

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEVRO CORP.,
Petitioner,

v.

BOSTON SCIENTIFIC NEUROMODULATION CORP.,
Patent Owner.

Case IPR2017-01811
Patent 6,895,280 B2

Before HUBERT C. LORIN, MICHAEL W. KIM, and AMANDA F. WIEKER,
Administrative Patent Judges.

WIEKER, *Administrative Patent Judge.*

DECISION
Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

A. *Background*

Nevro Corp. (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1, 4, 7–9, 11, 18, 19, and 21 (“the challenged claims”) of U.S. Patent No. 6,895,280 B2 (Ex. 1001, “the ’280 patent”). Paper 1 (“Pet.”). Boston Scientific Neuromodulation Corp. (“Patent Owner”) filed a Preliminary Response. Paper 8 (“Prelim. Resp.”).

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition and the Preliminary Response 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; *see also* 37 C.F.R § 42.4(a) (“The Board institutes the trial on behalf of the Director.”). Taking into account the arguments presented in the Preliminary Response, we conclude that the information presented in the Petition does not establish a reasonable likelihood that Petitioner would prevail with respect to the challenged claims.

Accordingly, we decline to institute an *inter partes* review.

B. *Related Proceedings*

The parties represent that the ’280 patent is at issue in *Boston Scientific Corp. and Boston Scientific Neuromodulation Corp. v. Nevro Corp.*, Case No. 1:16-cv-01163-GMS (D. Del). Pet. 76; Paper 5, ii.

Petitioner also represents that the ’280 patent is the subject of IPR2017-01812, filed concurrently with the instant Petition. Pet. 76. IPR2017-01920, between the same parties, also involves challenges to certain claims of the ’280 patent.

C. The '280 Patent

The '280 patent is titled "Rechargeable Spinal Cord Stimulator System," and issued on May 17, 2005 from U.S. Application No. 10/307,098, filed Nov. 27, 2002. Ex. 1001, (21), (22), (45), (54).

The '280 patent explains that spinal cord stimulation is used to reduce a patient's pain by providing electrical pulses to electrodes implanted at the patient's spinal cord. *Id.* at 1:23–32. Figure 1 of the '280 patent is reproduced below.

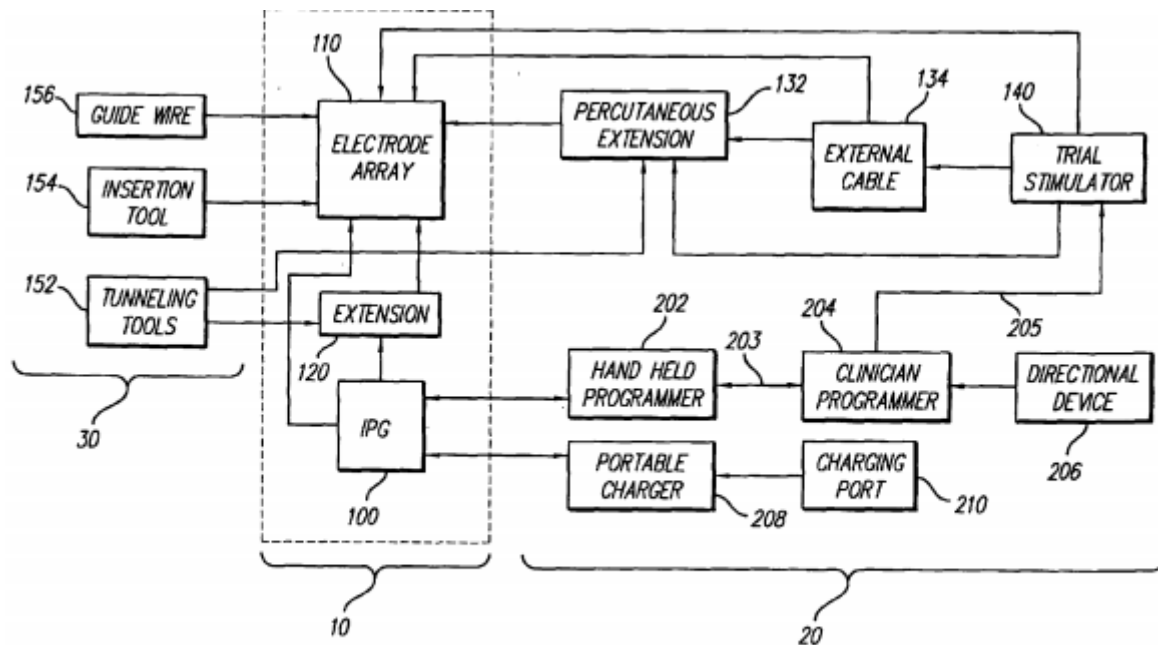


FIG. 1

Figure 1 depicts a block diagram of a spinal cord stimulation system, and identifies its implantable, external, and surgical components. *Id.* at 7:3–5, 8:33–35.

Implantable components 10 of the system include implantable pulse generator (IPG) 100, electrode array 110, and lead extension 120. *Id.* at 4:13–18, 8:38–41.

These elements are implanted in the patient through use of surgical components 30. *Id.* at 8:35–38.

External components 20 include, for example, various programmers 202, 204, external battery charger 208, and trial stimulator 140. *Id.* at Fig. 1, 4:18–21.

The spinal cord stimulation system disclosed in the '280 patent purports to provide several advantages over prior art systems including, *inter alia*, the ability to provide unique stimulation parameters across multiple channels of electrodes (*id.* at 2:47–51, 3:16–20), the ability to non-invasively recharge the power source of the implanted components with charger 208 (*id.* at 2:54–58, 3:30–58), and the ability to perform a temporary evaluation of stimulus levels, through use of external trial stimulator 140, prior to implantation of the IPG (*id.* at 6:6–16).

Of particular relevance to this proceeding, the disclosed system also “offers a simple connection scheme for detachably connecting a lead system thereto.” *Id.* at 2:62–64. The '280 patent explains that although “the lead system [(comprising lead extension 120 and electrode array 110)] is intended to be permanent, the IPG may be replaced should its power source fail, or for other reasons.” *Id.* at 27:26–38. Accordingly, a detachable connection is beneficial. *Id.* at 27:31–33; *see also id.* at 8:46–52 (electrode array 110 or lead extension 120 is “detachably secured, i.e., electrically connected,” to IPG 100).

D. Illustrative Claim

Each challenged claim is independent. Claim 1 is illustrative and is reproduced below, with additional formatting and emphasis added.

1. A spinal cord stimulation system comprising:
 - a multi-channel implantable pulse generator (IPG) having a replenishable power source, the IPG having a housing which contains IPG processing circuitry;
 - an implantable electrode array detachably connected to the IPG,* the electrode array having a multiplicity of n electrodes (En) thereon;
 - a multiplicity of m stimulation channels provided by the IPG, wherein each stimulation channel is independently programmable with different stimulation parameters,

wherein m is equal to or less than n, and m is 2 or greater; and means for non-invasively charging the replenishable power source,

wherein the different stimulation parameters include[:]
pulsewidth,
stimulation amplitude,
repetition rate or pulses per second (pps), and
an electrode configuration that may be either monopolar or bipolar;

wherein the IPG comprises processing circuitry including:
a control logic circuit,
a timer logic circuit,
a microcontroller circuit, and
a memory circuit coupled to the microcontroller circuit; and

wherein the control logic, timer logic and microcontroller circuits are responsive to programming signals stored in the memory circuit to generate stimulation pulses having a specified amplitude, pulsewidth and repetition rate (pps).

Ex. 1001, 50:4–33. The remainder of the challenged independent claims recite language identical to that emphasized above in claim 1. *Id.* at 51:41–42, 52:55–56, 53:7–8, 53:23–24, 54:59–60, 55:8, 55:43–44.

E. Applied References

Petitioner relies upon the following references, and the Declaration of Dr. Mark W. Kroll (Ex. 1003, “the Kroll Declaration”). Pet. 8–9.

Reference	Patent No.	Relevant Dates	Exhibit No.
Holsheimer	U.S. Patent 5,501,703	Filed Jan. 24, 1994 Issued Mar. 26, 1996	Ex. 1004
Munshi	U.S. Patent 5,411,537	Filed Oct. 29, 1993 Issued May 2, 1995	Ex. 1005
Law	U.S. Patent 6,609,031	Filed June 7, 1996 Issued Aug. 19, 2003	Ex. 1006

Reference	Patent No.	Relevant Dates	Exhibit No.
Rutecki	U.S. Patent 5,330,515	Filed June 17, 1992 Issued July 19, 1994	Ex. 1007

F. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1, 4, 7–9, 11, 18, 19, and 21 of the '280 patent based on the following grounds. Pet. 8–9.

References	Basis	Claims Challenged
Holsheimer and Munshi	§ 103	1, 4, 9, 11, and 21
Holsheimer, Munshi, and Law	§ 103	1 and 4
Holsheimer, Munshi, and Rutecki	§ 103	7, 8, 18, and 19

II. DISCUSSION

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable interpretation in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Tech., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, we generally give claim terms their ordinary and customary meaning, as understood by a person of ordinary skill in the art in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

The parties propose for construction various claim language. See Pet. 10–17; Prelim. Resp. 17–18.

We determine that no claim term requires express construction for purposes of this Decision. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

B. Principles of Law

A claim is unpatentable under 35 U.S.C. § 103(a) if “the differences between the subject matter sought to be patented and the prior art are such that the subject

matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

“In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). The burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

We analyze the challenges presented in the Petition in accordance with the above-stated principles.

C. Level of Ordinary Skill in the Art

Petitioner contends that a person of ordinary skill in the art “would have had at least (1) a bachelor’s degree in electrical or biomedical engineering, or equivalent coursework, and (2) at least one year of experience researching or developing implantable medical devices.” Pet. 9 (citing Ex. 1003 ¶¶ 12–18). Patent Owner does not provide an assessment of the appropriate level of skill in the art. *See generally* Prelim. Resp.

At this stage of the proceeding, we are persuaded that the assessment proposed by Petitioner is correct. Further, in this case, the applied prior art reflects the appropriate level of skill at the time of the claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

*D. Obviousness over the Combined Teachings of
Holsheimer and Munshi*

Petitioner contends that claims 1, 4, 9, 11, and 21 of the '280 patent are unpatentable as obvious over Holsheimer and Munshi. Pet. 17–55. For reasons that follow, we determine Petitioner has not demonstrated a reasonable likelihood of prevailing as to the challenged claims.

1. Overview of Holsheimer (Ex. 1004)

Holsheimer is a U.S. Patent titled “Multichannel Apparatus for Epidural Spinal Cord Stimulation,” and discloses a pulse generator that drives a plurality of electrodes implanted near a patient’s spinal cord. Ex. 1004, [54], [57].

Holsheimer’s Figure 1 is reproduced below.

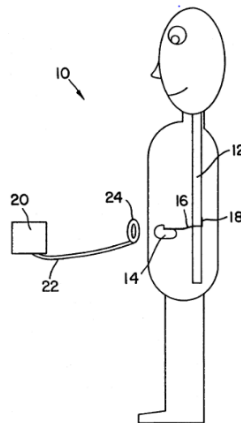


FIG. 1

Figure 1 depicts a schematic view of a patient with an implanted neurological stimulation system. *Id.* at 2:46–47. Figure 1 depicts implantable pulse generator 14, which produces “a number of independent stimulation pulses which are sent to spinal cord 12 by insulated lead 16 and coupled to the spinal cord by electrodes located at point 18.” *Id.* at 3:56–59.

2. Overview of Munshi (Ex. 1005)

Munshi is a U.S. Patent titled “Rechargeable Biomedical Battery Powered Devices with Recharging and Control System Therefore,” and discloses an

implantable device with a power source that is recharged by magnetic induction. Ex. 1005, [54], [57].

3. Analysis

Petitioner contends that claims 1, 4, 9, 11, and 21 would have been obvious based on the combined teachings of Holsheimer and Munshi. Pet. 17–55. Patent Owner disputes Petitioner’s contentions. Prelim. Resp. 22–29. Patent Owner argues, *inter alia*, that neither Holsheimer nor Munshi disclose the claimed “implantable electrode array detachably connected to the IPG.” *Id.* at 22–26.

After considering the parties’ arguments and evidence, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing on this ground.

i. Claim 1: “an implantable electrode array detachably connected to the IPG”

Independent claim 1 recites, *inter alia*, “an implantable electrode array detachably connected to the IPG.” Ex. 1001, 50:8–9. Petitioner contends that Holsheimer discloses an implanted lead with an electrode array, which is connected to a pulse generator. Pet. 26; Ex. 1004, 3:56–59 (pulse generator 14, lead 16, electrodes at 18), Fig. 1. Petitioner also contends that Holsheimer’s Figure 1 depicts “a standard connector notch commonly used to depict lead connectors.” Pet. 26–27 (*see e.g.*, Ex. 1018, Figs. 1, 3–4). According to Petitioner,

a [person of ordinary skill in the art] would have understood Holsheimer’s leads, which carry the electrode arrays, would have been detachably connected to the IPG because—as the ’280 admits—many different types of leads were known in the art and could be used with the same IPG. It was well-known at the time that leads can be attached and detached to IPGs, so medical professionals and patients could have the flexibility to select the type of lead that best suits the patient’s particular stimulation needs and so malfunctioning leads could be replaced without having to replace the entire IPG.

Id. at 27 (citing Ex. 1001, 9:8–11, 10:19–24; Ex. 1003 ¶¶ 85–87; Ex. 1016, Abstract, 2:66–3:2). Petitioner does not rely on Munshi with respect to this limitation. *Id.* at 19–20, 26–27.

Patent Owner argues that Holsheimer’s electrode array is not detachable from pulse generator 14. Prelim. Resp. 22–26. According to Patent Owner, wires connect the outputs of Holsheimer’s pulse generator to the electrodes of the array. *Id.* at 23–25 (citing Ex. 1004, 7:22–27, 7:47–58, Figs. 19–20). Thus, according to Patent Owner, “Petitioner’s conclusory assertion that Holsheimer utilized detachable leads is not only unsupported by the reference itself, but refuted by it.” *Id.*

We have considered the parties’ arguments and cited evidence, and we determine that the Petition does not demonstrate sufficiently that Holsheimer’s electrode array is detachably connected to pulse generator 14. The cited evidence supports Patent Owner’s argument that these elements are connected by wires 80. Holsheimer’s Figure 19 is reproduced below.

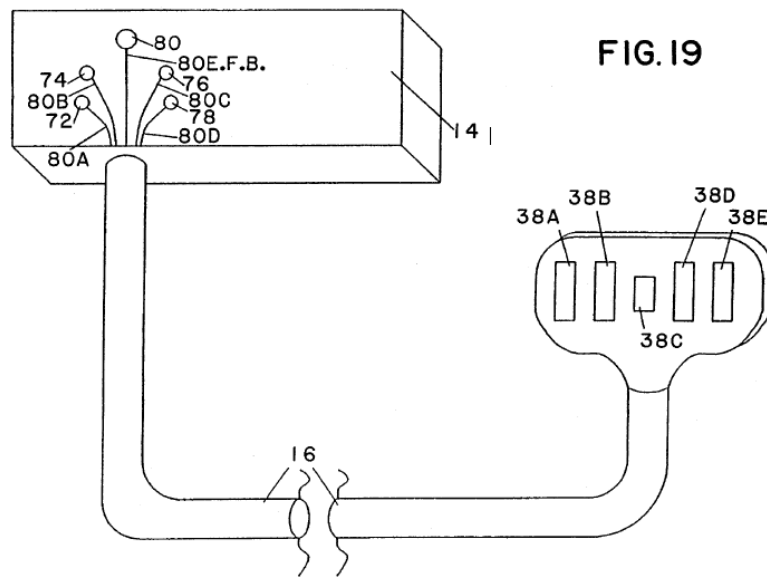


Figure 19 depicts a first embodiment of Holsheimer’s pulse generator and lead, and a second embodiment is depicted in Figure 20. *Id.* at 3:44–47. As shown, pulse

generator 14 includes outputs 72, 74, 76, 78. *Id.* at 7:17–20. “Line 16¹ has electrodes 38 connected to these outputs with *wire 80A connecting output 72 to electrode 38A*, wire 80B connecting output 74 to electrode 38B,” and so on. *Id.* at 7:23–28 (emphasis added); *see also id.* at 7:47–57 (describing a similar arrangement in Figure 20). The Petition does not explain how the electrode array and pulse generator 14 are considered to be “detachably connected,” when Figures 19 and 20, and their corresponding description, appear to disclose an apparently permanent, unitary connection with wires 80A–F. While the Petition does assert that “a [person of ordinary skill in the art] would have understood Holsheimer’s leads, which carry the electrode arrays, would have been detachably connected to the IPG . . . ,” the Petition does not provide any supporting evidentiary basis for this otherwise conclusory assertion that wires 80 are detachable from either electrode array 38 or from pulse generator 14. As such, we are unpersuaded that Petitioner demonstrates sufficiently that Figures 19–20 of Holsheimer disclose the recited detachable connection. Pet. 26.

Petitioner’s contention that Figure 1 depicts “a standard notch connector” is likewise unpersuasive to show that the electrode array is detachably connected to the pulse generator. Pet. 26–27. Figure 1 itself does not depict any details of the connection. Ex. 1004, Fig. 1. Similarly, Holsheimer’s disclosure regarding Figure 1 does not discuss “notch connectors,” or any other detachable connector, that would allow wires 80 to detach from the pulse generator or electrode array. *Id.* at 2:46–48, 3:53–4:5.

Petitioner’s citation to other prior art references, *see* Pet. 27 (citing Ex. 1018, Figs. 1, 3–4; Ex. 1016, Abstract, 2:66–3:2), also fails to shed light on the type of

¹ Elsewhere termed “lead 16.” *See* Ex. 1004, 3:58, 4:7.

connection between *Holsheimer's* components. At best, this evidence aligns with Petitioner's argument that "many different types of leads were known in the art and *could* be used with the same IPG" and that "leads *can be* attached and detached to IPGs." Pet. 27 (emphasis added). Again, however, these arguments do not establish that *this particular* arrangement disclosed by Holsheimer is detachable.²

The cited portions of the Kroll Declaration do not remedy the Petition's failure. Pet. 27 (citing Ex. 1003 ¶¶ 85–87). Like the Petition, Dr. Kroll's testimony that detachable connections *could be* used does not establish that Holsheimer's connection is detachable.

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing in demonstrating the unpatentability of claim 1.

ii. Claims 4, 9, 11, and 21

Independent claims 4, 9, 11, and 21 also recite "an implantable electrode array detachably connected to the IPG." Ex. 1001, 51:41–42, 53:23–24, 53:59–60, 55:43–44. For these claims, Petitioner relies on its contentions regarding claim 1. Pet. 37 ("Holsheimer discloses this limitation for the same reasons as claim [1.b]."), 44, 48, 49.

Accordingly, for the same reasons discussed above in Section II.D.3.i., we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing in demonstrating the unpatentability of claims 4, 9, 11, and 21.

² We note that Petitioner does not contend that it would have been obvious to have modified Holsheimer to include a detachable connection. *Id.* at 26–27; *see also* Prelim. Resp. 26–29.

*E. Obviousness over the Combined Teachings of
Holsheimer, Munshi, and Law*

Petitioner contends that claims 1 and 4 of the '280 patent are unpatentable as obvious over Holsheimer, Munshi, and Law. Pet. 56–60. For reasons that follow, we determine Petitioner has not demonstrated a reasonable likelihood of prevailing as to the challenged claims.

1. Overview of Law (Ex. 1006)

Law is a U.S. Patent titled “Multiprogrammable Tissue Stimulator and Method,” and discloses an electronic stimulation system with implanted leads that sequentially stimulate the patient. Ex. 1006, [54], [57].

2. Analysis

Independent claims 1 and 4 recite “an implantable electrode array detachably connected to the IPG.” Ex. 1001, 50:8–9, 51:41–42. In this asserted ground of unpatentability, Petitioner contends that Holsheimer discloses this limitation, relying on its contentions presented with respect to the ground based on Holsheimer and Munshi. Pet. 56–60. Petitioner does not rely on Law for these limitations. *Id.* at 56 (relying on Law only for claim elements [1.f] and [4.g]); *see also* Prelim. Resp. 29.

Accordingly, for the same reasons discussed above in Section II.D.3, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing in demonstrating the unpatentability of claims 1 and 4.

*F. Obviousness over the Combined Teachings of
Holsheimer, Munshi, and Rutecki*

Petitioner contends that claims 7, 8, 18, and 19 of the '280 patent are unpatentable as obvious over Holsheimer, Munshi, and Rutecki. Pet. 60–74. For reasons that follow, we determine Petitioner has not demonstrated a reasonable likelihood of prevailing as to the challenged claims.

1. Overview of Rutecki (Ex. 1007)

Rutecki is a U.S. Patent titled “Treatment of Pain by Vagal Afferent Stimulation,” and discloses applying programmable pulse waveforms to an implanted lead to treat pain. Ex. 1007, [54], [57].

2. Analysis

Independent claims 7, 8, 18, and 19 recite “an implantable electrode array detachably connected to the IPG.” Ex. 1001, 52:55–56, 53:7–8, 54:59–60, 55:8–9. In this asserted ground of unpatentability, Petitioner contends that Holsheimer discloses this limitation, relying on its contentions presented with respect to the ground based on Holsheimer and Munshi. Pet. 62, 67, 69, 71–72. Petitioner does not rely on Rutecki for this limitation. *Id.*; *see also* Prelim. Resp. 31.

Accordingly, for the same reasons discussed above in Section II.D.3, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing in demonstrating the unpatentability of claims 7, 8, 18, and 19.

III. CONCLUSION

For the foregoing reasons, we determine Petitioner has not demonstrated a reasonable likelihood it would prevail in establishing the unpatentability of challenged claims 1, 4, 7–9, 11, 18, 19, and 21 of the ’280 patent.

IV. ORDER

Upon consideration of the record before us, it is:

ORDERED that the Petition is *denied* as to all challenged claims, and no trial is instituted.

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Patent 6,895,280 B2

PETITIONER:

Ching-Lee Fukuda
Thomas Broughan
Sharon Lee
SIDLEY AUSTIN LLP
clfukuda@sidley.com
tbroughan@sidley.com
Sharon.lee@sidley.com

Jon E. Wright
Richard D. Collier III
STERNE, KESSLER, GOLDSTEIN
& FOX P.L.L.C.
Jwright-ptab@skgf.com
Rcollier-ptab@skgf.com

PATENT OWNER:

David Caine
Wallace Wu
ARNOLD & PORTER KAY SCHOLER LLP
David.caine@apks.com
Wallace.wu@apks.com