United States District Court
Northern District of California

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 GRANTING IN PART AND DENYING IN PART MOTION FOR SUMMARY JUDGMENT

[Re: ECF 257]

Plaintiff Phigenix, Inc. ("Phigenix") alleges that Defendant Genentech, Inc. ("Genentech") infringes certain claims of U.S. Patent No. 8,080,534 ("the '534 patent") based on Kadcyla, a drug targeting a type of metastatic breast cancer. Mot. 2, ECF 257. Before the Court is Genentech's motion for summary judgment for finding the '534 patent invalid on grounds of inadequate written description and anticipation. ECF 198. The Court, having considered the briefing submitted by the parties and the oral argument presented at the hearing on January 5, 2017, GRANTS IN PART and DENIES IN PART Genentech's motion.

I. BACKGROUND

From the parties' briefing, and evidence, the following facts relevant to the pending motion for summary judgment are undisputed unless otherwise noted.

Phigenix is a pharmaceutical and biomedical research company founded in 2007 by Dr. Carlton D. Donald, who is a named inventor on numerous issued and pending patents and patent applications, including the '534 patent. First Am. Compl. ("FAC") ¶ 1, ECF 21. The '534 patent is titled "Targeting PAX2 for the Treatment of Breast Cancer." Ex. A to Murray Decl., ECF 277-3 (the '534 patent). According to Phigenix, the '534 patent describes and claims methods of treating breast cancer by administering compositions to inhibit the expression or activity of paired

box protein 2 ("PAX2") or to increase expression of beta-defensin 1 ("DEFB1") within a cancer cell. *Id.* at 6:21-32, 7:17-29; Opp'n 3, ECF 278. Claims 1, 2, and 8 of the '534 patent are set forth below.

> Claim 1:
>
> > A method for treating a breast condition in a subject, comprising administering to a breast tissue of the subject, a composition that (1) inhibits PAX2 expression or PAX2 activity, (2) expresses DEFB1 or (3) inhibits PAX2 expression or PAX2 activity and expresses DEFB1.
>
> Claim 2:
>
> > The method of claim 1, wherein the breast condition is breast cancer or mammary intraepithelial neoplasia (MIN).
>
> Claim 8:
>
> > A method of treating breast cancer or MIN in a subject, comprising enhancing expression of DEFB1 in a breast cancer tissue or MIN tissue in the subject.

'534 patent 109:2-8, 26-28.

PAX2, a protein encoded by the PAX2 gene, acts as a transcription factor that binds to DNA to enhance or suppress expression of other genes. Opp'n 3. The '534 patent states that PAX2 expression is associated with certain types of cancers, including breast cancer. '534 patent at 6:56-7:15. The '534 patent also shows that DEFB1, a protein encoded by the DEFB1 gene, can be toxic to cells. *Id.* Fig. 3; Opp'n 3.

Genentech has developed a number of cancer treatments, including Kadcyla. *See generally* Ex. I to Girish Decl., ECF 259-9. Kadcyla is the trade name for T-DM1, an immunoconjugate that comprises trastuzumab linked to the highly cytotoxic agent DM1, a member of the maytansinoid drug class. FAC ¶ 11. Trastuzumab specifically targets a protein named HER2, which is expressed at high levels on the surface of cancer cells associated with certain aggressive cancers. Ex. I to Girish Decl.; Ex. G to Girish Decl. 25, ECF 259-7. Kadcyla can thus target HER2-positive cancer cells and deliver DM1 to kill those cells specifically, while minimizing adverse effects on non-cancerous cells in a patient. Ex. G to Girish Decl. 25, 28-29. Kadcyla is indicated for patients with HER2-positive metastatic breast cancer who have previously received trastuzumab and taxane treatments. Ex. I to Girish Decl. 1.

Phigenix alleges that Genentech's breast cancer drug, Kadcyla, infringes claims 1, 2, and 8

of the '534 patent. Opp'n 3. According to Phigenix's infringement theory, Kadcyla inhibits signaling of another protein, signal transducer and activator of transcription 3 ("STAT3"), resulting in the inhibition of PAX2 expression. '534 patent at 2:12-20; Ex. 1 to Chivvis Decl., ECF 258-1 ("Phigenix Supp. Infringement Contentions"). Phigenix also contends that when PAX2 expression is decreased, DEFB1 expression is increased. *Id.*

The priority history of the '534 patent is relevant here because the parties dispute whether the '534 patent is entitled to the October 14, 2005 priority date. Mot. 4; Opp'n 4. The '534 patent is a continuation-in-part of U.S. Application No. 12/090,191, which is a national stage entry of WO 2007/047512 (the "PCT application"). Exs. 2, 3 to Chivvis Decl. The PCT application claims priority to U.S. Provisional Application No. 60/726,921, filed on October 14, 2005 (the "2005 provisional application"). Exs. 3, 4 to Chivvis Decl. The 2005 provisional application is titled "Targeting PAX2 for the Induction of DEFB1-Mediated Tumor Immunity as a Therapy for Cancer." Ex. 4 to Chivvis Decl. Since the '534 patent is a continuation-in-part, it contains subject matter not disclosed in its parent patent application and the 2005 provisional patent application. Ex. 7 to Chivvis Decl.

II. LEGAL STANDARD

A. Summary Judgment

Federal Rule of Civil Procedure 56 governs motions for summary judgment. Summary judgment is appropriate if the evidence and all reasonable inferences in the light most favorable to the nonmoving party "show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

The moving party "bears the burden of showing there is no material factual dispute," *Hill v. R+L Carriers, Inc.*, 690 F. Supp. 2d 1001, 1004 (N.D. Cal. 2010), by "identifying for the court the portions of the materials on file that it believes demonstrate the absence of any genuine issue of material fact." *T.W. Elec. Serv. Inc. v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987). In judging evidence at the summary judgment stage, the Court "does not assess credibility or weigh the evidence, but simply determines whether there is a genuine factual issue

for trial." *House v. Bell*, 547 U.S. 518, 559-60 (2006). A fact is "material" if it "might affect the outcome of the suit under the governing law," and a dispute as to a material fact is "genuine" if there is sufficient evidence for a reasonable trier of fact to decide in favor of the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

Where the moving party will have the burden of proof on an issue at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. *Celotex*, 477 U.S. at 325; *Soremekun v. Thrifty Payless, Inc.*, 509 F.3d 978, 984 (9th Cir. 2007). Once the moving party meets its initial burden, the nonmoving party must set forth, by affidavit or as otherwise provided in Rule 56, "specific facts showing that there is a genuine issue for trial." *Liberty Lobby*, 477 U.S. at 250 (internal quotation marks omitted). If the nonmoving party's "evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50 (internal citations omitted). Mere conclusory, speculative testimony in affidavits and moving papers is also insufficient to raise genuine issues of fact and defeat summary judgment. *See Thornhill Publ'g Co. v. GTE Corp.*, 594 F.2d 730, 738 (9th Cir.1979). For a court to find that a genuine dispute of material fact exists, "there must be enough doubt for a reasonable trier of fact to find for the [non-moving party]." *Corales v. Bennett*, 567 F.3d 554, 562 (9th Cir. 2009).

B. Applicable Law on Patent Invalidity and the "Written Description" Requirement

Patents are presumed to be valid. 35 U.S.C. section 282(a). A party challenging the validity of a patent bears the burden of proving invalidity by clear and convincing evidence. *Microsoft Corp. v. I4I Ltd. P'ship*, 564 U.S. 91, 102 (2011).

Under 35 U.S.C. § 112(a), a patent specification must contain "a written description of the invention."[1] Under this written description requirement, the specification "must clearly allow

[1] On September 16, 2011, the America Invents Act was enacted into law. *See* Pub.L. 112–29, 125 Stat. 285 ("AIA"). AIA applies to patents filed on or after March 16, 2013. AIA § 3(e)(3) (stating that AIA takes effect upon "the expiration of the 18-month period beginning on the date of the enactment of this Act."). Because the '534 patent was filed on February 18, 2010, the AIA does not apply. Regardless, the AIA redesignated the provisions of section 112, such that what was previously designated the first paragraph of section 112 is now designated section 112(a) and did not materially affect the provision regarding the written description. AIA § 4(c). For

persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed.Cir.2010) (en banc) (internal quotation marks and alterations omitted). This test requires "an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art" to determine whether the specification shows that "the inventor actually invented the invention claimed." *Id.* Although "[c]ompliance with the written description requirement is a question of fact," it is, like most factual questions, "amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008). Under certain circumstances, a patent also can be held invalid for failure to meet the written description requirement based solely on the face of the patent specification. *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927 (Fed. Cir. 2004). Further, a patent application is entitled to the benefit of the filing date of an earlier filed application only if the disclosure of the earlier application provides support for the claims of the later application. *PowerOasis*, 522 F.3d at 1306.

III. DISCUSSION

A. Written Description Support in the '534 Patent

i. The Parties' Contentions

Genentech argues that the asserted claims are invalid because they lack adequate written description support in the specification of the '534 patent. Mot. 6. It points out that the claims refer to methods that employ "*any composition* that inhibits PAX2 or expresses DEFB1." *Id.* (emphasis in original). First, Genentech contends that these generic claims, defined only by the desired result: inhibition of PAX2 or enhanced expression of DEFB1, encompass both direct and indirect effects, as made clear by this Court in its claim construction order. *Id.* Genentech then asserts that the claims include not just methods that can inhibit PAX2 but any protein upstream in signaling pathways of PAX2. *Id.* at 7. Genentech lists angiotensis II, angiotensin converting enzyme, MEK, ERK1, 2, and STATS, as some of the potential targets to which the claimed

convenience, the Court refers to the redesignated provision of section 112.

method could be directed. *Id.* Second, Genentech argues that although the specification presents only siRNA and small molecules as working examples, the list of compositions that could be used by the claims broadly includes many other categories, such as "ribozymes," "triplex forming molecules," and "antibodies." Mot. 7; '534 patent 8:40-53; 22:44-54, 43:39-56. Genentech asserts that "[n]othing in the claims or the specification implies that PAX2 inhibitors are limited to molecules with any common structural elements." Mot. 4. Genentech then argues that the asserted claims are "vulnerable in highly unpredictable fields" and require disclosure of sufficiently representative species spanning the scope of the genus, which is lacking here. *Id.* at 7 (citing *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1299 (Fed. Cir. 2014)).

Phigenix, in opposition, generally advances the argument that the asserted claims have written description support without relying specifically on the disclosure in the '534 patent. Rather, Phigenix, supported by its expert Dr. Pestell, relies almost exclusively on the disclosure in the 2005 provisional application. *E.g.*, Opp'n 4; Ex. C to Murray Decl. ¶¶ 8, 11. Nevertheless, Phigenix argues that Genentech's motion should be denied on its face for failing to provide evidence demonstrating the skill of a person of ordinary skill in the art ("POSITA"). Opp'n 7. Given that the inquiry of written description is fact-laden, Phigenix contends that there are genuine issues of material fact and Genentech has failed to meet its burden in this motion. *Id.* at 8 (citing *AAT Bioquest, Inc. v. Texas Fluorescence Labs., Inc.*, No. 14-03909-DMR, 2015 WL 1738402, at *5 (N.D. Cal. Apr. 13, 2015)). Phigenix further cites to other cases where courts have denied summary judgment and argues that the cases relied upon by Genentech are inapposite because those cases involved full trial records. Opp'n 6, 9.

ii. Whether the '534 Patent Provides Adequate Written Description Support for the Asserted Claims is A Disputed Factual Issue

The Court looks to the '534 patent and the parties' submissions to determine if Genentech has demonstrated that no reasonable fact finder could conclude that the specification adequately supports the asserted Claims 1, 2, and 8.[2] The asserted claims are defined by functions –

[2] Although three claims are asserted here, claim 2 depends on claim 1 and both claims 1 and 3

inhibiting PAX2 expression or activity; or expressing or enhancing DEFB1 expression. '534 patent 109:2-8, 26-28. Given these functional limitations, the claims encompass both direct and indirect pathways of achieving the functional results (the "direct" subgenus, and "indirect" subgenus). Claim Construction Order, ECF 234. In other words, the claims cover methods that affect PAX2/DEFB1 either directly or indirectly.

Given that the asserted method claims in the '534 patent are defined by functional limitations, the *Ariad* court's holdings on the written description requirement as well as its findings relating to the method claims at issue there are particularly relevant. The Federal Circuit in *Ariad* held that to satisfy the written description requirement, the specification must demonstrate that the patent owner possessed the claimed methods by sufficiently disclosing species capable of performing the functional limitation so as to "satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed." 598 F.3d at 1355. The Federal Circuit further underscores that the problem of meeting the written description requirement "is especially acute with genus claims that use functional language to define the boundaries of a claimed genus." *Id.* at 1349. In *Ariad*, the jury found the claims not invalid for lack of written description and the lower court denied defendant Eli Lilly's motion for judgment as a matter of law. 598 F.3d at 1341. Appealing the denial of its JMOL motion, Eli Lilly argued that the claimed method of reducing binding of a transcription factor, NF-κB, lacked adequate written description support. *Id.* at 1340, 1354. Specifically, Eli Lilly offered undisputed expert testimony "that the field of the invention was particularly unpredictable" and averred that the specification merely hypothesized three classes of molecules that could achieve the claimed function. *Id.* at 1354-55. In reversing the lower court's order, the Federal Circuit held that a sufficient description of a genus "requires the disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill

require either (1) increasing PAX2 activity or expression; or (2) expressing or enhancing DEFB1 expression; or both. For the purpose of the written description analysis, the differences between the claims are not material.

in the art can 'visualize or recognize' the members of the genus." *Id.* at 1350 (citing *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997)). After reviewing the specification and the evidence, the Federal Circuit found that aside from the disclosure of one specific inhibitor, I-κB, a natural inhibitor of NF-κB, the specification provided no examples of any of the hypothesized three classes. *Id.* at 1356-57. For example, the court noted that the example structures of "decoy molecules" set forth in the specification had no relation to NF-κB and only represented a "desired outcome." *Id.* at 1357. The court then concluded that the asserted claims of the patent were invalid for lack of written description support. *Id.* at 1358.

Although the asserted claims here are also defined by functional limitations like the claims in *Ariad*, there are important distinguishing facts that create triable issues. As noted above, the claims encompass a "direct" subgenus and an "indirect" subgenus. With respect to the "direct" subgenus, the specification of the '534 patent provides at least some structural and sequence information on the PAX2/DEFB1 genes and proteins, unlike the case in *Ariad* where no common structural or sequence features were disclosed. *E.g.*, '534 patent at 6:22-56, 7:30-8:32; Ex. C to Murray Decl. ¶ 13-14 ("Pestell Decl."). Also in contrast to *Ariad*, where there were no working examples, the specification here discloses working examples using compositions such as siRNA to knock down expression of PAX2, *id.* at 11:1-21; 30:35-65, 35:17-36, 37:18-25 and short oligonucleotides, complementary to PAX2's DNA, to interfere with PAX2 binding so as to increase DEFB1 expression, *id.* at 37:36-38:49. Phigenix's expert has further declared that a POSITA "would have a general understanding on the structure of the target molecule [] and would be able to design inhibitors . . . based on the disclosed sequences." Pestell Decl. ¶ 16. Genentech rightly argues that the test for written description is not what a scientist "could design," but rather what invention the inventor already possessed. Reply 3. However, disclosing a common structure or formula, such as the sequence of the PAX2 gene or protein, is one of the ways that could enable one of skill in the art to "visualize or recognize" the members of the genus. *Ariad*, 598 F.3d at 1350; *cf. id.* at 1299 (finding claims invalid because the specification "does not define any structural features commonly possessed by members of the genus that distinguish them from others"). Given the structural information disclosed in the specification, and the supporting expert

declaration, a trier of fact could find that a POSITA could "visualize or recognize" the members of the "direct" subgenus.

Genentech also argues with respect to the "indirect" genus, and Phigenix does not dispute, that no common structural elements shared among species of the subgenus are disclosed. Mot. 4, 7. If no common structural elements are disclosed, the next consideration is "how large [the indirect subgenus] is [] and what species of the genus are described in the patent." *AbbVie*, 759 F.3d at 1299. The specification discloses a category named "Other Inhibitors." '534 patent at 12:1. This section in the specification identifies some specific proteins to be inhibited to achieve the claimed functional results – angiotensin II, angiotensin-converting enzyme (ACE), MEK, ERK1,2, or STATS; and other proteins in the mitogen-activated protein kinase (MAPK) signaling cascade and the RAS proteins, listed in column 12, lines 2-44. *Id.* at 12:2-34, 12:42-44. Specific chemical inhibitors disclosed in this category include enalapril, valsartan, olmesartan, telmisartan, PD98059, U0126, and an inhibitor of angiotensin (e.g., Losartan). *Id.* at 12:9-10; 40:63-67, 43:39-57. Again, this is unlike *Ariad*, where the patents disclosed only one example or prophetic examples that had no connection to the claimed functional results. Here, there is some written description support for the "indirect" subgenus. However, Genentech has submitted no evidence, in the form of an expert declaration or other evidence, on how large this subgenus is and whether the number of species disclosed is inadequate for a POSITA to "visualize or recognize" the members of the subgenus.

In an attempt to support the contention that the written description is inadequate, Genentech further asserts that the field is highly unpredictable and points to the '534 patent specification showing there are broad classes of compounds such as "antisense molecules, aptamers, ribozymes and triplex forming molecules, RNAi and external guide sequences" and those molecules can inhibit any proteins upstream in signaling pathways from PAX2. Mot. 7; '534 patent at 9:1-10:28. Although such disclosures may suggest that the scope of the subgenus is broad and the examples disclosed as "Other Inhibitors" may not be representative, they alone do not eliminate triable issues of material fact. This is because neither party has submitted evidence on the number of potential species in the claimed genus or subgenus, and whether the species

disclosed in the specification are representative and constitute a substantial portion of the genus. Without such information, the Court cannot resolve on summary judgment whether the "Other Inhibitors" disclosed in the specification are commensurate in scope with the claims. Accordingly, there remains a triable issue on whether the '534 patent disclosure would reasonably convey to a POSITA that the inventor had possession of the asserted claims, including the "indirect" subgenus. *Ariad*, 598 F.3d at 1351; *e.g.*, *AAT Bioquest, Inc. v. Texas Fluorescence Labs., Inc.*, No. 14-03909-DMR, 2015 WL 1738402, at *5 (N.D. Cal. Apr. 13, 2015) (denying summary judgment and noting that the defendant ignored the POSITA standard and failed to rebut an expert declaration on whether a POSITA at the time of the invention would have understood the claimed compound to be adequately supported).

B. Anticipation of the Asserted Claims by Public Use of Kadcyla

i. The Parties' Contentions

Genentech argues that the public use of Kadcyla before the 2010 filing date of the '534 patent anticipates the asserted claims. Mot. 8. According to Genentech, Kadcyla's public use is prior art because the asserted claims lack adequate written description in the specification of the 2005 provisional application and thus are not entitled to the October 14, 2005 priority date. *Id.* at 8-9. In support of this contention, Genentech first claims that the treatment of breast conditions or mammary intraepithelial neoplasia ("MIN") is new matter added after the 2005 provisional application. *Id.* at 9-10. Genentech also contends that a single reference to "breast cancer" cannot satisfy written description. *Id.* at 10. Genentech next avers that the specification of the 2005 provisional application does not support "the limitless 'genus' of structurally unbounded treatment compositions that affect PAX2 or DEFB1, directly or indirectly." Reply 2-3. Relying on *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, in which later-filed claims directed to antibodies with human variable regions were found to have inadequate written description in the specification of an earlier-filed patent describing mouse antibodies, Genentech concludes that the asserted claims should not be entitled to the earlier priority date. 636 F.3d 1341, 1344 (Fed. Cir. 2011); Mot. 10.

Phigenix counters that there is a triable issue as to whether Kadcyla's public use demonstrates inherent anticipation and a triable issue as to whether the 2005 provisional application provides adequate written description support. Phigenix underscores that, unlike Genentech, it has submitted an expert declaration in support of its opposition, demonstrating that the teachings of the 2005 provisional application are sufficient to show possession of the claimed invention. Opp'n 9; Pestell Decl. ¶¶ 11-19. Phigenix further argues in a footnote that a finding of anticipation by public use of Kadcyla would also require finding that the parent application of the '534 patent (U.S. Application No. 12/090,191, with a 35 U.S.C. section 371(c) date of September 15, 2008) fails to provide adequate written description. Opp'n 10 n.2.

ii. Written Description Support in U.S. Application No. 12/090,191

In support of its contention that the public use of Kadcyla is prior art, Genentech also makes a passing claim that the specification of the 2005 application and that U.S. Application No. 12/090,191 (the "'191 application") "do not differ materially for purposes of this motion." Mot. 4 (citing Ex. 6 to Chivvis Decl.). Phigenix disputes Genentech's claim in a footnote, arguing that the '191 application is not comparable to the 2005 provision application. Opp'n 10 n.2.

To the extent Genentech seeks a determination on whether the '191 application materially differs from the 2005 provisional application or whether the '191 application provides sufficient written description support, Genentech has failed to meet the moving party's burden. Aside from submitting a redlined version of the two applications, Genentech provides no argument and points to no supporting evidence as to whether the two applications are materially different. Ex. 6 to Chivvis Decl. A redlined document alone is insufficient to identify "for the court the portions of the materials on file that [Genentech] believes demonstrate the absence of any genuine issue of material fact." *See T.W. Elec. Serv.*, 809 F.2d at 630. Expert testimony would be expected to support this argument. The Court also will not consider Phigenix' counter-argument on this point made in a footnote. Opp'n 10 n.2. Mere conclusory arguments in the papers are insufficient to raise genuine issues of fact and defeat summary judgment. *See Thornhill Publ'g*, 594 F.2d at 738. Since neither party has adequately briefed or argued this issue to the Court, the Court will make no determination with respect to the '191 application.

iii. The 2005 Provisional Patent Application on Its Face Does Not Provide Adequate Written Description for the Asserted Claims

Before addressing whether the public use of Kadcyla anticipates the asserted claims, the Court will determine whether there is a triable issue on the written description support in the 2005 provisional patent application for the asserted claims.

As a preliminary matter, the Court notes the "level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Ariad*, 598 F.3d at 1351 (citing *Capon v. Eshhar*, 418 F.3d 1349, 1357-58 (Fed.Cir.2005)).

In this case, the asserted claims are directed to the biological and chemical arts, specifically for treating cancer by inhibiting or enhancing expression of one or two proteins. '534 patent 109:2-8, 26-28. "[T]he chemical arts have long been acknowledged to be unpredictable." *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1370 (Fed. Cir. 2011) (Gajarsa, J., concurring) (internal quotation marks omitted); *see Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533 (Fed. Cir. 1987). Further, patents in the field of chemical or biological arts are often found to lack sufficient written description. *See, e.g.*, *Rochester*, 358 F.3d at 918, 930 (finding claims directed to "administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product" invalid for lack of written description); *AbbVie*, 759 F.3d at 1350 (noting that the "fact that a fully-human antibody could be made does not suffice to show that the inventors of the '775 patent possessed such an antibody").

As noted above, the scope of the asserted claims are also broad. Not only are the claims defined by functional limitations, but they also extend to both direct and indirect pathways of achieving the functional results (the "direct" subgenus, and "indirect" subgenus). Claim Construction Order. Several Federal Circuit cases have addressed broad and functionally-defined claims in the chemical or biological arts such as the ones here. In *AbbVie*, the court found that "[f]unctionally defined genus claims can be inherently vulnerable to invalidity challenge for lack of written description support, especially in technology fields that are highly unpredictable, where it is difficult to establish a correlation between structure and function for the whole genus or to predict what would be covered by the functionally claimed genus." 759 F.3d at 1301; *see also*

Ariad, 598 F.3d at 1354-55 (stating that the written description problem "is particularly acute in the biological arts" and "when a patent claims a genus by its function or result, the specification [must] recite[] sufficient materials to accomplish that function"). A broad claim scope also requires more supporting detail because the recitation in the specification must "demonstrate that the inventor possesses the full scope of the invention." *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005).

The Court is also mindful that even in an "unpredictable art," "every species in a genus need not be described in order that a genus meet the written-description requirement." *Regents of Univ. of Cal. v. Eli Lilly*, 119 F.3d 1559, 1568 (Fed. Cir. 1997). If a POSITA can "visualize or recognize the identity of the members of [a substantial portion of] the genus," most often based on "structural features commonly possessed by members of the genus that distinguish them from others," the written description requirement can be met. *Id.* at 1568-69. However, a definition by function, without more, would not suffice to define the genus. *Id.* at 1568.

Turning to the 2005 provisional application, the Court finds that no reasonable trier of fact would find adequate written description support for the asserted claims. Specifically, the 2005 provisional application provides inadequate written description support for "treating a breast condition" or "mammary intraepithelial neoplasia (MIN)" and inadequate written description support for the "indirect" subgenus.

a. "Treating a Breast Condition" or "Mammary Intraepithelial Neoplasia (MIN)"

First, the 2005 provisional application contains insufficient disclosure for "treating a breast condition" or "mammary intraepithelial neoplasia (MIN)." The entire 2005 provisional application contains only one mention of breast cancer, in a laundry list of about 38 different types of conditions. Ex. 4 to Chivvis Decl. 7. This alone cannot constitute adequate written description for the limitations of "treating a breast condition" or "MIN." *See Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571 (Fed. Cir. 1996) (holding that a "laundry list" disclosure of every possible species in the genus cannot be adequate disclosure "because such a disclosure would not 'reasonably lead' those skilled in the art to any particular species"). Moreover, there are no prophetic or working

examples of treating breast cancer or experiments on breast cancer cell lines. The only examples involved experiments on prostate cancer cell lines. Ex. 4 to Chivvis Decl. 53-60.

Although Phigenix contends that its expert, Dr. Pestell, adequately refutes Genentech's arguments, Phigenix's expert declaration fails to create a triable issue of material fact on whether "treating a breast condition" is adequately supported in the 2005 provisional application. Opp'n 9. Phigenix's expert, Dr. Pestell, opines that the inventor had conceived and possessed the invention claimed in the asserted claims as of the 2005 filing date, based on the disclosure of the 2005 provisional application. Ex. C to Murray Decl. ¶ 19 ("Pestell Decl.").

The Federal Circuit in *Rochester* found that when written description support is deficient on the face of the patent specification, a conclusory expert opinion cannot remedy that deficiency. 358 F.3d at 925-26. In *Rochester*, the inventors discovered that there were two types of cyclooxygenase enzymes, COX-1 and COX-2, and that selective inhibition of COX-2 without inhibiting COX-1 could reduce inflammation without gastrointestinal side effects. *Id.* at 917. The discovery ultimately led to a patent, whose representative claim recites "[a] method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human host in need of such treatment." *Id.* at 918. The lower court found on summary judgment that the claims lacked adequate written description support because the patent "neither discloses any [non-steroidal] compound nor provides any suggestion as to how such a compound could be made or otherwise obtained other than by trial-and-error research." *Id.* at 919. Affirming the lower court, the Federal Circuit considered the patent owner's expert declarations but found them unpersuasive. *Id.* at 925. It agreed with the lower court's assessment of the expert evidence, that despite the experts' opinions that a POSITA would understand from reading the patent what method is claimed, "it is clear from reading the patent" that the compound inhibiting PGHS-2 activity was "hypothetical" and that "the inventors had neither possession nor knowledge of such a compound." *Id.* at 925-96; *see also id.* at 927 (holding that "a patent can be held invalid for failure to meet the written description requirement, based solely on the language of the patent specification.")

Similarly here, the 2005 provisional application on its face fails to meet the written

description requirement for the limitation of "treating a breast condition," and the opinions of Dr. Pestell fail to create a genuine triable issue. Dr. Pestell points to a laundry list of conditions disclosed in the application, and concludes that a POSITA would understand that "neoplasias" include "MIN." Pestell Decl. ¶ 12. However, what a POSITA would understand "neoplasias" to include does not shed light on whether a POSITA would recognize that the inventor had possession of an invention directed to treating a breast condition by affecting PAX2/DEFB1. Moreover, just like *Rochester*, the conclusory opinion of an expert, without any analysis or factual support, cannot defeat the deficiency that is evident on the face of a patent. Here, the sole mention of breast cancer in a laundry list of at least 38 conditions, and the mention of "neoplasia," which also includes many other conditions other than breast cancer, cannot plausibly convey to a POSITA that the inventor had possession of treating all the conditions in the list, including breast cancer. *Rochester*, 358 F.3d 925-96; *see id.* at 925 (in finding invalidity of the claims, noting that the expert declarations were silent on whether "one of skill in the art would, from reading the patent, understand what compound or compounds—which, as the patent makes clear, are necessary to practice the claimed method—would be suitable, nor would one know how to find such a compound except through trial and error."). "Such wholly conclusory assertions" cannot carry Phigenix's burden here. *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1068 (Fed. Cir. 2005) (finding that the expert declaration lacked substantive factual guidance and could not carry the burden on summary judgment).

In light of the above, the Court concludes that no reasonable trier of fact could find that the limitations of "treating a breast condition" or "MIN" as required by the asserted claims have adequate written description support in the 2005 provision application. The written description requirement prohibits inventors from " 'prempt[ing] the future before it has arrived,'" *Billups-Rothenberg, Inc. v. Associated Regional & Univ. Pathologists, Inc.*, 642 F.3d 1031, 1036 (Fed.Cir.2011) (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)), yet here, the inventor left "[t]he actual inventive work" underlying breast cancer treatment "for subsequent inventors to complete," *Centocor*, 636 F.3d at 1353. Accordingly, Claims 1, 2, and 8 of the '534 patent do not have adequate written description support in the 2005 provisional patent application

and are not entitled to the October 14, 2005 priority date.

b. The "Indirect" Subgenus

Another reason why the asserted claims are not entitled to the 2005 priority date is because the 2005 provisional application contains insufficient disclosure on the "indirect" subgenus," methods that achieve the claimed functional result indirectly. The Federal Circuit in *Boston Sci. Corp. v. Johnson & Johnson* was confronted with a similar situation where the specification failed to provide adequate written description support for a subgenus of a patent claim and affirmed summary judgment of invalidity based on a failure to meet the written description requirement. 647 F.3d 1353, 1369 (Fed. Cir. 2011). The claims at issue there concerned "drug-eluting stents using either rapamycin or a macrocyclic lactone analog of rapamycin." *Id.* at 1357. The Federal Circuit found that while there was disclosure of rapamycin, disclosure supporting "macrocyclic lactone analogs of rapamycin" was insufficient. *Id.* at 1364. Specifically, the court concluded that despite the vague indication in the patents that the macrocyclic lactone analog must be "structurally similar to rapamycin," such disclosure still lacked guidance for a POSITA "to properly determine whether a compound is a macrocyclic lactone analog of rapamycin." *Id.* "[T]he universe of potential compounds that are structurally similar to rapamycin and classifiable as macrocyclic lactones is potentially limitless." *Id.* The court further noted that the fact that "some species of this vast genus were known in the art" did not excuse the deficiency in written description especially given that the state of the art was unpredictable. *Id.*; *see also Centocor*, 636 F.3d at 1345, 1345-46, 1351 (finding inadequate written description support for the claims directed to fully human antibodies filed in later continuation-in-part applications because the specification disclosed only mouse and chimeric antibodies but did not disclose a single human variable region).

Here, the claimed genus includes a subgenus of using any of the *indirect* interactors with PAX2 and DEFB1 genes or proteins. Unlike the '534 patent, where some indirect inhibitors are disclosed, the specification of the 2005 provisional application is devoid of any example of such indirect interactors or any structural or formula common to the "indirect" subgenus. Exs. 4, 7 to Chivvis Decl. Thus, the specification of this provisional application on its face fails to provide a

representative number of species or structural features common to the members of the subgenus. *Ariad*, 598 F.3d at 1350; *Rochester*, 358 F.3d at 927.

The "indirect" subgenus is thus similar to the "universe" of "macrocyclic lactone analog of rapamycin" in *Boston Sci.*, in that the asserted claims attempt to cover a broad scope of subject matter that is not disclosed. The 2005 provisional application is even more deficient than the patent in *Boston Sci.*, where there was at least some teaching that the analog should be structurally similar to rapamycin, which the court still deemed inadequate. *Boston Sci*, 647 F.3d at 1364. And like *Centocor*, where the patent owner attempted to claim new subject matter in later-filed applications that was not disclosed in earlier applications, it would be improper for the asserted claims filed in the '534 continuation-in-part, to reach back to claim the 2005 priority date when the 2005 provisional application provides no disclosure with respect to this subgenus of indirect interactors. 636 F.3d at 1346, 1353; *see also Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1125 (Fed. Cir. 2008) (holding that specification that only discloses "the *polA* gene coding sequence from one bacterial source . . . fails to disclose or describe the *polA* gene coding sequence for any other bacterial species.").

Even though the specification contains some disclosures on "aptamers," "antisense molecules," "ribozymes," or "triplex forming functional nucleic acid molecules," that could potentially be used in the "indirect" subgenus, these disclosures are merely a "wish" or a "plan," without any connection to PAX2 or DEFB1. Mot. 7; Ex. 4 to Chivvis Decl. 19-21. Just like the "decoy molecules" in *Ariad*, the specification of the 2005 provisional application provides a generic definition of "aptamers" and others, without identifying any exact composition that can achieve the claimed functional result. *See* 598 F.3d at 1357; *id.* at 1351 (holding that "generic language in the application as filed does not automatically satisfy the written description requirement"); *id.* at 1350 (holding a claim amounts "to no more than a 'wish' or 'plan' for obtaining [the claimed invention]" fails the written description requirement) (citing *Fiers*, 984 F.2d at 1170-71). Without any guidance or examples in the specification, the asserted claims simply claim a desired result "without describing species that achieve that result." *Ariad*, 598 F.3d at 1349. Accordingly, a POSITA would not be able to recognize in the 2005 provisional

application the species of this subgenus that can accomplish the claimed functional results indirectly.

Although Phigenix contends that its expert, Dr. Pestell, adequately refutes Genentech's arguments, Phigenix's expert declaration fails to create a triable issue of material fact on whether the "indirect" subgenus is adequately supported in the 2005 provisional application. Opp'n 9. As noted above, Dr. Pestell concludes that the inventor had conceived and possessed the invention claimed in the asserted claims as of the 2005 filing date, based on the disclosure of the 2005 provisional application. Pestell Decl. ¶ 19. In reaching this conclusion, Dr. Pestell briefly discusses the siRNA experiment in prostate cancer cells that inhibit PAX2 expression. *Id.* ¶ 13-14; Ex. 4 to Chivvis Decl. 117. According to Dr. Pestell, the provisional application teaches the mRNA sequence and the amino acid sequence of PAX2. *Id.* ¶ 16. He also notes that the provisional application teaches technologies for delivering the composition to cells. *Id.* ¶ 17.

However, the Federal Circuit in *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.* held that expert statements that failed to address the deficiency in the written description could not defeat summary judgment. 541 F.3d 1115, 1126-27 (Fed. Cir. 2008). The *Carnegie Mellon* court found the claims invalid as they were "directed to recombinant plasmids that contain a DNA coding sequence that is broadly defined, and only by its function," without adequate written description support. *Id.* at 1123-24, 1127. Agreeing with the lower court's grant of summary judgment, the court found that that the narrow disclosure of one type of bacterial *polA* gene, the *E. coli polA* gene, was not representative of and fails to adequately support the entire claimed genus. *Id.* at 1126. The Federal Circuit also noted that to satisfy the written description requirement, "[o]ne must show that one has possession, as described in the application, of sufficient species to show that he or she invented and disclosed the totality of the genus." *Id.* at 1126. As to the appellants' argument regarding expert statements "concerning cloning techniques for purifying *polA* genes and experiments involving *E. coli*," the court found the statements to be immaterial to the relevant inquiry and thus did not raise genuine issues of material fact. *Id.* at 1127.

Similarly here, the opinions of Dr. Pestell are either immaterial or fail to create a triable issue. Dr. Pestell acknowledges that the claims encompass exerting both direct and indirect effects

on PAX2/DEFB1. Pestell Decl. ¶ 10. Yet, his declaration is completely silent on how a POSITA would have recognized any of the species in the "indirect" subgenus. Dr. Pestell discusses the siRNA experiment but the siRNAs were based on the actual gene sequence encoding PAX2, and were not indirect interactors. Just like *Carnegie Mellon* where the court found that "one type of bacterial *polA* gene" is not representative of the entire genus of bacterial *polA* gene," an example of directly affecting PAX2 is not representative of the whole genus covering "indirect" methods. Technology for delivering the composition is also immaterial to the issue of whether the "indirect" subgenus is adequately supported and does not remedy the lack of written description. Although Dr. Pestell opines that the inventor conceived and possessed the claimed invention, he provides no reasoning and points to no factual support for the "indirect" subgenus. Just like the limitation on "treating a breast condition," Dr. Pestell's conclusory assertions that the inventor had possession of the "indirect" subgenus carry no force. *See Invitrogen,* 429 F.3d at 1068.

In light of the above, the Court concludes that no reasonable trier of fact could find that the "indirect" subgenus of the asserted claims has adequate written description support in the 2005 provisional application. The inventor of the 2005 provisional application left "[t]he actual inventive work" underlying the vast scope of the "indirect" genus "for subsequent inventors to complete," *Centocor,* 636 F.3d at 1353. Given that the written description support is not commensurate in scope with the claims, the 2005 provisional patent application does not provide adequate written description support for Claims 1, 2, and 8 of the '534 patent.

iv. Evidence on POSITA's Skill is Not Necessary

Phigenix contends that summary judgment should be denied because Genentech did not submit evidence on the skill of a POSITA. Opp'n 7. However, evidence on a POSITA's skill is not necessary if the patent specification is clear on its face that the written description requirement is not met and Phigenix has not come forward with any evidence to create a genuine issue of material fact. *See Rochester,* 358 F.3d at 927.

As discussed above, the Federal Circuit in *Rochester* held that a patent on its face can fail to meet the written description requirement, if it is clear that the disclosure was "hypothetical" and that "the inventors had neither possession nor knowledge of [the species in the genus]." 358 F.3d

at 925-96. This is true especially in a case where the patent neither discloses any species in the genus, nor provides any suggestion as to how such a claimed species "could be made or otherwise obtained other than by trial-and-error research." *Rochester*, 358 F.3d at 919; *Ariad*, 598 F.3d at 1350 (holding that "a sufficient description of a genus . . . requires the disclosure of either a representative number of species falling within the scope of the genus or structural feature common to the members of the genus").

The case here is analogous to *Rochester*. The 2005 provisional application neither discloses any examples of any species in the "indirect" subgenus, nor provides any guidance on the structure or formula of any composition that can exert the indirect effects. As to the limitation of "treating a breast condition" or "MIN," one passing mention of "breast cancer" in a long list of conditions to treat is not enough to convey to a POSITA that the inventor had possession of the invention. See *Ariad*, 598 F.3d at 1351 (holding that "generic language in the application as filed does not automatically satisfy the written description requirement"). Given that the 2005 provisional application on its face provides no guidance to a POSITA and fails to convey that the inventor possessed an invention for "treating a breast condition" and the "indirect" subgenus at the time of invention, the Court finds that Genentech has met the moving party's initial burden without evidence on the skill of a POSITA.

Although Phigenix cites several cases purported to suggest that lack of evidence on the skill of a POSITA precludes summary judgment, they are distinguishable from this case. In *Vas-Cath Inc. v. Mahurkar*, the Federal Circuit found that the expert declaration addressed the concerns raised by the lower court on whether the diagram provided written description support for the patented design. 935 F.2d 1555, 1556-67 (Fed. Cir. 1991). Summary judgment was reversed because the lower court made several errors of law (*e.g.*, relating to whether the drawing could include diameters other than the claimed range, and to whether other patents should be taken into account) that affected the lower's court's interpretation of the expert declaration. *Id.* at 67. Given that the parties raised no legal issues that would affect the interpretation of an expert declaration, *Vas-Cath* is inapposite here.

In *Genentech, Inc. v. Trustees of Univ. of Pa.*, the key issue was whether "isolated tumor

cells" possessed properties of breast cancer cells. 871 F. Supp. 2d 963, 969 (N.D. Cal. 2012). In denying summary judgment, the court noted that the patent owner had provided expert evidence squarely addressing the disputed issue of whether a POSITA would know about the cancerous properties of these isolated tumor cells. *Id.* at 981. Like *Genentech*, the court in *Sanofi-Aventis Deutschland GMBH v. Genentech, Inc.* also denied summary judgment based on expert evidence that was on point. No. 08-4909-SI, 2011 WL 839411, at *17-18. (N.D. Cal. Mar. 7, 2011). The defendant in *Sanofi-Aventis* argued that the claim was overly broad for covering "the use of all DNA sequences of any length and any position that are derived from the 'upstream region' [of a gene of the human cytomegalovirus ("HCMV")] and function as an 'isolated DNA enhancer.'" *Id.* at *15. The patent owners' expert declaration pointed out in the specification that the locations of the "enhancer" were identified in relation to restriction sites, and stated that the HCMV genome restriction map had been known. *Id.* at *17-18. Given this evidence, the court denied summary judgment. *Id.* at *18; *see also AAT Bioquest, Inc. v. Texas Fluorescence Labs., Inc.*, No. 14-CV-03909-DMR, 2015 WL 1738402, at *5-6 (N.D. Cal. Apr. 13, 2015) (in the context of a patent claiming a specific compound that acts as a fluorescent calcium ion indicator, noting that the expert had pointed to relevant support in the patent applications and that the defendant conflated its contention on written description with that on inequitable conduct); *Karl Storz Endoscopy-Am., Inc. v. Stryker Corp.*, No. 09-00355-WHA, 2011 WL 5974668, at *7, 9 (N.D. Cal. Nov. 29, 2011) (in a patent case concerning surgical instruments, noting that the patent owner's expert cited to an article supporting the contention that a POSITA would understand "self-configuring bus" to include "plug-and-play capable buses" and that the defendant provided no evidence to rebut this expert evidence); *Regents of Univ. of Cal. v. Dako N. Am., Inc.*, No. 05-03955-MHP, 2009 WL 1083446, at *2, 9, 11 (N.D. Cal. Apr. 22, 2009) (in a case concerning staining chromosomal DNA using a blocking method, denying summary judgment because the defendant did not provide evidence of substantial variations in the blocking method to refute the patent owner's expert declaration that the method would apply equally to all types of DNA); *Medtronic, Inc. v. Telectronics, Inc.*, 686 F. Supp. 838, 842-43 (D. Colo. 1987) (noting that evidence relating to views of the POSITA was necessary to evaluate the arguments on whether "penetration of heart

tissue" differs from "perforation of the heart wall," and whether a statement on "possibility of perforation" sufficient disclosed "penetration prevention").

None of these cases is analogous to the case here. *Medtronic* concerned a situation where the specification was not deficient on its face. In the other cases, the expert evidence from the patent owner squarely addressed the issue of written description with sufficient analysis or corroborated evidence. In contrast, the 2005 provisional application here is deficient on its face with respect to written description support, and Phigenix's expert declaration is conclusory and fails to provide any support with respect to "treating a breast condition" or to the "indirect" subgenus. As such, these cases do not compel a different conclusion.

v. References Cited in the 2005 Provisional Application

Phigenix also argues that the 2005 provisional application incorporates references disclosing technologies that deliver compositions to treat cancers. Opp'n 4. Phigenix provides to the Court one such cited reference. Ex. D to Murray Decl. (the "Pietersz Publication").

"To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." *Zenon Envtl., Inc. v. U.S. Filter Corp.*, 506 F.3d 1370, 1378 (Fed. Cir. 2007) (citation and italics omitted); *see also Otto Bock HealthCare LP v. %20Ossur HF*, 557 F. App'x 950, 955 (Fed. Cir. 2014) (noting that "the use of the content of a nonpatent publication incorporated by reference to add structure to a means-plus-function claim" is foreclosed).

The Court need not reach a determination as to whether the Pietersz Publication and other nonpatent references were properly incorporated to meet the written description requirement. This is because the Pietersz Publication and other cited articles are generally directed to "technology to target specific proteins to tumor tissue." Ex. 4 to Chivvis Decl. 28, 38. They do not provide any information specifically on PAX2 or DEFB1, let alone affecting PAX2/DEFB1 to treat a breast condition or to achieve the claimed functional results indirectly. For example, the Pietersz Publication is a review article on the use of murine monoclonal antibodies conjugated to drugs to target solid tumors of breast, ovary, colon, prostate, and lung. Pietersz Pub. 57, 63, 64. Such disclosure on wide ranging subjects does not remedy the inadequate written description in support

of the "indirect" subgenus or of the limitations of treating a "breast condition," "breast cancer," or "MIN." *See Lizardtech*, 433 F.3d at 1379.

vi. Inherent Anticipation by Publicly Disclosed Uses of Kadcyla

Now that the Court has determined that the asserted claims lack adequate written description in the 2005 provisional application, the Court turns to whether the public use of Kadcyla in 2007 would anticipate the asserted claims, assuming that Kadcyla's public use is prior art.

Genentech argues that the asserted claims of the '534 patent are anticipated by public use of the accused product in 2007 given that the claims are not entitled to the 2005 priority date. Mot. 11. Specifically, Genentech claims that Kadcyla was used in clinical trials, which were made public as early as June 2007. *Id.* As such, Genentech concludes that the public use anticipates the asserted claims. *Id.* (citing *Upsher-Smith Labs., Inc. v. Pamlab, L.L.C.*, 412 F.3d 1319, 1322 (Fed. Cir. 2005) (holding that a product "which would literally infringe if later in time anticipates if earlier")).

In opposition, Phigenix argues that there is a factual dispute as to whether the public use "necessarily met the claim limitations." Opp'n 10. Phigenix also distinguishes *In re Montgomery*, because there is a dispute here whether Kadcyla actually inhibits PAX2. 677 F.3d 1375, 1381 (Fed. Cir. 2012) (noting that the patent holder "does not dispute that Ramipril [, a use of which is prior art,] is in fact effective at preventing or treating stroke, which is the entire premise of his patent"); Opp'n 10-11. Phigenix also contends that Genentech's evidence fails to show that the patient populations involved in the allegedly public use were the same as those for which Kadcyla is indicated. Opp'n 11-12. According to Phigenix, there is no foundation for Genentech's expert, Dr. Girish's declaration that "others would understand" that the patients in the clinical trial populations had previously received a taxane. *Id.* at 12.

A claim is anticipated "if each and every limitation is found either expressly or inherently in a single prior art reference." *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1274 (Fed. Cir. 2010). Alternatively, one could rely on the holding of *Upsher-Smith* to invalidate a patent claim, where a method that infringes later would anticipate if earlier. 412 F.3d at 1322 (holding

that a product "which would literally infringe if later in time anticipates if earlier"). In other words, for a method that infringes later to anticipate if earlier, the infringing method and anticipatory method must be identical.

The Court finds that there is a genuine issue of material fact as to whether Kadcyla's public use expressly or inherently anticipates the asserted claims. The FDA-approved use of Kadcyla, the allegedly infringing method, involves treating a patient population with HER2-positive metastatic breast cancer that has previously received trastuzumab and taxane treatments. In light of the principle articulated in *Upsher-Smith*, the public use must be identical to the allegedly infringing method for it to be anticipatory. Genentech proffers a number of references related to the clinical phase I trial of Kadcyla, the earliest of which was published on June 20, 2007. Ex. A to Girish Decl., ECF 259-1. One of the documents is a poster describing the phase I clinical trial, published on December 14, 2007, which states that "[i]n addition to Trastuzumab, all patients with objective responses had previously been treated with paclitaxel, docetaxel, and/or vinorelbine." Ex. C to Girish Decl., ECF 259-3; Ex. G to Girish Decl. 27, ECF 259-7.

However, when the evidence is viewed in a light most favorable to Phigenix, there is enough evidence for a reasonable trier of fact to find that the public use and the allegedly infringing method are not identical. Although paclitaxel and docetaxel are taxanes, vinorelbine is not a taxane. Given the disjunctive in the list of "paclitaxel, docetaxel, and/or vinorelbine," it is not impossible that the patients of the clinical phase I trial had received vinorelbine but not either of the two taxanes. Genentech's expert, Dr. Girish, declares that "attendees of these meetings and symposia would have understood that many of the patients enrolled in these phase I clinical trials had been previously treated with a 'T-containing regimen' that included a taxane along with trastuzumab." Girish Decl. ¶ 11, ECF 259. However, this statement in the declaration is conclusory and without factual support. *Invitrogen*, 429 F.3d at 1068 (finding that the expert declaration lacked substantive factual guidance and could not carry the burden on summary judgment). Accordingly, there is a genuine dispute as to whether the public use of Kadcyla anticipates the asserted claims.

IV. ORDER

For the foregoing reasons, IT IS HEREBY ORDERED that:

1. Genentech's motion for summary judgment is DENIED IN PART as to whether Claims 1, 2, and 8 of the '534 patent are invalid based on inadequate written description in the '534 patent in accordance with 35 U.S.C. section 112;
2. Genentech's motion for summary judgment is GRANTED IN PART as to the lack of adequate written description in the 2005 provisional patent application for Claims 1, 2, and 8 of the '534 patent in accordance with 35 U.S.C. section 112. Accordingly, Claims 1, 2, and 8 of the '534 patent are not entitled to claim the October 14, 2005 priority date based on the 2005 provisional patent application.
3. Genentech's motion for summary judgment is DENIED IN PART as to whether the public use of Kadcyla anticipates Claims 1, 2, and 8 of the '534 patent.

Dated: February 24, 2017

BETH LABSON FREEMAN
United States District Judge