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SUPERIOR COURT OF NEW JERSEY
APPELLATE DIVISION
DOCKET NO. A-2692-13T4

NOVEL LABORATORIES, INC.,

Plaintiff-Respondent,

v.

MUTHUSAMY SHANMUGAM,

Defendant,

and

KVK-TECH, INC. and
AMRUTHAM, INC.,

Defendants-Appellants.

Submitted January 14, 2015 - Decided February 3, 2015

Before Judges Maven and Carroll.

On appeal from the Superior Court of New Jersey, Chancery Division, General Equity Part, Somerset County, Docket No. C-12009-11.

Klehr Harrison Harvey Branzburg LLP, attorneys for appellants (William T. Hill, on the briefs).

Hillel I. Parness, attorney for respondent.

PER CURIAM

This appeal has its genesis in a dispute between rival pharmaceutical companies that initially sought to develop

generic versions of a brand-name drug known as SUPREP. Braintree Laboratories, Inc. (Braintree) owns the patent on the drug, a berry-flavored liquid laxative used in cleansing the bowel prior to a colonoscopy. Defendants KVK-Tech, Inc. (KVK) and Amrutham, Inc. (Amrutham) appeal from an October 10, 2013 Chancery Division order enforcing their settlement with plaintiff Novel Laboratories, Inc. (Novel). The agreement required defendants to withdraw their application to develop a powder-based form of SUPREP, and barred them from further filing applications relating to formulations of any kind of SUPREP. Defendants also appeal from a February 3, 2014 order denying reconsideration. After reviewing the record in light of the contentions advanced on appeal, we affirm.

I.

On August 5, 2010, the Food and Drug Administration (FDA) approved Braintree's SUPREP Bowel Test Kit under NDA No. N022372.[1] The FDA listed SUPREP in its "Orange Book," thereby notifying the pharmaceutical industry that the generic

[1] The federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 355(a), requires that a "New Drug Application" (NDA) must be filed in connection with the development of a new drug. An NDA must include "full reports of investigations which have been made to show" the new drug's efficacy and safety, the methodologies used to test it, its composition, and samples of the drug. 21 U.S.C.A. § 355(a).

equivalents of the drug could be developed and including the precise weights of SUPREP's active ingredients.

After the FDA listed SUPREP in the Orange Book, Amrutham developed a lemon-flavored, liquid version (Amrutham's Drug), for which Amrutham and KVK intended to submit an Abbreviated New Drug Application (ANDA) to the FDA.[2] However, on September 2, 2010, before the ANDA for Amrutham's Drug was filed, Novel sent KVK a letter asserting that Novel's former vice-president, defendant Muthusamy Shanmugam, was working with KVK on Amrutham's Drug and that this constituted a breach of his employment agreement with Novel. Novel demanded that KVK cease its work on Amrutham's Drug. On October 1, 2010, KVK responded that, "KVK has not had any discussions with Mr. Shanmugam about any products other than the potential generic equivalent of SUPREP . . . ."

On November 8, 2010, Novel filed an ANDA for a lemon-flavored liquid generic form of SUPREP (Novel's Drug). On November 18, 2010, Amrutham filed an ANDA application for Amrutham's Drug. That same day, KVK and Amrutham filed an

[2] An ANDA is less thorough than an NDA, and may only be used for a drug that, among other things, has the same "active ingredient(s)," the same "route of administration," same "dosage form," and same "strength" as a drug that has already been approved. 21 U.S.C.A. § 355(j)(2). See also 21 C.F.R. § 314.92.

action in Pennsylvania state court, seeking a declaration that their development of Amrutham's Drug did not violate the terms of Shanmugam's employment or confidentiality agreements with Novel (the Pennsylvania Action).

Novel instituted this action seeking injunctive relief on February 3, 2011. Novel alleged that Shanmugam learned about Novel's Drug while serving as its vice-president, and misappropriated that confidential information by working with KVK and Amrutham on the development of Amrutham's Drug. KVK and Amrutham answered and filed a counterclaim alleging tortious interference with prospective economic advantage.

On March 16, 2011, Braintree sued Amrutham in the Eastern District of Pennsylvania, alleging that Amrutham's Drug infringed on Braintree's patent for SUPREP. Braintree also filed a similar patent infringement suit against Novel in federal district court in New Jersey one week earlier.

At some point, KVK partnered with another company, Gator Pharmaceuticals, Inc. (Gator), to produce a powdered form of SUPREP that had the same active ingredients as SUPREP (Gator's Drug). While SUPREP is a berry-flavored solution, Gator's Drug is a lemon-flavored powder that must be mixed with water.

Litigation continued in this matter until October 3, 2012, when KVK, Amrutham, and Novel placed the terms of a settlement

on the record. The agreement, which also resolved the Pennsylvania Action, called for Novel to pay defendants $1,000,000 over an eight-year period. "In exchange, [d]efendants [would] . . . withdraw their application, the [ANDA] that had been filed with the FDA, and between now and then [agree] not to take any efforts to market the product . . . ." Novel would begin making payments, and defendants would withdraw the ANDA for the Amrutham Drug, when (1) the FDA approved Novel's Drug and (2) Novel "clear[ed] the patent issues with the brand name product manufacturer, Braintree." Notably, counsel for Novel also explained that, "both [d]efendant KVK-Tech and Amrutham would also, individuals of the covenants [sic] of a period that he [sic] won't be able to do formulations, etcetera and so forth." The parties agreed that the matter was settled, notwithstanding their intent to formalize the terms in a written agreement.

Subsequently, the parties exchanged draft settlement agreements. Relevant to this appeal, a draft agreement dated October 25, 2012, included the following provisions:

> 8.(d.) The KVK Parties covenant and agree that, as of the Effective Date and at any time thereafter, none of the KVK Parties will develop, manufacture, market, obtain any commercial benefit from, or transfer, assign, sell or promise to any other person or entity, the generic version of the Brand Product or the Amrutham ANDA, nor will the

> KVK Parties induce any third party to engage in any actions described in the Paragraph. Such prohibited marketing efforts include, but are not limited to, (i) any attempts to sell the Brand Product or the Amrutham ANDA or the Amrutham ANDA product, (ii) informing the KVK Parties' customers, potential customers or potential marketing partners that the Amrutham ANDA product is one they intend to sell or launch or is one for which they are awaiting approval, (iii) including the Amrutham ANDA product on a list of products in KVK or Amrutham's pipeline, and (iv) informing their customers or potential customers of potential launch dates for the Amrutham ANDA Product.
>
> 8.(e.) The KVK Parties covenant and agree that, as of the Effective Date and at any time thereafter, none of the KVK Parties have recreated or will recreate the generic formulation of the Brand Product reflected in the Amrutham ANDA, create a new formulation of the Brand Product, or inform or work with any other person or entity to formulate, file an ANDA for or otherwise develop, manufacture or market any other version of the Brand Product, without regard as to whether such version is to be marketed as a brand, generic or over-the-counter medicament, nor will the KVK Parties induce any third party to engage in any actions described in the Paragraph.

A second draft, dated January 22, 2013, did not modify the foregoing provisions.

The parties never executed a written settlement agreement. Rather, at some point "Novel learned of [the] collaboration between KVK and [Gator] to create a generic formulation of SUPREP and corresponding 505(b)(2) New Drug Application ('the

paper-NDA')[3] as a result of a Complaint filed by Braintree against KVK and Gator." Consequently, on July 24, 2013, Novel moved to enforce the terms of the settlement agreement to stop KVK's application with Gator for approval of Gator's Drug.

KVK opposed the motion and submitted the certification of its president, Frank Ripp, Jr. Ripp certified that he understood "that the settlement pertained only to KVK and Amrutham's development of a generic equivalent of SUPREP . . . because that was the sole focus of the litigation with Novel." "Specifically, the litigation with Novel centered on Defendants' development and submission to the FDA of an [ANDA] for a generic equivalent of the Brand Product — a liquid." Ripp further stated that "KVK's partnership with [Gator] is for the manufacture of an entirely new powder product with the same active ingredients as the Brand Product, and is not a generic equivalent of the Brand Product."

During oral argument on the motion on October 4, 2013, Novel emphasized that it brought this litigation "to stop the defendants from profiting from what plaintiff believed was misappropriation of confidential information." Accordingly,

[3] According to 21 C.F.R. § 314.54, "[a]ny person seeking approval of a drug product that represents a modification of a listed drug (e.g., a new indication or new dosage form) . . . may, except as provided in paragraph (b) of this section, submit a 505(b)(2) application."

"[t]he point of the settlement was to have the scope match the scope of the claims, and any further work that [defendants] would do that was derived from the misappropriation should be stopped . . . ." Counsel argued that:

> What they've now done by filing this new paper NDA for the powder formulation is try to find another way to go to market with the exact same product that they developed from the exact same allegedly misappropriated information, and to allow them to do that would be an end-run that would eviscerate the settlement agreement, and we're here to get relief so that that does not occur.

Defendants responded that the settlement placed on the record precluded them from pursuing any generic equivalents of SUPREP. Defendants maintained that the settlement agreement did not forbid KVK from working with Gator on its powdered drug which was a "modification," rather than a generic equivalent, of SUPREP.

Judge Yolanda Ciccone reserved decision, and on October 10, 2013, granted Novel's motion to enforce the settlement. Defendants were ordered to (1) "immediately withdraw their new paper-NDA application," and (2) "refrain from filing any further applications of any kind relating to formulations of any kind of SUPREP." In an accompanying written decision, Judge Ciccone noted that under the terms of the agreement placed on the record, at the prescribed time "[d]efendants would withdraw

their application for their generic version of the brand name product. Additionally, the [d]efendants agreed they would not 'be able to do formulations, etcetera and so forth.'" The judge found that:

> Defendant's paper-NDA is a formulation of SUPREP under the settlement agreement that was put on the record. This [c]ourt reads the settlement as [d]efendants being prohibited from any formulations that involve SUPREP. The powder paper-NDA is the bioequivalent of the liquid product that was at the heart of the settlement agreement and the [d]efendant must abide by the settlement agreement and not create formulations of SUPREP until the [p]laintiff has cleared the patent issues with Braintree.

Defendants moved for reconsideration, arguing that the court erred in its interpretation of the settlement agreement. Also, for the first time on reconsideration, defendants argued that they could not withdraw their FDA application for Gator's Drug because Gator was the applicant and was "a separate and distinct entity over which [d]efendants have no control, and which is not a party to this action." Defendants claimed that, "Gator owns the application. KVK assisted in the filing of it."

Judge Ciccone denied KVK's motion for reconsideration on February 3, 2014. In her written statement of reasons, she explained that KVK was "aware of the consequences" if the court granted plaintiff's motion to enforce the settlement. Defendants' argument that KVK could not control Gator should

have been raised during the original motion, and their failure to do so precluded defendants from raising the issue on reconsideration.

Judge Ciccone further determined that even if Gator's Drug was not the bioequivalent of SUPREP, the initial grant of plaintiff's motion to enforce the settlement was correct. The judge reasoned that the settlement forbade KVK from working on any "formulations" of SUPREP, irrespective of whether those formulations were bioequivalent to SUPREP. Similarly, the question of whether Gator's Drug was a "generic" of SUPREP was immaterial because the proper inquiry was whether it was a "formulation" of SUPREP, which was the language of the settlement. Defendants' appeal ensued.

II.

We briefly state the principles that guide our analysis. "'Settlement of litigation ranks high in our public policy.'" Nolan v. Lee Ho, 120 N.J. 465, 472 (1990) (quoting Jannarone v. W.T. Co., 65 N.J. Super. 472, 476 (App. Div.), certif. denied, 35 N.J. 61 (1961)). In furtherance of the strong policy of enforcing settlements, "our courts 'strain to give effect to the terms of a settlement wherever possible.'" Brundage v. Estate of Carambio, 195 N.J. 575, 601 (2008) (citation omitted). Therefore, an agreement to settle a lawsuit will be honored and

enforced in the absence of fraud or other compelling circumstances. Pascarella v. Bruck, 190 N.J. Super. 118, 124-25 (App. Div.), certif. denied, 94 N.J. 600 (1983).

That the agreement was oral, instead of written, is of no consequence. Id. at 124. "Where the parties agree upon the essential terms of a settlement, so that the mechanics can be 'fleshed out' in a writing to be thereafter executed, the settlement will be enforced notwithstanding the fact the writing does not materialize because a party later reneges." Lahue v. Pio Costa, 263 N.J. Super. 575, 596 (App. Div.), certif. denied, 134 N.J. 477 (1993).

"[T]he party seeking to set aside the settlement agreement has the burden of proving . . . extraordinary circumstance[s] sufficient to vitiate the agreement[,]" Jennings v. Reed, 381 N.J. Super. 217, 227 (App. Div. 2005), by clear and convincing evidence. Smith v. Fireworks by Girone, Inc., 380 N.J. Super. 273, 291 (App. Div. 2005), certif. denied, 186 N.J. 243 (2006). We review the trial judge's decision to enforce a settlement for abuse of discretion. Brundage, supra, 195 N.J. at 613; Chattin v. Cape May Greene, Inc., 216 N.J. Super. 618, 628 (App. Div.), certif. denied, 107 N.J. 148 (1987).

The "[i]nterpretation of a settlement agreement implicates significant legal and policy principles[.]" Kaur v. Assured

Lending Corp., 405 N.J. Super. 468, 474 (App. Div. 2009). When examining the terms of a settlement agreement, we are guided by the rules of contract construction. Brundage, supra, 195 N.J. at 600-01. See also Thompson v. City of Atl. City, 190 N.J. 359, 379 (2007). "The polestar of contract construction is to discover the intention of the parties as revealed by the language used by them." Karl's Sales & Serv., Inc. v. Gimbel Bros., 249 N.J. Super. 487, 492 (App. Div.), certif. denied, 127 N.J. 548 (1991). In interpreting a contract, the focus is on "the intention of the parties to the contract as revealed by the language used, taken as an entirety; and, in the quest for the intention, the situation of the parties, the attendant circumstances, and the objects they were thereby striving to attain . . . ." Lederman v. Prudential Life Ins. Co. of Am., Inc., 385 N.J. Super. 324, 339 (App. Div.) (citation and internal quotation marks omitted), certif. denied, 188 N.J. 353 (2006). In that regard, the court may not re-write a contract or grant a better deal than that for which the parties expressly bargained. Solondz v. Kornmehl, 317 N.J. Super. 16, 21 (App. Div. 1998). Moreover, "any action which would have the effect of vitiating the provisions of a particular settlement agreement and the concomitant effect of undermining public confidence in the settlement process in general, should not be countenanced."

Dep't. of Pub. Advocate, Div. of Rate Counsel v. N.J. Bd. of Pub. Utils., 206 N.J. Super. 523, 528 (App. Div. 1985).

On appeal, defendants argue that the scope of the settlement agreement covered only generics of SUPREP, thereby excluding Gator's Drug. Alternatively, defendants argue that the court erred in denying their motion for reconsideration because they are unable to withdraw the application for Gator's product without Gator's consent, which Gator has denied.

Having reviewed defendants' contentions in light of the record and applicable law, we find them to be without sufficient merit to warrant an extended discussion in a written opinion. R. 2:11-3(e)(1)(E). It is clear that the motion judge neither erred nor abused her discretion in enforcing the settlement or denying reconsideration. Consequently, we affirm essentially for the reasons set forth by Judge Ciccone in her thoughtful written decisions. We add only the following.

The plain terms of a settlement agreement must be enforced, as we have explained, unless they were procured by fraud or compelling reasons exist to withhold their implementation. Nolan, supra, 120 N.J. at 472. Here, the oral settlement that was placed on the record clearly was not limited to merely requiring defendants to withdraw the ANDA for their Amrutham Drug and thereafter not market it, as defendants would urge.

Rather, it also precluded defendants from developing "formulations, etcetera and so forth" of SUPREP.

Even where the language of a contract is clear on its face, courts may determine its meaning by looking to extrinsic evidence, such as "the situation of the parties, the attendant circumstances, and the objects they were . . . striving to attain." Atl. N. Airlines, Inc. v. Schwimmer, 12 N.J. 293, 301 (1953). Our courts "permit a broad use of extrinsic evidence to achieve the ultimate goal of discovering the intent of the parties." Conway v. 287 Corporate Ctr. Assocs., 187 N.J. 259, 270 (2006). In Sachau v. Sachau, 206 N.J. 1, 5-6 (2011) (quoting Schwimmer, supra, 12 N.J. at 302), the Court stated: "A court's role is to consider what is 'written in the context of the circumstances' at the time of drafting and to apply 'a rational meaning in keeping with the expressed general purpose.'"

Here, after the settlement was placed on the record, draft of a written settlement agreement were exchanged between the parties. We find it indicative of the scope of the parties' agreement that Paragraph 8(e) of both draft versions provides that:

> None of the [defendants] have recreated or will recreate the generic formulation of the Brand Product reflected in the Amrutham ANDA, create a new formulation of the Brand

> Product, or inform or work with any other person or entity to formulate, file an ANDA for or otherwise develop, manufacture or market any other version of the Brand Product, without regard as to whether such version is to be marketed as a brand, generic or over-the-counter medicament.

The written agreement was never executed, but nothing in the record suggests that this broad language, which would encompass Gator's Drug, was ever challenged or modified.

Defendants further assert that the term "formulations" is not a term-of-art in the pharmaceutical industry, "and is not defined by any FDA rule or regulation." Defendants' assertion is only partially correct. Without defining it, both the Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 355(j), as well as 21 C.F.R. § 314.53 employ the word "formulation." Specifically, 21 C.F.R. § 314.53 requires an applicant to submit with its NDA, "drug substance (active ingredient) patents, drug product (formulation and composition) patents, and method-of-use patents."

Various federal cases reference the term "formulation." In In re Omeprazole Patent Litig., 490 F. Supp. 2d 381, 392-94 (S.D.N.Y. 2007), the court explained that the drug omeprazole was "very difficult to formulate" due to the fact that it degraded in stomach acid, heat, moisture, etc. Plaintiffs "set out to develop an oral dosage form of omeprazole . . . ." Id.

at 392. They "made and tested many different formulations before creating an oral formulation" that contained a coating that would allow it to pass through the stomach without degrading. Ibid. Following clinical trials, plaintiffs filed patent applications for their omeprazole formulation. Ibid. Later, they developed a "new formulation" that essentially changed the coating of the drug module to make the final product. Id. at 393.

Other federal cases support a similar interpretation. To constitute different "formulations" of the same drug, the two need not have the same proportion of ingredients. See Upjohn Co. v. MOVA Pharm. Corp., 225 F.3d 1306, 1309 (Fed. Cir. 2000) (discussing differences between brand and generic formulations, which differed only in the proportions of ingredients). However, they may have the same proportions, and differ only in the particle size of the active ingredient. See Eli Lilly & Co. v. Teva Pharms. USA, Inc., 657 F. Supp. 2d 967, 994 (S.D. Ind. 2009) (discussing patents for different formulations of raloxifene involving different particle sizes). Or they may have the same ingredients, but be prepared via different means. See United States v. Premo Pharm. Labs., Inc., 511 F. Supp. 958, 964 n.3 (D.N.J. 1981) ("[C]hanging the solvent which is used to prepare the active ingredient or the form of the active

ingredient acid, base, or salt that is used to formulate the final dosage may result in a change in the properties of the active ingredient.").

The record in this case reveals that both SUPREP and Gator's Drug are composed of the same active ingredients and in the exact same proportions. They differ only in their inactive ingredients and their form, SUPREP being a berry-flavored liquid solution, while Gator's Drug is a lemon-flavored powder that needs to be mixed with water. Thus, Gator's Drug is a different formulation of SUPREP. It falls within the scope of activities that defendants agreed to forego because of Novel's $1,000,000 payment.

We similarly reject defendants' alternative argument that they are unable to comply with the enforcement order, which requires them to "immediately withdraw their new paper–NDA application." Initially we note that in opposing Novel's enforcement motion, KVK's president, Ripp, described the company's relationship with Gator in the manufacture of the powder product as a "partnership." On reconsideration, however, defendants asserted that KVK filed the application "on behalf of Gator," and argue that KVK is therefore not permitted to withdraw the application without Gator's consent.

We review the trial court's denial of a motion for reconsideration under an abuse of discretion standard. Marinelli v. Mitts & Merrill, 303 N.J. Super. 61, 77 (App. Div. 1997). Reconsideration is "'a matter within the sound discretion of the [c]ourt, to be exercised in the interest of justice[.]'" Palombi v. Palombi, 414 N.J. Super. 274, 288 (App. Div. 2010) (quoting D'Atria v. D'Atria, 242 N.J. Super. 392, 401 (Ch. Div. 1990)). Reconsideration is appropriate if "'1) the [c]ourt has expressed its decision based upon a palpably incorrect or irrational basis, or 2) it is obvious that the [c]ourt either did not consider, or failed to appreciate the significance of probative, competent evidence.'" Cummings v. Bahr, 295 N.J. Super. 374, 384 (App. Div. 1996) (quoting D'Atria, supra, 242 N.J. Super. at 401); see also Fusco v. Bd. of Educ. of City of Newark, 349 N.J. Super. 455, 461-62 (App. Div.), certif. denied, 174 N.J. 544 (2002). Reconsideration is not appropriate as a vehicle to bring to the court's attention evidence that was not presented, but was available, in connection with initial argument. Fusco, supra, 349 N.J. Super. at 463.

Here, defendants' argument on reconsideration that they cannot control Gator because Gator is a separate and distinct entity that submitted the application for the powder product is

seemingly inconsistent with defendant's original characterization of Gator as a partner in that venture. In any event, the motion judge correctly concluded that defendants were aware of this information and had the opportunity to assert this argument in their initial opposition to the enforcement motion but failed to do so. Accordingly, the judge did not abuse her discretion in denying defendants' reconsideration motion on this basis.

Affirmed.