

1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER

2

3 THE UNITED STATES DISTRICT COURT
4 FOR THE DISTRICT OF DELAWARE

5 -----)

6 ENDOHEART AG,)

7 Plaintiff,) Civil Action No.

8 v.) 1:14-cv-01473-LPS-CJB

9 EDWARDS LIFESCIENCES)

10 CORPORATION,)

11 Defendant.)
12 -----)

13 Videotape Deposition of:

14 CHRISTOPH H. HUBER, M.D.

15 30(b)(1) taken by BWH

16 Volume II - Pages 144 to 276

17 Date: January 29, 2016

18 Location: Paul Weiss - New York

19 Time: 8:00 a.m.

20

21 * * *

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24 Reporter:

25 Greg DiDonato, CSR, RPR, CM, CP, CRR

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 2 Friday, January 29, 2016
 3 8:00 A.M.
 4
 5 Continued Videotape 30(b)(1)
 6 deposition of Christoph Hans Huber, M.D.,
 7 pursuant to Notice, taken by BWH, held at the
 8 law offices of Paul Weiss Rifkind Wharton &
 9 Garrison LLP, 1285 Avenue of the Americas, New
 10 York, New York 10019, before Gregory T.
 11 DiDonato of DTI Court Reporting, Certified
 12 Realtime Reporter and Notary Public of the
 13 State of New York, there being present:
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 2 APPEARANCES:
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 20 FOR THE INTERVENOR:
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 ALSO PRESENT:
 Keith Newbury, Vice President
 Intellectual Property
 Edwards Lifesciences
 Michael Drenkalo, Videographer
 Petra S. Gehrung, Interpreter

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 2 P-R-O-C-E-E-D-I-N-G-S
 3 THE VIDEOGRAPHER: Now recording on
 4 record. Today's date is January 29, 2016, the
 5 time is 8:11 a.m. This is the beginning of
 6 volume II, file number 4, in the deposition of
 7 Dr. Christoph Huber.
 8 All counsel present will be noted on
 9 the record by the court reporter.
 10 I'll also remind the witness you're
 11 still under oath.
 12 (Exhibit Defendant's 112, Document in
 13 native format, EHT 15188, marked for
 14 identification.)
 15 CONTINUED EXAMINATION BY COUNSEL FOR INTERVENOR
 16 BY MR. ABRAMS:
 17 Q. Good morning, Dr. Huber.
 18 A. Good morning.
 19 Q. Yesterday we talked about some of the
 20 procedures you had done while you were a
 21 clinical surgeon at, your senior clinical
 22 fellowship at Brigham & Women's Hospital.
 23 Let me show you a document we'll mark
 24 as Exhibit 112. It does not bear a Bates
 25 number because it is produced in the native

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 2 format, but this is found at EHT 15188, and
 3 it's a multipage document, and I'll ask if you
 4 recognize this document?
 5 A. I think that's a continuation of the
 6 document we looked at yesterday with
 7 additional cases on it.
 8 (Exhibit Defendant's 111, PREVIOUSLY
 9 MARKED, used in the deposition.)
 10 BY MR. ABRAMS:
 11 Q. So, you're referring to, and I'll
 12 hand you Exhibit 111, which is the letter
 13 dated October 29th, 2004 that had a series of
 14 cases that had been done?
 15 A. I think that's, yeah, I agree on
 16 that.
 17 Q. So, is what is shown in Exhibit 112,
 18 is this an accurate summary of the cases that
 19 you were involved in as a cardiac fellow at
 20 Brigham & Women's Hospital, at least some of
 21 the cases you were involved in?
 22 A. This is a list of some of the cases,
 23 at least some of the cases I was involved with
 24 at Brigham and Women's Hospital.
 25 Q. And I ask you to look at Exhibit 112.

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 2 of the old valve.
 3 Q. So, as you say in the second
 4 paragraph, "As the old valve is left in place,
 5 and the new valve simply implanted, after the
 6 diseased valve has been compressed by a
 7 balloon or other mechanical device, there is
 8 first the risk of embolic stroke or embolic
 9 ischemia from valve or vascular wall debris
 10 liberated into the blood flow and moved
 11 downstream to smaller vessels creating vessel
 12 obstruction."
 13 And so, isn't that saying that
 14 there's a potential problem if you simply
 15 replace the old valve with the new valve by
 16 putting one, what did you say, orthotopically,
 17 with the other?
 18 A. Yeah, there could be a potential
 19 problem.
 20 Q. Right. Now, when you did the pig
 21 studies in CHUV, did you ever remove the
 22 original valve and replace it with a new
 23 valve?
 24 A. Did I ever remove pig valves? Yes, I
 25 did remove pig valves.

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 2 Q. Right. My question is with regard to
 3 the studies that you described when you talked
 4 about the transapical approach, and that type
 5 of thing, in those studies each of the valves
 6 is placed orthotopically; correct?
 7 A. Yes.
 8 Q. So, at the time you -- so, when did
 9 you come up with this understanding presented
 10 in this provisional that there is a potential
 11 problem with the orthotopic replacement and
 12 that it should be removed, the original valve
 13 should actually be removed?
 14 A. When I did cardiac surgery at CHUV.
 15 Q. And was that, what prompted you to
 16 believe that?
 17 A. Well, we had strokes after the
 18 surgical aortic valve replacement.
 19 Q. In those you were putting one valve
 20 on top of the other valve orthotopically?
 21 A. No. In the patients, we removed the
 22 old valve.
 23 Q. So, in removing the valve, you don't
 24 have this problem, do you, of high risk of
 25 embolic stroke?

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 2 A. Yes; you also have the risk of
 3 embolic stroke.
 4 Q. But, as you're describing here in the
 5 provisional, you're saying there's a specific
 6 potential problem with it when you do this
 7 orthotopic replacement; correct?
 8 A. Orthotopic is also what is performed
 9 surgically. Orthotopic just means the valve
 10 is being put there where the old valve was or
 11 still is; that means orthotopic, at the same
 12 place.
 13 Q. I see. So, in the pig studies, did
 14 you replace, did you put -- in the studies
 15 that are described in CHUV, done in CHUV
 16 regarding the pigs, did you use the
 17 transapical approach to remove the old valve
 18 and replace it with a new valve in the same
 19 place?
 20 A. In the pig studies that are
 21 described; no.
 22 Q. Now, with the, if you will look at
 23 the patent itself, in the patent there's
 24 described in the claims of the patent a means
 25 for preventing bleeding through the access

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 2 device.
 3 Are you familiar with that language
 4 in the patent claim?
 5 A. Yes, I am.
 6 Q. Now, as I understand it, that from
 7 documents that I've read in the case, that if
 8 you look at column 10 of the patent, lines 8
 9 through 16, that what is described in column
 10 10, lines 8 through 16, are the means for
 11 preventing bleeding?
 12 A. That's not precise enough.
 13 Q. Okay.
 14 A. Do you want me to -- what line
 15 exactly?
 16 Q. Why don't you read to yourself
 17 column 10, lines 8 through 16, and then I'll
 18 ask you some questions.
 19 A. 8 through 16?
 20 Q. Yes.
 21 A. Starting with "Access device 60"?
 22 Q. Correct.
 23 (Pause.)
 24 A. Okay. I read this.
 25 Q. It mentions in, the specification

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|---|---|
| <p style="text-align: right;">Page 245</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER</p> <p>2 mentions at column 10, line 10, it says,</p> <p>3 "Valve 63 may be mechanically operable as an</p> <p>4 iris diaphragm, e.g., like the aperture of a</p> <p>5 lens."</p> <p>6 Do you see that?</p> <p>7 A. Yes, I read there now.</p> <p>8 Q. Now, is that what's described there,</p> <p>9 the iris diaphragm, was that something that</p> <p>10 you used in the pig studies at CHUV?</p> <p>11 A. If I used a valve or a diaphragm as</p> <p>12 an isolated entity?</p> <p>13 Q. Well, when you did the pig studies,</p> <p>14 you had some sort of valve or some sort of way</p> <p>15 to prevent bleeding; correct?</p> <p>16 A. Bleeding through what?</p> <p>17 Q. It's my understanding that this</p> <p>18 access device that goes into the heart,</p> <p>19 there's a means to prevent bleeding that's</p> <p>20 described here?</p> <p>21 A. That's correct.</p> <p>22 Q. And it describes using some kind of</p> <p>23 valve. What I'm wondering is whether you used</p> <p>24 the specific valve described here as an, that</p> <p>25 includes an iris diaphragm, whether that</p> | <p style="text-align: right;">Page 247</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER</p> <p>2 of as many as possible ways of having a</p> <p>3 hemostatic valve in place of the access</p> <p>4 device. If I would have known more, I would</p> <p>5 have included more. But that's what I was</p> <p>6 aware of from a non-medical field related</p> <p>7 valve structures from engineering perspective,</p> <p>8 for example. So that's what is there.</p> <p>9 (Exhibit Defendant's 4, PREVIOUSLY</p> <p>10 MARKED, used in the deposition.)</p> <p>11 BY MR. ABRAMS:</p> <p>12 Q. Earlier you were asked some questions</p> <p>13 about, let me see, your declaration Exhibit 4.</p> <p>14 Here is a copy. Here is Exhibit 4.</p> <p>15 A. Thank you.</p> <p>16 Q. I would ask you to turn to your</p> <p>17 declaration, if you would.</p> <p>18 Now, attached to the declaration</p> <p>19 Exhibit 4 is a declaration that you filed in</p> <p>20 the patent office, correct, in 2009?</p> <p>21 A. I'm not sure I filed that in the</p> <p>22 patent office.</p> <p>23 Q. All right. Well, you signed it in</p> <p>24 2009, and it eventually made its way to the</p> <p>25 patent office; correct?</p> |
| <p style="text-align: right;">Page 246</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER</p> <p>2 specific structure was used in the pig</p> <p>3 studies?</p> <p>4 A. I don't know what the mechanism was</p> <p>5 in the pig study used device. It had a</p> <p>6 hemostatic, as we call, it valve.</p> <p>7 Q. You don't know what it was at that</p> <p>8 point?</p> <p>9 THE REPORTER: I'm sorry.</p> <p>10 "You don't know what it was at that</p> <p>11 point?"</p> <p>12 Q. Well, let me ask a different</p> <p>13 question.</p> <p>14 What do you -- do you recall when you</p> <p>15 conceived of this particular structure of the</p> <p>16 valve, meaning, an iris diaphragm type</p> <p>17 structure that's described here at column 10?</p> <p>18 A. That iris diaphragm structure is</p> <p>19 something that you could find in this kind of</p> <p>20 devices.</p> <p>21 Q. So, you don't recall anything in</p> <p>22 particular about it, you know, that when you</p> <p>23 came up with that particular use of that type</p> <p>24 of structure for this purpose here?</p> <p>25 A. The purpose of that was a description</p> | <p style="text-align: right;">Page 248</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER</p> <p>2 A. I agree.</p> <p>3 Q. And you understood that that</p> <p>4 declaration, which is two pages here, you</p> <p>5 understand in the paragraph at the end, it</p> <p>6 says that it was being made under oath, and</p> <p>7 subject to the penalties of perjury?</p> <p>8 A. What page are you on right now?</p> <p>9 Q. At the very end, where your signature</p> <p>10 is before March 29th, 2009.</p> <p>11 (Pause.)</p> <p>12 A. "Willful false statement"... Yes.</p> <p>13 Q. So, you understood the importance of</p> <p>14 the declaration being accurate and true?</p> <p>15 A. Yes.</p> <p>16 Q. And in the declaration, you make some</p> <p>17 statements with regard to in paragraph 5, you</p> <p>18 say, "I conceived the present invention prior</p> <p>19 to April 23rd."</p> <p>20 A. Where are you?</p> <p>21 Q. Last two pages, paragraph 5 in the</p> <p>22 declaration of the PD --</p> <p>23 A. Okay. Yes.</p> <p>24 Q. All right. And in there, you say, "I</p> <p>25 conceived the present invention prior to</p> |