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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION**

PHIGENIX, INC.,
Plaintiff,
v.
GENENTECH INC,
Defendant.

Case No. [15-cv-01238-BLF](#)

**ORDER CONSTRUING CLAIMS IN
U.S. PATENT NO. 8,080,534**

[Re: ECF 162]

Plaintiff Phigenix, Inc. (“Phigenix”) brings this patent infringement lawsuit against Defendant Genentech, Inc. (“Genentech”) alleging infringement of U.S. Patent No. 8,080,534B2 (“the ’534 Patent”). The Court held a tutorial on July 1, 2016, and a *Markman* hearing on July 8, 2016, for the purpose of construing four disputed terms in the ’534 Patent.

I. BACKGROUND ON THE ’534 PATENT

The ’534 Patent is titled “Targeting PAX2 for the Treatment of Breast Cancer.” It describes and claims methods of prevention and/or treatment of breast cancer and other breast conditions by administering compositions to inhibit the expression or activity of PAX2 and/or enhance the expression of DEFB1 proteins within a cancer cell. ’534 Patent at Abstract.

Paired box genes (“PAX”) are a family of nine developmental control genes coding for

1 specific transcription factors. *Id.* at 6:23-26. Beta-defensins, (“DEFB”) are peptides with broad-
2 spectrum antimicrobial activity. *Id.* at 7:17-18. As of the date the ’534 patent issued, five beta-
3 defensin genes had been identified in humans, including DEFB1. *Id.* at 7:24-25. DEFB1 forms
4 part of “an innate immune system involved in tumor immunity.” *Id.* at 30:11-13. Previous studies
5 reported that “PAX2 suppresses DEFB1 expression by binding to the DEFB1 promoter.” *Id.* at
6 6:47-49.

7 The Specification teaches that DEFB1 can be toxic to prostate cancer cells but not to
8 normal prostate cells. *Id.* at 30:10-17. However, certain cancerous and precancerous prostate cells
9 exhibit an overexpression of PAX2, which in turn inhibits DEFB1 expression. *Id.* at 33:57-60,
10 36:32-33, 42:54-56. As a result, inhibiting PAX2 expression in prostate cancer cells can enhance
11 the expression of DEFB1 and kill the cancerous prostate cells. *Id.* at 30:10-23. The ’534 Patent
12 describes prophetic examples that predict this phenomenon also occurs in breast cancer cells. *Id.*
13 at 53:61-54:49.

14 Phigenix asserts Genentech infringes claims 1, 2, and 8 of the ’534 Patent. Claims 1 and 8
15 are independent claims, and claim 2 is dependent on claim 1. All three claims are reproduced
16 below:

17 1. A method for treating a breast condition in a subject, comprising administering to a
18 breast tissue of the subject, a composition that (1) inhibits PAX2 expression or PAX2
19 activity, (2) expresses DEFB1 or (3) inhibits PAX2 expression or PAX2 activity and
expresses DEFB1.

20 2. The method of claim 1, wherein the breast condition is breast cancer or mammary
21 intraepithelial neoplasia (MIN).

22 8. A method of treating breast cancer or MIN in a subject, comprising enhancing
23 expression DEFB1 in a breast cancer tissue or MIN tissue in the subject.

24 *Id.* at 109:2-8, 26-28.

25 **II. LEGAL STANDARD**

26 Claim construction is a matter of law. *Markman v. Westview Instruments, Inc.*, 517 U.S.
27 370, 387 (1996). “It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the
28 invention to which the patentee is entitled the right to exclude,” *Phillips v. AWH Corp.*, 415 F.3d

1 1303, 1312 (Fed. Cir. 2005) (en banc) (internal citation omitted), and, as such, “[t]he appropriate
2 starting point . . . is always with the language of the asserted claim itself,” *Comark Commc ’ns, Inc.*
3 *v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998).

4 Claim terms “are generally given their ordinary and customary meaning,” defined as “the
5 meaning . . . the term would have to a person of ordinary skill in the art in question . . . as of the
6 effective filing date of the patent application.” *Phillips*, 415 F.3d at 1313 (internal citation
7 omitted). The court reads claims in light of the specification, which is “the single best guide to the
8 meaning of a disputed term.” *Id.* at 1315; *see also Lighting Ballast Control LLC v. Philips Elecs.*
9 *N. Am. Corp.*, 744 F.3d 1272, 1284-85 (Fed. Cir. 2014) (en banc). Furthermore, “the
10 interpretation to be given a term can only be determined and confirmed with a full understanding
11 of what the inventors actually invented and intended to envelop with the claim.” *Phillips*, 415
12 F.3d at 1316 (quoting *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed.
13 Cir. 1998)). The words of the claims must therefore be understood as the inventor used them, as
14 such understanding is revealed by the patent and prosecution history. *Id.* The claim language,
15 written description, and patent prosecution history thus form the intrinsic record that is most
16 significant when determining the proper meaning of a disputed claim limitation. *Id.* at 1315-17;
17 *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

18 Evidence external to the patent is less significant than the intrinsic record, but the court
19 may also consider such extrinsic evidence as expert and inventor testimony, dictionaries, and
20 learned treatises “if the court deems it helpful in determining ‘the true meaning of language used
21 in the patent claims.’” *Phillips*, 415 F.3d at 1318 (quoting *Markman*, 52 F.3d at 980). However,
22 extrinsic evidence may not be used to contradict or change the meaning of claims “in derogation
23 of the ‘indisputable public records consisting of the claims, the specification and the prosecution
24 history,’ thereby undermining the public notice function of patents.” *Id.* at 1319 (quoting
25 *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1578 (Fed. Cir. 1995)).

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1 **III. CONSTRUCTION OF DISPUTED TERMS¹**

2 **A. Treating Terms**

3 Term	Phigenix’s Proposal²	Genentech’s Proposal	Court’s Construction
4 Claim 1: “method for treating a breast condition in a subject”	No construction necessary.	This limitation does not require any particular level of therapeutic effectiveness; no further construction is necessary	No construction necessary
5 6 7 Claim 8: “method of treating breast cancer or MIN in a subject”	No construction necessary.	This limitation does not require any particular level of therapeutic effectiveness; no further construction is necessary	No construction necessary

10 Phigenix argues that no further construction is necessary for the phrases “method for
11 treating” and “method of treating” as they are easily understood by lay people and skilled artisans.
12 Mot. 8, ECF 162. Genentech, concerned that Phigenix may take a shifting sands approach to
13 infringement and validity, argues that the Court should clarify the terms do not require any
14 particular level of therapeutic effectiveness. Opp. 8-11, ECF 173.

15 The Court agrees with Phigenix that when read in light of the specification, a skilled
16 artisan would readily understand the meaning of the treating terms. Based on Genentech’s
17 concerns raised in the briefing, at the *Markman* hearing, the Court proposed adopting Phigenix’s
18 proposal of “no construction necessary” and ordering that neither party could argue the treating
19 terms require any particular level of therapeutic effectiveness. *Markman* Tr. 5:2-13, ECF 228.
20 Both parties were agreeable to this approach. *Markman* Tr. 10:16-17; 33:23-24, ECF 228.
21 Accordingly, “method for treating a breast condition in a subject” and “method of treating breast
22 cancer or MIN in a subject” are to be given their plain and ordinary meaning and neither party
23 may argue that these terms require any particular level of therapeutic effectiveness. *See, e.g.,*

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25 ¹ The parties disagree over the appropriate definition of a skilled artisan. Mot. 5-7, ECF 162; Opp.
26 7, ECF 173. However, they both agree that the proper construction of the claims is the same under
27 either of their definitions. *Id.* As a result, the Court need not resolve this issue at this juncture.

28 ² Phigenix offered alternative constructions during its meet and confers with Genentech. Mot. 8
n.5, ECF 162. For completeness, Phigenix included these alternative constructions in its claim
construction briefing but in that briefing, only advocates for and discusses why its “no
construction necessary” construction is appropriate. Thus, the Court does not discuss Phigenix’s
alternative proposals.

1 *Cellular Commc'n Equip. LLC v. LG Elec., Inc.*, Case No. 14-cv-982, 2016 WL 2808887, at *13
 2 (E.D. Tex. May 13, 2016) (construing term according to its plain and ordinary meaning but also
 3 clarifying what parties may argue); *Juniper Networks, Inc. v. Palo Alto Networks, Inc.*, 15 F.
 4 Supp. 3d 499, 522 (D. Del. 2014) (same); *Regents of Univ. of Cal. v. Dako N. Am., Inc.*, Case No.
 5 05-03955-MHP, 2006 WL 1867618, at *12 (N.D. Cal. July 5, 2006) (same).³

6 **B. Inhibit/Enhancing Terms**

Term	Phigenix's Proposal	Genentech's Proposal	Court's Construction
Claim 1: "inhibit PAX2 expression or PAX2 activity"	No construction necessary.	This limitation does not exclude indirect inhibition of PAX2 expression or PAX2 activity; no further construction is necessary	No construction necessary
Claim 8: "enhancing expression of DEFB1"	No construction necessary.	This limitation does not exclude indirect enhancement of expression of DEFB1; no further construction is necessary	No construction necessary

15 Phigenix argues that no further construction is necessary for the terms "inhibit PAX2
 16 expression or PAX2 activity" and "enhancing expression of DEFB1" because the meanings of
 17 "inhibit" and "enhancing" are understood by a skilled artisan. Mot. 11-14, ECF 162. Here too,
 18 Genentech seeks construction of these terms to prevent Phigenix from taking different positions
 19 regarding infringement and invalidity. Opp. 8-11, ECF 173.

20 The Court agrees with Phigenix that when read in light of the specification, a skilled
 21 artisan would easily understand the meaning of these terms. In light of Genentech's concerns, at
 22 the *Markman* hearing, the Court also proposed adopting Phigenix's proposal of "no construction
 23 necessary" and ordering that neither party could argue the term "inhibit PAX2 expression or
 24 PAX2 activity" excludes indirect inhibition of PAX2 expression or PAX2 activity and that neither
 25 party could argue that the term "enhancing expression of DEFB1" excludes indirect enhancement

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 27 ³ At this juncture, the Court is not planning on informing the jury about the Court's additional
 28 directive to the parties regarding the terms. However, should the need arise at trial either party
 may request an appropriate instruction. *See, e.g., Juniper*, Case No. 11-1258-SLR (D. Del.), Trial
 Tr. 618:14-619:17, ECF 335.

1 of expression of DEFB1. *Markman* Tr. 5:2-13, ECF 228. Phigenix and Genentech agreed to this
 2 approach. *Markman* Tr. 10:16-17; 33:23-24, ECF 228. Thus, “inhibit PAX2 expression or PAX2
 3 activity” is to be given its plain and ordinary meaning and the Court clarifies that this term does
 4 not exclude indirect inhibition of PAX2 expression or PAX2 activity. The term “enhancing
 5 expression of DEFB1” is also to be given its plain and ordinary meaning and the Court clarifies
 6 that this limitation does not exclude indirect enhancement of expression of DEFB1.⁴

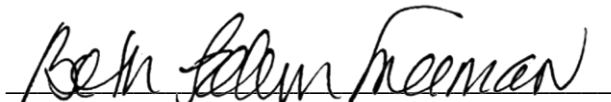
7 **IV. ORDER**

8 For the foregoing set forth above, the Court construes the disputed terms as follows:

Claim Term	Court’s Construction
Claim 1: “method for treating a breast condition in a subject”	No construction necessary
Claim 8: “method of treating breast cancer or MIN in a subject”	No construction necessary
Claim 1: “inhibit PAX2 expression or PAX2 activity”	No construction necessary
Claim 8: “enhancing expression of DEFB1”	No construction necessary

14 **IT IS SO ORDERED.**

15 Dated: August 8, 2016

16 
 17 BETH LABSON FREEMAN
 18 United States District Judge

28 ⁴ See *supra* 5 n.3.