UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

GENENTECH, INC., Plaintiff, v. THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, Defendant.	Case No.: C 10-2037 PSG **ORDER GRANTING-IN-PART DEFENDANT'S MOTION TO COMPEL** **(Re: Docket No. 288)**

In this patent infringement suit, Defendant and Counterclaim-Plaintiff The Trustees of the University of Pennsylvania ("Penn") moves to compel Plaintiff Genentech, Inc. ("Genentech") to produce documents responsive to Penn's request for production ("RFP") nos. 29, 34, 69, and 97, as well as responses to Penn's interrogatory nos. 17 and 18. Having considered the letter briefs, oral argument, evidence and authority presented by both parties, Penn's motion to compel is GRANTED-IN-PART.

I. BACKGROUND

On July 26, 2010, Penn served its first set of requests for production of documents to Genentech. This set includes RFP no. 29, which is the subject of the court's order of June 16, 2011 ("June 16 Order") granting in part Penn's previous motion to compel.[1] RFP no. 29 requests:

[1] *See* Docket No. 272.

> Documents sufficient to describe the results of all studies or experiments, or analysis of data, related to the mechanism of action of Trastuzumab, Pertuzumab, the antibodies designated as 4C8, 3E8, 3H8, 7.16.4, 7.5.5, 7.9.5, 7.21.2, or any other antibodies that bind to HER2, neu, or p185.[2]

In its June 16 Order, the court concluded that RFP no. 29 is appropriately limited to "documents *sufficient to describe* the results of all studies or experiments, or analysis of data related to the mechanism of action" of Herceptin and the recited antibodies in breast cells that overexpress p185 and that are not breast cancer cells.[3] The court ordered that Genentech conduct a "reasonable search" for these documents, including checking email records of lead researchers, interviewing researchers and scientists, searching for experiments regarding the 4D5 antibody after production in previous litigation, and searching internal presentations, summaries, and reports that relate to the defined criteria.[4]

Even prior to the June 16 Order, Genentech had produced a substantial number of documents relating to the mechanisms of action of Herceptin and the antibodies 4D5 and 7.16.4, including "over one million pages of responsive documents."[5] After the court's order, counsel interviewed Genentech's lead scientists on the issues directed by the court and produced additional, non-privileged materials, including minutes and presentations by several Herceptin teams at Genentech and materials from its research and development review committees.[6] Counsel also followed up with several individuals listed by a Genentech senior staff scientist in his deposition as "knowledgeable" or "qualified" to testify about the issue of "disseminated tumor cells and their

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[2] Docket No. 289, Ex. A.

[3] Docket No. 272 at 5:9-10 (emphasis in original).

[4] *Id.* at 10:17-11:1.

[5] *Id.* at 2:13-22.

[6] Docket No. 305-3 ¶¶ 4, 7, 8.

presence in patients, in the context of breast cancer."[7] Except for one set of documents already produced to Penn, Genentech found that none of the individuals had responsive documents.[8] In August 9, 2011, after several attempts to resolve disagreements over the sufficiency of this response to RFP no. 29 and the June 16 Order, Penn filed the motion now before the court.

Additionally, Penn challenges a number of Genentech's responses to Penn's other requests, specifically RFP nos. 34, 69, and 97, as well as Interrogatory nos. 17 and 18.

In RFP no. 34, Penn requests:

> Documents sufficient to describe the results of all studies or experiments, or analysis or data, related to the phenotype, genotype and other characteristics of cells involved in the spread of metastatic disease, and all internal presentations or discussions relating to the foregoing.[9]

Initially, Genentech stated a wide range of general objections to RFP no. 34, focusing especially on the phrase "all studies or experiments, or analysis of data."[10] It then offered to meet and confer with Penn regarding the scope of the request. Despite those attempts, Genentech continues to argue that RFP no. 34 is too broad and seeks discovery on issues far beyond the scope of this lawsuit.

A similar stalemate exists with respect to the other disputed matters. In RFP no. 69, Penn requests "[a]ll documents relating to whether Trastuzumab acts on breast cells that overexpress HER2 but that are outside of the breast."[11] Genentech responded that it was not aware of any responsive documents based on its stated interpretation of the request.[12] RFP no. 97 asks for "[a]ll documents relating to studies on ductal carcinoma in situ, circulating tumor cells, disseminated

[7] *Id.* ¶ 5.

[8] *Id.*

[9] Docket No. 289, Ex. A.

[10] *See id.* Ex. B.

[11] *Id.* Ex. C.

[12] Genentech interpreted RFP 69 as (1) being "directed to breast cells in human patients that receive Herceptin and not to cell lines," and (2) presuming "breast cells that overexpress HER2" to exclude cancer cells. *Id.* Ex. D.

tumor cells, and step cells that overexpress HER2."[13] For RFP no. 97, Genentech agreed, subject to numerous objections, to produce responsive documents relating to circulating tumor cells ("CTCs") and disseminated tumor cells ("DTCs") "to the extent they exist and can be located after a reasonable search."[14]

Penn remains dissatisfied with the scope of Genentech's responses, particularly as they relate to which cells are subject to discovery and whether Genentech believes those cells to be relevant in light of the court's claim construction. On largely these same bases, Penn claims that Genentech also has failed to respond fully or fairly to its Interrogatory nos. 17 and 18. Genentech argues that it is unable to respond to Penn's requests relating to at least one disputed cell category – the "isolated tumor cell" – because it constitutes a recently adopted, "newly-coined and thoroughly confused term" introduced by Penn as a means to obtain otherwise off-limits discovery. Otherwise, Genentech argues, it already has responded properly and in full to the RFPs and interrogatories raised in this motion.

II. LEGAL STANDARD

Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense. Relevant information need not be admissible at trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence. The court must limit the frequency or extent of discovery if it is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, or the burden or expense of the proposed discovery outweighs its likely benefit.[15]

[13] *Id.* Ex. C.

[14] *Id.* Ex. D.

[15] *See* Fed. R. Civ. P. 26.

III. DISCUSSION

A. June 16 Order and Requests for Production Nos. 29, 34, 69, 97

In a series of communications following the June 16 Order, Penn and Genentech dispute the sufficiency of Genentech's response to RFP nos. 29, 34, 69, and 97 and the June 16 order, specifically with respect to (1) the categories of cells subject to the requests and the June 16 Order, (2) the follow up with Genentech scientists and researchers identified as knowledgeable on key issues, (3) the level of p185/HER2 expression that qualifies as "overexpressing" for the purpose of producing discovery, and (4) whether Genentech is limiting its discovery efforts to include only *in vivo* patient research.

Penn notes that under the June 16 Order, Genentech must produce relevant documents pertaining to "HER2 overexpressing mammary epithelial cells that are not cancer cells" and are present at locations distant from the breast. According to Penn, this requires production of documents concerning isolated tumor cells ("ITCs")[16] and cancer stem cells ("CSCs"), in addition to DTCs and CTCs.

Genentech disputes this characterization of ITCs and CSCs and the manner in which Penn has introduced "new" terms into the litigation without clear definition. First, Genentech disputes Penn's assertion that ITCs and CSCs are not cancer, because Penn's own authorities suggest that ITCs and CSCs have the ability for uncontrolled growth. Genentech also states that Penn's "evasive, circular and inconsistent" references to what ITCs are or where they are found make it unclear whether ITC is simply a generic term for both DTCs and CTCs, in which case Genentech already has agreed to produce documents.[17] Finally, noting that Penn does not refer to ITCs either in the pending document request or in its briefings to the court during the previous motion to

[16] *See* Docket No. 289, Ex. V at 13-14 (describing ITCs as "individual or small groups of cells, that, among other things, 'do not typically show evidence of metastatic activity (e.g., proliferation)'").

[17] *See* Docket No. 305 at 2.

compel on RFP 29, Genentech argues that Penn actually is seeking reconsideration of the June 16 Order by demanding that Genentech update its document production to include ITCs.[18]

Penn is right that, even if certain ITCs and CSCs satisfy the court's "cancer" construction, and therefore fall outside the scope of appropriate discovery, this does not justify withholding discovery of all ITC and CSC-related studies that are otherwise relevant. As Genentech's expert Dr. Cote has explained, "[t]umor can refer to cancer and often does refer to cancer but tumor can also refer to non cancerous conditions."[19] Dr. Cote further explained that CSCs "have been demonstrated to exist as a subpopulation in DTCs."[20] To the extent that Genentech has performed otherwise relevant studies on ITCs and CSCs that lack malignant form and structure, the ability for uncontrolled growth, or the potential or ability to invade or metastasize, Penn is entitled to discovery on them.

As to Penn's assertions that Genentech has failed to follow up with key scientists and researchers, has used an arbitrary cut-off for the level of p185/HER2 expression that qualifies as "overexpressing," and has limited discovery efforts to include only *in vivo* patient research – the declarations of Genentech's counsel indicate otherwise. Nonetheless, there are a few gaps in Genentech's follow up to the June 16 Order that require a limited, supplemental discovery response.

First, Genentech must follow up with those researchers listed by Dr. Sliwkowski as knowledgeable or qualified to speak about the presence in patients of DTCs, pursuant to the June 16 Order to "conduct a reasonable search, *including* checking the email records of its lead researchers for internal studies or presentations, interviewing researchers to determine what studies

[18] Genentech cites June 16, 2011 as the first instance that Penn referred to ITCs. *See* Docket No. 305-4 ¶ 8.

[19] Docket No. 320, Ex. C at 5.

[20] *See* Docket No. 289, Ex. Z-2 at 7.

were performed, [and] speaking with its scientists who conduct research on the antibodies specified."[21] Dr. Sliwkowski's use of a qualifier prior to listing the individuals' names does not negate the fact that they may have relevant information that could lead to the discovery of admissible evidence. The fact that Genentech followed up and found only one person to have such information indicates that no further action is required with respect to that person. However, it is not clear from counsel's declaration whether Genentech interviewed ***all*** of the individuals listed.[22] The court agrees with Penn that Genentech must conduct a reasonable search with respect to all the researchers named by Dr. Sliwkowski, to ensure that no relevant and producible documents have been overlooked. To the extent that Genentech's counsel has not at least conducted an initial inquiry by interviewing each of the researchers on the list, the court finds it reasonable to require Genentech to do so.

Second, Genentech may not refuse to search for cells identified according to the same standard that is used in Penn's infringement contentions, specifically, "based on the fact that they stain for HER2 using immunohistochemistry (or show any amplification of the HER2 gene locus)."[23] Genentech notes simply that it refused only to search for all cells that stain for HER2 because the request was not limited to non-cancer cells or breast cells, and it would be unreasonable for Genentech to produce documents about the various normal cells and non-breast cancer cells that meet this standard. The court agrees that, to the extent Penn's request seeks documents on cells that stain for HER2 and are either cancerous or non-breast cells, Genentech need not respond. However, Genentech must respond regarding breast cells that overexpress p185

[21] Docket No. 272 at 10:17-20 (emphasis added).

[22] *See* Docket No. 305-3 (stating that counsel "followed up with individuals [Dr. Sliwkowski] had identified as possibly qualified to testify…." and determined not to collect e-mails from the individuals identified "because there was no reason to expect that there would be responsive information").

[23] *See* Docket No. 289, Ex. S at 3.

and are not cancer cells, and that stain for HER2 using immunohistochemistry or show any amplification of the HER2 gene locus.

Finally, Genentech disputes Penn's contention that it is limiting discovery efforts to Herceptin's effect on CTCs or DTCs in patients only. Genentech states that it has researched and produced discovery on both *in vivo* and *in vitro* research on CTCs and DTCs.[24] Given Genentech's sworn assertions to this effect, and the absence of any evidence to the contrary, the court finds this part of Penn's motion to compel to be without merit.

B. Interrogatory Nos. 17 and 18

On April 6, 2011, Penn served Interrogatory nos. 17 and 18 on Genentech as part of its sixth set of interrogatories. The same general arguments outlined above underlie Penn's motion to compel additional substantive response to these interrogatories.

1. Interrogatory no. 17

Interrogatory no. 17 states:

> Fully describe all data or analysis addressing whether TRASTUZUMAB acts on cells (including, but not limited to, mammary epithelial cells and including cells at locations outside of the breast) that overexpress HER2 but do not exhibit one or both of the properties of uncontrolled growth and invasiveness, identify all individuals at Genentech knowledgeable about the subject, and identify all documents relating to the above data or analysis.[25]

Through subsequent meet and confers and correspondence, Penn agreed to limit the scope of Interrogatory 17 such that Genentech need not respond as to cells that are not invasive but possess the property of uncontrolled growth; Penn also provided guidance for what constitutes "uncontrolled growth."[26] Yet according to Penn, Genentech nevertheless refuses to respond substantively by addressing the existence of any of the disputed cell types (i.e. ITCs, DTCs, CTCs,

[24] *See* Docket No. 305-3 ¶ 6; Docket No. 305-4 ¶¶ 9, 10.

[25] Docket No. 289, Ex. E.

[26] *Id.* Ex. P at 2.

or CSCs), even though whether, and to what extent, the cells at issue grow uncontrollably or are invasive is relevant to the question of whether they have the ability to do so.

Genentech objects to Interrogatory no. 17 on multiple grounds, including that it is overbroad and burdensome because it is "not limited to whether Trastuzumab acts on breast cells," and vague and ambiguous because "'at any given moment in time, it would be impossible to determine … whether a particular cell exhibits one or both properties' of uncontrolled growth or invasiveness."[27] Genentech also argues that the data Interrogatory 17 requests is rendered irrelevant under the claim construction, because it relates to cells that do not exhibit uncontrolled growth or invasiveness, rather than cells with the ability for uncontrolled growth and invasiveness.[28] And finally, Genentech contends that Penn now improperly seeks to transform the interrogatory into a new question about DTCs, CTCs, CSCs, and ITCs.

The court agrees with Penn that the characteristics of uncontrolled growth and invasiveness – or lack thereof – are relevant to whether the cells may exhibit the ability to do so. In this case, the difference between the court's construction and Penn's phrasing of the interrogatory does not render the question irrelevant: while *the ability for* uncontrolled growth is a necessary precursor to exhibition of that characteristic (and if known would definitively remove that cell or data from the scope of discovery), *an absence of* uncontrolled growth does not preclude the possibility that the cell nevertheless has the ability to develop the characteristic, and thus may remain within the scope of discovery.

In other words, Genentech need not describe data or analysis on breast cells for which the ability for uncontrolled growth or invasiveness is established, even if those cells do not yet exhibit such characteristics. But it must respond as to cells that do not exhibit uncontrolled growth and

[27] *See id.* Ex. F (quoting Docket No. 305, Ex. F at 169:17-21).

[28] *See id.* Ex. O at 4.

invasiveness but for which the ability to do so remains. To the extent there is any doubt about the ability of a particular cell type for uncontrolled growth, Genentech should err on the side of responding.

As to Genentech's contention that Penn seeks to transform Interrogatory no. 17 into a new question about DTCs, CTCs, CSCs, and ITCs, those cell types are necessarily included in the interrogatory to the extent that their definitions meet the description put forth by the interrogatory, *e.g.*, breast cells acted on by Herceptin, including but not limited to mammary epithelial cells and including cells at locations outside of the breast, that overexpress HER2 but do not exhibit one or both of the properties of uncontrolled growth and invasiveness.

2. Interrogatory no. 18

Interrogatory no. 18 states:

> Fully describe all data or analysis addressing whether TRASTUZUMAB acts on breast cells that overexpress HER2 but that are outside of the breast, identify all individuals at Genentech knowledgeable about the subject, and identify all documents relating to the above data or analysis.[29]

Genentech states that it understands the phrase "breast cells that overexpress p185" to refer to non-cancer breast cells, consistent with the claim term of the '752 patent. Based on this understanding, it initially responded that it is "unaware of any non-cancer breast cells that overexpress p185 but are outside of the breast" and that there is "no evidence that Trastuzumab acts on breast cells that overexpress HER2 but are outside of the breast."[30] Subsequently, Genentech agreed to provide supplemental discovery specifically as regards CTCs and DTCs, but not ITCs or CSCs.[31]

[29] *Id.* Ex. E.

[30] *See id.* Ex. F at 12.

[31] *See* Docket No. 305-1 ¶ 14.

Genentech's stated purpose behind this concession was to "specifically state why [Genentech] believes HER2 overexpressing breast CTCs and DTCs are cancer cells."[32]

According to Penn, Genentech's response amounts to a refusal to acknowledge that other cell types, including ITCs and CSCs, must be included as "breast cells that overexpress HER2 but that are outside of the breast." Genentech responds by reiterating its frustration with the term ITC as one that Penn recently introduced into the litigation, has failed to define clearly, and that appears either to be a generic term for DTCs or CTCs or to be something else that actually falls *within* the court's construction of cancer.

For the same reasons set forth in the court's earlier directive to the parties regarding ITCs and CSCs, Genentech may not avoid otherwise legitimate discovery simply because the discovery relates to an ITC or CSC. Accordingly, Genentech shall respond to this interrogatory with respect to any ITC or CSC that does not meet any one of the three requirements for "cancer" set forth by Judge Koh.

IV. CONCLUSION

No later than October 14, 2011, Genentech shall provide the discovery required by this order. All other relief requested by Penn is denied.

Dated: September 19, 2011

PAUL S. GREWAL
United States Magistrate Judge

[32] *See id.*