SUPERIOR COURT OF NEW JERSEY
SOMERSET, HUNTERDON & WARREN COUNTIES
VICINAGE 13

YOLANDA CICCONE
ASSIGNMENT JUDGE

SOMERSET COUNTY COURT HOUSE
P.O. BOX 3000
SOMERVILLE, NEW JERSEY 08876
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February 3, 2014

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Re: Novel Laboratories, Inc. v. KVK-Tech, Inc.
Docket SOM-C-12009-11

Dear Counselors:

Please allow the following letter to serve as the court's Opinion with regard to the Defendant's Motion for Reconsideration heard on January 31, 2014:

I. Introduction

This action arose out of the development of a generic version of a brand-name drug. The matter was settled on October 3, 2012 before this court, the terms of which were never memorialized in writing, but came to an oral settlement on the record in front of this Court. There is no dispute that the settlement occurred on this date.

Under the terms of the agreement, the Plaintiffs were to pay the Defendants $1 million over 8 years if: (i) their generic version of the product was approved by the FDA and (ii) Plaintiff cleared the patent issues with the brand name manufacturer, Braintree Laboratories, Inc. At the time both prongs were met, Defendants would withdraw their application for their generic version of the brand name product. Additionally, the Defendants agreed they would not "be able to do formulations, etcetera and so forth." This dispute arises out of the interpretation of the settlement agreement.

Prior to the settlement, Plaintiff alleged a former Vice President of Plaintiff's company, Novel Laboratories, Inc., breached his employment agreement by providing confidential information to the Defendants concerning the development of a generic version of the brand name drug product SUPREP. The Defendants denied the allegations that the former Vice President supplied them with information and ceased working with the individual.

The Plaintiffs moved for and were granted a temporary restraining order against the Defendants to prevent them from continuing development of the generic drug product. In April 2013, the Plaintiffs became aware of a lawsuit filed by Braintree Laboratories, Inc., against the Defendants for patent infringement in developing a generic formulation of SUPREP. The Plaintiffs believed this violated the settlement agreement put forth on the record and the Court ruled in favor of the Plaintiff. Defendants now file a Motion for Reconsideration.

II. **Standard**

A motion for reconsideration may be brought under R. 4:49-2. R. 4:49-2 states that, except for clerical errors, a motion for rehearing or reconsideration seeking to alter or amend a judgment or order shall be served within 20 days after service of the judgment or order upon all parties by the party obtaining it. Motions for reconsideration are applicable only when the court's reasoning is based on plainly incorrect reasoning, or when the court failed to consider Evidence, or there is good reason for it to consider new information on an issue decided. Cummings v. Bahr, 295 N.J. Super. 374, 384-85 (App. Div. 1996).

The same judge who heard the first motion in the cause shall hear all motions for reconsideration. R. 4:42-2. In addition, the motion shall state with specificity the basis on which it is made, including a statement of the matters or controlling decisions which counsel believes the court has overlooked or as to which it has erred. Motions for reconsideration are applicable only when the court's reasoning is based on plainly incorrect reasoning, or when the court failed to consider evidence, or there is good reason for it to consider new information on an issue decided. Cummings v. Bahr, 295 N.J.Super. 374, 384-385 (App. Div. 1996).

The party moving for reconsideration has the burden of demonstrating that the court either (1) expressed its decision based upon a palpably incorrect or irrational basis or (2) failed to appreciate the significance of probative, competent Evidence. Michel v. Michel, 210 N.J. Super. 218, 224-25 (Ch. Div. 1985). The Appellate Division elaborated on this standard in Cummings v. Bahr, 295 N.J. Super. 374, 384 (App. Div. 1996). The Cummings Court stated that "[r]econsideration should be utilized only for those cases which fall into that narrow corridor in which either 1) the Court has expressed its decision based upon a palpably incorrect or irrational basis, or 2) it is obvious that the Court either did not consider, or failed to appreciate the

significance of probative, competent evidence...." Id. The court must be sensitive and scrupulous in its analysis of the issues in a motion for reconsideration. Id. (citing D'Atria v. D'Atria, 242 N.J. Super. 392, 401-2 (Ch. Div.1990)). Further, it is imperative to note that reconsideration is not to be sought in instances where the litigant is not satisfied with the court's decision; instead, "the preferred course to be followed... is to seek relief by means of either a motion for leave to appeal or, if the Order is final, by a notice of appeal. D'Atria v. D'Atria, 242 N.J. Super. 392, 401 (Ch. Div. 1990).

III. **Analysis**

Defendants' motion shall be denied. Defendants argue this Court should: (a) amend the Order to strike the requirement that "defendants shall immediately withdraw their new paper-NDA application" because Gator Pharmaceuticals, Inc., is not a party to this action and Defendants do not have the ability to withdraw the application without Gator's consent; (b) reconsider the Order, upon a rehearing, with expert testimony; or (c) stay the Order pending Defendants appeal to the Appellate Division. The party moving for reconsideration has the burden of demonstrating that the court either (1) expressed its decision based upon a palpably incorrect or irrational basis or (2) failed to appreciate the significance of probative, competent Evidence. Michel v. Michel, 210 N.J. Super. 218, 224-25 (Ch. Div. 1985). This Court believes the Defendants have failed to meet this burden.

First, the Defendants' argument that they cannot control Gator because Gator is a separate and distinct corporation should have been raised during oral argument or through their motion papers. The Defendants claim the Plaintiff and Court were aware of Gator being the sole entity that submitted the application for the paper-NDA. Defendants point to the FDA Tentative Approval letter which is addressed as KVK "on behalf of" Gator and that KVK's role was assisting Gator in the preparation and filing of the application. The Court cannot infer from those documents that KVK's role was simply assisting Gator in the preparation and filing of the application. Defendants were aware of the consequences if the Court granted the Plaintiff's motion. Defendants had the opportunity to address the consequences with Gator prior to oral argument and neglected to inform this Court or Plaintiff that Gator controls all aspects of the drug formulation process. Thus, Defendants' argument to amend the Order because of Gator's refusal to consent fails.

Second, Defendants argue the Court erred in the decision to grant Plaintiff's motion. Defendants argue the Court was incorrect in concluding the Defendants product was the bioequivalent of the liquid product because no bioequivalency studies have been performed. Assuming, *arguendo*, that the Court was incorrect in their holding that the powder paper-NDA is

the bioequivalent of the liquid product, the reasoning behind the Court's Order to Enforce the Settlement Agreement was because this Court read the settlement as Defendants being prohibited from **any** formulations that involve SUPREP. The term **any** includes the powder paper-NDA that may or may not be the bioequivalent of the liquid product. As stated above, under the terms of the agreement, the Plaintiffs were to pay the Defendants $1 million over 8 years if: (i) their generic version of the product was approved by the FDA and (ii) Plaintiff cleared the patent issues with the brand name manufacturer, Braintree Laboratories, Inc. At the time both prongs were met, Defendants would withdraw their application for their generic version of the brand name product. Additionally, the Defendants agreed they would not "be able to do formulations, etcetera and so forth." This Court, as stated in the original opinion, believes the settlement agreement included **any** formulations until the prongs were met or not met. Thus, Defendants' bioequivalency argument fails.

Further, Defendants argue that Gator's product is not a generic of SUPREP. Defendants quote the Court on Page 3 of the opinion: "this Court believes the heart of the settlement was the question of whether both parties had the right to produce a generic formulation of SUPREP." However, the use of the word "generic" was not meant to only rule out the production of "generic" formulations. The Court is clear in their opinion of stating: "this Court reads the settlement as Defendants being prohibited from **any** formulations that involve SUPREP." Thus, Defendants' argument fails.

In addition, Defendants argue that Plaintiff has lost its litigation against Braintree. However, Plaintiff has appealed the decision of the Court and the case is currently in the Appellate Division. Thus, Plaintiff still has the opportunity to prevail on appeal.

Lastly, Defendants argue to stay the Order pending Defendants appeal to the Appellate Division because Defendants are likely to succeed on the merits. This Court questions why the Plaintiff is unlikely to prevail in their appeal, but Defendants claim they are likely to succeed on the merits of their appeal. Thus, this Court will not stay the Order.

IV. **Conclusion**

Based on the foregoing, Defendants' Motion for Reconsideration is **DENIED**.

Very truly yours,

Hon. Yolanda Ciccone, A.J.S.C.

YC:bd
Enclosures

DENIED

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NOVEL LABORATORIES, INC., Plaintiff, vs. MUTHUSAMY SHANMUGAM, KVK-TECH, INC. and AMRUTHAM, INC., Defendants.	SUPERIOR COURT OF NEW JERSEY GENERAL EQUITY PART SOMERSET COUNTY Civil Action DOCKET NO. NO. C-12009-11 **PROPOSED ORDER**

This matter having been brought before the Court by Defendants KVK-Tech, Inc. and Amrutham, Inc. ("Defendants"), on their Motion to Amend or to Reconsider, Upon Rehearing, the Court's Order Granting Novel Laboratories, Inc.'s ("Novel") Motion to Enforce Settlement Agreement (the "October 10 Order"), or in the Alternative, to Stay the October 10 Order Pending Defendants' Appeal; the Court having considered the matter, and for good cause shown,

It is on this 3rd day of February, 2014 ~~2013~~,

~~ORDERED that Defendants' Motion is GRANTED, insofar as the October 10 Order, upon reconsideration, is VACATED, and Novel's Motion to Enforce Settlement Agreement is DENIED.~~

_____, J.S.C.

See Letter Brief Attached