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UNITED STATES DISTRICT COURT EASTERN DISTRICT OF NEW YORK	
SAN FRANCISCO TECHNOLOGY, INC.,	>

Plaintiff.

-against-

ORDER 10-CV-3630 (SJF)(ETB)

HI-TECH PHARMACAL CO. INC.,

Defendant.

_____X

FEUERSTEIN, J.

On March 5, 2010, plaintiff commenced this action in the Northern District of California as a *qui tam* relator against defendant and several other parties alleging that defendant had falsely marked a product line with an expired patent in violation of 35 U.S.C. § 292 ("section 292") and seeking half of the civil penalty. On July 19, 2010, presiding Judge Jeremy Fogel ordered that plaintiff's case be severed as to each party, and that plaintiff's complaint against defendant be transferred to the Eastern District of New York. Defendant moved to dismiss the complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. For the reasons set forth herein, defendant's motion is granted.

I. Background

The complaint alleges that: defendant "makes and sells" Zostrix Neuropathy Cream, and "marks the packages in which its Zostrix Neuropathy Cream products are sold: 'Covered by U.S.

Patent No 4,997,853," ("patent 853") however, the patent expired "no later than" December 3, 2008, compl. ¶ 92; despite the expiration of the patent, this product is "being sold in retail in 2010," *id.* ¶ 93; "[u]pon information and belief," that defendant "has made many decisions to mark its falsely marked products after the expiration of [patent 853], including each time it has printed or otherwise created such packaging;" defendant "operates a website to advertise its falsely marked products" which indicates that they "can be purchased at retail store chains [in California]," *id.* ¶ 37; defendant "marks its products to induce the public to believe that each such product is supported by each patent listed" knowing that the patent is expired, and that therefore, defendant falsely marked the product "with intent to deceive the public." *Id.* ¶ 94.

The parties agree that in order to state a claim pursuant to 35 U.S.C. § 292, a plaintiff must adequately allege that a product is falsely marked "with intent to deceive the public." Memorandum in Support at 7; Memorandum in Opposition at 5-6. Defendant argues that the heightened pleading standard of Rule 9 of the Federal Rules of Civil Procedure should apply to plaintiff's claim, and that plaintiff's allegations do not meet the pleading standards of either Rule 8 or Rule 9. Plaintiff contends that the Rule 8 pleading standard should apply, but that in any event, plaintiff's claims are adequately plead by either standard.

II. Analysis

A. Rule 12(b)(6) Motion to Dismiss

In deciding a motion to dismiss, the Court must liberally construe the claims, accept all factual allegations in the complaint as true, and draw all reasonable inferences in favor of the

plaintiff. See Goldstein v. Pataki, 516 F.3d 50, 56 (2d Cir. 2008) (quoting Chambers v. Time Warner, Inc., 282 F.3d 147, 152 (2d Cir. 2002)). However, this standard "is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Ashcroft v. Iqbal, --- U.S. ---, 129 S. Ct. 1937, 1949, 173 L. Ed. 2d 868 (2009). "While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations." Id. at 1950.

In determining a motion to dismiss pursuant to Rule 12(b)(6), the Court must limit itself to the facts alleged in the complaint, which are accepted as true; to any documents attached to the complaint as exhibits or incorporated by reference therein; to matters of which judicial notice may be taken; or to documents upon the terms and effect of which the complaint "relies heavily" and which are, thus, rendered "integral" to the complaint. <u>Chambers</u>, 282 F.3d at 152-53.

1. Rule 8 Pleading Standard

Federal Rule of Civil Procedure 8(a)(2) requires only a "short and plain statement of the claim showing that the pleader is entitled to relief," in order to "give the defendant fair notice of what the ... claim is and the grounds upon which it rests," <u>Bell Atlantic Corp. v. Twombly</u>, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007) (citing <u>Conley v. Gibson</u>, 355 U.S. 41, 47, 78 S. Ct. 99, 2 L. Ed.2d 80 (1957)). The standard of review on a motion made pursuant to Rule 12(b)(6) and Rule 8 of the Federal Rules of Civil Procedure requires that a plaintiff plead sufficient facts "to state a claim for relief that is plausible on its face." <u>Twombly</u>, 550 U.S. at 547. A complaint must give the defendant "fair notice of what the . . . claim is and the grounds

upon which it rests." Erickson v. Pardus, 551 U.S. 89, 93, 127 S. Ct. 2197, 2200, 167 L. Ed. 2d 1081 (2007). See also Boykin v. KeyCorp, 521 F.3d 202, 214 (2d Cir. 2008). However, a "pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do." Iqbal, 129 S. Ct. at 1949 (2009) (quoting Twombly, 550 U.S. at 555). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of further factual enhancement." Iqbal, 129 S. Ct. at 1949 (quoting Twombly, 550 U.S. at 557). "Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." Twombly, 550 U.S. at 555. The plausibility standard requires "more than a sheer possibility that defendant has acted unlawfully." Iqbal, 129 S. Ct. at 1949.

2. Rule 9 Pleading Standard

Rule 9(b) of the Federal Rules of Civil Procedure provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Speculative and conclusory allegations of intent are insufficient. Eternity Global Master Fund Ltd. v. Morgan Guar. Trust Co. of N.Y., 375 F.3d 168, 187 (2d Cir. 2004). Although Rule 9(b) does not require a plaintiff to plead intent under its heightened pleading standard, all pleadings must comply with the requirements of Rule 8. Iqbal, 129 S. Ct. at 1954.

B. Analysis

Both parties rely upon <u>Clontech Laboratories</u>, Inc. v. Invitrogen Corp., 406 F.3d 1347 (Fed. Cir. 2005) and <u>Pequignot v. Solo Cup Co.</u>, 608 F.3d 1356 (Fed. Cir. 2010). Although <u>Clontech</u> and <u>Pequignot</u> did not interpret the pleading requirements of section 292, their analyses of the evidence required to prove such a claim is informative.

To establish the element of intent to deceive the public, "the *fact* of misrepresentation coupled with proof that the party making it had knowledge of its falsity is enough to warrant drawing the inference that there was a fraudulent intent." Clontech, 406 F.3d at 1352. The presumption of "fraudulent intent," although not specifically in the statute, prevents a defendant from avoiding section 292 liability by merely claiming that it did not "intend to deceive." Id. Clontech requires a section 292 plaintiff to establish that there was misrepresentation, and to prove that the defendant knew that the marking was false. Clontech also defined how the plaintiff could prove knowledge of the misrepresentation:

[I]n order to establish knowledge of falsity the plaintiff must show by a preponderance of the evidence that the party accused of false marking did not have a reasonable belief that the articles were properly marked (i.e., covered by a patent). Absent such proof of lack of reasonable belief, no liability under the statute ensues.

<u>Id.</u> at 392-93. Establishing "statutory deception" is a question of fact. <u>Id.</u>

The Federal Circuit narrowed the <u>Clontech</u> presumption, finding that the presumption was rebuttable. <u>Pequignot</u>, 608 F.3d at 1362-63. Although a defendant's claim alone that it did not intend to deceive the public would not rebut the <u>Clontech</u> presumption, a defendant may present evidence that would support the claim. <u>Id.</u> at 1363. The Circuit noted that the "bar for

proving deceptive intent [in a section 292 claim] is particularly high" because the statute is a criminal statute, and a defendant's "burden of proof is to show by a preponderance of the evidence that it did not have the requisite purpose to deceive." <u>Id.</u> at 1364.

The Court need not decide at this time whether to apply the pleading standards of Rule 8 or Rule 9. Rule 9(b) permits allegations of intent to be alleged generally, which "excuses a party from pleading . . . intent under an elevated pleading standard." <u>Iqbal</u> 129 S. Ct. at 1954. However, allegations of intent must at least comport with the "less rigid - though still operative strictures of Rule 8." Id. at 1954 ("Rule 8 does not empower [a plaintiff] to plead the bare elements of his cause of action, affix the label 'general allegation,' and expect his complaint to survive a motion to dismiss."). Based upon the proof requirements as discussed in Pequignot and <u>Clontech</u> and the pleading requirements as articulated in <u>Iqbal</u> and the Federal Circuit in <u>Exergen</u> Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1327 (Fed. Cir. 2009) (to adequately plead intent for a claim of inequitable conduct "requires that the pleadings allege sufficient underlying facts from which a court may reasonably infer that a party acted with the requisite state of mind."), plaintiff has failed to allege underlying facts that would allow a court to reasonably infer that defendant acted with intent to deceive the public. The complaint alleges that the defendant marked packages with patent number 853 and that the marked products are being sold after the expiration of the patent. Compl. ¶¶ 92-93. The allegation that defendant has "made many decisions" to mark the product after the expiration of the patent is made "[u]pon information and belief," Id. ¶¶ 93-94, but is not supported by any factual allegations. Although a product marked with an expired patent is falsely marked for the purposes of section 292, Pequignot, 608 F.3d at 1362, the conclusion that a product was marked with "intent to deceive the public" is not

supported by the factual allegation that the product is sold at a retail store after the patent has recently expired. There are no factual allegations that indicate when the products in the stores were marked, when the products left the custody and control of defendants, or whether defendants knew that the falsely marked products were still being sold. Plaintiff is entitled to the presumption of intent articulated in <u>Clontech</u> only after it proves that defendant marked the product and knew the marking was false; the presumption does not lower the pleading requirements of <u>Iqbal</u> and <u>Exergen</u>.

As plaintiff's failure to plead facts sufficient to support the element of "intent to deceive the public" requires dismissal of its section 292 claim, it is unnecessary to decide the alternative arguments presented in the motion at this time.

III. Leave to Amend

Rule 15(a)(2) of the Federal Rules of Civil Procedure provides that a party shall be given leave to amend "when justice so requires." "Leave to amend, though liberally granted, may properly be denied for: 'undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc." Ruotolo v. City of New York, 514 F.3d 184, 191 (2d Cir. 1998) (citing Forman v. Davis, 371 U.S. 178, 182, 83 S. Ct. 227, 9 L. Ed.2d 222 (1962)). "If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits." Forman, 371 U.S. at 182. However, if amendment would be futile, i.e., if it

could not withstand a motion to dismiss pursuant to Rule 12(b)(6), leave to amend may be

denied. See Lucente v. International Business Machines Corp., 310 F.3d 243, 258 (2d Cir.

2002). As plaintiff's complaint fails to allege facts crucial to the section 292 claim, plaintiff may

amend the complaint to add such factual allegations within thirty (30) days of the issuance of this

order.

IV. Conclusion

Based upon the foregoing, defendant's motion to dismiss the complaint pursuant to Rule

12(b)(6) of the Federal Rules of Civil Procedure is granted. Plaintiff's motion to amend the

complaint is granted insofar as plaintiff may file an amended complaint within thirty (30) days

from the issuance of this order. In the event plaintiff fails to amend the complaint in the

proscribed period, the remaining claims will be dismissed with prejudice for failure to prosecute,

and the clerk of the court is directed to close the case.

SO ORDERED.

SANDRA F FEUERSTEIN United States District Judge

2/4/11

Dated: February 4, 2011

Central Islip, New York

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