NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

SANOFI-AVENTIS, SANOFI-AVENTIS U.S. LLC, AND DEBIOPHARM, S.A.,
Plaintiffs-Appellees,

v.

SANDOZ, INC., TEVA PARENTERAL MEDICINES, INC.,
TEVA PHARMACEUTICALS USA, INC., DABUR ONCOLOGY PLC,
DABUR PHARMA LIMITED, FRESENIUS KABI ONCOLOGY, PHARMACHEMIE B.V.,
ACTAVIS TOTOWA LLC, ACTAVIS, INC., ACTAVIS GROUP HF,
MUSTAFA NEVZAT ILAC SANAYII A.S. (ALSO KNOWN AS MN PHARMACEUTICALS),
PAR PHARMACEUTICAL COMPANIES, INC., PAR PHARMACEUTICAL, INC.,
W.C. HERAEUS GMBH, ABRAXIS BIOSCIENCE, INC.,
APP PHARMACEUTICALS LLC, NEW ABRAXIS, INC., MAYNE PHARMA LIMITED,
MAYNE PHARMA (USA), INC., HOSPIRA AUSTRALIA PTY LTD, HOSPIRA, INC.,
AND FRESENIUS KABI PHARMA LIMITED,
Defendants,

and

SUN PHARMACEUTICAL INDUSTRIES, LTD. AND

CARACO PHARMACEUTICAL LABORATORIES, LTD.,
Defendants-Appellants.

2010-1338

Appeal from the United States District Court for the District of New Jersey in consolidated case no. 07-CV-2762, Judge Joel A. Pisano.

Decided: December 22, 2010

DOMINICK A. CONDE, Fitzpatrick, Cella, Harper & Scinto, of New York, New York, argued for plaintiffs-appellees. With him on the brief were WILLIAM E. SOLANDER, and NINA SHREVE.

DANIEL P. SHAPIRO, Katten Muchin & Rosenman LLP, of Chicago, Illinois, argued for defendants-appellants. With him on the brief were HEATHER J. KUHN O'TOOLE, AHARON S. KAYE and JENNIFER M. SABA.

Before DYK, PROST, and MOORE, *Circuit Judges*.

PROST, *Circuit Judge*.

Defendants-Appellants Sun Pharmaceutical Industries, Ltd. and Caraco Pharmaceutical Laboratories, Ltd. (collectively "Sun") appeal the district court's entry of consent judgment and an injunction enjoining it from the manufacture and sale of generic oxaliplatin. Plaintiffs-Appellees Sanofi-Aventis, Sanofi-Aventis U.S. LLC, and Debiopharm, S.A. (collectively "Sanofi") oppose and Sun replies. We *vacate* entry of both the consent judgment and the injunction and we *remand* for further proceedings.

BACKGROUND

Sanofi filed suit on July 23, 2007 based, in part, on Sun's filing of an Abbreviated New Drug Application ("ANDA") for a generic version of the colorectal cancer drug oxaliplatin. Around the same time, Sanofi also sued other various generic drug manufacturers based on related ANDA filings for a generic version of oxaliplatin. Sanofi and Sun entered into settlement negotiations and agreed upon non-binding terms in January 2009. These negotiations contemplated that other defendants might commence an at-risk launch (a launch before a final court decision) of their products. The term sheet included provisions regarding acceleration of Sun's Launch Date (the later of August 9, 2012 or the day on which Sun receives final FDA approval) of the generic drug and exceptions that would prevent Sun from launching before that date. One of the exceptions provided:

> 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 . . . .

J.A. 209 (emphasis added). Following a series of negotiations to determine the final terms to be incorporated in the settlement documents, the license agreement included a section corresponding to the term sheet provision quoted above. Specifically, Section 3.5 of the license agreement provided:

> **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.

J.A. 237–38 (emphasis added). The parties completed their negotiations and reached a final agreement on June 16, 2009.

Attached to the settlement documents submitted to the district court was a proposed consent judgment and order agreed upon by both parties. The proposed consent judgment and order included a provision at Paragraph 5 that defined the scope of an injunction preventing Sun from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, the generic drug "absent authorization by Plain-

tiffs in the License Agreement" under Section 3.5. The effect of this provision was to incorporate by reference the language in Section 3.5 of the license agreement. The language of Section 3.5 allowed Sun to market its version of the generic drug if other defendants were also on the market prior to a "Final Court Decision" in the suit against other defendants. However, Sun would thereafter be enjoined from marketing its version of the generic drug if a court entered a "decision(s) enjoining" defendants from marketing their "At-Risk-Launch products." In sum, if generic drug manufacturers were marketing a generic version of oxaliplatin, Sun could also market its version. If a "Court subsequently enter[ed] a decision(s) enjoining" other generic manufacturers from marketing a generic version of oxaliplatin, Sun would also be enjoined.

Two days after Sanofi and Sun reached a settlement agreement, the district court denied summary judgment of invalidity but granted summary judgment of non-infringement of U.S. Patent No. 5,338,874. *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 07-2762, 2009 WL 1741571, at *1 (D.N.J. June 18, 2009). Thereafter, Sanofi refused to deliver a fully-executed version of the agreed-upon settlement documents to Sun. A series of challenges to the original settlement agreement ensued.

On July 22, 2009, Sun filed a Motion for Miscellaneous Relief requesting the district court recognize that a binding settlement agreement had been reached between Sanofi and Sun. The court granted Sun's motion, holding that "[t]he Court finds that the parties reached a binding settlement agreement." *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 07-2762, 2009 WL 3230867, at *2 (D.N.J. Oct. 2, 2009). Having lost that challenge, one week later, Sanofi filed a motion requesting an Order that the Sun settlement agreement was unenforceable under

the statute of frauds. Sanofi also requested that the court defer entry of the Consent Judgment until after deciding its pending motion. The court denied that motion, confirming that the settlement agreement was enforceable. *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 07-2762, 2010 WL 697367, at *2 (D.N.J. Mar. 1, 2010).

While the parties worked through challenges to the enforceability of the original settlement agreement, other defendants launched at-risk versions of generic oxaliplatin in August 2009. *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, 345 Fed. Appx. 594, 596 (Fed. Cir. 2009). Following at-risk launches by other defendants, in January 2010, Sun launched a licensed version of generic oxaliplatin pursuant to the settlement and license agreements reached with Sanofi on June 16, 2009. Thereafter, Sanofi executed settlement agreements with various defendants. Each settlement included a proposed consent order with a specific provision requiring that Sun be enjoined from marketing a generic equivalent of oxaliplatin by June 30, 2010. They also provided that if Sun were not enjoined by various dates after June 30, 2010, the other generic defendants could reenter the market. Before those consent judgments were entered, however, Sanofi contacted Sun to determine whether Sun would immediately cease sales of the generic drug upon entry of injunctions against the other defendants pursuant to consent judgments. Sun responded that it would comply with the terms of the previously negotiated settlement and license agreements, but did not affirmatively indicate that it would cease generic sales. Sun also reminded the district court by letter that it had not yet entered the Consent Judgment agreed upon by the parties that was attached to the original settlement agreement.

Because of the ongoing uncertainty regarding the obligations created by the license agreement terms, Sanofi sent several letters to the district court seeking entry of a revised version of the Consent Judgment. In a March 26, 2010 letter to the court, Sanofi stated that "[its] version of the Consent Judgment takes full account of the current status of the litigation, finally resolves the issues between the Plaintiffs and Sun, and most important, clarifies Sun's obligations under the Settlement Agreement and License Agreement as incorporated into the Consent Judgment." J.A. 467. Sanofi's unilateral revision to the findings of fact that accompanied its revised Consent Judgment included a provision stating that "[u]nder the License Agreement, if an injunction [was] entered preventing the other defendants from selling their Eloxatin product at risk, then Sun [was] obligated to stop selling its generic Eloxatin product at risk." J.A. 473. Sanofi also altered the terms of Paragraph 5 of the Consent Judgment and Order. The effect of these revisions was to read out the term of Section 3.5 of the license agreement requiring a "decision(s) enjoining" an at-risk launch by the other defendants. *Compare* J.A. 227–30 *with* J.A. 471–74 and J.A. 237–38. Sanofi further notified the district court that if Sun was not enjoined, the injunctions imposed by consent judgments reached upon settlement with other defendants would be lifted, allowing them to resume marketing of generic oxaliplatin.

Sun responded to Sanofi's letters to the court with letters of its own on March 31, 2010, and April 15, 2010. Sun noted to the court that Sanofi's request urged the court to enter a Consent Judgment that was not the same Consent Judgment agreed upon by the parties pursuant to the settlement documents. Thus, Sun opposed entry of the revised Consent Judgment. Sun also noted that if Sanofi elected to continue its efforts to revise the Consent

Order, Sun would "cooperate with the Court to establish an appropriate schedule for briefing and for presentation of evidence and argument to uphold the Consent Order agreed to by the parties." J.A. 551.

On April 22, 2010, the district court entered the Findings of Fact and Consent Judgment and Order proposed by Sanofi but opposed by Sun.[1] J.A. 1–4. The district court did not allow for additional discovery or conduct a formal hearing prior to entering the opposed Consent Judgment. Sun timely appealed entry of the revised Findings of Fact and Consent Judgment and Order. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

On appeal, Sun argues that the district court erred by entering a consent judgment to which it did not agree. The entered consent judgment, Sun argues, is inconsistent with its obligations under the license agreement, which allows it to sell generic oxaliplatin unless "a Court subsequently enters a decision(s) enjoining" the other defendants' at-risk launches. Sanofi asserts that the language of Section 3.5 of the license agreement is "clear and unambiguous," and that the court correctly determined that Sun was required to cease sales of generic oxaliplatin "'from the time the Court enters injunction(s)'" against other defendants' at-risk products. Appellee Br. 20–21, 31. Therefore, in Sanofi's view, the revised Consent Judgment was correctly entered because it is consistent with the parties' license agreement. Sun disagrees

[1] Failure to enjoin Sun could have rendered "null and void" the executed settlement agreements and entered Consent Judgments and Orders enjoining the other defendants from selling generic oxaliplatin. *See* J.A. 476–482.

with Sanofi's interpretation, however, and further argues that its due process rights were violated when the district court enter a contested consent judgment and injunction without affording Sun a meaningful hearing regarding the ambiguity as to its obligations under the license agreement and proposed consent judgment. Appellant Reply Br. 3.

"Generally, interpretation of a settlement agreement is not an issue unique to patent law, even if arising in the context of a patent infringement suit." *Novamedix, Ltd. v. NDM Acquisition Corp.,* 166 F.3d 1177, 1180 (Fed. Cir. 1999). Accordingly, we apply the law of the appropriate regional circuit, which in this case is the Third Circuit. The Third Circuit views consent decrees as being analogous to contracts. *United States v. New Jersey*, 194 F.3d 426, 430 (3d Cir. 1999). Thus, traditional principles of contract interpretation apply. *See Fox v. U.S. Dep't of Hous. & Urban Dev.,* 680 F.2d 315, 319 (3d Cir. 1982) (citing *United States v. ITT Cont'l Baking Co.,* 420 U.S. 223, 236–38 (1975)). Under those traditional principles, "resort to extrinsic evidence is permissible, but only when the decree itself is ambiguous, although circumstances surrounding its formation are always relevant to its meaning." *See Fox*, 680 F.2d at 319–20. Whether extrinsic evidence is required to interpret a consent decree is itself a question of law that is reviewed de novo. *See id.* at 320.

I. Ambiguity

Sanofi argues that Section 3.5 of the license agreement is clear and unambiguous regarding Sun's obligations under the language of the provision. Specifically, it focuses on a portion of the language in the section requiring that "Sun will not sell its Generic Equivalent from the

time the Court enters an injunction(s) against" each of the other defendants' at-risk launch of generic oxaliplatin. Sanofi contends that this language requires Sun to cease generic sales of oxaliplatin when injunctions are entered against other defendants that launched at risk. Sanofi further argues that the operative language of Section 3.5 is not "decision(s) enjoining," but is instead "from the time the Court enters an injunction(s)." Under Sanofi's interpretation, Sun must cease sales of generic oxaliplatin after entry of an injunction against the other defendants—even if the injunction is the result of a consent judgment agreed to by any particular defendant. Sanofi contends that, in context, the term "decision(s) enjoining" is synonymous with "orders enjoining" or "judgments enjoining." Sanofi suggests that there is no reason to interpret the license agreement in a manner where Sun would only be obligated to exit the market when the other defendants were enjoined following a judicial decision on the merits as opposed to being enjoined upon entry of a consent judgment. Alternatively, Sanofi argues that if the operative language of Section 3.5 is "decision(s) enjoining," then the language clearly includes consent judgments because consent judgments are "decisions of the court." Appellee Br. 27.

Sun disagrees with Sanofi's interpretation of the meaning of Section 3.5 of the license agreement. Sun argues that Sanofi focuses on a limited portion of the language in Section 3.5 while ignoring the requirement that the injunction against other defendants' at-risk sales be predicated by a "Court . . . decision(s) enjoining" those defendants. Appellant Reply Br. 11–12. Sun contends that consideration of the entirety of Section 3.5 indicates that Sun has a right to continue selling generic oxaliplatin, even if other defendants settle and consent to an injunction, because an injunction entered by consent is

not the result of a court decision. Sun equates the language of the agreement—"decision(s) enjoining"—with a final court decision or decision on the merits. Sun further argues that it would be unreasonable to interpret the agreement so that its right to sell generic oxaliplatin under license would be susceptible to the business whims of other defendants that might choose to settle by consent, rather than litigate, for any number of reasons.

We find that Section 3.5 of the license agreement is objectively ambiguous. *See New Jersey*, 194 F.3d at 430 ("[A] provision in a decree is ambiguous only when, from an objective standpoint, it is reasonably susceptible to at least two different interpretations."). The language "decision(s) enjoining" in Section 3.5 is ambiguous as to whether a "decision" 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. The settlement agreement is not drafted to prevent sales by Sun whenever the defendants were barred from selling; Sanofi agrees, for example, that Sun could continue to sell if the defendants had agreed to cease sales without a court order. Thus, the disputed language is reasonably susceptible to two different interpretations.

The negotiation history further supports the objective ambiguity of the disputed language in the agreement. After negotiating the material terms of the license agreement, the parties drafted a term sheet memorializing the initial agreed-upon terms. The term sheet noted that Sun agreed to cease sales of generic oxaliplatin following a "final court decision" enjoining at-risk sales by the other defendants. Thereafter, the parties continued to negotiate the finer points of the final agreement. During negotiation of the final terms, however, the language changed

to require a "decision(s) enjoining" the other defendants before Sun was required to cease manufacture and sale of generic oxaliplatin. *Compare* J.A. 209 *with* J.A. 227–28. Sanofi's arguments notwithstanding, the parties directly dispute the meaning and effect of the "decision(s) enjoining" language in Section 3.5 of the license agreement. Sanofi argues that the language clearly includes consent judgments, while Sun argues that a consent judgment is not the result of judicial decision. One need not look beyond the parties' diametrically opposite arguments to determine that the term "decision(s) enjoining" is ambiguous. Even so, additional evidence informs the ambiguity analysis.

Sanofi has repeatedly challenged its settlement agreement with Sun. Just days after reaching a binding settlement, Sanofi refused to return fully-executed settlement documents to Sun. After losing that battle, Sanofi challenged the enforceability of the settlement agreement. It lost that battle as well. Undeterred, however, Sanofi set out on a course to rewrite the proposed Consent Judgment and Order. Regarding its justification for altering the agreed-upon Consent Judgment, Sanofi represented to the district court that "most important, it *clarifies* Sun's obligations under the Settlement Agreement and License Agreement as incorporated into the Consent Judgment." J.A. 612. Sanofi then received what it desired: a Consent Judgment entered by the district court—under protest by Sun—enjoining Sun from marketing generic oxaliplatin based on Sanofi's negotiated settlement agreements and injunctions entered into with other defendants. With its victory at hand, Sanofi now represents to this court that the license agreement is clear and unambiguous, despite its earlier need to "clarif[y] Sun's obligations." J.A. 612; Appellee Br. 23.

Sanofi's own recognition that the agreement required clarification is itself powerful evidence of ambiguity.

II. Contested Consent Judgment

In light of this ambiguity, Sun urges, at a minimum, that the district court erred by refusing to allow discovery and an evidentiary hearing before entering a consent judgment to which it did not consent. Sun points out that Sanofi does not dispute that parol evidence may be used to interpret an ambiguous agreement. Sun also contends that Sanofi implicitly admits that Section 3.5 is ambiguous because it attempted to renegotiate the original proposed Consent Order and submitted a revised Consent Order to the district court. Appellant Reply Br. 15.

Sanofi argues that the district court did not err because it simply enforced the parties' contractual settlement obligations and entered a consent judgment consistent with those obligations. Sanofi asserts that under our precedent, the district court had "inherent power summarily to enforce a settlement agreement," which included the power to enter a consent judgment that was consistent with the settlement terms. Appellee Br. 39. Sanofi also maintains that Sun's arguments against entry of the revised consent judgment were fully and fairly heard in view of several letters written to the judge and a "hearing" the day before the district court entered the Consent Judgment.

We agree with Sun. The district court erred by entering the contested Consent Judgment. The precedent cited by Sanofi does not give a court inherent authority to enter a contested Consent Judgment without a full and fair hearing as to material disputed language of the agreement. *See Core-Vent Corp. v. Implant Innovations, Inc.*,

53 F.3d 1252, 1259 (Fed. Cir. 1995) (noting that courts have inherent authority to summarily enforce a settlement agreement where "there were not disputed issues of material fact that required a hearing."). Sun was denied the opportunity to conduct formal discovery and gather evidence regarding the proper interpretation of material language in the license agreement. Sun was also denied the opportunity to submit its arguments either in formal briefing or during a hearing on the record. The Supreme Court has recognized that "[c]onsent decrees are entered into by parties to a case after careful negotiation has produced agreement on their precise terms . . . and the resultant decree embodies as much of those opposing purposes as the respective parties have the bargaining power and skill to achieve." *United States v. Armour & Co.*, 402 U.S. 673, 681 (1971). "[I]t is the parties' agreement that serves as the source of the court's authority to enter any judgment at all." *Local No. 93 v. City of Cleveland,* 478 U.S. 501, 522 (1986); *Harris v. Pernsley,* 820 F.2d 592, 603 (3d Cir. 1987) ("The source of the district court's authority to enter a consent decree is the parties' agreement."). Where a court enters a Consent Judgment and Order that is not the product of an agreement by the parties, entry of that Consent Judgment—without consent—is improper. *See, e.g.*, *Keen v. Adler*, 65 F. App'x. 408 (3d Cir. 2003) ("[W]ithout the consent of the parties to the settlement, a court lacks the power to enter a judgment purportedly based on consent.") (citing *Reynolds v. Roberts*, 251 F.3d 1350, 1357 (11th Cir. 2001)).

CONCLUSION

A court errs when it enters a contested consent judgment despite repeated protests and disagreement over the interpretation and effect of material terms defining the obligations of a party. Material terms of a consent judg-

ment that are objectively ambiguous and clearly contested prior to entry of the consent judgment require a determination by the court as to the parties' obligations under those terms before entry of that revised consent judgment. Because entry of the contested consent judgment was improper, we vacate the Consent Judgment and Order and resulting injunction. The district court is instructed 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. We remand the case for further proceedings consistent with this opinion.

VACATED AND REMANDED