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 10-02037 LHK (PSG) **ORDER GRANTING GENENTECH'S MOTION TO COMPEL** **(Re: Docket No. 178)**

Plaintiff Genentech Inc. ("Genentech") filed this motion to compel Defendant The Trustees of the University of Pennsylvania ("Penn") to fully respond to Genentech's interrogatory no. 2 and to Genentech's narrowed version of requests for production no. 35 and no. 68. The court heard oral argument on May 24, 2011.

This dispute centers around the question of the appropriate scope of discovery related to the defenses of enablement and written description in life sciences patent cases. Having considered the written briefs and oral argument, the motion to compel is GRANTED.

I. BACKGROUND

On July 27, 2011, Genentech served its first set of interrogatories on Penn, including interrogatory no. 2, which states:

> Identify anyone whom [Penn] is aware of having experience or knowledge or working in the field of cancer research, diagnosis and therapy who understood in or before 1994 that human non-cancer breast cells overexpress p185; all such human non-cancer breast cell(s) known in or before 1994 to overexpress p185; any and all

> Persons with knowledge of such cells; and all Documents and Things supporting Your response.[1]

Penn responded with on August 26, 2010 and supplemented its response on October 25, 2010. In sum, Penn objected to the interrogatory on several grounds and responded by identifying the three inventors of the '752 patent, a draft of a manuscript addressing experiments on cells in the breast tissue of mice described in the '752 patent, the '752, and "materials designated under Patent L-R 3-2" and listing the Bates Numbers of the documents supporting that response.

On July 27, 2010, Genentech served its first request for production of documents and on September 17, 2010 served its second request for production of documents. Genentech asks the court to compel production responsive to a narrowed request for production combining request no. 35 and no. 68 request as follows:

> Documents from the laboratory of inventor Mark Green pertaining to the development, characterization and testing of p185 antibodies for use in the treatment or prevention of cancer, including documents showing competitive binding with 7.16.4 and/or down regulation of the p185 receptor.[2]

Penn objected that work beyond the experiments directly related to the '752 patent was irrelevant to this litigation and so substantial as to be overly burdensome to produce. Penn produced the inventor's CVs, published and submitted articles, and p185-related grant submissions.

II. LEGAL STANDARD

Pursuant to Fed. R. Civ. P. 26, 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 the 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.

[1] 4/19/11 Declaration of Sarah B. Faulkner Ex. D. (Docket No. 79-1) ("Faulkner Decl.").

[2] *See* Faulkner Decl. Ex. M (narrowing requests), Ex. K (request no. 35), Ex. L (request no. 68).

III. DISCUSSION

A. INTERROGATORY NO. 2

Genentech argues that Penn's responses failed to identify any cells. As to the documents identified in the response by Bates Number, Genentech argues they are non-responsive based on Penn's explanation of their content in its opposition. Genentech further argues that Penn's identification of thousands of pages of documents without any further details violates Fed. R. Civ. P. 33(d). Essentially, Genentech argues that Penn's response does nothing more than identify the three inventors of the '752 patent.

Penn responds that it has already described the non-cancer, p185 overexpressing breast cells on which Herceptin acts in the relevant human patient population in its response to interrogatory no. 11. Penn further responds that Genentech's interrogatory requires Penn to do nothing less than survey every single member of the Penn community and ask what he believed every single individual involved with cancer in the world knew in 1994 regarding the p185 overexpressing cells that were not cancer cells, all of which Penn argues would not be relevant and would be extremely burdensome. A better approach, Penn suggests, is to have Genentech simply retain an expert to conduct a literature survey to determine the state of public knowledge in 1994.

The court finds that interrogatory no. 2 seeks information distinct from Penn's response to interrogatory no. 11 and that this information is relevant to Genentech's invalidity contentions. Interrogatory no. 2 is directed specifically to Genentech's non-enablement and lack of written description defenses that Penn cannot claim to have invented a method of treating non-cancer breast cells that overexpress p185 in humans because those cells were not known to exist by either the inventors or others of skill in the art and thus seeks information limited to cells known in or before 1994.[3] Interrogatory no. 11, on the other hand, is not time-limited, and Penn could and did

[3] Although related, the written description and enablement requirements of 35 U.S.C. § 112, ¶ 1 are distinct. See *Ariad Pharm. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) ("Since its inception, this court has consistently held that § 112, first paragraph, contains a written description requirement separate from enablement."); *Univ. of Rochester v. G.D. Searle & Co.*, 358 F. 3d 916, 921 (Fed. Cir. 2004) ("Although there is often significant overlap, they are nonetheless independent of each other. An invention may be described without being enabled, and vice versa"). The written description requirement serves to "prevent an applicant from later asserting that he invented that which he did not." *Amgen v. Hoechst Marion Roussel*, 314 F.3d 1313, 1330

respond by citing to studies that occurred well after 1994.[4] Furthermore, the court is unpersuaded by Penn's argument that this information can only be obtained by Penn by an extensive survey of thousands of people.

Accordingly, IT IS HEREBY ORDERED that Penn shall respond to Genentech's interrogatory no. 2 by providing a narrative response, with citations to specific page numbers in the documents for support, based on information disclosed in interviews of the three inventors, the people that worked with those three inventors on characterizing and working with anti-p185 antibodies, anyone listed in Faulkner Reply Decl. Ex. A with relevant knowledge, and any other people specifically identified as appropriate sources by the aforementioned individuals.

B. NARROWED REQUEST FOR PRODUCTION NO. 35 AND NO. 68

Genentech argues that a portion of the documents sought in its narrowed request for production, regarding Mark Greene's ("Greene") laboratory's failed attempts to develop effective antibodies to *human* p185, as opposed to mouse p185, are relevant to its enablement and written description defenses.[5] According to Genentech, the very fact that experimental antibodies failed to

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(Fed. Cir. 2003). The separate enablement requirement ensures that "the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims." *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc*., 166 F3d. 1190, 1195-96 (Fed. Cir. 1999). Both standards, however, are determined as of the effective filing date of the patent. See *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991); *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp*., 315 F.3d 1335, 1339 (Fed. Cir. 2003).

[4] *See* 5/10/11 Declaration of Sarah B. Faulkner in Supp. of Reply (Docket No. 218-1) ("Faulkner Reply Decl.") Ex B.

[5] *See Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp*., 24 F.3d 1347, 1362 (Fed. Cir. 2005) ("[A]n inventor's failed attempts to practice an invention are relevant evidence of non-enablement"); *Ormco Corp. v. Align Technology*, 498 F.3d 1307, 1319 (Fed. Cir. 2007) ("If an inventor attempts but fails to enable his invention in a commercial product that purports to be an embodiment of the patented invention, that is strong evidence that the patent specification lacks enablement"); *Liebel-Flarsheim Co. v. Medrad, Inc*., 481 F.3d 1371, 1379 (Fed. Cir. 2007) (finding non-enablement and explaining that "[t]he inventors admitted that they tried unsuccessfully to produce a [claimed invention] and that producing such a system would have required more experimentation and testing."); *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244-45 (Fed. Cir. 2003) ("[G]iven the specification's teaching away from the subject matter that was eventually claimed and AK Steel's own failures to make and use the later claimed invention at the time of the application, the district court correctly concluded that there was no genuine issue of material fact relating to undue experimentation as it relates to enablement."); *Enzo Biochem, Inc. v. Calgene, Inc*., 188 F.3d 1362, 1372 (Fed. Cir. 1999) ("The court noted that the record is replete with the inventor's own failed attempts to control the expression of other genes in prokaryotes or eukaryotes using antisense technology.").

meet the requirements of the patent claims make any such Greene studies relevant to Genentech's enablement defense. While both parties agree that experiments on molecules that are likely to compete with 7.16.4 for binding to p185 compose one such category of failed attempts, Genentech contends that failed experiments at binding *any* molecule to human p185 are relevant because they also would tend to prove Genentech's claim that Greene did not enable or possess what he claimed.

Penn argues that the request for production is overly broad because it seeks information about antibodies that are outside the scope of the '752 patent— specifically, antibodies that do not compete with the 7.16.4 antibody for binding to p185.[6] Penn states that it has already produced Greene's laboratory notebooks associated with experiments creating binding molecules based on 7.16.4 and that therefore are likely to compete with 7.16.4. Penn further argues that because the '752 patent claims a method of treatment using a particular type of antibody, not the antibody itself, a failed attempt to characterize such an antibody is not equivalent to a failed attempt to practice the invention.

Although the claims include additional requirements such that they do not cover the use of every antibody that binds to human p185, information about Greene's inability to find any antibody that would bind to human p185 is discoverable under *Novo Nordisk* and *Ormco*. The court is not persuaded that those cases do not apply here because the '752 patent claims a method of treatment rather than one or more particular antibodies. The reason is that, without the antibody, the method cannot be practiced. Furthermore, Penn has not cited any authority for its contention that discovery pertaining to an inventor's failed experimentation must be limited to information about attempts that successfully meet some limitations—such as identifying an antibody that competes with 7.16.4 for binding to p185—but not others—such as that antibody binding to human p185. Even if such information is ultimately deemed to be inadmissible on the questions of enablement and written

[6] Claim 1 recites "an antibody which competes with an antibody produced by cell line [American Type Culture Collection ("ATCC")] Deposit No. 10493." '752 Patent (Docket No. 7-1) at 8:52-54. The patent notes that "cell line producing monoclonal antibody 7.16.4 was deposited in the [ATCC] . . . and has accession number HB 10493." *Id*. at 6:555-59. At oral argument, counsel for Genentech stated that the parties agree that claim 1 requires an antibody that competes with an antibody produced by cell line ATCC Deposit No. 10493. Counsel clarified, however, that the parties have not agreed specifically that the antibody produced by that cell line is 7.16.4. FTR audio recording, May 24, 2011, 11:25:10 - 11:25:36 a.m.

description, the requested discovery is certainly "reasonably calculated to lead to the discovery of admissible evidence."[7] In sum, Genentech has demonstrated that all documents from Greene's laboratory pertaining to failed attempts to use human-p185 antibodies to treat or prevent cancer, including documents showing testing of competitive binding with 7.16.4 and/or down regulation of the human-p185 receptor, should be produced.

Accordingly, IT IS HEREBY ORDERED that, as part of its production responsive to the narrowed request, Penn shall produce all documents from Greene's laboratory pertaining to the development, characterization or testing of human-p185 antibodies for use in the treatment or prevention of cancer. This production shall include documents pertaining to any failed experiments, not merely those directed to antibodies that compete with 7.16.4. If Penn deems such a production unduly burdensome, Penn may make the materials available to Genentech for inspection.

IV. CONCLUSION

Penn shall comply with this order no later than June 19, 2011.

IT IS SO ORDERED.

Dated: June 9, 2011

PAUL S. GREWAL
United States Magistrate Judge

[7] *See* Fed. R. Civ. P. 26(b)(1).