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 LHK (PSG) **ORDER DENYING DEFENDANT'S MOTION TO STRIKE PORTIONS OF EXPERT REPORTS AND DENYING PLAINTIFF'S CONDITIONAL MOTION TO STRIKE** **(Re: Docket No. 447, 462)**

In this patent infringement suit, Defendant and Counterclaim-Plaintiff The Trustees of the University of Pennsylvania's ("the University") moves to strike sections of three expert reports offered by Plaintiff Genentech, Inc. ("Genentech"). Genentech opposes the motion. Genentech in response has moved to strike numerous expert report sections offered by the University. Genentech presents its motion as "conditional," to merit consideration only if the court adopts the University's position regarding the degree of alignment required between infringement or invalidity contentions and expert reports. The parties appeared for hearing on January 31 and February 7, 2012. Having considered the arguments and evidence presented, the court DENIES both motions.

I. STATEMENT OF ISSUES

The University seeks to exclude various portions of Genentech's expert reports that allegedly contain opinions offering "numerous new invalidity and inequitable conduct theories never disclosed in Genentech's invalidity contentions or pleadings."[1] The University complains about two classes of information – selections from the Clynes, Henderson, and Park Reports that purportedly advance theories not disclosed in Genentech's invalidity contentions, and assertions in the Henderson Report not alleged in Genentech's inequitable conduct claims.[2] Genentech disputes that the material identified by the University improperly exceeds the scope of Genentech's earlier disclosures and pleadings. Genentech criticizes the University's exacting approach as requiring "a party to plead or convey in patent rule disclosures every fact that will be included in its expert reports" – a position it argues is unsupported by case law or the federal and local rules.[3]

II. DISCUSSION

The court begins with the three invalidity theories and theories of inequitable conduct that the University highlights in its letter brief. Although the University challenges many additional instances as set forth in the supporting Wells Declaration – arguably in violation of the page limits for letter briefs set by this court – the court will refrain from addressing these additional challenges unless it finds merit in the University's position with respect to the passages it included in its letter brief.[4]

A. Theories Supporting Invalidity Contentions

Patent Local Rule 3-3 requires detailed disclosures of a party's invalidity contentions. These include, in relevant part: the identity of each item of prior art that allegedly anticipates each

[1] *See* Docket No. 447 at 1 (Def.'s Mot. to Strike).

[2] *See* Docket No. 448, Ex. 1 (Opening Expert Report of Dr. Raphael Clynes) ("Clynes Report"); Ex. 2 (Opening Expert Report of Dr. Craig Henderson) ("Henderson Report"); Ex. 3 (Opening Expert Report of Dr. John W. Park) ("Park Report").

[3] *See* Docket No. 456 at 2 (Pl.'s Opp'n to Mot. To Strike).

[4] *Cf. Oracle America, Inc. v. Google Inc.*, No. C 10-3561 WHA, 2011 WL 4479305, at *1 (N.D. Cal. Sept. 26, 2011) (noting the court had limited defendant to raising "three points of critique" respecting plaintiff's expert report, with the understanding that defendant would be permitted to raise additional points if it succeeded on the merits of the first three).

asserted claim or renders it obvious; whether the prior art anticipates the asserted claim or renders it obvious, and why (in the case of obviousness); and any grounds of invalidity based on enablement or written description under 35 U.S.C. § 112(1) of any of the asserted claims.[5] The purpose of the disclosure rules is "to further the goal of full, timely discovery and provide all parties with adequate notice of and information with which to litigate their cases."[6] In analyzing disclosures in the parallel context of infringement contentions pursuant to Patent L.R. 3-1, courts have distinguished between the "required identification of the precise element of any accused product" alleged to practice a particular claim limitation, and "every evidentiary *item of proof* showing that the accused element did in fact practice the limitation."[7]

Here, the court similarly looks to the nature and scope of the theory of invalidity disclosed and whether the challenged report section merely provides an evidentiary example or complementary proof in support thereof, or itself advances a new or alternate means by which the jury could find the claim at issue invalid. At a minimum, a key consideration for the court is the timing of the disclosure in relation to when the disclosing party had the information and when the opposing party would have needed the information in order to fairly conduct discovery or prepare a responsive strategy. The court must further consider the nature of the information being disclosed, whether it is subject to any work-product or other privilege, and whether a failure to disclose prior to serving expert reports prejudiced the opposing party. The goal of all this is to respect a party's legitimate need to refine its case and develop its positions while preventing litigation by ambush.

The University identifies the following three theories in its letter brief. The court addresses each in turn.

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[5] *See* Patent L.R. 3-3(a), (b), (d).

[6] See *IXYS Corp. v. Advanced Power Tech., Inc.*, No. C 02-3942, 2004 WL 1368860, at *3 (N.D. Cal. June 16, 2004).

[7] *See Oracle America, Inc.*, 2011 WL 4479305, at *3 (emphasis in the original). *See also Fenner Invs., Ltd. v. Hewlett-Packard Co.*, 2010 U.S. Cist. LEXIS 17536, at *2 (E.D. Tex. Feb. 26, 2010) ("The scope of infringement contentions and expert reports are not, however, coextensive. Infringement contentions need not disclose 'specific evidence nor do they require a plaintiff to prove its infringement case.'") (quoting *EON Corp. IP Holdings, LLC v. Sensus USA, Inc.*, No. 6:09–cv–116, 2010 WL 346218, at *2 (E.D. Tex. Jan. 21, 2010)).

1. Inadequate written description of the antibodies defined by claim 17 because the patent fails to identify antibodies that bind to the same epitope as the 7.16.4 antibody.[8]

The University argues that while Genentech's contentions do not suggest a theory of invalidity based on written description pertaining to claim 17, the Clynes report expressly suggests that claim 17 lacks written description because the patent fails to identify any antibodies that bind to the same epitope as the 7.16.4 antibody. Genentech responds that its contentions do explain that the asserted claims lack written description and are not enabled as to the full claim scope because the patent broadly claims a "genus" of antibodies with properties listed in the claims, yet provides no example other than the 7.16.4 antibody itself.[9] Indeed, the following contention language specifically disputes the sufficiency of the disclosure because of its failure to identify any antibody that competes for binding with 7.16.4: "The 7.16.4 antibody is the only antibody disclosed in the specification that allegedly down regulates p185 when administered in undisclosed 'sufficient amounts.' It is the only antibody disclosed that would compete with itself for binding to p185."[10] Because the patent itself teaches that competitive binding takes place at the same epitope,[11] this is more than sufficient to justify Clynes' discussion.

2. Data regarding "low-dose" group of treated mice as differentiated from "high-dose" mice in the specification not knowable and unable to support the claim.[12]

The University argues that Clynes' assertions regarding the "low-dose" mice group tread on the court's earlier rejection of Genentech's proposed amendments to the invalidity contentions that would have added theories based on the same mouse data. Genentech responds that Clynes'

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[8] *See* Clynes Report ¶¶ 573-77.

[9] *See* Docket No. 458 at 6-7 (citing Docket No. 460, Tiu Decl., Ex. A (Pl.'s Invalidity Contentions at 1:19-20, 1:22-24, 2:18-22, 3:5-10)).

[10] *See* Pl.'s Invalidity Contentions at 1:22-24.

[11] *See* Docket No. 448, Ex. 4 (U.S. Patent No. 6,733, 752 (filed May 11, 2004)) (claiming "[t]he method of claim 1 [… administering … an antibody which competes with an antibody produced by cell line ATCC Deposit. No. 10493 for binding to p185 and specifically binds to p185 in sufficient amount to down regulate the overexpressed p185 …] wherein said antibody binds to an epitope bound by the antibody produced by cell line ATCC Deposit No. 10493").

[12] *See* Clynes Report ¶¶ 425, 504.

opinion goes to the meaning of the patent claim regarding the requirement that the antibodies "inhibit the development" into breast cancer cells of breast cells that overexpress p185, not to proving invalidity under § 112, which the court clearly disallowed. Genentech explains that Clynes' reference to the low-dose data helps establish how a person skilled in the art would have understood the '752 experiment results with respect to the claimed method of "inhibiting development."[13] According to Genentech, this use of the data is consistent with the court's earlier ruling on amending its contentions, and in fact is appropriate in light of the patent having advanced differing theories as to what "inhibit the development" of breast cells overexpressing p185 into cancer cells, and of the court having declined to construe the particular term "inhibiting development."[14]

The court accepts Genentech's disavowal of any intention to rely on the low-dose and control mouse data for a § 112 defense. Based on Genentech's representations to that effect, the court finds no attempt by Genentech to commit an "end run" around the court's earlier order denying Genentech its motion to amend invalidity contentions. So long as Clynes relies on the low-dose and control data only to demonstrate his understanding of the method being claimed by the '752 patent as sufficient for inhibiting development of cancer cells, and not to use the low-dose or control data as evidence of a lack of written description or enablement, the court agrees that the reference in paragraphs 425 and 504 of the Clynes report may stand.[15]

[13] *See* Docket No. 458 at 6 (Kushan Decl.) (citing Pl.'s Invalidity Contentions at 6:11-15; 6:20-22; 8:10-19).

[14] *See id.* at 6. *See also* Docket No. 214 at (Order Construing Disputed Claim Terms of U.S. Patent No. 6,733,753) ("[I]n light of the constructions of 'down regulation' and 'breast cancer cells,' the court finds that the term 'inhibiting development into breast cancer' needs no further construction.").

[15] To the extent that Genentech intends to use Clynes' references at trial in support of asserting a claim term meaning that the presiding judge already determined needs no further construction, the undersigned leaves to the presiding judge any further determination of whether Genentech's effort is proper.

3. References to known history of clinical trials establishing course of development of adjuvant therapy.[16]

Turning to the Henderson report, the University argues that some twenty references to clinical trials not listed in the contentions "go beyond" the infringement contentions' disclosures related to obviousness. Genentech responds that Clynes' references provide background or details on what the person of ordinary skill in the art would know about adjuvant therapy and clinical trials for breast cancer, but are not the specific prior art that Genentech contends anticipate or render the patent obvious. According to Genentech, the references that it intends to rely on for invalidity purposes appear in Henderson's report at ¶¶ 90-97 and mirror the invalidity contentions. Genentech further argues that these additional references are no different from the numerous references appearing in the University's Aaronson report related to research not disclosed in its infringement contentions.

The University requires too much. The fact that a reference to a particular clinical trial was not disclosed in the invalidity contentions does not render it unusable for laying an historical foundation to research that was disclosed. Based on Genentech's representation that it will rely only on disclosed clinical trials as direct evidence of obviousness, and not any of the twenty references cited as background by Clynes, the court will not impose a strict rule against additional, supporting references.[17]

B. Theories Supporting Inequitable Conduct Claims

The University also complains of selections from the Henderson report that purportedly advance theories or facts not set forth in Genentech's inequitable conduct claims.[18] As with the invalidity theories, the University urges the court to strike these assertions, arguing they violate the particularized pleading requirements attached to any claim of inequitable conduct. In addition, the University argues that the references made in Genentech's expert reports come too late, because

[16] *See* Henderson Report ¶¶ 78-89, 96.

[17] *Cf. Oracle America, Inc.*, 2011 WL 4479305 at *3 ("That a particular document or source code file was not cited in a party's infringement disclosures does not automatically preclude the party from using that document or file to support a *theory* that was timely disclosed.").

[18] As above, the court will address only those portions of the reports that the University challenges in the body of its letter brief.

Genentech held onto the data for many months and failed to supplement in a timely manner its interrogatory responses under Fed. R. Civ. P. 26(e)(1)(A) or to seek leave to amend.

Like other allegations sounding in fraud, inequitable conduct must be pled with particularity under the federal rules.[19] This requires a party pleading inequitable conduct to "give notice to the other party of the facts on which the defense is premised."[20] Such notice must include specifically the individuals allegedly associated with the misconduct ("who"), what has been withheld and to what claims or references the withheld material is relevant (the "what" and "where), as well as "why" the information is material and "how" the patent examiner would have used this information.[21] The court thus reviews the challenged assertions for whether the University received appropriate notice based on Genentech's First Amended Complaint ("FAC") or timely disclosures during discovery, of the facts relied on in the expert reports.

In the FAC, Genentech pleads three categories of misrepresentation or "deceptions" in support of inequitable conduct.[22] Relevant here is Genentech's allegation that the University scientists Greene and Katsumata misrepresented "material experimental data" regarding the high-dose mice that remained tumor-free for more than ninety weeks.[23] Because the FAC alleges misrepresentation of the data only with respect to the high-dose treated mice, the University challenges Henderson's references to the low-dose and control group data as constituting "new and different theories of inequitable conduct related to mice."[24] The University specifically challenges Genentech's references to various data regarding the control and low-dose mice groups, including the size of the groups, how many developed cancer in the control group, and the p-value associated

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[19] *See Evergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009); *see also* Fed. R. Civ. P. 9(b).

[20] *See Cent. Admixture Pharm. Servs. v. Advanced Cardiac Solutions, P.C.*, 482 F.3d 1347, 1356-57 (Fed. Cir. 2007).

[21] *See Evergen Corp.*, 575 F.3d at 1329-1330.

[22] *See* Docket No. 241 ¶¶ 38-104 (Pl.'s First Amended Compl.) ("FAC").

[23] *See id.* ¶¶ 38-58.

[24] *See* Docket No. 447 at 4.

with average tumor onset in the low-dose group.[25] The University further contends that it has suffered prejudice based on Genentech's failure to disclose these "theories" early enough for the University to undertake relevant fact discovery or scientific testing, even though Genentech had the data sheets for months and could have supplemented its discovery responses earlier or included this information in its March 2011 motion for leave to amend its complaint.

Genentech responds that far from advancing new inequitable conduct facts or theories, its experts have "simply marshaled evidence that Genentech either months ago disclosed to UPenn, or that UPenn itself produced, to demonstrate why the false research results UPenn pass off about its high-dose mice experiment are material."[26] According to Genentech, the data on the control and low-dose groups represents nothing but "facts adduced to support the originally-pleaded fraud" and demonstrates not a new theory, but the "overall disregard for scientific rigor throughout the ['752 patent] experiment." Such disregard underscores "the materiality of the lie" told about the high-dose group and rebuts the University's anticipated position at trial that the misrepresentations amounted to "honest mistake."[27] Genentech also disputes any prejudice to the University, pointing out that in addition to supplementing its interrogatory responses at the close of discovery – *after* which the University deposed both of Genentech's witnesses on the transgenic mice experiments – Genentech thoroughly deposed the University's own witness, Dr. Greene, on the low-dose and control group data in July 2011.[28]

Henderson's references pertaining to the control and low-dose mouse data indeed fall outside the express allegations in the FAC, which are premised on Greene and Katsumata's misrepresentations regarding the high-dose group. The court thus agrees that insofar as proving its theory of inequitable misconduct based on the reporting of mouse data, Genentech may not rely on the low-dose and control data as one of the pled "deceptions." The court also agrees, however, that

[25] *See* Henderson Report ¶¶ 132-35, 138-39.

[26] *See* Docket No. 456 at 1.

[27] *See id.* at 2.

[28] *See id.* (citing Docket No. 459, Thayer Decl., Ex. K (Greene Dep. at 155-158)).

alleged false reporting of data related to the size of the mouse groups, how many developed cancer in the control group, and the p-value associated with average tumor onset in the low-dose group also are relevant to support Genentech's allegations regarding the high-dose group. This is, in fact, the approach that Henderson takes in his report,[29] and Genentech clearly set forth its position regarding the relevance of the control data to the materiality of the claim regarding the high-dose data in its supplemental interrogatory responses.[30] These interrogatory responses directly mirror the references in the Henderson report. Because the University had the opportunity to depose Genentech's witnesses with knowledge of the mouse experiments after these detailed disclosures in the supplemental interrogatory response, and because the University still has the opportunity to depose Henderson regarding his effort to tie the control and low-dose data to the materiality of the representation regarding the high-dose data, the court does not find any material prejudice to the University.

III. CONCLUSION

With respect to the issues raised directly in the University's letter brief, the court does not find sufficient grounds to strike the expert testimony. There are instances, however, in which the evidence offered by Genentech must be limited to certain purposes, as in the case of the low-dose

[29] *See, e.g.*, Henderson ¶¶ 132, 133 (addressing the statement by Greene and Katsumata during the patent prosecution that "50% [of the treated mice] remain tumor free at more than 90 weeks of age, compared to development of tumors in all untreated mice," and noting that this falsehood regarding the untreated or control mice "reinforced the credibility of the first false statement"); *See also id.* ¶ 135 ("Misrepresenting the control group data was highly significant because Dr. Katsumata and Dr. Greene's assertions of preventing cell transformation through down regulation were based entirely on comparing the high and low dose mice to the control group mice.").

[30] *See, e.g.*, Thayer Decl., Ex. N at 6 ("[D]ocuments produced by the University indicate that this representation too was false because at least one mouse in each control group died or was sacrificed without developing breast tumors … In other words, not all of the control mice developed breast cancer. This falsehood reinforced the credibility of the first false statement: if mice that did not receive antibody treatment consistently developed tumors, then one could have inferred that the 50% of mice who received treatment and did not develop tumors were tumor-free because of the antibody treatment. On the other hand, if only two mice failed to develop breast tumors while being treated with the antibody, while two mice who never received treatment also did not develop breast tumors, the conclusion that the antibody prevented mice from developing tumors … was tenuous at best.").

and control group mouse data.[31] The University's motion to strike portions of Genentech's expert reports is accordingly DENIED. Genentech's conditional motion therefore also is DENIED.

Dated: February 9, 2012

PAUL S. GREWAL
United States Magistrate Judge

[31] Genentech is bound to its representations regarding the narrow purpose for which it seeks to introduce this data at trial in the context of both its invalidity and inequitable conduct defenses.