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United States District Court
Northern District of California

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

ZELTIQ AESTHETICS, INC.,
Plaintiff,
v.
BTL INDUSTRIES, INC., et al.,
Defendants.

Case No. [13-cv-05473-JCS](#)

**ORDER DENYING MOTION FOR
PRELIMINARY INJUNCTION**

Dkt. No. 18

I. INTRODUCTION

Plaintiff Zeltiq Aesthetics, Inc. (“Zeltiq”) filed this action against Defendants BTL Industries, Inc. and Saturn Consulting LLC dba Monarch Laser Services (“Defendants”). Zeltiq alleges that Defendants falsely advertised that a medical device manufactured by BTL was approved by the federal Food and Drug Administration (“FDA”) to be used for fat reduction and body contouring. Zeltiq asserts claims under the Lanham Act, 15 U.S.C. § 1125, and claims for unfair competition under California’s Business and Professional Code § 17200 and Massachusetts General Laws ch. 93A § 2. Zeltiq filed a Motion for Preliminary Injunction (“Motion”). The Court held a hearing on the Motion on March 14, 2014, at 9:30 a.m. For the reasons explained below, the Motion for Preliminary Injunction is DENIED.¹

II. BACKGROUND

A. FDA’s Premarket Approval and 510(k) Clearance

In 1976, Congress amended the federal Food, Drug, and Cosmetic Act (“FDCA”), which previously only regulated food and drugs, with the Medical Device Amendments (“MDA”), 90

¹ The parties have consented to the jurisdiction of the undersigned magistrate judge pursuant to 28 U.S.C. § 636(c).

1 Stat. 539, 21 U.S.C. § 301. The MDA “classifies medical devices in three categories based on the
2 risk that they pose to the public.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). As
3 explained by the Supreme Court in *Medtronic*:

4 Devices that present no unreasonable risk of illness or injury are
5 designated Class I and are subject only to minimal regulation by
6 “general controls.” 21 U.S.C. § 360c(a)(1)(A). Devices that are
7 potentially more harmful are designated Class II; although they may
8 be marketed without advance approval, manufacturers of such
9 devices must comply with federal performance regulations known as
10 “special controls.” § 360c(a)(1)(B). Finally, devices that either
11 “presen[t] a potential unreasonable risk of illness or injury,” or
12 which are “purported or represented to be for a use in supporting or
13 sustaining human life or for a use which is of substantial importance
14 in preventing impairment of human health,” are designated Class III.
15 § 360c(a)(1)(C).

16 *Id.* at 476-77. While “Class III devices must complete a thorough review process with the FDA
17 before they may be marketed,” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 343
18 (2001), Class I and II devices only need to submit a “ ‘premarket notification’ to the FDA, in
19 accordance with the less burdensome ‘510(k) process.’ ” *PhotoMedex, Inc. v. Irwin*, 601 F.3d
20 919, 925 (9th Cir. 2010) (quoting *Medtronic*, 518 U.S. at 477-79).

21 “Under the 510(k) process,² if the Class II device is deemed ‘substantially equivalent’ to a
22 pre-existing device with prior clearance, ‘it can be marketed without further regulatory analysis.’”³
23 *Id.* (citing *Medtronic*, 518 U.S. at 478; 21 U.S.C. § 360(k); 21 C.F.R. § 807.100). “ ‘[S]ubstantial
24 equivalence’ ” means, with respect to a device being compared to a predicate device, that the
25 device has the *same intended use* as the predicate device....” 21 U.S.C. § 360c(i)(1)(A); *see also*
26 21 C.F.R. § 807.100 (“FDA will determine that a device is substantially equivalent to a predicate
27 device ... [if, *inter alia*, t]he device has the *same intended use* as the predicate device.”) (emphasis
28 added).

² The process is known as the “§ 510(k) process” because that was “the section in the original Act.” *Medtronic*, 518 U.S. at 478.

³ “Unlike premarket approval, 510(k) clearance ‘does not in any way denote official approval of the device.’ ” *PhotoMedex*, 601 F.3d at 925 n. 3 (quoting 21 C.F.R. § 807.97).

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B. Zeltiq’s CoolSculpting System

Zeltiq manufactures and markets a medical device known as CoolSculpting. Declaration of Patricia Altavilla (“Altavilla Decl.”) ¶ 6. CoolSculpting is designed to reduce the temperature of fat cells in the treated area, which is intended to cause fat cell elimination through a natural biological process known as “apoptosis” without causing scar tissue or damage to the skin, nerves or surrounding tissue. *Id.* ¶ 7. CoolSculpting is clinically proven to reduce fat bulges in a sixty-minute procedure. *Id.*

Zeltiq’s CoolSculpting system has been cleared by the FDA for cold-assisted lipolysis of the flank, or “love handles” and the abdomen. *Id.* ¶ 6. Zeltiq states that it “developed its CoolSculpting technology for a novel indication,” and therefore, “submitted clinical studies and other data to FDA to obtain 510(k) clearance for CoolSculpting.” Altavilla Decl. ¶ 8. Zeltiq states that it undertook the expensive endeavor of obtaining 510(k) clearance because clearance of a device for treatment of body fat conveys instant and substantial credibility to the device. *Id.*

As a result of its investment to secure FDA clearance, CoolSculpting has become the leading noninvasive medical device for reduction of body fat. *Id.* ¶ 9. In its most recent quarterly filing, Zeltiq reports having sold over 1,900 CoolSculpting devices and over 500 in the twelve months between September 30, 2012 and September 30, 2013. Declaration of Jeffrey E. Faucette (“Faucette Decl.”) ¶ 2, Exh. A at 19. Zeltiq also reports having generated over \$75 million in revenue in the nine months ending in September 30, 2013. *Id.* In a preliminary full year report, Zeltiq noted that its revenue increased approximately 91% in one year. Faucette Decl., Exh. G.

C. BTL’s Vanquish Device

Defendant BTL Industries, Inc. (“BTL”) is the United States distributor for BTL Industries, which is a worldwide manufacturer of medical devices. Declaration of Michael Besse (“Besse Decl.”) ¶ 2. BTL Industries has offices in over thirty countries and is one of the world’s major manufacturers of medical devices in medical aesthetics and other areas. *Id.* ¶¶ 2-3.

BTL submitted to a notice of intent under § 510(k) to market a device that it called “BTL Elite.” Altavilla Decl. ¶ 12. Zeltiq states that, like the predicate devices identified in BTL’s 510(k), the BTL Elite was designed to deliver heat to muscle tissue. *Id.* BTL asked for FDA

1 clearance to market its device for

2 use in applying therapeutic deep heat in body tissues for the
3 treatment of selected medical conditions such as: 1. Relieving pain;
4 2. Reducing muscle spasm; 3. Increasing range of motion of
5 contracted joints using heat and stretch techniques; and 4. Increasing
6 blood flow to tissues in the treatment area.

6 Altavilla Decl. ¶ 12, Exh. 1. The FDA send BTL a 510(k) letter of approval clearing the BTL
7 Elite for those proposed uses. *Id.*

8 BTL now manufactures and markets a device it calls “Vanquish.” Zeltiq does not contend
9 that Defendants unlawfully market Vanquish because it differs from the technology or design for
10 the BTL Elite. Rather, Zeltiq argues that Defendants unlawfully market the Vanquish device
11 because it is promoted for fat reduction and body contouring, which not a *use* that has been cleared
12 through the 510(k) process for the BTL Elite.

13 The “Instructions for Use” or “IFU” for the Vanquish device tracks the indications for use
14 that the FDA has cleared for the BTL Elite: the treatment of muscle aches and pains. Altavilla
15 Decl. ¶ 33, Exh. 20. The IFU for the Vanquish is found within the “Operator’s Manual” that is
16 provided to every physician who purchases the device. Declaration of Marcel Besse (“Besse
17 Decl.”) ¶ 14; Altavilla Decl. ¶ 33, Exh. 20. In the United States, BTL only sells the Vanquish
18 device to physicians and it cannot be purchased by consumers. Besse Decl. ¶ 13.

19 **D. Defendants’ Promotion of Vanquish**

20 Zeltiq contends that, despite having no FDA clearance to market and distribute Vanquish
21 for use in fat reduction and body contouring, Defendants have *only* promoted Vanquish for this
22 unapproved use. Zeltiq states that there is not a single instance in which Defendants promoted
23 Vanquish for the treatment of muscle aches and spasms, which is the only purpose for which it
24 was cleared. Altavilla Decl. ¶ 32. Zeltiq also accuses Defendants of promoting Vanquish
25 exclusively for fat reduction and body contouring while touting the device as “FDA-cleared”
26 without explaining the limits of the FDA’s clearance. Zeltiq asserts this is an attempt to mislead
27 physicians into believing that Vanquish is FDA-approved for fat reduction.

28 Defendants do not dispute that, in 2013, they promoted Vanquish for fat reduction—which

1 Defendants admit is an “off-label use.” Nor do Defendants dispute that they have only intended to
2 promote Vanquish for fat reduction. Indeed, BTL’s trademark registration describes Vanquish as
3 a “[b]ody treatment device using heating and cooling for fat cell reduction.” Declaration of
4 Thomas Hanrahan (“Hanrahan Decl.”), Exh. 22. Defendants contend, however, that they no
5 longer promote Vanquish in the United States for any off-label use, and further contend that they
6 never directly or indirectly represented that Vanquish has received FDA clearance for fat
7 reduction or body contouring. Besse Decl. ¶ 14.

8 **1. Defendants’ Promotion of Vanquish to Physicians at Medical**
9 **Conferences and Workshops**

10 In the spring of 2013, BTL launched Vanquish at three medical conferences: a meeting in
11 Boston of the American Society for Lasers Medicine and Surgery, a meeting in Miami of the
12 American Academy of Dermatology, and a meeting in New York of the American Society for
13 Aesthetic Plastic Surgery. Altavilla Decl. ¶ 15. Plaintiff states that at these conferences, BTL did
14 not talk about using Vanquish for its cleared use—the treatment of aches and pains. Rather, BTL
15 promoted Vanquish as able to “reduce fat.” *Id.*

16 Zeltiq states that after the initial launch of Vanquish, Defendants hosted several workshops
17 in the United States in which they promoted the use of Vanquish for fat reduction. For instance,
18 on September 29, 2013, Defendants held a workshop in Los Angeles at the Westin Hotel at the
19 Los Angeles International Airport. Altavilla Decl. ¶ 27; Declaration of Kevin Meyers (“Meyers
20 Decl.”) ¶ 5. A similar event was held in Carlsbad, California in early October 2013. *Id.* Zeltiq
21 states that at these events, Defendants distributed literature depicting Vanquish as a product for
22 body shaping and contouring. *Id.* The main presenter at the Los Angeles workshop focused his
23 remarks on fat reduction and body contouring using BTL’s Vanquish device and other products.
24 Altavilla Decl. ¶ 27; *see also* Meyers Decl. ¶ 5. Defendants state that at these workshops, they did
25 not represent that the Vanquish device had FDA clearance for fat reduction or body contouring.
26 Meyers Decl. ¶ 6.

27 In October 2013, BTL was one of the sponsors at the annual meeting for the American
28 Society for Dermatologic Surgery. Altavilla Decl. ¶ 31. In connection with this meeting, BTL

1 invited doctors to a private demonstration of the Vanquish device with the following invitation:
2 “Join us for a private demonstration of a newly FDA cleared technology ... The only complete
3 solution for non-invasive body shaping.” *Id.*, Exh. 19. Zeltiq states that this invitation is
4 misleading, as it implies that the Vanquish device is FDA approved for body shaping.

5 Defendants claim that in 2014, there have been no company-sponsored events or
6 presentations in the United States regarding the use of Vanquish for fat reduction. Besse Decl. ¶
7 12; Meyers Decl. ¶ 7. Zeltiq submitted evidence which shows that BTL was and is a planned
8 exhibitor for two events in California in February and April of 2014. Supplemental Declaration of
9 Thomas Hanrahan ¶¶ 2-3, Exh. 23-24. The exhibitor lists show that BTL planned to display three
10 aesthetic devices, including the Vanquish device. *Id.* The Vanquish device is not described in
11 these 2014 exhibitor lists as a fat reduction device. Rather, Vanquish is obscurely described as
12 delivering “sub-cutaneous heating for body treatment based on induced apoptosis using a contract-
13 free operator-monitored clinical approach.” *Id.*

14 2. Defendants’ Promotion to the End Consumer

15 Despite the fact the Vanquish device may only be sold to physicians, Zeltiq has submitted
16 evidence that BTL has also promoted the fat reduction qualities of the Vanquish device to the end
17 consumer. For instance, on the cover of the summer issue of *New You*, a promotional message for
18 Vanquish states that the technology “is proven to destroy fat cells.” Altavilla Decl. ¶ 19, Exh. 3.

19 Zeltiq also states that Vanquish is featured in a March 7, 2013 article in *Allure* magazine
20 that describes Vanquish as “a new fat-reduction machine.” Altavilla Decl. ¶ 20, Exh. 4. The
21 article also notes that there are several other devices are “awaiting FDA approval,” and then
22 comments that Vanquish “is approved for deep-tissue heating, a known method for targeting fat,
23 and has minimal side effects.” *Id.* BLT states that this article was not published in *Allure*
24 magazine as Zeltiq claims, but rather posted on a blog maintained by an *Allure* reporter. Besse
25 Decl. ¶ 6. BLT states that it was only asked to supply a photograph for this article, and had no
26 control over the content or publication of the blog post. *Id.*

27 Zeltiq also claims that BTL recruited certain physicians to promote Vanquish as a fat
28 reduction device despite its lack of FDA clearance for fat reduction. Altavilla Decl. ¶ 16. Zeltiq

1 states that in April 2013, coincident with the launch announcement of Vanquish, a physician in
2 Nevada wrote an article about Vanquish on www.vanquishfat.com. On that website—which does
3 not appear to be for a medical audience, the physician states that he had “heard about a new, fat
4 zipping device that’s about to receive FDA approval.” Altavilla Decl. ¶ 16, Exh. 2. Zeltiq also
5 states that this same physician created a “Vanquish Fat” Facebook page and claimed that
6 “Vanquish Melts Fat With No Pain.” Altavilla Decl. ¶ 16, Exh. 2. Unlike other websites discussed
7 below, Defendants do not submit any evidence in an attempt to disassociate from these
8 promotions.

9 3. BTL’s Official Websites

10 To promote Vanquish online, there is both a “United States” website at
11 www.bltvancouver.com and a “Non-United States” website (which used to be called the
12 “International” website) at www.bltvancouver.com/en/vancouver.html. Altavilla Decl. ¶ 24; Besse
13 Decl. ¶ 8. BTL states that it only controls the content of the United States website. Besse Decl. ¶
14 8. According to BTL, the content of the non-United States website is controlled overseas by BTL
15 Industries and is directed at a worldwide audience. *Id.*

16 Currently, only the non-United States website explicitly promotes the Vanquish device for
17 fat reduction. Altavilla Decl. ¶ 25d, Exhs. 9-12. According to Zeltiq, this was not always the
18 case. Zeltiq states that the United States website used to promote Vanquish for fat reduction by
19 displaying a video clip from a Texas doctor who declared that the Vanquish device “shrinks fat
20 cells,” and by quoting a number of other U.S. doctors extolling the benefits of Vanquish as a fat
21 reduction device. Altavilla Decl. ¶ 17. A printout depicting BTL’s original website is not in
22 evidence. Zeltiq states that BTL’s original website omitted any disclosure of the scope of FDA
23 clearance, and did not indicate that Vanquish was not FDA approved for fat reduction. Altavilla
24 Decl. ¶ 25a.

25 According to Zeltiq, after the filing of the Complaint in this action, BTL modified the
26 content of its United State website. Altavilla Decl. ¶ 25c; *see also* Besse Decl. ¶ , Ex. A (printout
27 of current website). Defendants state that in December 2013, BTL contracted with Michail M.
28 Prankratov to provide training to BTL regarding the regulations governing marketing of aesthetic

1 medical devices. Declaration of Michail M. Pankratov (“Pankratov Decl.”) ¶ 3.

2 The current United States website does not explicitly promote Vanquish for fat reduction
3 or body contouring. Rather, it describes Vanquish as “a revolutionary selective radiofrequency
4 system” that “delivers a non-invasive solution with unparalleled efficacy” and “is the first and
5 only non-invasive body treatment finally integrating all the most desired features.” *Id.* The
6 website states that “Vanquish is FDA cleared for deep tissue heating.” *Id.* Fine print at the
7 bottom of the website describes the specific intended uses of Vanquish:

8 In the US Vanquish is indicated for use in applying therapeutic deep
9 heat in body tissues for the treatment of selected medical conditions,
10 such as: 1. Relieving pain; 2. Reducing muscle spasm; 3. Increasing
11 range of motion of contracted joints using heat and stretch
12 techniques; and 4. Increasing blood flow to tissues in the treatment
13 area.

14 *Id.* The website also notes the following “Important Limitations”:

15 The information on this website is intended for US medical
16 professionals only. Vanquish is not cleared for the treatment of
17 adipose tissue. Treatment with Vanquish is not intended to
18 substitute for usual standard of care for adipose tissue treatment
19 regimes.

20 *Id.* “Adipose tissue” is the anatomical term for body fat. Altavilla Decl. ¶ 25c.

21 Zeltiq states that despite the purported separation of the two websites, the non-United
22 States website—both in its prior and modified form—is actually intended to promote the Vanquish
23 device to a United States audience. For instance, Zeltiq notes that BTL sent invitations for
24 physicians to attend a VIP Open House and Exhibit Display in Boston and New York, and only
25 listed the address for the non-United States website on the invitation. Altavilla Decl. ¶ 24, Exh. 7.
26 Moreover, until recently, the largest and boldest text on the United States website was a link in the
27 middle of the page that stated, “Go to Non-US Website.” Altavilla Decl. ¶ 25b-c, Exh. 8; Besse
28 Decl., Exh. A. The United States website contains hardly any information about Vanquish (the
majority of the text is quoted above). By contrast, the non-United States website features various
pages and links that promote Vanquish for fat reduction, including a “buzz” page that links
magazine articles and videos quoting United States doctors who promote Vanquish for fat
reduction. Altavilla Decl., Exhs. 9-13.

1 In addition, the “international” website used to include a page entitled “Scientific Seminars
2 for Physicians,” which is now entitled “Events” on the “non-United States” website. Altavilla
3 Decl. ¶ 25h. An earlier printout of this page lists five conferences that were to take place in
4 September and October of 2013 in New York City, Los Angeles, San Diego, Oklahoma City and
5 San Francisco. *Id.*, Exh. 14. Another printout of this page lists nine conferences that are to take
6 place in 2014. *Id.*, Exh. 15. The conferences planned for 2014 are both inside and outside the
7 United States, as the evidence shows that they are planned to take place in Bangkok, Maui, Paris,
8 Colorado, Monte Carlo, San Francisco, Arizona, Germany, Hong Kong and Singapore. *Id.*

9 **4. Other Websites Promoting Vanquish**

10 Zeltiq directs the Court to a number of other websites promoting Vanquish for fat
11 reduction, but for these websites, Defendants deny involvement or control. For instance, Zeltiq
12 notes that there used to be a Facebook page entitled “Vanquish by BTL” which claimed that
13 Vanquish “Zaps Fat With No Pain.” Altavilla Decl. ¶ 22, Exh. 5. BTL states, however, that it did
14 not create this Facebook page and believes it was created by a Malaysian company. Besse Decl. ¶
15 7. Under the contact information of the Facebook page, a Malaysian email address is listed.
16 Altavilla Decl., Exh. 5. The Facebook page is not currently available.

17 Zeltiq also points to three websites maintained by physicians promoting Vanquish for fat
18 reduction. *Id.* ¶ 18. A plastic surgeon from Georgia writes on his website: “If you have been
19 looking for a painless and non-invasive procedure for permanent fat removal and minimal risks,
20 look no further than Vanquish...” *Id.* A doctor in Colorado announces on his website that he is
21 “1 of Only 5 Physicians in the Country to Offer the New Vanquish Fat Reduction Treatment.” *Id.*
22 Another doctor from Atlanta claims on his website that “Vanquish is a new, revolutionary
23 procedure in permanent fat reduction.” *Id.* BTL states that it never asked anyone to create these
24 websites and has no control over these internet postings. Besse Decl. ¶ 5.

25 Zeltiq also states that BTL maintains the website www.aestheticmarketingshore.com where
26 physicians can purchase printed marketing brochures and in-office banners to promote Vanquish
27 for fat reduction. Altavilla Decl. ¶ 29, Exh. 18. However, BTL states that this website is an
28 independent source of marketing materials for various medical devices including Vanquish, and

1 there is no corporate relationship between BTL and the owners of this website. Besse Decl. ¶ 10.
2 BTL states that it does not share revenues generated from the sales of these marketing materials.
3 *Id.*

4 Zeltiq also states that recently, another website has begun to promote Vanquish for fat
5 removal: <http://vanquishfatremovalclinics.com/>. Altavilla Decl. ¶ 34. BTL again claims that it
6 does not own this website or have any control over it. Besse Decl. ¶ 14. The website lists the
7 clinics around the country which offer the Vanquish device as a method for fat reduction. *Id.* The
8 website also includes links to two video clips—according to Zeltiq, these are the same video clips
9 that were deleted from BTL’s original website. *Id.* In one of the video clips, Dr. Andrew
10 Campbell is interviewed by the hosts of The Morning Blend on Fox News. When asked whether
11 Vanquish is safe to use, Dr. Campbell responds as follows:

12 This is exceptionally safe. The FDA basically is there to provide
13 safety, it is not so much there to provide efficacy. *So when they do*
14 *these FDA approval studies, the number one, two and three thing*
15 *they are looking at is safety, and this is exceptionally safe. They –*
16 *even in the animal models, they looked at every part of the animal to*
17 *ensure that there was no damage to anything other than the fat.*

18 Zeltiq claims that the reference to “FDA approval studies” is clearly misleading, as it suggests that
19 the FDA has approved Vanquish for the purpose for which it is being promoted.

20 5. Physicians’ Understanding of the Scope of FDA Clearance

21 Both parties have submitted declarations by physicians in support of their respective
22 positions regarding whether Defendants’ conduct had a tendency to mislead physicians. Zeltiq
23 submitted the Declaration of Dr. Jill Waibel, who recognizes that physicians use medical devices
24 for a treatment that the FDA did not evaluate (often called an “off-label use”), but states that “off-
25 label” use generally develops only *after* physicians have had experience with the new device for
26 its approved use. Declaration of Jill Waibel (“Waibel Decl.”) ¶ 5. Waibel states that when a
27 manufacturer promotes a new device in the early stages after device is launched, physicians
28 presume that the new device has been approved by the FDA for the use that the manufacturer is
promoting. *Id.* Dr. Waibel further states that she is influenced by other physicians that promote
the Vanquish device and make “no mention of the approved use” especially “in the early

1 commercialization of a medical device when little other information is publically available.” *Id.* ¶
2 6.

3 Defendants submitted declarations from two other physicians: Robert Weiss, M.D. and
4 Rutledge Forney, M.D. Dr. Forney writes in his declaration that understanding the official FDA
5 clearances for an aesthetic device is important when making a decision to purchase a new device.
6 Declaration of Rutledge Forney (“Forney Decl.”) ¶ 3. Dr. Forney states that both the
7 CoolSculpting and Vanquish devices cost approximately \$80,000 to \$90,000, and thus represents a
8 significant capital expense in his practice. *Id.* ¶ 4. Both Dr. Forney and Dr. Weiss state that, prior
9 to their purchase of the Vanquish device for their respective practices, they were made aware of
10 the scope and limits of the FDA clearance. *Id.* ¶ 8; Declaration of Robert Weiss (“Weiss Decl.”) ¶
11 6.

12 **E. The Complaint**

13 Zeltiq asserts four causes of action in the Complaint. The first cause of action arises under
14 Lanham Act, 15 U.S.C. § 1125(a), which prohibits, *inter alia*, false or misleading statements in
15 connection with the marketing of goods. The other three causes of action arise under California’s
16 and Massachusetts’s unfair competitions laws. Zeltiq asserts that Defendants’ misleading and
17 deceptive advertising is a violation of California’s Business and Professions Code § 17200 (the
18 “UCL”) as well as Massachusetts General Law ch. 93A § 2. Zeltiq asserts another cause of action
19 under the UCL for Defendants’ allegedly unlawful conduct in violation of California’s Sherman
20 Act, which mirrors the requirements under the FDCA.

21 **III. DISCUSSION**

22 **A. Legal Standard – Motion for Preliminary Injunction**

23 “A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on
24 the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the
25 balance of equities tips in his favor, and that an injunction is in the public interest.” *Winter v.*
26 *Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Irreparable harm must be likely—it is no
27 longer sufficient to grant a preliminary injunction upon a mere showing of a “possibility” of
28 irreparable harm when the other factors weigh heavily in favor of the plaintiff. *Alliance for the*

1 *Wild Rockies v. Cottrell*, 632 F.3d 1127, 1132 (9th Cir. 2011). Nonetheless, the Ninth Circuit still
2 evaluates the likelihood of success on such a “sliding scale.” *Id.* A preliminary injunction may be
3 warranted upon a showing of “*serious questions* going to the merits” as well as “a hardship
4 balance that tips *sharply* toward the plaintiff,” so long as the plaintiff is likely to suffer irreparable
5 harm and the injunction is in the public interest. *Id.* (emphasis added).

6 **B. Whether Zeltiq is Likely to Succeed on the Merits of its Claims⁴**

7 **1. Deceptive Advertising in Violation of the Lanham Act and Unfair**
8 **Competition Laws**

9 The gravamen of Zeltiq’s Complaint is that Defendants’ promotion of the Vanquish device
10 is false and misleading in violation of the Lanham Act, and California and Massachusetts unfair
11 competition law. As both parties recognize, the Ninth Circuit “has consistently held that state
12 common law claims of unfair competition and actions pursuant to California Business and
13 Professions Code § 17200 are ‘substantially congruent’ to claims made under the Lanham Act.”
14 *Cleary v. News Corp.*, 30 F.3d 1255, 1262-63 (9th Cir. 1994) (citations omitted). Under the
15 Lanham Act, Defendants are prohibited from making a “false or misleading representation of fact”
16 which “is likely ... to deceive....” 15 U.S.C. § 1125(a)(1)(A). Under California’s UCL, the test is

17
18 ⁴ Defendants argue that Zeltiq’s claims fail to the extent they are preempted or conflict
19 with the FDA’s exclusive jurisdiction to enforce the FDCA. Although this argument raises serious
20 issues in this case, they are more appropriately dealt with at the dispositive motion stage based on
21 a full record. In any event, the preemption argument here does not appear to bar *all* claims raised.
22 First, at the hearing on this Motion, counsel for Defendants conceded that Zeltiq’s claims are not
23 preempted and do not conflict with the FDCA to the extent Zeltiq can show that there was a false
24 or misleading representation that the Vanquish device is FDA cleared for fat reduction. *See*
PhotoMedex, Inc. v. Irwin, 601 F.3d 919, 925 (9th Cir. 2010) (“If, for example, it was clear that an
affirmative statement of approval by the FDA was required before a given product could be
marketed and that no such FDA approval had been granted, a Lanham Act claim could be pursued
for injuries suffered by a competitor as a result of a false assertion that approval had been
granted.”).

25 Second, based on the evidence submitted at this time, the Court would distinguish this case
26 from the Ninth Circuit’s decision in *PhotoMedex*. The Lanham Act claim in *PhotoMedex* was
27 based on the contention that a marketed laser varied enough from a FDA cleared laser so as to
28 require new 510(k) clearance. Because the parties disputed whether new 510(k) clearance for the
laser was required, the court found that deciding the Lanham Act claim would require interpreting
provisions of the FDCA, and would usurp the FDA’s exclusive authority to enforce the FDCA. In
this case, by contrast, Defendants do not dispute that they promoted the Vanquish device for a use
that is not FDA cleared. Accordingly, the Court need not interpret provisions of the FDCA to
decide the Lanham Act and analogous state law claims.

1 whether Defendants engaged in any “unfair, deceptive, untrue or misleading advertising,”
2 California Business & Professions Code § 17200, that was “ ‘likely to deceive’ the reasonable
3 consumer to whom the practice was directed.” *South Bay Chevrolet v. General Motors*
4 *Acceptance Corp.*, 72 Cal.App.4th 861, 878 (1999). The “ultimate test” in both cases is whether
5 the consumers of the good are “likely to be deceived...” *Acad. of Motion Picture Arts & Sciences*
6 *v. Creative House Promotions, Inc.*, 944 F.2d 1446, 1457 (9th Cir. 1991) (internal quotations
7 omitted); *see also Spalding Sports Worldwide, Inc. v. Wilson Sporting Goods Co.*, 198 F.Supp.2d
8 59, 64 (D. Mass. 2002) (considering the false advertising claim under Massachusetts General Law
9 ch. 93A together with the Lanham Act claim). Accordingly, the following discussion considers
10 the likelihood of success on the merits of Plaintiff’s first, third and fourth causes of action.⁵

11 When asserting a claim under the Lanham Act, a plaintiff may establish the “falsity” of the
12 advertisement in one of two ways. *Southland Sod Farms*, 108 F.3d at 1139. A “plaintiff may
13 show that the statement was literally false, either on its face or by necessary implication, or that
14 the statement was literally true but likely to mislead or confuse consumers.” *Id.* As Zeltiq
15 recognizes, different evidentiary burdens may correspond to statements that are “literally false,”
16 and those that are “literally true” but likely to mislead or confuse consumers. The difference is
17 that “[a] literally false statement may violate Section 43(a) ‘without evidence of consumer
18 deception,’ while an implied falsehood may require some extrinsic evidence that the challenged
19 statement has a tendency to mislead or confuse consumers.” Motion at 14 (quoting *Mut. Pharm.*
20 *Co. v. Ivax Pharm., Inc.*, 459 F.Supp.2d 925, 933 (C.D. Cal. 2006) (citations omitted)). This is the
21 rule adopted by most circuits. *See e.g., Pizza Hut, Inc. v. Papa John’s Int’l, Inc.*, 227 F.3d 489,
22 497 (5th Cir. 2000) (“if the statements at issue are either ambiguous or true but misleading, the
23 plaintiff must present evidence of actual deception”). The Ninth Circuit has held that “[w]here a
24 statement is not literally false and is only misleading in context, ... proof that the advertising
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27 ⁵ Zeltiq’s second cause of action regarding alleged “unlawful” conduct in violation of
28 California’s UCL is based on specific violations of California’s Sherman Act, and is therefore
distinct from Plaintiff’s claim under the Lanham Act claim relating to misleading advertising. The
likelihood of success on this claim is discussed below.

1 actually conveyed the implied message and thereby deceived a significant portion of the recipients
2 becomes critical.” *William H. Morris Co. v. Grp. W, Inc.*, 66 F.3d 255, 258 (9th Cir. 1995).

3 Zeltiq has not presented evidence of any literally false statement. In response to
4 Defendants’ argument that Zeltiq has failed to produce such evidence, Zeltiq points to two items.
5 Reply at 13. The first is the invitation BTL invitation sent to doctors inviting them to attend a
6 demonstration of the Vanquish device. The invitation reads: “Join us for a private demonstration
7 of a newly FDA cleared technology ... The only complete solution for non-invasive body
8 shaping.” Altavilla Decl. ¶ 31, Exh. 19. This invitation is not *literally* false because the FDA
9 issued a 510(k) clearance for the “technology” that was to be demonstrated by clearing the BTL
10 Elite. Second, Zeltiq directs the Court to BTL’s website, which still states that the Vanquish
11 device is cleared by the FDA “for deep tissue heating.” Altavilla Decl., Exh. 8; Besse Decl., Exh.
12 A. This statement, however, is *literally true*—Vanquish is cleared by the FDA “for deep tissue
13 heating”—and Zeltiq recognizes as much.

14 In an attempt to avoid the evidentiary requirements for a misleading statement as opposed
15 to “literally false statement” under the Lanham Act, Zeltiq contends that these statements are
16 “literally false by necessary implication.” Reply at 14 (quoting *Southland Sod Farms*, 108 F.3d at
17 1139 (A “plaintiff may show that the statement was literally false, either on its face *or by*
18 *necessary implication....*”) (emphasis added) (citing *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939,
19 946-47 (3d Cir. 1993))). In *Castrol*, the Third Circuit cited the following example of a statement
20 that is “literally false by necessary implication” from an advertisement at issue in a district court
21 case:

22 Robot-Coupe: 21
23 Cuisinart: 0

24 When all 21 of the three-star restaurants in France’s Michelin Guide
25 choose the same professional model food processor, somebody
26 knows the score-shouldn’t you?

27 *Castrol Inc.*, 987 F.2d at 946 (citing *Cuisinarts, Inc. v. Robot-Coupe Int’l Corp.*, No. 81-0731,
28 1982 WL 121559, *2 (S.D.N.Y. June 9, 1982)). The advertisement above does not literally say
that all twenty-one restaurants chose to buy the Robot-Coupe over the Cuisinart, but that is
necessarily implied from what is said. In this case, Zeltiq has submitted no evidence of statements

1 that necessarily imply the Vanquish device is FDA cleared for fat reduction and body contouring.
2 *Cf. Castrol Inc.*, 987 F.2d at 946; *Cuisinarts*, 1982 WL 121559, *2.

3 Zeltiq also argues that Defendants told “half-truths” when stating that the Vanquish device
4 was a “newly FDA cleared technology,” and that was FDA cleared “for deep tissue heating.”
5 Reply at 13-14 (citing Altavilla Decl., Exhs. 8, 19). *Id.*, Exh. 8. Zeltiq contends that by telling
6 such “half-truths,” Defendants had a duty to speak the whole truth—that the Vanquish device was
7 not FDA cleared for fat reduction and body contouring. Nevertheless, Zeltiq does not cite one
8 case in which a “half-truth” constituted a literally false statement under the Lanham Act or state
9 unfair competition law. The only cases cited by Zeltiq address claims for *common law fraud*
10 under California and Oregon law. *See Meade v. Cedarapids, Inc.*, 164 F.3d 1218, 1222 (9th Cir.
11 1999) (addressing fraud claim under Oregon law); *Whiteley v. Philip Morris Inc.*, 117 Cal.App.4th
12 635, 675 (2004); *Randi W. v. Muroc Joint Unified School Dist.*, 14 Cal.4th 1066, 1082 (1997).

13 Unlike claims for common law fraud, the Lanham Act is “not limited to literal falsehoods;
14 it extends to false representations made by implication or innuendo.” *Cook, Perkiss & Liehe, Inc.*
15 *v. N. California Collection Serv. Inc.*, 911 F.2d 242, 245 (9th Cir. 1990). In addition to “literally
16 false statements,” a plaintiff can prevail on a Lanham Act claim through a statement that is
17 “literally true but likely to mislead or confuse consumers.” *Southland Sod Farms*, 108 F.3d at
18 1139. Similarly, claims for unfair competition based on fraudulent conduct are distinct from
19 claims for ordinary fraud because a “‘fraudulent’ representation may include a false statement, or
20 one which, though strictly accurate, nonetheless has the likely effect of misleading or deceiving
21 the public.” *Garcia v. Sony Computer Entm't Am., LLC*, 859 F.Supp.2d 1056, 1062 (N.D. Cal.
22 2012). Thus, the concept of “half-truths” that has developed within the doctrine of common law
23 fraud may also be actionable under the Lanham Act and State unfair competition laws.
24 Nevertheless, such “misleading half-truths” (as they are referred to in the cases cited above) would
25 be “literally true” statements that are “misleading” because the representations in themselves are
26 not literally false.

27 Although Zeltiq failed to present evidence of any literally false statements, Zeltiq did
28 present evidence of promotions that could misleadingly imply that Vanquish is FDA cleared for

1 fat reduction. Since the launch of Vanquish, Defendants have *only* promoted the device for use in
2 fat reduction—despite the fact this is not a FDA cleared use. In some of the promotional material,
3 Defendants even make a brief reference to “FDA clearance” without disclosing the limitations of
4 such clearance. *See* Altavilla Decl. ¶¶ 13, 16, 20 Exhs. 2, 4, 19. In light of the fact Vanquish has
5 only been promoted for fat reduction, such references to FDA clearance obscures the true scope of
6 such clearance. Moreover, the fact Defendants alluded to FDA clearance in their promotional
7 materials implies that FDA clearance is a material factor which influences physicians to buy the
8 device.

9 Nevertheless, Zeltiq did not submit any evidence to show that any physician was actually
10 deceived by Defendants’ promotions of the Vanquish device.⁶ Zeltiq only submitted evidence to
11 show that when a medical device is promoted in the early stages after it is launched, physicians
12 will presume that the device is FDA cleared for the purpose for which it is promoted. Waibel
13 Decl. ¶ 3. According to Dr. Waibel, this is because “off-label” use of a medical device generally
14 only develops *after* physicians have had experience with the new device for its approved use. *Id.* ¶
15 5. Thus, Zeltiq believes that because Defendants were marketing the Vanquish device for fat
16 reduction so early after its initial launch, physicians were misled into believing the Vanquish
17 device is FDA cleared for fat reduction.

18 At best, Zeltiq’s evidence shows that physicians in general presume the Vanquish device is
19 FDA cleared for fat reduction because it was marketed for that use in the early stages after its
20 launch. While that constitutes some evidence of deception, it is only a general claim of deceptive
21 impact. In the face of Defendant’s evidence on this subject, Zeltiq presents no evidence that
22 physicians who actually purchase the Vanquish device believed it was FDA cleared for this
23 purpose. *See Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 228-29 (3d Cir.
24 1990) (plaintiff “cannot obtain relief by arguing how consumers *could* react; it must show how
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27 ⁶ Defendants submitted two declarations from physicians who wrote that when they
28 purchased the Vanquish device, they understood that it was not FDA cleared for use in fat
reduction. *See* Forney Decl. ¶ 8; Weiss Decl. ¶ 6.

1 consumers *actually do react*”). Defendants’ evidence shows that the Vanquish device costs
2 approximately \$80,000 to \$90,000. Forney Decl. ¶ 4. The only individuals eligible to purchase
3 the device are physicians. Besse Decl. ¶ 13. There is evidence in the record which shows that at
4 least one group of physicians decides to purchase such an expensive medical device only after
5 fully evaluating the device’s efficacy and safety for patients and understanding the official FDA
6 clearances. *Id.* ¶ 3. In light of the high cost of the Vanquish device, as well as the fact the only
7 purchasers of the Vanquish device are physicians, Zeltiq is not likely to be able to prove that
8 physicians who purchase the Vanquish device would be deceived into believing the device is FDA
9 cleared for fat reduction.

10 Accordingly, Zeltiq has not demonstrated that it is likely to prevail on the merits of any of
11 its Lanham Act claim or the analogous state law unfair competition claims based on false
12 advertising. Nevertheless, the Court finds that Zeltiq has raised *serious questions* going to the
13 merits of such claims.

14 2. *Unlawful Conduct in Violation of California’s UCL*

15 In addition to Zeltiq’s claims based on allegations of false and misleading advertising,
16 Zeltiq asserts a separate claim under the “unlawful” prong of California’s UCL based on
17 allegations of specific violations of California’s Sherman Act. First, Zeltiq alleges that BTL sold
18 and distributed the Vanquish device without 510(k) clearance in violation of California Health and
19 Safety Code § 111550. Section 111550 provides, in pertinent part, that “[n]o person shall sell,
20 deliver, or give away any ... new device unless ... [i]t is ... [a] device that is reported under
21 Section 510(k) of the federal act (21 U.S.C. Sec. 360(k))....” Cal. Health & Safety Code §
22 111550(a)(3). Applied to this case, the statute would prohibit the sale of the Vanquish device had
23 it not received 510(k) clearance. Zeltiq’s problem, however, is that the Vanquish device *has*
24 received 510(k) clearance. *See* Altavilla Decl., Exh. 1.

25 Zeltiq maintains that Defendants violated § 111550 by marketing Vanquish for a *use* not
26 included in the 510(k) clearance. Zeltiq claims that “the text of Section 111550 makes plain that
27 the relevant approval is use-specific.” Motion at 18. The Court disagrees. The relevant provision
28 of § 111550 falls under subsection (a), which provides the option for a manufacturer to sell a

1 device after receiving 510(k) clearance. Zeltiq quotes language from subsection (b) of the
2 statute—which relates to *premarket approval* for Class III devices—to argue that the 510(k)
3 clearance is only valid to the extent the device is sold for use “under the conditions prescribed,
4 recommended, or suggested in the ... advertising of the new drug or device.” Cal. Health &
5 Safety Code § 111550(b)(1). This quote is taken out of its context. The Vanquish device had
6 510(k) clearance prior to being sold in California. Accordingly, the Court finds that Plaintiff is
7 not likely to show a violation of § 111550.

8 Zeltiq also bases the UCL-unlawful conduct claim on the allegation that BTL violated the
9 Sherman Act by “misbranding” the Vanquish device. *See* Cal. Health & Safety Code § 111440
10 (“It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug that is
11 misbranded.”); *Id.* § 111445 (“It is unlawful for any person to misbrand any drug or device.”); *see*
12 *also id.* § 111450. Section 111375 of the Code provides the definition of ‘misbranding’:

13 Any drug or device is misbranded unless *its labeling* bears all of the
14 following information:

15 (a) *Adequate directions for use.*

16 (b) Such adequate warnings against use in pathological
17 conditions or by children where its use may be dangerous to health.

18 (c) Adequate warning against unsafe dosage or methods or
19 duration of administration or application.

20 Warnings shall be in a manner and form as are necessary for the
21 protection of users.

22 Cal. Health & Safety Code § 111375 (emphasis added). The implementing regulations of the
23 FDCA define “[a]dequate instructions for use” as “directions under which the layman can use a
24 drug safely and *for the purposes for which it is intended.*” 21 C.F.R. § 201.5 (emphasis added).

25 Zeltiq argues that the Vanquish device is misbranded because its labeling fails to include
26 “adequate directions for use” in fat reduction procedures. In light of the fact the FDCA
27 regulations require instructions to be catered to “the purposes for which [the device] is intended,”
28 21 C.F.R. § 201.5, Zeltiq raises an interesting argument. Nevertheless, § 111375 specifically
refers to the device’s “labeling” as the source of any potential misbranding. Evidence in the
record shows that whenever the Vanquish device is sold, the purchaser is given the “Operator’s
Manual,” which includes the “Instructions for Use” detailing the FDA cleared uses of the device

1 and providing directions for such uses. Besse Decl. ¶ 14. Zeltiq has not cited any authority to
2 suggest that a device may be “misbranded” by virtue of its overall promotional practices as
3 opposed to the more obvious source of “labeling”: the Instructions for Use in the Operator’s
4 Manual. Accordingly, while the Court finds that Zeltiq has raised serious questions going to the
5 merits of this issue, the Court does not find that Zeltiq is likely to prevail on this claim.

6 **C. Whether the Balance of Harships Tips Sharply in Zeltiq’s Favor**

7 Having found that Zeltiq raised serious questions going to the merits of its claims, the
8 Court now considers whether the balance of hardships tips “sharply” in Zeltiq’s favor. *Cottrell*,
9 632 F.3d at 1132 (“serious questions going to the merits and a hardship balance that tips sharply
10 toward the plaintiff can support issuance of an injunction, assuming the other two elements of the
11 ... test [for preliminary injunction] are also met.”).

12 Zeltiq may suffer hardship if an injunction is not issued. Zeltiq devoted resources to
13 obtaining FDA clearance for its CoolSculpting device. Having carved a unique place in the
14 market as the first non-invasive fat reduction device with FDA clearance, Zeltiq stands to lose
15 market share by deceptive advertising which touts other devices as having the same FDA
16 clearance. On the other hand, Zeltiq has not presented any evidence to show that Defendants’
17 promotions of Vanquish actually deceive physicians who purchase the device.

18 BTL will endure hardship if an injunction is issued. Zeltiq seeks a broad injunction that, in
19 addition to prohibiting promotions which falsely state or imply the Vanquish device is cleared for
20 fat reduction, would also prohibit lawful conduct and impose affirmative obligations. The
21 injunction would require Defendants to de-link the United States website from the non-United
22 States website, and to provide written notification to every physician who has purchased the
23 Vanquish informing them it is not FDA cleared for fat reduction.

24 Moreover, Zeltiq’s requested injunction would prohibit Defendants from selling the
25 Vanquish device for any use that is not FDA cleared, and from working with any physician who
26 employs the Vanquish device for fat reduction. Physicians, however, have the right to use the
27 Vanquish device for fat reduction. Even the Supreme Court has recognized that such off-label use
28 “is an accepted and necessary corollary of the FDA’s mission to regulate in this area without

1 directly interfering with the practice of medicine.” *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531
2 U.S. 341, 350 (2001). In light of these considerations, the Court does not find that the balance of
3 hardships tips “sharply” in Zeltiq’s favor.

4 **D. Whether Zeltiq will Suffer Irreparable Injury if an Injunction is not Issued**

5 Even if the balance of equities tipped sharply in Zeltiq’s favor, the Court would still deny
6 Zeltiq’s Motion for Preliminary Injunction because of the lack of evidence that Zeltiq will suffer
7 an irreparable injury if an injunction is not issued. This Court has recognized that irreparable
8 harm may result from the “loss of market share.” *See Funai Elec. Co., Ltd. v. Daewoo Electronics*
9 *Corp.*, 593 F.Supp.2d 1088, 1111 (N.D. Cal. 2009) *aff’d*, 616 F.3d 1357 (Fed. Cir. 2010).
10 Nevertheless, Zeltiq has not presented any evidence that it actually lost market share as a result of
11 Defendants’ promotion of Vanquish. Zeltiq states in a declaration that BTL has captured some
12 undetermined amount of market share and that “the long-term impact on Zeltiq is difficult to
13 quantify.” Altavilla Decl. ¶ 36. This is insufficient.

14 Zeltiq contends that it may prove a likelihood of irreparable injury by showing evidence
15 “(i) that the parties are competitors in the relevant market, and (ii) that there is a logical causal
16 connection between the alleged false advertising and its own sales position.” Reply at 5 (quoting
17 *Euro-Pro Operating LLC dba Euro-Pro Corporation v. Euroflex Americas*, No. 08-6231, 2008
18 WL 5137060, at *4 (S.D.N.Y. Dec. 8, 2008) (quoting *Zeneca Inc. v. Eli Lilly & Co.*, No. 99-1452,
19 1999 WL 509471, *36 (S.D.N.Y. July 19, 1999) (quoting *Johnson & Johnson v. Carter-Wallace,*
20 *Inc.*, 631 F.2d 186, 190 (2d Cir. 1980))). In the Court’s view, merely showing this logical
21 connection and competition is not sufficient in light of the Supreme Court’s 2008 decision in
22 *Winter*, where the Court held that a plaintiff seeking a preliminary injunction must always
23 “demonstrate that irreparable injury is *likely* in the absence of an injunction.” *Winter*, 555 U.S. at
24 20 (emphasis in original). Merely showing that the parties are competitors and that there is a
25 logical connection between the false advertising and the plaintiff’s sales may be sufficient to show
26 a *possibility* of irreparable harm, but is insufficient to show a *likelihood* of irreparable harm
27 without additional evidence. Accordingly, the Court finds that, even if Zeltiq could prevail on the
28 merits of its claims, Zeltiq has not demonstrated that it is likely to suffer irreparable harm.

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Having concluded that Zeltiq has not shown that the balance of equities tips sharply in its favor or that it will likely suffer irreparable injury if an injunction is not issued, the preliminary injunction cannot be issued. *Winter*, 555 U.S. at 20. The Court need not address whether a preliminary injunction would be in the public interest.

IV. CONCLUSION

For the foregoing reasons, the Motion for Preliminary Injunction is DENIED.

IT IS SO ORDERED.

Dated: March 25, 2014



JOSEPH C. SPERO
United States Magistrate Judge