NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, et al. Plaintiffs, v. SANDOZ, INC. Defendants.	Civil Action No. 07-2762 (JAP) **OPINION**

PISANO, District Judge.

I. Introduction

In this Hatch-Waxman patent infringement action, plaintiffs Sanofi-Aventis U.S. LLC, Sanofi-Aventis, Debiopharm, S.A. (collectively "Sanofi") alleged that defendants Sun Pharmaceutical Industries Ltd. and Caraco Pharmaceutical Laboratories, Ltd. (together, "Sun" or "Defendant") and others infringed United States Patent No. 5,338,874 (the " '874 patent"). The '874 patent relates to the chemical compound oxaliplatin. On October 2, 2009, in response to a motion by Sun to enforce a settlement, this Court found that Sanofi and Sun entered into a settlement agreement resolving all the claims in this litigation. However, a dispute has arisen as to the scope of a particular component of the parties' settlement agreement, as discussed more fully below. An evidentiary hearing on the disputed issue was held, and the Court herein sets forth its findings and conclusions.

II. The Dispute

In 2007, Sanofi sued Sun and several other generic drug manufacturers alleging, *inter alia*, they had infringed the '874 patent relating to oxaliplatin, a drug developed and manufactured by Sanofi and used in the treatment of colorectal cancer. Beginning sometime in 2008, Sanofi and Sun engaged in settlement discussions to resolve the litigation. After many months of negotiations and repeated exchanges of revised drafts of settlement documentation, in June of 2009, the parties reached a settlement agreement.

After the parties had reduced their settlement agreement to writing but prior to the parties obtaining all the requisite signatures on the execution copies, on June 18, 2009, the Court issued a decision granting a motion for summary judgment of noninfringement of the '874 patent. Thereafter, Sanofi refused the consummate the settlement and did not deliver executed copies of the settlement agreement to Sun. Sun moved this Court to enforce the settlement agreement, and the Court granted the motion on October 2, 2009.[1]

The settlement agreement between Sun and Sanofi contained a proposed Consent Judgment and Order and a License Agreement. The proposed Consent Judgment and Order included a provision enjoining Sun from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, their generic oxaliplatin product "absent authorization by Plaintiffs in [Section 3.5 of] the License Agreement."[2] Section 3.5

[1] Subsequently, Sanofi filed a motion asking the Court to find the settlement agreement with Sun unenforceable under the statute of frauds. The Court denied that motion.

[2] In its entirety, paragraph 5 of the original proposed consent judgment and order read as follows:

> Sun, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, the oxaliplatin for injection defined by ANDA No. 78-818 during the life of the '874 and '133 Patents, including any extensions and pediatric exclusivity, absent authorization by Plaintiffs in the License Agreement.

of the License Agreement permitted Sun to launch its generic oxaliplatin product if other defendants went on the market with generic oxaliplatin prior to a "Final Court Decision" (*i.e.*, if other defendants launched "at-risk"). Section 3.5 further provided that if Sun were to launch its product and a Court "subsequently enters a decision(s) enjoining" each of the other defendants from marketing their generic product, Sun was required to come off of the market as well. *See* Ex.18, Section 3.5. The original proposed Consent Judgment and Order that was part of the settlement, however, was never entered by the Court.

On August 7, 2009, the FDA granted final approval of the ANDAs held by Sun and certain other defendants. Some of the defendants began selling their generic oxaliplatin products at that time. Sun launched its generic oxaliplatin product in January 2010, several months after the Court granted Sun's motion and found that a settlement had been reached between Sanofi and Sun.

By early April 2010, Sanofi had reached settlement agreements with each of the other defendants in this case, including those that had already launched at-risk. In accordance with the terms of each of these settlements, the parties requested that the Court make certain factual findings and enter judgments which, among other things, enjoined each of the settling defendants from selling generic oxaliplatin after June 30, 2010. The Court entered these consent judgments on April 14, 2010.

As noted above, the proposed Consent Judgment and Order that originally accompanied the Sanofi/Sun settlement was never entered by the Court. After the Court's decision finding that a binding settlement had been reached between Sanofi and Sun, and in light of the on-going developments in the litigation, Sanofi had presented the Court with an

alternative, revised consent judgment, which, as compared to the original Consent Judgment and Order, added the following finding of fact:

> Under the License Agreement, if an injunction is entered preventing the other defendants from selling their Eloxatin product at risk, then Sun is obligated to stop selling its generic Eloxatin product at risk. If all defendants are enjoined as of June 30, 2010, then Sun will be enjoined as of that date.

D.I. 661, Findings of Fact ¶ 9. Sanofi also revised paragraph 5 of the Consent Judgment and Order, which, as revised, read as follows:

> If all other defendants are enjoined as of June 30, 2010, or on some later date, then Sun, … [is] hereby enjoined as of June 30, 2010 … from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, the oxaliplatin for injection defined by ANDA No. 78-818.

D.I. 661, Consent Judgment and Order ¶ 5. As noted by the Federal Circuit, "[t]he effect of these revisions was to read out the term of Section 3.5 of the [L]icense [A]greement requiring a "decision(s) enjoining" an at-risk launch by the other defendants." *Sanofi-Aventis v. Sandoz, Inc.*, 405 Fed. Appx. 493, 496-497 (Fed. Cir. 2010).

Sun opposed entry of the revised Consent Judgment and Order. Over Sun's objections, on April 22, 2010, the Court entered the revised Consent Judgment proffered by Sanofi. Sun appealed, arguing on appeal that the revised Consent Judgment and Order was inconsistent with Sun's obligations under Section 3.5 of the License Agreement, which allowed Sun to sell generic oxaliplatin unless "a Court subsequently enters a decision(s) enjoining" the other defendants' at-risk launches. In particular, Sun argued that Section 3.5 permits Sun to continue selling generic oxaliplatin even if the other defendants settle and consent to entry of an injunction because an injunction entered by consent is not a final court decision or a decision on the merits and, thus, is not a "decision(s) enjoining." It was Sanofi's contention, on the other hand, that Sun was required under Section 3.5 to cease sales of

generic oxaliplatin even if an injunction was entered as the result of a consent judgments agreed to by the other defendants. Finding that Section 3.5 of the License Agreement was "objectively ambiguous," the Federal Circuit vacated the consent judgment entered by this Court and instructed the Court "to provide the parties an opportunity to conduct discovery and present their evidence as to the proper resolution of the ambiguous language in the license agreement that is incorporated into the parties' original proposed Consent Judgment." 405 Fed. Appx. at 500.

The Federal Circuit has framed the issue to be addressed by this Court as follows:

> [W]hether a "decision" [as contained in the phrase "decision(s) enjoining" in Section 3.5 of the License Agreement] includes a consent judgment and injunction resulting from a settlement between parties or whether it requires an injunction issued by a court following a decision on the merits.

405 Fed. Appx. at 498. It is Sanofi's position that "decision(s) enjoining" under Section 3.5 of the License Agreement means a judicial act – including entry of a consent judgment – that results in an injunction. Sun's position, on the other hand, seems to be something of a moving target. At oral argument, Sun's counsel stated that Sun was "not taking the position that a 'decision' constitutes a decision on the merits with respect to the validity of the patent. ... not taking the position … that a 'decision' means a decision with respect to the validity and enforceability of a patent." Tr. 6:12-13, 20-22. However, Sun stated in its post-hearing brief that "[i]t is Sun's position that 'decision' under Section 3.5 of the License Agreement means a determination on the merits by the Court." Sun's Post-Hearing Proposed Findings of Fact, D.I. 738.

The parties have undertaken the requisite discovery on the issue. An evidentiary hearing was held, and the parties each presented two witnesses. Testifying for Sanofi were

(1) Dominick Conde, Sanofi's outside counsel, who was involved in the settlement negotiations between Sanofi and all defendants including Sun; and (2) Martin Travers, Associate General Counsel for Sanofi at the time of settlement negotiations. Testifying for Sun were (1) Scott Feder, Sun's outside counsel, who was involved the settlement negotiations between Sanofi and Sun; and (2) Dr. Ratnesh Shrivastava,[3] a vice-president at Sun at the time of the settlement negotiations between Sanofi and Sun.

The Court has considered the testimony and documentary evidence introduced by the parties and sets forth herein its findings of fact and conclusion of law. For the reasons below, the Court finds that, contrary to the contentions by Sun, the injunctions entered against the settling defendants fall within the scope of the disputed language of Section 3.5 of the License Agreement.

III. Relevant Legal Principles

1. The language in Section 3.5 of the License Agreement, specifically, "decision(s) enjoining," is ambiguous, as it is reasonably susceptible to two different interpretations. "The language … is ambiguous as to whether 'decision' includes a consent judgment and injunction resulting from a settlement between the parties or whether it requires an injunction issued by the court following a decision on the merits." 405 Fed. Appx. at 498.

2. Under New York law,[4] where the terms of a contract are ambiguous and susceptible of more than one meaning, the court may consider evidence outside of the contract as an aid to interpret the meaning of the language chosen by parties. *See Sayers v. Rochester Tel. Corp. Supplemental Mgmt. Pension Plan*, 7 F.3d 1091, 1095 (2d Cir. 1993). "Parol evidence of conversations, negotiations and agreements made prior to or contemporaneous

[3] Dr. Shrivastava testimony was presented via video deposition.
[4] The parties agree that New York law applies to this dispute.

with the contract in question and relating to the subject matter of the contract, the purpose or object of the contract, or of a specific provision of the contract, and of industry custom and usage, is admissible to explain an ambiguity." *Winston v. Mezzanine Investments, L.P.*, 648 N.Y.S.2d 493, 499 (N.Y. Sup. 1996) (citations omitted). *See also Lawrence v. Cohn*, 197 F. Supp. 2d 16, 25 (S.D.N.Y. 2002) ("In discerning the proper construction of this contractual language, it is useful to explore four questions: (1) Have the parties by their conduct manifested a practical interpretation of the pertinent terms? (2) Is there a recognized custom and usage in the drafting of partnership agreements that give meaning to the pertinent terms? (3) Does case law furnish guidance in the interpretation of the pertinent terms? (4) Can one of the two competing interpretations be characterized as more rational in the context of the overall contractual scheme?); *Rudman v. Cowles Commc'ns, Inc.*, 30 N.Y.2d 1, 11, (1972) (stating that, when a contract is ambiguous, "the court may and should look to the prior negotiations [of the parties] to determine what was intended"); *Kitching v. Brown*, 180 N.Y. 414, 420 (1905) ("One of the familiar rules applicable to the interpretation of ambiguous covenants and agreements is to ascertain, as nearly as may be, the situation of the parties, their surroundings and circumstances, the occasion and apparent object of their stipulations, and from all these sources to gather the meaning and intent of their language.").

3. As both parties point out, ultimately, proper construction of ambiguous contractual language "involves an application of the doctrine of common sense." *Lawrence*, 197 F. Supp. 2d at 25.

4. "[A] contract should not be interpreted to produce a result that is absurd, commercially unreasonable or contrary to the reasonable expectations of the parties." *Greenwich Capital Fin. Prods., Inc. v. Negrin*, 903 N.Y.S.2d 346, 348 (App. Div. 2010).

III. The Parties' Negotiation History as well as the Language and Purpose of the Relevant Documents Establish That The Scope Of The Term "decision(s) enjoining" Is Broad

A. Early Discussions

5. Sanofi initiated settlement talks with each of the defendants in spring of 2008 after the Magistrate Judge ordered the parties to determine whether settlement was possible and instructed Sanofi to submit an *ex parte* report to the Court on status of the settlement negotiations by July 2008. Tr. 24:16-24. Sanofi informed Sun that it was serious about settling the action with Sun as well as each of the other defendants, and provided Sun with a general structure for settlement. Tr. 26:11 to 27:10. Sanofi also informed Sun that this general structure would apply to each defendant and that it was having the same conversation as to the proposed structure with each of the defendants. *Id.*

6. Sanofi further told Sun that any settlement agreement would involve negotiation of a "launch date," *i.e.*, a license agreement in which Sanofi would permit each defendant to sell their generic oxaliplatin product prior to the expiration of the patent exclusivity for Eloxatin. Tr. 26:2 to 27:10. Sanofi informed Sun that all of the defendants would have the same launch date and would be treated equally in that respect. Tr. 26:13-19; 31:14-17. The "launch date" was an essential feature of the settlement because it provided certainty to both Sanofi and the defendants. *See, e.g.*, Tr. 30:11-18.

7. In its settlement negotiations with other defendants, Sanofi was permitted to disclose to the other defendants the launch date agreed to between Sun and Sanofi. Letter of Intent, Ex. 13 at SUNP0004114. The License Agreement expressly permitted Sanofi to disclose the contents of the Settlement Agreement and License Agreement, with the exception

of Section 3.5 of the License Agreement, to the other defendants. License Agreement, Pl. Ex. 18 at 4.4.

8. Sanofi and Sun discussed the benefits that settlement would provide to both parties. Under the general framework of the proposed settlement, Sun and the other defendants would be able to launch their generic products on a date certain before the patents at issue expired. A defendant that did not settle potentially would not be able to get on the market until patent exclusivity for Eloxatin ended. *See* Tr. 30:9 to 31:11. As far as the potential benefit to Sanofi, the settlement would provide a date certain for a generic oxaliplatin launch and Sanofi could anticipate when generic competition would begin.

9. Sanofi informed Sun early in the settlement negotiations that Sanofi understood that each of the defendants would not agree to a launch date unless these defendants received contractual protection in the form of acceleration provisions that protected a defendant from being disadvantaged in the marketplace if one of the other defendants launched their generic product prior to the agreed upon launch date. Tr. 26:11-27 to 27:1; 29:8-15. That is, a defendant would not settle if it had to wait until a specified launch date while others were permitted to launch their generic oxaliplatin product earlier. Sanofi told Sun that it was willing to include such contractual protections so long as Sanofi was not adversely affected in the marketplace. Thus, under the framework anticipated by Sanofi, all of the defendants would go on the market at the same time as any non-settling defendants that launch prior to the launch date. Tr. 31:12-17. Consistent with Sanofi's needs, however, the settlement would also provide that the generics be off of the market for as much as possible. Tr. 31:18-20. It was Sanofi's intent that the agreement provide that either all of the defendants were going to be on the market (thus fulfilling defendants' requirements) or none

of them were going to be on the market until the launch date (thus fulfilling Sanofi's requirements). Tr. 31:20-24.

10. Sun and Sanofi agreed upon an August 9, 2012 launch date (the "Launch Date"), more than 13 months before Eloxatin exclusivity based upon the '874 patent would expire. Tr. 27:24 to 28:24.

A. Letter of Intent and Term Sheet

11. On October 21, 2008, as a precursor to the Settlement Agreement and its attachments, Sanofi sent Sun an initial draft Term Sheet and Letter of Intent. Stip. ¶ 5; Ex. 2.

12. Paragraph 2A of the draft Term Sheet, which was the basis for Section 3.3 of the License Agreement, provided:

> In the event Plaintiffs grant a third-party a license allowing that third-party to sell a generic version of Eloxatin prior to the Launch Date, Sun's Launch Date shall be amended to the earliest date the third party is permitted to begin marketing their generic Eloxatin product.

Initial Draft Term Sheet, Ex. 2.

13. Paragraph 2.B of that draft, which was the basis for Section 3.4 of the License Agreement, provided:

> In the event there is a Court decision in a litigation between Plaintiffs and a third party, from which no appeal has been or can be taken, holding that [the '874 patent] is unenforceable, or that all asserted claims of the '874 patent are invalid, or not infringed ("Final Court Decision") prior to the Launch Date, Sun's Launch Date shall be amended to the date on which that Court decision becomes final.

Initial Draft Term Sheet, Ex. 2.

14. Paragraph 2.C of that draft, which was the basis for Section 3.5 of the License Agreement, provided:

> In the event that any Defendant in the Consolidated Eloxatin Patent Litigation begins marketing a generic version of Eloxatin prior to a Final Court Decision ("At-Risk Launch"), Sun will have the option of marketing its generic equivalent prior to the Launch Date. However, in the event a Court finds at least one of the patents-in-suit valid, enforceable and infringed by such an At-Risk Launch, Sun agrees to pay Plaintiffs damages in an amount equal to Sanofi's gross profit per unit of Eloxatin (calculated using the average gross profit over the six months preceding the At-Risk Launch) multiplied by the number of units sold by Sun. This damage amount will be enhanced commensurate with the any enhanced damages awarded in the At-Risk Launch litigation. Sun also agrees to pay Plaintiffs their attorney fees to enforce this provision. Sun agrees that if this damages provision is held unenforceable, Plaintiffs can seek patent infringement damages in Federal Court against Sun for any sales of generic Eloxatin by Sun after the At-Risk Launch and prior to the Launch Date.

Initial Draft Term Sheet, Ex. 2.

15. In this initial draft Term Sheet, Sanofi did not include any provision requiring Sun to come off of the market in the event Sun launched its generic product. Rather, Sanofi's initial draft was designed to be a disincentive for Sun to launch at all. Tr. 41:23-24.

16. On November 26, 2008, Sun rejected Section 2.C of the initial draft term sheet. On November 29, 2008, Sun proposed the following changes to Section 2.C of the Term Sheet:

> In the event that any Defendant in the Consolidated Eloxatin Patent Litigation begin marketing a generic version of Eloxatin prior to a Final Court Decision ("At-Risk Launch"), Sun will have the option of marketing its generic equivalent prior to the Launch Date. However, in the event a Court finds ~~at least one of~~ the ~~patents-in-suit~~ <u>'874 patent</u> valid, enforceable and infringed by such an At-Risk Launch, Sun agrees ~~to pay Plaintiffs damages in an amount equal to Sanofi's gross profit per unit of Eloxatin (calculated using the average gross profit over the six months preceding the At-Risk Launch) multiplied by the number of units sold by Sun. This damage amount will be enhanced commensurate with the any enhanced damages awarded in the At-Risk Launch litigation. Sun also agrees to pay Plaintiffs their attorney fees to enforce this provision. Sun agrees that if this damages provision is held unenforceable~~, <u>that</u> Plaintiffs can seek patent infringement damages in Federal Court against Sun for any sales of generic Eloxatin by Sun after the At-Risk Launch and prior to

> the Launch Date and Sun agrees to pay damages or reasonable royalty as may be determined by the court.

Ex. 5 (strike-through and underline added).

17. Sun's changes primarily focused on the damages provision, removing the requirement that Sun pay liquidated damages and requiring Sanofi to seek relief in federal court in order to collect damages.

18. Sanofi responded to Sun's proposal on December 8, 2008, and proposed further revisions to Section 2.C, as follows:

> In the event that any Defendant in the Consolidated Eloxatin Patent Litigation begin marketing a generic version of Eloxatin prior to a Final Court Decision ("At-Risk Launch"), Sun will have the option of marketing its generic equivalent prior to the Launch Date. However, in the event a Court ~~finds~~ enters a final court decision, finding the '874 patent valid, enforceable and infringed by such an At- Risk Launch, Sun agrees that if the Court enjoins such product, Sun will cease selling its product and ~~that Plaintiffs can seek patent infringement damages in Federal Court against Sun for any~~ will pay Plaintiffs 90 % of Sun's actual gross profit earned with respect to its sales of Sun's generic version of Eloxatin ~~by Sun~~ after the At-Risk Launch and prior to the Launch Date ~~and Sun agrees to pay damages or reasonable royalty as may be determined by the court~~.

Ex. 6 (strike-through and underline in original).

19. In this second revised draft, because Sun had rejected the provision designed by Sanofi to be a disincentive for Sun to launch, Sanofi introduced the concept of Sun being required to exit the market after an At-Risk Launch. Tr. 42:4-7. As revised by Sanofi, Section 2.C of the Term Sheet provided that "in the event a court enters a final court decision finding that the patent is valid, enforceable and infringed by such an at-risk launch, Sun agrees that if the court enjoins such products, Sun will cease selling the product ..." *Id.*

20. On December 11, 2008, Sun responded with further revisions to Section 2.C:

> In the event that any Defendant(s) in the Consolidated Eloxatin Patent Litigation begin marketing a generic version of Eloxatin prior to a Final Court

> Decision ("At-Risk Launch"), Sun will have the option of marketing its generic equivalent prior to the Launch Date. However, in the event a Court enters a final court decision, finding the '874 patent valid, enforceable and infringed by each such ~~an~~ At-Risk Launch, Sun agrees that if the Court enjoins such product(s) of each such At-Risk Launch, Sun will ~~cease selling~~ not sell its product until the Launch Date and will pay Plaintiffs ~~90~~50% of Sun's actual gross profit earned with respect to its sales of Sun's generic version of Eloxatin after the At-Risk Launch and prior to the Launch Date ~~and Sun agrees to pay damages or reasonable royalty as may be determined by the court~~.

Ex. 8 (strike-through and underline added).

21. In this draft, Sun accepted the requirement that it stop selling its product upon entry of the specified final court decision, and clarified that all defendants must be enjoined for the obligation to arise.

22. Several more drafts of the Term Sheet were exchanged by the parties on December 24, 2008, January 2, 2008 and January 8, 2009. *See* Exs. 10, 11, 12. The remaining revisions focused on the amount of liquidated damages Sun would owe and a Launch Date was agreed upon.

23. In the final executed Term Sheet, exchanged by the parties on January 29, 2009, Section 2.C states, in the relevant part, as follows:

> However, in the event a Court enters a final court decision, finding the '874 patent valid, enforceable and infringed by each such At-Risk Launch, Sun agrees that if the Court enjoins such product(s) of each such At-Risk Launch, Sun will not sell its product(s) until the Launch Date and will pay Plaintiffs 60% of Sun Global's and its distributor Caraco's gross profits earned with respect to its sales of generic version of Eloxatin to third parties after the At-Risk Launch and prior to the Launch Date.

Ex. 13.

B. Settlement Agreement and License Agreement

24. On January 15, 2009, Sanofi sent to Sun an initial draft of the Settlement Agreement and the License Agreement. *See* Ex. 14.

25. The initial draft license included a non-exclusive, royalty-free license permitting Sun to sell its generic oxaliplatin product beginning on the August 9, 2012 Launch Date. *Id.*

26. Sections 3.3, 3.4 and 3.5 of the initial draft license included acceleration provisions and corresponded with sections 2.A, 2.B and 2.C, respectively, on the Term Sheet.

27. Section 3.3 of the initial draft license read as follows:

> **Effect of Granting Certain Licenses to Third Parties.** In the event that Plaintiffs enter into an agreement with any Third Party granting such party a license under the Licensed Patents in the Territory that permit such Third Party to launch a Generic Equivalent of any of the Sanofi NDA products in the Territory Prior to the Launch Date, Plaintiffs shall inform Sun within five (5) business days after entering such an agreement and Sun's Launch Date shall be considered automatically amended to the earliest date any such Third Party is permitted to begin marketing its Generic Equivalent.

Ex. 14.

28. Section 3.4 of the initial draft license read as follows:

> **Effect of Final Court Decisions.** In the event that a Third Party obtains a Final Court Decision of non-infringement and/or invalidity of the '874 Patent and/or holding that the '874 Patent is unenforceable, that permit such Third Party to launch a Generic Equivalent to one or more of the Sanofi NDA products, then the relevant Launch Date shall automatically be amended to the date on which that Court decision becomes final.

Ex. 14.

29. Section 3.5 of the initial draft license read, in the relevant part, as follows:

> **At-Risk-Launch.** In the event that, during the term of the Licensed Patents and without Sanofi's permission, any Defendant in the Consolidated Eloxatin Patent Litigation sells a generic version of a Sanofi NDA Product in the Territory prior to a Final Court Decision ("At-Risk Launch"), Sun will have the option of selling its Generic Equivalent prior to the Launch Date. Should Sun exercise such an option and a Court subsequently enters a decision(s) enjoining each such At-Risk Launch product(s), Sun agrees that Sun will not sell its Generic Equivalent from the time the Court enters an injunction(s) against each such At-Risk Launch Product(s) until the Launch Date, and to pay Plaintiffs 60% of Sun Gross Profits earned with respect to

> sales of Licensed Products to Third Parties after the At-Risk Launch and prior to the Launch Date.

Ex. 14 at SUNP0004087.

30. Sun required these acceleration provisions as part of the settlement. Tr. 29:8-15. Such provisions provided protection for Sun against being left out of the formation of the generic market for oxaliplatin. In accordance with these provisions, if another generic company went on the market with its oxaliplatin product, Sun would be permitted to go on the market as well. Sanofi's counsel advised Sun's counsel that each of the other defendants had the same requirements. Tr. 29:14-15.

31. Section 3.5 of the initial draft license proposed by Sanofi differs from the corresponding section 2.C of the final Term Sheet. In the initial draft of Section 3.5 proposed by Sanofi, Sanofi eliminated the language from the Term Sheet requiring a court to "enter a final court decision, finding the '874 patent valid enforceable and infringed" as the trigger for Sun's obligation to cease sale of its product. Instead, Sanofi's draft of Section 3.5 simply required a court to "enter[] a decision(s) enjoining" each of the defendants who launched at-risk in order to trigger Sun's obligations. Compare Ex. 13 § 2.C to Ex. 14 § 3.5.

32. Sanofi proposed this modification because Sanofi intended "to make Section 3.5 broad and that it would cover any situation where the court entered an injunction, by any means, in which the at-risk launch defendants came off the market." Tr. 53:2-7.

33. Sanofi was willing to grant Sun the option to launch at-risk (upon a non-settling defendant's launch) only if Sanofi received "corresponding protection." Tr. 50:4-24, 53:2-24. That is, while Sun sought the acceleration provisions so it could launch in the event its competitors (*i.e.*, the non-settling defendants) went to market with generic oxaliplatin,

Sanofi sought the converse -- if Sanofi were successful in getting the Sun's competitors off of the market, Sanofi wanted Sun to come off as well. If there was an at-risk launch and Sanofi was successful in enjoining the defendants who launched, Sanofi wanted the benefit of whatever period of Eloxatin exclusivity remained before the August 9, 2012 Launch Date. *Id.* Sanofi wanted to ensure that if it was successful in enjoining the at-risk defendants who launched by any means, all of the defendants would be off of the market.

34. On February 27, 2009, Sun sent a revised draft of the Settlement and License Agreements to Sanofi proposing the following modification to the relevant part of Section 3.5:

> 3.5 At-Risk-Launch. In the event that, during the term of the Licensed Patents and without Sanofi's permission, any Defendant in the Consolidated Eloxatin Patent Litigation sells a generic version of a Sanofi NDA Product in the Territory prior to a Final Court Decision ("At-Risk Launch"), Sun will have the option of selling its Generic Equivalent prior to the Launch Date. Should Sun exercise such an option and a Court subsequently enters a decision(s) enjoining each such At-Risk Launch product(s), Sun agrees that Sun will not sell its Generic Equivalent from the time the Court enters an injunction(s) against each such At-Risk Launch Product(s) until the Launch Date~~, and~~. In the event a Court enters a Final Court Decision finding the '874 patent infringed by each and every Defendant in the Consolidated Eloxatin Patent Litigation that carried out an At-Risk Launch and does not find the '874 patent invalid or unenforceable, Sun agrees to pay Plaintiffs 60% of Sun Global's and its distributor Caraco's Gross Profits earned with respect to sales of Licensed Products to Third Parties after the At-Risk Launch by Sun ("the Sun At-Risk Launch Date") and prior to the Launch Date.

Ex. 15 at SUNP0004841 (strikethrough and underlining added)

35. Sun's changes were incorporated into the final Sun license. Thus, he relevant part of Section 3.5 of the final License Agreement read as follows:

> Should Sun exercise such an option and a Court subsequently enters a decision(s) enjoining each such At-Risk Launch product(s), Sun agrees that

> Sun will not sell its Generic Equivalent from the time the Court enters an injunction(s) against each such At-Risk Launch Product(s) until the Launch Date. In the event a Court enters a Final Court Decision finding the '874 patent infringed by each and every defendant in the Consolidated Eloxatin Patent Litigation that carried out an At-Risk Launch and does not find the '874 patent invalid or unenforceable, Sun agrees to pay Plaintiffs 60% of Sun Global's and its distributor Caraco's Gross Profits earned with respect to sales of Licensed Products to Third Parties after the At-Risk Launch by Sun ("the Sun At-Risk Launch Date") and prior to the Launch Date.

Ex. 18 § 3.5.

36. Significantly, Sun's modification to Sanofi's initial draft of Section 3.5 separated the condition that would trigger the requirement that Sun pay damages to Sanofi from the condition that would trigger the requirement that Sun pull its oxaliplatin product from the market. As modified, Sun's obligation to pay damages to Sanofi would be triggered only by a final decision on the merits of the issues in the litigation. In contrast, any "decision(s) enjoining" the other at-risk launchers would trigger the requirement that Sun pull its product from the market.

37. In responding to Sanofi's initial draft of Section 3.5, Sun did not suggest modifying or narrowing the phrase "decision(s) enjoining" by, for example, adding the more limited language of Section 2.C of the Term Sheet that would have required "a final court decision, finding the '874 patent valid, enforceable and infringed."

38. Counsel for Sun and Sanofi discussed the meaning of "decision(s) enjoining" and Sanofi's counsel specifically explained that the phrase as it appeared in the initial draft license was deliberately broader than what was in the Term Sheet because Sanofi wanted to be sure it covered "every situation where the court entered an injunction in which the defendants came off the market," Tr. 58:19-23. This was consistent with the overall purpose of that language in that section, which appears to be that either all defendants could be on the

generic oxaliplatin market before the Launch Date or that none would be on the market before that date. There is no indication in the language of the agreement or in the history of the negotiations between the parties that the parties ever intended there be a circumstance where Sun would remain on the market after Sanofi successfully enjoined the at-risk launches.

39. Sun's counsel, Mr. Feder, does not deny that Sanofi's counsel, Mr. Conde, advised him that Sanofi had intentionally revised the relevant language in the License Agreement to make it significantly broader than the Term Sheet, but rather Mr. Feder testified that he did not recall such a conversation. Tr. 122:21 to 123:1. Mr. Feder stated that he believed that would remember such conversations if they occurred because, given that Eloxatin's annual sales were between $1 and $2 billion, "it was just not conceivable" to him that Sanofi would settle, rather than "litigate and win and get an injunction," if any defendants launched at risk. Tr. 122:25 to 123:1; 122:13-20.

40. Mr. Feder's explanation does not address why he believes he would recall the conversations at issue, nor does he explain why settlement with other defendants would no longer be an possible after an at-risk launch. Additionally, his assertion that a settlement was "not conceivable" is undercut by the fact that, although Sanofi was engaged in the process of litigating against at-risk launchers at the time the Sanofi and the remaining defendants settled, settlement is what ultimately occurred.

41. While Sun has taken the position that a "decision(s) enjoining" requires a decision on the merits, Sun's witnesses have somewhat inconsistent understandings of what that means. Dr. Shrivastava testified that a "decision enjoining" does not include a preliminary injunction. Ex. 72 at 37:4-6. Mr. Feder testified that it could include a preliminary injunction. See Tr. 148:21 to 150:8. This discrepancy indicates to the Court that

these parties did not discuss the provision in any detail and that during negotiations it was not something with which Sun was particularly concerned.

42. Based on the documents and testimony, Sun's primary focus while negotiating Section 3.5 revolved around the conditions under which Sun would be required to pay damages to Sanofi for an at-risk launch. Sun was not concerned with the clarifying or narrowing the conditions under which Sun would be required to cease selling its generic product. Sanofi, on the other hand, sought to ensure that the scope of the trigger requiring Sun to cease its generic product sales was broad. There is no rational basis to believe that Sanofi would agree to exclude from that scope the possibility of settlement with defendants who launched at-risk. Sun accepted Sanofi's modification to Section 3.5 that deliberately expanded the triggering event requiring Sun to cease sales from "a final court decision, finding the '874 patent valid, enforceable and infringed" to "a decision(s) enjoining."

43. Thus, the Court finds that the overall conduct of the settlement negotiations as well as the language and purpose of the relevant documents show that the parties intended the phrase "decision(s) enjoining" to be construed broadly.

IV. The Term "decision(s) enjoining" is not Limited to a Decision on the Merits

44. The Court further finds, contrary to the contention of Sun, that "decision(s) enjoining" is not limited to decisions on the merits. As an initial matter, it is notable that Black's Law Dictionary contains separate entries for the terms "decision" and "decision on merits," indicating that as a general matter that a "decision" need not involve adjudication of the merits. Moreover, "decision" is a term that has a very broad meaning:

> **Decision**. A determination arrived at after consideration of facts, and, in legal context, law. A popular rather than technical or legal word; a comprehensive

> term having no fixed, legal meaning. It may be employed as referring to ministerial acts as well as to those that are judicial or of a judicial character.
>
> A determination of a judicial or quasi judicial nature. A judgment, decree, or order pronounced by a court in settlement of a controversy submitted to it and by way of authoritative answer to the questions raised before it. The term is broad enough to cover both final judgments and interlocutory orders. And though sometimes limited to the sense of judgment, the term is at other times understood as meaning simply the first step leading to a judgment; or as an order for judgment. The word may also include various rulings, as well as orders, including agency and commission orders.
>
> The findings of fact and conclusions of law which must be in writing and filed with the clerk.
>
> 'Decision' is not necessarily synonymous with 'opinion.' A decision of the court is its judgment; the opinion is the reasons given for that judgment, or the expression of the views of the judge. But the two words are sometimes used interchangeably.

Black's Law Dictionary 407 (6th ed. 1990) (citations omitted). This dictionary definition was consulted by Sanofi's counsel during the negotiations of the License Agreement. Sanofi's counsel testified that Sanofi would not have settled if it believed that "decision(s) enjoining" was limited to a decision on the merits. Tr. 61:24 to 66:14.

45. Further, a comparison of the language in the parties' January 2009 Term Sheet and the final License Agreement show that "decision(s) enjoining" was not intended to be limited to a decision on the merits. The Term Sheet requires that Sun cease selling its generic product and pay Sanofi damages if the "Court enters a final court decision, finding the '874 patent valid, enforceable and infringed" -- that is, if the Court were to enter a decision on the merits. With respect to Sun's requirement to cease selling its product, this language was intentionally eliminated in the final License Agreement in favor of the broader phrase "decision(s) enjoining."

46. In the Term Sheet, a single sentence defines Sun's obligation to cease its generic oxaliplatin sales and pay damages to Sanofi on the sales made. In that sentence, both of these obligations arise in the event of "a final court decision, finding the '874 patent valid, enforceable and infringed." Ex. 13 § 2.C. However, as discussed above, Sun revisions to the final License Agreement including breaking down these obligations in two separate sentences; one sentence defining Sun's obligation to cease sales of its product and the other sentence defining the circumstances under which Sun must pay damages to Sanofi. The first sentence requires Sun to stop selling its product if the Court enters a "decision(s) enjoining." The second sentence requires Sun to pay damages under more limited circumstances; *i.e.*, entry of a "Final Court Decision" finding the '874 patent infringed and not finding the patent invalid or unenforceable. *See* Ex. 18 § 3.5. Thus, because the second sentence is expressly limited to decisions on the merits, it is clear that the parties intended that the first sentence not be limited to the same.

47. Testimony by Sun's witnesses that the difference between the two sentences is merely one regarding the finality of the "decision" is contradicted by a plain, logical reading of the sentences as well as the negotiation history and purposes of the agreement as discussed above. *See* Tr. 125:24 to 126:4 (testifying that "decision" means the same thing in both sentences); Ex. 72 at 38:18 to 39:23 (testifying that "decision" in both sentences means a decision on the merits; "decision" in second sentence is one from which no appeal can be taken). If the interpretation expressed by Sun's witnesses were correct, there would have been no need for Sun to modify the second sentence so as to specify that the court decision at issue had to be one finding the '874 patent infringed and not finding the patent invalid or unenforceable. Said another way, if Sun had believed that "decision" as used in the first

sentence was limited to a decision on the merits, there would have been no reason for Sun to specify in the second sentence that the decision had to be a decision on the merits.

48. It is clear that the purpose of the License Agreement is to allow Sun to bring its generic oxaliplatin product to market more than a year earlier than would be possible if it litigated and lost and were required to wait until expiration of the '874 patent, and for Sanofi to obtain certainty as to the remaining period of exclusivity for its Eloxatin product. Section 3.5 provides a mechanism by which Sanofi could regain exclusivity after at-risk launches are enjoined. Interpreting "decision(s) enjoining" to require only a decision on the merits would be inconsistent with this purpose.

V. Conclusion

49. In light of the Court's findings that "decision(s) enjoining" was intended to be interpreted broadly and is not limited to decisions on the merits, and given the broad general understanding of the term "decision" in the legal context, the Court construes "decision(s) enjoining" to mean a judicial act that results in an injunction. As such, the Court finds that the term "decision(s) enjoining" as used in Section 3.5 of the License Agreement includes the consent judgments containing injunctions that have been entered by this Court. The Court shall reinstate the Judgment entered on April 22, 2010. An appropriate Order accompanies this Opinion.

/s/ JOEL A. PISANO
United States District Judge

Dated: September 15, 2011