

**United States Court of Appeals  
for the Federal Circuit**

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**SANOFI-AVENTIS, SANOFI-SYNTHELABO, INC.,  
AND BRISTOL-MYERS SQUIBB SANOFI  
PHARMACEUTICALS HOLDING PARTNERSHIP,**  
*Plaintiffs-Appellees,*

**v.**

**APOTEX INC. AND APOTEX CORP.,**  
*Defendants-Appellants.*

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2011-1048

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Appeal from the United States Court for the Southern  
District of New York in Case No. 02-CV-2255, Judge  
Sidney H. Stein.

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Decided: October 18, 2011

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EVAN R. CHESLER, Cravath, Swaine & Moore, LLP, of  
New York, New York, argued for plaintiffs-appellees.  
With him on the brief were RICHARD J. STARK and DAVID  
GREENWALD. Of counsel on the brief were ROBERT L.  
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York, New York.

ROBERT B. BREISBLATT, Katten Muchin & Rosenman, LLP, of Chicago, Illinois, argued for defendants-appellants. With him on the brief was ERIC C. COHEN. Of counsel was STEPHEN P. BENSON.

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Before NEWMAN, SCHALL, and MOORE, *Circuit Judges*.

Opinion for the court filed by Circuit Judge MOORE.

Circuit Judge NEWMAN dissents-in-part.

MOORE, *Circuit Judge*.

Apotex Inc. and Apotex Corp. (collectively, Apotex) appeal the United States District Court for the Southern District of New York's award of prejudgment interest to Sanofi-Aventis, Sanofi-Synthelabo, Inc., and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership (collectively, Sanofi) and its holding that Apotex Inc. is jointly and severally liable for damages. *Sanofi-Aventis v. Apotex Inc.*, 748 F. Supp. 2d 293 (S.D.N.Y. 2010). Apotex also appeals the district court's denial of its motion for leave to file a supplemental answer, affirmative defenses, and counterclaims pleading patent misuse and breach of contract. J.A. 2.1-2.22. Because the district court erred by awarding prejudgment interest in addition to Sanofi's "actual damages" specified in the parties' settlement agreement, we reverse-in-part. We affirm the district court's holding that Apotex Inc. is jointly and severally liable for all damages and its denial of Apotex's motion for leave to file a supplemental answer, affirmative defenses, and counterclaims.

#### BACKGROUND

This is the third appeal we have heard in this nearly decade old Hatch-Waxman dispute regarding clopidogrel bisulfate tablets, sold by Sanofi under the brand name

Plavix®. In the first appeal, we affirmed the district court's grant of a preliminary injunction. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368 (Fed. Cir. 2006) (*Plavix I*). In the second appeal, we affirmed the district court's judgment that the patent-in-suit is not invalid, infringed, and not unenforceable. *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075 (Fed. Cir. 2008) (*Plavix II*). The facts most relevant to this appeal are set forth as follows.

On November 21, 2001, Apotex Inc., through its U.S. agent, Apotex Corp., filed an Abbreviated New Drug Application (ANDA) with the United States Food and Drug Administration (FDA) seeking approval for the sale of generic clopidogrel bisulfate tablets prior to the expiration of U.S. Patent No. 4,847,265 (the '265 patent). *Plavix I*, 470 F.3d at 1372-73. The submission included a paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '265 patent is invalid. *Id.* at 1373. In response to the submission, Sanofi filed suit on March 21, 2002, alleging that the filing of the ANDA constituted an act of infringement under 35 U.S.C. § 271(e)(2). *Id.* Although Apotex admitted that its proposed generic product would infringe claim 3 of the '265 patent, Apotex counterclaimed seeking a declaration that the '265 patent is invalid and unenforceable. *Id.* Sanofi's filing of the suit within forty-five days of receiving notice of Apotex's paragraph IV certification triggered a thirty-month stay of FDA approval for the ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). *Id.*

The stay expired on May 17, 2005, and on January 20, 2006, the FDA gave Apotex final approval to sell its generic product. *Id.* Prior to the FDA's approval, the parties initiated settlement negotiations that culminated in a tentative agreement on March 17, 2006 (the March 2006 agreement). *Id.* In the March 2006 agreement,

Sanofi granted Apotex a future license under the '265 patent, which would allow Apotex to begin sale of its generic product several months before the patent expired. J.A. 683. Sanofi also expressly agreed, *inter alia*, that during the pendency of the license it would not launch an authorized generic. *Id.*

An authorized generic is a generic drug sold by the company who markets the brand name drug (or a third party licensee). *See Mylan Pharm., Inc. v. U.S. Food & Drug Admin.*, 454 F.3d 270, 273 (4th Cir. 2006). Authorized generics, like other generics, are sold at a reduced price compared to the brand name drug. Under the provisions of the Hatch-Waxman Act in effect at the time Apotex filed its ANDA, Apotex was entitled to a 180-day period of exclusivity during which the FDA would not approve other generic clopidogrel bisulfate products once Apotex received approval from the FDA. 21 U.S.C. § 355(j)(5)(B)(iv). However, the branded company may still market an authorized generic during this 180-day exclusivity period. *Mylan Pharm., Inc.*, 454 F.3d at 273. The sale of an authorized generic benefits patients (through lower prices) and the branded company, but harms the first-to-file generic by introducing generic competition. *Id.*

Although Bristol-Myers Squibb Company (BMS) is not a party to this litigation, it is an owner of plaintiff Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership. As a result of orders entered in a previous litigation involving BMS, the March 2006 agreement was subject to approval by the Federal Trade Commission (FTC) and a consortium of state attorneys general. The FTC objected to multiple provisions of the March 2006 agreement, including the provision preventing Sanofi from launching an authorized generic during the period of Apotex's license. In view of these objections, Sanofi withdrew the

agreement from administrative review and the parties reinstated settlement negotiations.

On May 26, 2006, the parties executed a second settlement agreement – the terms of which are partially at issue in this appeal (the May 2006 agreement). Unlike the March 2006 agreement, Sanofi did not expressly agree in the May 2006 agreement not to launch an authorized generic during the pendency of Apotex’s license. The BMS executive negotiating the settlement on behalf of Sanofi, however, orally promised Apotex that Sanofi would not launch an authorized generic during this time period. On May 30, 2006, BMS presented the May 2006 agreement to the FTC for approval, but failed to disclose the existence of the oral agreement regarding an authorized generic. On June 5, 2006, Apotex disclosed the oral agreement to the FTC. In light of Apotex’s disclosure, the FTC requested a written certification from BMS to confirm that BMS had made no oral promise not to launch an authorized generic during the pendency of Apotex’s license. The BMS executive submitted the certification as requested without disclosing the oral promise. On July 28, 2006, the state attorneys general informed the parties that they would not approve the May 2006 agreement, but promised to reconsider pending an investigation into the existence of the oral agreement between the parties.

On July 31, 2006, Apotex declared a regulatory denial pursuant to its rights under the May 2006 agreement, which provided that “[i]f Regulatory Review has not been completed by July 31, 2006, either party has the right to declare that there has been a Regulatory Denial [and] . . . the litigations will be resumed . . .” J.A. 693. On August 8, 2006, Apotex launched its generic clopidogrel bisulfate product. Sanofi moved for a preliminary injunction, which the district court granted on August 31, 2006, *Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317

(S.D.N.Y. 2006), and which we affirmed in *Plavix I*.<sup>1</sup> In the few weeks that Apotex marketed its generic product it had \$884,418,724 in net sales.

The district court held a bench trial regarding liability between January 22 and February 15, 2007 and on June 19, 2007 issued an opinion holding that the '265 patent was both not invalid and not unenforceable. *Sanofi-Synthelabo v. Apotex Inc.*, 492 F. Supp. 2d 353 (S.D.N.Y. 2007). Infringement was not an issue at the trial: Apotex previously admitted that it infringed under § 271(e)(2) because its generic product would infringe claim 3 of the '265 patent. Additionally, Sanofi never amended its pleadings to specifically allege infringement under § 271(a)-(b) after Apotex began selling its generic product. The district court bifurcated the issue of damages, which was scheduled for future proceedings pursuant to § 271(e)(4)(C). *Id.* at 397. On December 12, 2008, we affirmed the district court's decision in *Plavix II*.

During the pendency of the liability trial and appeal, the government pursued charges against BMS in relation to its failure to disclose the oral agreement and its later false certification to the FTC. On May 30, 2007, after the liability trial had ended, but before the district court entered its decision, BMS pleaded guilty to making false statements to the FTC in violation of 18 U.S.C. § 1001. J.A. 1826-41. On March 26, 2009, the FTC brought a civil action against BMS, resulting in a consent judgment wherein BMS admitted it was in violation of its obligations to truthfully disclose all provisions of the May 2006

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<sup>1</sup> In paragraph 9 of the May 2006 agreement Apotex consented to personal jurisdiction and venue in the Southern District of New York for purposes of any action by Sanofi arising out of a sale by Apotex of its generic product prior to the effective date of its license.

agreement. BMS agreed to pay a civil penalty of \$2,100,000.

On May 22, 2009, during the damages stage of the litigation, Apotex sought leave to file a supplemental answer, affirmative defenses, and counterclaims. In the supplemental answer, Apotex alleged that the '265 patent was unenforceable for patent misuse due to BMS's failure to disclose the oral agreement to the FTC and its later false certification to the FTC. Apotex also added a counterclaim for breach of contract, alleging that BMS breached its duty to use reasonable efforts to secure regulatory approval of the May 2006 agreement.

The district court denied Apotex's motion on September 3, 2009. J.A. 2.1-2.23. Regarding the patent misuse claim, the district court determined that the claim was "an 'unnecessary and inappropriate diversion' from [the] action," J.A. 2.8, that would "expand, complicate and prolong discovery in [the] action and prolong its ultimate resolution." *Id.* at 2.10. The district court also determined that given our recent *en banc* decision in *Princo Corp. v. International Trade Commission*, 616 F.3d 1318 (Fed. Cir. 2010) (*en banc*), BMS's actions likely did not constitute patent misuse. *Id.* at 2.9. The district court similarly denied the motion to add the breach of contract counterclaim. In doing so, the district court determined that Apotex could file the breach of contract suit separately and that granting the motion "would both delay disposition of this litigation and . . . prejudice Sanofi by requiring it to address an additional area of discovery." *Id.* at 2.11.

The May 2006 agreement set Sanofi's "actual damages" as "50% of Apotex's net sales." J.A. 693. On December 18, 2009, Sanofi moved for summary judgment on the issue of damages. On October 9, 2010, the district

court granted Sanofi's motion for summary judgment and ordered Apotex to pay \$442,209,362 in damages (50% of Apotex's net sales) and an additional \$107,930,857 in prejudgment interest.<sup>2</sup> J.A. 17. In awarding prejudgment interest, the district court rejected Apotex's arguments that the May 2006 agreement precluded such an award. *Sanofi-Aventis*, 748 F. Supp. 2d at 296-97. The district court also rejected Apotex's arguments that prejudgment interest was not available as a remedy pursuant to 35 U.S.C. § 271(e)(4)(c). *Id.* The district court further held that Apotex Inc. and Apotex Corp. were jointly and severally liable for the damages. *Id.* at 295. Apotex appeals and we have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

#### DISCUSSION

On appeal, Apotex argues that the district court erred by: 1) granting Sanofi prejudgment interest in addition to the damages specified in the May 2006 agreement; 2) awarding the interest at the prime rate; 3) holding Apotex Inc. jointly and severally liable for Sanofi's damages; and 4) denying Apotex's motion for leave to file a supplemental answer, affirmative defenses, and counterclaims pleading patent misuse and breach of contract.

#### Prejudgment Interest

We review a district court's grant of prejudgment interest for an abuse of discretion. *Electro Scientific Indus. v. Gen. Scanning Inc.*, 247 F.3d 1341, 1349 (Fed. Cir. 2001). "A district court abuses its discretion when its decision is based on clearly erroneous findings of fact, is based on erroneous interpretations of the law, or is clearly

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<sup>2</sup> The district court calculated prejudgment interest at the average annual prime rate, compounded quarterly from August 19, 2006 until October 19, 2010. J.A. 17.

unreasonable, arbitrary or fanciful.” *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1460 (Fed. Cir. 1998) (en banc).

The parties dispute whether paragraph 14(ii) of the May 2006 agreement limits Sanofi’s recovery of damages. Paragraph 14 states that if regulatory denial occurs the litigation between the parties will resume and:

If the litigation results in a judgment that the ’265 patent is not invalid or unenforceable, *Sanofi agrees that its actual damages for any past infringement by Apotex, up to the date on which Apotex is enjoined, will be 50% of Apotex’s net sales of clopidogrel products . . . .* Sanofi further agrees that it will not seek increased damages under 35 U.S.C. § 284.

J.A. 693 (emphasis added).

The district court held that paragraph 14(ii) did not bar the award of prejudgment interest. *Sanofi-Aventis*, 748 F. Supp. 2d at 296-97. The district court reasoned that for acts of infringement under 35 U.S.C. § 271(e)(2) courts may award “damages or other monetary relief” pursuant to 35 U.S.C. § 271(e)(4)(C) after there has been a commercial importation or sale of the generic drug. *Id.* The district court determined that such damages are defined by 35 U.S.C. § 284, under which “[d]amages and interest are distinct categories of recovery.” *Id.* at 297. Because the May 2006 agreement only “explicitly limits *damages*” the district court determined that it did not prevent an additional award of “*interest* on those damages” pursuant to § 284. *Id.* at 297. The district court concluded that “[i]n the absence of any agreement to the contrary, the general rule awarding interest on damages in patent infringement actions remains unaltered.” *Id.* at 297.

Apotex contends that the district court abused its discretion by awarding prejudgment interest in addition to the amount of “actual damages” specified in the May 2006 agreement. Apotex argues that the May 2006 agreement, when read as a whole, shows that Sanofi contractually limited its full recovery to 50% of Apotex’s net sales. Apotex contends when the parties contemplated a separate interest payment the May 2006 agreement expressly provided for it. Apotex points to paragraph 10 of the agreement, which defines the amount Sanofi will reimburse Apotex for Apotex’s investment in inventory:

Sanofi will reimburse Apotex for Apotex’s stock of clopidogrel bisulfate bulk and finished goods . . . for a price not to exceed \$40 million, which Apotex represents and warrants is its actual, fully loaded cost for that inventory, as evidenced by documents Apotex will provide. That sum will be payable within 30 days after Regulatory Clearance . . . *with interest from the date of execution of this agreement at an annual interest rate of 6.5%, compounded monthly.*

J.A. 691 (emphasis added).

Sanofi argues that the district court did not abuse its discretion by awarding prejudgment interest. Sanofi contends that because the agreement is silent regarding prejudgment interest, the district court correctly applied the general rule that “prejudgment interest should ordinarily be awarded.” *Gen. Motors Corp. v. Devex Corp.*, 461 U.S. 648, 655 (1983).

Sanofi argues that it is inconsequential that interest is expressly included in paragraph 10 of the May 2006 agreement, but not in paragraph 14. Sanofi contends that absent the contractual language, Apotex would have no statutory right to the interest in connection with reim-

bursements for inventory specified in paragraph 10. In contrast, Sanofi contends that under § 284 it has a statutory right to prejudgment interest that it did not need to preserve in the settlement agreement.

Because the interpretation of a settlement agreement is not an issue unique to patent law, we apply the law of the appropriate regional circuit. *Novamedix, Ltd. v. NDM Acquisition Corp.*, 166 F.3d 1177, 1180 (Fed. Cir. 1999). The Second Circuit reviews the district court's interpretation of a settlement agreement *de novo*. *Hatalmud v. Spellings*, 505 F.3d 139, 145 (2d Cir. 2007).

The parties appear to agree that New York contract law governs the interpretation of the May 2006 agreement. *See* Appellants' Br. 50-51 (citing New York contract law); Appellees' Br. 22 (citing New York contract law). Under New York law a court may interpret a contract as a matter of law without resorting to extrinsic evidence if the contract is straightforward and unambiguous. *Postlewaite v. McGraw-Hill, Inc.*, 411 F.3d 63, 67 (2d Cir. 2005). Even where a contractual term is ambiguous, if the intention of the parties is clear from the four corners of the agreement, interpretation of the contract is a matter of law, and the court may appropriately rule on summary judgment. *See id.*

The parties' dispute hinges on whether paragraph 14(ii) of the May 2006 agreement allows for the imposition of prejudgment interest in addition to "actual damages," or whether the "actual damages" award is the full measure of Sanofi's damages. After reviewing the May 2006 agreement, we conclude that the parties intended that the phrase "actual damages" include all damages necessary to compensate Sanofi for Apotex's infringement. Because prejudgment interest is a form of compensatory

damages, the district court erred by awarding additional prejudgment interest pursuant to 35 U.S.C. § 284.

Courts have long held that prejudgment interest is a form of compensatory relief. “No matter what area of law is considered, prejudgment interest, when awarded, is part of a successful plaintiff’s complete compensation.” *Transmatic, Inc. v. Gulston Indus.*, 180 F.3d 1343, 1347-48 (Fed. Cir. 1999); *see also Oiness v. Walgreen Co.*, 88 F.3d 1025, 1033 (Fed. Cir. 1996) (“Prejudgment interest has no punitive, but only compensatory, purposes. Interest compensates the patent owner for the use of its money between the date of injury and the date of judgment.”). The Supreme Court explained the policy behind awarding prejudgment interest under the patent laws:

An award of *interest* from the time that the royalty payments would have been received *merely serves to make the patent owner whole, since his damages consist not only of the value of the royalty payments but also of the forgone use of the money between the time of infringement and the date of judgment.*

*Gen. Motors Corp.*, 461 U.S. at 655-56 (emphasis added).

The May 2006 agreement supports this interpretation of “actual damages.” By allowing Sanofi “actual damages” but expressly excluding increased damages under the Patent Act, paragraph 14(ii) indicates that the parties intended to account for *all* potential damages at issue:

Sanofi agrees that its actual damages for any past infringement by Apotex, up to the date on which Apotex is enjoined, will be 50% of Apotex’s net sales . . . . Sanofi further agrees that it will not seek increased damages under 35 U.S.C. § 284.

J.A. 693. Increased damages under § 284 are not compensatory in nature but punitive. *See, e.g., Sensonic, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1574 (Fed. Cir. 1996). Thus, the natural reading of paragraph 14(ii) is that Sanofi was entitled to collect 50% of Apotex's net sales as its "actual damages" (*i.e.* compensatory damages), but could not collect any "increased damages" (*i.e.* punitive damages). As the Supreme Court's decision in *General Motors Corp.* makes clear, the patentee's damages consist not only of traditional valuations of patent damages such as a reasonable royalty or the patentee's lost profits, but also prejudgment interest.

Moreover, in a separate section of the agreement, paragraph 10, the parties expressly stated that prejudgment interest should be awarded and the agreement specifically set forth how to calculate such interest. J.A. 691 ("That sum will be payable . . . with interest from the date of execution of this agreement at an annual interest rate of 6.5%, compounded monthly."). We conclude that the May 2006 agreement, taken as a whole, indicates that when the parties agreed upon the amount of "actual damages" they intended this to be the compensatory damages necessary to compensate Sanofi for Apotex's infringement. We interpret the words "actual damages" *in this contract* to be the full measure of all compensatory damages (including prejudgment interest).

Indeed, to construe "actual damages" not to already include prejudgment interest would lead to a result counter to the general purpose of the agreement. *Postlewaite*, 411 F.3d at 67 ("Contracts must be read as a whole, and if possible, courts must interpret them to effect the general purpose of the contract."). By agreeing to a simple formula to quantify Sanofi's "actual damages" in paragraph 14(ii), the parties avoided litigating a potentially complex issue. Such certainty is beneficial to both

parties. Apotex benefited by knowing the exact amount of its potential liability. Sanofi benefited because it could fix damages without having to resort to further litigation, including complex and potentially lengthy discovery. These benefits disappear, however, if prejudgment interest is not included in “actual damages” since – as demonstrated here – the parties must engage in further litigation over an additional large liability.

Sanofi argues that the district court correctly concluded that it did not need to preserve the right to prejudgment interest, because there is a statutory right to interest under 35 U.S.C. § 284. Both parties also make numerous arguments regarding whether the award of prejudgment interest is appropriate in a § 271(e)(2) infringement action based on their interpretation of the term “damages” in 35 U.S.C. §§ 271(e)(4)(C) and 284. While interesting, these arguments neither illuminate nor resolve the issue before us – the meaning of “actual damages” in the May 2006 agreement. The agreed upon “actual damages” are a creature of contract and not of the Patent Act. By entering into the May 2006 agreement, the parties decided that the agreement itself – not § 271(e)(4)(C) or § 284 – would govern the appropriate measure of damages from Apotex’s infringement.

As the district court correctly noted, “[i]n the absence of any agreement to the contrary, the general rule awarding interest on damages in patent infringement actions remains unaltered.” *Sanofi-Aventis*, 748 F. Supp. 2d at 297. Such an agreement exists here. To the extent the parties intended “actual damages” to mean only a reasonable royalty they would have expressly chosen such language as they did in regard to “increased damages.” J.A. 693 (“Sanofi further agrees that it will not seek increased damages under 35 U.S.C. § 284.”). By failing to do so, the parties manifested a clear intent to have the

settlement agreement define the full scope of Sanofi's potential recovery.<sup>3</sup>

The law strongly favors the settlement of all litigation, including patent disputes. *See, e.g., Hemstreet v. Spiegel, Inc.*, 851 F.2d 348, 350 (Fed. Cir. 1988). By agreeing to a formula to calculate Sanofi's "actual damages" in the May 2006 agreement, Sanofi gave up any right to supplement its recovery with additional prejudgment interest. Because the district court erred in its interpretation of the May 2006 agreement, we reverse the district court's award of interest pursuant to 35 U.S.C. § 284.<sup>4</sup>

#### Apotex Inc.'s Liability

After Apotex engaged in the commercial sale of its generic product, Sanofi never amended its complaint to allege either direct infringement under 35 U.S.C. § 271(a) or induced infringement under 35 U.S.C. § 271(b). Instead, Sanofi only alleged that Apotex infringed pursuant to 35 U.S.C. § 271(e)(2) – the infringement provision of the Hatch-Waxman Act. Infringement under § 271(e)(2) "is a hypothetical case that asks the factfinder to determine whether the drug that will be sold upon approval of

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<sup>3</sup> The dissent argues that *Bank of New York v. Amoco Oil Co.*, 35 F.3d 643 (2d Cir. 1994), requires us to award prejudgment interest in this case. In *Bank of New York*, however, the settlement agreement at issue was ambiguous and the court found no clear indication of the parties' intent within the agreement. *Bank of New York*, 35 F.3d at 662. In contrast, in this case the parties' intention to include prejudgment interest in "actual damages" is clear from the four corners of the contract. *Cf. Postlewaite*, 411 F.3d at 67.

<sup>4</sup> Because the district court erred in awarding prejudgment interest, we need not address Apotex's arguments that the district court also erred by awarding interest at the prime rate.

the ANDA will infringe the asserted patent.” *In re Brimonidine Patent Litig.*, 643 F.3d 1366, 1377 (Fed. Cir. 2011). Section 271(e)(4) sets out “the only remedies which may be granted by a court for an act of infringement [under § 271(e)(2).]” Relevant here, the statute sets forth that damages are only available in specific instances, namely:

[D]amages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug . . . .

§ 271(e)(4)(C).

Apotex does not argue that Apotex Inc. is not “an infringer” under § 271(e)(2). However, during the damages phase of the lawsuit, Apotex argued for the first time that Apotex Inc. is not liable for damages, because it never engaged in the “commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug,” as required by § 271(e)(4)(C). Instead, Apotex argued that Apotex Corp. alone imported the drug and made all commercial sales in the United States. Although Apotex Inc. conceded that it manufactured the drug in Canada, Apotex nevertheless argues that Sanofi failed to present any evidence showing that Apotex Inc.’s actions took place in the United States. As a result, Apotex Inc. claims that it cannot be held liable for infringement under § 271(e)(4)(C).

The district court determined that the May 2006 agreement governed the damages at issue, and that both Apotex Inc. and Apotex Corp. were parties to the agreement. *Sanofi-Aventis*, 748 F. Supp. 2d at 295. The district court also noted that Apotex waited until the damages phase of the trial, after the trial on liability

already concluded, “to draw a distinction for these purposes between Apotex Inc. and Apotex Corp., and to assert for the first time a defense to Apotex Inc.’s liability for damages.” *Id.* at n.2.

We agree with the district court that the May 2006 agreement governs liability in this case and need not address Apotex’s statutory arguments. As discussed above, the clear purpose of paragraph 14(ii) of the May 2006 agreement was to define Sanofi’s compensatory damages from Apotex’s infringement. The May 2006 agreement broadly defines “Apotex” to include “Apotex Inc. and Apotex Corp., collectively and individually, and including any entity now or hereafter owned or controlled by any of them.” J.A. 690. Dr. Barry Sherman, the Chairman and CEO of Apotex Inc., signed the agreement on behalf of both Apotex Inc. and Apotex Corp. J.A. 694. Additionally, in the parties’ Stipulated Statement of Facts in the Joint Pre-Trial Order, Apotex admitted that “the acts of Apotex Corp. with respect to the subject matter of this action were done at the direction of, with the authorization of and with the cooperation, participation and assistance of Apotex Inc.” J.A. 2498. Thus, the only logical reading of the May 2006 agreement is that both Apotex Inc. and Apotex Corp. agreed to be jointly and severally liable for Sanofi’s “actual damages.” Therefore, we affirm the district court’s determination that Apotex Inc. is jointly and severally liable for Sanofi’s damages.

#### Apotex’s Supplemental Answer

Although a “court should freely give leave [to amend] when justice so requires,” Fed. R. Civ. P. 15(a), in the Second Circuit “it is within the sound discretion of the district court to grant or deny leave to amend.” *Green v. Mattingly*, 585 F.3d 97, 104 (2d Cir. 2009). The Second Circuit reviews the denial of a motion to amend the

pleadings for an abuse of discretion. *Id.* A district court abuses its discretion if it bases its ruling on an erroneous view of the law or a clearly erroneous assessment of the evidence. *Id.* A district court should grant leave to amend “[i]n the absence of any apparent or declared reason – such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, [or] futility of amendment . . . .” *See Foman v. Davis*, 371 U.S. 178, 182 (1962); *see also McCarthy v. Dun & Broadstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007) (“A district court has discretion to deny leave for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party.”). To the extent the district court bases the denial of leave to amend upon a legal interpretation, the Second Circuit reviews the denial *de novo*. *Spiegel v. Schulmann*, 604 F.3d 72, 78 (2d Cir. 2010).

Apotex argues that the district court abused its discretion by denying Apotex’s leave to amend to add an affirmative defense of patent misuse and a counterclaim for breach of contract. We disagree.

Apotex’s allegations regarding patent misuse arise entirely from BMS’s conduct surrounding its failure to disclose the existence of the oral agreement regarding an authorized generic to the FTC and the consortium of state attorneys general. Apotex contends that under both Federal law and the FTC’s prior judgments, BMS had a duty to inform the FTC of its oral promise not to launch an authorized generic. Apotex argues that BMS’s failure to disclose the oral agreement, despite this affirmative duty to disclose, rises to the level of patent misuse that rendered the ’265 patent unenforceable during the entire period Apotex sold its generic product.

The district court properly rejected Apotex's patent misuse defense as futile. *See Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 55 (2d Cir. 1995) ("One good reason to deny leave to amend is when such leave would be futile."). In *Princo*, 616 F.3d at 1328, we held "that the key inquiry under the patent misuse doctrine is whether . . . the patentee has impermissibly broadened the physical or temporal scope of the patent grant and has done so in a manner that has anticompetitive effects." BMS's failure to disclose the oral side deal with Apotex, and its false certification to the FTC regarding the same, in no way broadened the scope of the '265 patent grant. Although it is perhaps plausible that the scope of the '265 patent grant could have been broadened if the FTC failed to discover BMS's nefarious conduct, such a hypothetical is irrelevant here – the FTC quickly discovered the existence of the oral agreement and BMS's false certification prior to either the FTC or the state attorneys general giving approval to the May 2006 agreement.

Apotex contends that our decision in *Qualcomm Inc. v. Broadcom Corp.*, 548 F.3d 1004, 1021-22 n.8 (Fed. Cir. 2008), supports its argument that a patent may be held unenforceable for the failure to comply with a statutory obligation to disclose information relating to a patent license and settlement agreement. *Qualcomm* is not, however, a case regarding patent misuse, but instead concerns whether a patentee waived its rights to enforce its patents due to its failure to disclose their existence to a standard-setting organization. *Id.* at 1008. *Qualcomm*, therefore, provides no basis for distinguishing our later en banc decision in *Princo*. As we expressly held in *Princo*, "the defense of patent misuse is not available to a presumptive infringer simply because a patentee engages in some kind of wrongful commercial conduct, even conduct that may have anticompetitive effects." 616 F.3d at 1329.

As reprehensible as BMS's actions may be, they do not constitute patent misuse: "Where the patentee has not leveraged its patent beyond the scope of rights grant by the Patent Act, misuse has not been found." *Id.* at 1328.

Next we turn to the district court's decision to deny Apotex's motion to add a counterclaim for breach of contract. Apotex's counterclaim alleges that Sanofi breached the May 2006 agreement by failing to disclose the oral side agreement to the FTC. Specifically, Apotex contends that BMS's failure to disclose the oral agreement breached paragraph 13 of the May 2006 agreement's requirement that both parties "use reasonable efforts" to obtain FTC approval. The district court denied Apotex's motion to add the counterclaim, determining that "it would both delay disposition of this litigation and . . . prejudice Sanofi by requiring it to address an additional area of discovery." J.A. 2.11. Apotex contends that the district court abused its discretion because the judge could have reopened discovery into the contract claim. Apotex notes that seventeen months passed between the time Apotex moved for leave to amend and the district court granted summary judgment on the issue of damages.

A court may deny a motion to amend where it would "significantly delay the resolution of the dispute." *Block v. First Blood Assocs.*, 988 F.2d 344, 350 (2d Cir. 1993). When the district court denied Apotex's motion, the litigation had spanned nearly eight years. In fact, a full trial and appeal on the issue of liability for the patent claims had already occurred. *See Gussack Realty Co. v. Zerox Corp.*, 224 F.3d 85, 94 (2d Cir. 2000) ("Generally, introducing new claims for liability on the last day of trial will prejudice the defendant."). Therefore, we cannot say that the district court abused its discretion when it determined that adding the counterclaim would delay the

resolution of the underlying patent dispute. Furthermore, the denial in no way prejudiced Apotex who has brought a claim against Sanofi for breach of contract in Florida state court. *See Apotex Inc. v. Sanofi-Aventis*, Civ. A. No. CACE11001243 (Fla. Broward County Ct. 2011).

#### CONCLUSION

For the forgoing reasons we reverse the district court's grant of prejudgment interest, we affirm its holding that Apotex Inc. is jointly and severally liable for all damages, and affirm its denial of Apotex's motion for leave to file a supplemental answer, affirmative defenses, and counterclaims.

**REVERSED-IN-PART, AFFIRMED-IN-PART**

#### COSTS

No Costs.

**United States Court of Appeals  
for the Federal Circuit**

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**SANOFI-AVENTIS, SANOFI-SYNTHELABO, INC.,  
AND BRISTOL-MYERS SQUIBB SANOFI  
PHARMACEUTICALS HOLDING PARTNERSHIP,**  
*Plaintiffs-Appellees,*

**v.**

**APOTEX, INC. AND APOTEX CORP.,**  
*Defendants-Appellants.*

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2011-1048

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Appeal from the United States Court for the Southern  
District of New York in Case No. 02-CV-2255, Judge Sidney  
H. Stein.

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NEWMAN, *Circuit Judge*, dissenting in part.

I respectfully dissent from Part I of the court's opinion, which reverses the district court's award of prejudgment interest on the agreed conditional damages. The May 2006 Agreement did not alter the general rule that prejudgment interest is awarded on damages for patent infringement. The general rule does not depend on whether damages are measured by the amount of lost profits, or as a royalty on infringing sales, or, as here, an agreed percentage of sales. Thus, to make the injured party whole, interest is paid on the monetary loss. The district court correctly so recog-

nized. The district court, applying Supreme Court and Federal Circuit precedent, has not been shown to have erred.

The Court explained in *General Motors Corp. v. Devex Corp.*, 461 U.S. 648, 654 (1983), that “prejudgment interest should ordinarily be awarded where necessary to afford the plaintiff full compensation for the infringement.” Federal Circuit precedent has been faithful to this rule, recognizing that the award of prejudgment interest on patent damages is the rule, not the exception. *See, e.g., Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1353 (Fed. Cir. 2009) (“When a patentee asserts a patent claim that is held to be valid and infringed, prejudgment interest is generally awarded.”); *Crystal Semiconductor Corp. v. Tritech Microelectronics Int’l*, 246 F.3d 1336, 1346 (Fed. Cir. 2001) (“the discretion of the district court in denying prejudgment interest is limited to specific circumstances”); *Lummus Indus., Inc. v. D.M. & E. Corp.*, 862 F.2d 267, 275 (Fed. Cir. 1988) (“It is clear from *General Motors* that the withholding of prejudgment interest based on delay is the exception, not the rule . . . .”); *Gyromat Corp. v. Champion Spark Plug Co.*, 735 F.2d 549, 555 (Fed. Cir. 1984) (“the Court’s repeated statements that prejudgment interest ‘should ordinarily be awarded’ indicates that that is the governing principle the Court enunciated”); *Paper Converting Mach. Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 23 (Fed. Cir. 1984) (“Prejudgment interest should *ordinarily* be awarded absent some justification for withholding such an award, *Leinoff v. Louis Milona & Sons, Inc.*, 726 F.2d 734, 743 (Fed. Cir. 1984); it is to compensate for the delay a patentee experiences in obtaining money he would have received sooner if no infringement had occurred, *Central Soya Co. v. Geo. A. Hormel & Co.*, 723 F.2d 1573, 1578 (Fed. Cir. 1983).”).

The district court observed that “[w]hile the Settlement Agreement explicitly limits *damages*, it does not in any way restrict an award of *interest* on those damages.” *Sanofi-Aventis v. Apotex Inc.*, 748 F. Supp. 2d 293, 297 (S.D.N.Y. 2010). Paragraph 14 of the Settlement Agreement states the way damages shall be measured, and does not mention that such damages shall be free of the routine award of interest. The district court correctly interpreted the contract, applying New York contract law and precedent, and held that “[i]n the absence of any agreement to the contrary, the general rule awarding interest on damages in patent infringement actions remains unaltered.” *Sanofi-Aventis*, 748 F. Supp. 2d at 297 (citing 35 U.S.C. §284; *Gen. Motors*, 461 U.S. at 657).

The panel majority proposes that the contract’s silence on prejudgment interest means that the parties intended and agreed, by their silence, to forgo such interest. But as the Court confirmed in *General Motors*, the background rule is that prejudgment interest is awarded on damages for patent infringement, as required by statute. See 6 Corbin on Contracts §26.1 (“The critical concept is that parties apply the background rule if their contract is silent. Assuming that the rule is defeasible, and may be changed by agreement, the parties have the choice of saying nothing and keeping it, or affirmatively modifying or displacing it.”).

If the parties had intended to prevent the award of interest they would have done so explicitly, for the award of interest is the statutory rule, not the exception. *Gen. Motors*, 461 U.S. at 657 (“[P]rejudgment interest should be awarded under §284 absent some justification for withholding such an award.”). Section 284 requires “damages adequate to compensate for the infringement . . . together with interest and costs . . . .” 35 U.S.C. §284.

The panel majority incorrectly states that interest is included in the “actual damages” measured as a percentage of sales. “Actual damages” and “prejudgment interest” are separate categories, as the district court correctly observed. *Sanofi-Aventis*, 748 F. Supp. 2d at 297 (“Damages and interest are distinct categories of recovery.”). Prejudgment interest is awarded on actual damages in order to treat the injured party fairly. In *Beatrice Foods Co. v. New England Printing & Lithographing Co.*, 923 F.2d 1576, 1580 (Fed. Cir. 1991), the court explained that “prejudgment interest can only be applied to the primary or actual damage portion and not to the punitive or enhanced portion,” and that “prejudgment interest is designed ‘to compensate for the delay a patentee experiences in obtaining money he would have received sooner if no infringement occurred,’ while ‘on the other hand, damages are trebled as punishment,’” citing *Paper Converting*, 745 F.2d at 23. *See also Gen. Motors*, 461 U.S. at 655-56 (“An award of interest from the time that the royalty payments would have been received merely serves to make the patent owner whole, since his damages consist not only of the value of the royalty payments but also of the forgone use of the money between the time of infringement and the date of the judgment.”); *Roton Barrier, Inc. v. Stanley Works*, 79 F.3d 1112, 1128 (Fed. Cir. 1996) (awarding actual damages plus prejudgment interest on the actual damages). The parties’ agreement that punitive damages would not be sought was not an agreement to forgo the standard award of interest on the actual damages.

This court must interpret the Settlement Agreement in accordance with the intent of the parties, as required by the law of New York. *See, e.g., Greenfield v. Philles Records, Inc.*, 780 N.E.2d 166, 170 (N.Y. 2002) (“The fundamental, neutral precept of contract interpretation is that agreements are construed in accord with the parties’ intent.”); *Snug Harbor Square Venture v. Never Home Laundry, Inc.*,

675 N.Y.S.2d 365, 366 (App. Div. 1998) (“In construing a contract, the document must be read as a whole to determine the parties’ purpose and intent, giving a practical interpretation to the language employed so that the parties’ reasonable expectations are realized.”). Under New York law, “[w]here one interpretation is broader than another, courts should not apply the broader interpretation absent a clear manifestation of intent.” *Bank of New York v. Amoco Oil Co.*, 35 F.3d 643, 662 (2nd Cir. 1994). In *Bank of New York* the parties had agreed to limit “any recovery of damages” to no more than \$550,000 and did not discuss prejudgment interest in the agreement, and the Second Circuit upheld the award of prejudgment interest such that the total amount exceeded \$550,000, explaining that:

[R]easonable business people could not know with precision how the inclusion of prejudgment interest should affect the level of the cap on damages. After all, neither party could know with precision when final judgment would be rendered . . . . Absent a clear intent to include prejudgment interest within the meaning of “damages,” we think that reasonable businesspeople faced with uncertainty over how much prejudgment interest there would be would exclude prejudgment interest from the meaning of “damages.”

35 F.3d at 662. The Second Circuit’s reasoning is applicable here; the New York district court correctly applied New York law. In contrast, this court’s decision is contrary to New York law, for the panel majority interprets the Settlement Agreement, by its silence concerning interest, as opting out of the general rule that interest is awarded despite the lack of any “clear manifestation of intent” to withhold interest.

Awarding prejudgment interest is not “a result counter to the general purpose of the agreement,” as the panel majority argues. Maj. Op. at 13. The purpose of the Agreement is to state the measure of damages as a specified percentage of sales. That the parties, in a different section of the Agreement dealing with purchase of inventory, expressly provided for payment of interest on those purchases, does not support the panel majority’s theory, for prejudgment interest on sale of inventory is not the established rule, as is prejudgment interest on infringement damages. The district court correctly ruled that “the fact that the parties agreed on an interest rate for one obligation (*see* Settlement Agreement ¶ 10), but not for damages, does not vitiate Sanofi’s statutory right pursuant to section 284 to prejudgment interest.” *Sanofi-Aventis*, 748 F. Supp. 2d at 297.

My colleagues err in reading the contract’s silence on interest for infringement as meaning that the parties intended and agreed to forgo the interest to which the patentee is entitled by statute and precedent. I must, respectfully, dissent.