

United States District Court
District of Massachusetts

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CYNOSURE, INC. and)	
EL. EN. S.P.A.,)	
Plaintiffs,)	
)	Civil Action No.
v.)	08-10026-NMG
)	
COOLTOUCH, INC.,)	
Defendant.)	
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MEMORANDUM & ORDER

GORTON, J.

This is a patent infringement action involving aesthetic skin care treatment technologies brought by Cynosure, Inc. ("Cynosure"), the exclusive licensee of U.S. Patent No. 6,206,873 ("the '873 patent") and El. En. S.P.S. (together with Cynosure, "the plaintiffs"), owner of the '873 patent, against defendant New Star Lasers, doing business as CoolTouch Inc. ("CoolTouch"). Before the Court are cross-motions for summary judgment and Cynosure's motion to strike declarations by CoolTouch experts.

I. Background

A. Factual Background

The '873 patent describes a method for removing subcutaneous layers of fat (i.e., adipose layers). The procedure is accomplished by placing a laser fiber encased in a needle under a patient's skin. Energy emitted from the tip of the laser irradiates fat cells, causing them to liquefy, or melt. The

liquefied fat is then suctioned away or left to be absorbed by the patient. Apparently such a method of removing fat is less harmful to surrounding tissue than traditional liposuction.

The '873 patent has a total of 19 claims. In this suit, only two groups of claims are at issue: 1) independent Claim 1 and its dependent Claims 2, 8 and 9 and 2) independent Claim 13 and its dependent Claim 16. Claim 1 reads as follows:

1. A method for the removal of subcutaneous adipose layers, the method comprising the steps of:
 - providing a hollow needle with a tip;
 - providing a laser source with emitting characteristics for generating a laser beam having an intensity and a wavelength for causing lipolysis of adipose cells;
 - generating a laser beam with said laser source;
 - arranging an optical fiber inside said needle with one end of said optical fiber adjacent to said tip of said needle and with another end of said fiber connected to an output of said laser source;
 - piercing the skin of a patient and bringing said needle tip into a subcutaneous adipose layer of the patient;
 - irradiating said adipose layer with said laser beam to cause lipolysis of said adipose layer and rupturing membranes of cells forming the adipose layer, thus transforming adeps forming said adipose layer into a liquid substance.

The terms in Claim 13 are substantially similar to Claim 1. Claims 2 and 16 are identical and provide "[t]he method in accordance with claim [1 or 13, respectively], further comprising: suctioning said liquid substance away from the

adipose layer." Claim 8 discloses "[t]he method in accordance with claim 1, further comprising: irradiating the adipose layer with another laser beam to provide transcutaneous vision."

Finally, Claim 9 states "[t]he method in accordance with claim 1, wherein: said generating is performed to generate said laser beam as a pulsed laser beam."

On December 22, 2008, the Court issued a Markman Order construing the disputed terms (underlined above) in Claims 1 and 13 as follows:

- 1) "providing a hollow needle with a tip" means "providing a slender hollow instrument for introducing material or removing material from the body";
- 2) "adjacent" means "next to"; and
- 3) "piercing the skin of the patient" and "irradiating said adipose layer with said laser beam" were given no further construction.

Cynosure, Inc. v. Cooltouch Inc., No. 08-cv-10026 (NMG), 2008 WL 5736984 (D. Mass. Dec. 22, 2008).

B. Procedural History

Plaintiffs filed a complaint on January 9, 2008 alleging that CoolTouch infringed the '873 patent and seeking a declaratory judgment that three patents owned by CoolTouch, U.S. Patent Nos. 7,217,265 ("the '265 patent"), 6,451,007 ("the '007 patent") and 7,122,029 ("the '029 patent"), were invalid and not infringed by Cynosure. On January 31, 2008, Defendant CoolTouch answered by denying all of Cynosure's allegations, making

counterclaims that its '265, '007 and '029 patents were infringed and seeking a declaratory judgment of non-infringement and invalidity of Cynosure's '873 patent.

Subsequently, all claims related to CoolTouch's three patents were voluntarily dropped. On February 18, 2009, CoolTouch stipulated to the dismissal of its counterclaims for infringement of the '265 and '007 patents. Then, on September 22, 2009, pursuant to a covenant not to sue, the parties filed a stipulation of dismissal of 1) all claims and counterclaims related to the '029 patent and 2) Cynosure's claims for declaratory judgment of non-infringement and invalidity of the '265 and '007 patents.

As a result of these stipulations, only claims related to Cynosure's '873 patent remain at issue. That patent is currently subject to reexamination proceedings by the Patent and Trademark Office ("the PTO"). On April 15, 2009, CoolTouch moved to stay litigation pending the PTO's decision but this Court denied that motion on August 10, 2009. Cynosure, Inc. v. Cooltouch Inc., No. 08-cv-10026 (NMG), 2009 WL 2462565 (D. Mass. Aug. 10, 2009).

On May 15, 2009, both sides moved for summary judgment. On June 26, 2009, Cynosure also moved to strike the declarations of Dr. Robert Weiss ("Dr. Weiss") (in full) and David Hennings ("Mr. Hennings") (in part) filed in support of CoolTouch's opposition to Cynosure's summary judgment motion. Those motions are

presently before the Court.

II. Motions for Summary Judgment

A. Legal Standard

The role of summary judgment is "to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." Mesnick v. General Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991) (quoting Garside v. Osco Drug, Inc., 895 F.2d 46, 50 (1st Cir. 1990)). The burden is upon the moving party to show, based upon the pleadings, discovery and affidavits, "that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c).

A fact is material if it "might affect the outcome of the suit under the governing law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "Factual disputes that are irrelevant or unnecessary will not be counted." Id. A genuine issue of material fact exists where the evidence with respect to the material fact in dispute "is such that a reasonable jury could return a verdict for the nonmoving party." Id.

Once the moving party has satisfied its burden, the burden shifts to the non-moving party to set forth specific facts showing that there is a genuine, triable issue. Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986). The Court must view the entire record in the light most hospitable to the non-moving

party and indulge all reasonable inferences in that party's favor. O'Connor v. Steeves, 994 F.2d 905, 907 (1st Cir. 1993). If, after viewing the record in the non-moving party's favor, the Court determines that no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law, summary judgment is appropriate.

B. CoolTouch's Motion for Summary Judgment of Invalidity of the '873 Patent

Under the United States Patent Act ("the Patent Act"), all patents are presumed to be valid. 35 U.S.C. § 282. As a result, the party asserting the invalidity of a patent bears the burden of proving the alleged invalidity by clear and convincing evidence. AK Steel Corp. v. Sollac, 344 F.3d 1234, 1238-39 (Fed. Cir. 2003).

In its motion for summary judgment, CoolTouch contends that all six claims of the '873 patent at issue in this case (Claims 1, 2, 8, 9, 13 and 16) are invalid.¹ It argues that Claims 1, 2,

¹ On August 31, 2009, as part of its reexamination proceedings, the PTO issued a non-final decision rejecting Claims 1, 2 and 8-16 of the patent as anticipated or obvious for the identical reasons submitted to the Court by CoolTouch. The PTO made its decision without any input from Cynosure, which has two months to oppose the action. This PTO action has no bearing on the instant motions because "litigation and reexamination are distinct proceedings, with distinct parties, purposes, procedures, and outcomes.... The two forums take different approaches in determining invalidity and on the same evidence could quite correctly come to different conclusions." Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1427-28 (Fed. Cir. 1988) (citations omitted).

9, 13 and 16 are invalid by reason of anticipation pursuant to 35 U.S.C. § 102(b) and that Claim 8 is invalid as obvious pursuant to 35 U.S.C. § 103.

1. Anticipation

a. Legal Standard

Section 102(b) of the Patent Act provides that an invention is not patentable if it is "described in a printed publication ... more than one year prior to the [application] date." To prove invalidity by anticipation, the movant must show that

every element and limitation of the claim was previously described in a single prior art reference, either expressly or inherently, so as to place a person of ordinary skill in possession of the invention.

Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075, 1082 (Fed. Cir. 2008). "[D]ifferences between the prior art reference and a claimed invention, however slight, invoke the question of obviousness, not anticipation." Net MoneyIN, Inc. v. VeriSign, Inc., 545 F.3d 1359, 1371 (Fed. Cir. 2008). Anticipation is a question of fact and thus summary judgment of invalidity is proper only "if no reasonable jury could find that the patent is not anticipated." Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1327 (Fed. Cir. 2001).

b. Application

CoolTouch argues that the claims at issue are anticipated by a single source: Apfelberg, et al., Progress Report on Multicenter Study of Laser-Assisted Liposuction, 18 Aesth. Plast.

Surg. 259 (1994) (hereinafter "Apfelberg"). It is undisputed that Apfelberg was not before the PTO when it considered the '873 patent application and was published more than one year prior to the filing of that application. Cynosure contends, however, that Apfelberg does not anticipate three specific claim limitations.

- i. **"Providing a laser source with emitting characteristics for generating a laser beam having an intensity and a wavelength for causing lipolysis of adipose cells" (Claim 1) or "... for liquefying, and maintaining liquid, the adipose cells" (Claim 13)**

Apfelberg and the '873 patent both address the use of a laser to draw fat from the body. Apfelberg calls for the use of a "YAG laser ... with 40 W of power, a pulse duration of 0.2 s, and an interval between pulses of 0.2 s," the result of which he describes as: 1) "the fat appears as a light yellow emulsification," 2) "fat emulsifies and then is drawn out by suction" and 3) "the laser melts and emulsifies the fat." Under the '873 patent, the laser must be intense enough to cause lipolysis (Claim 1) or to liquefy the fat cells (Claim 13). Lipolysis is not explicitly defined in the '873 patent but it describes bringing about

the lipolysis of the adipose cells ..., that is a rupturing of the membranes of the cells themselves, with consequent transformation of the adeps into a liquid substance which is then sucked out....

Thus, Claims 1 and 13 both appear to require a laser source capable of liquefying adipose cells.

CoolTouch argues that because Apfelberg reports "melt[ing]" and "emulsif[ying]" the fat, his laser "liquefies" fat just like the laser claimed in the '873 patent. CoolTouch also points out that the PTO found the patented invention to be novel because no prior art disclosed a laser capable of liquefying the adipose cells. CoolTouch insists, therefore, that Apfelberg is distinguishable from other prior art and anticipates the claim.

Cynosure responds, based on expert testimony, that CoolTouch's reading of Apfelberg is incorrect. Specifically, Cynosure's expert Dr. Bruce Katz ("Dr. Katz") states that a laser with the characteristics described in Apfelberg is incapable of performing lipolysis or melting or liquefying fat. The peak power of the Apfelberg laser is apparently over six times lower than the peak power instructed by the '873 patent. Moreover, according to Dr. Katz, emulsification (referred to three times in Apfelberg) means mixing which is distinct from melting or liquefying. Thus, Cynosure claims that whatever Apfelberg meant by his singular use of the word "melt," he could not possibly have been describing a laser with the capabilities required by the '873 patent to liquefy adipose cells or to cause lipolysis.

Cynosure's rebuttal is persuasive. Although Apfelberg does, in one instance, describe "melt[ing]" fat, that lone use of the word is not enough to prove that no reasonable jury could find that the '873 patent was not anticipated. In light of the

contradicting evidence presented by Cynosure, the Court holds that CoolTouch has not carried its heavy burden of proving that no material issues of fact are in dispute with respect to anticipation of these limitations.

- ii. "Irradiating said adipose layer with said laser beam to cause lipolysis of said adipose layer ... thus transforming adeps forming said adipose layer into a liquid substance" (Claim 1) or "irradiating adipose cells ... with said laser beam from said optical fiber to transform the adipose cells into, and maintain the adipose cells as, a liquid substance" (Claim 13)**

The arguments and counter-arguments for why this claim limitation is or is not anticipated are virtually identical to those given in the preceding section. Accordingly, for the same reasons, the Court rejects CoolTouch's argument that the claims are indisputably anticipated by Apfelberg.

- iii. "Arranging an optical fiber inside said needle with one end of said optical fiber adjacent to said tip of said needle" (Claim 1) or "providing ... an optical fiber inside said needle with one end of said optical fiber adjacent to said tip of said needle" (Claim 13)²**

CoolTouch argues that Apfelberg discloses the limitation that one end of the optical fiber be "next to" the tip of the needle. Apfelberg shows a picture of his needle, reproduced in CoolTouch's brief at page 5. There, the cannula has an opening on its side, near the tip of the needle. The optical fiber is threaded such that it ends 2 mm short of that side opening and

² In its Markman Order, the Court construed the term "adjacent to" to mean "next to."

thus even farther from the actual tip. Because the side opening appears to be close to the tip of the needle, CoolTouch asserts that the optical fiber is "next to" the tip.³

Cynosure rebuts that assertion and argues, with the support of Dr. Katz, that the fiber is too far from the tip of the needle to be labeled "next to" it. Indeed, Cynosure cites CoolTouch's own Mr. Hennings for the proposition that a distance of only 1-2 mm from the tip of the needle, much less than the distance in Apfelberg, is "clearly not 'adjacent' to the tip." Thus, Cynosure states that the fiber in Apfelberg is only "next to" the opening in the cannula but not "next to" its tip.

The Court rejects CoolTouch's anticipation argument with respect to these limitations. Without even knowing how far the tip of the fiber in Apfelberg is from the end of the needle, it is impossible to determine whether it can conclusively be described as "adjacent to" or "next to" the tip, as the claims require. In fact, in construing the term "adjacent to" in its Markman Order, the Court did not consider an arrangement such as the one in Apfelberg, with a hole in the side of the cannula, as conceivably covered by the claims. Cynosure has, in any case, presented sufficient evidence to create a factual dispute.

³ Ironically, the construction for which CoolTouch advocated at the Markman hearing was considerably more limited than what the Court adopted and would have conclusively foreclosed the arguments that it makes here.

Accordingly, the Court finds that Apfelberg does not anticipate these limitations on the record before it.

iv. The Remaining Limitations in Independent Claims 1 and 13 and Dependent Claims 2, 9 and 16

Having found that CoolTouch has failed to meet its burden of proof for anticipation on the three limitations in Claims 1 and 13 above, the Court declines to consider whether Apfelberg anticipates the remaining claims at issue. Every element and limitation of a claim must be contained in the prior work. Sanofi-Synthelabo, 550 F.3d at 1082. Accordingly, a failure to demonstrate that just one limitation of a claim is anticipated means that the movant cannot prove anticipation of the claim as a whole. The remaining disputed claims are dependent upon Claims 1 and 13 and, as a result, are “construed to incorporate by reference all the limitations of [those two claims].” 35 U.S.C. § 112, ¶ 4. Thus, because CoolTouch cannot establish that Claims 1 and 13 are anticipated, it cannot show that Apfelberg anticipates the dependent claims and summary judgment will be denied.

2. Obviousness

a. Legal Standard

Pursuant to § 103 of the Patent Act, a patent is invalid if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103(a). See generally KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).

When evaluating whether a claim based on the combination of elements found in prior art is obvious, a court must first, of course, determine that all elements of the claim are found in prior art. E.g., U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1564-65, (Fed. Cir. 1997) (affirming jury instructions stating that "the prior art must show ... all of the elements of the claimed combination"). A patent composed of several elements, however, "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." KSR Int'l Co., 550 U.S. at 418. A court must also decide "whether the improvement [i.e., the combination] is more than the predictable use of prior art elements according to their established functions." Id. at 417.

b. Application

CoolTouch contends that Claim 8, a dependent claim disclosing "[t]he method in accordance with claim 1, further comprising: irradiating the adipose layer with another beam to provide transcutaneous vision," is an obvious combination of Apfelberg and either of two prior works. CoolTouch's argument appears to be as follows. First, Apfelberg renders Claim 1, which is incorporated into Claim 8, obvious because an anticipated claim is also obvious and CoolTouch maintains that

Claim 1 is anticipated. Then, the two other identified sources, which disclose using a second laser with a visible aiming beam, instruct the additional limitation of Claim 8. Thus, "a person of ordinary skill in the art would be able to modify Apfelberg in view of either [work] to produce the method of claim 8."

The Court rejects CoolTouch's position in light of its finding on anticipation. To prove that a claim is an obvious combination of prior art, as CoolTouch attempts to do here, the movant must first show that each element was known in the prior art. KSR Int'l Co., 550 U.S. at 418. Accordingly, CoolTouch must show that Claim 1, which is incorporated into Claim 8, was known and obvious. CoolTouch, however, has not made any argument that Claim 1 is obvious in view of Apfelberg over and above its contention that Apfelberg anticipates Claim 1. CoolTouch bears the burden of proof and thus by failing to demonstrate that Claim 1 was anticipated (and therefore obvious), CoolTouch has not met its burden of showing that each element of Claim 8 (let alone the combination of elements) was obvious in light of prior art. As such, summary judgment will be denied in that respect.

3. Request for 56(d) Rulings

At the conclusion of its brief, Cynosure states that the Court should make a finding, pursuant to Fed. R. Civ. P. 56(d), that the validity of the '873 patent is factually undisputed. It contends that Apfelberg does not

disclose ... any claim of the ... patent and there was no reason to combine [it] with White or Vassiliadis, which would not have achieved the claimed invention in any event.

The Court declines to make such a ruling on the record before it. Rule 56(d)(1) provides that

[i]f summary judgment is not rendered on the whole action, the court should, to the extent practicable, determine what material facts are not genuinely at issue ... [and] then issue an order specifying what facts are not genuinely at issue.

Fed. R. Civ. P. 56(d)(1) (emphasis added). Certainly, Cynosure has forcefully rebutted CoolTouch's motion for summary judgment and has made a strong affirmative case for the validity of the '873 patent. Nonetheless, the Court is unprepared to make a conclusive finding in its favor at this stage because CoolTouch has demonstrated that the underlying (and technical) facts at issue remain controverted. Thus, a Rule 56(d) finding is unwarranted.

C. Cynosure's Motion for Summary Judgment of Non-Infringement and Invalidity of the '029 Patent

In light of the stipulation of dismissal filed on September 22, 2009, this motion will be denied as moot.

III. Motion to Strike

In addition to its summary judgment motion, Cynosure filed a motion to strike the expert declaration of Dr. Weiss in full and the declaration of Mr. Hennings in part, both of which requests were filed in support of CoolTouch's opposition to the motion for

summary judgment on the '029 patent. As with Cynosure's summary judgment motion, the Court will deny that motion as moot.

ORDER

In accordance with the foregoing:

- 1) the defendant's motion for summary judgment on invalidity of the '873 patent (Docket No. 43) is **DENIED**;
- 2) the plaintiffs' motion for summary judgment on invalidity and non-infringement of the '029 patent (Docket No. 47) is **DENIED AS MOOT**; and
- 3) the plaintiffs' motion to strike expert declarations (Docket No. 65) is **DENIED AS MOOT**.

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated October 1, 2009