

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EDWARDS LIFESCIENCES AG and)	
EDWARDS LIFESCIENCES LLC,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 08-91-GMS
)	
COREVALVE, INC.,)	
)	
Defendant.)	
)	
)	

ORDER

1. On February 12, 2008, plaintiffs Edwards Lifesciences AG and Edwards Lifesciences LLC (“Edwards”) filed this action for infringement against defendant CoreValve Inc. (“CoreValve”). Presently before the court is CoreValve’s Motion in Limine No. 2 to Exclude Expert Testimony from Dr. Nigel Buller (D.I. 205). In its motion, CoreValve argues that portions of Dr. Buller’s proposed testimony should be excluded for two reasons: “1) the claims expressly refer to the invention *before* implantation; and 2) the accused products are exported outside the United States while still in the ‘as-manufactured’ shape, and have never been implanted into patients in the United States.” (D.I. 205 at 1 (emphasis in original).) For the reasons that follow, CoreValve’s motion will be granted in part and denied in part.

2. As to CoreValve’s first argument, the court rejects CoreValve’s proposed temporal limitation on the term “cylindrical.” CoreValve’s argument stems from the court’s construction of the terms “cylindrical” and “cylindrical support means” as used in the ‘552 and ‘462 patents. While the court ruled on the geometric and spatial components of the term “cylindrical” in its claim construction order, the court did not rule on whether there was a temporal limitation to the

term. CoreValve argues that “cylindrical” should be interpreted as referring only to the shape of the device before it is compressed for catheterization. (See D.I. 205 at 1.) The court now clarifies that there is no such temporal limitation to the terms “cylindrical” and “cylindrical support means” as those terms are used in the ‘552 and ‘462 patents. The court rejects CoreValve’s proposed construction because such a temporal limitation is not supported by the specification or the prosecution history.¹ Thus, CoreValve’s motion in limine is denied to the extent that it seeks to preclude Dr. Buller from testifying that the term “cylindrical” may refer to the shape of the valve prosthesis after it is compressed into a catheter or after it has been implanted in a patient.

3. As to CoreValve’s second argument, Edwards asserts in its response to CoreValve’s motion that under § 271(f), the shape of CoreValve’s device as used abroad is relevant to infringement. (D.I. 211 at 3-5.) In its reply brief, CoreValve objected to Edwards’ claim for infringement under § 271(f) on the ground that Edwards had never asserted infringement of the ‘552 or ‘462 patent under § 271(f) prior to the filing of the motions in limine. (D.I. 230 at 1-3.) The parties disputed this issue at the pre-trial conference conducted on February 16, 2010 (see D.I. 276 at 58-81), and again in letters submitted to the court after the pre-trial conference. (D.I. 274, 277, 279.) The court notes that the parties neither requested nor were granted leave to file supplemental letters concerning this issue. Nonetheless, the court will consider the representations made in these letters, since those representations help clarify the issue. Indeed,

¹ CoreValve’s contends that the grammar of the claim language and the specification indicate that the claims refer only to the valve prosthesis before it is compressed in the catheter. CoreValve has not, however, cited any portion of the prosecution history suggesting that either the patent office or the inventor intended to impose, or even contemplated, such a limitation to the claims during prosecution. Absent evidence of such intent, the court will not imply a

the letters appear to confirm that Edwards had not asserted infringement of the ‘552 or ‘462 patents under § 271(f) until well after the close of discovery.

4. Edwards contends that CoreValve “had ample opportunity to move for summary judgment on its § 271(f) theory.” (D.I. 277.) This argument is unavailing, however, since the parties’ representations in their papers and at the pre-trial conference indicate that during the discovery process, § 271(f) was never specifically asserted as a basis for infringement with respect to the ‘552 and ‘462 patents. During discovery, CoreValve propounded an interrogatory that asked Edwards to “[i]dentify with specificity the grounds supporting [Edwards’] contention that CoreValve’s heart valve prosthesis, or method of use thereof infringes any claim of the patents-in-suit under § 271(f).” (See D.I. 233 at 11 (sealed).) In response, Edwards specified the nature of their § 271(f) infringement claim with respect to the ‘614 patent (see *id.* at 12), but made no mention of the ‘552 and ‘462 patents except that “Edwards expressly reserves the right to assert any and all claims of the [‘552 and ‘462] patents under . . . § 271(f) after CoreValve produces documents and things.” (*Id.* at 13.) Edwards did not supplement its interrogatory responses or otherwise indicate to CoreValve that it believed it had a viable claim under § 271(f) with respect to those patents until December 31, 2009. On that date – more than seven months after the close of fact discovery, more than four months after the close of expert discovery, and more than three months after the deadline for requests to file dispositive motions – Edwards filed a supplemental interrogatory response stating that it still “reserves its rights to assert infringement under” § 271(f). (See D.I. 233, Ex. 18.) The court agrees with CoreValve that

limitation based solely on CoreValve’s interpretation of the claims’ grammar.

“Edwards’ attempt to ‘reserve its rights’ to assert § 271(f) on the eve of trial is much too little, and comes far too late.” (See D.I. 230 at 2.)

5. In its letter opposing CoreValve’s motion, Edwards only cites two documents produced before the filing of dispositive motions that purportedly support Edwards’ claim that CoreValve was on notice of this infringement theory. The first contains a single sentence from a report produced by one of CoreValve’s experts that Edwards interprets as disputing its § 271(f) theory.²

The second is the following sentence in Edwards’ complaint:

Upon information and belief, and in violation of 35 U.S.C. § 271, CoreValve has been and is now infringing the ‘552 Patent by manufacturing, using, importing, selling, offering to sell and/or supplying heart valve prostheses covered by one or more claims of the ‘552 patent . . .

(D.I. 1 ¶ 11; see also *id.* ¶ 21 (using identical language to allege infringement of the ‘462 patent).) This paragraph of the complaint is in stark contrast to ¶ 16, which alleges infringement of the ‘614 patent under § 271(f). Paragraph 16 uses language that much more specifically alleges violations of § 271(f) and closely tracks the statutory language of § 271(f)(2):

Upon information and belief, and in violation of 35 U.S.C. § 271, CoreValve has been and is now infringing the ‘614 Patent by supplying or causing to be supplied in or from the United States a component of the invention claimed in the ‘614 patent . . . *that is made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the . . . patent if such combination occurred within the United States.*³

² Specifically, Edwards asserts that the Rebuttal Expert Report of CoreValve expert Martin Rothman states that “as a matter of U.S. patent law, the state of the CoreValve Product when compressed or after implantation would still be irrelevant to the infringement analysis because both steps occur outside the United States.” (See D.I. 277 at 1.)

³ Compare italicized language with 35 U.S.C. § 271(f)(2):

(Id. ¶ 16 (emphasis added).)⁴

6. Edwards cites no deposition testimony nor any interrogatory responses from before the close of discovery that more specifically indicate that they intended to pursue a theory of infringement under §271(f) with respect to the ‘552 or ‘462 patents. Consequently, the only bases Edwards has asserted for its contention that CoreValve was on notice of such claims are a single sentence in a CoreValve expert report that contains what is, at most, an oblique reference to § 271(f); a formalistic recitation in the original complaint of all possible modes of infringement under § 271 that Edwards might later assert; and an assertion made long after the close of discovery that Edwards “reserved its rights” to assert § 271(f). This is not sufficient to put CoreValve on notice that § 271(f) would be asserted at trial with respect to the ‘552 and ‘462 patents. CoreValve had no motivation to seek permission to move for summary judgment on an issue that it reasonably believed was not in controversy. Given these circumstances, the court concludes that allowing Edwards to assert this theory of infringement at trial without the benefit of discovery would be unfairly prejudicial to CoreValve. Thus, Edwards will be precluded from

Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

⁴ The parties agreed at the pre-trial conference that the ‘614 patent should be dismissed from the case due to the Federal Circuit’s decision in *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 576 F.3d 1348 (Fed. Cir. 2009). (See D.I. 276 at 8-9, 63.) To date, the parties have not filed a stipulation of dismissal, but the court relies on the parties’ representations that the ‘614 patent is no longer being asserted in this case.

infringement under § 271(f) at trial. Dr. Buller will not be permitted to testify as to whether the accused product infringes the '552 or '462 patents under § 271(f).

Therefore, for the reasons stated above, IT IS HEREBY ORDERED that CoreValve's Motion in Limine No. 2 to Exclude Expert Testimony from Dr. Nigel Buller (D.I. 205) is GRANTED IN PART AND DENIED IN PART.

February 26, 2010


CHIEF, UNITED STATES DISTRICT JUDGE