

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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EDWARDS LIFESCIENCES CORPORATION

Petitioner

v.

MEDTRONIC, INC.

Patent Owner

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Case IPR2014-00362

U.S. Patent 6,306,141

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**MEDTRONIC, INC.'S PRELIMINARY RESPONSE**

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United States Patent and Trademark Office  
P.O. Box 1450  
Arlington, VA 22313-1450**

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## EXHIBIT LIST

Ex. #	Exhibit Description
2001	D. Stoeckel, "The Shape Memory Effect – Phenomenon, Alloys and Applications," <i>Proceedings: Shape Memory Alloys for Power Sys. EPRI</i> , 1-13 (2005)
2002	Biscarini et al., "Enhanced Nitinol Properties for Biomedical Applications," <i>Recent Patents on Biomed. Eng'g</i> , No. 1, 180-196 (2008)
2003	<i>Medtronic, Inc. v. AGA Med. Corp.</i> , Case No. 07-00567 MMC (Trial Exhibit)
2004	<i>Medtronic, Inc. v. AGA Med. Corp.</i> , Case No. 07-00567 MMC, 2009 WL 1163976 (N.D. Cal. Apr. 28, 2009)
2005	<i>Medtronic, Inc. v. AGA Med. Corp.</i> , Case No. 07-00567 MMC, (N.D. Cal. Aug. 6, 2009) (Verdict Form)
2006	<i>Medtronic, Inc. v. W.L. Gore &amp; Assoc., Inc.</i> , Case No. 06-04455 JSW, 2008 WL 5191846 (N.D. Cal. Dec. 9, 2008)
2007	Press Release, <i>Medtronic and W.L. Gore &amp; Associates Settle Patent Dispute</i> , Sept. 16, 2009
2008	M. Wu, "Fabrication of Nitinol Materials and Components," <i>Proceedings of Int'l Conference on Shape Memory &amp; Superelastic Techs.</i> , 285-92 (2001)
2009	U.S. Publication No. 2004/0193257 to Wu and Poncet (filed Mar. 2004; published Sept. 20, 2004)

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## I. INTRODUCTION

Patent Owner Medtronic, Inc. (“Medtronic”) respectfully submits this Preliminary Response to the Petition filed by Edwards Lifesciences Corporation (“Petitioner”) seeking *inter partes* review of Claims 1-22 of U.S. Patent No. 6,306,141 (the “’141 patent”). The Petition for *inter partes* review of the ’141 patent should be denied, as it fails to demonstrate a reasonable likelihood of prevailing as to any claim on any of Petitioner’s five asserted Grounds.

As for obviousness-type double patenting (“ODP”) (Ground #5), this argument is not a permissible Ground on which to base *inter partes* review. Such proceedings may only be based on patents or printed publications under 35 U.S.C. §§ 102 or 103. The ODP doctrine, by contrast, is judicially-created and rooted in 35 U.S.C. § 101.

As for anticipation, Grounds #1 (Cragg I) and #2 (Cragg II) fail for at least two reasons. First, Cragg I and Cragg II fail to expressly disclose a key limitation recited in all of the claims, namely the stress-induced martensite limitation. That is because those references exclusively teach medical devices made of shape memory alloys (“SMA devices”) that are deployed in the body by *temperature-induced martensite* (“TIM”), while the ’141 patent claims SMA devices deployed in the body by *stress-induced martensite* (“SIM”). Second, Petitioner’s argument that Cragg I and Cragg II inherently teach the SIM limitation is based upon an expert

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