Trials@uspto.gov
Tel: 571-272-7822

Paper 75
Date: July 8, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CARDIOVASCULAR SYSTEMS, INC.,
Petitioner,

v.

SHOCKWAVE MEDICAL, INC.,
Patent Owner.

IPR2019-00409
Patent 8,728,091 B2

Before MITCHELL G. WEATHERLY, RICHARD H. MARSCHALL, and AVELYN M. ROSS, *Administrative Patent Judges.*

ROSS, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Denying Petitioner's Motion to Exclude
Denying Patent Owner's Motion to Exclude
35 U.S.C. § 318(a); 37 C.F.R. § 42.64

I. INTRODUCTION

We have jurisdiction to hear this *inter partes* review under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons discussed herein, we determine that Cardiovascular Systems, Inc., ("Petitioner") has shown, by a preponderance of the evidence, that claims 1–14 ("the challenged claims") of U.S. Patent No. 8,728,091 B2 (Ex. 1001, "the '091 patent") are unpatentable.

A. Procedural History

Petitioner filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–14 of the '091 patent. Petitioner relies on the declaration testimony of Dr. Morten Olgaard Jensen (Ex. 1002) to support its positions. Shockwave Medical, Inc., ("Patent Owner") filed a Preliminary Response to the Petition (Paper 11, "Prelim. Resp."). Pursuant to 35 U.S.C. § 314(a), on July 11, 2019, *inter partes* review was instituted on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–14	103	Hawkins[1] and Li[2]
1–3, 10	103	Hawkins and Chernenko[3]
1–14	103	Hawkins, Chernenko and Li
1–14	103	Hawkins and Heeren[4]

[1] Hawkins, et al., US 2009/0312768 A1, published December 17, 2009 (Ex. 1003).
[2] US 2006/0221528 A1, published October 5, 2006 (Ex. 1004).
[3] US 2003/0176873 A1, published September 18, 2003 (Ex. 1005).
[4] US 2013/0041355 A1, published February 14, 2013 (Ex. 1006).

See Paper 14 ("Inst. Dec.").

Subsequent to institution, Patent Owner filed a Patent Owner Response (Paper 34, "PO Resp."), along with a Declaration of Daniel W. van der Weide, Ph.D. (Ex. 2100) to support its positions. Petitioner filed a Reply (Paper 48, "Pet. Reply") to the Patent Owner Response, along with a Supplemental Declaration of Dr. Jensen (Ex. 1200), and Patent Owner filed a Sur-Reply (Paper 55, "Sur-Reply").

Petitioner filed a Motion to Exclude certain exhibits. Paper 62 ("Pet. MTE"). Thereafter, Patent Owner filed an Opposition to Petitioner's Motion to Exclude (Paper 65, "PO MTE Opp.").

Patent Owner also filed a Motion to Exclude certain exhibits. Paper 61 ("PO MTE"). Petitioner filed an Opposition to Patent Owner's Motion to Exclude (Paper 63, "Pet. MTE Opp.").

An oral hearing was held on April 16, 2020. A transcript of the hearing is included in the record. Paper 74 ("Tr.").

B. Related Proceedings

Petitioner states that it "is not aware of any judicial or administrative matter that would affect, or be affected by, a decision in the proceeding." Pet. 64. Patent Owner identifies concurrently filed petitions for *inter partes* review, IPR2019-00405 and IPR2019-00408, as related proceedings. Paper 3, 2. In addition, Patent Owner identifies several issued U.S. patents and applications as related matters. *Id.* at 2–3.

C. The '091 Patent

The '091 patent "relates to a treatment system for percutaneous coronary angioplasty or peripheral angioplasty in which a dilation catheter is

used to cross a lesion in order to dilate the lesion and restore normal blood flow in the artery." Ex. 1001, 1:15–18. Figure 1 below illustrates a simplified view of an angioplasty balloon catheter.

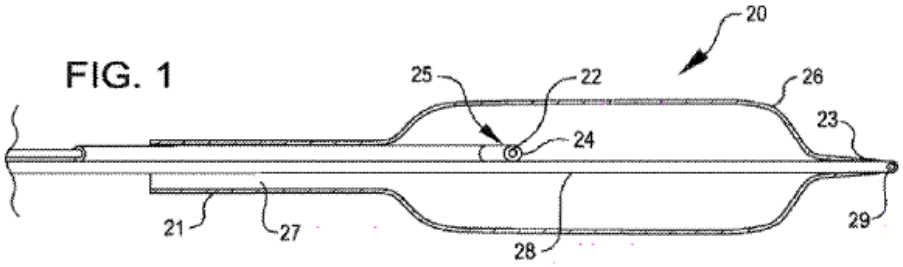

Figure 1 shows an angioplasty balloon catheter 20 including hollow sheath 21, dilating balloon 26, and guidewire 28. *Id.* at 7:34–40. The catheter includes shock wave generator 25, i.e., at least one pair of electrodes 22 and 24, within balloon 26 to generate a high voltage arc across the electrodes. *Id.* at 1:45–51. "The arc in turn causes a steam bubble to form" and "[e]ach steam bubble has the potential of producing two shock waves, a leading edge shock wave as a result of bubble expansion and a trailing edge wave as a result of bubble collapse." *Id.* at 1:56–62. Through use of repeated shockwaves, the calcified lesions can be broken up without damaging the surrounding tissue. *Id.* at 1:53–54. Because the trailing edge shock waves exhibit highly variable and greater energy levels, the '091 patent describes using the leading edge shock waves to create the steam bubble. *Id.* at 2:8–10. Even though the leading edge shock waves exhibit lower energy levels, these shock waves are a more consistent energy level. *Id.*

The '091 patent explains that "it has been learned that to sustain a leading edge shock wave, it is not necessary to sustain the high voltage

throughout the shock wave" because it does not produce a shock wave of greater intensity and the heat produced by the steam bubbles may damage tissue. *Id*. at 2:21–29. Therefore, "there is a need to control the applied energy to assure appropriate bubble and shock wave formation while at the same time conserving electrode material and assuring tissue safety." *Id.* at 2:49–52. The '091 patent explains that problems may be avoided and certain advantages are achieved by including a power source with a current sensor that sends signals to terminate the high voltage supply when current flow reaches a predetermined limit. *Id.* at 3:1–10, 8:20–40.

D. Illustrative Claims

Petitioner challenges claims 1–14 of the '091 patent. Independent claims 1 and 10 are illustrative of the challenged claims and are reproduced below:

> 1. A balloon catheter for delivering shockwaves to a calcified lesion comprising:
>
> an elongated carrier;
>
> a flexible balloon mounted on the elongate carrier,
>
> said balloon being fillable with a conductive fluid;
>
> a pair of electrodes on the elongated carrier within the balloon; and
>
> a power source coupled to the electrodes for supplying voltage pulses to the electrodes, each voltage pulse generating an arc in the fluid within the balloon and causing current to flow between the electrodes and producing a shockwave;
>
> wherein the power source includes a current sensor for detecting the current flow between the electrodes during each voltage pulse, and wherein when the current reaches a predetermined value during each voltage pulse, the sensor

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