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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

LIFESCAN, INC. and LIFESCAN SCOTLAND,))
LTD.,))
))
Plaintiffs,))
))
v.))
))
SHASTA TECHNOLOGIES, LLC,))
INSTACARE CORP., PHARMATECH))
SOLUTIONS, INC., and CONDUCTIVE))
TECHNOLOGIES, INC.,))
))
Defendants.))

Case No.: 5:11-CV-04494-EJD

**ORDER GRANTING PLAINTIFFS’
MOTION FOR PRELIMINARY
INJUNCTION; DENYING
DEFENDANTS’ MOTION TO
DISMISS**

[Re: Docket Nos. 174, 176]

This action arises out of Defendants Shasta Technologies, LLC (“Shasta”), Instacare Corp. (“Instacare”), Pharmatech Solutions, Inc. (“Pharmatech”), and Conductive Technologies, Inc.’s (“Conductive”) (collectively, “Defendants”) development and sale of GenStrips: blood glucose test strips intended for use in Plaintiffs’ LifeScan, Inc. and LifeScan Scotland, Ltd.’s (collectively, “Plaintiffs”) OneTouch Ultra test meter. Plaintiffs allege that Defendants’ test strips infringe their U.S. Patent Nos. 6,241,862 (“the ’862 patent”) and 5,708,247 (“the ’247 patent”) and that Defendants indirectly infringe Plaintiffs’ U.S. Patent No. 7,250,105 (“the ’105 patent”). The court previously stayed this action as to the ’862 and ’247 patents. Dkt. No. 245.

Presently before the court is Plaintiffs’ Motion for Preliminary Injunction (Dkt. No. 176) and Defendants’ Motion to Dismiss as to Count 3 of the First Amended Complaint (Dkt. No. 174). The court held a hearing on Plaintiffs’ Motion for Preliminary Injunction on February 21, 2013 and took Defendants’ Motion to Dismiss under submission. Having reviewed the parties’ briefing and



1 heard the parties' arguments, the court GRANTS Plaintiffs' Motion for Preliminary Injunction and
2 DENIES Defendants' Motion to Dismiss for the reasons set forth below.

3 1. TECHNOLOGY BACKGROUND

4 The parties are competitors in the blood glucose monitoring systems industry. Since 2000,
5 Plaintiffs have marketed and sold the OneTouch Ultra System, a glucose monitoring system used
6 by patients with diabetes. See Pl. Mtn. for Prelim. Inj. 3-4, Dkt. No. 176; Def. Opp. 2; Dkt. No.
7 203. Plaintiffs are the market leader in glucose monitoring systems, and generate approximately \$1
8 billion in sales annually. Dkt. No. 203 at 2. The system is composed of both a meter and
9 disposable test strips. Dkt. No. 176 at 3. To use the system, a patient places a disposable test strip
10 in the meter, draws a small drop of blood using a lancet, and places the blood on the test strip. Dkt.
11 No. 176 at 3-4. The meter then determines the glucose level in the blood by measuring the
12 electrical current produced when an electrochemical reaction is triggered in the strip by the
13 glucose. Id. at 4.

14 Plaintiffs' competitive advantage appears to be in its DoubleSure Technology, which is the
15 subject of the '105 patent. Id. DoubleSure Technology is a method designed to improve the
16 reliability and accuracy of glucose measurements. Id. It uses a self-testing strip design, using
17 multiple sensors in a downstream configuration. Id. at 6. Figure 2 depicts the test strip design:

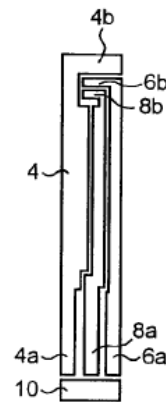


FIG. 2

26 A drop of blood applied to the top of the test strip flows downstream by capillary action.

27 Id. The test strip has two working sensors (6b and 8b), with one sensor downstream from the

1 other. Id. This design ensures that the first sensor is completely covered in blood before the
2 second sensor is reached, allowing for more accurate results. Id. The currents are measured at
3 each sensor, and if the values are within a pre-determined range of one another, the reading is
4 accurate. Id. If the difference in values is outside of the acceptable range, the reading may not be
5 accurate and the test strip can be discarded. Id. at 6-7.

6 Defendants' GenStrips are nearly identical to Plaintiffs' test strips, and are designed
7 specifically to work with the OneTouch Ultra meter. See id. at 5. GenStrips received FDA
8 approval in January of this year, but are not approved for use in any device other than the
9 OneTouch Ultra meter. Id. While GenStrips have not been on the market for the majority of this
10 litigation, Defendants confirmed at the preliminary injunction hearing that their product is now
11 available for purchase. Prelim. Inj. Hr'g Tr. (Rough) 80:20-21 (Feb. 21, 2013).

12 **2. PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

13 **2.1 Legal Standard**

14 Because this motion for preliminary injunction arises in the context of a patent infringement
15 action, the court will apply Federal Circuit law. See Hybritech Inc. v. Abbott Labs., 849 F.2d
16 1446, 1450, n. 12 (Fed. Cir. 1988). The Federal Circuit requires the court to consider four factors
17 of "universal applicability" in determining whether a grant of a preliminary injunction is
18 appropriate: (1) reasonable likelihood of success on the merits; (2) irreparable harm; (3) the
19 balance of hardships tips in the plaintiff's favor; and (4) the injunction is in the public interest.
20 Titan Tire Corp. v. Case New Holland, Inc., 566 F.3d 1372, 1375-76 (Fed. Cir. 2009) (citing
21 Winter v. Natural Res. Def. Council, Inc., 555 U.S. 7 (2008)). Each of these four factors must be
22 weighed and assessed against the others and against the form and magnitude of the relief requested.
23 Hybritech, 849 F.2d at 1451.

24 **2.2 Likelihood of Success on the Merits**

25 In a patent infringement case, "reasonable likelihood of success on the merits" means that a
26 patentee must show (1) it will likely prove infringement; and (2) its infringement claim will likely
27 withstand challenges to the patent's validity and enforceability. Purdue Pharma L.P. v. Boehringer

1 Ingelheim GmbH, 237 F.3d 1359, 1363 (Fed. Cir. 2001). Even at this stage, the court must
2 consider the evidence in light of the presumptions and burdens that will apply at trial. Titan Tire,
3 566 F.3d at 1376.

4 A patent is presumed valid at trial. 35 U.S.C. § 282. Thus, the alleged infringer bears the
5 burden of proving an affirmative defense of invalidity by clear and convincing evidence. Titan
6 Tire, 566 F.3d at 1376. If the accused infringer successfully meets its burden, the plaintiff then
7 must come forward with contrary evidence sufficient to overcome the accused infringer's showing.
8 Id. At the preliminary injunction stage, a patent is also presumed to be valid. Similarly, the
9 accused infringer bears the burden to present evidence of invalidity. However, unlike at trial, the
10 accused infringer need only raise a "substantial question" regarding validity. Sciele Pharma Inc. v.
11 Lupin Ltd., 684 F.3d 1253, 1263 (Fed. Cir. 2012); Abbot Labs. v. Sandoz, Inc., 544 F.3d 1341,
12 1364 (Fed. Cir. 2008); Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1359 (Fed.
13 Cir. 2001) (finding that the defendants' burden to raise a "substantial question" did not equate to
14 the "clear and convincing" standard required at trial, but instead could be met by showing
15 "vulnerability"). Notwithstanding the accused infringer's duty to bring forward evidence of
16 invalidity, the ultimate burden remains on the plaintiff to show that the alleged infringer's defense
17 "lacks substantial merit," and that plaintiff is likely to succeed at trial despite the validity
18 challenge. Titan Tire, 566 F.3d at 1377 (quoting New England Braiding Co. v. A.W. Chesterton
19 Co., 970 F.2d 878, 883 (Fed. Cir. 1992)). In determining the likelihood of success on the validity
20 issue, the court must "weigh the evidence both for and against validity that is available at this
21 preliminary injunction stage...[t]hen...if the [court] concludes there is a 'substantial question'
22 concerning the validity of the patent, meaning that the alleged infringer has presented an invalidity
23 defense that the patentee has not shown lacks substantial merit, it necessarily follows that the
24 patentee has not succeeded in showing it is likely to succeed at trial on the merits of the validity
25 issue." Id.

2.2.1 Patent Exhaustion

1 Before reaching the issues of infringement and invalidity, the court must first consider
2 whether Plaintiffs are likely to show that the '105 patent has not been exhausted. "The declared
3 purpose of the patent law is to promote the progress of science and the useful arts by granting to
4 the inventor a limited monopoly, the exercise of which will enable him to secure the financial
5 rewards for his invention." Univis Lens Co. v. United States, 316 U.S. 241, 250 (1942) (citing
6 U.S. Const. Art. I, § 8, cl. 8). To strike the proper balance between the public's interest in
7 innovation and an inventor's need for remuneration, the law extends to patentees a monopoly for a
8 limited period of time, during which the patentee maintains the exclusive "right to make, use, and
9 sell" the invention. See Bauer & Cie v. O'Donnell, 229 U.S. 1, 10 (1913). However, that
10 monopoly is not unlimited. Once a patentee sells the patented invention in whole or, under certain
11 circumstances, in part, the monopoly is exhausted. Univis, 316 U.S. at 249. This principle of
12 patent exhaustion is also called the first sale doctrine. See Static Control Components, Inc. v.
13 Lexmark Int'l Inc., 615 F.Supp.2d 575, 578 (E.D. Ky. 2009).

15 As the Supreme Court recently articulated, the first sale doctrine provides that "the initial
16 authorized sale of a patented item terminates all patent rights to that item." Quanta Comp., Inc. v.
17 LG Electronics, Inc., 553 U.S. 617, 625 (2008). In operation, the doctrine "prohibits patent
18 holders from selling a patented article and then 'invoking patent law to control postsale use of the
19 article.'" Excelstor Tech., Inc. v. Papst Licensing GmbH & Co. KG, 541 F.3d 1373, 1376 (Fed.
20 Cir. 2008) (citing Quanta, 553 U.S. at 638). Because application of the doctrine extinguishes a
21 patentee's monopoly right over the patented item, "[e]xhaustion is triggered only by a sale
22 authorized by the patent holder." Quanta, 553 U.S. at 636.

23 The parties dispute whether an "authorized sale" has occurred such that the '105 patent
24 could be deemed exhausted. Plaintiffs first distribute their OneTouch Ultra products either by (1)
25 having doctors distribute a free OneTouch Ultra kit, comprised of a meter and 10 test strips, to
26 diabetic patients, or (2) selling the OneTouch Ultra meter alone at a reduced price. Defendants
27 contend that under either distribution scheme, Plaintiffs have transferred ownership of their
28

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