In the
UNITED STATES DISTRICT COURT
for the SOUTHERN DISTRICT OF INDIANA,
INDIANAPOLIS DIVISION

NIGHTINGALE HOME HEALTHCARE, INC.,	)	
Plaintiff,	)	
vs.	)	**CAUSE NO. 1:06-cv-1435-SEB-JMS**
ANODYNE THERAPY, LLC,	)	
Defendant.	)	

E N T R Y

Defendant's Motion for Summary Judgment (doc. 69)
Defendant's Request for Oral Argument (doc. 99)

Anodyne Therapy, LLC ("Anodyne") acquired the rights to an infrared lamp that relieves pain and improves circulation through the use of infrared photo energy. Flexible pads containing light-emitting diodes are placed in direct contact with a patient's skin at affected areas and infrared light is applied at different strengths and durations depending on the patient's condition. Anodyne manufactured a professional model, the "480," containing eight pads and adjustable power levels, which it marketed to health-care providers — *e.g.*, physicians, nursing homes, physical-therapy clinics, and home health-care agencies. It also manufactured a home model, the "120," for individuals to use on their own. The "120" contained four pads and operated at a lower energy level than the "480" and the power level was not adjustable. Anodyne marketed the "120" to individuals indirectly, relying on the health-care providers from whom patients were receiving treatments with the professional model to inform their patients of the availability of the

home model when the course of professional treatment was concluded.[1]

Anodyne's infrared lamp is a Class III medical device under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c, which requires premarket approval before, *inter alia*, being introduced or delivered for introduction into interstate commerce, or being received in interstate commerce, *id.*, §§ 331 and 360e. Prior to Anodyne's acquisition of the lamp, its inventor applied to the Food and Drug Administration ("FDA") for premarket approval and, in the application, described the device as intended "for relief of minor muscle and joint pain and improvement of superficial circulation." The FDA granted the application in 1994. Anodyne was formed in 2000 or 2001 and began marketing the device to health-care providers as a treatment for peripheral neuropathy, among other conditions, such as wound care.

Peripheral neuropathy is a degenerative condition of nerves extending from the central nervous system (the spinal cord and brain) that results in loss of sensation, weakness and atrophy of muscles, decreased deep reflexes, and decreased circulation. The disorder is usually manifested in the extremities and is often characterized by increasing motor deficiencies and pain. Peripheral neuropathy can be caused by many conditions, including trauma, toxins, metabolic diseases such as diabetes, physical impingement of the nerves, infections such as Lyme disease, auto-immune reactions, and nutritional deficiencies. 4 J. E. Schmidt, *Attorneys' Dictionary of Medicine and Word Finder*, pp. –90 and P-181 to P-182 (2007). Peripheral neuropathy can often be a circular process: degeneration of the nerves that control the blood vessels cause the vessels to constrict, the decreased blood flow irritates the nerves causing pain

[1] The record was not clear whether the providers referred their patients to Anodyne for the purchase of a unit or the providers obtained the units for them.

and further degeneration, which results in more pain, numbness, and atrophy. *Id.*; Brar Deposition, pp. 53-54. Relying on studies and research showing circulatory benefits of infrared photo therapy, Anodyne promoted its infrared lamp as a means of increasing blood flow in the affected areas of the body and thus providing temporary relief of pain and numbness associated with peripheral neuropathy and improved nerve function.

In November 2004, Nightingale Home Healthcare, Inc., a provider of home health care services, purchased four "480" professional lamps from Anodyne for use in its Indiana market. Nightingale's purchase decision followed an in-person demonstration of the device by an Anodyne sales representative at Nightingale's facility. The evidence is in dispute about the representations that Anodyne made to Nightingale before it made its purchase decision, but there is no dispute that, at a minimum, Anodyne stated — through its sales representative, in promotional literature given to Nightingale, and on Anodyne's website to which it referred Nightingale — that Anodyne's infrared lamp is a treatment for peripheral neuropathy, among other conditions; that Nightingale could so market the device; that the lamp was FDA-approved; and that, while Medicare did not then cover Nightingale's use of the device, Anodyne was actively working on obtaining Medicare reimbursement for use of the device.

Nightingale began using the units immediately and actively marketed and promoted the Anodyne lamp to its referral sources and the general public as a treatment for peripheral neuropathy and other circulation-related conditions such as wound recovery. Nightingale noticed a positive effect on its clients who were referred with symptoms of peripheral neuropathy: treatments improved circulation in their extremities leading to temporary relief of pain, numbness, and nerve damage. Brar Dep., p. 102. Nightingale began purchasing additional

"480" units to better supply its Indiana market and markets in other states: it purchased an additional 2 units in March 2005, 1 unit in July 2005, 2 units in September 2005, and 4 or 5 units in January 2006. Turtzo Affidavit, ¶¶ 10-13; (Response, p. 4).

In June and July, 2005, the FDA conducted a regular inspection[2] of Anodyne's manufacturing facility in Florida. In December 2005, it sent a Warning Letter to Anodyne notifying it that its marketing and promotion of the infrared lamp "for use in the treatment of wounds and ulcers, loss of protective sensation, gait and balance impairment, and other Diabetic Peripheral Neuropathy conditions, as well as conditions associated with Non-diabetic Neuropathies" and for "the treatment of conditions including, but not limited to, soft tissue injuries, Carpal Tunnel Syndrome (CTS), and lymphedema" exceeded the device's premarket approval that was granted based on the description of the device's intended use for only "relief of minor muscle and joint pain and improvement of superficial circulation." The letter stated that the promotion and introduction of the device into interstate commerce for those uncleared indications rendered the device "adulterated" under 21 U.S.C. § 351(f)(1)(B) and that the uncleared indications represented new uses that require a new application for premarket approval before being so marketed and promoted. Anodyne revised its marketing to eliminate mention of the uncleared uses for the lamp. It did not immediately inform Nightingale of the subject of the Warning Letter.

Sometime in February 2006, Nightingale independently learned of the FDA's December 2005 Warning Letter and Anodyne's promotion of its lamp for uncleared uses — after it had

[2] The record indicated that the FDA audited registered manufacturers of medical devices every eighteen months.

already purchased an additional 4 or 5 of the devices in January 2006 in response to a special promotion by Anodyne. Nightingale began revising its marketing and advertising to remove promotion of the Anodyne lamp as a treatment for peripheral neuropathy and other uncleared conditions and it contacted its referral sources to inform them of the revisions.

In October 2006, the Centers for Medicare and Medicaid Services ("CMS") issued a National Coverage Determination ("NCD") that the use of infrared devices is not reasonable and necessary for the treatment of Medicare beneficiaries for diabetic and non-diabetic peripheral sensory neuropathy, wounds and ulcers, and similar related conditions, including symptoms such as pain arising from these conditions, and therefore that such treatments would not be covered under Medicare. Anodyne again changed its marketing and promotion efforts, removing previous statements that reimbursement codes had been assigned, some reimbursements had been made, and that it was actively working for Medicare coverage. It also informed Nightingale that the NCD meant that its uses of the Anodyne lamps would not be reimburseable by Medicare.

Nightingale claims that it was misled and mistreated by Anodyne. Because of Anodyne's alleged misrepresentations about the approved uses of the lamps, Nightingale aggressively promoted and used them as a treatment for peripheral neuropathy, to the injury of its reputation among its clients and referral sources when it had to backtrack following issuance of the Warning Letter. In deciding to purchase the lamps, Nightingale also relied on Anodyne's representation that Medicare reimbursement would be approved in the future; instead it was stuck with 13 or 14 machines for which it could never expect to receive reimbursement. It contends that, rather than inform Nightingale of the Warning Letter's subject when it was

received in December 2005, Anodyne ran a special promotion for the "480" and allowed Nightingale to purchase an additional 4 or 5 units in January 2006, knowing that Nightingale would have to significantly restrict its marketing of the devices. At some point in 2006, Nightingale stopped using the Anodyne devices and purchased and began using a similar number of a competitor's infrared lamps. When Anodyne refused Nightingale's demand that it rectify the situation by, at least, buying back its devices and reimbursing Nightingale for training and promotion costs, Nightingale filed the present suit against Anodyne.

The Complaint is in four counts: Count 1 is a federal Lanham Act claim for false advertising; Count 2 is a breach of contract claim under Florida law; Count 3 is a common-law fraud claim under Indiana law; and Count 4 is a statutory product liability claim under Indiana law. Anodyne now moves for summary judgment on all counts.

Count 4 alleges that Nightingale is unable to use Anodyne's lamps because they are in an inherently dangerous and defective condition and that Anodyne failed to provide adequate instructions and warnings for their use. The claim relates to reports that some patients, including one of Nightingale's clients, might have suffered burns while being treated with the lamps. Because Nightingale failed to respond to Anodyne's substantive and supported arguments for summary judgment on this count, we consider Anodyne to have abandoned it, in effect conceding judgment.

Summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

Count 1 — Lanham Act

As relevant to Nightingale's claim, the Lanham Act provides:

> Any person who . . . in connection with any goods . . . uses in commerce any . . .false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1). To establish a claim for deceptive advertising, a plaintiff must prove five elements: (1) a false statement of fact by defendant in a commercial advertisement about its own product; (2) the false statement actually deceived or had the tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence purchasing decisions; (4) the defendant caused its false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result, either by direct diversion of sales from itself to defendant or by a loss of goodwill associated with its products. *Hot Wax, Inc. v. Turtle Wax, Inc.*, 191 F.3d 813, 819 (7th Cir. 1999).

Anodyne first contends that Nightingale lacks standing because it is not a competitor with Anodyne and it is a end consumer of Anodyne's device; therefore, Nightingale cannot suffer the competitive injury required for asserting a Lanham Act claim. Nightingale contends that it is a commercial party asserting a commercial injury because both it and Anodyne compete for the same patient dollars for the treatment of peripheral neuropathy: every sale of a self-use Model 120 to an individual based on Anodyne's false advertising that it is a treatment for peripheral neuropathy is a lost sale by Nightingale for its more-comprehensive range of in-home services for the relief of peripheral neuropathy symptoms. Anodyne replied that Nightingale's

argument is contrary to the evidence because both companies promoted Anodyne's device for the treatment of peripheral neuropathy; Nightingale continued to promote it after Anodyne ceased; and, while Anodyne was prohibited by law from promoting the device for peripheral neuropathy, Nightingale was not prohibited from continuing to use it for peripheral-neuropathy treatments.

Neither side supplied authority for their respective positions on the particular competitive context between them. While Nightingale did not point to any statistics or studies indicating actual or likely losses of sales of its home-care services due to consumer purchases of the Model 120, and it seems likely that such an impact on its overall market performance *vis-a-vis* Anodyne's would be small, its market model is reasonable and no authority was presented requiring a level of competitive injury for Lanham Act standing. In addition, it is unclear how the facts that both companies promoted the use of Anodyne's lamp for the treatment of peripheral neuropathy and Nightingale's continued ability to use the lamp for such treatment are contrary to the companies' status as competitors. According to Nightingale's competitive model, if neither company had promoted the device for the treatment of peripheral neuropathy, Nightingale's promotion of its varied program of in-home services for peripheral-neuropathy patients, including the use of the lamp, would have had a greater impact on its sales. Further, we do not find that the evidence upon which Anodyne presumably relies for its assertion that Nightingale continued to promote its ability to treat peripheral neuropathy with Anodyne's, and later a competitor's, lamps so indicates. Therefore, we find that Nightingale was indeed a competitor with Anodyne and, therefore, has standing to assert its Lanham Act claim.

We conclude, however, that Nightingale has failed to demonstrate that it can prove a

Lanham Act violation by Anodyne because it cannot establish the first element: a false statement of fact by Anodyne made in a commercial advertisement. Nightingale alleges two false statements by Anodyne: that its infrared lamp is a treatment for peripheral neuropathy and that the FDA had approved or cleared the device as a treatment for peripheral neuropathy.[3] Neither qualifies as a Lanham Act violation. First, no evidence was cited that Anodyne's alleged misrepresentation regarding FDA clearance of the device specifically for the treatment of peripheral neuropathy were made in commercial advertisements. The only evidence cited on this representation was that it was made personally from Anodyne's sales representative to Nightingale personnel, which is not grounds for a Lanham Act claim.

Second, a representation that the Anodyne lamp is a treatment for peripheral neuropathy is not false. Nightingale's argument that it is false is twofold: first, the device is not approved by the FDA for the treatment of peripheral neuropathy and, second, the device provides only symptomatic relief for peripheral neuropathy but does not treat or cure the condition itself. Nightingale does not contend that infrared photo therapy in general, or the Anodyne lamp in particular, is effective in providing relief to its peripheral-neuropathy patients.

Nightingale misunderstands the process and effect of FDA premarket approval of medical devices. A Class III device, such as Anodyne's infrared lamp, is required to have an approved premarket application before it may be introduced into interstate commerce. 21 U.S.C. §§ 360e(a), 331(a), and 351(f)(1)(B). While the application requires that the manufacturer

[3] In response to Anodyne's motion on Count 1, Nightingale did not attempt to support its Lanham Act claim by relying on any statements by Anodyne regarding Medicare reimbursement.

submit all information regarding investigations into whether the device is safe and effective, 21 U.S.C. § 360e(c)(1)(A), it also requires "[a] general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended", 21 C.F.R. § 814.20(b)(3)(i), and copies of the proposed labeling, including any information, literature, or advertising that constitutes labeling, 21 U.S.C. § 360e(c)(1)(F); 21 C.F.R. § 814.20(b)(10). A premarket application shall be denied if there is a lack of a showing of reasonable assurance that such device is safe and effective "under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof", 21 U.S.C. § 360e(d)(2), and "[a] device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA [premarket approval] order for the device", 21 C.F.R. § 814.80. FDA premarket clearance, therefore, is limited in scope to the indications and uses declared by the applicant in its application.

In this case, the premarket application for Anodyne's lamp declared that is was "for relief of minor muscle and joint pain and improvement of superficial circulation" which thus defined the permissible scope of Anodyne's promotion and marketing of the device. The December 2005 FDA Warning Letter, therefore, was not based on the dangerousness or ineffectiveness of the lamp for treating patients with diagnoses of peripheral neuropathy, but solely on the fact that Anodyne's marketing and promotion exceeded the bounds of its premarket clearance. While the premarket application process tends to ensure that only safe and effective devices are marketed for intended uses, Anodyne's violation was a regulatory marketing or promotional one. The Food, Drug, and Cosmetic Act is clear that it does not "limit or interfere with the authority of a

health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396. Thus, the FDA does not approve or disapprove the use of medical devices for specific treatments. The fact that Anodyne's lamp's marketing clearance was self-limited to pain and circulation does not mean that it was not a safe and effective treatment for peripheral neuropathy.

Secondly, Nightingale's interpretation of the term "treatment" is too narrow. There is no dispute that Anodyne promoted its lamp generally as a treatment for peripheral neuropathy.[4] Anodyne contends that it meant that the lamp provides relief from the symptoms of pain and numbness associated with peripheral neuropathy. Nightingale contends that "treatment," without further qualification, means only that it is a cure or treatment for the disease or disorder of peripheral neuropathy itself, not that it provides only symptomatic relief, and because there is no cure or treatment for peripheral neuropathy, Anodyne's commercial advertisements were false.

Neither side provided authorities for the definition of "treatment," either in common parlance or the medical context. Consulting medical sources, we found the following definitions of treatment:

(1) "the management and care of a patient for the purpose of combating disease or disorder." Subparts of this definition include "active," "curative," and "causal" treatment, meaning "treatment designed to cure an existing disease, as opposed to palliative" treatment,

[4] There is a dispute, however, as to whether Anodyne told Nightingale that the FDA had approved the device for treatment of peripheral neuropathy.

which is defined as "treatment designed to relieve pain and distress, but not attempting a cure." *Dorland's Illustrated Medical Dictionary*, 29th ed., p. 1868 (W. B. Saunders Co. 2000).

(2) "Medical or surgical management of a patient." Subparts of this definition include "active" treatment, meaning "a therapeutic substance or course intended to ameliorate the basic disease problem, as opposed to supportive or palliative" treatment; "causal" treatment which is "aimed at reversing the causal factor in a disease"; and "palliative" and "symptomatic" treatment which is treatment "to alleviate symptoms without curing the disease" and "therapy aimed at relieving symptoms without necessarily affecting the basic underlying cause(s) of the symptoms." *Stedman's Medical Dictionary*, 28th ed., p. 2022 (Lippincott Williams & Wilkins, 2006).

(3) "Any course of action or program adopted to restore health, prevent disease, or relieve symptoms." Subparts include "palliative" treatment, "aimed at mitigating symptoms rather than curing disease." *American Jurisprudence*, *Proof of Facts*, *3rd Series*, *Attorney's Illustrated Medical Dictionary*, p. T65 (West 2002).

(4) "to care for or deal with medically or surgically: deal with by medical or surgical means . . . ." *Webster's Medical Desk Dictionary*, p. 728 (Merriam-Webster, Inc., 1986) (entry for "treat").

> (5) A course of medical or surgical care. A physician designs a treatment plan for a person to cure or improve his or her condition. Types of care may include drug therapy, psychotherapy or counseling, surgery, or rehabilitation. Even when a medical problem cannot be reversed, it may be ameliorated by treatment to relieve pain and distress. In other cases, treatment consists of preventive or prophylactic measures to prevent a disease, disorder, or injury.

American Medical Association, *Complete Medical Encyclopedia*, p. 1236 (Random House

Reference, 2003).

(6) "Interventions intended to cure or ameliorate the effects of a disease or condition." Ellen Freudenheim, *Healthspeak: a Complete Dictionary of America's Health Care System*, p. 279 (Facts on File, Inc., 1996).

(7) 1. Medical, surgical, dental, or psychiatric management of a patient. 2. Any specific procedure used for the cure or the amelioration of a disease or pathological condition.

Taber's Cyclopedic Medical Dictionary, 16th ed., p. 1897 (Lawyer's Cooperative Publg., 1989) (subparts for active, causal, palliative, and symptomatic treatment).

(8) "Any measure taken to prevent or cure a disease or disorder or to relieve symptoms." American Medical Association, *Encyclopedia of Medicine*, p. 1008 (Random House, 1989).

All of these definitions include the concepts both of cure or action directed to the disease or disorder itself and the amelioration or relief of symptoms. No medical dictionary that we consulted defined the term "treatment" only in terms of cure. General dictionaries similarly define the term. *Webster's Third New International Dictionary of the English Language, Unabridged*, pp. 2434-35 (treatment and treat) (G. & C. Merriam Co., 1976); *American Heritage Dictionary of the English Language*, 3rd ed., pp. 1526 and 1906 (Houghton Mifflin Co. 1996) (treatment and remedy); *Random House Webster's College Dictionary*, 2nd ed., pp. 1370-71 (Random House, 1997).

Furthermore, Dr. Dev Brar, the president of Nightingale and a physician, testified that, while the symptoms of peripheral neuropathy can be ameliorated — including through the use of Anodyne's lamp — there is no cure or direct treatment for the condition itself. Brar Deposition, pp. 21, 52-55, 98. In fact, peripheral neuropathy itself is an effect or symptom of an underlying

cause, whether diabetes, trauma, impingement, toxins, malnutrition, *etc.* *The Merck Manual*, 18th ed. , pp. 1903 ff. (Merck Research Laboratories, 2006);[5] *The Merck Manual of Medical Information*, Second Home Edition, pp. 575-88 (Merck Research Laboratories, 2003); 2 *Harrison's Principles of Internal Medicine*, 17th ed., pp. 2651, 2653 (McGraw-Hill Cos., Inc., 2008) ("*What treatment is appropriate*? Treatment of the underlying disorder, pain management, and supportive care to protect and rehabilitate damaged tissue all need to be considered").

In light of the common and medical definition of the word "treatment" as including providing relief of symptoms, the nature of peripheral neurology, and Dr. Brar's own testimony of his understanding of that condition, we find that there is no genuine dispute that Anodyne's commercial advertisements stating that its lamp is a treatment for peripheral neuropathy was not false or misleading.[6] Because Nightingale is thus unable to prove the first element of a Lanham

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[5] "Underlying disorders are treated." *Merck Manual*, p. 1904. "Treatment focuses on correcting the causes when possible; a causative drug or toxin can be eliminated, or a dietary deficiency corrected. . . . If the cause cannot be corrected, treatment focuses on minimizing disability and pain." *Id.*, p. 1906.

[6] Dr. Brar averred that Anodyne's sales representative never stated that Anodyne's lamps "were a treatment for the symptoms of peripheral neuropathy nor did he state that these units treated only the pain associated with peripheral neuropathy." Brar Affidavit, ¶ 8; Brar Deposition, p. 95. Dr. Brar also testified that, whether Anodyne's salesman used the word "cure" or "treat" (he could not recall the words used), he "never cast doubt" on the fact that the lamp was a treatment in the sense of a cure. Brar Deposition, p. 95. Aside from the unpersuasiveness of negative representations in isolation (the salesman "never stated", "never cast doubt on"), these representations or non-representations were made or not made personally to Nightingale personnel, not in commercial advertisements, and therefore do not support a Lanham Act claim.

We also note that, in response to Anodyne's motion, Nightingale did not rely on or argue any alleged misrepresentations by Anodyne regarding Medicare reimbursement to support its Lanham Act claim.

Act violation, summary judgment is warranted on Count 1 of the Complaint.

Count 2 — Breach of Contract

Count 2 of Nightingale's Complaint alleges that Anodyne made two misrepresentations describing its product which became part of the parties' contract: (1) Anodyne's lamp is a proper treatment for neuropathy and (2) the cost of treatment is reimbursable by Medicare. Anodyne breached the contract when it became clear that neither description was true. These allegations underwent a transformation in Nightingale's response to Anodyne's motion. The two misdescriptions that Nightingale now alleges are: (1) Anodyne's units were FDA-approved as a treatment for peripheral neuropathy and (2) Anodyne's units can be marketed by Nightingale as a treatment for peripheral neuropathy. (Response, pp. 16, 17, 20, 21).[7] We conclude that Nightingale has dropped reliance on any statements regarding Medicare reimbursement and the general effectiveness or propriety of using Anodyne's lamp as a treatment for peripheral neuropathy as a basis for its breach-of-contract claim. At any rate, Nightingale did not factually or legally develop any arguments relating to these allegations and, therefore, waived them.

Citing *Dick Winning Chrysler-Plymouth of Ft. Myers, Inc. v. Chrysler Motors Corp.*, 750 F.2d 895 (11th Cir. 1985), and *Monumental Life Ins. Co. v. Commonwealth Land Title Ins. Co.*, 435 So.2d 975 (Fla. Dist. Ct. App. 1983), Anodyne argued that, under Florida law, the

[7] A different version of the alleged descriptions is mentioned once in Nightingale's Response: (1) Anodyne's lamp treats and/or cures peripheral neuropathy, (2) Anodyne's lamp can be marketed as a treatment for peripheral neuropathy, and (3) Anodyne's treatments would be covered by Medicare. (Response, p. 14). Nightingale did not further mention, or develop arguments relating to, allegations (1) and (3) in its brief.

complete terms of the parties' contract are contained in the two initial "Anodyne Health Care Professional Evaluation Agreements" executed by Nightingale on November 5, 2004, (Appendix of Exhibits in Support of Motion for Summary Judgment (doc. 70), Exhibit A), and no prior oral understandings or negotiations are effective. Further, the Agreements contain a clause stating that the rights and obligations of the parties may not be changed, modified, or waived verbally. However, both *Dick Winning* and *Monumental Life*, are based on the principle that written agreements prevail over previous *contrary* oral agreements or understandings and the two Professional Evaluation Agreements contain no terms contrary to Nightingale's alleged misrepresentations by Anodyne. Further, while the no-oral-modifications clauses of the Agreements have prospective effect, they do not amount to integration or merger clauses eliminating the effect of prior representations or understandings.

In response, Nightingale contends that, under Florida's Uniform Commercial Code,[8] Anodyne's two representations, as descriptions of its goods, became express warranties and implied warranties of fitness for a particular purpose that were then breached when Nightingale discovered that the FDA had not approved Anodyne's devices for the treatment of peripheral neuropathy and that Nightingale could not market the devices as such a treatment. Anodyne did not dispute the applicability of Florida's U.C.C. to the parties' agreement.

There is a genuine dispute in the evidence whether Anodyne's sales representative told Nightingale personnel before the sale of the devices that they were FDA-approved for the treatment of peripheral neuropathy. See Brar Affidavit, ¶¶ 6 and 14; Kirby Affidavit, ¶¶ 6, 11,

[8] The Professional Evaluation Agreements contain a forum-selection clause in favor of Florida law and Anodyne does not dispute that Florida law governs Nightingale's contract claim.

and 12.[9] In reply, Anodyne simply states that, to the extent that there was such a warranty, it was not breached. (Reply, p. 15). Because the devices were not FDA-approved for the treatment of peripheral neuropathy, if such a representation were made as a description of Anodyne's lamps, then the warranty could have been breached.

Nightingale has not shown, however, how Anodyne's lack of FDA premarket approval of its device for the treatment of peripheral neuropathy, FDA's Warning Letter, or any other consideration prevented Nightingale's referral sources from ordering, or Nightingale from using or promoting, the devices for the treatment of the symptoms of peripheral neuropathy. See 21 U.S.C. § 396 (quoted above). It might have preferred not using or promoting a device that had not received FDA pre-market clearance, but it would have been for reasons unrelated to any representations by Anodyne. There is no dispute, therefore, that Anodyne's warranty that Nightingale could promote its lamps as a treatment for peripheral neuropathy was not breached.

Also in its Reply, Anodyne argued that Nightingale cannot show that it suffered any damages, measured as the difference in value between the goods as accepted and as they would have had if they had been as warranted. Raised for the first time in reply, the argument cannot be considered on this motion.

Summary judgment on Count 2 is granted except to the extent that Nightingale alleges breach of Anodyne's express and/or implied warranty that its infrared lamps were FDA-approved for the treatment of peripheral neuropathy.

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[9] There is no dispute that Anodyne represented to Nightingale, in one form or another, that the devices were FDA-approved, without specification of purpose.

Count 3 — Fraudulent Misrepresentation

The Complaint alleges that Anodyne defrauded Nightingale by representing that (1) its infrared device is a proper treatment for neuropathy and (2) the costs of treatment is reimbursed by Medicare to the patient. Complaint, ¶ 28. In Nightingale's Response, the alleged fraudulent statements made by Anodyne were changed to: (1) the Anodyne units were FDA-approved for the treatment of peripheral neuropathy, (2) they can be marketed by Nightingale as a treatment for peripheral neuropathy, and (3) the use of the units will be covered by Medicare. (Response, p. 24).[10] These are now the three operative alleged misrepresentations.

Anodyne argues that Nightingale cannot show either the materiality of or its reliance on the statements relating to FDA approval for peripheral neuropathy or Medicare reimbursement because it did not care about either of these facts when it purchased and now is using a competitor's infrared photo device.[11] Nightingale's uncontradicted evidence is that the competitor represented that its device is not FDA-approved for the treatment of peripheral neuropathy and is not reimbursable by Medicare. Whatever factors motivated Nightingale's decision at the time of its purchase of Anodyne's devices might be changed after it discovered that neither Anodyne's nor any other infrared photo therapy device is FDA-approved for peripheral neuropathy and after issuance of Medicare's National Coverage Decision that no infrared photo therapy device will be covered by Medicare. Anodyne's argument would have

[10] Anodyne did not file a motion under Fed. R. Civ. P. 9(b) asserting that Nightingale had failed to state with particularity the circumstances constituting fraud in Count 3.

[11] As discussed above, Nightingale has failed to show how Anodyne's alleged representation regarding the ability of Nightingale to market and use its lamp as a treatment for peripheral neuropathy is false.

force if other competitors offered FDA-approved and reimbursable infrared lamps.

Anodyne argues that Nightingale cannot show that the alleged misrepresentations regarding Medicare reimbursement and FDA-approval, if made, were knowingly or recklessly false because it had good-faith grounds for believing that the treatment of peripheral-neuropathy symptoms fell within the bounds of its premarket clearance and that Medicare would issue a National Coverage Decision or other reimbursement instruction in its favor. Nightingale presents sufficient evidence to create a genuine dispute about both facts. First, there is no dispute that Anodyne represented to Nightingale at the time of purchase that use of its lamps by Nightingale was not then reimburseable but that Anodyne was working on obtaining approval for reimbursement. There is a dispute in the evidence, however, about how Anodyne described the status of future reimbursement. Other evidence tends to show that Anodyne merely stated that it was working on the issue with Medicare, that the process was difficult and lengthy, that approval would be granted soon, and that approval was virtually assured and merely administrative steps needed to be completed. A fact-finder must resolve this dispute. Similarly, a fact-finder must determine whether Anodyne represented that its lamps were FDA-approved for peripheral neuropathy and whether it knowingly or recklessly did so. No evidence was presented on the latter point and it is more a matter for interpretation from the circumstances.

Anodyne also argued that the alleged misrepresentation regarding the prospect of Medicare reimbursement cannot constitute actual fraud because it is a statement about a future event. However, any representation made about the current status of obtaining that approval from Medicare would have been a statement about a contemporaneous fact. In addition, as Nightingale pointed out, representations about future events can constitute constructive fraud.

Count 3 is not specific about the type of fraud alleged and Anodyne did not seek further clarification.

Finally, Anodyne argues that Nightingale cannot demonstrate the final element of a fraud claim, damages, because it saw an increase in sales after the use of the Anodyne lamps and it has not quantified its damages. Nightingale responds that Anodyne's misrepresentations caused it to expend thousands of dollars for purchases and leases of Anodyne's lamps, training costs for its staff, extensive advertising and marketing campaigns. In addition, after it discovered that the units were not FDA-approved for the treatment of peripheral neuropathy and would not be reimbursed by Medicare, it incurred expenses for revising its marketing materials and its reputation was damaged. A fact-finder must determine the extent of Nightingale's damages, if any.

Conclusion

Defendant's motion for summary judgment (doc. 69) is GRANTED IN PART and DENIED IN PART. Summary judgment is granted in Defendant's favor on (1) Count 1, Lanham Act, in its entirety; (2) Count 2, breach of contract, except to the extent that Nightingale alleges breach of express and/or implied warranty that its infrared lamps were FDA-approved for the treatment of peripheral neuropathy; (3) Count 3, fraudulent misrepresentation, to the extent that it depends on the alleged misrepresentation that Anodyne's devices could be marketed by Nightingale as a treatment for peripheral neuropathy; and (4) Count 4 in its entirety. Summary judgment is otherwise denied.

Defendant's Request for Oral Argument (doc. 99) is DENIED.

Date: 09/18/2008

SARAH EVANS BARKER, JUDGE
United States District Court
Southern District of Indiana

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