

United States District Court
For the Northern District of California

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

MEDTRONIC, INC., et al.,
Plaintiffs,
v.
AGA MEDICAL CORPORATION,
Defendant.

No. C-07-0567 MMC

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT ON GROUNDS OTHER THAN ABSENCE OF STRESS-INDUCED MARTENSITE

Before the Court is defendant AGA Medical Corporation's ("AGA") "Motion for Summary Judgment (#3) on Grounds other than the Absence of Stress-Induced Martensite," filed February 27, 2009. Plaintiffs Medtronic, Inc., Medtronic USA, Inc., and Medtronic Vascular, Inc. (collectively, "Medtronic") have filed opposition, to which AGA has replied. Having read and considered the papers filed in support of and in opposition to the motion, the Court rules as follows.

DISCUSSION

A. '957 Patent

1. Direct Infringement

In its motion, AGA argues it has not directly infringed any of the asserted claims of United States Patents Number 5,067,967 ("957 patent"), which claims relate generally to methods for implanting certain medical devices, and that Medtronic has no evidence that

1 AGA has directly infringed such claims. In particular, AGA argues it has not practiced the
2 asserted claims and that, even assuming, arguendo, AGA's physician customers have
3 practiced such claims, they have not done so under the "control or direction" of AGA. See
4 Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318, 1329 (Fed. Cir. 2008) (holding "where
5 the actions of multiple parties combine to perform every step of a claimed method, the
6 claim is directly infringed only if one party exercises 'control or direction' over the entire
7 process such that every step is attributable to the controlling party, i.e., the 'mastermind'"
8 (internal citation omitted). In support of such argument, AGA points to evidence that
9 physicians "have sole responsibility for exactly how a medical device is used in patients"
10 (see Decl. Charles E. Mullins, M.D. ("Mullins Decl.") ¶ 6) and that, once physicians are
11 trained by AGA, AGA has "no input as to how the physician utilizes the AGA devices" (see
12 Decl. Steven D. Hemminger ("Hemminger Decl.") Ex. 33 ("Deposition of Derek Wise") at
13 125:18-20).

14 In response, Medtronic asserts there is a triable issue as to whether physicians who
15 use the accused products practice each of the limitations of the asserted claims under the
16 "control or direction" of AGA. In support of its argument, Medtronic points to evidence that
17 AGA instructs and trains physicians on the use of the accused products. (See, e.g., Decl.
18 Joshua C. Walsh-Benson ("Walsh-Benson Decl.") Ex. 23 (Instructions for Use of certain of
19 accused products ("Instructions for Use")) at unnumbered 4, 11, 16, 21-22, 24-25, 36-37;
20 id. Ex. 24 ("Deposition of Derek Wise") at 106:13-107:2.) Such evidence, however, is
21 insufficient to raise a triable issue as whether AGA exercises the requisite "control or
22 direction" over its physician customers. See Muniauction, 532 F.3d at 1330 ("That [the
23 defendant] controls access to its system and instructs [third parties] on its use is not
24 sufficient to incur liability for direct infringement").

25 Accordingly, to the extent AGA seeks summary judgment on the issue of direct
26 infringement of the '957 patent, AGA's motion will be granted.

27 **2. Indirect Infringement**

28 AGA next argues Medtronic has no evidence that AGA has indirectly infringed any of

1 the asserted claims of the '957 patent. In response, Medtronic contends there are triable
2 issues as to AGA's liability for both inducement of infringement and contributory
3 infringement. As set forth below, the Court agrees with Medtronic.

4 "In order to succeed on a claim of inducement [of infringement], the patentee must
5 show, first that there has been direct infringement, and second, that the alleged infringer
6 knowingly induced infringement and possessed specific intent to encourage infringement."
7 See MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp., 420 F.3d 1369, 1378
8 (Fed. Cir. 2005); see also 35 U.S.C. § 271(b). Here, Medtronic has submitted evidence of
9 instances in which physicians have implanted the accused products in accordance with the
10 products' Instructions for Use (see, e.g., Walsh-Benson Decl. Ex. 26 ("Deposition of Gary
11 Thill") at 30:2-4); id. Ex. 34 ("Deposition of John Oslund") at 103:6-11) and that such
12 implantation procedures practice each of the limitations of the asserted method claims of
13 the '957 patent, other than those limitations that require the display of stress-induced
14 martensite¹ (see Decl. Jeffrey A. Feinstein, M.D. ("Feinstein Decl.") ¶¶ 78-99²; see also
15 Instructions for Use at unnumbered 4, 11, 16, 21-22, 24-25, 36-37; Walsh-Benson Decl.
16 Ex. 32 ("Deposition of Charles E. Mullins, M.D.") at 38:7-52:21 (discussing implantation
17 procedure)).

18 Further, Medtronic has submitted evidence that AGA, despite its awareness of
19 Medtronic's patents, continued to train and instruct physicians to use the accused products
20 in accordance with the Instructions for Use. (See Deposition of Derek Wise at 79:12-13
21 ("We always teach or instruct to the instructions for use"); id. at 80:1-5 (stating AGA gives
22 distributors "the direction that they must instruct their customer physicians to only deploy

23
24 ¹The issue of whether the accused products exhibit stress-induced martensite is the
25 subject of AGA's "Motion for Summary Judgment (#1) of Noninfringement on the Ground
26 that the Accused Products Do Not Exhibit Stress-Induced Martensite," which motion is
27 addressed by order filed concurrently herewith.

28 ²Contrary to AGA's argument, the Feinstein Declaration is not "conclusory." (See
29 Reply at 13:6, 13:16.) Rather, the declaration adequately describes how, in Dr. Feinstein's
30 opinion, each of the limitations at issue herein is practiced during the implantation of the
31 accused products in accordance with their Instructions for Use. (See Feinstein Decl. ¶¶ 78-
32 99.)

1 the devices per the instructions for use”); id. at 106:13-107:2 (stating document titled
2 “Physician Training and Hospital Requirements . . . lays out the level of training
3 requirements that AGA requires before we will ship products to a particular physician or
4 institution”); Walsh-Benson Decl. Ex. 37 (AGA’s Responses to Medtronic’s First Set of
5 Interrogatories) at 6:18-20 (stating AGA “became aware of each of the Medtronic Patents
6 by at least the Spring of 2004”).)

7 Such evidence is sufficient to support an inference that AGA had the requisite intent
8 to induce infringement. See Symantec Corp. v. Computer Assocs. Int’l, Inc., 522 F.3d
9 1279, 1293 (Fed. Cir. 2008) (finding triable issue as to whether defendant induced its
10 customers to infringe where defendant’s product manual “encouraged customers” to use
11 accused products in infringing combination with other products); Golden Blount, Inc. v.
12 Robert H. Peterson Co., 438 F.3d 1354, 1364 & n.4 (Fed. Cir. 2006) (finding defendant
13 induced infringement where customers’ following instructions for assembly of accused
14 product resulted in infringing apparatus and defendant “intended to have customers
15 assemble the apparatus in accordance with the instructions” and “had notice of the
16 patent”); Metabolite Labs., Inc. v. Lab. Corp. of Amer. Holdings, 370 F.3d 1354, 1365 (Fed.
17 Cir. 2004) (holding publications “promot[ing]” infringing method sufficient to support jury
18 finding of intent to induce infringement); Chiuminatta Concrete Concepts, Inc. v. Cardinal
19 Indus., Inc., 145 F.3d 1303, 1311-12 (Fed. Cir. 1998) (holding advertisements that
20 “encourage[d]” infringement of method claims sufficient to support finding, as matter of law,
21 of intent to induce infringement).

22 In sum a triable issue exists with respect to the issue of inducement of infringement
23 of the ‘957 patent.

24 Additionally, a triable issue exists as to the issue of contributory infringement.
25 Liability for contributory infringement is governed by 35 U.S.C. § 271(c), which provides, in
26 relevant part:

27 Whoever . . . sells within the United States . . . a component of a patented machine,
28 manufacture, combination or composition, or a material or apparatus for use in
 practicing a patented process, constituting a material part of the invention, knowing

1 the same to be especially made or especially adapted for use in an infringement of
2 such patent, and not a staple article or commodity of commerce suitable for
substantial noninfringing use, shall be liable as a contributory infringer.

3 See § 271(c).

4 As noted, Medtronic has submitted sufficient evidence to raise a triable issue as to
5 whether certain physicians using the accused products have practiced every limitation of
6 the asserted claims of the '957 patent, and Medtronic has shown AGA was aware of the
7 '957 patent. Further, although AGA has presented evidence that some physicians have, at
8 times, used the accused products "off-label," i.e., in situations other than those for which
9 the products were approved by the Food and Drug Administration (see, e.g., Hemminger
10 Decl. Ex. 32 ("Deposition of Jeffrey Feinstein") at 25:6-26:14)), such evidence fails to
11 demonstrate the accused products are "suitable for substantial noninfringing use," see §
12 271(c). In particular, AGA has failed to argue, let alone to present any evidence to
13 suggest, that such "off-label" uses did not employ the same steps as those taught in the
14 Instructions for Use.

15 Accordingly, to the extent AGA seeks summary judgment on the issues of
16 inducement and contributory infringement of the '957 patent, AGA's motion will be denied.

17 **B. '546 Patent**

18 AGA argues it has not directly or indirectly infringed the one claim asserted with
19 respect to United States Patent Number 5,190,546 ("546 patent"), which claim discloses a
20 method for "removing" a medical device from a mammalian body (see '546 Patent, col. 12,
21 ll. 66-67), and that Medtronic has no evidence that AGA has infringed such claim. In
22 response, Medtronic points to evidence that the Instructions for Use contemplate the
23 removal of the accused products (see, e.g., Instructions for Use at unnumbered 37), that,
24 on occasion, a removal does occur (see Mullins Decl. ¶ 5 (stating "withdrawal likely occurs
25 in less than 2-5% of the cases implanted in the hands of competent interventionalists")),
26 and that a removal in accordance with the Instructions for Use would infringe the '546
27 patent (see Feinstein Decl. ¶¶ 101, 103). Medtronic has presented no evidence, however,
28 of any instance in which any accused product actually was removed from a patient in

1 accordance with the Instructions for Use, and, indeed, AGA has presented evidence that
2 removal generally is accomplished through a process different than that described in the
3 Instructions for Use. (See Mullins Decl. ¶ 4 (stating “removal is completed through . . .
4 procedures such as using a gooseneck snare to attempt to capture the attachment pin on
5 the moving device, or through open heart surgery”); Instructions for Use at unnumbered 37
6 (stating, if position of device is “unsatisfactory,” physician should “[s]tabilize the delivery
7 cable and re-advance the delivery sheath until the device is completely within the sheath”
8 and then “[r]eposition the device and deploy it again, or remove the device from the
9 patient”).) Consequently, Medtronic has failed to raise a triable issue as to whether AGA’s
10 physician customers directly infringe the ‘546 patent, and, thus, Medtronic’s claim of
11 infringement by AGA necessarily fails. See Met-Coil Sys. Corp. v. Korners Unlimited, Inc.,
12 803 F.2d 684, 687 (Fed. Cir. 1986) (holding “[a]bsent direct infringement of the patent
13 claims, there can be neither contributory infringement, nor inducement of infringement”)
14 (citations omitted).

15 Accordingly, to the extent AGA seeks summary judgment of noninfringement of the
16 ‘546 patent, AGA’s motion will be granted.

17 **C. ‘141 Patent**

18 **1. Direct Infringement**

19 AGA argues it has not directly infringed the asserted claims of United States Patent
20 Number 6,306,141 (“‘141 patent”), for the reason that none of the accused products is sold
21 with a “hollow placement device,” a “guide wire,” or a “restraint” or “restraining means,”
22 each of which is a limitation of at least one of the asserted claims of the ‘141 Patent. (See,
23 e.g., ‘141 Patent col. 10, l. 62; col. 11, l. 5; col. 12, l. 5; col. 14, l. 4.) Medtronic, however,
24 has presented evidence that AGA tests each accused product by attaching such product to
25 a “delivery cable,” placing the product in a “loader,” and pushing the product out of the
26 loader to “deploy” it. (See Walsh-Benson Decl. Ex. 7 (“Final Device Inspection”) at 4, 7.)
27 AGA does not dispute that the term “delivery cable” is synonymous with “guide wire” (see
28 Mot. at 21:11-15), and Medtronic has presented evidence that AGA’s “loader” is both a

1 “restraint” or “restraining means” and a “hollow placement device”³ (see Feinstein Decl. ¶¶
2 108, 118). Such evidence is sufficient to support an inference that AGA has made an
3 “operable assembly” that infringes the asserted claims of the ‘141 patent.⁴ See 35 U.S.C. §
4 271(a) (providing “whoever without authority makes [or] uses . . . any patented invention,
5 within the United States . . . during the term of the patent therefor, infringes the patent”);
6 Paper Converting Machine Co. v. Magna-Graphics Corp., 745 F.2d 11, 18-19 (Fed. Cir.
7 1984) (noting “if the infringer makes an ‘operable assembly’ of the components of the
8 patented invention, sufficient for testing, it need not be the same thing as the complete and
9 entire invention”; further noting “use” under § 271(a) “includes use for the purpose of
10 testing”).

11 Accordingly, to the extent AGA seeks summary judgment with respect to the issue of
12 direct infringement of the ‘141 patent, AGA’s motion will be denied.

13 **2. Indirect Infringement**

14 AGA next argues it has not indirectly infringed the asserted claims of the ‘141 patent.
15 Medtronic, however, has presented sufficient evidence to create a triable issue as to
16 indirect infringement. As noted, Medtronic has presented evidence of instances in which
17 physicians have implanted the accused products in accordance with the applicable
18 Instructions for Use. Further, Medtronic has presented evidence that such implantation
19 procedures combine each element of the asserted claims of the ‘141 patent, other than
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21 ³The Court has construed both “restraint” and “restraining means” as “a device
22 component that prevents the transformation of the shape memory alloy element back into
23 its original shape.” (See Order Construing Claims, filed Feb. 6, 2008, at 5:8-10.) The
24 Court has construed “hollow placement device” as “a hollow device for positioning an object
25 within the body.” (See id. at 4:10-11.)

26 ⁴The Court finds unpersuasive AGA’s argument that its tests are performed at room
27 temperature and thus do not demonstrate that the accused products display stress-induced
28 martensite at body temperature. (See Reply at 10:1-3.) In particular, AGA has cited no
authority suggesting that if the products do, in fact, display stress-induced martensite at
body temperature, such display, in order to support an inference of infringement, must be
apparent from its tests. As noted, the issue of whether the accused products display
stress-induced martensite is the subject of AGA’s “Motion for Summary Judgment (#1) of
Noninfringement on the Ground that the Accused Products Do Not Exhibit Stress-Induced
Martensite,” which motion is addressed by order filed concurrently herewith.

1 those elements that require the presence of stress-induced martensite. (See Feinstein
2 Decl. ¶¶ 105-120.) Lastly, for the reasons discussed above in connection with the '957
3 patent, Medtronic has submitted sufficient evidence to support an inference that AGA had
4 the requisite intent to induce infringement, pursuant to § 271(b), and that the accused
5 products have no substantial noninfringing use, pursuant to § 271(c).

6 Accordingly, to the extent AGA seeks summary judgment with respect to the issue of
7 indirect infringement of the '141 patent, AGA's motion will be denied.

8 **CONCLUSION**

9 For the reasons stated above,

10 1. To the extent AGA seeks summary judgment in its favor on the issue of direct
11 infringement of the '957 patent, AGA's motion is hereby GRANTED.

12 2. To the extent AGA seeks summary judgment in its favor on the issue of
13 infringement of the '546 patent, AGA's motion is hereby GRANTED.

14 3. In all other respects, AGA's motion is hereby DENIED.

15 **IT IS SO ORDERED.**

16
17 Dated: April 28, 2009


MAXINE M. CHESNEY
United States District Judge