NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

PHIGENIX, INC.,
Plaintiff-Appellant

v.

GENENTECH, INC.,
Defendant-Cross-Appellant

2017-2617, 2018-1042

Appeals from the United States District Court for the Northern District of California in No. 5:15-cv-01238-BLF, Judge Beth Labson Freeman.

Decided: September 5, 2019

BENJAMIN THOMPSON, Fish & Richardson, P.C., Atlanta, GA, argued for plaintiff-appellant. Also represented by AHMED JAMAL DAVIS, Washington, DC; MATTHEW C. BERNTSEN, Boston, MA; ALANA CANFIELD MANNIGE, Redwood City, CA; SARAH CORK, Proskauer Rose, Los Angeles, CA.

DEANNE MAYNARD, Morrison & Foerster LLP, Washington, DC, argued for defendant-cross-appellant. Also represented by SETH W. LLOYD, BRIAN ROBERT MATSUI;

MATTHEW A. CHIVVIS, MICHAEL ALLEN JACOBS, MATTHEW IAN KREEGER, San Francisco, CA.

Before REYNA, BRYSON, and STOLL, *Circuit Judges.*

STOLL, *Circuit Judge.*

Phigenix, Inc. sued Genentech, Inc. for induced infringement of various claims of U.S. Patent No. 8,080,534. After striking the infringement opinion of Phigenix's expert, the district court granted summary judgment of noninfringement based on a lack of evidence of both direct infringement and intent to induce infringement. The district court also denied summary judgment of invalidity based on various utility, enablement, and written description challenges advanced by Genentech.

Phigenix appeals the order striking its expert report and the grant of summary judgment of noninfringement. Genentech conditionally cross-appeals the denial of summary judgment of invalidity. Because the district court did not abuse its discretion, we affirm its order striking the infringement opinion of Phigenix's expert. We further affirm the district court's grant of summary judgment of noninfringement based on a lack of evidence of direct infringement. Because we affirm the district court's judgment of noninfringement, we do not address Genentech's conditional cross-appeal.

BACKGROUND

I

The '534 patent is titled "Targeting PAX2 for the Treatment of Breast Cancer." It is a continuation-in-part of a prior application that issued as U.S. Patent No. 7,964,577, and it claims priority to a provisional application filed on October 14, 2005. The specification of the '534 patent describes preventing or treating breast conditions (including breast cancer) by administering a composition that inhibits

and/or enhances the expression of certain genes (PAX2 and DEFB1, respectively). *See, e.g.*, '534 patent col. 1 l. 51–col. 2 l. 39, col. 6 l. 22–col. 8 l. 37.[1] Claim 1 recites "[a] method for treating a breast condition" by administering a composition that inhibits PAX2 expression or activity, and/or expresses DEFB1. *Id.* at col. 109 ll. 2–6.

II

In January 2014, Phigenix sued Genentech for infringement of the '534 patent based on Genentech's product Kadcyla, a pharmaceutical indicated for treating drug-resistant breast cancer. In its complaint, Phigenix alleged that Genentech induced infringement of the '534 patent by encouraging health care professionals to prescribe and administer Kadcyla to breast cancer patients who had previously received the chemotherapy drugs "trastuzumab and a taxane, separately or in combination." J.A. 531–32. Phigenix's infringement contentions, last supplemented in October 2014, similarly identified the relevant population as Kadcyla patients who had "previously received trastuzumab and a taxane." J.A. 1168–74.

In February 2017, the district court issued a summary judgment order holding that the asserted claims of the '534 patent are not entitled to the priority date of the 2005 provisional application. Phigenix did not move to amend its infringement contentions in response. Several months later—after fact discovery had closed and expert reports had been exchanged—Phigenix narrowed the relevant population to Kadcyla patients who were pretreated *exclusively* with trastuzumab and a taxane—i.e., trastuzumab, a taxane, and "and nothing else." J.A. 317–19. Phigenix did not do so by affirmatively moving for leave to amend its infringement contentions. Instead, Phigenix first revealed

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[1] We take no position on the content or adequacy of the disclosure of the '534 patent.

its narrowed definition during the deposition of its expert on May 23, 2017, and only in response to questioning by Genentech. Phigenix does not dispute that the narrowed population of relevant patients comprises only about 4% of the total population of Kadcyla patients. Oral Arg. at 2:23–3:01, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2017-2617.mp3. Yet at no point did Phigenix move to amend its infringement contentions to reflect this narrower population.

After learning about the narrowed patient population, Genentech moved to strike the infringement opinion of Phigenix's expert. Agreeing that Phigenix had failed to provide adequate notice of its narrowed infringement theory, the district court struck Phigenix's expert infringement opinion and granted summary judgment of noninfringement based on the resulting lack of direct infringement evidence. The district court specifically noted that if its determination regarding the 2005 priority date was the impetus for Phigenix's narrowed infringement theory, then "Phigenix could have moved soon thereafter to amend its infringement contentions and to notify Genentech of this change in position." J.A. 16. Phigenix's failure to do so "deprived Genentech [of] a timely disclosure of this new theory, as well as any potential accommodation in the case schedule the Court would entertain." *Id.*

The district court also granted summary judgment of noninfringement based on a lack of evidence of specific intent to induce infringement under Phigenix's narrowed theory. The district court further denied summary judgment of invalidity based on various utility, enablement, and written description challenges advanced by Genentech. Phigenix timely appealed the grant of summary judgment of noninfringement, and Genentech conditionally cross-appealed the denial of summary judgment of invalidity. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

I

Like many district courts, the U.S. District Court for the Northern District of California has established local rules of practice specifically for patent cases. *See* N.D. Cal. Patent L.R. 1-1, 1-2. We review the validity and interpretation of these patent local rules under Federal Circuit law, applying an abuse of discretion standard. *See O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1364, 1366–67 (Fed. Cir. 2006). This court grants "broad deference" to district courts in the enforcement of their patent local rules. *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1292 (Fed. Cir. 2005) (citing *Genentech, Inc. v. Amgen, Inc.*, 289 F.3d 761, 774 (Fed. Cir. 2002)). "Decisions enforcing local rules in patent cases will be affirmed unless clearly unreasonable, arbitrary, or fanciful; based on erroneous conclusions of law; clearly erroneous; or unsupported by any evidence." *O2 Micro*, 467 F.3d at 1366–67 (citing *Genentech*, 289 F.3d at 774). Because patent local rules "are essentially a series of case management orders," a district court "may impose any 'just' sanction for the failure to obey" them, including "refusing to allow the disobedient party to support or oppose designated claims or defenses, or prohibiting that party from introducing designated matters in evidence." *Id.* at 1363 (quoting Fed. R. Civ. P. 37(b)(2)(B) (2000)).

This court has observed that some patent local rules serve an objective that "has been difficult to achieve through traditional discovery mechanisms such as contention interrogatories," namely, to provide the parties with early notice of their opponent's theories of liability. *Id.* at 1365–66. In doing so, these patent local rules "seek to balance the right to develop new information in discovery with the need for certainty as to the legal theories." *Id.* at 1366. They accordingly require the parties to provide "early notice of their infringement and invalidity

contentions, and to proceed with diligence in amending those contentions when new information comes to light in the course of discovery." *Id.* at 1365–66.

Consistent with that objective, the patent local rules of the Northern District of California require a party claiming patent infringement to serve infringement contentions on all parties within 14 days of the initial case management conference. N.D. Cal. Patent L.R. 3-1. In relevant part, the infringement contentions must separately identify, for each asserted claim:

> [E]ach accused apparatus, product, device, process, method, act, or other instrumentality . . . of each opposing party of which the party is aware. This identification shall be as specific as possible. Each product, device, and apparatus shall be identified by name or model number, if known. Each method or process shall be identified by name, if known, or by any product, device, or apparatus which, when used, allegedly results in the practice of the claimed method or process[.]

Id. at 3-1(b). Infringement contentions may only be amended by order of the district court upon a timely showing of good cause—such as an adverse claim construction, a recent discovery of prior art, or a recent discovery of non-public information about the accused instrumentalities. *Id.* at 3-6. The duty to supplement discovery responses under the Federal Rules, moreover, "does not excuse the need to obtain leave of court to amend contentions." *Id.*; *see also* Fed. R. Civ. P. 26(e) (describing duty to supplement discovery responses).

II

A

We hold that the district court was within its discretion to exclude the infringement opinion of Phigenix's expert in response to Phigenix's failure to timely disclose its

narrowed infringement theory. Phigenix narrowed the relevant patient population from "Kadcyla patients who were pretreated with trastuzumab and a taxane" to "Kadcyla patients who were pretreated with trastuzumab and a taxane *and nothing else*." Phigenix did so not in response to new evidence or a claim construction, but instead following the district court's February 2017 rejection of a 2005 priority date for the '534 patent. Regardless of the source of Phigenix's motivation to narrow the relevant patient population, it is clear that Phigenix did not take *any* deliberate action to proactively put Genentech on notice that it had done so. Instead, Phigenix first disclosed the narrowed scope through the deposition of its expert in May 2017, after fact discovery had closed.

Phigenix does not dispute that the narrowed patient group is only about 4% of the full Kadcyla patient population. Oral Arg. at 2:23–3:01. We agree with the district court that such a dramatic narrowing at such a late stage in the litigation prejudiced Genentech because it "markedly transformed the nature of the infringement theory, and consequently, impacted Genentech's ability to prepare a defense." J.A. 15–16. As counsel made clear at oral argument, Genentech relied on Phigenix's early disclosure of its original infringement theory to develop noninfringement and invalidity theories that would need to be substantially revised under Phigenix's narrowed infringement theory. *See generally* Oral Arg. at 12:40–19:55. With regard to noninfringement, Genentech had already commissioned laboratory experiments and prepared an expert report—efforts that would need to be repeated under the new infringement theory. *See id.* at 15:41–16:52. Genentech would also likely require additional discovery to understand the basis for Phigenix's new infringement theory—i.e., what aspect of the narrowed patient population causes it to infringe even as the rest of the Kadcyla population does not infringe. *Id.* With regard to invalidity, Genentech and its expert had already developed and

advanced a theory that the Kadcyla clinical trials anticipate the asserted claims. Oral Arg. at 17:54–18:52; *see also* J.A. 190–93 (Genentech expert opinion regarding Kadcyla clinical trials). By effectively adding a negative limitation to the invalidity analysis, Phigenix would send Genentech back to the drawing board on invalidity quite late in the litigation.[2]

We agree with Phigenix that narrowing the scope of accused infringement will not *always* result in a failure to adequately disclose infringement contentions. But, here, where the relevant patient population was narrowed after the close of fact discovery to a small percentage of its original size, and where Genentech convincingly explained the prejudicial consequences of the narrowing on its case, we discern no abuse of discretion by the district court in striking Phigenix's expert opinion on infringement. Accordingly, we affirm the district court on this issue.

B

Phigenix advances several arguments in support of its claim that the district court abused its discretion, but they are insufficient to cure Phigenix's untimely disclosure of its narrowed infringement theory.

1

Phigenix first argues that its revised infringement theory is not newly propounded because it falls wholly within the scope of its original infringement contentions. While technically accurate, this argument fails to acknowledge the notice function served by infringement contentions.

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[2] We further note an adverse consequence for judicial efficiency: such a dramatic narrowing of the relevant patient population could have increased Genentech's willingness to settle the litigation early on, thereby conserving limited judicial resources.

Patent local rules bolster discovery under the Federal Rules because they "allow the defendant to pin down the plaintiff's theories of liability . . . thus confining discovery and trial preparation to information that is pertinent to the theories of the case." *O2 Micro*, 467 F.3d at 1365 (first citing *Hickman v. Taylor*, 329 U.S. 495, 501 (1947); then citing CHARLES ALAN WRIGHT, ARTHUR R. MILLER & RICHARD L. MARCUS, FEDERAL PRACTICE AND PROCEDURE § 2001 (2d ed. 1994); and then citing Fed. R. Civ. P. 33, advisory committee's note to 1970 amendment of subsection (b)). The Northern District's patent local rules, furthermore, expressly require that the identification of the accused methods in infringement contentions "shall be as specific as possible." N.D. Cal. Patent L.R. 3-1(b). We agree with the district court that the broader theory disclosed in Phigenix's infringement contentions is not sufficiently specific to disclose its narrowed theory. If, as Phigenix suggests, plaintiffs could include broadly scoped infringement theories in their contentions only to unilaterally narrow them after the close of fact discovery, infringement contentions would provide little relief to defendants.

2

Next, Phigenix seizes on a brief statement at a January 2017 hearing to assert that it did in fact put Genentech on notice of its narrowed infringement theory. *See* Appellant's Br. 8–9 (quoting J.A. 429–30). This argument is ineffective. The brief statement identified by Phigenix—made in the course of challenging the prior art status of a particular clinical trial—is far from clear notice of a narrowed infringement theory:

> *The prescribing data that's been approved and that's the subject of this lawsuit is previously received trastuzumab and a taxane*, which is a subset of the population that they're looking at in here of compositions. The patients in this Exhibit H clinical trial are being given a much different cocktail

> here. . . . [I]n addition to a taxane and the trastuzumab, *they're providing three other chemotherapy agents* [anthracycline, lapatinib, and capecitabine] *as either prior or co-therapy with this*. So we would disagree that this is actually describing the same patient population. It's not the same clinical trial we believe led to the approval [of Kadcyla], which is the EMILIA trial, which we don't see information on that.

J.A. 429–30 (emphases added); *see also* J.A. 1706–08 (referenced clinical trial exhibit). This statement does not identify any changed position, much less suggest that the relevant patient population had changed.

3

Phigenix's reliance on case law is similarly unavailing. Phigenix asserts that the opinions cited by the district court are inapposite because they only address "ambush" tactics. Appellant's Br. at 33–36.[3] Phigenix also points to various district court opinions purportedly allowing plaintiffs to narrow their infringement theories after propounding broader infringement contentions. Appellant's Reply at 8–10.[4] We are not persuaded by these decisions

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[3] *Adobe Sys. Inc. v. WowzaMedia Sys.*, No. 11-02243-JST, 2014 WL 709865, at *13–15 (N.D. Cal. Feb. 23, 2014); *Genentech Inc. v. Trustees of Univ. of Pa.*, No. 10-2037-LHK-PSG, 2012 U.S. Dist. LEXIS 16959, at *6 (N.D. Cal. Feb. 9, 2012); *Oracle Am., Inc. v. Google Inc.*, No. 10-03561-WHA, 2011 WL 4802535, at *2 (N.D. Cal. Oct. 11, 2011); *Linex Techs., Inc. v. Belkin Int'l, Inc.*, 628 F. Supp. 2d 703, 707 (E.D. Tex. 2008).

[4] *Trading Techs. Int'l, Inc. v. CQG, Inc.*, No. 05-cv-4811, 2014 U.S. Dist. LEXIS 127615, at *12 (N.D. Ill. Sep. 10, 2014); *Dig. Reg of Tex., LLC v. Adobe Sys.*, No. CV

considering the broad deference that this court grants to district courts in the enforcement of their patent local rules. *See SanDisk*, 415 F.3d at 1292. And on the merits, these cases are readily distinguishable because the moving party in each demonstrated early notice, diligence, new evidence, and/or leave obtained from the district court—none of which apply here.

The only controlling authority cited by Phigenix, *Kemin Foods L.C. v. Pigmentos Vegetales Del Centro S.A. de C.V.*, does not compel a different result. 464 F.3d 1339 (Fed. Cir. 2006). *Kemin Foods* is inapposite because it addresses the scope of asserted *claims* and does not apply patent local rules. *See generally id.* Furthermore, in *Kemin Foods*, this court relied on the fact that the plaintiff—who had been diligent in giving notice and pursuing evidence to support its infringement claim—could have done "nothing more" to keep the disputed claim in the case. *Id.* at 1351–52. In contrast, Phigenix plainly could have done more to put Genentech on notice about the change in the scope of its infringement allegations.

4

Finally, Phigenix argues that striking Phigenix's entire expert infringement opinion is an abuse of discretion because it is (at least in Phigenix's view) heavy-handed. In support, Phigenix avers that Genentech has not adequately explained how it was prejudiced. Phigenix further argues that Genentech fails to explain why a less severe sanction would not address any concern the district court had. Phigenix even boldly asserts that Genentech was obligated to seek clarification if it was confused by the scope of Phigenix's infringement contentions.

12-01971-CW (KAW), 2014 U.S. Dist. LEXIS 58113, at *7 (N.D. Cal. Apr. 24, 2014).

As a threshold matter, we need not consider the prejudice to Genentech in evaluating whether the court abused its discretion. *See O2 Micro*, 467 F.3d at 1368 ("Having concluded that the district court could properly conclude that [the plaintiff] did not act diligently in moving to amend its infringement contentions, we see no need to consider the question of prejudice to [the defendant]."). In any event, Genentech adequately explained how it was prejudiced by Phigenix's untimely narrowing of its infringement theory.

The consequences imposed on Phigenix, furthermore, are not beyond the discretion of the district court. Both the Ninth Circuit and this court have concluded that the exclusion of evidence is often an appropriate sanction for a party's failure to comply with the patent local rules. *O2 Micro*, 467 F.3d at 1369 (first citing *SanDisk*, 415 F.3d at 1292; then citing *Wong v. Regents of Univ. of Cal.*, 410 F.3d 1052, 1060 (9th Cir. 2005)). Thus, even if other courts might have chosen a less potent remedy in these circumstances, we assess only whether the district court abused its discretion in prescribing a harsher one. On these facts, we conclude that it did not.

III

Without its expert report, Phigenix's direct infringement case fails, so we affirm the district court's grant of summary judgment of noninfringement on that basis. Because we affirm the district court's determination of no direct infringement, we do not address the district court's summary judgment of no induced infringement, as there can be no inducement liability without direct infringement. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 921 (2014) (citing *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 341 (1961)). At oral argument, Genentech's counsel indicated that its cross-appeal is conditional on non-affirmance of the district court's

judgment. Oral Arg. at 30:06–30:21. Having affirmed the district court's judgment, we do not address the cross-appeal.

CONCLUSION

For the foregoing reasons, we affirm the district court's order striking Phigenix's expert infringement opinion and its grant of summary judgment of noninfringement.

AFFIRMED