

United States District Court
For the Northern District of California

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

GENENTECH, INC.,)	Case No.: 10-CV-02037-LHK
)	
Plaintiff,)	ORDER DENYING U PENN’S MOTION
v.)	FOR SUMMARY ADJUDICATION;
)	AND DENYING GENENTECH’S
THE TRUSTEES OF THE UNIVERSITY OF)	MOTION FOR SUMMARY JUDGMENT
PENNSYLVANIA, a Pennsylvania non-profit)	
corporation,)	
)	
Defendant.)	

Plaintiff Genentech, Inc. (“Genentech”) brings this suit against Defendant Trustees of the University of Pennsylvania (“U Penn”) seeking a declaratory judgment of non-infringement and invalidity of U.S. Patent No. 6,733,752 (the “752 patent”). By counterclaim, U Penn asserts infringement by Genentech. The Court issued an Order Construing Disputed Claim Terms in the ’752 Patent on May 9, 2011. See ECF No. 214 (“Markman Order”). Now before the Court are two motions: (1) U Penn’s Motion for Summary Adjudication of Undisputed Material Facts, ECF No. 469 (“Penn MSA”), and (2) Genentech’s Motion for Summary Judgment, ECF No. 509 (“Genentech MSJ”). The Court held a hearing on both motions on April 19, 2012. Having considered the submissions of the parties and the relevant law, and for the reasons discussed herein, U Penn’s Motion for Summary Adjudication is DENIED, and Genentech’s Motion for Summary Judgment is DENIED.

1 **I. BACKGROUND**

2 **A. The '752 Patent**

3 The technology at issue is a method of adjuvant cancer therapy using antibodies to prevent
4 a form of breast cancer characterized by the overexpression of HER2 receptors, also referred to as
5 p185. The '752 patent, entitled "Prevention of Tumors with Monoclonal Antibodies Against Neu,"
6 was issued on May 11, 2004 and has a presumptive priority date of March 30, 1994.¹ The '752
7 patent describes antibodies to the protein expressed by the *neu* oncogene. '752 Patent 1:34-39.
8 The *neu* oncogene codes for a cell surface receptor protein named p185, referred to in humans as
9 HER2. *Id.* Amplification of the *neu* oncogene (and resulting overexpression of p185) has been
10 linked to certain types of cancers, including breast cancer. *Id.* at 1:40-53; 2:45-55. The '752 patent
11 discloses a method for preventing transformation of a breast cell that overexpresses p185 into a
12 cancer cell by treatment with anti-p185 antibodies. These antibodies specifically bind to p185 on
13 the cell surface, and thereby "interfer[e]" with the transformation of the cell into a cancer cell. *Id.*
14 at 2:32-38.

15 In Example 1, the '752 inventors describe production of anti-p185 mouse antibodies. *Id.* at
16 4:51-6:60. One of the resulting antibodies was named 7.16.4. *Id.* Cells producing this antibody
17 were deposited in the American Type Culture Collection (ATCC) as accession number HB 10493.
18 *Id.* In Example 2, the inventors of the '752 patent describe an experiment using transgenic mice
19 that overexpress a rat *neu* oncogene ("Bouchard" mice). *Id.* at 6:62-7:14. The Bouchard mice
20 develop breast tumors at about 40 weeks of age. *Id.* The inventors treated the Bouchard mice with
21 low and high doses of the 7.16.4 antibodies, and reported that the high dose of antibody suppressed
22 tumor formation in half the mice. *Id.* at 7:65-8:12.

23 **B. Accused Instrumentalities**

24 Genentech is a biotechnology company that manufactures the FDA-approved drug
25 Herceptin (active ingredient trastuzumab). Herceptin is a humanized monoclonal antibody for the
26 treatment of a form of breast cancer characterized by the overexpression of HER2 receptors.

27 ¹ The '752 Patent claims priority to a Patent Cooperation Treaty (PCT) application, number
28 08/525,800, filed March 30, 1994. The priority date is not in dispute in the parties' motions.

1 Although Herceptin has an indication as a first-line treatment for metastatic breast cancer, the
2 instant litigation concerns the method of administering Herceptin as indicated for adjuvant
3 treatment to reduce the risk of cancer recurrence in patients who have been diagnosed with primary
4 breast cancer and who have been treated by surgical removal of their breast tumor(s) (“resection”)
5 (the “Adjuvant Population”). *See* Decl. of Jason Sheasby in Supp. of U Penn’s MSJ, ECF No. 438
6 (“Sheasby Decl.”), Ex. 1 [Penn’s 3d Am. Infringement Contentions], at 2.

7 The FDA-approved package insert for Herceptin (“Herceptin Label”) instructs that
8 “Herceptin is indicated for adjuvant treatment of HER2 overexpressing node positive or node
9 negative (ER/PR negative or with one high risk feature . . .) breast cancer [a] as part of a treatment
10 regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel[; b] with
11 docetaxel and carboplatin[; or c] as a single agent following multi-modality anthracycline based
12 therapy.” Sheasby Decl. Ex. 4 [Herceptin Label], at 2.² A recent study in 2011, funded by
13 Genentech’s parent company, Roche, tested the efficacy of trastuzumab in clearing HER2/neu-
14 positive ITC from the bone marrow of patients completing primary treatment, and concluded that
15 trastuzumab is effective in clearing HER2+ ITCs from bone marrow during recurrence-free follow-
16 up in breast cancer patients. Sheasby Decl. Ex. 41 [Rack et al., “Trastuzumab clears HER2/neu-
17 positive isolated tumor cells from bone marrow in primary breast cancer patients,” June 30, 2011
18 (“Rack 2011”)]. U Penn submits that administration of Herceptin to patients who have had HER2+
19 primary breast tumors removed, in accordance with the “Adjuvant Treatment, Breast Cancer”
20 indications of the Herceptin Label, directly infringes the ’752 patent because Herceptin acts on
21 p185-overexpressing isolated tumor cells (“ITCs”) that are not “breast cancer cells” within the
22 meaning of the ’752 patent, and prevents their transformation into cancer cells. To the extent
23 Genentech induces health care providers to administer Herceptin in a manner that directly infringes
24 the ’752 patent, through Genentech’s provision of Herceptin, its FDA-approved Herceptin Label,
25 and its marketing, advertising, detailing, training, studies, presentations, publications, and
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27 ² While Herceptin’s FDA-approved label serves as the primary basis for U Penn’s infringement
28 contentions, U Penn has also adduced surveys of medical practitioners as additional evidence.

1 demonstrations on Herceptin, U Penn seeks to hold Genentech liable for indirect infringement
2 under 35 U.S.C. § 271(b).

3 **C. Claim Construction Order**

4 After holding a technology tutorial and claim construction hearing, the Court issued an
5 order on May 9, 2011, construing eight disputed claim terms in the '752 Patent. *See* ECF No. 214
6 (“*Markman* Order”). Of those eight terms, only three – all appearing only in independent claim 1
7 of the '752 Patent – are of particular relevance to the parties’ cross-motions now before the Court:
8 (1) “breast cancer cells;” (2) “breast cells that overexpress p185;” and (3) “an individual in need of
9 such inhibition.” Claim 1 recites:

10 A method of inhibiting development into **breast cancer cells** of **breast cells that**
11 **overexpress p185 in an individual in need of such inhibition** which comprises
12 administering to said individual an antibody which competes with an antibody
13 produced by cell line ATCC Deposit No. 10493 for binding to p185 and specifically
14 binds to p185 in sufficient amount to down regulate the overexpressed p185 and
inhibit the development of said breast cells that overexpress p185 into breast cancer
cells.

15 '752 Patent 8:49-57 (emphases added).

16 **1. “breast cancer cells”**

17 The Court construed the term “breast cancer cells” to mean “**cells from the breast that**
18 **have malignant form and structure, the ability for uncontrolled growth, and the potential or**
19 **ability to invade or metastasize.”** *Markman* Order at 10. In reaching this construction, the Court
20 considered the various limitations proposed by the parties. U Penn argued that “breast cancer cells
21 are “cells, the origin of which is breast tissue, that have the properties of uncontrolled growth and
22 invasiveness.” *Id.* at 4. Genentech argued that the term means “cells from the breast that (a) have
23 malignant form and structure and the potential to invade and metastasize or (b) have invaded or
24 metastasized.” *Id.* The Court determined that U Penn’s proposal limited the term to only the most
25 advanced forms of invasive tumors without adequate support for doing so, and found that the
26 intrinsic evidence supported Genentech’s broader construction, which would include non-invasive
27 tumors such as ductal carcinoma in situ (“DCIS”). The Court further concluded that the ability for
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1 uncontrolled growth is what permits a tumor to form and therefore included that property in the
2 claim construction.

3 **2. “breast cells that overexpress p185”**

4 The Court adopted U Penn’s proposed construction of the claim term “breast cells that
5 overexpress p185” and construed the term to mean **“cells, the origin of which is breast tissue,
6 that overexpress p185 and are not breast cancer cells.”** *Markman* Order at 12. Genentech
7 advocated for two limitations, both of which the Court rejected. First, Genentech argued that the
8 cells in question must be “normal” because the specification repeatedly states that the invention is
9 directed to preventing “normal cells from transforming into tumor cells.” ’752 Patent 3:11-12.
10 The Court rejected Genentech’s proposal to re-introduce the term “normal” into the claim in light
11 of the fact that U Penn had to remove “normal” from the claims during prosecution of the patent
12 before the PTO. *Markman* Order at 11. Second, Genentech advocated for a locational limitation,
13 arguing that the term should be limited to cells located in the breast. This limitation was rejected
14 as superfluous because neither party introduced evidence of non-cancerous p185-overexpressing
15 breast cells that occur outside the breast. *Id.* at 11-12.

16 **3. “an individual in need of such inhibition”**

17 Finally, the Court construed “an individual in need of such inhibition” to mean **“an
18 individual who (i) has a family history of *neu*-associated breast cancer or a genetic
19 predisposition to *neu*-associated breast cancer but who has not developed *neu*-associated
20 breast cancer; or (ii) has had her/his *neu*-associated breast cancer tumors removed by
21 surgical resection, or has been diagnosed as having *neu*-associated breast cancer enter
22 remission.”** *Markman* Order at 15-16. In doing so, the Court rejected Genentech’s prosecution
23 argument that U Penn clearly and unmistakably disclaimed the tumor-removal/remission class of
24 patients. *Id.* at 14-15.

25 **II. LEGAL STANDARD**

26 Summary judgment is appropriate if, viewing the evidence and drawing all reasonable
27 inferences in the light most favorable to the nonmoving party, there are no genuine issues of
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1 material fact, and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a);
2 *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). At the summary judgment stage, the Court
3 “does not assess credibility or weigh the evidence, but simply determines whether there is a
4 genuine factual issue for trial.” *House v. Bell*, 547 U.S. 518, 559-60 (2006). A fact is “material” if
5 it “might affect the outcome of the suit under the governing law,” and a dispute as to a material fact
6 is “genuine” if there is sufficient evidence for a reasonable trier of fact to decide in favor of the
7 nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). “If the evidence is
8 merely colorable, or is not significantly probative, summary judgment may be granted.” *Id.*
9 (internal citations omitted).

10 The moving party bears the initial burden of identifying those portions of the pleadings,
11 discovery, and affidavits that demonstrate the absence of a genuine issue of material fact. *Celotex*
12 *Corp.*, 477 U.S. at 323. Where the moving party will have the burden of proof on an issue at trial,
13 it must affirmatively demonstrate that no reasonable trier of fact could find other than for the
14 moving party, but on an issue for which the opposing party will have the burden of proof at trial,
15 the party moving for summary judgment need only point out “that there is an absence of evidence
16 to support the nonmoving party’s case.” *Id.* at 325; accord *Soremekun v. Thrifty Payless, Inc.*, 509
17 F.3d 978, 984 (9th Cir. 2007). Once the moving party meets its initial burden, the nonmoving
18 party must set forth, by affidavit or as otherwise provided in Rule 56, “specific facts showing that
19 there is a genuine issue for trial.” *Anderson*, 477 U.S. at 250 (internal quotation marks omitted).

20 The Federal Circuit has consistently held that the application of a court’s claim construction
21 to undisputed facts is a proper subject of summary judgment or summary adjudication. *See, e.g.*,
22 *Innovention Toys, LLC v. MGA Entm’t, Inc.*, 637 F.3d 1314, 1319 (Fed. Cir. 2011). Summary
23 judgment of noninfringement requires a two-step analysis. “First, the claims of the patent must be
24 construed to determine their scope. Second, a determination must be made as to whether the
25 properly construed claims read on the accused device.” *Pitney Bowes, Inc. v. Hewlett-Packard*
26 *Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999) (internal citations omitted). “[S]ummary judgment of
27 non-infringement can only be granted if, after viewing the alleged facts in the light most favorable
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1 to the non-movant, there is no genuine issue whether the accused device is encompassed by the
2 claims.” *Id.*

3 **III. DISCUSSION**

4 **A. Literal Infringement**

5 U Penn alleges that administering Herceptin to the Adjuvant Population according to the
6 procedures set out in the FDA-approved Package Insert for Herceptin (the “Herceptin Label”) acts
7 on ITCs and inhibits them from transforming into breast cancer cells, thus satisfying the limitations
8 of claim 1 of the ’752 patent. U Penn argues that this practice infringes its method claims and thus
9 seeks summary adjudication of two material facts it claims are undisputed: (1) ITCs are not “breast
10 cancer cells” under the Court’s claim construction; and (2) Herceptin can act on ITCs to inhibit
11 them from becoming cancer cells. Penn MSA at 1. Genentech contends that ITCs *are* “breast
12 cancer cells” and therefore seeks summary judgment on the basis of noninfringement. The Court
13 considers each of these two material facts in turn to determine whether a genuine dispute exists.

14 **1. Whether ITCs are Cancer Cells**

15 The central dispute in the parties’ cross-motions is whether ITCs in the bone marrow of
16 early-stage breast-cancer patients are “breast cancer cells,” and thus not “breast cells that
17 overexpress p185,” under the Court’s construction of those terms as they are used in the ’752
18 patent. As a preliminary matter, however, the parties fundamentally disagree as to whether this
19 very question is a matter of claim construction for the Court to decide or a matter of infringement
20 for the trier of fact. The Court therefore resolves this threshold dispute before turning to assess the
21 parties’ evidence.

22 **a. Question of Law or Fact**

23 Determination of patent infringement involves a two-step process. Claim construction is
24 the first step, wherein the court resolves any disputes regarding the meaning and scope of the claim
25 terms, “and when necessary [explains] what the patentee covered by the claims, for use in the
26 determination of infringement.” *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed.
27 Cir. 1997). In the second step, the trier of fact must “determine[] whether every claim limitation,
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1 or its equivalent, is found in the accused device.” *Roche Palo Alto LLC v. Apotex, Inc.*, 531 F.3d
2 1372, 1377 (Fed. Cir. 2008) (citation omitted).

3 Although the Court has already construed the term “breast cancer cells,” Genentech argues
4 that “[t]he question now before the Court . . . is whether a proper construction of ‘breast cancer
5 cells’ includes ITCs, as it does DCIS and micrometastases, such that their treatment is outside the
6 scope of the ’752 patent.” Genentech MSJ at 9. Genentech believes that the Court can resolve the
7 question of infringement purely as a matter of claim construction for two reasons. First, Genentech
8 argues that “[t]his is a question of claim construction that implicates the scope of claim terms the
9 Court has interpreted.” Genentech MSJ at 9. Second, Genentech argues that “[w]here, as here,
10 the parties do not dispute any relevant facts regarding the accused product but disagree over which
11 of two possible meanings of [a claim] is the proper one, the question of literal infringement
12 collapses to one of claim construction and is thus amenable to summary judgment.” *Id.* (quoting
13 *Athletic Alts., Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1578 (Fed. Cir. 1996)). Genentech contends
14 that there is no dispute here about what Herceptin does and thus no dispute about the “accused
15 product”; rather, the dispute is about whether ITCs fall within the scope of Claim 1 of the ’752
16 patent.

17 The Court disagrees on both counts. First, the Court has already construed the term “breast
18 cancer cells” to mean “cells from the breast that have malignant form and structure, the ability for
19 uncontrolled growth, and the potential or ability to invade or metastasize.” *Markman* Order at 10.
20 Thus, the scope of the claim term is clear and is not erroneously left for the jury to decide. *Cf. O2*
21 *Micro Int’l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1361-62 (Fed. Cir. 2008)
22 (where parties dispute the scope of claim terms, courts have a duty to construe the terms).

23 Genentech does not seek clarification of any of the terms used in the Court’s construction of
24 “breast cancer cells.” *Cf. Every Penny Counts, Inc. v. Am. Express Co.*, 563 F.3d 1378, 1384 (Fed.
25 Cir. 2009) (district court did not err by interpreting the party’s proposed construction). Nor does
26 Genentech advocate for a different construction of the term “breast cancer cells” based on newly
27 introduced evidence of what was known about ITCs in 1994. For example, if Genentech were
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1 arguing that persons of ordinary skill in the art in 1994 considered ITCs to be cancer cells *and* that
2 it was known in 1994 that ITCs lack the ability for uncontrolled growth, then Genentech would
3 have a reasonable basis for asking the Court to excise the “ability for uncontrolled growth”
4 limitation of its construction of the term “breast cancer cell.” But that is not what Genentech
5 argues now. Instead, Genentech simply argues that the construction the Court has already adopted
6 necessarily encompasses ITCs because ITCs were thought to be micrometastases, which were
7 thought to be cancer cells, at the time of the invention. In construing the term “breast cancer cells”
8 during the *Markman* proceedings, however, the Court already considered the known properties of
9 micrometastases, which include the “ability for uncontrolled growth.” *See Markman* Order at 12.
10 Thus, the Court is not persuaded that it must re-construe “breast cancer cells” in order to account
11 for ITCs.

12 Second, while claim construction involves determining the scope of the claim terms as a
13 matter of law, it is decidedly not the task of the court to determine whether every accused product
14 falls within the “scope” of the terms once the terms are construed. A court may not, “under the
15 rubric of claim construction, [] give a claim whatever additional precision or specificity is
16 necessary to facilitate a comparison between the claim and the accused product. Rather, after the
17 court has defined the claim with whatever specificity and precision is warranted by the language of
18 the claim and the evidence bearing on the proper construction, the task of determining whether the
19 construed claim reads on the accused product is for the finder of fact.” *PPG Indus. v. Guardian*
20 *Indus. Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998). Were it otherwise, “all questions of
21 infringement [would] collapse into questions of claim construction.” *Penn Opp’n* at 9. The
22 Federal Circuit has explained that the infringement question collapses into one of claim
23 construction only where the parties agree that the accused product infringes under one claim
24 construction and that the accused product does not infringe under an alternative claim construction.
25 *See Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1302 (Fed. Cir. 2011). Here, however, as
26 in *Uniloc*, “the claim construction itself is not contested, but the application of that claim
27 construction to the accused device is.” *Id.* While ITCs themselves are not the accused infringing
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1 product, the administration of Herceptin to patients who have HER2+ ITCs in the bone marrow is
2 the accused infringing method. Thus, to the extent the parties disagree on the properties of ITCs as
3 understood today, the Court finds that there is a dispute over relevant facts concerning the accused
4 method. The Court therefore agrees with U Penn that this is a factual question of infringement, i.e.,
5 a question of “whether the construed claim reads on the accused product.” *PPG Indus.*, 156 F.3d
6 at 1355; *see, e.g., Biotec Biologische Naturverpackungen GmbH & Co. KB v. Biocorp., Inc.*, 249
7 F.3d 1341, 1349 (Fed. Cir. 2001) (upholding district court’s determination that disputed issue was
8 the proper application of a claim term to an accused process rather than the scope of the term
9 itself).

10 In any event, even if the Court were to consider the properties of ITCs as understood by
11 persons of ordinary skill in the art in 1994 as part of claim construction, doing so would not obviate
12 the independent factual inquiry into whether ITCs, as understood today, possess the properties of a
13 “breast cancer cell” as used in the ’752 patent. “[A]s is well established, an applicant is not
14 required to describe in the specification every conceivable and possible future embodiment of his
15 invention.” *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1370 (Fed. Cir. 2008) (citing *SRI*
16 *Int’l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985)). Federal Circuit case
17 law clearly “allows for after-arising technology to be captured within the literal scope of valid
18 claims that are drafted broadly enough,” and thus even if ITCs were thought to have the ability for
19 uncontrolled growth in 1994, such would not preclude a method that acts on HER2+ ITCs from
20 infringing the claims now, if it is now understood that ITCs do not meet the definition of a “breast
21 cancer cell” as defined within the ’752 patent. *See id.* at 1371-72; *SuperGuide Corp. v. DirecTV*
22 *Enters., Inc.*, 358 F.3d 870, 878-80 (Fed. Cir. 2004) (finding that the claim limitation “regularly
23 received television signal” was broad enough to encompass digital signals even though televisions
24 that could receive digital signals did not exist as of the filing date).

25 Had the ’752 patent claimed a method for inhibiting development of “ITCs” or
26 “micrometastases,” the scope of the claimed invention would be locked in and limited to the
27 understanding of the term “ITCs” or “micrometastases” by one skilled in the art at the time of the
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1 invention. The actual claims of the '752 patent, however, do not include any mention of ITCs,
2 micrometastases, or other specific cell types. To the contrary, the '752 patent claims a method
3 only for inhibiting development of “breast cancer cells,” as that term was understood by skilled
4 artisans in 1994. The '752 patent thus employs a term broad enough to encompass or exclude
5 different cell types as the scientific community’s understanding of those cell types evolves over
6 time.

7 In summary, to the extent ITCs were considered cancerous by skilled artisans in 1994, a
8 proper construction of the term “breast cancer cells” might be informed by what skilled artisans in
9 1994 believed to be the properties of ITCs. Genentech, however, does not advocate for a different
10 construction of “breast cancer cells” than the one adopted in the Court’s *Markman* Order, and thus
11 the construction set forth in the *Markman* Order stands. Furthermore, to the extent Penn presents
12 evidence that the modern day scientific understanding of the properties of ITCs is different from
13 what was known about ITCs in 1994, the ultimate infringement question of whether ITCs – as
14 understood today – satisfy the '752 patent’s definition of “breast cancer cells” stands separate and
15 apart from the Court’s construction of the claim terms.

16 **b. Whether ITCs Have the Ability for Uncontrolled Growth**

17 In contrast to claim construction, “infringement, whether literal or under the doctrine of
18 equivalents, is a question of fact.” *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1356
19 (Fed. Cir. 2007). Having construed the claim term “breast cancer cells,” the Court now must
20 consider whether the limitations of claim 1 read onto the accused method of administering
21 Herceptin to Adjuvant patients in accordance with the Herceptin Label. Because the parties bring
22 cross-motions for summary adjudication of this material fact, the Court must determine whether the
23 parties’ competing evidence creates a genuine dispute as to whether ITCs satisfy the '752 patent
24 definition of breast cancer cells, that is, whether ITCs have: (1) malignant form and structure; (2)
25 the ability for uncontrolled growth; and (3) the potential or ability to invade or metastasize.
26 Because the Court finds a material dispute as to whether ITCs have the ability for uncontrolled
27 growth, as detailed below, Genentech’s motion for summary judgment on the basis of
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1 noninfringement is denied, as is U Penn’s motion for summary adjudication of this fact, and the
2 Court need not consider whether a genuine issue exists with respect to malignant form and
3 structure, or the potential or ability to invade or metastasize.

4 The central factual dispute concerns whether ITCs have the ability for uncontrolled growth.
5 Genentech cites several expert declarations in support of its argument that ITCs have the ability for
6 uncontrolled growth because they are, by name, “tumor cells” that have spread from the primary
7 breast tumor. *See* Cote Decl. ¶¶ 33, 87; Pantel Decl. ¶ 26; Park Decl. ¶ 52; Vogel Decl. ¶ 39.
8 Genentech also cites evidence that, as demonstrated by their detection in the bone marrow, these
9 cells have necessarily invaded through the basal lamina of the breast duct and made their way
10 through foreign tissue, thus already exhibiting the ability for uncontrolled growth and invasion.
11 *See, e.g.*, Pantel Decl. ¶¶ 26, 67, 82, 99. Genentech also submits evidence that, even by 1994, it
12 was known that ITCs could give rise to tumors in secondary sites. *See* Pantel Decl. ¶ 37 & Ex. OO
13 (G. Riethmuller et al., “Immunological Analysis of Micrometastases and the Metastatic Phenotype
14 of Human Tumors,” 1989), at 1084. Furthermore, Genentech cites to various studies finding a
15 correlation between the presence of ITCs in bone marrow and the increased frequency of cancer
16 relapse after surgery as evidence that ITCs are tumorigenic and therefore have the ability for
17 uncontrolled growth outside the breast. *See, e.g.*, Pantel Decl. ¶¶ 41-43, 84, 96; Cote Decl. ¶¶ 29,
18 224-26.

19 U Penn introduces competing expert testimony in support of its argument that ITCs lack the
20 ability for uncontrolled growth. First, U Penn introduces evidence that, although it may have long
21 been presumed that ITCs derive from primary breast tumors, recent studies suggest that ITCs may
22 originate from atypical ductal hyperplasia (“ADH”), which the parties seem to agree is
23 noncancerous. *See* Sheasby Decl. Ex. 56 [Husemann et al., “Systemic Spread Is an Early Step in
24 Breast Cancer,” January 2008]. U Penn introduces other evidence that ITCs disseminate very early
25 from the primary tumor and develop separately, exhibiting different chromosomal mutations than
26 the cells of the primary tumor. *See* Aaronson Decl. ¶ 89 & Ex. 29 [Aaronson 1st Rep.], ¶¶ 301-08.
27 U Penn argues that, like ADH cells, ITCs are a type of precancerous cell, and though ITCs may
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1 have a risk of developing into '752 patent breast cancer cells, this risk does not make ITCs
2 themselves cancer cells. Penn MSA at 14-15.

3 Second, U Penn puts forth evidence that under the “TNM System” for classification of
4 cancer staging, ITCs at distant locations like bone marrow are categorized as noncancerous. *See*
5 Penn MSA at 18. The TNM System, a widely used means for classifying the extent of cancer
6 spread, has been adopted by a world-wide body of national committees. The TNM System is
7 applied to cancer patients who have presented with a primary tumor, such as a breast tumor, and
8 describes the extent of the patient’s disease based on three variables: T, the “primary” site; N,
9 presence in “regional lymph node[s];” and M, presence of “distant” metastasis. Sheasby Decl. Ex.
10 44 [UICC TNM Classification Manual, 7th Ed.], at 7. The TNM system classifies ITCs as M0,
11 meaning cancer is not present at distant sites. *See id.* at 13-15. U Penn argues that, contrary to
12 Genentech’s assertion that ITCs and micrometastases exhibit the same properties, ITCs and
13 micrometastases are in fact biologically distinct entities, as evidenced by the fact that ITCs are
14 staged M0, while micrometastases are staged M1 under the TNM system.

15 Third, U Penn introduces evidence that Genentech’s own experts agree that the ability for
16 uncontrolled growth requires several properties, including the cell’s ability to grow autonomously,
17 generate its own growth signals, and proliferate without environmental cues. *See* Sheasby Decl.
18 Ex. 39 [Stern Dep.], at 35:5-17; Sheasby Decl. Ex. 22 [Cohen Dep.], at 214:15-215:9. U Penn
19 introduces evidence that Genentech’s own expert, Dr. Klaus Pantel, agrees that additional triggers
20 are necessary for ITCs in M0 patients “to develop the ability of uncontrolled growth.” Sheasby
21 Decl. Ex. 30 [Pantel Dep.], at 124:24-125:25.

22 Based on this record, the Court concludes that there is a genuine dispute as to whether ITCs
23 possess the ability for uncontrolled growth. Accordingly, U Penn’s motion for summary
24 adjudication of this fact is DENIED, and Genentech’s motion for summary judgment on the basis
25 of noninfringement is likewise DENIED.

26 **2. Whether Herceptin “Acts on ITCs to Inhibit them From Becoming**
27 **Cancer Cells”**

1 U Penn also seeks summary adjudication that “Herceptin can act on ITCs to inhibit them
2 from becoming cancer cells.” In support of its motion, U Penn submits evidence that Genentech’s
3 senior Herceptin pathologist, Dr. Howard Stern, and Genentech’s 30(b)(6) witness on Herceptin’s
4 activity on ITCs, Senior Fellow Dr. Robert Cohen, agree that when administered as adjuvant
5 therapy, Herceptin “acts on” ITCs at distant locations to prevent recurrence in the Adjuvant
6 Population. *See, e.g.*, Sheasby Decl. Ex. 39 [Stern Dep.], at 166:15-168:3; Ex. 24 [Cohen II Dep.],
7 at 458:8-459:13; Ex. 22 [Cohen Dep.], at 186:22-187:21. Furthermore, U Penn points to a 2011
8 study funded by Roche, Genentech’s parent company, which reported that “[p]ersistent bone
9 marrow ITC predict an increased risk of relapse and reduced survival” and concluded that
10 Herceptin “is effective in clearing HER2+ ITCs from bone marrow during recurrence-free follow-
11 up in breast cancer patients.” Sheasby Decl. Ex. 41 [Rack 2011].

12 Although U Penn presents evidence that Herceptin “acts on” ITCs, the Court does not agree
13 that the evidence uncontrovertibly establishes that Herceptin acts on ITCs “to inhibit them from
14 *becoming cancer cells.*” To the extent Genentech has raised a genuine issue of material fact
15 regarding whether ITCs are “breast cancer cells,” the same genuine dispute precludes the Court
16 from granting summary adjudication on whether Herceptin “acts on ITCs to inhibit them from
17 becoming cancer cells,” since this latter fact presumes that ITCs are not already cancer cells. The
18 Court also agrees with Genentech that the phrase “acts on” is not a claim limitation that appears in
19 the ’752 patent and is therefore immaterial to proving infringement of the ’752 patent.
20 Accordingly, U Penn’s motion for summary adjudication of this fact is DENIED.

21 **B. Infringement by Equivalents**

22 U Penn’s infringement contentions accuse Herceptin of infringing both literally and under
23 the doctrine of equivalents. “The doctrine of equivalents allows the patentee to claim those
24 insubstantial alterations that were not captured in drafting the original patent claim but which could
25 be created through trivial changes.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co, Ltd.*,
26 535 U.S. 722, 733 (2002). Under this doctrine, “an accused product that differs from the claim,
27 and thus does not literally infringe, nonetheless infringes if its difference from that claim is
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1 insubstantial from the perspective of one of ordinary skill in the relevant art.” *Athletic Alts.*, 73
2 F.3d at 1581 (citation omitted). The doctrine of equivalents, however, “is not a license to ignore or
3 ‘erase . . . structural and functional limitations of the claim,’ limitations ‘on which the public is
4 entitled to rely in avoiding infringement.’” *Id.* at 1582 (quoting *Perkin-Elmer Corp. v.*
5 *Westinghouse Elec. Corp.*, 822 F.2d 1528, 1532 (Fed. Cir. 1987)).

6 “Whether a claim is infringed under the doctrine of equivalents may be decided on
7 summary judgment if no reasonable jury could determine that the limitation and the element at
8 issue are equivalent.” *Zelinski v. Brunswick Corp.*, 185 F.3d 1311, 1317 (Fed. Cir. 1999) (citing
9 *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997)). U Penn argues
10 that, because Genentech’s motion does not seek summary judgment of U Penn’s claim for
11 infringement under the doctrine of equivalents, trial on the question of equivalents is inevitable.
12 Penn Opp’n at 13. Genentech offers no response to U Penn’s position. In any event, because the
13 Court finds triable issues of fact on U Penn’s literal infringement claim, even if Genentech had
14 moved for summary judgment on this ground, the Court necessarily also finds triable issues of fact
15 on U Penn’s claim of infringement by equivalents. Both claims therefore must go to a jury.

16 C. Inducement

17 U Penn accuses Genentech of inducing infringement by actively inducing physicians to
18 prescribe the administration of Herceptin to members of the Adjuvant Population for the treatment
19 of HER2+ ITCs in the bone marrow. Genentech asserts that, even if the Court finds genuine issues
20 of fact as to whether administering Herceptin in the adjuvant setting to act on HER2+ ITCs directly
21 infringes the ’752 patent, summary judgment should still be granted on U Penn’s inducement claim
22 because: (1) U Penn has not put forth sufficient evidence to create a genuine issue of fact as to
23 whether direct infringement occurred; and (2) U Penn has not presented sufficient evidence from
24 which a jury can infer inducement based on Genentech’s instructions to physicians.

25 Patent law provides that “whoever actively induces infringement of a patent shall be liable
26 as an infringer.” 35 U.S.C. § 271(b). Unlike a claim for direct infringement, which requires
27 neither scienter nor mens rea, a claim for actively inducing infringement requires both, as recently
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1 confirmed by the Supreme Court. *See Global-Tech Applicances, Inc. v. SEB S.A.*, 131 S. Ct. 2060,
2 2068 (2011). Thus, to prevail on an inducement claim, a patentee must show “first that there has
3 been direct infringement, and second that the alleged infringer knowingly induced infringement
4 and possessed specific intent to encourage another’s infringement.” *Kyocera Wireless Corp. v.*
5 *Int’l Trade Comm’n*, 545 F.3d 1340, 1353-54 (Fed. Cir. 2008) (internal quotation marks and
6 citation omitted); *accord DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en
7 banc).

8 **1. Evidence of Direct Infringement**

9 To prove direct infringement, a patentee must either (1) “point to specific instances of
10 direct infringement,” or (2) “show that the accused device necessarily infringes the patent in suit.”
11 *ACCO Brands, Inc. v. ABA Locks Mfrs. Co.*, 501 F.3d 1307, 1313 (Fed. Cir. 2007) (citing
12 *Dynacore Holdings corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1275-76 (Fed. Cir. 2004)).
13 Genentech argues that it is entitled to summary judgment on U Penn’s inducement claim because U
14 Penn fails to identify specific instances of direct infringement and because U Penn fails to create a
15 triable issue of fact as to whether Herceptin “necessarily infringes” the ’752 patent.

16 First, Genentech argues that in order for U Penn to show a specific instance of direct
17 infringement under its infringement theory, U Penn “must show that Herceptin administered in the
18 adjuvant setting specifically acts on HER2 overexpressing ITCs to inhibit their development into
19 breast-cancer cells, and not on, for example, HER2 overexpressing micrometastases, which [U
20 Penn] concedes are cancerous.” Genentech MSJ at 19. Based on this understanding of what
21 evidence is required to show direct infringement, Genentech argues that “Penn has not attempted to
22 identify any patient in the accused adjuvant population who had ITCs, but not micrometastases,
23 who was administered Herceptin after surgery, and whose ITCs were inhibited from developing
24 into breast-cancer cells.” *Id.*

25 The Court is not persuaded that there is an absence of material dispute as to direct
26 infringement. Assuming resolution of the dispute over whether ITCs are “breast cancer cells” in
27 favor of U Penn, the non-moving party, the Court finds that U Penn has presented direct evidence
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1 that Herceptin is administered, at least in some instances, in an infringing manner. Specifically, U
2 Penn has done so through expert testimony, physician surveys, and clinical studies collectively
3 showing that: (1) HER2 overexpressing ITCs are detected in the bone marrow of approximately
4 20% to 40% of the Adjuvant Population, *see* Sheasby Decl. Ex. 30 [Pantel Dep.] at 105:11-106:4;
5 (2) Herceptin is administered to the Adjuvant Population to prevent recurrence, *see* Sheasby Decl.
6 Ex. 41 [Rack 2011]; and (3) Herceptin achieves its results via down regulation of the
7 overexpressed p185 receptors on HER2 overexpressing ITCs, as that term has been construed by
8 the Court, i.e., without reliance on ADCC or CDC, *see id.*; Aaronson Decl. ¶¶ 95-103. The Court
9 agrees with U Penn that this evidence is sufficient to establish a triable issue as to whether there
10 were specific instances of direct infringement among the Adjuvant Population.

11 Second, Genentech further argues that U Penn’s inducement claim fails as a matter of law
12 because U Penn cannot prove that any use of Herceptin in adjuvant therapy necessarily infringes.
13 An accused product does not “necessarily infringe” if it “can be used at any given time in a
14 noninfringing manner.” *ACCO*, 501 F.3d at 1313. Genentech posits that “[b]y sweeping the entire
15 adjuvant population into its infringement claim but admitting that only a minority of that
16 population may possess the cells on which its claimed invention operates to prevent transformation,
17 Penn has accused substantial non-infringing uses of Herceptin.” Genentech MSJ at 20-21.
18 However, because U Penn has presented sufficient evidence to create a genuine issue of fact as to
19 whether specific instances of direct infringement exist among the Adjuvant Population, U Penn
20 need not present evidence that use of Herceptin “necessarily infringes” the ’752 patent in order to
21 survive summary judgment.

22 Finally, Genentech argues that U Penn must present evidence “that Herceptin act[s] to
23 ‘inhibit the development’ of p185 overexpressing ITCs without relying on ADCC or CDC” in
24 order to sufficiently support the direct infringement element of its induced infringement claim for
25 the purposes of this Motion. Genentech’s argument is undermined by the fact that Genentech has
26 withdrawn its noninfringement contention based on the down regulation limitation. *See* Sheasby
27 Opp’n Decl. ¶¶ 51-53. In any event, U Penn submits evidence that Herceptin does, in fact, achieve
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1 its results without relying on ADCC or CDC, which is sufficient to raise a triable issue of fact. *See*
2 Aaronson Decl. ¶¶ 95-103. Accordingly, because U Penn has presented sufficient evidence from
3 which a jury could make a finding of direct infringement, summary judgment on this ground is
4 improper.

5 **2. Knowledge and Intent**

6 In addition to proving direct infringement, U Penn must show knowledge and intent to
7 induce such infringement. “[M]ere knowledge of possible infringement by others does not amount
8 to inducement; [rather,] specific intent and action to induce infringement must be proven.”
9 *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003) (citing *Manville Sales*
10 *Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 554 (Fed. Cir. 1990)). Genentech argues that, even
11 assuming that certain uses of Herceptin can infringe the ’752 patent, summary judgment on the
12 inducement claim should be granted in its favor because U Penn has failed to adduce evidence
13 from which a reasonable jury can infer that Genentech possessed the requisite knowledge and
14 intent to induce infringement.

15 “While proof of intent is necessary, direct evidence is not required; rather, circumstantial
16 evidence may suffice.” *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988);
17 *accord AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010). Genentech argues
18 that U Penn has failed to present direct evidence of intent to induce infringement and that U Penn’s
19 circumstantial evidence is insufficient to give rise to a reasonable inference of intent. Genentech
20 argues that it is “undisputedly possible to use the accused [product] as directed without ever
21 practicing the claimed method,” *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1329 (Fed.
22 Cir. 2009), because it is undisputed that Herceptin is administered in the adjuvant setting in several
23 substantial, non-infringing ways, including to treat micrometastases. Genentech MSJ at 19.

24 Genentech relies on *Warner-Lambert*, in which the Federal Circuit rejected the patentee’s
25 arguments that intent to induce infringement could be inferred from the fact that 2.1% of
26 prescriptions written for the accused drug were for an infringing use. 316 F.3d at 1365. The
27 Federal Circuit explained, “[w]here there are many uses for a product, . . . and fewer than 1 in 46
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1 sales of that product are for infringing uses, [the Court is] not in a position to infer or not infer
2 intent on the part [of the accused] without any direct evidence.” *Id.* Genentech is correct that
3 “where a product has substantial noninfringing uses, intent to induce infringement cannot be
4 inferred even when the [alleged inducer] has actual knowledge that some users of its product may
5 be infringing the patent.” *Id.* “[N]on-infringing uses are substantial when they are not unusual,
6 far-fetched, illusory, impractical, occasional, aberrant, or experimental.” *Vita-Mix*, 581 F.3d at
7 1327 (defining “substantial non-infringing use” in the context of contributory infringement under
8 35 U.S.C. § 271(c)). Genentech argues that intent to induce infringement cannot be inferred based
9 on the record presented here because Herceptin has substantial noninfringing uses, such as acting
10 on micrometastases, which the Court has already determined are “breast cancer cells” as defined
11 under the ’752 patent.

12 Nevertheless, while actual knowledge of potential infringement may not be sufficient to
13 infer intent to induce infringement where a product also has substantial noninfringing uses, Federal
14 Circuit cases more recent than *Warner-Lambert* have clarified that “liability for active inducement
15 may be found ‘where evidence goes beyond a product’s characteristics or the knowledge that it
16 may be put to infringing uses, and shows statements or actions directed to promoting
17 infringement.’” *Ricoh Co. v. Quanta Computer Inc.*, 550 F.3d 1325, 1341 (Fed. Cir. 2008)
18 (quoting *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 935 & n.10 (2005)
19 (“*Grokster*”). In other words, even where a product has substantial noninfringing uses, an accused
20 can still be liable for inducement if the patentee establishes the alleged inducer’s “‘affirmative
21 intent that the product be used to infringe.’” *AstraZeneca*, 633 F.3d at 1059 (quoting *Grokster*, 545
22 U.S. at 936 (internal quotation marks and citations omitted)). Such affirmative intent can be
23 proven by presenting “[e]vidence of active steps . . . taken to encourage direct infringement, such
24 as advertising an infringing use or instructing how to engage in an infringing use.” *Id.* (quoting
25 *Grokster*, 545 U.S. at 936) (internal quotation marks and citations omitted)). In *AstraZeneca*, the
26 Federal Circuit found that intent to induce could be inferred where the accused inducer was on
27 notice that the product’s proposed label could cause at least some users to infringe the asserted
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1 method claims by following the label instructions, yet the accused inducer failed to take any action
2 to rectify the label. *AstraZeneca* demonstrates that, to find induced infringement, the Court need
3 not find that the drug label teaches infringement in every instance, so long as “the language . . .
4 would inevitably lead *some* consumers to practice the claimed method.” *Id.* at 1060 (emphasis
5 added).

6 Here, U Penn has presented sufficient evidence from which a jury could infer that
7 Genentech intended to induce infringement of the '752 patent. Specifically, U Penn presents the
8 following evidence of Genentech’s “active steps” to encourage direct infringement: (1) Genentech
9 has known of the '752 patent since it was published as an application in 2000, long before it sought
10 approval for Herceptin in the Adjuvant Population, Aaronson Decl. ¶ 112; (2) the Herceptin Label
11 expressly instructs physicians to use Herceptin in the Adjuvant Population, in which HER2+ ITCs
12 are detected in the bone marrow of 20-40%, as acknowledged by Genentech’s own experts, *see*
13 Sheasby Decl. Ex. 30 [Pantel Dep.], at 105:21-106:4; Sheasby Decl. Ex. 4 [Herceptin Label], at 2;
14 Aaronson Decl. ¶¶ 113-18; Sharma Decl. ¶¶ 26-33; (3) the Herceptin Label does not state that the
15 drug should be used to act on '752 patent breast cancer cells or should not act on ITCs in the
16 adjuvant setting, though Genentech admits it could attempt to draft the label to exclude ITCs if it
17 wanted to do so, Aaronson Decl. ¶¶ 115, 118; (4) Genentech actively markets Herceptin in the
18 Adjuvant Population to prevent “recurrence” and to keep patients “cancer free” via “anti-
19 signaling,” which is understood as teaching action on ITCs by downregulation, Aaronson Decl. ¶¶
20 132-34, 98; Sharma Decl. ¶¶ 31-32; (5) Genentech’s parent company, Roche, funded a
21 sophisticated molecular biological study of patients establishing that Herceptin acts on p185
22 overexpressing ITCs, *see* Sheasby Decl. Ex. 41 [Rack 2011]; Aaronson Decl. ¶¶ 127-30; (6)
23 Genentech markets Herceptin based on the TNM System, which classifies ITCs as M0, and which
24 Genentech experts agree means “no detectable cancer cells at distant locations,” Sharma Decl. ¶¶
25 42, 44, 48-49; and (7) Genentech represents to the public that Herceptin targets malignant and non-
26 malignant tumor cells alike, Aaronson Decl. ¶¶ 85-88.³

27 ³ U Penn has filed an Administrative Motion to File Under Seal Portions of Its Opposition to
28 Genentech’s Motion for Summary Judgment and accompanying exhibits, on which the Court will

1 From these facts, viewed in the light most favorable to U Penn, a jury could find that
2 Genentech knew Herceptin acted on HER2+ ITCs in the Adjuvant Population, that this infringed
3 the '752 patent's method claims, and that Genentech nonetheless continued to encourage this use
4 of Herceptin. This case is therefore distinguishable from *Warner-Lambert*, in which the label did
5 not prescribe using the drug in an infringing manner, and where the proof of actual infringement
6 was relatively minimal (2.1% of prescriptions).⁴ See 316 F.3d at 1365. Accordingly, Genentech
7 has not shown an absence of a triable fact concerning U Penn's inducement claim, and summary
8 judgment on this claim must therefore be DENIED.

9 **D. Invalidity Based on Inadequate Written Description**

10 Finally, Genentech argues in the alternative that, even if whether the '752 patent covers
11 ITCs is not a matter of claim construction, summary judgment should be granted in Genentech's

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13 issue a separate ruling. See ECF No. 532. To the extent this Order recites any material from U
14 Penn's Opposition that U Penn seeks to file under seal, the Court includes only material whose
15 redaction has not been adequately supported by a showing of compelling reasons. See *Kamakana*
16 *v. City & Cnty. of Honolulu*, 447 F.3d 1172, 1178 (9th Cir. 2006).

17 ⁴ Genentech moves to strike from the record pursuant to Federal Rule of Evidence 702 portions of
18 the declarations of Drs. Sharma, Aaronson, and Jensen addressing U Penn's arguments that: (1)
19 "more likely than not," all Adjuvant patients have HER2+ ITCs; and (2) Adjuvant patients receive
20 treatment because they have ITCs, not micrometastases. See ECF No. 541. Genentech also
21 separately objects to the Second Declaration of Dr. Roy Jensen, ECF No. 544 ("Jensen Decl. II"),
22 submitted by U Penn as an attachment to its Reply in Support of U Penn's MSA, to the extent it
23 opines that ITCs are present throughout the Adjuvant Population, on the ground that this opinion
24 was not disclosed during expert discovery. ECF No. 557. However, the case law on inducement
25 does not require U Penn to demonstrate that the administration of Herceptin in the adjuvant setting
26 infringes in every instance, and thus the Court's ruling on Genentech's summary judgment motion
27 does not depend on U Penn's evidence that all Adjuvant patients "more likely than not" have ITCs,
28 even if those ITCs are not detected. Furthermore, the Court's summary judgment ruling does not
depend on U Penn's expert evidence that Herceptin treats ITCs, not micrometastases, because U
Penn has introduced other evidence – such as the Rack 2011 study funded by Roche – that
Herceptin has been found effective specifically when targeted at ITCs. In short, the Court finds U
Penn's evidence that HER2 overexpressing ITCs are detected in the bone marrow of at least 20-
40% of Adjuvant patients, combined with U Penn's evidence of Genentech's awareness of the
effectiveness of administering Herceptin to Adjuvant patients with HER2 overexpressing ITCs in
the bone marrow, sufficient to create a genuine issue of material fact as to inducement. Because
the Court's rulings on the pending summary adjudication and summary judgment motions do not
rely on the disputed declarations, the Court defers ruling on Genentech's motion to strike and will
instead address it along with the parties' other motions *in limine* at the pretrial conference. For the
same reasons, the Court need not rule on Genentech's objection to the Second Jensen Declaration.

1 favor because the asserted claims are invalid due to inadequate written description. To the extent
2 U Penn asserts that the '752 patent covers a method for inhibiting the transformation into cancer
3 cells of non-cancerous p185-overexpressing breast cells outside of the breast, and specifically of
4 ITCs, Genentech contends “there is no evidence that a person of ordinary skill in the art, reading
5 the application that led to the '752 patent, would understand that the applicants possessed a method
6 for treating ITCs.” Genentech MSJ at 25. Genentech points to the absence of any mention of ITCs
7 or any other disseminated tumor cell in the patent’s specification, and argues that the patent
8 therefore fails to disclose a method for treating such cells. Genentech MSJ at 3. Accordingly,
9 under Genentech’s view, the written description of the '752 patent is inadequate, rendering the
10 patent invalid as a matter of law.

11 The “written description” requirement set forth in 35 U.S.C. § 112 provides that “[t]he
12 specification shall contain a written description of the invention, and of the manner and process of
13 making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in
14 the art to which it pertains, or with which it is most nearly connected, to make and use the same,
15 and shall set forth the best mode contemplated by the inventor of carrying out his invention.” 35
16 U.S.C. § 112. “The purpose of the written description requirement is to prevent an applicant from
17 later asserting that he invented that which he did not.” *Amgen, Inc. v. Hoechst Marion Roussel,*
18 *Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003). In other words, the written description requirement “is
19 part of the *quid pro quo* of the patent grant” and ensures meaningful disclosure of what the
20 inventor possessed at the time of the invention. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d
21 1336, 1354 (Fed. Cir. 2010) (en banc).

22 Because patents are presumed to be valid, the party seeking to invalidate a patent based on
23 inadequate written description bears the burden of showing, by clear and convincing evidence, that
24 the claims lack an adequate written description. *See* 35 U.S.C. § 282; *Hynix Semiconductor Inc. v.*
25 *Rambus Inc.*, 645 F.3d 1336, 1351 (Fed. Cir. 2011). Whether the written description requirement
26 is met is typically a fact question for the jury; however, a written description determination “is
27 amenable to summary judgment in cases where no reasonable fact finder could return a verdict for
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1 the non-moving party.” *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir.
2 2008) (citation omitted). The test for determining the sufficiency of the written description “is
3 whether the disclosure of the application relied upon reasonably conveys to those skilled in the art
4 that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad*, 598
5 F.3d at 1351. However, “it is unnecessary to spell out every detail of the invention in the
6 specification; only enough must be included to convince a person of skill in the art that inventor
7 possessed the invention” *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345
8 (Fed. Cir. 2005). “[T]he level of detail required to satisfy the written description requirement
9 varies depending on the nature and scope of the claims and on the complexity and predictability of
10 the relevant technology.” *Ariad*, 598 F.3d at 1351 (citation omitted). Thus, the question presented
11 is whether the specification of the ’752 patent conveys to those skilled in the art that the inventors
12 were in possession of the claimed subject matter on March 30, 1994.

13 Genentech argues that the ’752 patent is invalid for lack of written description because the
14 specification is devoid of any evidence of ITCs and any evidence of non-cancerous p185
15 overexpressing breast cells outside of the breast. See Genentech MSJ at 24. When the
16 specification discloses the invention, the “claims may be no broader than the supporting disclosure
17”⁵ *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1480 (Fed. Cir. 1998). Thus, the
18 Federal Circuit has held a patent invalid based on a lack of written description where the
19 specification discloses an invention that is narrower than the claims of the patent. See, e.g., *Tronzo*
20 *v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed. Cir. 1998) (lack of written description where the
21 specification touted the advantage of a conical shape but the claims imposed no such limitation);
22 *LizardTech*, 424 F.3d at 1345 (lack of written description where the specification described only
23 one embodiment of the invention claimed); *Gentry Gallery*, 134 F.3d at 1480 (lack of written
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26 ⁵ To the extent Genentech’s statement of the law suggests that the test for written description is
27 whether the limitation is an “essential element” of the claimed invention, Federal Circuit case law
28 has clarified that this is not, in fact, the test to be applied to the written description requirement.
Cooper Cameron Corp. v. Kvaerner Oilfield Prods. Inc., 291 F.3d 1317, 1322 (Fed. Cir. 2002).

1 description where the disclosure unambiguously limited the invention beyond the scope of the
2 claims).

3 On the other hand, “[a] claim will not be invalidated on section 112 grounds simply because
4 the embodiments of the specification do not contain examples explicitly covering the full scope of
5 the claim language.” *LizardTech*, 424 F.3d at 1345 (citation omitted). Because the patent
6 specification is written for a person skilled in the art, “such a person comes to the patent with the
7 knowledge of what has come before.” *Id.* (citation omitted). As such, it is unnecessary to spell out
8 every detail in the invention: “only enough must be included to convince a person of skill in the art
9 that the inventor possessed the invention.” *Id.* Thus, the lack of a reference to ITCs or
10 disseminated cells in the ’752 patent does not automatically render Claim 1 invalid for lack of
11 written description, absent evidence that the invention was unambiguously narrower than the
12 claims or that a person of ordinary skill in the art at the time of the invention would understand that
13 the description of the invention is narrower than the claims.

14 Here, the disputed claim language is: “[a] method of inhibiting development into breast
15 cancer cells of breast cells that overexpress p185” ’752 patent 8:49-50. While it is true that
16 the ’752 patent specification neither discusses ITCs nor specifically describes non-cancerous p185
17 overexpressing breast cells outside of the breast, it is not clear on the face of the specification that
18 the claim terms are unambiguously broader than the disclosed invention (as opposed to a disclosed
19 embodiment). Thus, the Court must look to the evidence identified by the parties to determine
20 whether a reasonable trier of fact could find that U Penn possessed and disclosed the invention that
21 U Penn is now asserting. *See PowerOasis, Inc.*, 522 F.3d at 1307; *Ariad*, 598 F.3d at 1355.

22 Genentech is correct that evidence of what a person of ordinary skill in the art knew must
23 arise at the time of the filing date in 1994. Evidence regarding what a person of ordinary skill in
24 the art knows now is not legally relevant. *See Ariad*, 598 F.3d at 1355-56. For example, in *Ariad*,
25 the Federal Circuit reversed a jury determination that the patent in suit was not invalid for lack of
26 written description because most of the evidence presented by the patent-holder was “irrelevant to
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1 the question whether the inventors were in possession of the claimed invention as of the 1989
2 priority date.” *Id.* at 1357.

3 In this case, based on the evidence provided by the parties, there is sufficient evidence from
4 which a reasonable jury could conclude that the inventor possessed and disclosed a method “of
5 inhibiting development into breast cancer cells of breast cells that overexpress p185,” where breast
6 cells that overexpress p185 included ITCs. The specification does not limit the term “breast cells
7 that overexpress p185” to cells located in the breast. Indeed, in construing this term, the Court
8 rejected Genentech’s argument to include a locational limitation. *See Markman* Order at 12. U
9 Penn has provided expert evidence that by 1994, researchers understood that human p185
10 overexpressing breast cells could exist both inside and outside of the breast but were not “breast
11 cancer cells.” *See Jensen Decl.* ¶¶ 128-72, 324-30. U Penn has further introduced evidence that by
12 1994, persons of ordinary skill in the art understood that ITCs and micrometastases were
13 biologically distinct entities, and that ITCs lacked the ability for uncontrolled growth. *See Jensen*
14 *Decl.* ¶¶ 128-72. This evidence suggests that a person of ordinary skill in the art may have
15 understood the invention to apply to ITCs. Although Genentech disputes this evidence, and argues
16 that there is no intrinsic evidence in the ’752 patent that the invention applies to disseminated cells,
17 there is sufficient evidence in the record from which a reasonable jury could find in U Penn’s favor
18 regarding what a skilled artisan understood the scope of the invention to be at the time of the filing
19 of the patent application.

20 Construing the evidence in the light most favorable to U Penn, a reasonable jury could find
21 that the ’752 patent’s disclosure of a “method of inhibiting development into breast cancer cells of
22 breast cells that overexpress p185” conveys to those skilled in the art that the inventor had
23 possession of a method of inhibiting ITCs from developing into breast cancer cells at the time of
24 the invention. Accordingly, Genentech’s motion for summary judgment based on inadequate
25 written description is DENIED.

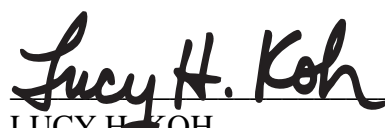
26 **IV. CONCLUSION**

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For the reasons stated herein, the Court’s construction of the disputed claim term “breast cancer cell” remains as set forth in the May 24, 2011 *Markman* Order, ECF No. 241. U Penn’s Motion for Summary Adjudication is: (1) DENIED as to the fact that ITCs are breast cancer cells for purposes of the ’752 patent; and (2) DENIED as to the fact that Herceptin can act on ITCs to inhibit them from becoming cancer cells. Genentech’s Motion for Summary Judgment is DENIED. The pretrial conference remains as set for May 30, 2012, at 2:00 p.m., and trial will begin on June 11, 2012, at 9:00 a.m.

IT IS SO ORDERED.

Dated: May 14, 2012



LUCY H. KOH
United States District Judge