UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SANOFI-AVENTIS *et al.*,	:		
	:		
Plaintiffs,	:	Civil Action No.:	09-1495 (RMU)
	:		
v.	:	Re Document No.:	26, 32, 34
	:		
FOOD AND DRUG ADMINISTRATION *et al.*,	:		
	:		
Defendants.	:		

MEMORANDUM OPINION

DENYING THE PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT; GRANTING THE DEFENDANTS' AND THE INTERVENOR-DEFENDANTS' CROSS-MOTIONS FOR SUMMARY JUDGMENT

I. INTRODUCTION

This matter comes before the court on the plaintiffs' motion for summary judgment and the defendants' and the intervenor-defendants' cross-motions for summary judgment. Plaintiff Debiopharm S.A. ("Debiopharm") is a Swiss company that holds the patent for the anti-cancer drug oxaliplatin. Plaintiff Sanofi-Aventis is the pioneer manufacturer of the drug and plaintiff Sanofi-Aventis U.S. LLC (collectively "Sanofi-Aventis") holds the exclusive license for the drug in the United States. Sanofi-Aventis markets and sells oxaliplatin under the brand name Eloxatin®. The plaintiffs allege that the Food and Drug Administration ("FDA") violated the Administrative Procedures Act ("APA"), 5 U.S.C. §§ 701 *et seq.*, when it approved applications to manufacture generic oxaliplatin. They seek a court order requiring the FDA to rescind all generic oxaliplatin approvals and to refrain from granting any further approvals until the expiration of an automatic thirty-month stay mandated under the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355. For the reasons stated below, the court denies the plaintiffs' motion

for summary judgment and grants the defendants' and intervenor-defendants' cross-motions for summary judgment.

II. FACTUAL & PROCEDURAL BACKGROUND

A. Statutory Framework

The FDCA provides that before any new drug can be introduced into the U.S. market, the FDA must determine that it is safe and effective. 21 U.S.C. § 355(a). The first, or "pioneer," applicant for a given drug must submit to the FDA a new drug application ("NDA"), containing, among other things, "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 . . . a full list of the articles used as components of such drug . . . [and] a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drugs." *Id.* § 355(b). Once approved, the pioneer drug is referred to as a "listed" drug. *Id.*

Companies seeking to manufacture new prescription drugs must file new drug applications ("NDAs") with the FDA demonstrating their drugs' safety and effectiveness before they can market them. *Id.* § 355(b)(1). Recognizing that the NDA process is costly and time-consuming, Congress amended the FDCA in 1984 pursuant to the "Hatch-Waxman Amendments." *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1316 (D.C. Cir. 1998) (citing H.R. Rep. No. 98-857, pt. 1 at 14 (1984)). In an effort "to make available more low cost drugs," *id.*, the FDCA permits the manufacturer of a generic version of a listed drug to obtain FDA approval through a far simpler, abbreviated new drug application ("ANDA") containing a more limited set

of information than that required for an NDA.[1] 21 U.S.C. § 355(j). The relevant provisions of the approval process for NDAs and ANDAs are identical. *See id.* §§ 355(c)(3)(C), (j)(5)(B)(iii).

Among other things, the FDCA requires a drug manufacturer seeking approval to produce a generic version of a drug to certify that the patent for the corresponding brand-name version of the drug "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). The patent holder has forty-five days after receiving notification of the certification to bring a patent infringement action against the drug manufacturer that filed the certification. *Id.* §§ 355(c)(3)(C), (j)(5)(B)(iii). Once such an action is filed, the FDA must withhold approval of the application to produce a generic drug ("generic drug application") for a thirty-month period ("thirty-month stay"). *Id.* The thirty-month stay may be terminated, however, if "the district court [in which the patent infringement action is brought] decides that the patent is invalid or not infringed," *id.* §§ 355(c)(3)(C)(i), (j)(5)(B)(iii)(I). If the court renders such a ruling, provided other conditions for approval have been met, the FDA's approval becomes effective on "date on which the court enters judgment reflecting the decision," *id.* §§ 355(c)(3)(C)(i)(I), (j)(5)(B)(iii)(I)(aa) ("the entry of judgment provisions").

B. Factual & Procedural History

The plaintiffs in this action are the patent holder, manufacturer and licensee of the anti-cancer drug oxaliplatin, marketed under the brand name Eloxatin®, the name brand for oxaliplatin. Pls.' Statement of Facts ("Pls.' Statement") ¶ 4; Defs.' Statement of Facts ("Defs.'

[1] The provisions governing the approval process for NDAs and ANDAs, respectively, appear in two different sections of the FDCA but are stated in identical language. *See generally* 21 U.S.C. §§ 355(c)(3)(C), (j)(5). Because this case concerns the approval of NDAs and ANDAs, the court cites to both sets of provisions throughout this Memorandum Opinion.

Statement") ¶ 1. In June and July 2007, the plaintiffs commenced a patent infringement suit in the United States District Court for the District of New Jersey against a number of drug manufacturers who sought to produce generic oxaliplatin. Pls.' Statement ¶ 3; Defs.' Statement ¶ 2. On June 30, 2009, the New Jersey district court entered judgment, ruling that the plaintiffs' patent had not been infringed. Pls.' Statement ¶ 5; Defs.' Statement ¶ 4. The FDA subsequently approved the generic drug applications of several pharmaceutical manufacturers seeking to produce and market generic oxaliplatin.[2] Pls.' Statement ¶ 9; Defs.' Statement ¶ 6. The plaintiffs appealed the judgment of the New Jersey district court, and the Federal Circuit first stayed and then, on September 10, 2009, vacated the judgment entered by the New Jersey district court and remanded the case back to that court. Pls.' Statement ¶ 12; Defs.' Statement ¶¶ 5, 7.

On August 10, 2009, after the Federal Circuit stayed but before it vacated the New Jersey district court's judgment, the plaintiffs filed suit in this court against the FDA and the Department of Health and Human Services, requesting an injunction that would require the FDA to rescind its approval of the generic drug applications and refrain from granting further approvals until the expiration of the thirty-month stay.[3] *See generally* Compl.; Pls.' Mot. for TRO and Prelim. Inj. After hearing oral argument on the motion, the court denied the plaintiffs' motion for a temporary restraining order and preliminary injunction, holding that the Federal Circuit's stay of the New Jersey district court's judgment did not effectively reinstated the thirty-month stay under the FDCA. *See generally* Mem. Op. (Aug. 18, 2009). The court subsequently granted leave to intervene to Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc.,

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[2] The FDA had previously determined that these generic drug applications were otherwise eligible for final approval. Defs.' Cross-Mot. for Summ. J. at 10.

[3] The thirty-month stay would have expired, absent action from the New Jersey district court, on August 9, 2010. *See* 21 U.S.C. §§ 355(c)(3)(C), (j)(5)(B)(iii); Compl. ¶ 6; Pls. Mot. at 1.

Pharmachemie B.V., Barr Laboratories, Inc., and Pliva-Lachema a.s. (collectively, "TEVA") and Hospira Worldwide Pty, Hospira Inc., Hospira Australia Pty Ltd. d/b/a Mayne Pharma Limited and Mayne Pharma (USA) Inc. (collectively, "Hospira"), manufacturers and distributors of generic oxaliplatin. *See* Minute Order (Aug. 11, 2009); Minute Order (Dec. 24, 2009).

On September 14, 2009, the plaintiffs filed a motion for summary judgment, arguing that the FDA acted unlawfully in granting the generic drug applications. *See generally* Pls.' Mot. for Summ. J. ("Pls.' Mot."). The defendants and intervenor-defendants filed cross-motions for summary judgment on September 28, 2009. *See generally* Defs.' Cross-Mot. for Summ. J. ("Defs.' Mot."); Intervenor-Defs.' Cross-Mot. for Summ. J. ("Intervenors' Mot."). The motions have been fully briefed, and the court now turns to the applicable legal standard and the parties' arguments.

III. ANALYSIS

A. Legal Standard for Summary Judgment

Summary judgment is appropriate when "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Diamond v. Atwood*, 43 F.3d 1538, 1540 (D.C. Cir. 1995). To determine which facts are "material," a court must look to the substantive law on which each claim rests. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A "genuine issue" is one whose resolution could establish an element of a claim or defense and, therefore, affect the outcome of the action. *Celotex*, 477 U.S. at 322; *Anderson*, 477 U.S. at 248.

In ruling on cross-motions for summary judgment, the court shall grant summary judgment only if one of the parties is entitled to judgment as a matter of law upon material facts that are not genuinely disputed. *Citizens for Responsibility & Ethics in Wash. v. U.S. Dep't of Justice*, 658 F. Supp. 2d 217, 224 (D.D.C. 2009) (citing *Rhoads v. McFerran*, 517 F.2d 66, 67 (2d Cir.1975)). To prevail on a motion for summary judgment, the moving party must show that the opposing party "fail[ed] to make a showing sufficient to establish the existence of an element essential to that party's case." *Celotex*, 477 U.S. at 322. By pointing to the absence of evidence proffered by the opposing party, a moving party may succeed on summary judgment. *Id.*

The opposing party may defeat summary judgment through factual representations made in a sworn affidavit if he "support[s] his allegations . . . with facts in the record," *Greene v. Dalton*, 164 F.3d 671, 675 (D.C. Cir. 1999) (quoting *Harding v. Gray*, 9 F.3d 150, 154 (D.C. Cir. 1993)), or provides "direct testimonial evidence," *Arrington v. United States*, 473 F.3d 329, 338 (D.C. Cir. 2006).

B. Legal Standard for Judicial Review of Agency Actions

The APA entitles "a person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action . . . to judicial review thereof." 5 U.S.C. § 702. Under the APA, a reviewing court must set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706; *Tourus Records, Inc. v. Drug Enforcement Admin.*, 259 F.3d 731, 736 (D.C. Cir. 2001). In making this inquiry, the reviewing court "must consider whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Marsh v. Or. Natural Res. Council*, 490 U.S. 360, 378 (1989) (internal quotations omitted). At a minimum, the agency must have considered relevant data and articulated an explanation establishing a "rational

connection between the facts found and the choice made." *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 626 (1986); *Tourus Records*, 259 F.3d at 736. An agency action usually is arbitrary or capricious if

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Motor Veh. Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); *see also County of L.A. v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999) (stating that "[w]here the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, [the court] must undo its action").

As the Supreme Court has explained, however, "the scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Motor Veh. Mfrs. Ass'n*, 463 U.S. at 43. Rather, the agency action under review is "entitled to a presumption of regularity." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977).

The Supreme Court set forth a two-step approach to determine whether an agency's interpretation of a statute is valid under the APA. *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984). This approach, commonly referred to as "*Chevron* deference," requires the court to first look to "whether Congress has spoken to the precise question at issue." *Id.* at 842. If so, the court ends its inquiry. *Id.* But, if the statute is ambiguous or silent, the second step requires the court to defer to the agency's position, so long as it is reasonable. *Id.* at 843; *Sea-Land Servs., Inc. v. Dep't of Transp.*, 137 F.3d 640, 645 (D.C. Cir. 1998) (holding that "[*Chevron*] deference comes into play of course, only as a consequence

of statutory ambiguity, and then only if the reviewing court finds an implicit delegation of authority to the agency"). In applying *Chevron*, the Supreme Court has held that "[a]dministrative implementation of a particular statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226-27 (2001). Indeed, "judgment about the best regulatory tools to employ in a particular situation is . . . entitled to considerable deference from the generalist judiciary." *W. Union Int'l, Inc. v. Fed. Commc'ns Comm'n*, 804 F.2d 1280, 1292 (D.C. Cir. 1986).

C. The Court Denies the Plaintiffs' Motion for Summary Judgment and Grants the Defendants' and the Intervenor-Defendants' Cross-Motions for Summary Judgment

The plaintiffs argue that because the Federal Circuit vacated the New Jersey district court's judgment, the thirty-month stay was effectively reinstated and the FDA should not have approved any pending generic drug applications for oxaliplatin. *See generally* Pls.' Mot. They assert that the Federal Circuit's decision also vacated any effect the New Jersey district court's judgment had on the thirty-month stay. *Id.* at 14-15. The defendants respond that the FDA was bound by the FDCA to approve the generic drug applications once the New Jersey district court entered its judgment, regardless of the Federal Circuit's stay and subsequent vacatur. Defs.' Mot. at 2; Intervenors' Mot. at 11. The parties agree that the material facts are undisputed, and the court is left to determine the purely legal issue of whether a vacatur entered by an appellate court overrides the terminating effect that the entry of a district court judgment has on the thirty-month stay under the FDCA. Pls.' Mot. at 9-10; Defs.' Mot. at 1.

As a general rule, the "intent of the lawmaker is to be found in the language that he has used." *Teva Pharm. v. Food & Drug Admin.*, 355 F. Supp. 2d 111, 116-17 (D.D.C. 2004) (*quoting United States v. Goldenberg*, 168 U.S. 95, 102-03 (1897)). *Chevron* dictates that the court first look to see if Congress has addressed the issue, 467 U.S. at 842, and this court recognizes that "the starting point, and the most traditional tool of statutory construction, is to read the text itself," *S. Cal. Edison Co. v. Fed. Energy Regulatory Comm'n*, 195 F.3d 17, 23 (D.C. Cir. 1999). The court should not limit itself to examining a statutory provision in isolation but must look to the language and design of the statute as a whole, as "[i]t is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 120 (2000); *S. Calif. Edison*, 195 F.3d at 23.

The entry of judgment provisions state that if, before the expiration of the automatic 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 [FDA] approval [of generic drug applications] shall be made effective on . . . the date on which the court enters judgment reflecting the decision." 21 U.S.C. §§ 355(c)(3)(C)(i)(I), (j)(5)(B)(iii)(I)(aa) (emphasis added). Because the district court is the only court referred to in this section, "the court" plainly refers to the district court.

The date a district court "enters judgment" is a specific, unambiguous event described in Federal Rule of Civil Procedure 58. *See generally* FED. R. CIV. P. 58. With certain exceptions not relevant here, Rule 58 provides that every judgment must be "set out in a separate document" and entered in the civil docket by the clerk pursuant to Rule 79(a). *Id.*; *see also United States v. Indrelunas*, 411 U.S. 216, 219 (1973) (per curiam) (noting that "Rule 58 was substantially

amended in 1963 to remove uncertainties as to when a judgment is entered"); FED. PROC. & PRAC. CIV. 2d § 2781 (explaining the importance of knowing precisely when judgment is entered because the time for appeal and post-trial motions runs from the entry of judgment). The parties agree that the New Jersey district court entered judgment ruling that the plaintiffs' patent had not been infringed on June 30, 2009. Pls.' Statement ¶ 5; Defs.' Statement ¶ 4.

The entry of judgment provisions, which address the consequences of a district court judgment that a patent is invalid or not infringed, are succeeded by sections ("the successive sections") discussing the series of events that may follow a district court judgment that the patent is valid and infringed.[4] 21 U.S.C. §§ 355(c)(3)(C)(ii), (j)(5)(B)(iii)(II). Tellingly, in the successive sections, unlike in the entry of judgment provisions, Congress specifically enumerates the procedure to be followed if the district court's ruling is appealed. *Id.* §§ 355(c)(3)(C)(ii)(I), 355(j)(5)(B)(iii)(II)(aa). Specifically, the statute provides that if the district court determines that a valid patent has been infringed, the FDA's approval of the generic drug application

> shall be made effective on the date on which the court of appeals decides that the patent is invalid or not infringed . . . or the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent . . . is invalid or not infringed.

Id. §§ 355(c)(3)(C)(ii), (j)(5)(B)(iii)(II). In the entry of judgment provisions at issue here, which appear immediately prior to the sections quoted above, Congress makes no mention of appellate proceedings. *See generally id.* §§ 355(c)(3)(C)(i)(I), (j)(5)(B)(iii)(I)(aa).

In short, there are two ways the thirty-month stay can terminate prematurely. The first – addressed in the entry of judgment provisions – arises when the district court rules that the patent

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[4] As with the entry of judgment provisions, there are two successive sections, one relating to NDAs, 21 U.S.C. § 355(c)(3)(C)(ii), and one for ANDAs, *id*. § 355(j)(5)(B)(iii)(II). These sections are identical to one another. *Compare id*. § 355(c)(3)(C)(ii) *with* id § 355(j)(5)(B)(iii)(II).

is invalid or not infringed or endorses a settlement agreement stating that the patent is invalid or not infringed prior to entering judgment. *Id.* §§ 355(c)(3)(C)(i), (j)(5)(B)(iii)(I). That scenario ends with the district court; there is no provision for what happens if the district court's judgment is appealed, *see generally id*. The other scenario occurs when the district court determines that the patent is valid and infringed, the judgment is appealed and the court of appeals either reverses the district court judgment and determines that the patent is invalid or not infringed or endorses a settlement agreement stating that the patent is invalid or not infringed before issuing an opinion.[5] *Id.* §§ 355(c)(3)(C)(ii)(I), (j)(5)(B)(iii)(II)(aa). When viewed in context, the omission of a discussion of the appellate process in the entry of judgment provisions is glaring. Accordingly, the court takes this omission to be intentional and concludes that Congress intended the thirty-month stay to terminate upon the entry of judgment by a district court that a patent is invalid or not infringed without regard to the appellate process. *See Halverson v. Slater*, 129 F.3d 180, 186 (D.C. Cir. 1997) (explaining that, "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion") (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)).

These successive sections are not the only times Congress makes reference to the appellate process in the FDCA. For example, a subsequent provision of the FDCA describes a forfeiture event ("the forfeiture provision") that occurs when "a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has or can be taken." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA). Although this provision is not implicated in this

[5] The thirty-month stay can also be terminated early if the district court determines that the patent is infringed and that judgment is never appealed or is affirmed. 21 U.S.C. §§ 355(c)(3)(C)(ii)(II), (j)(5)(iii)(II)(bb).

case, it serves as further evidence of Congress's intent in omitting the appellate process in the entry of judgment provisions. *Cf. Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 452-53 (2002) (holding that "[w]here Congress wanted to provide for successor liability in the Coal Act, it did so explicitly, as demonstrated by other sections in the Act that give the option of attaching liability to 'successors' and 'successors in interest'"); *Halverson*, 129 F.3d at 186 (examining the explicit language of one section of the Great Lakes Pilotage Act to determine Congress's intent with respect to another section of the same act). For instance, the successive sections and the forfeiture provision make it clear that Congress understood that a district court judgment can be appealed and contemplated the effect of such an appeal by including language providing for that eventuality. Moreover, no provision in the statute mentions the implication of a vacated judgment. *See generally* 21 U.S.C. § 355. Thus, the court determines that the lack of limiting language in the entry of judgment provisions – in contrast to the successive sections and the forfeiture provision – is sufficient to demonstrate Congress's intent that the entry of judgment by the district court be the event that triggers the termination of the thirty-month stay notwithstanding any subsequent appeal or ruling by the appellate court. *Cf. Russello*, 464 U.S. at 23 (holding that, had Congress intended to restrict one subsection of the act, "it presumably would have done so expressly as it did in the immediately following subsection"); *United States v. Villanueva-Sotelo*, 515 F.3d 1234, 1257 (D.C. Cir. 2008) (determining that if Congress had intended one section of the aggravated identity theft statute to include the same mens rea requirement found in another section of that statute, it would have done so explicitly); *Fla. Pub. Telecomms. Ass'n v. Fed. Commc'ns Comm'n*, 54 F.3d 857, 860 (D.C. Cir. 1995) (holding that "when Congress uses different language in different sections of a statute it does so intentionally").

Because the face of the statute is clear and unambiguous in expressly stating that the event which terminates the thirty-month stay and prompts the FDA's approval of generic drug applications is "the date on which the [district] court enters judgment," *id.* §§ 355(c)(3)(C)(i)(I), (j)(5)(B)(iii)(I)(aa), and the statute does not address the implications of a scenario in which the district court judgment is vacated, the court must "presume that Congress meant precisely what it said," *Nat'l Public Radio, Inc. v. Fed. Commc'ns Comm'n*, 254 F.3d 226, 230 (D.C. Cir. 2001); *see also Bates v. United States*, 522 U.S. 23, 39 (1997) (explaining that the court "ordinarily resist[s] reading words or elements into a statute that do not appear on its face"); *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 254 (1992) (holding that Congress "says in a statute what it means and means in a statute what it says"). Given that the entry of judgment provisions have a plain meaning, the court will not read into the statute any implication a vacated judgment might have on those provisions. *See Goldenberg*, 168 U.S. at 217 (stating that "[n]o mere omission . . . which it may seem wise to have specifically provided for, justif[ies] any judicial addition to the language of the statute"); *Qi-Zhuo v. Meissner*, 70 F.3d 136, 140 (D.C. Cir. 1995) (holding that if the plain language of the statute is clear, the court need not inquire further into its meaning, at least in the absence of "a clearly expressed legislative intent to the contrary") (*quoting Reves v. Ernst & Young*, 507 U.S. 170, 177 (1993)); *Nat'l Women, Infants, & Children Grocers Ass'n v. Food & Nutrition Serv.*, 416 F. Supp. 2d 92, 100 (D.D.C. 2006) (ruling that the court will not read into a section what is not stated therein nor ignore its plain language). The court thus determines that plain language of the statute dictates that the thirty-month stay terminate upon the entry of judgment by a district court that a patent is invalid or not infringed, regardless of any subsequent appeal, and that the FDA was bound to follow this directive. Accordingly, the court grants summary judgment to the defendants and intervenor-defendants.

IV. CONCLUSION

For the foregoing reasons, the court denies the plaintiffs' motion for summary judgment and grants the defendants' and intervenor-defendants' cross-motions for summary judgment. An Order consistent with this Memorandum Opinion is separately and contemporaneously issued this 26th day of July, 2010.

RICARDO M. URBINA
United States District Judge