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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COOK INCORPORATED, COOK GROUP INCORPORATED, AND COOK MEDICAL LLC,
Petitioner,

v.

MEDTRONIC, INC.,
Patent Owner.

Case IPR2019-00123
Patent 6,306,141 B1

Before JAMESON LEE, KEN B. BARRETT, and
JAMES A. TARTAL, *Administrative Patent Judges*.

BARRETT, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

A. Background and Summary

Cook Incorporated, Cook Group Incorporated, and Cook Medical LLC (collectively, "Petitioner")[1] filed a Petition requesting *inter partes* review of U.S. Patent No. 6,306,141 B1 ("the '141 patent," Ex. 1001). Paper 1 ("Pet."). The Petition challenges the patentability of claims 1–22 of the '141 patent. Medtronic, Inc., ("Patent Owner")[2] filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp."). Petitioner, pursuant to our authorization, Paper 9, filed a Reply to Patent Owner's Preliminary Response, Paper 10 ("Pet. Reply to Prelim. Resp.").

An *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . 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). Having considered the arguments and evidence presented by Petitioner and Patent Owner, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in showing that at least one of the challenged claims of the '141 patent is unpatentable. Accordingly, we institute an *inter partes* review as to all the challenged claims of the '141 patent on all the grounds of unpatentability set forth in the Petition.

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[1] Petitioner identifies Cook Incorporated, Cook Group Incorporated, and Cook Medical LLC as real parties-in-interest. Pet. 1.

[2] Patent Owner, under the heading "Real Party-In-Interest," states that Medtronic, Inc. is the owner of the '141 patent and that "Medtronic plc is the ultimate parent of Medtronic, Inc." Paper 3, 1–2.

B. Related Proceedings

One or both parties identify, as matters involving or related to the ’141 patent, *Medtronic, Inc. v. W.L. Gore & Assocs., Inc.*, No. 06-cv-04455 (N.D. Cal.), and *Medtronic, Inc. v. AGA Med. Corp.*, No. 07-cv-00567 (N.D. Cal.) and Patent Trial and Appeal Board cases IPR2013-00269 and IPR2014-00362. Pet. 1; Paper 3.

C. The ’141 Patent

The ’141 patent pertains to medical devices incorporating shape memory alloys (SMAs) and, specifically, to medical devices incorporating stress-induced martensite (SIM) alloys. Ex. 1001, Abstract, 1:21–23. According to the Abstract of the ’141 patent:

> Medical devices which are currently proposed to use elements made from shape memory alloys may be improved by the use of stress-induced martensite alloy elements instead. The use of stress-induced martensite decreases the temperature sensitivity of the devices, thereby making them easier to install and/or remove.

Ex. 1001, Abstract.

The Specification explains that shape memory alloys were well known. *Id.* at 1:26–27. An article made from a shape memory alloy can be deformed from its original, heat stable configuration to a second, heat unstable configuration, and, upon application of heat alone, can be caused to revert to its original configuration. *Id.* at 1:27–34.

> Among metallic alloys, the ability to possess shape memory is a result of the fact that the alloy undergoes a reversible transformation from an austenitic state to a martensitic state with a change in temperature. This transformation is sometimes referred to as a thermoelastic martensitic transformation. An article made from such an alloy, for example a hollow sleeve, is easily deformed from its original configuration to a new

> configuration when cooled below the temperature at which the alloy is transformed from the austenitic state to the martensitic state. The temperature at which this transformation begins is usually referred to as M_s and the temperature at which it finishes M_f. When an article thus deformed is warmed to the temperature at which the alloy starts to revert back to austenite, referred to as A_s (A_f being the temperature at which the reversion is complete) the deformed object will begin to return to its original configuration.

Id. at 1:35–51. The parties refer to the property or behavior associated with an austenitic-to-martensitic transformation related to a temperature change as "temperature-induced martensite" or "TIM." See*, e.g.*, Prelim. Resp. 6; Pet. 7, 10.

The Specification further explains that a martensite state also may be induced by stress:

> Many shape memory alloys (SHAs [sic, SMAs]) are known to display stress-induced martensite (SIM). When an SMA sample exhibiting stress-induced martensite is stressed at a temperature above M_s (so that the austenitic state is initially stable), but below M_d (the maximum temperature at which martensite formation can occur even under stress) it first deforms elastically and then, at a critical stress, begins to transform by the formation of stress-induced martensite. Depending on whether the temperature is above or below A_s, the behavior when the deforming stress is released differs. If the temperature is below A_s, the stress-induced martensite is stable; but if the temperature is above A_s, the martensite is unstable and transforms back to austenite, with the sample returning (or attempting to return) to its original shape. The effect is seen in almost all alloys which exhibit a thermoelastic martensitic transformation, along with the shape memory effect. However, the extent of the temperature range over which SIM is seen and the stress and strain ranges for the effect vary greatly with the alloy.

Ex. 1001, 1:52–2:3. "The recoverable deformation associated with the formation and reversion of stress-induced martensite has been referred to as pseudoelasticity." *Id.* at 4:12–15.

"Various proposals have also been made to employ shape memory alloys in the medical field . . . [and t]hese medical SMA devices . . . rely on the fact that when an SMA element is cooled to its martensitic state and is subsequently deformed, it will retain its new shape; but when it is warmed to its austenitic state, the original shape will be recovered." *Id.* at 2:15–28. According to the Specification, there were two principal disadvantages with this use of SMAs—it was difficult to control the transformation temperatures of SMAs with accuracy and many SMAs had a large hysteresis associated with the state transformation thus requiring a significant temperature excursion to reverse the state. *Id.* at 2:29–41. Additionally, it was "inconvenient to have to engage in any temperature manipulation" and human tissue could be damaged by temperatures outside of narrow limits. *Id.* at 2:41–48.

The '141 patent purports to disclose the discovery "that if, in a medical device containing a shape memory alloy element which uses the shape memory property of that alloy, an element which shows the property of stress-induced martensite is used instead, an improved device results." *Id.* at 2:59–63. The Specification characterizes the improvement due to the claimed invention as "compris[ing] the substitution of an alloy element which displays stress induced martensite at said body temperature for the shape memory alloy element [in a medical device intended for use in a mammalian body or a device that is substantially at body temperature]." *Id.* at 2:64–3:4.

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