

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ST. JUDE MEDICAL, CARDIOLOGY  
DIVISION, INC., ST. JUDE MEDICAL  
SYSTEMS AB, and ST. JUDE MEDICAL  
S.C., INC.,

Plaintiffs,

v.

VOLCANO CORPORATION,

Defendant.

Civil Action No. 12-441-RGA

MEMORANDUM ORDER

Before the Court is St. Jude's Motion to Dismiss Volcano's Inequitable Conduct Counterclaim and to Strike its Affirmative Defense Pursuant to Rules 12(b)(6) and 12(f). (D.I. 155). The briefing is complete (D.I. 156, 166 & 177), and the Court heard oral argument on June 6, 2014. For the reasons set forth below, St. Jude's motion **IS GRANTED** with respect to Glenn Law, and **GRANTED WITH LEAVE TO AMEND** with respect to Johan Svanerudh and Sauli Tulkki.

In order to establish inequitable conduct, an accused infringer must prove that a specific individual with a duty of candor to the PTO "misrepresented or omitted material information with the specific intent to deceive the PTO." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (en banc). Allegations of inequitable conduct must be pled with particularity. *Exergen Corp. v. Wal-Mart Stores*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). "[T]o plead the 'circumstances' of inequitable conduct with the requisite 'particularity' under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the

material misrepresentation or omission committed before the PTO.” *Id.* The pleading must also show that the omitted information is not cumulative of the information already on the record by identifying the particular claim limitations that are absent from the record. *Id.* at 1329-30 (“Such allegations are necessary to explain both ‘why’ the withheld information is material and not cumulative, and ‘how’ an examiner would have used this information in assessing the patentability of the claims.”). Finally, “[a] charge of inequitable conduct based on a failure to disclose will survive a motion to dismiss only if the plaintiff’s complaint recites facts from which the court may reasonably infer that a specific individual both knew of invalidating information that was withheld from the PTO and withheld that information with a specific intent to deceive the PTO.” *Delano Farms Co. v. Cal. Table Grape Comm’n*, 655 F.3d 1337, 1350 (Fed. Cir. 2011). St. Jude asserts Volcano’s inequitable conduct counterclaim and affirmative defense<sup>1</sup> are legally deficient for failing to adequately plead the who, where, what, why, and how, as well as materiality and intent to deceive the PTO. (D.I. 156, pp. 2-3).

Volcano alleges three individuals committed inequitable conduct: Johan Svanerudh, Sauli Tulkki, and Glenn Law. Messrs. Svanerudh and Tulkki were employees of Radi Medical Systems AB, a predecessor to St. Jude, and are the named inventors on the ’514 patent. Mr. Law prosecuted the ’514 patent application. These three individuals, according to Volcano, provided an incomplete and misleading representation to the PTO regarding the capabilities of Volcano’s prior art WaveMap system. (D.I. 166, pp. 1-4).

One of the advances embodied in the ’514 patent is the ability to calculate and “graphically display[] physiological variables related to blood pressure.” ’514 patent, 1:11-12.

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<sup>1</sup> Because both an affirmative defense and a counterclaim asserting inequitable conduct must meet the particularity requirements dictated by Rule 9(b), Volcano’s “counterclaim and affirmative defense for inequitable conduct rise or fall together.” *Senju Pharm. Co., Ltd. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 306 (D. Del. 2013).

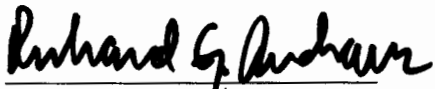
Volcano asserts its WaveMap system possessed this capability when connected to a hemodynamic monitoring system, and that Messrs. Svanerudh and Tulkki knew this based on their familiarity with several Volcano documents, none of which were disclosed to the PTO. These documents include the December 1996 version of the WaveMap Operator's Manual, the WaveMap brochure, the WaveWire brochure, and the WaveMap® Pressure Guide Wire System, Operator's Manual. (D.I. 148, ¶¶ 83 & 92). In addition, Mr. Svanerudh drafted a written report detailing the WaveMap's functionality after experimenting with it (*id.*, ¶ 91), and another Radi employee prepared a video demonstrating how to connect a hemodynamic monitoring system to the WaveMap device. (*Id.*, ¶ 93). By failing to disclose these documents and falsely representing to the PTO that the WaveMap "do[es] not have a graphical interface, only numerical displays showing measured values" ('514 patent, 1:53-56), Volcano asserts Messrs. Svanerudh and Tulkki committed inequitable conduct. As for Mr. Law, Volcano alleges he was aware of the WaveMap's capabilities based on his knowledge of the December 1996 version of the WaveMap Operator's Manual, the WaveMap brochure, and the WaveWire brochure. (D.I. 148, ¶ 83). Indeed, while prosecuting a separate patent for St. Jude in 2000, Mr. Law submitted a 1998 WaveWire brochure and other Volcano documents as part of the Information Disclosure Statement to the PTO. (D.I. 166, p. 7; D.I. 148, ¶¶ 66 & 67). Volcano maintains Mr. Law's failure to submit these documents relating to the WaveMap when prosecuting the '514 patent constitutes inequitable conduct.

The Court agrees that Volcano has failed to adequately plead the inequitable conduct allegations. There are no facts in Volcano's complaint that would allow the Court to "reasonably infer" Mr. Law withheld documents detailing the WaveMap's functionality with the specific intent to deceive the PTO. *See Delano Farms Co.*, 655 F.3d at 1350. Mr. Law's disclosure of

certain WaveMap documents during the prosecution of a different Radi patent but not for the '514 patent is insufficient to infer an intent to deceive. The complaint is also insufficient with respect to Messrs. Svanerudh and Tulkki because it fails to sort out the specific facts and attribute them to a particular individual. (*See, e.g.*, D.I. 148, ¶¶ 95, 98, 104 & 107 (referring to “the applicants for the '514 patent and other individuals that had a duty of candor and good faith in dealing with the USPTO”)). Volcano needs to individually identify whose actions constitute affirmative misconduct or were contrary to the duty of candor, and material to the issuance of the '514 patent, on particular dates, with the intent to deceive the PTO. Volcano should also plead facts explaining why the omitted references are not cumulative of other prior art reviewed during prosecution, specifically U.S. Patent No. 6,193,669.

The Court grants the motion to dismiss the inequitable conduct counterclaim and affirmative defense (D.I. 155), but with leave to amend against Messrs. Svanerudh and Tulkki within ten days.

Entered this 11<sup>th</sup> day of June, 2014.

  
United States District Judge