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Intellectual Property

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Heightened Pleading Standard of Fed. R. Civ. P.9(b) Applied to False Marking Claims

On August 25, 2010, Judge Sue L. Robinson of the U.S. District Court for the District of Delaware issued a decision dismissing a *qui tam* suit accusing Bayer of falsely marking its Aleve® Liquid Gels, Aleve® Caplets, and Aleve® Smooth Gels with expired patents. Judge Robinson's <u>ruling</u> in *Brinkmeier v. Bayer HealthCare LLC*, Case No.1:10-cv-00001-SLR (D. Del. filed Jan. 3, 2010) dismissed the plaintiff's claims for failure to sufficiently plead an intent to deceive, as required under 35 U.S.C. § 292, the false marking statute.

Since the December 2009 Federal Circuit decision in Forest Group, Inc. v. Bon Tool Co. holding each occasion of false marking may constitute a fine of up to \$500, qui tam false marking actions have flooded the district court dockets. Defendants have adopted several strategies in response to the hundreds of false marking cases filed since January 2010, including filing motions to dismiss for failure to state a claim. Principally, defendants are arguing that claims brought under § 292 are fraud-based claims subject to the heightened pleading requirements of Fed. R. Civ. P. 9(b) because § 292 requires the marker act with "an intent to deceive" and that the conclusory allegations of the qui tam plaintiff's complaint do not rise to this standard.

The Federal Circuit has yet to determine whether the requisite "intent to deceive" of § 292 must be pled with particularity under Fed. R. Civ. P. 9(b) or, rather, may be averred generally under the more relaxed pleading standard of Fed. R. Civ. P. 8(a). In its June 2010 *Pequignot v. Solo Cup Co.* decision, the Federal Circuit addressed the meaning of "intent" under § 292, stating "[b]ecause [§ 292] requires that the false marker act for the purpose of deceiving the public, a purpose of deceit rather than simply knowledge that the statement is false, is required." However, despite recognizing that "the bar for proving deceptive intent is particularly high," the Federal Circuit did not address the pleading standard for alleging "intent to deceive."

Judge Robinson's opinion in *Brinkmeier v. Bayer HealthCare* is one of a growing number of district court decisions grappling with the pleading standard for false marking actions. Some district courts have determined, like Judge Robinson, that § 292 is a fraud-based claim subject to the heightened pleading requirements of Rule 9(b), while others have declined to adopt the Rule 9(b) standard; yet other courts apply the more liberal pleading requirements of Rule 8(a) without deciding whether Rule 9(b) applies. Even where district courts hold that Rule 9(b) applies, the courts differ as to the type of allegations they find sufficient under the heightened pleading requirement. For example, in *Simonian v. Oreck Corp.*, the Northern District of Illinois found that the plaintiff's assertions that the defendant "had knowledge that these patents were expired" was sufficient to show intent to deceive under Rule 9(b). In contrast, the Eastern District of Pennsylvania, in *Hollander v. Etymotic Research, Inc.*, held similar allegations of knowledge to be insufficient under Rule 9(b) "because mere knowledge does not support an inference of intent to deceive."

Brinkmeier v. Bayer HealthCare LLC is one of the few cases explicitly holding that Rule 9(b) applies and concurrently finding that the plaintiff's allegations are insufficient. The lawsuit, filed in the District of Delaware on January 3, 2010, by qui tam relator Jennifer L. Brinkmeier, alleged that Bayer, with an intent to deceive the public, marked the safety bottles for its Aleve® Products with U.S. Patent Nos. D330,677 and 4,948,002 after the patents expired. Bayer, represented by Ropes & Gray, moved to dismiss the Complaint

arguing that Brinkmeier's claims for false marking, which sound in fraud, must be pled with particularity under Fed. R. Civ. P. 9(b), and that the conclusory allegations of intent contained in Brinkmeier's Complaint were insufficient to survive a motion to dismiss.

Without responding to Bayer's motion to dismiss, Brinkmeier attempted to cure the deficiencies by filing an Amended Complaint. Brinkmeier's Amended Complaint alleged "on information and belief" that Bayer "is a sophisticated company with years of experience applying for, obtaining, and litigating patents"; "has decades of experience performing due diligence"; and has an "in-house legal department that should be aware of \$292 requirements." Brinkmeier went on to allege that Bayer "marks products with expired patents for the purpose of deceiving the public." In response, Bayer renewed its motion to dismiss contending that Brinkmeier's "sweeping allegations of intent . . . do not permit the court to infer more than the mere possibility of misconduct" and, therefore, fail to state a claim.

Judge Robinson, agreeing with Bayer, first found § 292 claims are fraud-based claims subject to the heightened pleading standard of Rule 9(b). Judge Robinson then concluded that aside from conclusory allegations, Brinkmeier "pleads no facts to support her contentions that Bayer included the '002 and/or '677 patents on any products with the intent to deceive the public." In support of her conclusion, Judge Robinson noted that "defendant's knowledge of the limited duration of patents and the actual expiration of the patents do not create an inference that defendant knew that the patents at issue actually expired."

In addition to this case, Ropes & Gray is handling a number of other false marking actions under 35 U.S.C. § 292. To find out how this evolving area of the law, including the decision in *Brinkmeier v. Bayer HealthCare LLC* affects your interests, please contact your usual Ropes & Gray attorney or one of the following Ropes & Gray IP attorneys:

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