district court. As a result, FDA approval would turn *not* on the merits of the ANDA or the policies underlying the Hatch-Waxman Act,

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[10] Sanofi observes in a footnote that FDA's lawyer did not rely on *Chevron* and suggests, based on *Peter Pan Bus Lines, Inc. v. FMCSA*, 471 F.3d 1350 (D.C. Cir. 2006), that no deference to the FDA is warranted. Sanofi Br. at 11 n.10. But *Peter Pan* does not help Sanofi. In that case, the D.C. Circuit recognized that *Chevron* deference is warranted where the agency does not "simply … pars[e] … the statutory language" but rather "bring[s] its experience and expertise to bear in light of the competing interests at stake." *Id.* at 1354 (quoting *PDK Labs., Inc. v. U.S. DEA*, 362 F.3d 786, 797-98 (D.C. Cir. 2004)). Even a casual reading of the FDA Memorandum makes it clear that FDA did not simply rely on the language of the Act. It reevaluated the policies that justified the 2000 guidance, weighed the competing interests (such as the effect of approval on the exclusivity of first filing generic companies and the desirability of having a clear and uniform date for final approval), analyzed the structure of the Act as amended, and considered the availability of alternative remedies for patentees under the patent laws. This is plainly a situation in which "*Chevron* step two" deference is warranted.

but rather on an unseemly race between FDA and the Federal Circuit. There is no sense in that, and no reason to think that that is what Congress had in mind.

In short, FDA's construction of the Act's command to approve on "the date on which the court enters judgment" is firmly grounded in the Act's language, its legislative history and legitimate policy considerations. This construction is manifestly "permissible" and should be accepted by the Court for that reason.

C. The *Nken* decision has no bearing here.

Sanofi contends that FDA final approval before the expiration of the statutory 30-month stay somehow interferes with the power of federal appellate courts to stay district court judgments. But this Court correctly recognized the flaw in this argument. The power of an appellate court to stay a judgment is the power to prevent the judgment from being *enforced*. Thus, in *Nken*, an alien challenged his deportation order on appeal and requested a stay of that order. The Supreme Court ruled that the limitations that Congress had imposed on the issuance of injunctions had no bearing on the standards governing the stay of a deportation order. And with the order stayed, the INS had no authority to enforce that order to deport the alien.

The Supreme Court underscored the meaning of the term "stay." An injunction is "directed at someone, and governs that party's conduct." 129 S. Ct. at 1757. By contrast, a stay "operates upon the judicial proceeding itself. It does so either by halting or postponing some portion of the proceeding, or by temporarily divesting an order of *enforceability.*" *Id.* at 1758 (emphasis added). The Federal Circuit's stay of the New Jersey court's judgment now has and always had the effect of preventing the enforcement of that judgment, and if the mandate issues on the September 10 Federal Circuit panel decision, that judgment likely never will be enforced.

By contrast, FDA's final approval of Teva's generic drug application does not "enforce" Judge Pisano's judgment of non-infringement. FDA's power to approve generic drug

applications does not derive from that judgment; rather, its power — indeed, its *duty* — derives from Congress' unambiguous direction set forth in the Hatch-Waxman Act.[11]

Sanofi cites Judge Moore's disagreement with this conclusion in her concurrence in the Federal Circuit's denial of Sanofi's motion for reconsideration. Sanofi Br. at 2, 3. Neither of the other two judges on the panel joined her opinion. Moreover, her statements are *obiter dicta* since they had no bearing on her ultimate conclusion that, since Sanofi failed to address the standard for a preliminary injunction against Teva, its motion to "enforce" the stay had to be denied.

In addition, Judge Moore's suggestion that FDA's position was "contrary to *Nken*," is simply wrong. *Nken* did not indicate that the stay of a judgment "voids any legal effect" of the judgment, as Judge Moore states. The Supreme Court said that the stay of a judgment prevents its *enforcement*. Judge Moore never explains how FDA's approval of Teva's generic drug application "enforced" the judgment of non-infringement. Indeed, her acknowledgment that the Federal Circuit lacked power to direct FDA to refrain from granting that approval recognizes that the FDA approval process is entirely collateral to the patent litigation and that FDA is *not* in any sense enforcing the judgment stayed by the Federal Circuit.

The Federal Circuit's decision to vacate the judgment of non-infringement after FDA's final approval adds nothing to Sanofi's argument. The cases that Sanofi cites recognize that the

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[11] Sanofi states that "FDA and Intervenors have acknowledged [that] entry of the judgment is the source of FDA's authority to enforce or give effect to the judgment by granting final approval." Sanofi Br. at 13. Sanofi cites nothing in support of this assertion and it is false. FDA and Teva have consistently argued that the Hatch-Waxman Act is the source of FDA authority, *not* the judgment, and that the entry of judgment of non-infringement simply dissolves the statutory stay on the exercise of that authority.

Sanofi also states that the Federal Circuit's stay order "effectively 'un-entered' the judgment" by restoring the status quo. *Id.* But this *ipse dixit* is plainly wrong. The entry of a judgment is a discrete event. The judgment itself may be stayed or vacated, but neither action can alter the historical fact that a judgment was entered. The docket of the patent case in the District of New Jersey undoubtedly still reflects the entry of judgment.

vacation of a judgment eliminates the legal effect of the judgment *qua* judgment[12], but, as noted above, FDA approval of a generic drug application does not constitute an enforcement of the judgment. It is entirely collateral to the litigation in which the judgment was entered. The Hatch-Waxman Act simply identifies the district court's entry of judgment of invalidity or non-infringement as a discrete event with a specific consequence, i.e. the dissolution of the statutory 30-month stay of FDA approval. Once the stay is dissolved, FDA is directed to issue final approval.[13] Thereafter, the patentee can prevent generic competition only by obtaining a preliminary injunction or prevailing in its infringement suit.

It is also important to consider what consequences would flow from Sanofi's theory that the validity of a final approval depends on the ongoing *enforceability* of the judgment the entry of which triggers approval. In the typical case, FDA will issue final approval shortly after the generic company obtains a favorable decision or the 30-month stay expires. The brand company will seek a preliminary injunction. If the preliminary injunction is denied and the generic company launches, as FDA's final approval will permit it to do, it will ship products to

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[12] *Friends of the Everglades v. S. Fla. Water Mgt. Dist.*, 570 F.3d 1210, 1218 (11th Cir. 2009) (vacated decision lacks precedential value, though court is "free to give statements in a vacated opinion persuasive value if we think they deserve it"). *See also Alabama Power Co. v. EPA*, 40 F.3d 450, 456 (D.C. Cir. 1994) (vacation of rule suspends obligation to comply with rule).

[13] Sanofi tries to make something of the fact that the FDA does not always issue final approval *immediately* upon the entry of judgment. Sanofi Br. at 14. But that is not surprising. The substantive standards for approval set forth in the Hatch-Waxman Act must also be satisfied before final approval, and, if there is any question concerning those standards, final approval will be delayed even if the statutory stay of approval has dissolved. In this case, FDA delayed final approval for several weeks as it considered the legal issues raised by the stay and issued final approval only after it had satisfied itself that that was the correct result. While Teva would have preferred earlier action, Sanofi was the beneficiary of the delay and has no standing to complain about it. The delay certainly does not prove that the Federal Circuit stay of the judgment of non-infringement had any bearing on FDA's power to approve.

distributors, pharmacy chains and hospitals that will, in turn, resell or dispense the drug. Meanwhile, the brand company will have appealed either the final adverse judgment or the denial of its motion for a preliminary injunction. If Sanofi's view prevails, every brand company will request a stay of the judgment and will argue on the merits for its reversal or vacatur. If it succeeds in any of these efforts *and success requires the suspension of FDA final approval as Sanofi argues,* then not only will the generic company be precluded from selling additional products, but also the myriad distributors, pharmacies, physicians and even patients who have purchased the generic products will be thrown into confusion, wondering whether the law permits them to sell or use a product that no longer enjoys a final FDA approval, even though the suspension of final approval has nothing to do with safety or efficacy concerns. Such confusion can be multiplied if the status of the judgment changes multiple times, as it can be with the opportunities for panel and *en banc* reconsideration on appeal applicable both to orders on interim remedies and the ultimate decision on the merits, and the potential for further changes in circumstances on remand. No good can come from such confusion.

That is why FDA's interpretation of the Hatch-Waxman Act makes practical as well as legal sense. It permits generic drugs legally introduced into the stream of commerce to remain available for use in the treatment of patients without being affected by the vicissitudes of trial and appellate litigation. If the brand company ultimately prevails in the patent litigation, it can recover damages for infringement. If the generic company ultimately prevails, the public can escape the "tax" of unwarranted monopoly profits that much sooner. That is certainly consistent with the purposes of the Hatch-Waxman Act.

II. Sanofi's motion should be denied because it has not addressed any of the requirements for injunctive relief other than success on the merits.

The law is clear that a claim for a permanent injunction requires more than just the establishment of a party's legal theory. The equitable requirements of irreparable harm, a favorable balance of equities and a favorable impact on the public interest must be satisfied before any injunction can issue. *Winter v. Natural Res. Def. Council, Inc.*, 129 S. Ct. 365, 374 (2008). Sanofi has made no attempt whatever to address these additional requirements, much less show that there is no genuine factual dispute as to their application or that on the undisputed facts the requirements are satisfied. Accordingly, the Court should deny Sanofi's motion for summary judgment on its claim for injunctive relief.

CONCLUSION

The Court should deny Sanofi's motion for summary judgment and grant Teva's motion for summary judgment.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, William F. Sheehan, hereby certify that the foregoing documents filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and below, and paper copies will be sent to those indicated as non-registered participants on September 28, 2009.

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