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 DENYING MOTION FOR SANCTIONS

[Re: ECF 198]

Plaintiff Phigenix, Inc. ("Phigenix") brings this patent infringement lawsuit against Defendant Genentech, Inc. ("Genentech") alleging infringement of U.S. Patent No. 8,080,534 ("the '534 patent"). ECF 21. Before the Court is Genentech's motion for sanctions under Fed. R. Civ. P. 11. ECF 198. The Court, having considered the briefing submitted by the parties and the oral argument presented at the hearing on August 18, 2017, DENIES Genentech's motion.

I. BACKGROUND

Phigenix's complaint alleges that Genentech's breast cancer drug, Kadcyla, infringes claims 1, 2, and 8 of the '534 patent. ECF 21. Kadcyla comprises the antibody trastuzumab linked to DM1, a cytotoxic agent that belongs to the maytansinoid drug class. Mot. 3. Trastuzumab specifically targets a protein named HER2, which is expressed at high levels on the surface of cancer cells associated with certain aggressive cancers. *Id.* 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. *Id.* Kadcyla is indicated for patients with

HER2- positive metastatic breast cancer who have previously received trastuzumab and taxane treatments. *Id.* at 3-4.

Before Phigenix filed its complaint, Phigenix contacted Genentech to offer a license to its patent portfolio, and informed Genentech of its theory on how Kadcyla infringes the '534 patent. *Id.* at 4. According to Phigenix's infringement theory, Kadcyla inhibits PAX2 and enhances DEFB1 expression and thus infringes the '534 patent. *Id.* Claim 1 of the '534 patent is representative:

> 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.

Genentech declined Phigenix's licensing offer and alerted Phigenix to PCT publication WO 01/00244 ("the '244 application"), a reference that Genentech believes invalidates the '534 patent under Phigenix's infringement theory. Mot. 4. Phigenix was not persuaded by the '244 application and related to Genentech other studies supporting its theory of infringement. Opp. 3. According to Phigenix, Genentech took no position on the issue of infringement during the parties' pre-filing communications. Opp. 3.

After a six-month dialog between the parties, Phigenix filed this suit in January 2014. Opp. 3. In June 2014, Genentech told Phigenix that the complaint warrants a Rule 11 sanctions, to which Phigenix disagreed. Opp. 4. On May 10, 2016, Genentech filed the present motion. ECF 198.

At the hearing on August 18, 2017, the parties discussed with the Court that they were expecting results from Phigenix's testing of Kadcyla. Hr'g Tr. 4:3-6. The parties agreed to submit supplemental briefing after receiving Phigenix's test results. *Id.* at 34:12-35:25. On October 11, 2016, the parties filed their supplemental briefing after receiving the test results and an opportunity to depose Dr. Mauricio Reginato, Phigenix's expert on the test results. ECF 269, 271, 273.

II. LEGAL STANDARD

Rule 11 of the Federal Rules of Civil Procedure imposes upon attorneys a duty to certify

that they have read any pleadings or motions they file with the court and that such pleadings and motions are well-grounded in fact, have a colorable basis in law, and are not filed for an improper purpose. Fed. R. Civ. P. 11(b); *Business Guides, Inc. v. Chromatic Comm. Enters., Inc.*, 498 U.S. 533, 542 (1991). If a court finds Rule 11(b) has been violated, the court may impose appropriate sanctions to deter similar conduct. Fed. R. Civ. P. 11(c)(1); *see also Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 393 (1990) ("[T]he central purpose of Rule 11 is to deter baseless filings in district court."). However, "Rule 11 is an extraordinary remedy, one to be exercised with extreme caution." *Operating Eng'rs Pension Trust v. A-C Co.*, 859 F.2d 1336, 1345 (9th Cir. 1988). Rule 11 sanctions should be reserved for the "rare and exceptional case where the action is clearly frivolous, legally unreasonable or without legal foundation, or brought for an improper purpose." *Id*. at 1344. "Rule 11 must not be construed so as to conflict with the primary duty of an attorney to represent his or her client zealously." *Id.*

In determining whether Rule 11 has been violated, a "court must consider factual questions regarding the nature of the attorney's pre-filing inquiry and the factual basis of the pleading." *Cooter*, 496 U.S. at 399. However, courts should "avoid using the wisdom of hindsight and should test the signer's conduct by inquiring what was reasonable to believe at the time the pleading, motion, or other paper was submitted." Fed. R. Civ. P. 11 Advisory Comm. Notes (1993 Amendments). "[T]he imposition of a Rule 11 sanction is not a judgment on the merits of an action. Rather, it requires the determination of a collateral issue: whether the attorney has abused the judicial process, and, if so, what sanction would be appropriate." *Cooter*, 496 U.S. at 396.

In patent infringement cases, the Court applies regional circuit law to Rule 11 motions. *E.g.*, *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 873 (Fed. Cir. 2010). In the Ninth Circuit, Rule 11 sanctions are appropriately imposed where: (1) a paper is filed with the court for an improper purpose; or (2) the paper is "frivolous." *Intamin Ltd. v. Magnetar Techs., Corp.*, 483 F.3d 1328, 1338 (Fed. Cir. 2007). "A 'frivolous' argument or claim is one that is '*both* baseless *and* made without a reasonable and competent inquiry.'" S. *Bravo Sys, Inc. v. Containment Techs. Corp.*, 96 F.3d 1372, 1375 (Fed. Cir. 1996) (quoting *Townsend v. Holman Consulting Corp.*, 929 F.2d 1358, 1362 (9th Cir. 1990)) (emphasis added). Accordingly, when sanctions are sought on

the basis of a complaint, the Court must determine: "(1) whether the complaint is legally or factually 'baseless' from an objective perspective, and (2) if the attorney has conducted 'a reasonable and competent inquiry' before signing and filing it." *Christian v. Mattel, Inc.*, 286 F.3d 1118, 1127 (9th Cir. 2002).

The Federal Circuit, applying Ninth Circuit law, stated that the second prong—a reasonable and competent inquiry—in the patent context requires "at a minimum, that an attorney interpret the asserted patent claims and compare the accused device with those claims before filing a claim alleging infringement." *Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1300 (Fed. Cir. 2004). The district court need not determine whether plaintiff's pre-filing interpretation of the asserted claims was correct, but rather only whether such interpretation was frivolous. *Id*. at 1301. Nevertheless, even in the patent context, the Federal Circuit has acknowledged that a defective pre-filing inquiry alone is not sanctionable if the complaint is not objectively baseless. *View Eng'g, Inc. v. Robotic Vision Sys., Inc.*, 208 F.3d 981, 985 n.4 (Fed. Cir. 2000) ("The 9th Circuit has held that an attorney may not be sanctioned under Rule 11 for a complaint that is not well-founded, so long as she conducted a reasonable inquiry nor may she be sanctioned for a complaint which is well-founded, solely because she failed to conduct a reasonable inquiry.").

III. DISCUSSION

Based on the legal standard, Phigenix would only violate Rule 11 in filing of its complaint if both of the following prongs are met: "(1) the complaint is legally or factually 'baseless' from an objective perspective," and (2) the attorney has not conducted "'a reasonable and competent inquiry' before signing and filing it." *Christian*, 286 F.3d at 1127.

In its opposition and at the hearing, Phigenix chose not to address its pre-filing investigation for risk of waiving work product immunity and attorney-client privilege. Opp. 3; Hr'g Tr. 18:14-19:9. Phigenix thus concedes that the Court cannot evaluate the second prong – whether Phigenix has conducted "a reasonable and competent inquiry" before filing the complaint. *Id.* at 18:18-19:9. In light of Phigenix's decision, the Court must presume Genentech has demonstrated that Phigenix has not conducted a reasonable and competent pre-filing inquiry, and will focus only on the first prong – whether the complaint is legally or factually "baseless" in

determining whether to grant this motion.

A. Basis for Phigenix's Infringement Theory

In support of its motion, Genentech first argues that Phigenix's infringement theory lacks sufficient basis. Genentech faults Phigenix for not performing any pre-filing testing of Kadcyla. Mot. at 5. Genentech also found inadequate the articles that Phigenix relied upon for its theory – the '534 patent publication, "Bose article," and the "Walker articles." *Id*. at 5-6, Exs. B, 5, and 6. Specifically, Genentech contends that these publications do not establish direct effect of STAT3 inhibiting PAX2, do not establish that this effect would be found in HER2-positive breast cancer cells, and do not establish that Kadcyla would inhibit STAT3. *Id.* at 6. Genentech provides a declaration (the "Walker Declaration") from one of the authors of the Walker articles – Dr. Walker – stating that an extrapolation from the publications to Phigenix's infringement theory is speculative and unsupported. *Id.* Phigenix disputes that its theory is founded on speculation and further argues that the Walker Declaration fails to establish that Phigenix's claim is baseless. Opp. 7.

As a preliminary matter, since Phigenix concedes that it performed no pre-filing testing and has chosen not to reveal its attorneys' infringement analysis, the publications purported to support Phigenix's infringement theory are the only basis available to the Court to evaluate whether the complaint is factually or legally baseless. Turning to these publications, the Court finds that they provide some basis for Phigenix's theory. First, it is not disputed that DM1, a component of Kadcyla, is a microtubule inhibitor. Opp. 2; Mot. 6, Ex. B (Kadcyla Full Prescribing Information; Kadcyla Label). Second, the Walker articles show that treating cultured cells with microtubule-targeted drugs, such as paclitaxel, inhibits STAT3 activity and could be effective in treating cancer. Mot. Ex. 5, at 903 and Ex. 6, at 1. The Walker articles also state that STAT3 activity is increased in breast cancer cells relative to non-cancer cells and is also known to be associated with microtubule. Mot. Ex. 5, at 903 and Ex. 6, at 3. Based on the Walker articles, one could infer that DM1 would inhibit STAT3 activity, too, because it is a microtubule inhibitor like paclitaxel. *See* Mot. Ex. 5, at 908 and Ex. 6, at 6. Third, the '534 patent itself and the Bose article provide cell culture experimental data showing that suppressing STAT3 activity in prostate

cancer cell lines also suppresses PAX2 activity. '534 patent at 42:29-48, Figs. 25A, B, and C; Mot. Ex. 7, at 1341, Fig. 5. Accordingly, Phigenix's infringement theory links all these observations together to conclude that if DM1 inhibits microtubule, it would inhibit STAT3 activity and, in turn, PAX2 activity.

Genentech argues that Phigenix's inference that DM1 would behave similarly to paclitaxel, the microtubule inhibitor used in Walker's articles, is mere speculation. Mot. 6. However, one of the Walker articles tested another microtubule-destablizing agent in addition to paclitaxel, vinorelbine, which was also found to inhibit STAT3 activity. Mot., Ex. 5, at 905. In both articles, the authors concluded that microtubule-target therapy generally would inhibit STAT3 signaling without limiting their conclusion to only paclitaxel. *Id.* at 908; Mot., Ex. 6 at 6. Genentech offers Dr. Walker's declaration, asserting that the effect of DM1 is unknown since it was not tested and also that the cells used in the experiments were not HER2-positive cells. However, Dr. Walker conceded that these opinions derived from other studies and the publications Phigenix relied upon are completely silent on DM1 or the HER2-expression levels of the cell lines. Opp. Ex. 7 (Walker Dep.) at 25:2-13; 27:15-24; 28:7-13. Dr. Walker also admitted that the articles do not limit their conclusions to particular cell lines. *Id.* at 26:16-27:8.

Genentech also offers Dr. Geistlinger's Declaration, whose published work ("Hurtado") shows that tamoxifen cancer drug is effective because PAX2 plays a role in suppressing the expression of HER2. Mot. 6-7; Ex. D. Accordingly, if Kadcyla inhibits PAX2 activity in accordance with Phigenix's theory, it would not be an effective drug. Mot. 6-7. However, Dr. Geistlinger admitted that the cell lines used in his experiments were limited to cells positive for the oestrogen receptor (ER). Opp. Ex. 9 (Geistlinger Dep.) at 25:8-13. Moreover, Dr. Geistlinger also stated that cells positive for ER behave differently from cells negative for ER. *Id.* at 32:5-8. Although it is unclear whether Kadcyla is more effective on ER-positive than on ER-negative cells, *id.* at 52:17-56:9, what is clear is that Kadcyla is not solely indicated for tamoxifen-treated patients with ER-positive cancer cells. Opp. 10; Mot. Ex. B (Kadcyla Label); Reply Ex. T at 76:18-77:1. Accordingly, it is not a foregone conclusion that the Hurtado reference and Dr. Geistlinger's declaration are more relevant than the publications Phigenix relies on.

Based on these references, the Court finds that Genentech has not met its burden of demonstrating how Phigenix's complaint is "baseless." *See Tom Growney Equip., Inc. v. Shelly Irrigation Dev.*, Inc., 834 F.2d 833, 837 (9th Cir. 1987) (noting that the moving party bears the burden to demonstrate why sanctions are justified). Phigenix has properly relied on scientific, peer-reviewed articles to formulate its infringement theory and the parties' submissions here do not demonstrate that the reliance is baseless or unreasonable. Genentech might have raised valid questions challenging Phigenix's basis for its infringement theory but those challenges go more to the merits of the claim than to whether Phigenix has violated the judicial process under Rule 11.

The parties' supplemental briefing based on Phigenix's test results does not compel a different conclusion. Phigenix argues in its supplemental brief that Dr. Reginato's experiments show that Kadcyla inhibits PAX2 expression in MDA-MB-453 cells. Phigenix Supp. 3-4. Genentech counters that MDA-MB-453 is the wrong cell line for the experiment because the cell line does not express HER2 at the level for which Kadcyla is indicated. Genentech Supp. 1-2. However, Genentech also acknowledges that in one publication, the authors recognized that there are "disparities in the literature regarding HER2 expression of MDA-MB-453." *Id.* at 2. In reviewing the parties' briefing, as well as the other publications the parties discussed therein, the Court observes that none of the experiments perfectly duplicates the indication of Kadcyla in cell culture and that each type of study has its own strengths and weaknesses. A study in cell culture that replicates every detail of the Kadcyla indication for human patients might also simply be impossible to perform in the present case. It is more suited for experts to opine and a trier of fact to weigh the value of these different studies. To delve further into the details to decipher which experiment is more meritorious only detracts the Court from the main question in this motion – whether Phigenix has abused the judicial process under Rule 11. *Cooter*, 496 U.S. at 396.

In sum, given that one could reasonably infer Phigenix's theory from the various cited references, Phigenix's complaint is not objectively baseless. Moreover, the Court recognizes that most cell culture experiments that seek to replicate Kadcyla indication for human cancer would be susceptible to some criticisms, and expert opinions might differ on how best to replicate Kadcyla treatment in cell culture. For the Court to further evaluate the weight of the evidence and expert

declarations would be to examine the merit of Phigenix's infringement theory, which is not the purpose of this motion. Even if Genentech were to be correct in its challenge to Phigenix's reliance on those references and on Dr. Reginato's experiments, the challenge would be better reserved for other motions or for trial, but not on a Rule 11 motion for sanctions.

B. Inherent Anticipation by Paclitaxel

Genentech further argues that Phigenix brought the case knowing that the '534 patent is invalidated by its own infringement theory, violating Rule 11. Mot. 12-13 (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")). Specifically, Genentech contends that the references Phigenix cites in support of its infringement theory used paclitaxel, a taxane that has been approved as a breast cancer drug since the early '90s. Mot. 13. If the Kadcyla component, DM1, acts like paclitaxel and infringes the asserted claims, Genentech argues that paclitaxel would similarly invalidate the asserted claims. *Id.* at 13-14.

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). The asserted claims here are method of treatment claims, and require the limitations of "administering to a breast tissue of the subject," and inhibiting "PAX2 expression or PAX2 activity," or expressing "DEFB1." '534 patent, Claim 1. All the limitations of the claim must be necessarily present in the prior use of paclitaxel for the claims to be anticipated. As such, with respect to a method of treatment claim, it is the use of paclitaxel that is pertinent here and not paclitaxel itself. Alternatively, one could rely on the holding of *Upsher-Smith* to invalidate a method of use claim, where the analogous test here would be that a method that infringes later would anticipate if earlier. In other words, for a method that infringes later to anticipate if earlier, the infringing method and anticipatory method must be identical.

Here, Genentech has provided nothing other than attorney arguments to support that paclitaxel has been used in such a way that would make inhibiting PAX2 or expressing DEFB1 necessarily present. Merely pointing out that paclitaxel is used in the prior art is not enough. Genentech must show that the FDA-approved method of using paclitaxel necessarily inhibits

PAX2 or expresses DEFB1, which it has not. Alternatively, Genentech could show that that paclitaxel has been used in the FDA-approved methods in exactly the same way as how paclitaxel was used in the references discussed above linking paclitaxel to PAX2 inhibition. This could support Genentech's claim that the use of paclitaxel in treating human breast cancer would inhibit PAX2 like the paclitaxel in the references. However, Genentech has made no such showing. Relatedly, in those references, paclitaxel was used in cell culture experiments and was not administered to "a breast tissue of the subject," as required by the claims. As such, a gap remains between how paclitaxel behaves in cell culture and how it acts in human patients. Regardless, if the anticipatory and the infringing methods are not identical, the holding of *Upsher-Smith* cannot apply and the mere presence of paclitaxel would not render a method claim expressly or inherently anticipated. Genentech thus fails to bear the burden of showing how the use of FDA-approved paclitaxel drug necessarily reads on each and every element of the asserted claims.

The Court also notes that Genentech conflates the Rule 11 standard with the test for inherent anticipation. Under Rule 11, it might be reasonable to draw inferences from published paclitaxel experiments to support a theory that another microtubule-destabilizing agent, such as DM1, reads on the asserted claims. But under the test for inherent anticipation, a patent challenger must show that all elements of the asserted claims are *necessarily* present in the prior art to invalidate the patent. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003); *King Pharm.*, 616 F.3d at 1274. This is also consistent with the statutory presumption of validity and it is not unreasonable for a Phigenix to believe its patent to be valid in the first instance. *Q-Pharma*, 360 F.3d at 1303; 35 U.S.C. § 282. Accordingly, the Court does not find that Phigenix's claim to be factually or legally baseless merely because of the use of paclitaxel as a breast cancer drug.

C. Inherent Anticipation by the '244 Application

Genentech also contends that Phigenix's complaint is baseless because the '244 application inherently anticipates the '534 patent. Mot. 14; Reply 6. Genentech argues that the '244 application discloses "anti-HER2-maytansinoid conjugates, including trastuzumab-DM1 conjugates, for the treatment of breast cancer." *Id.* Phigenix knew of the '244 application because

Genentech alerted Phigenix to this reference during the pre-filing discussion. Mot. at 14. Phigenix counters that the '244 application fails to disclose PAX2 or DEFB1 expression and fails to disclose administration of Kadcyla to patents previously treated with a taxane. Opp. 11.

Since the '244 application does not disclose anything related to PAX2 or DEFB1, it can only anticipate if there is inherent anticipation, as acknowledged by Genentech. Inherent anticipation would require that inhibiting PAX2 or expressing DEFB1 be necessarily present in the method disclosed by the '244 application. *See Schering*, 339 F.3d at 1377. As discussed above, an alternative way to demonstrate anticipation, in accordance with the holding in *Upsher-Smith*, is to show that the method that infringes later anticipates if earlier. Given Phigenix's infringement theory that the Kadcyla's indication infringes its patent, if the '244 application discloses a method administered under exactly the same conditions as set forth in the Kadcyla indication, the '244 application would anticipate.

The Kadcyla indication label states that Kadcyla "is a HER2-targeted antibody and microtubule inhibitor conjugate . . . for the treatment of patients with HER2-positive, metastatic breast cancer who previously received trastuzumab and a taxane, separately or in combination." Kadcyla Label. The Court now turns to the '244 application to examine if it discloses a method that is exactly the same as the Kadcyla indication. The '244 application discloses that "the patient may be treated with a first anti-ErB2 antibody-maytasinoid conjugate in which the antibody is growth inhibitory . . . ." '244 application at 40:32-33. The Court notes that "anti-ErB2 antibody-maytasinoid conjugate" encompasses Kadcyla.[1] The '244 application also states that the treatment can target "ErbB overexpressing tumors that do not respond or respond poorly, to treatment with an unconjugated anti-ErB antibody." *Id.* at 40:13-14. Based on this statement, the disclosed treatment targets HER2-expressing tumor that has previously been treated with trastuzumab.[2] The reference further discloses a mouse experiment in which trastuzumab alone has not effectively

[1] Defendant admits that the '244 application discloses a trastuzumab-DM1 conjugate with exactly the same linker as Kadcyla. Reply 6, Ex. R (Weiner Decl.). The Court does not determine whether the '244 application actually discloses Kadcyla itself.

[2] The Court understands that an HER2-positive tumor is also an ErbB overexpressing tumor, that Kadcyla is an anti-ERB2 antibody-maytasinoid conjugate, and that trastuzumab is an unconjugated anti-ErB antibody.

treated mice bearing tumors positive for HER2 but the trastuzumab-DM1 conjugate has. *Id.* at 47:18-33. Based on these disclosures, the Court concludes that the '244 application discloses a method treating patients with HER2-positive tumor with a drug like Kadcyla, who have previously received unconjugated trastuzumab as treatment.

However, the reference is silent on whether the patients to be treated have previously received a taxane. This is consistent with Phigenix's argument that Kadcyla is indicated for a patient population that is not exactly the same as the method disclosed in the '244 application. Opp. 12. Accordingly, if the method disclosed in the prior art is not exactly the same as the allegedly infringing method, and in the absence of any other information, the Court does not have enough information at this juncture to determine whether the elements of the asserted claims are necessarily present.

Similar to the arguments Genentech made for inherent anticipation by paclitaxel, Genentech also argues that Phigenix's infringement theory that DM1 affects STAT3 and PAX2 necessarily makes '224 anticipatory. Reply 6. Genentech again conflates the Rule 11 standard with the test for inherent anticipation. Phigenix's infringement theory that DM1 would affect STAT3 and PAX2 is in the context of the treatment for which Kadcyla is indicated, and not for every use of DM1 in the prior art. To demonstrate that a reference is inherently anticipatory, Genentech at least must show that the claimed elements are necessarily present. Alternatively, Genentech can show the allegedly infringing method is exactly the same as the method disclosed in the reference in accordance with the holding in *Upsher-Smith*. Genentech has shown neither. As such, the Court does not find that Phigenix's complaint legally or factually baseless based on its knowledge of the '244 application.

IV. ORDER

For the foregoing reasons, the Court DENIES Genentech's motion for Rule 11 sanctions. Although the Court finds that Genentech has not demonstrated Phigenix's failure to fulfill its Rule 11 obligations at this stage of the proceedings, Genentech has presented strong argument and evidence supporting potentially significant weaknesses in Phigenix's theory of infringement. This Order is issued without prejudice to Genentech's opportunity to request Rule 11 sanctions if

successful at summary judgment or to submit a motion for extraordinary case fees pursuant to 35 U.S.C. section 285 in the event that it obtains judgment in its favor.

Dated: October 31, 2016

BETH LABSON FREEMAN
United States District Judge

United States District Court
Northern District of California