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JAMES N. HATTEN, Clerk
J. Hatten
Deputy Clerk

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

INTENDIS, INC. and DOW
PHARMACEUTICAL SCIENCES, INC.,

Plaintiffs,

v.

RIVER'S EDGE PHARMACEUTICALS,
LLC,

Defendant.

CIVIL ACTION

NO. 1:11-CV-01634-RLV

O R D E R

This case involves a claim for patent infringement by Intendis, Inc. ("Intendis") and Dow Pharmaceutical Sciences, Inc. ("Dow") (collectively, the "plaintiffs") against River's Edge Pharmaceuticals, LLC ("River's Edge" or the "defendant").

The plaintiffs filed the instant action in this court on May 19, 2012. Thereafter, the defendant filed a motion to dismiss [Doc. No. 15]. On January 10, 2012, the court issued an order denying the defendant's motion and permitting the plaintiffs to amend their complaint [Doc. No. 35]. The plaintiffs filed their amended complaint on February 9, 2012 [Doc. No. 43]. The defendant filed its amended answer on April 18, 2012 [Doc. No. 61]. This matter now comes before the court on the defendant's motion for judgment on the pleadings [Doc. No. 71].

I. Factual Background

A. Patent

Because this court has already recited detailed facts in an order dated January 10, 2012 [Doc. No. 35], the court will briefly summarize the relevant facts. Dow is the owner of United States Patent No. 6,387,383, entitled "TOPICAL LOW-VISCOSITY GEL COMPOSITION" (the "'383 patent"). The '383 patent is listed by the Food and Drug Administration (FDA) as covering Desonate[®], which is a topical aqueous gel composition indicated for the treatment of skin disorders such as acne. Intendis is the owner of an approved New Drug Application (NDA) for Desonate[®]. Intendis is also an exclusive licensee of the '383 patent with the right to enforce the '383 patent.

The defendant River's Edge submitted an Abbreviated New Drug Application (ANDA) to the FDA pursuant to § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 355(j), seeking to engage in the commercial manufacture, use, sale, offer for sale or importation of a generic desonide gel, 0.05% formulation (the "ANDA product") based on the listed drug Desonate[®].

B. Desonate and the ANDA product

Intendis's Desonate[®] product comprises 0.05% desonide, a corticosteroid that is therapeutically effective for the treatment

of skin disorders such as acne. Desonate[®] also comprises Carbopol[®] 981, a polyacrylic acid polymer that is compatible with desonide. The defendant's generic ANDA product is similarly indicated for the treatment of acne and other skin conditions. The ANDA product comprises 0.05% desonide and Carbopol[®] 974P, another polyacrylic acid polymer that is also compatible with desonide.

According to the plaintiffs, the ANDA product is covered by one or more claims of the '383 patent despite the fact that the defendant filed the ANDA with a "Paragraph IV" certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the ANDA formulation does not infringe the '383 patent. The plaintiffs aver that the filing of the ANDA product is an act of infringement under 35 U.S.C § 271(e)(2)(A) because the '383 patent has not yet expired.

As mentioned above, the defendant filed a motion for judgment on the pleadings [Doc. No. 71], which is now pending before the court.

II. Standard of Review

A motion for judgment on the pleadings is governed by the same standard as a Federal Rule of Civil Procedure 12(b)(6) motion to dismiss. See Roma Outdoor Creations, Inc. v. City of Cumming, 558 F. Supp. 2d 1283, 1284 (N.D. Ga. 2008). To survive a motion to

dismiss pursuant to Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). The Supreme Court has explained this standard as follows:

A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for misconduct alleged. The plausibility standard is not akin to a "probability requirement," but it asks for more than a sheer possibility that a defendant has acted unlawfully.

Iqbal, 556 U.S. at 678 (citations omitted).

In considering a party's motion to dismiss under Rule 12(b)(6), all facts alleged in the pleading must be accepted as true and construed in the light most favorable to the non-moving party. Powell v. Thomas, 643 F.3d 1300, 1302 (11th Cir. 2011). But the court need not accept legal conclusions or conclusions disguised as factual allegations. See id. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements do not suffice." Iqbal, 556 U.S. at 678. Thus, evaluation of a motion to dismiss requires two steps: (1) eliminate any allegations in the pleading that are merely legal conclusions, and (2) where there are well-pleaded factual allegations, "assume

their veracity and . . . determine whether they plausibly give rise to an entitlement to relief." Id. at 679.

III. Discussion

The defendant argues that there can be no literal infringement as a matter of law because the infringement allegations are expressly contradicted by the patent specifications attached to the plaintiffs' amended complaint. The plaintiffs contend that at this stage of the litigation, the relevant inquiry does not involve assessing the merits of the claim but involves whether the plaintiffs are entitled to reach the discovery stage of litigation in order to seek evidence to support their claim.

The court agrees with the plaintiffs. In reaching this conclusion, the court examined the pleadings, the Federal Rules of Civil Procedure (FRCP), and the relevant sections of the Hatch-Waxman Act, 35 U.S.C. § 271(e), which provides a cause of action for patent infringement.

Rule 84 provides that the forms in the Appendix of the FRCP illustrate the brevity that the rules contemplate. Form 18 of the FRCP Appendix of Forms sets forth an example of a complaint for patent infringement. Form 18 requires:

(1) an allegation of jurisdiction; (2) a statement that the plaintiff owns the patent; (3) a statement that defendant has been infringing the patent "by making,

selling, and using [the device] embodying the patent"; (4) a statement that the plaintiff has given the defendant notice of its infringement; and (5) a demand for an injunction and damages.

Sikes Cookers & Grill, Inc. v. Vidalia Outdoor Prods., No. 08-CV-0750, 2009 U.S. Dist. LEXIS 13094, at *6-7 (N.D. Ga. Feb. 19, 2009).

Section 271(e) (2) of the Hatch-Waxman Act provides that:

(2) It shall be an act of infringement to submit-
(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b) (2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. 271(e) (2) (A).

The Federal Circuit has made clear that under the Hatch-Waxman Act "an ANDA filer may infringe without even engaging in any actual commercial activities. The mere act of filing an ANDA constitutes infringement." Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1346 (Fed. Cir. 2000).

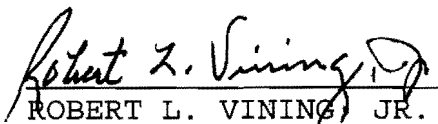
In the instant case, this court ordered the plaintiffs to amend their complaint [Doc. No. 35]. Thereafter, the plaintiffs amended their complaint to include detailed allegations of patent infringement, including identifying which claims are purportedly

being infringed and how those claims are being infringed. Assuming the veracity of all of the plaintiffs' allegations, the plaintiffs have met their burden to state a claim for relief, even in light of Iqbal and Twombly.¹ Therefore, the court DENIES defendant's motion for judgment on the pleadings.

IV. Conclusion

For the reasons stated above, the court DENIES the defendant's motion for judgment on the pleadings [Doc. No. 71].

SO ORDERED, this 23rd day of August, 2012.


ROBERT L. VINING, JR.

Senior United States District Judge

¹ Although courts in this district have found that plaintiffs may survive a motion to dismiss by complying strictly with Form 18, see, e.g., CBT Flint Partners, LLC v. Goodmail Sys., 529 F. Supp. 2d 1376, 1380-81 (N.D. Ga. 2007), the court does not need to address whether the recitation of the minimally detailed requirements of Form 18 is sufficient to survive a motion for judgment on the pleadings because the amended complaint satisfies Iqbal and Twombly.