IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

In this action, plaintiffs Sanofi-Aventis, Sanofi-Aventis US, LLC, and Debiopharm S.A. (collectively "Sanofi"), challenge approval by the Food and Drug Administration ("FDA") of a generic version of their cancer drug Eloxatin ("oxaliplatin"). Sanofi has now moved for summary judgment under Rule 56 of the Federal Rules of Civil Procedure, and the federal defendants both oppose Sanofi's motion and cross-move for summary judgment in their own behalf.

Rule 56 provides that summary judgment should be granted where "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). The only fact truly material to this case, and one that is not disputed by any party, is set forth in Sanofi's statement of material facts: "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." Statement of Undisputed Material Facts in Support of Plaintiffs' Motion for Summary Judgment (Doc. No 26) (Plaintiffs' Statement), ¶ 5. All of the other facts

set forth in the various parties' statements provide context to this one fact, but none of them are necessary to this court determining whether and which parties are entitled to judgment as a matter of law.

This court recognized, in denying the preliminary relief sought previously in this case, that the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (the "FDCA" or the "Act"), insofar as is relevant here, requires FDA to approve a generic version of a patented drug when a United States district court enters judgement reflecting a decision that the generic drug does not infringe the patent. 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa). And as acknowledged in plaintiffs' statement just quoted, the United States District Court for the District of New Jersey entered such a judgment with respect to a patent for Eloxatin.

It is true that on July 10, 2009, the United States Court of Appeals for the Federal Circuit stayed the New Jersey district court's judgment. Plaintiffs' Statement,¶ 8. It is equally true that on September 10, 2009, the Federal Circuit vacated the district court's judgment and remanded the patent litigation to the district court. Plaintiffs' Statement, ¶ 12. Neither the stay nor the vacating of the district court's judgment, however, has any affect on the outcome in this case. Rather, entry of the judgment by the New Jersey district court, in accord with the plain words of the FDCA and without regard to subsequent events in the Federal Circuit, compels entry of summary judgment against Sanofi and for the defendants.

STATUTORY AND REGULATORY BACKGROUND

I. New Drug Applications

Under the FDCA, pharmaceutical companies seeking to market a so-called "pioneer" or "innovator" drugs must first obtain FDA approval by filing a new drug application ("NDA")

containing extensive scientific data demonstrating the safety and effectiveness of the drug. 21 U.S.C. §§ 355(a), (b). An NDA applicant must also submit information on any patent that claims the drug, or a method of using the drug, and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. 21 U.S.C. §§ 355(b)(1), (c)(2). FDA must publish the patent information it receives, and does so in "Approved Drug Products with Therapeutic Evaluations" (the "Orange Book"). Id.; see also 21 C.F.R. § 314.53(e).

II. Abbreviated New Drug Applications

The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"), codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, and 282, permits manufacturers to submit abbreviated new drug applications ("ANDA"s) requesting approval of generic versions of approved drug products. 21 U.S.C. § 355(j). The Hatch-Waxman Amendments were intended to strike a balance between encouraging innovation in the development of new drugs and accelerating the availability to consumers of lower cost alternatives to innovator drugs. See H.R. Rep. No. 98-857 (Part I), 98th Cong., 2d Sess. at 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647-48; see also, e.g., Tri-Bio Labs., Inc. v. United States, 836 F.2d 135, 139 (3d Cir. 1987).

ANDA applicants, unlike NDA applicants, need not submit clinical data to demonstrate the safety and efficacy of the generic product. See 21 U.S.C. § 355(j). Rather, an ANDA relies on FDA's previous findings that the product approved under the NDA is safe and effective. Exclusive of such clinical safety and efficacy data, the FDCA sets forth in detail the information an ANDA must contain. See 21 U.S.C. § 355(j)(2)(A). Among other information, an ANDA must include data showing that the generic drug product is bioequivalent to the pioneer drug

product. 21 U.S.C. §§ 355(j)(2)(A)(iv), (j)(4)(F); 21 C.F.R. §§ 314.127(a)(6)(i), 314.94(a)(7). A drug is considered to be bioequivalent if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed [pioneer] drug." 21 U.S.C. § 355(j)(8)(B)(i).

The timing for approval of an ANDA depends, in part, on statutory patent protections afforded to the innovator drug. Among other things, an ANDA must contain one of four specified certifications for each patent that "claims the listed drug" or claims "a use for such listed drug for which the applicant is seeking approval." 21 U.S.C. § 355(j)(2)(A)(vii). This certification must state one of the following:

> (I) that such patent information has not been filed,
> (II) that such patent has expired,
> (III) . . . the date on which such patent will expire, or
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

21 U.S.C. § 355(j)(2)(A)(vii).

If a certification is made under paragraph I or II indicating, respectively, that patent information pertaining to the drug or its use has not been filed with FDA or that the patent has expired, the ANDA may be approved immediately. 21 U.S.C. § 355(j)(5)(B)(i). A paragraph III certification indicates that the ANDA applicant does not intend to market the drug until after the applicable patent has expired, and approval of the ANDA may be made effective on the patent expiration date. 21 U.S.C. § 355(j)(5)(B)(ii).

If an applicant wishes to challenge the validity of a patent, or to claim that the patent would not be infringed by the product covered by the ANDA, the applicant must submit a certification pursuant to paragraph IV. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The applicant

must also provide notice of its paragraph IV certification to the NDA holder and the patent owner explaining the factual and legal basis for the applicant's opinion that the patent is invalid or not infringed. 21 U.S.C. § 355(j)(2)(B).

The filing of a paragraph IV certification "for a drug claimed in a patent or the use of which is claimed in a patent" is an act of infringement. 35 U.S.C. § 271(e)(2)(A). This enables the NDA holder and patent owner to sue the ANDA applicant. If such a suit is brought within 45 days of the date notice of the certification was received by the patent owner or NDA holder, FDA must stay approval of the ANDA for 30 months from that date. 21 U.S.C. § 355(j)(5)(B)(iii). The Act further provides, however, that "if before the expiration of such [30 month] period the district court decides that the patent is invalid or not infringed … the approval shall be made effective on … the date on which the court enters judgment reflecting the decision." 21 U.S.C. § 355(j)(5)(B)(iii)(I) (emphasis added). If no action is brought within the requisite 45-day period, FDA may approve an ANDA with a paragraph IV certification effective immediately, provided that other conditions for approval have been met. 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(f)(2).

III. Section 505(b)(2) Applications

An application submitted pursuant to 21 U.S.C. § 355(b)(2) (a "505(b)(2) application") is a sub-category of NDAs, but it shares certain characteristics of an ANDA as well. For a 505(b)(2) application, the FDCA permits the submission of reports of investigations that "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted." 21 U.S.C. § 355(b)(2). In other words, a 505(b)(2) application must satisfy the same requirements as a

stand-alone NDA, except that a 505(b)(2) applicant may rely, in part, on clinical safety and effectiveness studies not conducted or owned by the applicant.

In this regard, a 505(b)(2) application is similar to an ANDA in that both a 505(b)(2) application and an ANDA rely on the approval of an NDA for another drug, specifically, as applies in this case, on the previous FDA findings that an approved innovator drug is safe and effective. As with an ANDA, entry of a judgment reflecting a decision that a relevant patent is not infringed authorizes FDA to approve a 505(b)(2) application where all other approval requirements have been satisfied. 21 U.S.C. 355(c)(3)(C)(i)(I) ("the approval shall be made effective on ... the date on which the court enters judgment reflecting the decision").

FACTUAL BACKGROUND

Sanofi holds the NDAs for Eloxatin. Plaintiffs' Statement, ¶ 2. Teva filed a 505(b)(2) application for oxaliplatin, and several ANDAs were also filed by other sponsors, including Mayne/Hospira. All of these applications contained paragraph IV certifications to U.S. Patent No. 5,338,874 ("the '874 patent"). In June and July 2007, within 45 days of receiving notice of the paragraph IV certifications, Sanofi initiated patent infringement litigation against Teva and three ANDA applicants in the U.S. District Court for the District of New Jersey. Plaintiff's Statement, ¶ 3. On June 18, 2009, the New Jersey district court ruled that the '874 patent was not infringed and, on June 30, 2009, entered a judgment reflecting that ruling. Plaintiffs' Statement, ¶ 5.

On July 1, 2009, the Federal Circuit temporarily stayed the district court judgment, pending that court's consideration of a petition for writ of mandamus and a motion for a stay pending appeal. Plaintiffs' Statement, ¶ 7. On July 10, 2009, the Federal Circuit stayed, pending

appeal, the district court's judgment. Plaintiffs' Statement, ¶ 8. On August 7, 2009, FDA approved the pending 505(b)(2) application and an ANDA for generic oxaliplatin. Plaintiffs' Statement, ¶ 9. The Federal Circuit, on September 2, 2009, heard argument in Sanofi's appeal of the New Jersey district court's decision, and, on September 10, 2009, vacated the district court's judgment and remanded the case to the district court. Plaintiffs' Statement, ¶ 12.

STANDARD OF REVIEW

Summary judgment is appropriate if "there is no genuine issue as to any material fact" and "the movant is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); Czekalski v. Peters, 475 F.3d 360, 363 (D.C. Cir. 2007). The party seeking summary judgment bears the initial burden of demonstrating to the court that the standard for summary judgment has been met, see Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986), and all facts are viewed in the light most favorable to the non-moving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587-88 (1986). Regarding materiality, "the substantive law will identify which facts are material. Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

FDA's administrative decisions are subject to review by the courts under the Administrative Procedure Act ("APA"), and may be disturbed only if "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This standard is highly deferential to the agency. Citizens to Preserve Overton Park, Inc. v. Volpe,

401 U.S. 402, 416 (1971). "There is a presumption in favor of the validity of the administrative action." Bristol-Myers Squibb Co. v. Shalala, 923 F. Supp. 212, 216 (D.D.C. 1996).

Under the "arbitrary and capricious" standard, agency action must be upheld if the action is rational, based upon relevant factors, and within the agency's authority. Motor Vehicle Mfrs. Ass'n of the United States, Inc., v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42-43 (1983); see also Overton Park, 401 U.S. at 416; AT&T Corp. v. FCC, 349 F.3d 692, 698 (D.C. Cir. 2003). Further, "under this narrow scope of review, '[t]he court is not empowered to substitute its judgment for that of the agency.'" Bristol-Myers, 923 F. Supp. at 216 (quoting Overton Park, 401 U.S. at 416); see also Motor Vehicle Mfrs. Ass'n, 463 U.S. at 43 ("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.").

When a court reviews an agency's construction and application of statutory provisions, it is governed by the two-step analysis of Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984). First, the Court must inquire "whether Congress has directly spoken to the precise question at issue;" if Congress's intent is clear, the Court "must give effect to [such] unambiguously expressed intent." Id. at 842-43. Formulated another way, the Court must initially decide "whether the statute unambiguously forbids the Agency's interpretation." Barnhart v. Walton, 535 U.S. 212, 218 (2002) (emphasis added). As this Court explained in Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30 (D.D.C. 2000), "Chevron analysis often begins and ends with the statutory text because 'the language of the statute itself is always the best indication of congressional intent.'" Id. at 37 (quoting Abbott Labs. v. Young, 920 F.2d 984, 987 (D.C. Cir. 1990)).

Sanofi contends that "[b]oth in the prior hearing in this Court and in the D.C. Circuit, FDA expressly disclaimed any reliance on *Chevron*." Memorandum of Points and Authorities in Support of Plaintiffs' Motion for Summary Judgment (Doc. No. 26) (Pl. Mem.) at 11, n.10. FDA did no such thing. Rather, in the hearing on Sanofi's motion for a temporary restraining order and preliminary injunction, counsel for the government said, "I'm not even arguing Chevron deference here, Your Honor." Transcript (Doc. No. 24) at 14. But counsel also said, "this Court has to find in order to enter the TRO that the plaintiffs want this evening a likelihood that they're right about what the statute says and F.D.A. is wrong" and "F.D.A. believes that the statute means what it says." Id. at 12, 14.

Likewise, in opposing Sanofi's emergency motion for a stay pending appeal in the D.C. Circuit, the government argued, on behalf of FDA, "The question thus presented, first to FDA and now to this court, is whether, under 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa), the New Jersey district court's entry of judgment that the '874 patent is not infringed authorized FDA to approve oxaliplatin ANDAs that were otherwise eligible for final approval, notwithstanding a subsequent stay of that judgment by the Federal Circuit. The question is answered by the plain words of the FDCA." In re Sealed Case, No 09-5278, Defendant-Appellees' Opposition to Plaintiff-Appellants' Emergency Motion for Injunction Pending Appeal. Thus, far from disclaiming any reliance on Chevron, the government has consistently argued that FDA properly applied the plain words of the relevant statute, i.e., Sanofi loses at Chevron step one.

ARGUMENT

The basis for all of Sanofi's arguments is a Federal Circuit ruling in patent litigation to which FDA is not a party and which does not control FDA's approval of drug applications under

the FDCA. More specifically, the issue that FDA had to decide, and that gave rise to Sanofi's suit, was whether, following the New Jersey district court's entry of judgment that the '874 patent is not infringed, FDA had any discretion not to approve oxaliplatin ANDAs that were otherwise eligible for final approval. As noted, the FDCA provides generally that if, as with the ANDAs at issue, the ANDA applicant submits a paragraph IV certification to the listed patent and gives appropriate notice of the certification, and the patent owner or NDA holder sues the applicant within 45 days of that notice, the applications may not be approved for 30 months from the date of notice. 21 U.S.C. § 355(j)(5)(B)(iii). The FDCA mandates, however, that "if before the expiration of such [30 month] period the district court decides that the patent is invalid or not infringed … *the approval shall be made effective on … the date on which the court enters judgment reflecting the decision* . . ." 21 U.S.C. § 355(j)(5)(B)(iii)(I) (emphasis added).

It is well settled that "[t]he preeminent canon of statutory interpretation requires us to 'presume that [the] legislature says in a statute what it means and means in a statute what it says there.'" BedRoc Ltd., LLC v. United States, 541 U.S. 176, 183 (2004) (citations omitted); accord, Conn. Nat'l Bank v. Germain, 503 U.S. 249, 253-54 (1992) (same); Qi-Zhuo v. Meissner, 70 F.3d 136, 140 (D.C. Cir. 1995). "Extremely strong, this presumption is rebuttable only in the 'rare cases [in which] the literal application of a statute will produce a result demonstrably at odds with the intentions of its drafters.'" Nat'l Pub. Radio, Inc. v. FCC, 254 F.3d 226, 230 (D.C. Cir. 2001) (quoting United States v. Ron Pair Enters., 489 U.S. 235, 242 (1989)). While Sanofi argues vigorously about an appellate court's inherent authority to stay a judgment of a district court, such arguments are not relevant to the FDCA provision at issue. Here, "because the statute is clear, and the FDA's application of the statute is consistent with the plain

meaning of the statute, it's decision cannot be considered arbitrary, capricious, or contrary to law." Teva Pharms. v. FDA, 355 F. Supp. 2d 111, 118 (D.D.C. 2004).

The current language of 21 U.S.C. § 355(j)(5)(B)(iii)(I) was enacted in 2003 by the Medicare Modernization Act ("MMA"), which amended certain ANDA-related provisions of the FDCA. Before the 2003 amendments, that provision provided that "if before the expiration of such [30-month] period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision." 21 U.S.C. § 355(j)(5)(B)(iii)(I) (2002). The 2003 revision provided clarity in that the statute was revised from the somewhat ambiguous "date of the court decision" to the very specific "date on which the court enters judgment reflecting the decision."[1]

While the "decision" described in the pre-MMA version of the statute 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, decision on appeal, etc.), "entry of judgment" refers to a specific recognized act described in Federal Rule of Civil Procedure 58 and not likely to vary among courts. Thus, the revised provision specifically directs that FDA *shall approve* an otherwise approvable ANDA on the date on which a district court enters judgment reflecting the court's decision that the patent is invalid or not infringed. See 21 U.S.C. § 355(j)(5)(B)(iii)(I).

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[1] FDA issued a regulation intended to resolve the ambiguity in the term "court decision," in the pre-MMA version of the statute. That regulation defined "court decision" as one that was final and not appealable or, if appealable, from which no appeal had been take within the requisite time. FDA's regulatory effort to bring certainty to the statute was, however, rejected in Mylan Pharms., Inc. v. Shalala, 81 F.Supp. 2d 30 (D.D.C. 2000). The current language of the statute eliminates all ambiguity and, consequently, the need for any such regulatory interpretation by FDA.

Not only is the FDCA silent regarding the effect of a stay or appeal of the district court's judgment on the timing of approval of an ANDA, despite the universal awareness of the availability of potential stays and appeals, there is nothing in the text or structure of the Act to suggest that a stay or appeal of the district court's judgment after its entry permits FDA to delay approving an otherwise approvable ANDA until the stay is lifted, appeals have been exhausted, or there is finality to the district court's decision regarding invalidity or non-infringement. The statute does not say that the agency may approve on the date "on which the court enters judgment … unless that judgment is stayed or appealed," nor does it otherwise qualify the description of the event that mandates approval.[2]

It is clear, however, from other provisions of section 355(j)(5) enacted in the MMA, that Congress knew how to impose such limitations where they are intended. For example, section 355(j)(5)(D)(i)(I)(bb)(AA) describes a forfeiture event 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 been or can be taken." Congress did not impose any such limitation in

[2] Sanofi attempts to make something of the fact that judgment was entered in the New Jersey district court on June 30, 2009, while the oxaliplatin approvals were not granted by FDA until "more than a month after the district court entered its judgment." Pl. Mem. At 14 (Sanofi's emphasis). From this, Sanofi argues that "FDA has never read [the Act] to require immediate approval of generic drug applications on the date a district court judgment was entered." Id. (Sanofi's emphasis). There is, of course, a perfectly reasonable explanation why such approvals are not instantaneous, and Sanofi supplies it: "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.'" Id. (Sanofi's emphasis; citations omitted). Thus, as even Sanofi would have it, though FDA did not grant the final oxaliplatin approvals on June 30, 2009, it did so "as soon thereafter as possible." Id.

section 355(j)(5)(B)(iii)(I) when describing the entry of judgment by the district court as the critical act.

There is likewise no indication that Congress intended to prevent approval of ANDAs before all related patent litigation was finally resolved. Indeed, the FDCA specifically provides for the possibility that an ANDA may be approved at the termination of the 30-month stay, before even the district court has rendered its decision regarding patent rights. See 21 U.S.C. § 355(j)(5)(B)(iii). A district court judgment of non-infringement or invalidity - including a judgment that has been stayed - provides more certainty regarding patent rights than exists when an ANDA is approved at the end of the 30-month stay, before the district court has rendered any decision whatsoever on patent rights. Moreover, given the possibility of an appeal, a district court judgment of invalidity or non-infringement - including one that is not stayed - does not provide patent certainty. As just noted, even when Congress wanted to identify a patent infringement decision about which there was some certainty (i.e., a final decision from which no appeal has been or can be taken), it did not require a complete exhaustion of judicial remedies, including a petition for certiorari to the Supreme Court.

Sanofi relies almost entirely on the Supreme Court's decision in Nken v. Holder, 129 S. Ct. 1749 (2009), to support its contentions regarding the impact an appellate court's ruling has on a district court's judgment. See, e.g., Pl. Mem. at 1-2, 10-11, 12, 13, 15. FDA does not dispute that a federal circuit court possesses the inherent authority to stay the judgment of a federal district court, and that the Hatch-Waxman Amendments do not purport to address that authority.

That does not affect, however, FDA's application of its organic statute, the FDCA.[3] As this court explained, "[t]he *Nken* decision does not address the central issue in the instant case." Mem. Op. (Doc. No. 21) at 6. Sanofi's continued reliance on Nken, and, in the same vein, In re Aventis Pharma S.A., 314 Fed. Appx. 291 (Fed. Cir. 2008), is thus misplaced.

Nor can Sanofi bootstrap its Nken argument with the Federal Circuit's ultimate vacating of the New Jersey district court's judgment. Sanofi says that "[t]he Federal Circuit's vacatur of the New Jersey court's judgment makes permanent the 'temporary setting aside' of that judgment effected by the stay." Pl. Mem. At 14. But the vacating of the district court's judgment is nothing more than what occurs in the vast majority of appeals where a district court decision is reversed. When Congress made entry of a judgment of patent invalidity or non-infringement by the district court the operative event for ANDA approval, it knew that district court judgments are often reversed and vacated on appeal.

Certainly, Sanofi is not arguing that ultimate reversal/vacating on appeal of a district court decision of patent invalidity or non-infringement acts to undo an ANDA approval granted when the judgment reflecting the district court decision was entered. That would gut the statute of all meaning and make appellate decisions, not entry of district court judgments, the operative approval event. But if a final appellate decision reversing a district court judgment does not void

[3] Despite Sanofi's repeated assertions to the contrary, see, e.g., Pl. Mem. at 1, 10, 13, the "source" of FDA's authority to approve the 505(b)(2) application and ANDAs for oxaliplatin is not the New Jersey district court's entry of judgment, but rather is the FDCA itself. The entry of judgment was simply the applicable trigger that affected the timing of the approvals, but that judgment in no way operated to grant FDA the authority to approve drug applications, nor did any events with respect to that judgment subsequent to its entry deprive FDA of that authority.

ANDA approval, how can a stay, which by its own terms applies only pending such a final decision, invalidate the approval?

CONCLUSION

In sum, the plain language of the FDCA is as dispositive now as it was when this Court denied Sanofi's motion for preliminary relief, see Mem. Op. at 6-7, notwithstanding any or all of the Federal Circuit's actions in Sanofi's patent litigation. For that reason, and all of the reasons discussed above, Sanofi's motion for summary judgment should be denied and defendants motion for summary judgment should be granted.

Respectfully submitted,

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