

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEOCHORD, INC.,
Petitioner,

v.

UNIVERSITY OF MARYLAND, BALTIMORE and
HARPOON MEDICAL, INC.,
Patent Owner.

Case IPR2016-00208
Patent 7,635,386 B1

Before SALLY C. MEDLEY, ERICA A. FRANKLIN, and
JAMES A. WORTH, *Administrative Patent Judges*.

WORTH, *Administrative Patent Judge*.

DECISION

Decision on Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

On November 18, 2015, Petitioner NeoChord, Inc. filed a Petition (Paper 2, “Pet.”) requesting *inter partes* review of claims 1–23 of U.S. Patent No. 7,635,386 B1 (the ’386 patent, Ex. 1001). No Preliminary Response was filed.

The University of Maryland, Baltimore, filed a mandatory notice pursuant to 37 C.F.R. § 42.8, representing that it is the Patent Owner and a real party-in-interest. Paper 5, 2. The University of Maryland, Baltimore, further states that Harpoon Medical, Inc. is the exclusive licensee and is also a real party-in-interest. *Id.*

Institution of an *inter partes* review is authorized by statute when “the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a); *see also* 37 C.F.R. § 42.108. For the reasons set forth below, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail in showing that claims 1–23 of the ’386 patent are unpatentable.

Accordingly, we institute an *inter partes* review for the challenged claims.

A. Related Matters

The parties state that they are unaware of any related judicial or administrative proceedings. Pet. 2; Paper 5, 2.

B. The ’386 Patent (Ex. 1001)

The ’386 patent is titled “Methods and Devices for Performing Cardiac Valve Repair,” and relates to methods for performing repairs to

cardiac valves, and in particular, the mitral and tricuspid valves. Ex. 1001, at [57], 1:14–16. Such repairs may include implantation of artificial chordae tendinae,¹ valve resection, implantation of an annuloplasty ring, and bow-tie repair. *Id.* at [57], 4:59–5:11.

The '386 patent states that the conventional approach for valve repair is problematic because it requires stopping the heart, which makes it difficult to accurately determine, assess, and secure the appropriate length for artificial chordae to ensure proper functioning of the valve. *Id.* at 4:36–47. Further, the '386 states that as a general matter, cardiopulmonary bypass required by the conventional approach may adversely affect almost all of the organ systems of the body, and lead to strokes, myocardial damage, respiratory failure, kidney failure, bleeding, or death. *Id.* at 4:10–35.

The '386 patent is directed to a minimally invasive surgical approach in which valve repair may be performed while the heart is still beating with small incisions using specialized instruments under audio or visual guidance. *Id.* at 4:59–64, 6:13–14, 6:22–27. The '386 patent describes accessing the heart through a small incision between the ribs or through the abdomen, followed by a small incision in the heart wall at or near the apex of the heart. *Id.* at 6:54–67, 9:43–10:2. An access port, including a manifold, may be inserted into the site of entry. *Id.* at 10:13–14. The '386 patent describes, as an alternative approach to the heart, a percutaneous, endovascular approach through the femoral or internal jugular veins, or through the femoral artery, using needle puncture to access the apical region of the heart. *Id.* at 6:27–31, 10:2–7.

¹ The '386 patent refers to these structures with alternate spellings, i.e., both as “chordae tendinae” and as “chordae tendineae.”

The surgical approach described in the '386 patent is depicted below in Figure 6:

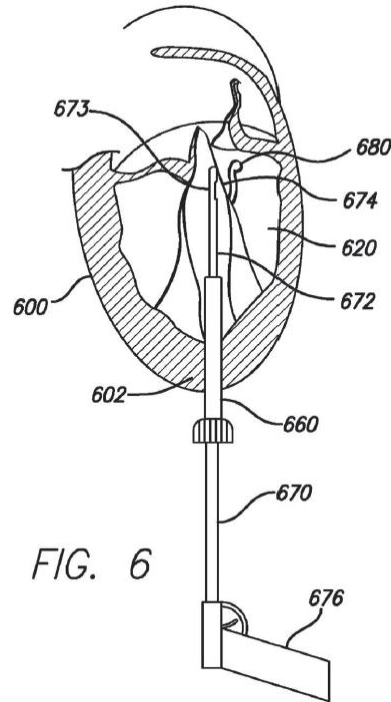


Figure 6 depicts an instrument inserted through an incision in the apex of the heart. For a repair that inserts artificial chordae tendinae, the instrument may attach a suture to a leaflet of the mitral valve, and attach the other end of the suture near the apex of the heart. *Id.* at 13:60–14:5. See Figure 9 below:

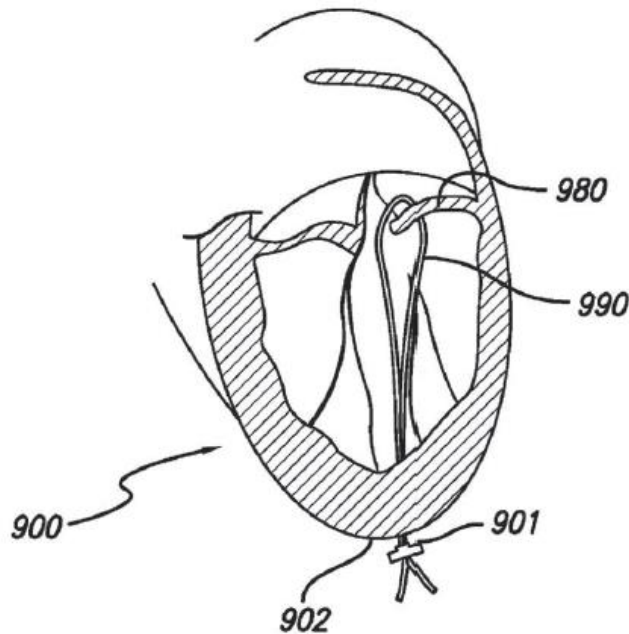


FIG. 9

Figure 9 shows suture placement in one embodiment to form an artificial chorda.

C. Illustrative Claims

The Petition challenges claims 1–23 of the '386 patent. Of these, claims 1 and 19 are recited as independent claims directed to methods.

Independent claim 1, reproduced below, is representative of the subject matter on appeal:

1. A method for repairing a defective mitral or tricuspid valve, comprising:
 - creating an access in an apical region of a heart through which a defective cardiac valve is accessed;
 - introducing a device through said access; and
 - repairing said cardiac valve by use of said device, wherein the repairing comprises replacing one or more chordae tendineae, and using said device to implant one or more artificial chordae tendineae, and

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