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IN THE UNITED STATES DISTRICT COURT

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FOR THE NORTHERN DISTRICT OF CALIFORNIA

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SAN JOSE DIVISION

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HOLOGIC, INC., CYTYC CORP. and
HOLOGIC L.P.,

No. C-08-00133 RMW

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Plaintiffs,

14

v.

ORDER REGARDING SUBSTANTIVE
DISPUTED LEGAL ISSUES

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SENORX, INC.,

[Re Docket No. 357]

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Defendant.

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On September 25, 2009, plaintiffs Hologic, Inc., Cytac Corp., and Hologic, L.P. (collectively "Hologic") and defendant SenoRx, Inc. ("SenoRx") set forth the following disputed legal issues to be determined by the court: (1) whether the "asymmetric isodose curves" language in claim 1 of United States Patent No. 6,482,142 ("142 Patent") refers to aggregate asymmetric isodose curves, and (2) whether prosecution history estoppel bars Hologic from making a doctrine of equivalents argument with respect to the "predetermined spacing" limitation in claim 3 of United States Patent No. 6,413,204 ("204 Patent"). The court settles these disputed legal issues as set forth below.

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I. BACKGROUND

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The parties develop products for use in breast brachytherapy. Brachytherapy is a form of radiation therapy whereby a radioactive source is placed inside or near an area requiring treatment.

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1 For breast brachytherapy, breast tumors are removed via a lumpectomy procedure and a device for
2 delivering radiation is placed in the tumor cavity. The goal of such treatment is to more efficiently
3 deliver radiation to any remaining cancerous tissue while minimizing damage to healthy tissue.

4 SenoRx markets a balloon brachytherapy device known as the Contura Multi-Lumen Balloon
5 ("Contura") which allegedly infringes Hologic's patents. The Contura has five lumens, one straight
6 central lumen and four surrounding curved lumens arranged at ninety degree increments around the
7 central lumen. Within each lumen, radioactive sources can be placed at different positions (called
8 "dwell positions") along the length of the lumen within the balloon. Physicians develop dose plans
9 during treatment to deliver a particular prescribed radiation dose to the target tissue. Because the
10 Contura has multiple dwell positions and multiple lumens in which sources can be placed as part of
11 the dose plan, the parties divide the plans into three relevant categories: (1) plans that utilize
12 multiple dwell positions including the central lumen/central dwell position ("multi-dwell/central"
13 category), (2) those that utilize multiple dwell positions but do not utilize the central lumen/central
14 dwell position ("multi-dwell/no central" category), and (3) those that use the central lumen/central
15 dwell position only ("single-dwell/central" category).

16 II. ANALYSIS

17 A. "Asymmetric Isodose Curves" Language in Claim 1 of the '142 Patent

18 In its claim construction order, the court construed "predetermined asymmetric isodose
19 curves" to mean "isodose curves determined before radiation is administered which are not
20 substantially the same shape as the apparatus volume and/or not concentric with the apparatus
21 volume." Claim Construction Order p. 16. SenoRx now contends that "asymmetric isodose curves"
22 should be construed to be the aggregate dose curves, while Hologic argues that there should be no
23 such limitation. If "asymmetric isodose curves" were found to mean "aggregate asymmetric isodose
24 curves," then as a matter of law, use of the Contura's off-center dwell positions in a multi-dwell plan
25 to create symmetric aggregate isodose curves does not infringe claim 8 of the '142 Patent, which is
26 dependent upon claim 1.

27 SenoRx argues that the curves from each source position in a multi-dwell plan should not be
28 considered individually because when they are considered individually, the purpose of the invention

1 is not met. As described in the '142 Patent, the purpose of the invention is to deliver asymmetric
2 doses of radiation such that sensitive tissue will not receive the full dosage. '142 Patent 2:38-42.
3 However, the purpose of the invention does not limit the scope of the claims. *Vehicular Techs.*
4 *Corp. v. Titan Wheel Intern., Inc.*, 141 F.3d 1084, 1096 (Fed. Cir. 1998) (citing *Applied Materials,*
5 *Inc. v. Advanced Semiconductor Materials America, Inc.*, 98 F.3d 1563, 1574 (Fed. Cir. 1996))
6 ("only when the inventor's purpose is included in the claims does the purpose serve as a 'limitation
7 of the claimed invention [that] should be met either literally or equivalently in order to satisfy the
8 criteria of infringement"). Using the Contura's off-center dwell positions in a multi-dwell plan to
9 provide symmetric aggregate isodose curves may fail to serve the purpose set forth in the '142
10 Patent, but such use would nonetheless infringe claim 1 of '142 Patent if it meets all of the
11 limitations of the claim.

12 SenoRx's argument for construing "asymmetric isodose curves" to be the aggregate isodose
13 curves thus boils down to the fact that the patent specification refers to or depicts a single
14 asymmetric isodose curve when discussing or showing embodiments that contain more than one
15 radiation source. *See, e.g.*, '142 Patent 3:7-11 ("the radiation source comprises a plurality of spaced
16 apart solid radioactive particles disposed within the apparatus volume and arranged to provide a
17 predetermined asymmetric isodose curve within the target tissue"); Fig. 1; 5:18-20 ("[t]he
18 asymmetrically shaped isodose curve 40 may be created by providing a plurality of solid radioactive
19 particles 36"). This shows that when multiple radiation sources are used at the same time,
20 "asymmetric isodose curves" refers to the sum of radiation delivered by all the sources to the tissue.
21 The question is whether this also shows that "asymmetric isodose curves" is limited to the aggregate
22 radiation accumulated over time when a single radiation source is used sequentially (moving to
23 different positions). The court finds that it does not. Faced with a similar question when construing
24 the term "plurality," the court differentiated between multiple radiation sources used at the same
25 time and a single source used sequentially over time. Claim Construction Order pp. 18-19.
26 Likewise, the court declines to limit "asymmetric isodose curves" to aggregate asymmetric isodose
27 curves based on language and depictions in the specification relating only to embodiments with
28 multiple radiation sources used at the same time. Because there is no intrinsic evidence requiring

1 such a limitation, the court finds that "asymmetric isodose curves" is not limited to aggregate
2 asymmetric isodose curves.

3 **B. "Predetermined Spacing" Limitation in Claim 3 of the '204 Patent**

4 In its claim construction order, the court construed "predetermined spacing" to mean "fixed
5 spacing, predetermined by one skilled in the art before administering radiation, between the wall or
6 edge of the inner spatial volume and radiation transparent wall of the outer, closed inflatable
7 chamber, when inflated, which for each point on the wall or edge of the inner spatial volume, the
8 distance to the closest point on the outer chamber is the same (i.e. the inner spatial volume and the
9 outer chamber are concentric and the same shape)." Claim Construction Order p. 24. In order to
10 show that the Contura infringes upon claim 4 of the '204 Patent, Hologic asserts that the
11 "predetermined spacing" limitation in claim 3 (upon which claim 4 is dependent) is met under the
12 doctrine of equivalents. SenoRx contends that Hologic is estopped from making a doctrine of
13 equivalents argument because Hologic allegedly disclaimed devices where the inner spatial volume
14 has a shape different from the expandable surface element during its prosecution of United States
15 Patent No. 5,913,813 ("813 Patent") and its prosecution of the '204 Patent. When the scope of a
16 claim has been narrowed during prosecution, prosecution history estoppel may bar the patentee from
17 asserting equivalents. *Felix v. American Honda Motor Co., Inc.*, 562 F.3d 1167, 1181 (Fed. Cir.
18 2009). The doctrine of prosecution history estoppel applies to bar the assertion of equivalents when
19 there has been a "clear and unmistakable" disavowal of claim scope. *Cordis Corp. v. Medtronic*
20 *Ave., Inc.*, 511 F.3d 1157, 1178 (Fed. Cir. 2008).

21 Having reviewed the parties' briefs and the prosecution history of the relevant patents, the
22 court finds that prosecution history estoppel does not bar Hologic from making a doctrine of
23 equivalents argument with respect to the "predetermined spacing" limitation in claim 3 of the '204
24 Patent. The '204 Patent contains a "substantially similar in shape" limitation in claim 1, which
25 requires the isodose profile to be substantially similar in shape to the expandable surface element.
26 The '204 Patent also contains a "predetermined spacing" limitation in claim 3, which requires the
27 inner spatial volume and the expandable surface element to be concentric and the same shape. The
28 prosecution history reflects a clear disclaimer by Hologic of subject matter which fails to satisfy the

1 "substantially similar in shape" limitation but no such "clear and unmistakable" disclaimer of
2 devices where the inner spatial volume and the expandable surface element are not perfectly
3 concentric and exactly the same shape.

4 While prosecuting the '204 Patent, Hologic never amended claim 3, which contains the
5 "predetermined spacing" limitation. Rather, Hologic amended claim 1 to add the "substantially
6 similar in shape" limitation in response to the examiner's earlier finding that claim 1 was anticipated
7 by United States Patent Nos. 5,106,360 ("Ishiwara") and 5,924,973 ("Weinberger"). December 20,
8 2000 Amendments, '204 Prosecution History at 2. In arguing that its invention was not anticipated
9 by Ishiwara and Weinberger, Hologic points out that "Ishiwara and Weinberger do not provide an
10 apparatus that can produce isodose profiles that are substantially similar in shape to the outer
11 lumen." *Id.* at 12-13. This argument disclaims subject matter which fails to satisfy the
12 "substantially similar in shape" limitation but does not address the "predetermined spacing"
13 limitation.

14 In distinguishing its invention from the prior art, Hologic does state that "the inner volumes
15 of Ishiwara and Weinberger are not substantially similar in shape to their outer expandable
16 elements." *Id.* at 12. However, whenever Hologic points out differences between the shape of the
17 inner spatial volume and the expandable surface element in the prior art, it explains that this is
18 relevant because it results in a three-dimensional isodose profile that is not substantially similar in
19 shape to the expandable surface element – tying the analysis back to the "substantially similar in
20 shape" limitation. *Id.* Moreover, even looking at these statements in a vacuum, they do not clearly
21 and unmistakably disclaim the subject matter at issue. At most, Hologic's statements made to the
22 examiner during prosecution of the '204 Patent can be read as disclaiming devices where the inner
23 spatial volume is not substantially similar in shape to the expandable surface element. *See id.* ("the
24 inner volumes of Ishiwara and Weinberger are not *substantially similar in shape* to their outer
25 expandable elements") (emphasis added). Hologic's doctrine of equivalents argument with respect
26 to the "predetermined spacing" limitation is that the inner spatial volume *is* substantially the same
27 shape as the expandable surface element. Consequently, prosecution history estoppel does not bar
28 this line of argument.

1 SenoRx contends that amendments and arguments made by Hologic during its prosecution of
2 the '813 Patent bar Hologic from asserting equivalents with respect to the '204 Patent, which is a
3 continuation in part of the '813 Patent. "[T]he prosecution of one claim term in a parent application
4 will generally not limit different claim language in a continuation application." *Invitrogen Corp. v.*
5 *Clontech Laboratories, Inc.*, 429 F.3d 1052, 1078 (Fed. Cir. 2005). However, there is an exception,
6 "where an amendment to a related limitation in the parent application distinguishes prior art and
7 thereby specifically disclaims a later (though differently worded) limitation in the continuation
8 application." *Id.* (citing *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999)).
9 While prosecuting the '813 Patent, Hologic amended claim 1 to have the limitation "predetermined
10 constant spacing" as opposed to just "predetermined spacing" to distinguish the invention from
11 Ishiwara. Sept. 1, 1998 Amendments, '813 Prosecution History at 2. However, the word "constant"
12 is absent from claim 3 of the '204 Patent. Thus, in order to show that Hologic has specifically
13 disclaimed equivalents with respect to the "predetermined spacing" limitation, SenoRx must show
14 that Hologic affirmatively linked the meaning of claim 3 of the '204 Patent to claim 1 of the '813
15 Patent. *See Elkay*, 192 F.3d at 980 (finding limitation on claims in the parent application to apply to
16 claims in the continuation application because the patentee affirmatively linked the meaning of the
17 claims).

18 Though Hologic pointed to some of its arguments made in the prosecution of the '813 Patent
19 when prosecuting the '204 Patent, the language it quoted focused on the shape of the dose profile
20 (which addresses the "substantially similar in shape" limitation), not that of the inner spatial volume
21 (which addresses the "predetermined spacing" limitation). December 20, 2000 Amendments, '204
22 Prosecution History at 11. When it did refer to the shape of the inner spatial volume, Hologic
23 explained that this shape is relevant because if the inner spatial volume is not substantially the same
24 shape as the outer spatial volume, then "the radiation source disposed in the inner spatial volume of
25 Ishiwara would not generate a three-dimensional profile that is substantially similar in shape to the
26 expandable surface element." *Id.* at 12. Hence, the focus is always on the "substantially similar in
27 shape" limitation. "Predetermined spacing" is never even mentioned because Hologic did not seek
28 to distinguish claim 3 (which contains the "predetermined spacing" limitation) over the prior art.

1 Rather, the prosecution history shows that Hologic made amendments and arguments relating to the
2 "substantially similar in shape" limitation in order to distinguish claim 1 over the prior art. As
3 Hologic points out, since claim 3 is narrower than claim 1, once claim 1 has been distinguished over
4 prior art, there is no need to further distinguish claim 3 over the prior art.


5 The court finds that Hologic did not affirmatively link the meaning of claim 3 of the '204
6 Patent to claim 1 of the '813 Patent in its prosecution history. Though the court has construed
7 "predetermined spacing" in claim 3 of the '204 Patent to have the same meaning as "predetermined
8 constant spacing" in claim 1 of the '813 Patent, the court's construction merely defines the term and
9 does not give rise to prosecution history estoppel. Therefore, Hologic is not barred from asserting
10 equivalents with respect to the "predetermined spacing" limitation.

11 **III. ORDER**

12 For the foregoing reasons, the court:

- 13 1. finds that the "asymmetric isodose curves" language in claim 1 of the '142 Patent is
14 not limited to aggregate asymmetric isodose curves; and
- 15 2. finds that prosecution history estoppel does not bar a doctrine of equivalents
16 argument with respect to the "predetermined spacing" limitation in claim 3 of '204
17 Patent.

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20 DATED: 11/30/09



RONALD M. WHYTE
United States District Judge

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Dated: 12/1/09

CCL
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