UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

BRAINTREE LABORATORIES, INC.,

Plaintiff,

Civil Action No. 3:13-cv-00389-TJC- MCR

v.

GATOR PHARMACEUTICALS, INC.;
KVK-TECH, Inc.

Defendants.
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PLAINTIFF BRAINTREE LABORATORIES, INC.'S MOTION AND SUPPORTING MEMORANDUM TO DISMISS DEFENDANTS' SECOND COUNTERCLAIM

Plaintiff, Braintree Laboratories, Inc. ("Braintree"), moves to dismiss the Second Counterclaim of Defendants, Gator Pharmaceuticals, Inc. ("Gator") and KVK-TECH, Inc. ("KVK"), pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

The grounds and authority for this motion are set forth in the following supporting memorandum. The supporting memorandum is incorporated as part of this motion.

MEMORANDUM

Braintree respectfully submits the following memorandum in support of its Motion to Dismiss Defendants' Second Counterclaim.

I. INTRODUCTION

This is a patent infringement action under the Hatch-Waxman Act. The case concerns U.S. Patent No. 6,946,149 ("the '149 patent"), which covers SUPREP® Bowel Prep Kit ("SUPREP"), a sodium sulfate, potassium sulfate, and magnesium sulfate osmotic laxative

approved for cleansing the colon in preparation for colonoscopy in adults. SUPREP was developed and is sold by the '149 patent holder, Braintree.

Defendants Gator and KVK (collectively "Defendants") have filed a New Drug Application ("NDA") under 21 U.S.C. § 355(b)(2) seeking to make and sell a generic copy of SUPREP. Braintree alleges, pursuant to 35 U.S.C. § 271(e)(2), that the filing of the NDA by the Defendants infringes the '149 patent.

In their Second Counterclaim, Defendants allege patent misuse. Dkt No. 17, Gator/KVK Counterclaims, ¶¶ 77-81. Specifically, Defendants allege that: (1) the '149 patent does not cover SUPREP; (2) Braintree "know[s]" that the '149 patent does not cover SUPREP; (3) Braintree "knowingly and willfully" maintains its listing of the '149 patent for SUPREP in the Food and Drug Administration's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") despite Braintree's "know[ledge]" of the scope of the '149 patent; and, (4) Braintree initiated this litigation in bad faith. *See id.*

Pursuant to Federal Rule of Civil Procedure 12(b)(6), Defendants' patent misuse counterclaim should be dismissed for each of four reasons:

First, Defendants' patent misuse counterclaim is precluded under the Hatch-Waxman Act. At bottom, Defendants' patent misuse counterclaim is one for Orange Book mislisting. As two U.S. District Judges have already ruled in related cases concerning the '149 patent, the Hatch-Waxman Act only authorizes a limited counterclaim for alleged Orange Book mislisting in patent infringement actions[1]. Such a limited counterclaim for delisting has been asserted by these defendants. *See* Dkt. No. 17, Gator/KVK Counterclaims, ¶¶75-76. Because the Hatch-

[1] The two related cases are *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, D.N.J., C.A. No. 11-1341 ("*Braintree v. Novel*") and *Braintree Laboratories, Inc. v. Amrutham Inc.*, E.D.Pa., Civ. No. 11-01854 ("*Braintree v. Amrutham*").

Waxman Act does not allow for a delisting counterclaim in any other form, Defendants' patent misuse counterclaim is improper and should be dismissed.

Second, Defendants have failed to plead facially plausible claims under the standard of *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Defendants fail to allege any facts (because none exist) to support a conclusion that Braintree knows that SUPREP is not covered by the '149 patent. Defendants' patent misuse allegations are baseless because Braintree filed this action ***after*** U.S. District Judge Peter G. Sheridan had made findings and rulings in the related *Braintree v. Novel* case that the '149 patent does cover SUPREP and had not been proved invalid.

Third, Defendants' patent misuse claim fails because it does not allege anticompetitive effects, a required element of a patent misuse claim where, as here, *per se* patent misuse is not alleged. *See Princo Corp. v. ITC*, 616 F.3d 1318, 1329-1331 (Fed. Cir. 2010) (*en banc*).

Fourth, Defendants' patent misuse counterclaim is improper on its face because patent misuse is an affirmative defense, not a cause of action.[2]

II. LEGAL STANDARD ON A MOTION TO DISMISS

Under Federal Rule of Civil Procedure 12(b)(6), a motion to dismiss should be granted unless the counterclaim plaintiff has pled "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic*, 550 U.S. at 570. The factual allegations in the counterclaims "must be enough to raise a right to relief above the speculative level." *Id.* at 555 (citation omitted). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory

[2] Defendants have also asserted an affirmative defense of patent misuse. While that defense is without legal or factual basis for all the reasons described in this motion, Braintree is aware of the Middle District of Florida law that motions to strike are disfavored. *E.g., Ahamad v. Maxim Healthcare Servs., Inc.*, No. 5:13-CV-338-OC-10PRL, 2013 WL 5781245 at *1 (M.D. Fla. Oct. 25, 2013). Consequently, Braintree is not making a motion to strike or dismiss this defense at this time. At a later stage of the case, Braintree will file the appropriate motion to have this defense dismissed.

statements," do not suffice to support a claim. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "The plausibility standard calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the [counterclaim] defendant's liability." *Miyahira v. Vitacost.com, Inc.*, 715 F.3d 1257, 1265 (11th Cir. 2013) (internal quotation and citation omitted).

III. DEFENDANTS' SECOND COUNTERCLAIM FOR PATENT MISUSE DOES NOT STATE A CLAIM

A. Defendants' Second Counterclaim Should Be Dismissed Because It Is Not Permitted Under the Hatch-Waxman Act.

Defendants' patent misuse counterclaim is based on the assertion that the listing of the '149 patent for SUPREP in the Orange Book is improper. *See* Dkt. No. 17, Gator/KVK Counterclaims ¶¶ 13, 56-74, 76, 78-79. This counterclaim is prohibited under the Hatch-Waxman Act because Congress has only authorized a limited counterclaim by an NDA applicant/patent infringement defendant alleging improper Orange Book listing:

> (ii) Counterclaim to infringement action.—
>
> (I) In general.— If [the patent or NDA holder]… brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) of this section or this subsection on the ground that the patent does not claim either—
>
> (aa) the drug for which the application was approved; or
>
> (bb) an approved method of using the drug.

21 U.S.C. § 355(c)(3)(D)(ii). This provision does not authorize any other form of improper Orange Book listing claim. *See* 21 U.S.C. § 355(c(3)(d)(ii)(II). ("Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I)."). Nor is there any other legal basis to assert any other form of Orange Book delisting defense to an infringement action. *See Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1332-1333 & n.3 (Fed. Cir. 2001) (holding, prior to

Congress's authorization of narrow Orange Book delisting counterclaim, that "a declaratory relief action to 'delist' is unavailable under the patent laws," and that such an action would be an improper attempt to assert a private right of action under Federal Food, Drug, and Cosmetic Act).

Here, Defendants assert a counterclaim pursuant to 21 U.S.C. § 355(c)(3)(D)(ii) for delisting of the '149 patent. *See* Dkt. No. 17, Gator/KVK Counterclaims, ¶¶ 75-76. Defendants base their additional patent misuse counterclaim on identical allegations of improper Orange Book listing. *See id.* ¶¶ 77-81. The Hatch-Waxman Act precludes such a patent misuse counterclaim, and dismissal is therefore appropriate. *See, e.g., Takeda Pharm. Co., Ltd. v. Zydus Pharm. USA Inc.*, No. 10-1723, 2011 U.S. Dist. LEXIS 56328, at *9-17 (D.N.J. May 25, 2011) (dismissing patent misuse counterclaim under the Hatch Waxman Act because "[t]he central, if not sole, element of Defendants' misuse claim" was improper Orange Book listing); *Schwarz Pharma, Inc. v. Teva Pharm. USA, Inc.*, No. 01-4995, 2005 WL 4158850, at *5 (D.N.J. Feb. 4, 2005) (holding that "in a patent action[,] improper listing in the Orange Book cannot be the basis of a misuse defense") (*citing Mylan*, 268 F.3d 1323)[3].

Notably, in the related cases of *Braintree v. Amrutham* and *Braintree v. Novel*, *see* note 1 *supra*, U.S. District Judges Diamond and Sheridan, respectively, dismissed the defendants' counterclaims that were not limited to the statutory delisting claims because they were precluded by the Hatch-Waxman Act. In *Braintree v. Amrutham*, Judge Diamond granted Braintree's motion to dismiss Amrutham's patent misuse and unclean hands counterclaims because they were precluded by the Hatch-Waxman Act. A copy of the *Amrutham* Opinion on Motion to

[3] Although these cases address the § 355(j)(5)(C)(ii) delisting counterclaim, for ANDA applicants, there is no basis to distinguish Defendants' § 355(c)(3)(D)(ii) delisting counterclaim for NDA applicants. In 2003, Congress created two delisting counterclaims under § 355(c) and § 355(j)—with essentially identical provisions barring any other counterclaim. *See Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1678 (2012); *Mylan*, 268 F.3d at 1332.

Dismiss is attached as Exhibit 1. Similarly, in *Braintree v. Novel*, Judge Sheridan granted Braintree's Motion for Summary Judgment dismissing Novel's false marking and unfair competition counterclaims as precluded by the Hatch-Waxman Act (as well as on other grounds). A copy of the *Novel* Summary Judgment Opinion is attached as Exhibit 3.

Braintree requests that this Court take judicial notice of these decisions in evaluating this motion to dismiss. *See* Fed. R. Evid. 201(b); *Lozman v. City of Riviera Beach*, 713 F.3d 1066, 1076 (11th Cir. 2013) ("Although this matter is before the court on a motion to dismiss, we may take judicial notice of the court documents from the state eviction action." (citing Fed. R. Evid. 201(b))).

B. Even If a Patent Misuse Counterclaim Were Cognizable, Defendants Have Failed to Plead Facts that Are Facially Plausible.

Defendants' Second Counterclaim for patent misuse should also be dismissed because it lacks facial plausibility. *See Twombly*, 550 U.S. at 570; *Miyahira*, 715 F.3d at 1265. Defendants allege that Braintree "knowingly and willfully caused the '149 patent to be listed in the Orange Book for SUPREP, knowing that the '149 patent does not cover either SUPREP or an approved method of using SUPREP." Dkt. No. 17, Gator/KVK Counterclaims, ¶ 78. Defendants further allege, without factual support, that "Braintree filed a complaint in bad faith against Defendants for infringement of the '149 patent." *Id.* ¶ 80. Defendants' conclusory charge of bad faith is not plausible.

In the related case of *Braintree v. Novel*, Judge Sheridan construed the disputed claim term "clinically significant electrolyte shifts" (the claim term on which Defendants base their patent misuse counterclaim (*see* Dkt. No. 17, Gator/KVK Counterclaims, ¶¶ 1-54)). A copy of the *Novel* Order on Claim Construction is attached as Exhibit 2. Applying that construction, Judge Sheridan later granted Braintree's Motion for Summary Judgment that Novel's proposed

generic copy of SUPREP, and its proposed use, would infringe the '149 patent – thereby finding that the '149 patent covers SUPREP[4]. Ex. 3, *Novel* Summary Judgment Opinion, at 2-22.

Judge Sheridan rendered his infringement decision on January 18, 2013—nearly ***three months before*** Braintree filed this lawsuit. As a result, there is no basis for Defendants' allegation that Braintree filed this infringement suit against Defendants in bad faith. *See* Dkt. No. 17, Gator/KVK Counterclaims, ¶80. For the same reason, there is no basis for Defendants' allegation that Braintree "knowingly and willfully" caused the '149 patent to be falsely listed in the Orange Book as covering SUPREP. *Id.* ¶¶ 78-79. The reasonable basis for Braintree's claims here of infringement and validity of the '149 patent is set forth – in great detail – in the written decisions of Judge Sheridan. *See* Exs. 2, 3, 4, *Novel* Claim Construction Opinion, Summary Judgment Opinion, and Motion for Reconsideration Order. Defendants do not allege, because they cannot, any facts to overcome Judge Sheridan's claim construction, infringement, and validity rulings in Braintree's favor. All Defendants can do is make conclusory charges of Braintree's alleged bad faith and alleged intentional Orange Book mislisting.

Defendants' conclusory allegations, which are contrary to the findings of a United States District Court judge, makes Defendants' patent misuse counterclaim not only plainly baseless, but also facially implausible. Defendant's patent misuse counterclaim should be dismissed. *See Twombly*, 550 U.S. at 570; *Miyahira*, 715 F.3d at 1265.

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[4] In *Braintree v. Novel*, Judge Sheridan made his rulings on claim construction after briefing and a two-day *Markman* hearing involving testimony from three expert witnesses. Ex. 2, Claim Construction Opinion. Judge Sheridan made his infringement ruling, granting Braintree's Motion for Summary Judgment of Infringement and denying Novel's Motion for Summary Judgment of Non-Infringement, after briefing and oral argument, and after a Motion for Reconsideration by Novel. Ex. 3, Summary Judgment Opinion; Ex. 4, Motion for Reconsideration Order. After a 6-day trial, Judge Sheridan ruled that the '149 patent had not been proved invalid. *See Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, D.N.J., C.A. No. 11-1341, Dkt. Nos. 380, 381.

C. **Defendants' Patent Misuse Counterclaim Fails as a Matter of Law.**

Braintree's alleged conduct, even if taken as true (which it is not) solely for purposes of this motion, cannot constitute patent misuse as a matter of law because Defendants do not allege activity by Braintree that is cognizable as patent misuse. *See, e.g., Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 868 (Fed. Cir. 1997). The Federal Circuit and Congress have restricted the patent misuse doctrine to specific activity not alleged in Defendants' Counterclaims. *See Princo*, 616 F.3d at 1329 ("Recognizing the narrow scope of the doctrine, we have emphasized that the defense of patent misuse is not available to a presumptive infringer simply because a patentee engages in some kind of wrongful commercial conduct, even conduct that may have anticompetitive effects."); *Id.* at 1329-1330 ("Importantly, Congress enacted section 271(d) not to broaden the doctrine of patent misuse, but to cabin it."); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1373 (Fed. Cir. 1998) ("Although the defense of patent misuse ... evolved to protect against 'wrongful' use of patents, the catalog of practices labeled 'patent misuse' does not include a general notion of 'wrongful' use.").

The Federal Circuit has established a two-step process for evaluating patent misuse. *See, e.g., Virginia Panel*, 133 F.3d at 869. First, certain specific practices have been held by the United States Supreme Court to be *per se* patent misuse, such as "tying" arrangements in which a patentee, with market power, conditions a license under a patent on the purchase of a separable, staple good, and arrangements in which a patentee leverages its patent to obtain post-expiration royalties. *Id.* Second, when a practice alleged to constitute patent misuse is not classified as *per se* patent misuse, it can only be patent misuse if the conduct has the effect of broadening the scope of the patent ***with an anticompetitive effect***. The anticompetitive effects and procompetitive benefits are then weighed under the "rule of reason." *See Princo*, 616 F.3d at 1328, 1334; *U.S. Philips Corp. v. ITC*, 424 F.3d 1179, 1184-1186 (Fed. Cir. 2005); *Virginia*

Panel, 133 F.3d at 869; *Windsurfing Int'l Inc. v. AMF, Inc.*, 782 F.2d 995, 1001-1002 (Fed. Cir. 1986).

Here, Defendants do not allege *per se* patent misuse (nor could they do so). *See generally* Dkt. No. 17, Gator/KVK Counterclaims. To state a claim, Defendants therefore must allege that Braintree has broadened the scope of the '149 patent with anticompetitive effects. *See Princo*, 616 F.3d at 1328, 1334. Defendants' counterclaim does not include any allegation of anticompetitive effects. As a consequence, this counterclaim fails as a matter of law, even taking its allegations as true for purposes of this motion. *See generally* Dkt. No. 17, Gator/KVK Counterclaims.

There are also additional grounds to dismiss Defendants' patent misuse counterclaim. Defendants' conclusory assertion that Braintree "filed a complaint in bad faith against Defendants for infringement of the '149 patent" (Dkt. No. 17, Gator/KVK Counterclaims, ¶ 80) does not save its patent misuse claim. "The bringing of a lawsuit to enforce legal rights does not of itself constitute . . . patent misuse; there must be bad faith and improper purpose in bringing the suit, in implementation of an illegal restraint of trade." *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1558 (Fed. Cir. 1995). "A purpose is improper if its goal is not to win a favorable judgment, but to harass a competitor and deter others from competition, by engaging the litigation process itself, regardless of the outcome." *Id.*

Defendants have not alleged such a specific purpose here. Nor could they in light of the Hatch-Waxman Act's authorization for a patent holder to challenge a generic drug company's filing of an NDA under 21 U.S.C. § 355(b)(2), and Judge Sheridan's affirmative rulings in favor of Braintree on all key issues. *See* Exs. 2, 3, 4, *Novel* Claim Construction Opinion, Summary Judgment Opinion, and Motion for Reconsideration Order; *see also Eli Lilly & Co. v. Medtronic,*

Inc., 496 U.S. 661, 676-677 (1990) (describing the "important new mechanism" of § 271(e)(2) infringement under the Hatch-Waxman Act, "designed to guard against infringement of patents relating to pioneer drugs" that could otherwise occur, due to the new streamlined generic approval process).

Given that "a patent infringement suit is presumed to be brought in good faith," *Atari Games Corp. v. Nintendo of Am., Inc.*, 897 F.2d 1572, 1577 (Fed. Cir. 1990), Defendants must present specific facts supporting its allegation that Braintree's infringement action was brought for an improper purpose. *See Semiconductor Energy Lab. Co. v. Chi Mei Optoelectronics Corp.*, 531 F. Supp. 2d 1084, 1101 (N.D. Cal. 2007). Defendants do not and cannot allege any such facts. Defendants' contrary claim construction theory to avoid infringement of the '149 patent—one that has been rejected by a District Court—cannot support a finding of bad faith. *Cf. Sprint Commc'n Co. L.P. v. Vonage Holdings Corp.*, 500 F. Supp. 2d 1290, 1340 (D. Kan. 2007) (granting summary judgment dismissing patent misuse claim where, in support of the claim, Vonage "advances nothing more than an argument that it disagrees with Sprint's proposed scope of some of the claim terms . . . which is the type of claim construction argument that is common in most patent infringement actions.").

D. **Patent Misuse is an Affirmative Defense, Not a Cause of Action.**

Defendants' patent misuse counterclaim should also be dismissed because patent misuse may not be pled as a stand-alone claim, but only as an affirmative defense. *See e.g. B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1428 (Fed. Cir. 1997) ("patent misuse simply renders the patent unenforceable ... [T]he defense of patent misuse may not be converted to an affirmative claim for damages simply by restyling it as a declaratory judgment counterclaim."); *Too Marker Prod., Inc. v. Shinhan Art Materials, Inc.*, No. CV 09-1013, 2010 U.S. Dist. LEXIS 18731, at *11 (D. Or. Feb. 9, 2010) (dismissing patent misuse cause of action because "patent

misuse is not an independent cause of action, but rather an affirmative defense to a charge of infringement."); *Depuy, Inc. v. Zimmer Holdings, Inc.*, 343 F. Supp. 2d 675, 684 n.4 (N.D. Ill. 2004) ("patent misuse is an affirmative defense, not a counterclaim"); *see also U.S. Philips Corp.*, 424 F.3d at 1184 ("Patent misuse is an equitable defense to patent infringement."). For this reason alone, Defendants' counterclaim for patent misuse should be dismissed.

IV. CONCLUSION

For each of the reasons stated above, Defendants' Second Counterclaim should be dismissed with prejudice.

Dated: November 12, 2013

Respectfully submitted,

/s/ John P. Marino

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on November 12, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system. I also certify that the foregoing document is also being furnished to counsel of record as identified below, either via transmission of Notices of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive Notices of Electronic Filing via the CM/ECF system:

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