

1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER

2

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

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5 )

6 ENDOHEART AG, )

7 )

8 Plaintiff, ) Civil Action No.

9 )

10 ) 1:14-cv-01473-LPS-CJB

11 v. )

12 )

13 EDWARDS LIFESCIENCES )

14 CORPORATION, )

15 )

16 Defendant. )

17 ----- )

18

19 30(b)(1) Videotape Deposition of:

20 CHRISTOPH H. HUBER, M.D.

21 Taken by: Edwards Lifesciences

22 Date: January 27, 2016

23 Location: Paul Weiss - New York

24 Time: 8:30 a.m.

25

26 \* \* \*

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30 Reporter:

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

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<p style="text-align: right;">Page 2</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER  2 Wednesday, January 27, 2016  3 8:30 A.M.  4  5 Videotape 30(b)(1) deposition of Christoph  6 Hans Huber, M.D., pursuant to Notice, taken by  7 Defendant Edwards Lifesciences, held at the  8 law offices of Paul Weiss Rifkind Wharton &amp;  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:  14  15  16  17  18  19  20  21  22  23  24  25</p>	<p style="text-align: right;">Page 4</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER  2 P-R-O-C-E-E-D-I-N-G-S  3 THE VIDEOGRAPHER: We're now  4 recording on the record. My name is Michael  5 Drenkalo, certified legal specialist with DTI.  6 Today's date is January 27, 2016. The time is  7 8:55 a.m.  8 We're at the office of Paul Weiss,  9 1285 Avenue of the Americas, New York, New  10 York to take the video deposition of  11 Dr. Christoph Huber in the matter of Endoheart  12 AG versus Edwards Lifesciences Corporation,  13 United States District Court for the District  14 of Delaware.  15 Counsel will please introduce  16 themselves for the record.  17 MR. BLOOMBERG: Mark Bloomberg, Zuber  18 Lawler &amp; Del Duca representing plaintiff  19 Endoheart and the witness.  20 MR. MALONEY: John C. Maloney, Jr.,  21 from Zuber Lawler &amp; Del Duca also representing  22 Endoheart and the witness.  23 MR. ABRAMS: Hugh Abrams from Sidley  24 Austin representing Brigham and Women's  25 Hospital, the intervenor.</p>
<p style="text-align: right;">Page 3</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER  2 APPEARANCES:  3 FOR THE PLAINTIFF AND THE WITNESS:  4 MARK BLOOMBERG, ESQ.  5 JOHN C. MALONEY, JR., ESQ.  6 Zuber Lawler &amp; Del Duca LLP  7 420 Lexington Avenue  8 Suite 2640  9 New York, NY 10170  10 mbloomberg@zuberlaw.com  11 jmaloney@zuberlaw.com  12  13 FOR THE DEFENDANT:  14 CATHERINE NYARADY, ESQ.  15 WILLIAM O'HARE, ESQ.  16 KIRA A. DAVIS, ESQ.  17 Paul Weiss Rifkind Wharton &amp; Garrison LLP  18 1285 Avenue of the Americas  19 New York, NY 10019  20 cnyarady@paulweiss.com  21 wohare@paulweiss.com  22 kdavis@paulweiss.com  23  24 FOR THE INTERVENOR:  25 HUGH ABRAMS, ESQ.  26 Sidley Austin LLP  27 One South Dearborn  28 Chicago, IL 60603  29 habrams@sidley.com  30  31 ALSO PRESENT:  32 Michael Drenkalo, Videographer  33 Petra S. Gehrung, Interpreter</p>	<p style="text-align: right;">Page 5</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER  2 MS. NYARADY: Catherine Nyarady from  3 Paul Weiss representing Edwards Lifesciences  4 Corporation, and I'm joined with my colleagues  5 also from Paul Weiss, William O'Hara and Kira  6 Davis.  7 THE VIDEOGRAPHER: The court reporter  8 is Greg DiDonato who will first swear in the  9 interpreter and then the witness.  10 THE REPORTER: Raise your right hand,  11 please.  12 Do you solemnly swear that you will  13 interpret the testimony and colloquy of  14 counsel to the best of your ability?  15 THE INTERPRETER: Yes, I do.  16 THE REPORTER: Raise your right hand,  17 please.  18 Do you solemnly swear to tell the  19 truth, the whole truth, and nothing but the  20 truth, so help you God?  21 THE WITNESS: Yes, I do.  22 MR. BLOOMBERG: Just for a quick  23 housekeeping matter, we're going to want to  24 designate the matter as "Highly Confidential"  25 under the Protective Order for all three days.</p>

<p style="text-align: right;">Page 14</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER</p> <p>2 Q. So, you're not claiming to have</p> <p>3 invented the transcatheter heart valve; right?</p> <p>4 A. I don't claim to have invented the</p> <p>5 device; no.</p> <p>6 Q. And you haven't -- did you ever make</p> <p>7 a guide wire or did you always use</p> <p>8 off-the-shelf guide wires?</p> <p>9 A. We used guide wires that were</p> <p>10 available at the moment for the animal</p> <p>11 experiments, for example.</p> <p>12 Q. So, whatever was available at the</p> <p>13 hospital, you were using, you didn't build the</p> <p>14 guide wire; right?</p> <p>15 A. No. I didn't specifically use soft</p> <p>16 guide wires in animals. I used whatever guide</p> <p>17 wires, because we took guide wires that were</p> <p>18 already used in patients for cost reasons.</p> <p>19 Those guide wires are sometimes they might</p> <p>20 have been soft, sometimes they have been hard,</p> <p>21 etcetera, but we used those guide wires in</p> <p>22 animals, whatever we had at hand, really.</p> <p>23 Q. So, for the animals, you didn't, you</p> <p>24 didn't think that the type of guide wire</p> <p>25 mattered, you could use any type of guide</p>	<p style="text-align: right;">Page 16</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER</p> <p>2 make sure I understand. One is because of the</p> <p>3 stenosis, the size of the aortic opening</p> <p>4 varies between pigs and humans; right?</p> <p>5 A. Yes.</p> <p>6 Q. And the other is the risk of injury</p> <p>7 depending on what guide wire you use?</p> <p>8 A. Yes.</p> <p>9 Q. So, I want to take those in pieces.</p> <p>10 Let's start with the risk of injury, and I</p> <p>11 just want to make sure I understand the</p> <p>12 concept.</p> <p>13 You're saying that for a -- you don't</p> <p>14 want to puncture an artery or, I mean, is that</p> <p>15 basically what you're saying, you don't want</p> <p>16 to puncture an artery if you use, for example,</p> <p>17 a stiff guide wire and you poke through</p> <p>18 something?</p> <p>19 A. There's a technique called Seldinger</p> <p>20 technique, that is a known technique, and it's</p> <p>21 for someone skilled in the art normal that he</p> <p>22 starts the procedure with a wire that has less</p> <p>23 risk of traumatizing the tissue.</p> <p>24 Q. So, this was already, it was known</p> <p>25 that using a soft guide wire and, in fact,</p>
<p style="text-align: right;">Page 15</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER</p> <p>2 wire; is that right?</p> <p>3 A. Yes, that's right.</p> <p>4 Q. So, can you explain to me why, as I</p> <p>5 understand it, your position is that in humans</p> <p>6 it matters what type of guide wire you used;</p> <p>7 is that correct?</p> <p>8 A. That's correct.</p> <p>9 Q. Can you explain to me why it doesn't</p> <p>10 matter in pigs but it does matter in humans?</p> <p>11 A. Well, there's an important</p> <p>12 difference. In pigs, you cannot create what</p> <p>13 is called an animal model that simulates</p> <p>14 accurately aortic valve stenosis. Pigs are</p> <p>15 healthy animals with large aortic openings,</p> <p>16 and risk of injury to the pig is, of course,</p> <p>17 not as important as in a patient under the</p> <p>18 clinical setting.</p> <p>19 So, in pigs, we just had to use</p> <p>20 anything that allowed us to create the rail</p> <p>21 from getting to the heart, reaching to the</p> <p>22 aortic valve and beyond, and relatively it was</p> <p>23 absolutely of no matter or concern.</p> <p>24 Q. I think there were two separate</p> <p>25 concepts that you just covered, and I want to</p>	<p style="text-align: right;">Page 17</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER</p> <p>2 what we referred to already as the starting</p> <p>3 guide wires that were commercially available,</p> <p>4 would you agree with me that it was generally</p> <p>5 known that those were good for starting the</p> <p>6 procedure because they were softer and less</p> <p>7 risk of puncture?</p> <p>8 A. That's right; at least for target</p> <p>9 organs like vessels, because at that moment in</p> <p>10 time, at least by my best knowledge, nobody</p> <p>11 tried this technique in pigs. So, I didn't</p> <p>12 know what was best for pigs; therefore, I</p> <p>13 didn't care, I took whatever wire I had at</p> <p>14 hand, as I mentioned.</p> <p>15 But accessing artery or vein, usually</p> <p>16 it was performed by using wire that was less</p> <p>17 traumatic in a clinical setting.</p> <p>18 Q. So, turning to the second point you</p> <p>19 had about size of the opening in the pig</p> <p>20 versus the human, can you explain to me how</p> <p>21 your invention solves that problem that you've</p> <p>22 identified?</p> <p>23 A. So, as I mentioned with pigs, there</p> <p>24 is no heart, no animal model that allows you</p> <p>25 to accurately simulate aortic valve stenosis,</p>

<p style="text-align: right;">Page 18</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER  2 for example, pigs. So, I was left with one  3 issue. The pig animals were presented and  4 seemed to work very fine, but I didn't know  5 what happened if you had aortic valve stenosis  6 to cope with.  7 And this was one of my reflections  8 and issues I had to solve to get that  9 procedure successful; because, ultimately, it  10 was supposed to save the patients' lives, and  11 that's what I wanted, that's what I was  12 trained for, that's what my aim is and  13 profession is, to help patients and save  14 patients lives.  15 While I didn't have the solution  16 while doing those animal experiments, and  17 while I was on my way from Switzerland from  18 Lausanne with my wife, pregnant with twins, on  19 my way from Geneva to Boston, I stood at  20 Geneva airport, and while I was quite stressed  21 we might miss the plane, even though we got  22 there in time, and we couldn't move as fast as  23 we wanted to, but we were standing there  24 watching people trying to push through the  25 gates. And there was quite a large crowd</p>	<p style="text-align: right;">Page 20</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER  2 soft enough to help by the stream to go to the  3 gate, go through the aortic valve, that will  4 be most likely the solution.  5 I didn't have proof of concept, but  6 for me that was the key element to my  7 invention that bonded and joined all different  8 steps that are found in claim 1 to make the  9 whole claim 1 work; that was to take a wire  10 that was configure, or configured, you call it  11 soft, to allow it to go through the narrow  12 passageway, the gate or the aortic valve, and  13 aided or helped by the blood flow to do so.  14 <b>Q. And I didn't mean to put my words in  15 place of yours, and I did call it soft, you're  16 right.</b>  17 <b>Is that fair, are soft guide wires as  18 a category configured to conform to the  19 direction of blood flow?</b>  20 A. I would say that's fair to say, a  21 soft guide wire, as you mentioned, there are  22 different grades of softness, and I'm not a  23 med-tech technical specialist, but there is  24 softnesses understood as being a wire that  25 could do the job, or firmer wires that are in</p>
<p style="text-align: right;">Page 19</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER  2 outside the gates, and obviously there was  3 very little, only one by one, like a drop by  4 drop going through the gate.  5 And this interesting concept suddenly  6 made me aware that the solution was right in  7 front of my eyes; that the gate was the  8 stenosis, and all the people trying to get  9 through the gate were, was the blood in the  10 left ventricle. And they tried to push  11 through, and people in the middle were  12 principally dragged nearly through that gate.  13 And that's where I said, well, yes,  14 that's the trick, that's the invention; that  15 if we can, if this works, then that's the  16 solution to the problem.  17 <b>Q. And did you -- so, okay.</b>  18 <b>You saw the people going through the  19 gate, and you thought about this drag. How  20 did that then translate into the next thought,  21 how did that lead to, oh, it's a soft guide  22 wire, or whatever your next realization was?</b>  23 A. Well, it was pure deduction, I said,  24 if people, this is a flexible mass of people,  25 if I put anything into that stream that is</p>	<p style="text-align: right;">Page 21</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER  2 the intermediate range, and then there are  3 other wires that are stiff wires. But there's  4 a clear group of wires that we call soft  5 wires, and those wires, suddenly some of those  6 wires would work.  7 <b>Q. Some but not all?</b>  8 A. This is something I haven't tried;  9 so, I couldn't give you an honest answer to  10 that. I would assume that if they are in this  11 category, this group of designated wires, it  12 would work; but I don't have personal  13 experience with it, so I couldn't give you the  14 honest truth about that.  15 <b>Q. So, again, I just want to make sure I  16 understand what you're saying.</b>  17 <b>You're guess is that soft guide wires  18 would all conform to the direction of blood  19 flow, but because you haven't tried every  20 single one, you can't say for sure; is that  21 right?</b>  22 A. Yes. I would agree on this  23 statement.  24 <b>Q. So, then you also mentioned there's a  25 category of intermediate guide wires, and</b></p>

<p style="text-align: right;">Page 22</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER</p> <p>2 that's very helpful to me, because when I've</p> <p>3 been looking into the guide wire, I noticed</p> <p>4 that some of them are called soft, some are</p> <p>5 called stiff, and there are some that aren't</p> <p>6 called anything. And so, maybe that's the</p> <p>7 intermediate category.</p> <p>8 But, for the intermediate category,</p> <p>9 how could you tell whether or not a guide wire</p> <p>10 in the intermediate category is configured to</p> <p>11 conform to a direction of blood flow?</p> <p>12 A. Well, I didn't use wires, at least</p> <p>13 not in patients that were in the immediate</p> <p>14 category. So, it's difficult to give you an</p> <p>15 exact answer on that. And I don't know what</p> <p>16 you define at the end of intermediate</p> <p>17 categories, because it doesn't mean the wire</p> <p>18 is marked with soft, or with stiff, it doesn't</p> <p>19 mean it is intermediate, and I don't know if</p> <p>20 there is a definition of an intermediate wire;</p> <p>21 so, it would be really challenging for me to</p> <p>22 give you any clear-cut definitions.</p> <p>23 What I know is that principally there</p> <p>24 are two types of wires that are being used,</p> <p>25 soft wires and stiff wires; The rest is all</p>	<p style="text-align: right;">Page 24</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER</p> <p>2 that makes the answer much easier. That could</p> <p>3 be a soft guide wire, that could as well be a</p> <p>4 hard guide wire that has capabilities of</p> <p>5 behaving like a soft guide wire for part of</p> <p>6 its length.</p> <p>7 So, let's put the term as it is put</p> <p>8 in claim 1 and issued by the U.S. Patent &amp;</p> <p>9 Trademark Office, I'll be happy to read that:</p> <p>10 "Configured to conform to the direction of</p> <p>11 blood flow." That's why it has been put that</p> <p>12 way.</p> <p>13 Q. And so, a couple of questions on</p> <p>14 that.</p> <p>15 You were talking about a stiff guide</p> <p>16 wire could have a portion that, I'll use my</p> <p>17 term, softer. So, I've seen guide wires, for</p> <p>18 example, in some in some of the brochures that</p> <p>19 say stiff with a floppy tip.</p> <p>20 Would that be examples of what you're</p> <p>21 talking about, most of the guide wire will be</p> <p>22 stiff but at the end it will be much softer or</p> <p>23 floppier?</p> <p>24 A. Put the question back to you. Do you</p> <p>25 think that wire would be aided by the blood</p>
<p style="text-align: right;">Page 23</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER</p> <p>2 interpretation.</p> <p>3 THE REPORTER: Interpretation?</p> <p>4 THE WITNESS: Interpretation;</p> <p>5 correct.</p> <p>6 Q. So, forget the label, intermediate.</p> <p>7 But just with respect to any guide wire, and</p> <p>8 if it makes the question easier, you know, you</p> <p>9 can assume it's a stiff guide wire -- well,</p> <p>10 let me ask you this.</p> <p>11 Are there stiff guide wires that</p> <p>12 could fall into the category of being</p> <p>13 configured to conform to a direction of blood</p> <p>14 flow?</p> <p>15 A. No. It depends how you define wire</p> <p>16 and what part of the wire you define.</p> <p>17 Wire can be having uniform</p> <p>18 characteristics over its whole length, but</p> <p>19 wire could have nonuniform characteristics</p> <p>20 over its whole length; wire could have a part</p> <p>21 of the wire that is very soft and a part of</p> <p>22 the wire that is more rigid.</p> <p>23 Now, how to define this wire by using</p> <p>24 the term soft or hard is tricky; but if you</p> <p>25 use the term that is, wires configured, then</p>	<p style="text-align: right;">Page 25</p> <p>1 CONFIDENTIAL - PURSUANT TO PROTECTIVE ORDER</p> <p>2 flow if just a very centimeter at the tip</p> <p>3 really is soft?</p> <p>4 If you read the claim here it says,</p> <p>5 the feeding continues, configured to conform</p> <p>6 to the direction of blood flow, the feeding</p> <p>7 continuing such that the wire follows the</p> <p>8 blood flow until length of the wire extends</p> <p>9 from the ventricle apex of the heart.</p> <p>10 That will give you some indication</p> <p>11 how long this floppy wire has to be. It's</p> <p>12 just the tip. The rigidity of the rest of the</p> <p>13 wire will not really help it to aid it or</p> <p>14 direct it by the blood flow.</p> <p>15 Q. I see. So, it is really a longer</p> <p>16 piece than just the tip you're talking about?</p> <p>17 THE REPORTER: Verbally, sir.</p> <p>18 THE WITNESS: Sorry?</p> <p>19 THE REPORTER: Respond verbally.</p> <p>20 MS. NYARADY: You were nodding.</p> <p>21 A. Yes. Sorry.</p> <p>22 Q. Can I ask you a question?</p> <p>23 What is, if you know, I see the term</p> <p>24 soft, and then I see the term floppy. Are</p> <p>25 those terms interchangeable in your field?</p>

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