

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No. SACV 11-0961 JVS (MLGx) Date June 25, 2012

Title Medtronic Corevalve LLC, et qal. V. Edwards Lifesciences Corp., et al.

Present: The James V. Selna
Honorable

Karla J. Tunis
Deputy Clerk

Not Present
Court Reporter

Attorneys Present for Plaintiffs:
Not Present

Attorneys Present for Defendants:
Not Present

Proceedings: (IN CHAMBERS) Order GRANTING Defendants’ Motion for Leave to Amend Preliminary Invalidity Contentions (Fld 5-23-12)

The Court, having been informed by counsel in this action that they submit on the Court’s tentative ruling previously issued, hereby GRANTS the defendants’ motion referenced above and rules in accordance with the tentative ruling as follows:

Defendants Edwards Lifesciences Corporation, Edwards Lifesciences (U.S.) Inc., and Edwards Lifesciences LLC (collectively, “Edwards”) move this Court, pursuant to Patent Local Rule 3-6,¹ for leave to amend their preliminary invalidity contentions. (Mot. Br., Docket No. 125.) Plaintiffs Medtronic CoreValve LLC, Medtronic CV Luxembourg S.a.r.l., and Medtronic Vascular Galway Ltd. (collectively, “Medtronic”) oppose the motion. (Opp’n Br., Docket No. 131.) For the following reasons, the motion is GRANTED.

I. Background

Medtronic served preliminary infringement contentions on Edwards on January 25, 2012. (Terranova Decl. ¶ 6, May 23, 2012, Docket No. 126.) On February 1, 2012, Medtronic filed the First Supplemental Complaint, asserting new claims for indirect infringement of U.S. Patent No. 7,892,281 (the “281 Patent” or the “Seguin Patent”). Medtronic asserted the new claims after the FDA approved Edwards’ SAPIEN Transcatheter Heart Valve for commercial use in the United States. (See Docket Nos. 82, 85.) Edwards filed with the U.S. Patent and Trademark Office a request for *inter partes*

¹ The Court has adopted the Local Patent Rules of the Northern District of California.

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reexamination of the '281 Patent on March 2, 2012. On March 5, 2012, Edwards moved to stay this case pending the reexamination. (Docket 93.)

Edwards served preliminary invalidity contentions on Medtronic on March 9, 2012.² (Terranova Decl. ¶ 2, Ex. A.) On April 11, 2012, the Court denied without prejudice Edwards' motion to stay this case.³ (Docket No. 105.) On April 23, 2012, the Court entered a revised scheduling order. (Docket No. 115.) The proposed claim terms for construction were exchanged on May 30, 2012. (See Mot. Br. 2; Opp'n Br. 2.) The claim construction hearing is set for October 15, 2012, with opening briefs due on August 31, 2012. The fact discovery cut-off date is December 14, 2012, and the expert discovery cut-off date is April 30, 2013. At this time, no depositions have been taken or noticed, nor have any expert reports been served. (Mot. Br. 2, 11.) The law and motion cut-off date is August 5, 2013. Trial is set to begin on September 24, 2013.

Edwards met with Medtronic on May 9, 2012 and requested consent to add prior art references to the preliminary invalidity contentions. (Mot. Br. 4; see also Terranova Decl., Ex. G.) Medtronic declined to allow the amendment. (Terranova Decl., Ex. G.) Nevertheless, on May 11, 2012, Edwards served on Medtronic amended invalidity contentions. (Id. ¶ 3, Ex. B.) Medtronic denied another request by Edwards to allow the amendment on May 14, 2012. (Mot. Br. 5.)

Medtronic served amended infringement contentions on Edwards on May 18, 2012.⁴ (Terranova Decl. ¶ 7, Ex. F.) Medtronic has not yet filed a motion for leave to

² Under Patent Local Rule 3-3, invalidity contentions are due "[n]ot later than 45 days after service . . . of the 'Disclosure of Asserted Claims and Infringement Contentions'" In the preliminary invalidity contentions, Edwards stated that "[b]ecause the parties' January 13, 2012 proposed case schedule was not entered by the Court and does not have binding effect, Edwards' Invalidity Contentions . . . are not due at this time. . . . Edwards reserves all rights to supplement and amend these Invalidity Contentions should the case, including discovery, proceed." (Terranova Decl., Ex. A, at 1-2.)

³ Edwards filed a renewed motion to stay this case on April 30, 2012 (Docket No. 116), which the Court again denied without prejudice on May 29, 2012 (Docket No. 127).

⁴ In the amended infringement contentions, Medtronic "reserves the right to amend, modify or supplement these [infringement] contentions, including with Medtronic's expert reports." (Terranova Decl. ¶ 7, Ex. F, Claim Charts A-B.)

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amend the infringement contentions. See Patent Local Rule 3-6 (“Amendment of the Infringement Contentions . . . may be made only by order of the Court upon a timely showing of good cause.”).

II. Legal Standard

Under Patent Local Rule 3-6, a party may amend its preliminary invalidity contentions “only by order of the Court upon a timely showing of good cause.” The “good cause” inquiry “first considers whether [the] plaintiff was diligent in amending its contentions and then considers prejudice to the non-moving party.” CBS Interactive, Inc. v. Etilize, Inc., 257 F.R.D. 195, 201 (N.D. Cal. 2009) (citing O2 Micro Int’l Ltd. v. Monolithic Power Sys., Inc., 467 F.3d 1355, 1366-68 (Fed. Cir. 2006)). “The party seeking to amend its contentions bears the burden of establishing diligence.” Id. (citing O2 Micro, 467 F.3d at 1366-67). The moving party must show not only that it was diligent in moving to amend its preliminary invalidity contentions, but also that it “was diligent in discovering the basis for the proposed amendment.” West v. Jewelry Innovations, Inc., No. C 07-1812 JF (HRL), 2008 U.S. Dist. LEXIS 84928, at *6 (N.D. Cal. Oct. 8, 2008). To satisfy the diligence requirement, the moving party must offer specific facts to explain why there was a delay in discovering the prior art. See C & C Jewelry Mfg. v. West, No. 5:09-cv-01303-JF, 2011 U.S. Dist. LEXIS 102161, at * 9-10 (N.D. Cal. Mar. 4, 2011).

“Unlike the liberal policy for amending pleadings, the philosophy behind amending claim charts is decidedly conservative, and designed to prevent the ‘shifting sands’ approach to claim construction.” Id. at * 4 (internal quotation marks omitted). Nevertheless, the Patent Local Rules are “not a straitjacket into which litigants are locked from the moment their contentions are served. There is a modest degree of flexibility, at least near the outset.” Comcast Cable Commc’ns Corp., LLC v. Finisar Corp., No. C06-04206, 2007 WL 716131, at *2 (N.D. Cal. Mar.2, 2007).

III. Discussion

Edwards asserts that there is good cause for the proposed amendment. The Court must first consider whether Edwards acted diligently in discovering the bases for the amendment and whether Edwards timely moved for leave to amend. If the Court finds that Edwards acted diligently, then it must also consider whether Medtronic will be

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prejudiced by the amendment.

A. Diligence

Edwards contends that the Court should grant leave to amend because “[o]nce Edwards discovered the bases for the amendment, Edwards acted diligently to amend its contentions and did so at ‘a very early stage’ of the case.” (Mot. Br. 6.) Edwards asserts that Medtronic’s First Supplemental Complaint⁵ was the catalyst of an additional investigation that led Edwards to amend the preliminary invalidity contentions. (*Id.* at 7-8.)

On the other hand, Medtronic contends that the Court should not grant leave to amend because “[e]ach of the five allegedly ‘new’ prior art references Edwards seeks to assert were in fact known to it well before it served its original Invalidity Contentions on March 9, 2012. Indeed, at least four of the references were known to Edwards as early as between 2002-2007.” (Opp’n Br. 1.) According to Medtronic, Edwards was aware that Medtronic would be asserting method claims in the First Supplemental Complaint six weeks before the agreed upon deadline for Edwards’ invalidity contentions. (*Id.* at 9.) Furthermore, Edwards filed the reexamination request on March 2, 2012, indicating that it had sufficient time to discover the prior art and make invalidity arguments as to the newly asserted claims. (*Id.* at 10.)

With respect to asserted claims 3, 4, and 7, Edwards identifies in the amended invalidity contentions as new prior art U.S. Patent No. 6,458,153 to Bailey *et al.* (“Bailey”), German Patent DE 195 46 692 to Figulla (“Figulla”), and Uchida *et al.*, “Modifications of Gianturco Expandable Wire Stents,” *American Journal of Roentgenology* 150:1185-1187 (May 1988) (“Uchida”). (Mot. Br. 8.) In the initial Complaint, Medtronic asserted only device claims. Asserted claims 3, 4, and 7 are anchor method claims, which were not in issue during the first six months of the case.

⁵ Medtronic filed the First Supplemental Complaint on February 1, 2012, after the Court granted an unopposed motion to do so. (*See* Docket Nos. 82-85.) Medtronic claims that it notified Edwards of its intention to supplement its Complaint to assert method claims on January 17, 2012, and also provided Edwards a copy of the First Supplemental Complaint that day. (Opp’n Br. 5.) The parties previously set March 14, 2012 as the deadline for filing amended pleadings. (Docket No. 73.) Accordingly, the Court does not agree with Edwards that Medtronic’s First Supplemental Complaint was late. (*See* Mot. Br. 8.)

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According to Edwards, it researched and discovered Bailey, Figulla, and Uchida – which are important to the newly asserted claims – shortly after Medtronic served upon Edwards the First Supplemental Complaint. (Reply Br. 9-10, Docket No. 133.)

Edwards also added the combination of U.S. Patent No. 5,957,949 to Leonhardt *et al.* (“Leonhardt”) and European Patent Publication EP 0 850 607 to its invalidity contentions. Although both references were disclosed and charted in the preliminary invalidity contentions, Edwards amended the contentions shortly after the PTO’s April 18, 2012 ruling that Leonhardt anticipates the ‘281 Patent. Edwards contends that combining Leonhardt with EP 0 850 607 shows that the ‘281 Patent claims were obvious. (Mot. Br. 8.)

With respect to asserted claims 12, 14, and 15, Edwards amended the preliminary invalidity contentions to identify a 2002 presentation by Dr. Cribier and WO 01/54625 to Obermiller *et al.* (“Obermiller”), an application filed under the Patent Cooperation Treaty approximately ten years ago. (Mot. Br. 8-9.) Edwards asserts that it identified the 2002 presentation in the course of discovery. The delay in discovering this ten-year old presentation by a person who was not an employee of Edwards was not unreasonable. Furthermore, Edwards explains that it located and analyzed Obermiller only after determining that Uchida was important prior art to Medtronic’s newly asserted claims. (Reply Br. 11.)

Finally, Edwards added to its invalidity contentions a reference to Medtronic’s opposition to Edwards’ European Patent No. 1 441 672 (Spenser *et al.*)⁶ and priority defects of the ‘281 Patent. (Mot. Br. 9; Reply Br. 1.) Medtronic apparently does not challenge these references.⁷

Edwards has provided specific facts explaining why there was a delay in discovering the prior art added to the preliminary invalidity contentions. See C & C

⁶ In the opposition, Medtronic stated that “[t]he provision of bores in support beams or struts to assist in the attachment of a valve assembly to a frame is well known from the prior art.” (Terranova Decl., Ex. B, at 41-43.) Edwards apparently relied on this admission and the art cited by Medtronic with respect to claims 12, 14, and 15, which concern “longitudinal bars” with “a plurality of holes.” (Mot. Br. 9.)

⁷ Edwards also points out that none of the references nor the combination that Medtronic challenges were cited as invalidating prior art in the reexamination request. (Reply Br. 8 n.4.)

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Jewelry, 2011 U.S. Dist. LEXIS 102161, at * 9-10. The Court is satisfied that Edwards was diligent in discovering the bases for the amendment, which was made at a relatively early stage in the case. See Tessera, Inc. v. Advanced Micro Devices, Inc., No. C05-4063, 2007 WL 1288199, at *2 (N.D. Cal. Apr.30, 2007) (finding that allowing defendants to amend preliminary invalidity contentions at a relatively early stage in the case would “promote the fair resolution of [the case] without causing any prejudice” to the plaintiff). Edwards also timely moved for leave to amend. Edwards filed the instant motion on May 23, 2012, one month after the Court entered the revised scheduling order and less than two weeks after Edwards served the amended invalidity contentions on Medtronic.

In sum, the Court finds that Edwards was diligent in discovering the bases for the amendment and in moving for leave to amend. The Court must next consider whether Medtronic will be prejudiced by the amendment.

B. Prejudice

Edwards contends that Medtronic will not be prejudiced by the amendment because Medtronic’s own infringement contentions are “preliminary” and Medtronic has acknowledged that “[d]iscovery in this matter is at a very early stage and is ongoing.” (Mot. Br. 9.) Furthermore, Medtronic has reserved the right to amend, modify, or supplement the infringement contentions. (Id. at 9-10.) It would be unfair to allow Medtronic to amend without granting the same benefit to Edwards. (See id. at 10.)

On the other hand, Medtronic contends that it will be prejudiced by the amendment because the parties will have exchanged their claim terms and proposed constructions by June 20, 2012, five days before this motion will be heard by the Court. (Opp’n Br. 11.) Therefore, Medtronic “will . . . be forced to approach the early stages of claim construction without knowing whether the new references will be allowed into the case.” (Id.) Furthermore, Medtronic worries that if good cause for the amendment is found here, Edwards will “almost certainly continue its ‘search for and analysis of relevant prior art’” and seek leave to amend the invalidity contentions again in the future. (Id. at 12.)

Although the parties will have exchanged their claim terms and proposed

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constructions before this motion is heard, Medtronic’s opening claim construction brief is not due until August 31, 2012, and the claim construction hearing is not until October 15, 2012. Furthermore, trial is still more than a year away. This case is in its early stages. See Comcast Cable, 2007 WL 716131, at *1 (finding the case was in its early stages where very little discovery had occurred and trial was a year away). Medtronic received Edwards’ amended invalidity contentions on May 11, 2012. Even after this Order is issued, Edwards will have two months to examine Edwards’ amended invalidity contentions and prepare its opening claim construction brief. See Halo Elecs., Inc. v. Bel Fuse Inc., No. C07-06222 RMW (HRL), 2010 WL 3489593, at *2 (N.D. Cal. Sept. 3, 2010) (granting leave to amend invalidity contentions when claim construction hearing was less than two months away).

Medtronic’s argument that Edwards will continue to search for prior art and seek leave to amend the invalidity contentions again in the future does not raise a valid concern. Any future amendment to Edwards’ invalidity contentions must be approved by the Court. The Court will not grant a motion for leave to amend without a showing of good cause. Accordingly, Medtronic need not worry about a “shifting sands” approach to claim construction.

In sum, the Court finds that Medtronic will not be prejudiced by the amendment. Therefore, Edwards has shown good cause for the proposed amendment to the preliminary invalidity contentions.

IV. Conclusion

For the foregoing reasons, the motion is GRANTED.

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