IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDOHEART AG,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 14-1473 (LPS) (CJB)
	)	
EDWARDS LIFESCIENCES CORPORATION,	)	
	)	
	)	
Defendant.	)	

DEFENDANT EDWARDS LIFESCIENCES CORPORATION'S
OPENING CLAIM CONSTRUCTION BRIEF

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CASES

Defendant Edwards Lifesciences Corporation ("Edwards") respectfully submits this brief in support of its proposed constructions of the claim terms of U.S. Patent No. 8,182,530 ("the '530 patent").

I. INTRODUCTION

Claims 1 and 6 of the '530 patent are directed to methods of implanting transcatheter heart valves. Transcatheter heart valves allow doctors to replace a patient's defective heart valve—the aortic valve in this case—by mounting an artificial heart valve on a stent and introducing it through a narrow catheter in the vascular system. This technology avoids the need for open-heart surgical valve replacement in patients who cannot or will not undergo such a highly invasive procedure.

Plaintiff Endoheart AG does not contend that the named inventor of the '530 patent, Dr. Christoph Huber, invented the concept of transcatheter heart valve replacement. Nor could it, because it is Edwards that pioneered the lifesaving transcatheter heart valve technology. Rather, Endoheart claims that its '530 patent covers the "transapical approach," by which the transcatheter heart valve is implanted directly into the heart through a chest and heart incision, rather than through a patient's vasculature. In the transapical approach, the transcatheter valve is delivered to the diseased heart valve through a puncture made at the ventricular apex of the heart, as opposed to, for example, a transfemoral approach (in which a valve is delivered through the femoral artery). Endoheart has sued Edwards, alleging that Edwards induces infringement of '530 patent claims 1 and 6 by selling its SAPIEN line of transcatheter heart valve products with its Ascendra line of delivery systems. (*See* D.I. 1 at ¶ 11)

Edwards proposed six terms for construction. All remain disputed.

II. BACKGROUND

Defendant Edwards is the global leader in the science of heart valves. Over the last 55 years, Edwards has invented and developed new ways to treat patients with heart valve disease, including the transcatheter heart valve. Previously, patients with degenerating aortic valves had to undergo open heart surgery to replace the valve, an invasive procedure with a long and difficult recovery period. (Ex. 1 at 1:29–51.)[1] Transcatheter heart valve technology—technology for implanting prosthetic valves using a catheter—avoids the need for this extreme procedure (*id.* at 1:10–25), allowing a prosthetic heart valve to be delivered percutaneously (through the skin), or by a minimally invasive surgical procedure.

According to Endoheart, the '530 patent claims an approach for performing transcatheter heart valve replacement, the "transapical" approach, so named because access is gained through the apex of the heart. Claims 1 and 6 are below (terms at issue are underlined):

> 1. A method for implanting a heart valve comprising:
>
> accessing a patient's heart by piercing a myocardium with a cannulated needle having a sharp end;
>
> feeding through the cannulated needle an elongated wire configured to conform to a direction of blood flow, the feeding continuing such that the wire follows the blood flow until a length of the wire extends at least from a ventricular apex of the heart through an aortic valve of the heart;
>
> installing an access device in a wall of the heart, the access device having means for preventing bleeding through the access device;
>
> inserting a valve delivery device through the access device; and
>
> installing the heart valve.

[1] "Ex. __" refers to exhibits to the declaration of Christopher Terranova, filed herewith.

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