FILED on 10/30/09

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC.; CYTYC CORPORATION; and HOLOGIC LP,

Plaintiffs,

v.

SENORX, INC.,

Defendant.

No. C-08-00133 RMW

ORDER REGARDING MOTIONS FOR SUMMARY JUDGMENT OF INVALIDITY, NON-INFRINGEMENT, AND INFRINGEMENT

[Docket Nos. 280, 284]

This case is a dispute over three patents covering medical devices that treat breast cancer using a short range radiation-based technique known as brachytherapy. The patents-in-suit are United States Patent Nos. 5,913,813 ("'813 patent"), 6,413,204 ("'204 patent"); and 6,482,142 ("'142 patent"). Defendant SenoRx, Inc. ("SenoRx") moves for summary judgment that the '142 Patent is invalid and that SenoRx's product, the Contura Multi-Lumen Balloon, ("Contura") does not infringe the asserted claims of the '813 and '204 Patents. Plaintiffs Hologic, Inc., Cytyc Corp., and Hologic, L.P. (collectively "Hologic"), who make the MammoSite Radiation Therapy System

("MammoSite"), move for summary judgment that the Contura infringes certain claims of the '813, '204, and '142 Patents.[1] The court hereby issues its order on the various motions.

I. BACKGROUND

A. Breast Brachytherapy, the MammoSite, and the Contura

The three patents-in-suit describe brachytherapy devices with catheter bodies and a balloon on one end that, when inserted into the void left after a tumor is removed, irradiates the surrounding tissue to treat cancerous cells that remain. In the past, breast cancer has commonly been treated with a mastectomy, that is, by surgically removing the entire affected breast. SenoRx MSJ 3. Although effective, mastectomies have been increasingly replaced by "breast conservation" therapies, which treat the afflicted tissue without requiring that the breast be completely removed. Ex. A. (Muñoz Dep.) at 15:17-16:15. Breast conservation therapy generally includes a surgical removal of the tumor, a "lumpectomy," followed by X-ray radiation treatment of the whole breast. *Id*; *see* Ex. C (*Multi-Institutional Experience Using the MammoSite Radiation Therapy System in the Treatment of Early-Stage Breast Cancer: 2-Year Results*, INT. J. RADIATION ONCOLOGY BIOL. PHYS. (2007)) at SRX-HOL00002241. Whole-breast irradiation of this sort is delivered daily, five days per week for five to six-and-one-half weeks. Ex. C at SRX-HOL00002241. Although treatment including such a protracted course of radiation therapy is more successful than a lumpectomy alone, many patients choose either to have a mastectomy performed or receive only a lumpectomy and forego radiation therapy entirely. *Id.* at SRX-HOL00002241-42. There are undesirable effects of whole-breast irradiation, including effects on the skin, symmetry of the breasts, and the effects of radiation treatment on healthy body tissue. Ex. A. (Muñoz Dep.) at 58:3-22.

As a result, patients and physicians have explored "accelerated partial breast irradiation" ("APBI"), which treats a significantly reduced volume of the breast. Ex. L (Martin Keisch & Douglas W. Arthur, *Current Perspective on the MammoSite Radiation Therapy System – A Balloon*

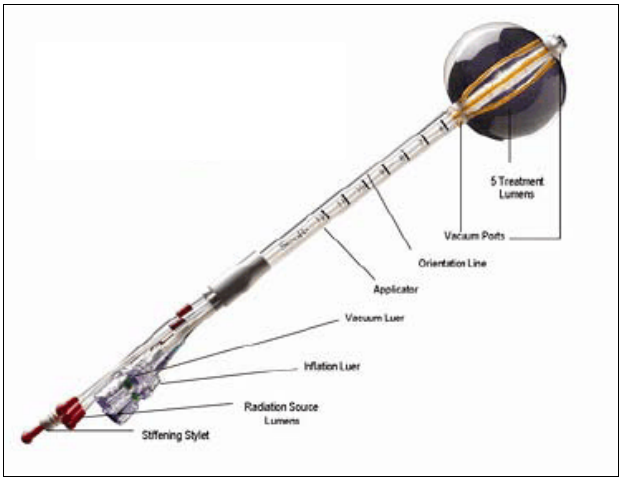
[1] The briefing in the motions presently at issue comprise a total of six briefs: a motion for summary judgment, opposition, and reply for each party. The court will herein refer to the papers for citation purposes as "[Party Name] MSJ," "[Party Name] Opp.," and "[Party Name] Reply." In citing to exhibits, the court will adopt the practice used by the parties in their briefing and cite directly to the exhibit number or letter. Hologic has used lettered exhibits A through LLLL and SenoRx numbered exhibits 1 through 35.

Breast Brachytherapy Applicator, 4 BRACHYTHERAPY 177 (2005)) ("Current Perspectives on the MammoSite"). Because less tissue is treated, the course of radiation can be completed more quickly – a necessary dose can be delivered in five days. *Id.* APBI is less likely to cause some of the undesirable effects of whole-breast radiation. Ex. A. (Muñoz Dep.) at 58:3-22. Nonetheless, the standard breast-cancer treatment today remains surgical removal of the tumor, followed by whole-breast radiotherapy. Ex. C. at SRX-HOL00002241; Ex. A. (Muñoz Dep.) at 21:3-8.

Hologic's MammoSite and SenoRx's Contura are examples of devices which use APBI. It is undisputed that the general structure and use of the MammoSite and Contura are the same. Both devices consist of a catheter body with an inflatable balloon on one end. Both devices are inserted into the lumpectomy cavity of a breast. During treatment, the balloon portion of the device is inflated and radiation is delivered by a radioactive source inserted through a lumen. The MammoSite has a single central lumen through which a radiation source is inserted into the balloon. The Contura, by contrast, has five lumens, one straight central lumen and four curved surrounding lumens arranged at ninety degree increments (i.e., top, bottom, and either side) around the central lumen. Within each lumen, radioactive sources can be placed at different positions (called "dwell positions") along the length of the lumen within the balloon.

The MammoSite

The Contura



Physicians develop dose plans during treatment to deliver a particular prescribed radiation dose to the target tissue. Ex. 5 (Orton 5/20/08 Decl.) ¶¶ 18. Because the Contura has multiple dwell positions and multiple lumens into which sources can be placed as part of the dose plan, the parties divide the plans into three relevant categories: (1) plans that utilize multiple dwell positions, including the central dwell position ("multi-dwell/central" category"); (2) those that utilize multiple dwell positions but do not utilize the central lumen/central dwell position ("multi-dwell/no central" category); and (3) those that use the central lumen/central dwell position only ("single-dwell/central" category). SenoRx MSJ 30.

B. The Patents-In-Suit

All three patents-in-suit are related. The '813 Patent is the parent and the '204 and '142 Patents are continuations-in-part of the '813 patent. The '813 and '204 Patents claim apparatuses that deliver radiation in a uniform manner surrounding the outer expandable surface (the balloon). The '142 Patent apparatus, on the other hand, is directed at delivering radiation that is non-uniform with respect to the outer balloon.

Hologic contends in this suit that the Contura infringes claim 11 of the '813 Patent, claims 4 and 17 of the '204 Patent, and claims 1 and 8 of the '142 Patent. With respect to the '813 and '204 Patents, Hologic does not assert that SenoRx infringes in the multi-dwell/no central category. Hologic Opp. 29 n.19. And in its reply, SenoRx withdraws its motion for summary judgment of

non-infringement as to the single-dwell/central only uses. SenoRx Reply 24 n.19. For the '813 and '204 Patents, then, the only active dispute is whether SenoRx infringes when using dose plans which have multiple dwell positions using only the central lumen.

Claim 11 of the '813 Patent depends from claim 1 (through claims 2 and 8), and thus requires:

> 1. Apparatus for delivering radioactive emissions to a body location with a uniform radiation profile, comprising:
> (a) a catheter body member having a proximal end and distal end;
> (b) an inner spatial volume disposed proximate the distal end of the catheter body member;
> (c) an outer, closed, inflatable, chamber defined by a radiation transparent wall affixed to the body member proximate the distal end thereof in surrounding relation to the inner spatial volume with a predetermined constant spacing between said inner spatial volume and the radiation transparent wall;
> (d) a material containing a radionuclide(s) disposed in one of the inner spatial volume and outer chamber; and
> (e) means disposed in the other of the inner spatial volume and outer chamber for rendering uniform the radial absorbed dose profile of the emissions from the one of the inner spatial volume and outer chamber containing the radionuclides.
> 2. The apparatus as in claim 1 wherein said inner spatial volume is an inner closed, chamber defined by a further radiation transparent wall.
> 8. The apparatus as in claim 2 wherein the inner chamber contains the radioactive material.
> 11. The apparatus as in claim 8 wherein the radioactive material is a solid.

'813 Patent at 4:33-5:8.

Claim 4 of the '204 Patent depends from claim 1 (through claims 2 and 3) and thus contains the following limitations:

> 1. An interstitial brachytherapy apparatus for delivering radioactive emissions to an internal body location comprising:
> (a) a catheter body member having a proximal end and distal end;
> (b) an inner spatial volume disposed proximate to the distal end of the catheter body member;
> (c) an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume; and
> (d) a radiation source disposed in the inner spatial volume and generating a three-dimensional isodose profile that is substantially similar in shape to the expandable surface element.
> 2. The apparatus of claim 1, wherein the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue, the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface, the apparatus providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue proximate to the expandable surface.

> 3. The apparatus of claim 2, wherein a predetermined spacing is provided between said inner spatial volume and the expandable surface element.
> 4. The apparatus of claim 3, wherein the expandable surface element is adapted to contact tissue surrounding a resected cavity and adapted to conform the tissue to the desired shape of the expandable surface element.

'204 Patent at 8:14-46. Claim 17 of the '204 patent depends from claim 1 and adds the limitation that "the radiation source is a plurality of solid radiation sources arranged to provide an isodose profile having a shape substantially similar to the shape of the outer spacial volume." *Id.* at 9:13-16.

Finally, claim 8 of the '142 patent depends from claim 1 (Hologic asserts that SenoRx infringes both claims 1 and 8) and requires:

> 1. An interstitial brachytherapy apparatus for treating target tissue surrounding a surgical extraction comprising:
> an expandable outer surface defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated;
> a radiation source disposed completely within the expandable outer surface and located so as to be spaced apart from the apparatus volume, the radiation source further being asymmetrically located and arranged within the expandable surface to provide predetermined asymmetric isodose curves with respect to the apparatus volume.
> 8. The apparatus of claim 1, wherein the expandable outer surface is sufficiently rigid to deform the target tissue into the shape of the expandable outer surface, causing the predetermined asymmetric isodose curves to penetrate into the target tissue to a prescribed depth.

'142 Patent at 8:61-9:6, 9:25-31.

SenoRx moves for summary judgment that: (1) the '142 Patent is invalid as anticipated by prior art; (2) the Contura does not infringe the claim 11 of the '813 Patent; and (3) the Contura does not infringe claims 4 and 17 of the '204 Patent. Hologic moves for summary judgment that the Contura: (1) infringes claim 11 of the '813 Patent; (2) infringes claim 4 of the '204 Patent; and (3) infringes claims 1 and 8 of the '142 Patent.

II. ANALYSIS

"Summary judgment is appropriate in a patent case, as in other cases, when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." *Nike, Inc. v. Wolverine World Wide, Inc.*, 43 F.3d 644, 646 (Fed. Cir. 1994) (citations omitted). Thus, summary judgment may be granted when no "reasonable jury could return a verdict for the nonmoving party." *Revolution Eyewear, Inc. v. Aspex Eyewear, Inc.*, 563 F.3d 1358, 1365 (Fed. Cir. 2009). Infringement, non-infringement and invalidity are all amenable to summary

judgment. *Avia Group Intern., Inc. v. L.A. Gear California, Inc.*, 853 F.2d 1557, 1560 (Fed. Cir. 1988); *Golden Bridge Technology, Inc. v. Nokia, Inc.*, 527 F.3d 1318, 1321 (Fed. Cir. 2008).

A. Validity of the '142 Patent

1. Requirements for Anticipation

SenoRx moves for summary judgment that the '142 Patent is invalid as anticipated by Ashpole, et al., *A New Technique of Brachytherapy for Malignant Cliomas with Caesium-137: A New Method for Utilizing a Remote Afterloading System*, Clinical Oncology 2:333-337 (1990) (hereinafter "Ashpole"). "Anticipation" means that the claimed invention was previously known, and that all of the limitations of the claim are described in a single prior art reference. *Hakim v. Cannon Avent Group, PLC*, 479 F.3d 1313, 1319 (Fed. Cir. 2007). And those limitations must be arranged in the reference, when viewed as a whole, as they are in the claim. *Net Money IN, Inc. v. VeriSign, Inc.*, 543 F.3d 1359, 1369 n.5 (Fed. Cir. 2008). But the reference need not use the exact same terms used in the patent to disclose the elements of the invention. *Akzo N.V. v. U.S. Intern. Trade Com'n.*, 808 F.2d 1471, 1479 (Fed. Cir. 1986) (disavowing an *ipsissimis verbis* test). But the reference's disclosure must "enable one of ordinary skill in the art to make the invention without undue experimentation." *Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1314 (Fed.Cir. 2008).

Because a patent is presumed valid, a party challenging a patent must prove facts supporting a determination of invalidity by clear and convincing evidence. *Schumer v. Laboratory Computer Systems, Inc.*, 308 F.3d 1304, 1315 (Fed. Cir. 2002). And as usual at summary judgment, all justifiable inferences must be drawn in favor of the non-movant, here Hologic. *Id.*

2. The Ashpole Reference

Ashpole describes a method of "using intracranial radiation utilizing a remotely controlled afterloading system with a modified endotracheal tube as an applicator."[2] Ashpole at 333. The parties dispute the import of the Ashpole article, both as to what it describes and the broader purpose

[2] The radiation is necessarily "intracranial," (i.e., from within the cranium) because, according to Ashpole, previous therapeutic failure "is wholly attributable to the inability of surgery and external beam radiotherapy to locally eradicate tumour cells . . . ." Ashpole at 333. An endotracheal catheter is typically used in a patient's windpipe to assist breaching. Hologic Opp. 3.

of its stated invention, but the following characteristics are not in dispute. Like the patents-in-suit, Ashpole describes a method of irradiating remaining possibly cancerous cells from surrounding tissue after a tumor has been removed. *See* Ashpole at 334. The article describes a device with a balloon on one end of a catheter which is inserted into the void left after excision of a brain tumor. *Id.* The balloon acts both as a buffer against the high-intensity radiation near the source and anchors the tube and stabilizes the device. *Id.* at 336. The balloon is then inflated with "radio-opaque contrast medium" to "facilitate later X-ray visualization and dosimetry calculations." *Id.* at 334. The catheter is inserted such that "the inflated balloon fill[s] the postsurgical cavity, and the stem [is] brought out through one of the existing burr-holes." *Id.* Figure 1 of Ashpole depicts the modified catheter attached to the inflated balloon and is reproduced below. *Id.*

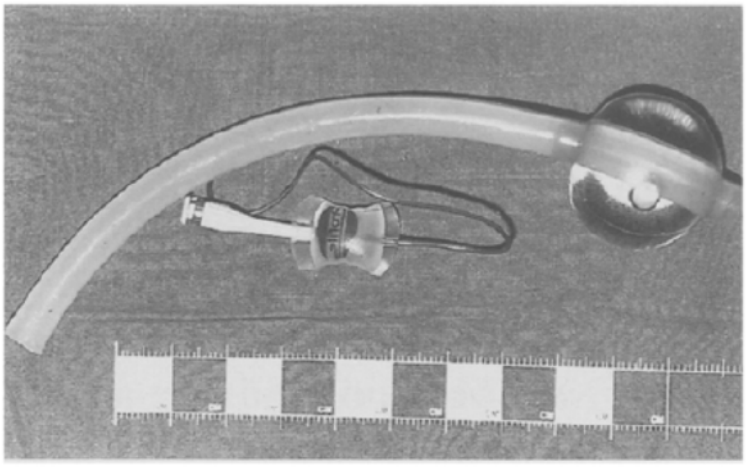


Fig. 1. The modified catheter with the sealed distal end and inflated balloon.

Radiation is introduced into the device through radioactive beads arranged into a "source train." Before radioactive beads are used, a dummy source train (which uses inactive beads) is inserted into the catheter and X-rays are taken to aid in determining the number and position of active beads that will yield isodose curves matching the cavity shape.[3] *Id.* at 335. The authors Ashpole state that they "aim to produce a mean dose rate of about 250 cGy/h at a distance of 0.5 cm

[3] A sample X-ray appears in Ashpole's Figure 3. Ashpole at 335.

from the balloon's surface . . . ."[4] *Id.* Ashpole also states in its discussion section that "[a] certain measure of dosimetrical versatility is possible in that the positions of the active beads can be changed to produce an isodose distribution specific to the geometry of the individual tumour beds." *Id.* at 336.

Hologic argues that the device disclosed in Ashpole is "fundamentally different" from the invention in the patents-in-suit in various ways. Hologic Opp. 4. Hologic states, for instance, that the Ashpole article had a different purpose than Hologic's patents, that it was never clinically or commercially successful, that most of the ten patients passed away (apparently due to their brain tumors) within six months of treatment, and that the Ashpole article itself is not well known in the field. Hologic's Opp. 2, 8, 10, 15. SenoRx correctly argues that these differences are immaterial to the question of anticipation: "[A] reference may be from an entirely different field of endeavor than that of the claimed invention or may be directed to an entirely different problem from the one addressed by the inventor, yet the reference will still anticipate if it explicitly or inherently discloses every limitation recited in the claims." *State Contracting and Eng'g Corp. v. Condotte America, Inc.*, 346 F.3d 1057, 1068 (Fed. Cir. 2003). Further, neither the success nor failure of particular implementations of the method nor the ultimate notoriety of the article itself bear on whether a prior reference fully discloses the limitations of an invention. *See Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 1379 ("[A]nticipation does not require actual performance of suggestions in a disclosure."); *In re Martin Gleave*, 560 F.3d 1331, 1335 (Fed. Cir. 2009) ("A reference need not disclose 'proof of efficacy' to anticipate a claim.").[5]

a. Ashpole Discloses a Balloon Configured to Fill an Interstitial Void and the Balloon Does Define an Inner Boundary of the Target Tissue Being Treated

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[4] A gray is "a unit of absorbed dose of ionizing radiation, corresponding to the absorption of 1 joule of energy per kilogram[ ] of absorbing material." OXFORD ENGLISH DICTIONARY, "gray" (Online Ed. 2009).

[5] Although prior art need not disclose actual performance in order to anticipate, it must nonetheless enable performance by one skilled in the art. *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985) "It is well settled that prior art . . . must sufficiently describe the invention to have placed the public in possession of it. Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention." *Id.* (internal citations omitted).

The '142 Patent requires "an expandable outer surface defining a three dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue and define an inner boundary of the target tissue being treated." '142 Patent at 8:64-67. Hologic asserts that Ashpole does not meet this limitation for two reasons: first, the Ashpole balloon is not configured to fill an interstitial void; and second, the balloon does not "define an inner boundary of the target tissue being treated." Hologic Opp. 10. Ashpole states that the "catheter was then inserted under direct vision so that the inflated balloon filled the postsurgical cavity . . . ." Ashpole at 334. Hologic states that the balloon's "primary purpose was to anchor the device within the cavity" and speculates that the author's observation that the balloon "filled" the cavity is "just as likely (if not more so) [the] result of the known propensity of brain tissue to swell after surgery." Hologic Opp. 10. SenoRx responds that Hologic has already admitted in a request for admission that "Ashpole describes an interstitial brachytherapy device having an expandable outer surface defining a three-dimensional apparatus volume configured to fill an interstitial void created by the surgical extraction of diseased tissue." Harber Decl. Ex 9 (Response for Request for Admission No. 22). A matter admitted under Rule 36 of the Federal Rules of Civil Procedure is "conclusively established" unless the court permits it to be withdrawn by motion. Fed. R. Civ. P. 36(b). Such a matter "cannot be overcome at the summary judgment stage by contradictory affidavit testimony or other evidence in the summary judgment record." *In re Carney*, 258 F.3d 415, 420 (5th Cir. 2001). Hologic therefore cannot deny that the Ashpole balloon fills the interstitial void.[6]

Hologic next denies that the balloon "defines an inner boundary of the target tissue being treated." Hologic Opp. 10. Hologic first contends that in order to "define" a boundary the outer surface of the device must be in contact with and conform the target tissue. *Id.* And second, Hologic argues that Ashpole does not disclose that the balloon be in contact with and conform the target tissue. SenoRx responds that conformance is not required by the claim language, and that

[6] Regardless, Hologic's reasons for denying that the balloon fills the postsurgical void are without merit. Hologic's statement that the primary purpose of the balloon is to anchor the device within the cavity is unsupported by its cited authority and contradicted by Ashpole itself. *See* Altemus Decl., Ex. LLL at 26:21-25 (Coakham Dep. stating that *a*, not the *primary*, purpose of the balloon is to anchor the device.); Ashpole at 336 ("The balloon also acts as a buffer that absorbs the unacceptably high doses close to the sources and has a mechanical function in that it anchors the tube and acts as a stabilizer.").

even if conformance were required, Ashpole discloses a balloon in conformance with the target tissue. SenoRx MSJ 9-14.

b. Claim 1 Does Not Require the Balloon Conform the Target Tissue

The parties first disagree as to whether the claim requires that the apparatus volume "conform" the target tissue in order to meet the limitation that it "define an inner boundary of the target tissue to be treated." Hologic's position is that the balloon must conform, based on prosecution and testimony of its expert, Dr. Lynn Verhey. Hologic Opp. 10. SenoRx argues that the "define an inner boundary" language should be understood not to impose any physical requirement on the balloon, but rather to state the result of the balloon filling the postsurgical cavity: the surface of the balloon sets an inner limit of the target tissue. SenoRx MSJ 11-14.

Although the dispute regards the import of claim 1, claim 8 of the '142 Patent notably includes an express requirement related to conformance: that "the expandable outer surface is sufficiently rigid to deform the target tissue." '142 Patent at 10:13-15. Claim 1, on the other hand, does not mention conformance. Still, the language of claim 1 is instructive. As the parties recognize, the first limitation of claim 1 imposes two requirements on the "expandable outer surface." First, it must "fill an interstitial void," and second, it "define[s] an inner boundary of the target tissue to be treated." '142 Patent at 8:62-67. The parties also agree that different claim terms are presumed to have different meanings. *Bd. of Regents of the Univ. of Texas Sys. v. BENQ America Corp.*, 533 F.3d 1362, 1371 (2008). Hologic interprets these dual requirements to impose separate physical restrictions on the outer expandable surface. Although Hologic's interpretation of "fill" is not entirely clear, the idea appears to be that one volume (e.g., a spherical balloon) "fills" a void (a volume of a different shape, like a cube) when the first volume expands to its maximum possible size without deforming the second volume.[7] In this way, a spherical balloon can "fill" a cube-shaped cavity. *See* Ex. RRR (Verhey Dep.) at 75:19-76:5. But the balloon does not "conform" the target tissue until it touches, or very nearly touches, the entire surface of the target tissue. *See* Ex. 12 (Verhey Expert Report 70). SenoRx counters, correctly, that this understanding reads the

[7] *See* Hr'g Tr. at 41:20-42:3; *see also id.* at 71:8-15 ("But your honor, we are perfectly comfortable with the notion of "fill" and "define" being construed any way that SenoRx wants, as long as by the time we are done, the balloon has been expanded to match the surface.")

"fills" requirement out of the claim because any volume that conformed the target tissue would also necessarily fill the interstitial void. SenoRx Reply 5-6.

Furthermore, the '142 Patent specification all but states that conformance is unnecessary. In the description of the preferred embodiments, the '142 Patent states:

> The size of the outer spatial volume 30 generally will correspond approximately to the amount of tissue resected. For some applications, the size of the outer spatial volume 30 may be slightly smaller than the resected volume while for other applications, the outer spatial will be slightly larger than the resected volume, allowing the expandable surface of the outer spatial volume to urge tissue on the surface of the resected region into the appropriate shape to promote an even dose distribution around the outer spatial volume in the target tissue.

'142 Patent at 4:46-57.[8] According to the specification, then, it should be possible for the expandable outer surface to conform, or "urge," the surrounding tissue to achieve a particular dose distribution. But the ballon can also be used in configurations that do not conform the outer tissue.

SenoRx offers a different understanding of the "define an inner boundary" requirement. Instead of imposing a physical limitation, SenoRx interprets the claim language to require that the outer surface of the balloon constitute the inner limit of the target tissue for the purpose of calculating the delivered dose. SenoRx MSJ 12; SenoRx Reply 6. This interpretation makes sense in light of one of the balloon's functions – to space the tissue apart from the radiation source. *See* '142 Patent at 2:43-53. SenoRx's interpretation is also more faithful to the plain meaning of the claim, "define an inner boundary of the target tissue to be treated." The drafters could have written that conformance was required instead of expressing the idea as to "define an inner boundary." The claimed definition allows a simplifying assumption to be made for dose-calculation purposes. The court therefore concludes that the requirement that the expandable outer surface "define an inner boundary of the target tissue to be treated" does not require that the surface conform the tissue to its shape.

Ashpole clearly discloses this limitation when it states that the authors "aim to produce a mean dose rate of 250 cGy/h at a distance of 0.5cm from the balloon's surface . . . ." Ashpole at 335. Hologic does not contend otherwise.

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[8] Hologic paraphrased this language in its slides at argument on the motions for summary judgment (at slide number 4). The slide, however, misleadingly omitted the critical statement that the outer spatial volume is sometimes *smaller* than the resected cavity.

c. Ashpole Discloses Predetermined Asymmetric Isodose Curves

Hologic next argues that Ashpole does not describe "predetermined asymmetric isodose curves" as claim 1 of the '142 Patent requires. '142 Patent at 9:5-6. In its order construing claims of the patents-in-suit, the court construed "predetermined asymmetric isodose curves" to mean "isodose curves determined before radiation is administered which are not substantially the same shape as the apparatus volume and/or not concentric with the apparatus volume." Claim Construction Order 16 (Docket No. 269). As described above, Ashpole contemplated the use of a "source train" which included active and inactive radiation sources, and which would be fed into the device through a catheter during treatment. Ashpole at 335, Figure 3 (a radiograph showing isodose curves computed around a dummy source train). These sources can be placed with some flexibility, although it appears only along the longitudinal axis of the device. *See* SenoRx MSJ 20 (quoting Ex. 14 (Verhey Dep.) 221:11-221:14 ("Q. And the Ashpole device gives you some flexibility in doing that, but only along the longitudinal axis of the device; correct? A. That's right, yes.")). Describing that flexibility, Ashpole states that "[a] certain measure of dosimetrical versatility in that the positions of the active beads can be changed to produce an isodose distribution specific to the geometry of the individual tumour beds." Ashpole at 336. SenoRx contends on that basis that Ashpole describes "predetermined asymmetric isodose curves."

In arguing that asymmetric isodose curves are not disclosed, Hologic first points to Ashpole's statement of its authors' aim: "We aim to produce a mean dose rate . . . at a distance of 0.5 cm from the balloon's surface . . . ." Hologic argues that this establishes Ashpole's aim to target tissue at a fixed depth from the balloon. Hologic Opp. 15 (quoting Ashpole at 335). Hologic then argues that the "dosimetrical flexibility" refers only to non-spherical dose profiles, which may or may not be asymmetrical under the court's claim construction. *Id.* 16-17. Hologic gives the example of a kidney-shaped cavity and balloon which produce a correspondingly kidney-shaped dose profile. *Id.* Such a dose profile would be the same shape as and concentric with the balloon, and therefore would not be "asymmetric" under the court's construction. *Id.* Hologic's position appears to be that, even when the active beads are positioned as Ashpole contemplates, it is still conceptually possible to have a dose distribution that is symmetric.

However, Hologic's hypothetical case of an irregularly shaped balloon has no basis in Ashpole, which mentions only spherical or nearly spherical balloons. Neither does Hologic offer a dose distribution along the longitudinal axis that would yield a kidney-shaped dose profile. The arrangement contemplated in Ashpole is that radiation-source positions would be varied along the longitudinal axis using a balloon like the one pictured and described. *See* Ashpole at 334-35, Figs 1-3; *see also* Ex. 14 (Verhey Dep) 223:16-224:13 (discussing import of Ashpole's "dosimetrical flexibility"); Ex. LLL (Coakham Dep.) 50:2-18 (same). Indeed, expert testimony in this case uniformly takes the view that Ashpole discloses the use of asymmetric isodose curves to one skilled in the art. Orton Expert Report ¶ 108; Arthur Export Report ¶ 122; Ex. 14 (Verhey Dep.) 222:22-224:1. Although it is possible to hypothesize varied bead positions along the longitudinal axis that produce symmetric dose curves, the court finds that one skilled in the art would not understand Ashpole's description as limited to dose profiles that are the same shape as the outer expandable surface. Although Ashpole does not describe the dose-profile flexibility explicitly in terms of dose-distribution symmetry, it does not need to repeat the exact words of the limitation. *See Akzo N.V.*, 808 F.2d at 1479. Therefore, Ashpole's statement that dosimetrical versatility can be deployed to yield "dose distributions specific to the geometry of the individual tumor beds" discloses an asymmetrical isodose profile.

Because the court concludes that Ashpole discloses the only contested limitations of claim 1 of the '142 Patent, SenoRx's motion for summary judgment that claim 1 is invalid as anticipated by Ashpole is granted.

d. Ashpole Does Not Clearly and Convincingly Disclose Claim 8's Requirement That the Expandable Outer Surface Be Sufficiently Rigid to Deform the Target Tissue into the Shape of the Expandable Outer Surface

Claim 8 of the '142 Patent requires that the expandable outer surface be "sufficiently rigid to deform the target tissue into the shape of the expandable outer surface, causing the predetermined asymmetric isodose curves to penetrate into the target tissue to a prescribed depth." '142 Patent at 10:13-17. Hologic opposes summary judgment of invalidity of claim 8 of the '142 Patent on the basis that Ashpole does not disclose that the balloon is sufficiently rigid to deform the target brain tissue. Anticipation requires that every limitation in the claim be disclosed, either expressly or

inherently, in a single prior art reference. *In re Anthony J. Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). Hologic first contends that Ashpole does not expressly disclose that the balloon is sufficiently rigid to deform the target tissue. SenoRx does not contend that Ashpole anywhere states outright that the balloon is rigid enough to deform the brain tissue, and the court agrees with Hologic that the limitation is not expressly disclosed.

Hologic next argues that Ashpole does not inherently disclose that the balloon is sufficiently rigid to deform the target tissue. In order to inherently disclose a claim limitation, the evidence must "make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (9th Cir. 1991). In its motion for summary judgment, SenoRx cites expert testimony stating that the balloon in Ashpole, made with a particular type of endotracheal tube ("Portex, Blue Line, i.d., 8.0 with a Profile Cuff") is sufficiently rigid to deform brain tissue. Arthur Expert Report ¶ 74 ("These catheters were typically filled with fluid, and when inflated were sufficiently rigid to deform tissue.");[9] Orton Expert Report, ¶108 ("A person of ordinary skill in the art would understand that,[sic] the outer balloon of the Ashpole device . . . is sufficiently rigid when inflated to deform brain tissue into the shape of the expandable outer surface."). Against this evidence, Hologic offers testimony by Dr. Coakham, Ashpole's author, that the authors sought patients with more spherical rather than irregularly shaped tumors. Ex. LLL (Coakham Dep.) at 16:11-17. Coakham also states that a pear-shaped cavity would not have "that assurance of contact" and that the authors "never undertook to . . . change the shape . . . of the original shape of the tumor cavity." *Id.* at 76:11-19; 65:15-17. Coakham also states that brain tissue is a "more delicate structure" than breast tissue. *Id.* at 74:13-17.[10] Hologic concludes on this basis

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[9] Dr. Arthur is a radiation oncologist with experience using endotracheal tubes. Ex. 16 (Arthur Dep. 6/21/08) at 51:11-12, 12:22-24.

[10] At oral argument on the motions the parties disputed whether Dr. Coakham was qualified to testify as one skilled in the art, and the extent to which his testimony is relevant. In later letter briefs to the court the parties agree that Dr. Coakham is not skilled in the art. The primary dispute between the parties is over Dr. Coakham's testimony that the balloon in Ashpole did not conform the target tissue. That testimony is rendered irrelevant by the court's holding that conformance is not required under the '142 Patent. The court here relies on Dr. Coakham's testimony for the limited facts to which he testifies based on personal knowledge.

that it "is even less likely that they would select a balloon so rigid that it was actually capable of deforming the tissue around it." Hologic Opp. 21. Despite that Hologic's evidence is somewhat to the contrary, SenoRx's expert testimony that the actual balloon used in Ashpole is sufficiently rigid to deform the brain tissue demonstrates that the balloon is able to deform target tissue.

The parties arguments focus primarily on whether or not the actual device used in Ashpole bore the characteristic of having sufficient rigidity to deform brain tissue. But claim 8 requires something more. The rigidity must be sufficient to deform the tissue and cause the radiation to "penetrate into the target tissue to a prescribed depth." '142 Patent at 10:12-17. It is not enough to enable one skilled in the art to practice the invention that a "Portex Blue Line, i.d., 8.0 with a Profile Cuff" happens to be rigid enough to deform brain tissue. Instead, the reference must disclose that the specified rigidity is used towards the claim's stated therapeutic purpose. *See In re Donohue,* 766 F.2d at 533 ("It is well settled that prior art under 35 U.S.C.A. § 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it. Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention."). Ashpole does not teach that the balloon's rigidity has such a purpose, and SenoRx has not established that one skilled in the art would conclude that a balloon of a certain rigidity is a necessary component of the invention. Summary adjudication that a patent is invalid as anticipated requires that no reasonable jury could find that the limitation was not disclosed in the prior art by clear and convincing evidence. *Hakim,* 479 F.3d at 1319. *Revolution Eyewear, Inc*.. 563 F.3d at 1365. The court concludes that Ashpole's purported disclosure of a balloon sufficiently rigid to deform target tissue fails to satisfy this exacting standard.

The court therefore concludes that there is a genuine dispute of material fact as to whether Ashpole discloses each limitation of claim 8 of the '142 Patent. Summary judgment as to that claim's invalidity is therefore denied.

B. SenoRx's Motion for Summary Judgment of Non-Infringement

1. Standard for Summary Judgment of Non-Infringement

SenoRx moves for partial summary judgment of non-infringement as to claim 11 of the '813 Patent and claim 4 of the '204 patent, contending that, as used by physicians, there is no fixed

spacing between any inner spatial volume containing the radiation source and the balloon wall.[11] SenoRx also moves for summary judgment as to claim 11 of the '813 Patent on the basis that the Contura does not have an "inner spatial volume" that meets the claim limitations. Finally, SenoRx seeks summary judgment of non-infringement as to claim 17 of the '204 Patent because the Contura lacks a "plurality" of radiation sources.

To prove infringement, the patentee must show that the accused device meets each claim limitation, either literally or under the doctrine of equivalents. *Deering Precision Instruments, L.L.C. v. Vector Distrib. Sys., Inc.*, 347 F.3d 1314, 1324 (Fed. Cir. 2003). Summary judgment of non-infringement is proper when no reasonable jury could find that the accused device contains every limitation recited in the properly construed claim. *PC Connector Solutions LLC v. SmartDisk Corp.*, 406 F.3d 1359, 1362 (Fed. Cir. 2005).

a. The "Predetermined Constant Spacing" Requirement Does Not Require That the Radionuclide Be Fixed for the Entire Course of Treatment

Limitation 1(c) of Claim 1 of the '813 Patent (from which asserted claim 11 depends) requires that there be a "predetermined constant spacing" between the inner spatial volume and the radiation-transparent wall. '813 Patent at 4:43-45. Claim 3 of the '204 Patent (from which asserted claim 4 depends) requires a "predetermined spacing" between the inner spatial volume and the expandable surface element. At claim construction the parties stipulated, and the court agreed, to the construction of "predetermined constant spacing." Claim Construction Order 4. The court found that "predetermined spacing" should not be construed differently and thus construed both terms to require:

> fixed spacing, predetermined by one skilled in the art before administering radiation, between the wall or edge of the inner spatial volume and the radiation transparent wall of the outer, closed inflatable chamber, when inflated, which for each point on the wall or edge of the inner spatial volume, the distance to the closest point on the outer chamber is the same (i.e., the inner spatial volume and the outer chamber are concentric and the same shape)

Id.. The parties dispute whether the Contura infringes when used in dose plans which have multiple dwell positions using only the central lumen.

[11] Hologic no longer asserts claim 12 of the '813 Patent. Hologic Opp. 33 n. 26.

SenoRx contends that because the court construed "predetermined constant spacing" and "predetermined spacing" to require a "fixed spacing," any dose plan that uses multiple dwell positions does not infringe because the spacing is not "fixed." According to SenoRx, the "fixed" requirement mandates that the spacing between the inner spatial volume and expandable surface not change during treatment. Hologic's expert, Dr. Verhey, appeared to confirm this interpretation in his deposition. Ex. 14 (Verhey Dep.) 124:12-22.[12] Dr. Orton, SenoRx's expert, supports SenoRx's position. Orton Expert Report ¶ 27. Hologic argues, however, that SenoRx is inventing a temporal limitation where the claims include only spatial ones. So long as the source is stationary at a particular position for some period of time, Hologic argues, the spacing is "fixed" under the court's construction for that time.

SenoRx calls Hologic's view of the fixed requirement the "snapshot theory of infringement." SenoRx is correct that the spacing between the inner spatial volume and the outer surface cannot be changing. If a source is in motion, then the spacing between the inner spatial volume and the outer expandable surface is neither constant nor fixed; it is changing, moment to moment. SenoRx is thus correct that the limitation cannot *only* be spatial; it must also have a temporal component.[13] But SenoRx's further contention is that the spacing must be fixed not just for a short period of time, but over the entire course of treatment.

SenoRx provides no basis in the patents for such a temporal limitation, and including it would improperly narrow the patents' claims. First, at claim construction the court applied the stipulated construction of "predetermined spacing" to "predetermined constant spacing" on the basis

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[12] "Q. And you would agree that if the radiation plan involved moving the radiation source so that it dwelled for, say, five seconds in the central lumen central dwell position and then was moved for ten minutes to another dwell position and then was moved for ten minutes to another dwell position, that there would also not be constant spacing because the spacing wouldn't be constant, it would be changing; correct? A. Yes, that's correct. Q. So the only time there would be predetermined constant spacing would be if the Contura was used solely in the central lumen central dwell position? A. Correct." *Id.*

[13] Hologic is not contending, however, that a radiation source in motion has a "fixed" spacing from the outer spatial volume because, in a "snapshot" the source would appear not to be moving. Interestingly, such a claim is the basis for Zeno of Elea's famous Arrow Paradox. Zeno argued that since an arrow does not move in a infinitesimal period of time, it cannot move at all. *See Aristotle*, PHYSICS, 86-89 (R. P. Hardie, R. K. Gaye trans. Digireads.com 2006) (arguing that Zeno's "Arrow Paradox" is fallacious and therefore that objects in motion are not stationary, even when considered at infinitesimally small time scales).

of the similarity of the geometric limitations of the two claims. Claim Construction Order 4-5.[14] The court's claim construction order, then, should not be interpreted to endorse any temporal implications the parties may have understood to be incorporated into the stipulated construction. Next, the plain meaning of the word "fixed," even when used in the present context, does not sensibly require that inner and outer spatial volumes must be in a single configuration over the course of treatment. Rather, "fixed" means here simply that the source and the outer spatial volume are stationary with respect to each other.

The testimony of Dr. Verhey and Dr. Orton that the Contura does not meet the predetermined spacing limitations amount to conclusory statements that the limitations are not met. *See* Orton Report ¶ 27; Ex. 14 (Verhey Dep.) 124:12-22. Such expert testimony is accorded little weight. *See Symantec Corp. v. Computer Associates Intern., Inc.*, 522 F.3d 1279, 1290-91 (Fed. Cir. 2008) (expert testimony that "simply recites how each expert would construe" a term is due little weight). The court concludes that the requirement that the spacing between the inner spatial volume and the expandable surface be "fixed" requires only that the source be stationary (that is, with zero velocity and zero acceleration relative to the expandable outer surface). Partial summary judgment of non-infringement on this ground is therefore inappropriate.

b. "Minimum Prescribed Dose"

Claim 2 of the '204 Patent claims "[t]he apparatus of claim 1 wherein the inner and outer spatial volumes are configured to provide a minimum prescribed dose for delivering therapeutic effects to a target tissue." '204 Patent at 8:30-33. SenoRx contends in its motion for summary judgment that the multi-dwell position plans do not meet this "minimum prescribed dose" limitation. SenoRx MSJ 33. SenoRx's argument is that the minimum prescribed dose is the total delivered dose to the target tissue. As a result, for any particular dwell position and source in a multi-dwell plan, the dose of radiation delivered to the tissue will be *less* than the minimum prescribed dose because the dose delivered by sources at the other dwell positions contribute to the total dose.

[14] "Under claim 1 of the '204 Patent and claim 3 of the '813 Patent . . . the inner spatial volume must be concentric with and constantly spaced from the outer expandable surface if the radiation profile is to be the same shape as the outer expandable surface. This is the same geometric arrangement that the parties stipulated was required by the "predetermined constant spacing" limitation in claim 1 of the '813 Patent." *Id.*

The court finds that in light of the fact that claim 5 of the '204 Patent's claims "the apparatus of claim 2, wherein the minimum prescribed absorbed dose is 40 Gray," SenoRx's argument appears to have merit. '204 Patent 8:31-2. The parties agree that the total, cumulative dose delivered to tissue during treatment is 34 Gray (or 3.4 Gray for each individual treatment). *See* Ex. 20 (Arthur Report) ¶ 30; *see also* Hr'g Tr. at 105:15-25. Hologic contends, however, that "minimum prescribed dose" refers to the dose absorbed from the source's time spent at a particular dwell position. But claim 5 seems to foreclose that interpretation by claiming the apparatus where 40 Gray is the minimum prescribed dose. The court tentatively concludes that one skilled in the art would understand that 40 Gray refers to a total delivered dose rather than a portion or fraction of it, and therefore that in claim 2, "minimum prescribed absorbed dose" must also refer to the total dose delivered to the tissue.

SenoRx advanced this argument in its motion for summary judgment, and Hologic did not respond until its reply in support of its own motion for summary judgment. Hologic argued there (and during argument on the motion) that SenoRx had failed to previously disclose this non-infringement position. Hologic Reply 22; *see also* Hr'g Tr. at 115:25-116:6 At argument Hologic requested further briefing on the issue if the court were inclined to grant the motion. *Id.* at 119:10-20. The court finds that further briefing is appropriate and will withhold ruling on SenoRx's motion for summary judgment with respect to the "minimum prescribed dose limitation" until such supplemental briefing has been completed.

c. SenoRx's Contura Does Not Have an Inner Spatial Volume as Required by Claim 11 of the '813 Patent

SenoRx also moves for summary judgment of non-infringement of claim 11 of the '813 Patent on the basis that the Contura includes no inner spatial volume that meets all the patent's requirements. As described above, limitation 1(c) requires that there be a "predetermined constant spacing" between the inner spatial volume and radiation-transparent wall. Next, claim 2 of the '813 Patent (from which asserted claim 11 depends) requires that the inner spatial volume be an "inner closed, chamber defined by a further radiation transparent wall." '813 Patent at 4:53-55. In its claim construction order, the court construed the term "inner spatial volume" to mean "a region of space

surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide."

In its motion for summary judgment of non-infringement, SenoRx argues that Hologic is in the following double-bind. First, according to the terms of claim 1 of the '813 patent (from which asserted claim 11 depends), the only possible inner spatial volume is the radionuclide source. Second, according to the terms of claim 2, the only possible inner spatial volume is the treatment lumens. Therefore, argues SenoRx, no inner spatial volume meets the dual requirements of claims 1 and 2, and therefore the Contura cannot infringe claim 11.

The details of this purported double bind are important. Hologic's final infringement contentions for limitation 1(b) state two possible structures that could constitute an "inner spatial volume" under limitation 1(b). The limitation requires "an inner spatial volume disposed proximate the distal end of the catheter body member." '813 Patent at 4:37-38. Hologic states in its infringement contentions for limitation 1(b) that either the treatment lumens or the radionuclide itself can constitute an inner spatial volume:

> Each of the five treatment lumens inside the Contura balloon comprises a region of space surrounded by an outer spatial volume and enclosed by a polymeric film wall and therefore embodies an inner spatial volume proximate to the distal end of the Contura catheter. . . . Alternatively, the radionuclide itself comprises a region of space surrounded by an outer spatial volume and defined by the outside surface of a solid radionuclide and therefore embodies an inner spatial volume.

Ex. 7 (Hologic's Final Infringement Contentions) Appx. A, 4. Next, Hologic's infringement contentions for limitation 1(c) state that

> [t]he Contura's balloon surrounds and contains the inner spatial volume(s) discussed above. . . . For each point on the wall or edge of the inner spatial volume, the distance to the closest point on the outer chamber is the same (i.e., the inner spatial volume and the outer chamber are concentric and the same shape when the radiation source is positioned within the central dwell position of the central lumen).

Id. at 5. Although Hologic does not expressly state that only the radionuclide source can satisfy limitation 1(c), SenoRx so argues, and the court agrees. The surface of the treatment lumens encloses a roughly cylindrical volume that runs the length of the Contura's balloon along its diameter. The central lumen is not the same shape as the balloon, and the distances from points on its surface to the nearest point on the balloon wall differ significantly. *See* SenoRx MSJ 36; *id.* Fig. 2 (depicting the difference in distances from two points on the surface of the central lumen). In

referring to the radionuclide's placement in the central dwell position in its infringement contentions, Hologic seems to recognize that the central lumen cannot meet the limitations of the claim. Thus, between the central lumen and the radionuclide, only the radionuclide can satisfy claim 1.

Claim 2 imposes an additional limitation, that the inner spatial volume be an "inner closed, chamber defined by a further radiation transparent wall." '813 Patent at 4:53-55. Hologic's infringement contentions confirm the plain import of the claim language: that the radionuclide itself cannot be an "inner closed chamber defined by a further radiation transparent wall." In its infringement contentions for claim 2, Hologic points only to the Contura's lumens as infringing: "Each of the five treatment lumens inside the Contura balloon (the inner spatial volumes) comprises a region of space (an inner, closed chamber) which is located inside the outer spatial volume and enclosed by a radiation transparent wall." Ex. 7 (Hologic's Final Infringement Contentions) Appx. A, 9.

Thus, Hologic's infringement contentions apparently fail to set forth any particular inner spatial volume that meets the limitations of both claims 1 and 2, from which claim 11 depends. Those limitations are necessary to show infringement under claim 11. *See Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1383 (Fed. Cir. 2000).

In its opposition, Hologic responds that the "the treatment lumen surrounding the radionuclide" constitutes an inner spatial volume that meets the predetermined spacing limitations. Hologic states that "[i]t is not the full length of the treatment lumen that is at issue, however; rather, it is that portion of the lumen around the radiation source when the source is in the central dwell position." Hologic Opp. 30.

SenoRx argues that this notion of an inner spatial volume, a portion of a treatment lumen instead of the full length of it, is not disclosed in Hologic's infringement contentions, and that Hologic should be precluded from asserting it. The Patent Local Rules require a party claiming infringement to disclose "a chart identifying specifically where each limitation of each asserted claim is found within each Accused Instrumentality . . . " Patent L.R. 3-1(c). SenoRx states that this theory of infringement could have been raised before the *Markman* hearing, and that in raising it now, Hologic has prejudiced SenoRx in numerous ways. SenoRx Opp. 9. SenoRx asserts that it is

prejudiced because, by waiting to disclose a theory of infringement until after the claim construction, the close of fact and expert discovery, and opening summary judgment briefs, Hologic has deprived SenoRx of an opportunity to further an opposition at each of those stages. *Id.* 9-10.

In its reply, Hologic contends that the "portion of the lumen" was previously asserted in its infringement contentions and expert testimony. Hologic points first to its infringement contentions for the '204 Patent, which state that:

> The spacing, predetermined by one of skill in the art before administering radiation, between *the wall or edge of the inner spatial volume* and the wall of the expandable surface element (the wall of the inflated Contura balloon) is fixed and the distance to the closest point on the outer chamber is the same ***when the radioactive source is centered within the central lumen (i.e., the inner spatial volume and the expandable surface element are concentric and the same shape when the radiation source is positioned within the central dwell position of the central lumen).***

Ex. 7 (Hologic's Final Infringement Contentions) Appx. B, 13 (bold and italic emphasis from Hologic's Reply). Hologic also states that Dr. Verhey discussed in his expert report "why the treatment lumen around the central dwell position constitutes an inner spatial volume" when he stated "it is clear that *by using the central dwell point in the central lumen, the device is capable of providing a predetermined (and constant) spacing between the location of the radiation source* ***in the inner spatial volume*** *and the expandable surface element.*" Hologic Reply 12 (quoting Ex. TTT at § 5.1.3.7) (bold and italic emphasis from Hologic's Reply).

These purported disclosures fall far short of specifying where each limitation is found in the Contura. Hologic now contends that the inner spatial volume limitation is met in the Contura device by "a portion of the lumen around the radiation source when the source is in the central dwell position." This contention has at least two characteristics that are not clearly set forth in the infringement contentions or Dr. Verhey's expert report. First, that the inner spatial volume is met by *a portion* of the central lumen. One imagines a slice of the lumen, like a section of pipe, as the physical object to which Hologic refers. Given the earlier statement in the final infringement contentions that the inner spatial volume is *either* the treatment lumen or the radionuclide, the notion of a portion of a lumen constituting an inner spatial volume is new and should have been disclosed. *See* Ex. 7 (Hologic's Final Infringement Contentions) Appx. A, 4; Appx. B, 4. Second, the infringement contentions and Dr. Verhey's Expert Report fail to disclose that the stated portion of

the lumen only constitutes an "inner spatial volume" when the radionuclide is in the central lumen central dwell position. This temporal restriction is also not clearly disclosed.

Dr. Verhey's testimony has the additional deficit of misstating the requirements of the claim. Dr. Verhey states that "the device is capable of providing a predetermined constant spacing between the *location of the radiation source* in the inner spatial volume and the *expandable surface element*." Ex. TTT (Verhey Report) at § 5.1.3.7 (emphasis added). The claim-required predetermined constant spacing, however, must be between the inner spatial volume, *not* the location of the radiation source, and the expandable surface element. The next sentence of Dr. Verhey's report only compounds the confusion. He states that "[t]he central lumen within the inner spatial volume serves as the structure for providing a constant spacing relative to the outer, closed, inflatable chamber when the central dwell position is used." *Id.* This contradicts even Hologic's notion of an inner spatial volume advanced in the present motions because it states that the central lumen is *within* the inner spatial volume. Dr. Verhey's report therefore fails to disclose an inner spatial volume that is a portion of the central lumen.

The court additionally finds that Hologic's offered "inner spatial volume" in the Contura fails on its merits. At claim construction the court construed "inner spatial volume" to mean "a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide." Claim Construction Order 8. Furthermore, any purported inner spatial volume must meet the "predetermined constant spacing" limitation in claim 1 and the "inner closed chamber" limitation in claim 2. '813 Patent at 4:43-45, 53-55.

Two of the requirements that any inner spatial volume in the Contura must meet relate to whether the volume is "closed" or "enclosed." The court's claim construction requires that the inner spatial volume be "enclosed by a polymeric film wall." Claim Construction Order 8. And claim 2 requires that the inner spatial volume is an "inner closed chamber defined by a further radiation transparent wall." Hologic does not explain how a "portion" of the treatment lumen meets either of these requirements. Geometrically, a section of pipe is not closed, it is open at the ends, and that is the structure that Hologic contends constitutes an inner spatial volume. Similarly, Hologic points to no "radiation transparent wall" that defines the cylindrical portion of the central lumen. At best the

lumen itself defines the radius of the cylindrical volume, but the limits of the lumen "portion" along the longitudinal axis are not defined by anything at all (much less by a radiation transparent wall).

Any inner spatial volume must also meet the predetermined spacing limitations in claim 1. That is, the inner spatial volume and the expandable outer surface must be "concentric and the same shape." Hologic agrees that the Contura's outer surface is roughly spherical and that Hologic's proposed inner spatial volume is cylindrical. Hologic does not contend that cylinders are the same shape as spheres. Rather, Hologic argues that first, all points on the surface of the lumen surrounding the radiation source are equidistant from the outer-chamber wall. Hologic MSJ 20. Hologic makes this argument apparently on the basis of a two-dimensional diagram. See *id*. The depicted two-dimensional slice is misleading. Although the points encircling the center of the lumen portion might be equally spaced from the outer surface, points more distal or proximal along the lumen would not be. Indeed, any point off center would be unequally spaced from the outer surface. *Cf.* SenoRx Opp. 25, Figure 2 (depicting the source and balloon size, drawn to scale).

Hologic next argues that the lumen portion and the outer spatial volume are "functionally the same shape" because the outer chamber is not perfectly spherical. Hologic MSJ 21-22. What is therefore important, Hologic claims, is that the dose profile generated by the cylindrical seed is "substantially the same shape" as the spherical balloon. *Id.* This is an argument better directed at infringement under the doctrine of equivalents than literal infringement. As construed, the shapes of the inner and outer volumes must be concentric and the same shape. Claim Construction Order 8. Hologic's proposed cylindrical inner spatial volume is not the same shape as the spherical outer balloon. Whether the purpose of the predetermined spacing limitations is nonetheless satisfied does not bring such a different shape within the literal scope of the '813 Patent's claimed invention.

The court therefore concludes: (1) that Hologic did not properly disclose the basis on which it now claims the Contura meets the "inner spatial volume" limitation; and (2) that Hologic's new proposed inner spatial volume is inconsistent with the claim language. Hologic is precluded from advancing it. Because Hologic advances no other basis for infringement under the '813 Patent, SenoRx's motion for summary judgment of non-infringement as to claim 11 is also granted.

c. SenoRx's Contura Lacks a "Plurality of Radiation Sources"

In SenoRx's remaining argument in favor of summary judgment of non-infringement, it argues that the Contura does not infringe claim 17 of the '204 Patent because the Contura lacks a "plurality" of radiation sources, as that claim requires. The court construed the term "plurality of radiation sources" as "two or more separate radioactive solid sources placed in the inner spatial volume at the same time." Claim Construction Order 17. Hologic does not now assert that the Contura literally infringes claim 17 of the '204 Patent. Rather, it asserts that the Contura infringes under the doctrine of equivalents. SenoRx moves for summary judgment of non-infringement on the basis that: (1) Hologic is precluded as a matter of law from asserting infringement under the doctrine of equivalents; and (2) there is no genuine dispute of material fact as to whether a single radiation source is equivalent to a plurality of sources.

d. SenoRx's Contura Does Not Have an Equivalent to a "Plurality of Radiation Sources"

An accused product that does not literally infringe may still be found to infringe under the doctrine of equivalents. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). Infringement under the doctrine of equivalents is found where the accused product does not literally correspond to the asserted claim but functions in the same way and obtain the same result as the asserted claim. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950). District courts are obliged to grant summary judgment "[w]here the evidence is such that no reasonable jury could determine two elements to be equivalent" or where "under the particular facts of a case . . . a theory of equivalence would entirely vitiate a particular claim element." *Warner-Jenkinson*, 520 U.S. at 39 n.8; *see also DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1016 (Fed. Cir. 2006).

The parties' dispute over infringement under the doctrine of equivalence boils down to a disagreement over the nature of the asserted equivalence. SenoRx characterizes Hologic's equivalence position as claiming that a single source is equivalent to a plurality, or two or more, sources. Hologic argues that it claims only that multiple sources introduced simultaneously is equivalent to multiple sources introduced sequentially. Although it is accurate that the Contura introduces one source into the outer spatial volume at a time, the Contura achieves its final dose profile through the composite use of a source placed at different positions. The relevant equivalence

in terms of the court's claim construction, is whether "two or more separate radioactive sources placed in the inner spatial volume at the same time" is equivalent to a single source placed in different positions sequentially.

Under the "all elements rule" a patentee may not use the doctrine of equivalents when its application would "vitiate a claim limitation." *Abbot Laboratories v. Andrx Pharmaceuticals*, 473 F.3d 1196, 1212 (Fed. Cir. 2007). In order to find that a claim limitation would be vitiated by the doctrine of equivalents, a court must conclude that "the evidence is such that no reasonable jury could conclude that an element of an accused device is equivalent to an element called for in the claim, or that a theory of equivalence to support the conclusion of infringement otherwise lacks legal sufficiency." *Id.* Equivalences should be rejected when they replace a claim term with its opposite, or a term antithetical to it. *See, e.g., Moore U.S.A. Inc. v. Standard Register Co.*, 229 F.3d 1091, 1095 (Fed. Cir. 2000) (holding that allowing a minority to be equivalent to a "majority" would vitiate the claim); *Planet Bingo, LLC v. Gametech International, Inc.*, 472 F.3d 1338, 1345 (Fed. Cir. 2007) (holding that a "predetermined [before a game starts] winning combination" could not be determined after the game had begun); *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 74 F.3d 1573, 1582-83 (Fed. Cir. 1996) (concluding that a requirement that a distance value take on at least three values was not equivalent to a distance that took on only two values).

The court construed "plurality of radiation sources" as "two or more separate radioactive solid sources placed in the inner spatial volume at the same time." Claim Construction Order 17. Hologic's proposed equivalence is directly at odds with this construction in two ways. First, the Contura uses a single, instead of "two or more sources." And relatedly, the sources (even if there were more than one, or if each insertion constituted a separate "source") are not used "at the same time." These purported equivalences together would vitiate the patent's limitation of a "plurality of sources."

The court therefore concludes that Hologic may not assert infringement of claim 17 of the '204 Patent under the doctrine of equivalents. Because Hologic does not assert that the claim is literally infringed, the court grants SenoRx's motion for summary judgment of non-infringement that the Contura does not infringe claim 17 of the '204 Patent.

C. Hologic's Motion for Summary Judgment of Infringement

Hologic's motion for summary judgment of infringement of claim 11 of the '813 Patent is resolved by the court's analysis of SenoRx's motion for summary judgment. Because the court above grants SenoRx's motion for summary judgment of non-infringement as to claim 11 of the '813 Patent, Hologic's motion for summary judgment of infringement of that claim is denied.

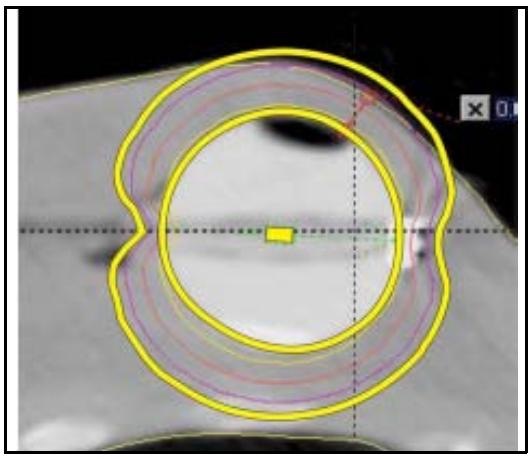
Hologic moves for summary judgment that the Contura infringes claims 1 and 8 of the '142 Patent and claim 4 of the '204 Patent. Hologic also moves for summary judgment that SenoRx is liable for direct and indirect infringement of the same patents.

1. Infringement of the '142 Patent

SenoRx states in its opposition to Hologic's motion for summary judgment that "[i]f the claims of the '142 Patent are applied as the court construed them, SenoRx does not dispute that the Contura infringes the asserted claims of the '142 Patent. However, if the Contura infringes the '142 patent, the patent is anticipated by the prior art." SenoRx Opp. 1-2. Since SenoRx does not dispute infringement based upon the court's construction, the court summarily adjudicates that claims 1 and 8 of the '142 Patent read on SenoRx's Contura. However, since the court also concludes that claim 1 of the '142 Patent is invalid as anticipated by Ashpole, the court grants only Hologic's motion for summary judgment that the Contura infringes claim 8 of the '142 Patent.

2. Infringement of Claim 4 of the '204 Patent

Hologic moves for summary judgment that the Contura infringes claim 4 of the '204 Patent. Limitation 1(d) of claim 1, from which claim 4 depends, requires that the radiation source generate a "three-dimensional isodose profile that is substantially similar in shape to the expandable surface element." '204 Patent at 8:26-29. SenoRx contends that, because of a phenomena known as "anisotropy," there is a genuine dispute of fact as to whether the Contura generates dose profiles "substantially similar in shape" to its outer spherical balloon. "Anisotropy" refers to the self-absorption of radiation; when a cylindrical source is used, the radiation is internally absorbed within the source to a greater degree along the cylinder's axis than in other directions. *See* Ex. 23 (Verhey Dep.) at 41:16-22. This creates a dose profile with "dimples" along the longitudinal axis of the cylindrical source, as depicted below:



SenoRx Opp. 31, Fig. 3. SenoRx offers expert testimony that an anisotropic dose profile would not be substantially the same shape as the Contura's approximately spherical balloon (in the above figure, the inner circular shape and outer tracing of the dose profile with dimples). Ex. 20 (Arthur Decl.) ¶ 65-66; Ex. 5 (Orton Decl.) ¶ 41. Hologic offers pre-litigation statements from Dr. Arthur stating that the MammoSite with a single seed in the central dwell position generates an isodose curve that "virtually perfectly matches the shape of the spherical balloon." *See* Ex. L (Current Perspectives on the MammoSite) at 179; *see also* Ex. W. (SenoRx Contura Study) at SRX-HOL00036372 (referring to the MammoSite's radiation delivery as "symmetrical."). Although these statements concerned the MammoSite, Hologic states that the two devices use an identical radionuclide. Hologic Reply 20 (citing Ex. K (Keisch Dep.) at 69:20-24). Since SenoRx only needs to raise a triable issue of fact to defeat summary judgment, the court concludes that SenoRx has submitted sufficient evidence to create a genuine dispute of fact on the issue of whether the Contura's generates an isodose profile substantially similar in shape to the outer balloon when used in a single-dwell/central lumen configuration. Hologic's motion for summary judgment of infringement of claim 4 of the '204 Patent is therefore denied.

3. Direct and Indirect Infringement

a. Direct Infringement

Finally, Hologic moves for summary judgment that SenoRx directly and indirectly infringes the asserted claims of the patents-in-suit. Because the court concludes above that the Contura does not infringe the '813 Patent, Hologic's motion for summary judgment that SenoRx directly and

indirectly infringes the '813 Patent is denied. The court, therefore, now addresses the questions of whether SenoRx directly or indirectly infringes claim 4 of the '204 Patent and claim 8 of the '142 Patent.

Hologic first moves for summary judgment that SenoRx directly infringes asserted claims of the patents-in-suit through the manufacture, use, sale, and offer for sale of the Contura. *See* 35 U.S.C. § 271(a). Hologic does not appear to dispute that the patents-in-suit require that a radiation source be present within the inner spatial volume in order to infringe,[15] nor that the radiation source is not included when SenoRx manufactures or sells the Contura. *See* Ex. TTT (Verhey Expert Report) 30. Instead, Hologic argues that SenoRx infringes because "[t]he fact that end users ultimately configure the Contura with a radiation source so as to infringe the asserted claims is immaterial." Hologic MSJ 31-32. SenoRx responds that until the radiation source is introduced into the Contura by a physician during treatment, the elements required for direct infringement do not exist.

The parties dispute in this case is similar to that considered by the Federal Circuit in *Cross Medical Products v. Medtronic Sofamor Danke, Inc.*, 424 F.3d 1293 (Fed. Cir. 2005). In that case Cross Medical sued Medtronic for infringement of two patents involving orthopedic surgical implants used to stabilize and align the bones of a patient's spine. *Id.* at 1297. The patent-at- issue was directed at a common problem in spinal fixation devices: how to secure the device to the spine without damaging the spinal cord. *Id.* The patented invention allowed the physician to place a series of bone screws into the bones of a patient, each carrying an "anchor seat" and connected to a stabilization rod that links to the anchors on adjacent bones. *Id.* at 1298. In this way the invention allows a surgeon to fix the position of the patient's spine as desired. *Id.* The claim language describing this mechanism recites an "anchor seat means which has a lower bone interface operatively joined to said bone segment." *Id.* at 1305. In construing this language, the court wrote that "[u]se of the word 'joined' indicates that the 'interface' and the 'bone' must be brought together or connected to form a single unit, a whole, or a continuity, and thus that the interface and the bone are

[15] *See* '204 Patent at 8:26-27("a radiation source disposed in the inner spatial volume and generating a three dimensional isodose profile"); '142 Patent at 9:1-2 ("a radiation source disposed completely within the expandable outer surface").

in contact." *Id.* Medtronic argued that it did not infringe because it did not make an anchor seat which contacts bone, nor did it perform surgery. *Id.* at 1311. The court in *Cross Medical* held that Medtronic did not directly infringe, concluding that no reasonable juror could find that Medtronic "makes or uses the entire claimed apparatus" because "the anchor seat of the device does not contact bone until the surgeon implants it." *Id.* at 1312. Here, SenoRx similarly contends that it does not make or include the radiation source with the Contura.

Hologic cites *Fantasy Sports v. Sportsline.com, Inc.*, 287 F.3d 1108 (Fed. Cir. 2002) in favor of its position. *Fantasy Sports* concerned whether Sportsline.com's "Commissioner.com" software product infringed a patent covering a "computer for playing football." *Id.* at 1118. One claim at issue in *Fantasy Sports* included a requirement that the software contain a "means for scoring . . . bonus points." The court found that the requirement was met because the software "presents the user with a number of different options" that can be selected, one of which meets the claim limitation. *Id.* According to Hologic, the Contura directly infringes because it "presents end users (i.e., physicians) with the option to include an infringing feature (i.e., radiation source)." Hologic Reply 25.

Hologic misinterprets *Fantasy Sports*, and *Cross Medical* controls. The court in *Fantasy Sports* noted that, "as in every infringement analysis, the language of the claims, as well as the nature of the accused produce, dictates whether an infringement has occurred." 287 F.3d at 1118. As for the option presented to the user, the court wrote that "although a user must activate the functions programmed into a piece of software by selecting those options, the user is only activating means that are *already present in the underlying software*." *Id.* (emphasis original). That is, *Fantasy Sports* stands for the proposition, as *Cross Medical* does, that the accused device must meet all of the claim limitations in order to infringe.[16]

[16] Neither is this a case where the claim language "specifies that the claim is drawn to capability" as the Federal Circuit in *Ball Aerosol and Specialty Container, Inc. v. Limited Brands, Inc.*, 555 F.3d 984, 994-95 (Fed. Cir. 2009) described *Fantasy Sports*. The claims clearly require that the radiation source actually be present in the device, and not, for example, that the device be capable of accepting a radiation source for a particular purpose. *See* '204 Patent at 8:26-27("a radiation source disposed in the inner spatial volume and generating a three dimensional isodose profile"); '142 Patent at 9:1-2 ("a radiation source disposed completely within the expandable outer surface").

Because SenoRx does not use, manufacture, sell, or offer for sale the Contura including a radiation source, which the patents require, Hologic's motion for summary judgment that SenoRx directly infringes the '142 and '204 Patents is denied.

b. Indirect Infringement

1. Evidence of Direct Infringement

There also appears to be a question of fact as to whether there is a direct infringer of the '204 Patent. As discussed above, additional briefing is necessary on the question of whether the Contura meets the "minimum prescribed absorbed dose" limitation of claim 2 of the '204 Patent when the Contura is used in the multi-dwell configuration. There also remains a triable issue of fact as to whether the Contura generates isodose curves that are "substantially similar in shape to the expandable surface element" as claim 1 of the '204 Patent requires. Finally, a genuine dispute of fact remains as to whether SenoRx has the necessary intent to induce infringement of the '142 and '204 Patents. Therefore, summary judgment of inducement to infringe the '204 Patent cannot be granted. Nonetheless, the parties dispute whether Hologic has made a sufficient showing that the Contura has been used in single-dwell/central lumen configurations.[17] The court will consider the matter in order to clarify issues for trial.

In order to prove direct infringement, Hologic must either point to specific instances of direct infringement or show that the accused device necessarily infringes the patents-in-suit. *ACCO Brands, Inc. v. ABA Locks Mfr. Co. Ltd.*, 501 F.3d 1307, 1313 (Fed. Cir. 2007). In *ACCO*, the court concluded that because "the accused device can be used at any given time in a noninfringing manner, the accused device does not necessarily infringe." *Id.* Here, there is no dispute that the Contura can be and is used in configurations that do not infringe the '204 Patent. The Contura therefore does not necessarily infringe. Hologic contends that the circumstantial evidence supports a

[17] SenoRx appears to concede in its reply brief that the Contura has been used in one case since the January 2008 commercial launch in a single-dwell/central lumen configuration. See SenoRx Reply 24 n. 19 ("It has since come to SenoRx's attention that there has been one [central-dwell only] such use."). According to SenoRx, the center where the use occurred "did not have updated treatment planning software and its staff had not yet been trained on multi-lumen multi-dwell treatment planning." Despite this admission, Hologic does not point to this use as an act of direct infringement upon which a claim for inducement could be based, instead relying on circumstantial evidence of single-dwell/central lumen use. *See* Hologic's Reply 27-28.

finding that physicians have used the Contura in single-dwell/central lumen configurations. In particular, Hologic offers a number of emails and a presentation representing communications between SenoRx and potential customers stating that the Contura can be used, like the MammoSite, in single-dwell/central lumen configurations.[18] These emails demonstrate that SenoRx has pointed out that the Contura functions properly in a single-dwell/central lumen configuration, and has encouraged potential customers to use it as such. But Hologic has not submitted any evidence that in these instances where single-dwell/central lumen use was encouraged, it was actually used. In addition, SenoRx contends that it markets the Contura as a multi-lumen/multi-dwell device. *See* Gearhart Decl. ISO SenoRx Opp. ¶ 6-10. Hologic's submitted emails and presentation are consistent with such a marketing strategy.[19] There is therefore a triable issue of fact as to whether physicians directly infringe by using the Contura in a single-dwell/central lumen configuration.

2. Inducement - Specific Intent

Hologic next moves for summary judgment that SenoRx indirectly infringes the '142 and '204 Patents, both by inducing infringement and contributorily infringing.

In light of the court's conclusions in SenoRx's motion for summary judgment of invalidity above, SenoRx does not dispute that physicians directly infringe the '142 Patent when they use the Contura. SenoRx Opp. 1 ("[T]he Contura is used by physicians to deliver asymmetric radiation doses. If the claims of the '142 patent are applied as the Court construed them, SenoRx does not dispute that the Contura infringes the asserted claims of the '142 Patent."); *see also id.* at 48 (contesting that physicians directly infringe only if the '142 Patent requires conformance to infringe).

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[18] See Exs. X, LL, MM, NN, QQ, TT, FFF, KKK (stating, e.g., "[T]he treatment plan proceeds just like the MammoSite with a single dwell central position in the middle." Ex. X at SRX-HOL00012798).

[19] The emails often characterize single-dwell/central lumen use as an acceptable alternative if a multi-dwell use is unnecessary. *See* Ex. X at SRX-HOL00025106 ("If the balloon is dead in the center of the breast with no skin distance issues, no concern for dose to the ribs, perfect conformance, then the treatment plan proceeds just like a MammoSite with a single dwell position in the middle. . . . The benefit of the Contura is that the radiation oncologist and physicist do not have to struggle to make an imperfect implant look perfect."); Ex. MM at SRX-HOL00006492 ("If desired and appropriate, cases may be treated using simple loading with acceptable results [(]Central lumen/central dwell[).] Why not move beyond acceptable treatment plans to "optimal" treatment plans...");

SenoRx opposes summary judgment of inducement to infringe the '142 and '204 Patents on the basis that it lacked the necessary specific intent. To make the necessary showing of intent to induce infringement, "the plaintiff has the burden of showing that the infringer's actions induced infringing acts and that he knew or should have known his actions would induce actual infringements." *DSU Medical Corp. v. JMS Co. Ltd.*, 471 F.3d 1293, 1304 (Fed. Cir. 2006). That is:

> It must be established that the defendant possessed specific intent to encourage another's infringement and not merely that the defendant had knowledge of the acts alleged to constitute inducement. The plaintiff has the burden of showing that the alleged infringer's actions induced infringing acts *and* that he knew or should have known his actions would induce actual infringements.

Id. at 1306 (quoting *Manville Sales Corp. v. Paramount Systems, Inc.*, 917 F.3d 544, 553 (Fed. Cir. 2005).[20]

SenoRx contends that there is a genuine issue of fact as to whether it had the necessary level of intent. SenoRx was aware of the patents as it developed the Contura. Lubock Decl. ISO SenoRx Opp. ¶ 7 ("Lubock Decl."). SenoRx received an opinion from its patent counsel that the Contura did not infringe the patents-in-suit and that the validity of the patents-in-suit was questionable. *Id.* ¶ 8. After the lawsuit was filed, SenoRx engaged outside counsel, who concluded that the Contura did not infringe the patents-in-suit and that the patents-in-suit were invalid over the prior art. *Id.* ¶ 9. Hologic responds that SenoRx's purported belief that the '142 Patent is not infringed is not credible because, first, the court has rejected SenoRx's only non-infringement theory (that the '142 Patent requires the source to be simultaneously inside and outside of the outer surface element). And second, because SenoRx now admits that, as the claims are construed, the Contura infringes the '142 Patent. Hologic Reply 26.

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[20] Hologic cites *MEMC Electronic Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1378 n. 4 (Fed. Cir. 2005) for the proposition that inducement can be found on the basis of knowledge of the patents and intent to cause acts constituting infringement. MEMC highlighted the "lack of clarity" in Federal Circuit law regarding whether only intent to induce acts that constitute infringement is required, or whether the alleged inducer must have known (or should have known) that his actions would induce actual infringements. *Id.* (citing *Manville*, 917 F.3d at 553, and *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 909 F.2d 1464, 1469 (Fed. Cir. 1990)). *DSU* resolves that lack of clarity in favor of requiring knowledge on the part of the inducer that his actions would induce actual infringement. 471 F.3d at 1304.

Hologic's arguments are properly made to a jury. In *DSU* the Federal Circuit upheld a jury verdict concluding that a party lacked the necessary intent to infringe after receiving opinions from counsel that the accused product did not infringe. 47 F.3d at 1307. And in *Kinetic Concepts, Inc. v. Blue Sky Medical Group, Inc.*, 554 F.3d 1010 (Fed. Cir. 2009), the court upheld a jury finding that intent to induce infringement was lacking because the defendant thought the accused device merely practiced the prior art in the public domain. *Id.* at 1024-25. The court concludes that a genuine issue of fact exists as to whether SenoRx had the necessary intent to induce infringement of the '142 and '204 Patents. Hologic's motion for summary judgment of inducement is therefore denied.

SenoRx also disputes that it intended for users of the Contura to use the device in single-dwell/central lumen configurations. Hologic's evidence that SenoRx intended to induce physicians to use the Contura in single-dwell/central lumen configurations comprises the same emails offered as evidence of direct infringement. *See* Exs. X, LL, MM, NN, QQ, TT, FFF, KKK. One of those emails, apparently a sales email, states: "That being said, I hope that you will continue the use of Contura even as a single dwell, central lumen device because overall, it is still a better balloon than MammoSite." Ex. KKK at SRX-HOL00012584. The remaining emails emphasize that the Contura can be used in single-dwell/central lumen configurations. *See* Exs. X, LL, MM, NN, QQ, TT, FFF.

SenoRx states that it "does not intend for or encourage physicians" to use the Contura in single-dwell/central lumen configurations. SenoRx Opp. 54-55. According to SenoRx, multi-lumen/multi-dwell plans are usually better for patients and the success of the Contura depends on distinguishing it from the MammoSite. Gearhart Decl. ISO SenoRx Opp. ¶ 6-10. For this reason, SenoRx states that it "discourages physicians from using the Contura" in single-dwell/central lumen configurations. SenoRx Opp. 55. It does appear based on the evidence submitted that SenoRx would prefer physicians to use the Contura as a multi-dwell/multi-lumen device. However, the sales emails are directed at encouraging customers, in the alternative, to use the Contura as a single-dwell/central lumen replacement for the MammoSite.[21] At present issue is whether SenoRx intended

[21] "If the balloon is dead in the center of the breast with no skin distance issues, no concern for dose to the ribs, perfect conformance, then the treatment plan proceeds just like a MammoSite with a single dwell position in the middle. . . . The benefit of the Contura is that the radiation oncologist and physicist do not have to struggle to make an imperfect implant look perfect." Ex. X at SRX-HOL00025106. "As for the reimbursement to the radiation oncologist: to too will remain exactly

to induce users of the Contura to use the device in single-dwell/central lumen configurations. SenoRx may encourage such use only as a last resort for competitive reasons, but the evidence is unequivocal that SenoRx intended the Contura to be used, in certain circumstances, in a single-dwell/central lumen configuration.

Although the court denies Hologic's motion for summary judgment that SenoRx induced infringement of the '204 Patent, it is not genuinely in dispute that SenoRx intended to induce physicians to use the Contura in single-dwell/central lumen configurations. That fact shall be treated as established in this action.

3. Contributory Infringement of the '204 Patent

Hologic finally moves for summary judgment that SenoRx contributorily infringes the '142 and '204 Patent. SenoRx does not dispute that it contributorily infringes the '142 Patent. SenoRx Opp. 57 n. 32 ("To the extent the Court finds the Contura infringes the '142 patent, SenoRx concedes that it contributes to that infringement.").[22]

To prove contributory infringement, Hologic must demonstrate that the item sold is not a staple article or commodity of commerce suitable for substantial noninfringing use. *DSU Medical*, 471 F.3d at 1303. The parties dispute whether the Contura has substantial non-infringing uses with respect to the '204 Patent. SenoRx argues that multi-dwell/multi-lumen uses of the Contura constitute substantial non-infringing uses because they deliver asymmetric dose profiles, which do not infringe the '204 Patent. SenoRx Opp. 56. From the perspective of the invention as a whole, these asymmetric-profile uses of the Contura appear to constitute a substantial subset of the available ways to configure the device. SenoRx's product strategy and marketing efforts are also

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the same if they choose to use the Contura like a MammoSite with a single dwell position in the central lumen." *Id.* "Since our device is also a balloon and may be used in a single central lumen/single central dwell fashion, all of that data translates to the Contura as well." Ex. LL at SRX HOL00012498. "If desired and appropriate, cases may be treated using simple loading with acceptable results [(]Central lumen/central dwell[).] Why not move beyond acceptable treatment plans to "optimal" treatment plans..." Ex. MM at SRX-HOL00006492.

[22] Hologic also argues that SenoRx should not be permitted to avoid contributory-infringement liability on each patent by arguing that the Contura has substantial non-infringing uses that allegedly fall within the other. See Hologic Reply 29. SenoRx does not advance such an argument. SenoRx Opp. 57 ("Thus, contrary to Plaintiffs' assertion, it is not SenoRx's position that the Contura's ability to deliver treatment using the central dwell position of the central lumen is a *substantial* use that does not infringe the '142 Patent.") (emphasis original).

directed significantly at encouraging these uses. The court therefore denies Hologic's motion for summary judgment of contributory infringement as to the '204 Patent.

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III. ORDER

For the reasons stated above, the court:

(1) grants SenoRx's motion for summary judgment that claim 1 of the '142 Patent is invalid as anticipated by Ashpole;

(2) denies SenoRx's motion for summary judgment that claim 8 of the '142 Patent is invalid as anticipated by Ashpole;

(3) grants SenoRx's motion for summary judgment of non-infringement as to claim 11 of the '813 patent;

(4) defers ruling on SenoRx's motion for summary judgment of non-infringement with respect to claim 4 of the '204 Patent and requests that the parties file supplemental briefs regarding whether the Contura meets the "minimum prescribed dose" limitation for multi-dwell dose plans and whether, if not, SenoRx should be granted summary judgment of non-infringement for multi-dwell dose plans on that basis. Hologic shall file its response brief, not to exceed five pages, by November 12, 2009. SenoRx may file a reply, also not to exceed five pages, by November 19, 2009;

(5) grants SenoRx's motion for summary judgment of claim 17 of non-infringement of the '204 Patent;

(6) denies Hologic's motion for summary judgment of infringement, including direct infringement, inducement to infringe, and contributory infringement, of claim 11 of the '813 Patent;

(7) grants Hologic's motion for summary judgment that the Contura infringes claim 8 of the '142 Patent;

(8) denies Hologic's motion for summary judgment that the Contura infringes claim 1 of the '142 Patent;

(9) denies Hologic's motion for summary judgment that the Contura infringes claim 4 of the '204 Patent;

(10) denies Hologic's motion for summary judgment that SenoRx directly infringes the '142 and '204 Patents;

(11) denies Hologic's motion for summary judgment that SenoRx induces infringement of the '142 and '204 Patents;

(12) grants Hologic's motion for summary judgment that SenoRx contributorily infringes the '142 Patent; and

(13) denies Hologic's motion for summary judgment that SenoRx contributorily infringes the '204 Patent.

DATED: 10/30/09

Ronald M. Whyte

RONALD M. WHYTE
United States District Judge

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Dated: 10/30/09

JAS
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