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Paper 14
Entered: April 8, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC.
Petitioner

v.

NUVASIVE, INC.
Patent Owner

Case IPR2014-00073
Patent 8,192,356 B2

Before FRANCISCO C. PRATS, SCOTT E. KAMHOLZ, and DAVID C. McKONE, *Administrative Patent Judges.*

PRATS, *Administrative Patent Judge*.

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

INTRODUCTION

A. Statement of the Case

Medtronic, Inc. ("Petitioner") filed a Corrected Petition (Paper 8, "Pet.") requesting an *inter partes* review ("IPR") of claims 21, 22, 24-26, 30, and 33-37 of U.S. Patent No. 8,192,356 B2 (Ex. 1018, "the '356 patent"). NuVasive, Inc. ("Patent Owner") filed a Preliminary Response (Paper 10, "Prelim. Resp.").

The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides as follows:

> THRESHOLD.—The Director may not authorize an inter partes review to be instituted unless the Director determines that 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.

Upon consideration of the Petition and Preliminary Response, we conclude that Petitioner has established a reasonable likelihood that it would prevail as to claims 21, 22, 24, 30, and 33-37. Accordingly, we institute an *inter partes* review of claims 21, 22, 24, 30, and 33-37 of the '356 patent.

We determine, however, that Petitioner has not established a reasonable likelihood that it would prevail with respect to claims 25 and 26. We, therefore, decline to institute an *inter partes* review as to those claims.

B. Related Cases

Petitioner has petitioned for an additional *inter partes* review of claims 21, 22, 24-26, 30, and 33-37 of the '356 patent on other grounds, IPR2014-00074. Pet. 1; Paper 6 at 2. Patent Owner has asserted the '356

patent against Petitioner in *Warsaw Orthopedic Inc. v. NuVasive Inc.*, Case No. 3:12-cv-02738-CAB-MDD (S.D. Cal.). Pet. 1; Paper 8 at 1.

C. References Relied Upon

Petitioner relies upon the following prior art references:

Ex. 1001	Cistac	DE 100 48 790 A1 (as translated, Ex. 1002)	April 25, 2002[1]
Ex. 1003	Kelleher	WO 01/37728 A1	May 31, 2001
Ex. 1004	Obenchain	US 5,313,962	May 24, 1994
Ex. 1005	Mathews	US 5,171,279	Dec. 15, 1992
Ex. 1006	Koros	US 6,139,493	Oct. 31, 2000
Ex. 1007	Michelson	US 5,772,661	Jun. 30, 1998
Ex. 1008	Jones	US 4,595,013	Jun. 17, 1986
Ex. 1009	Branch	US 6,945,933 B2 (filed Jun. 26, 2002)	Sep. 20, 2005
Ex. 1010	Blewett	WO 03/005887 A2 (filed Jul. 11, 2002)	Jan. 23, 2003
Ex. 1011	Onimus	WO 00/27291 A1 (as translated, Ex. 1012)	May 18, 2000
Ex. 1013	NIM Guide	MEDTRONIC XOMED SURGICAL PRODUCTS, INC., NIM-RESPONSE™, NERVE INTEGRITY MONITOR, INTRAOPERATIVE EMG MONITOR USER'S GUIDE (2000).	

[1] Petitioner asserts that, "[r]egardless of the priority filing date of the '356 patent," Cistac is prior art under 35 U.S.C. § 102(b) because it was "published more than a year prior to June 26, 2002." Pet. 6. The first page of the Cistac document shows a publication date of April 25, 2002, however. Ex. 1001, 1.

D. The Asserted Grounds

Petitioner contends that the challenged claims are unpatentable based on the following specific grounds (Pet. 3-5):[2]

References	Basis	Claims challenged
Cistac, Obenchain, Kelleher, and Mathews	§ 103(a)	21, 30, 33, and 34
Cistac, Obenchain, Kelleher, Mathews, and Koros	§ 103(a)	22 and 24-26
Cistac, Obenchain, Kelleher, Mathews, and NIM Guide	§ 103(a)	35
Cistac, Obenchain, Kelleher, Mathews, NIM Guide, and Jones	§ 103(a)	36 and 37
Cistac, Obenchain, Kelleher, Mathews, Koros, and Michelson	§ 103(a)	22 and 24-26
Branch, Obenchain, Blewett, and Onimus	§ 103(a)	21, 30, and 33-37
Branch, Blewett, Obenchain, Onimus, and Koros	§ 103(a)	22 and 24-26
Branch, Blewett, Obenchain, Koros, Onimus, and Michelson	§ 103(a)	22 and 24-26

E. The '356 Patent

The '356 patent describes methods and apparatuses for accessing a surgical target site, such as the lumbar spine, using minimally invasive techniques. Ex. 1018, 1:30-2:58. The surgical target site is accessed by first advancing a rigid, generally narrow (diameter about 1.5 millimeters), "K-

[2] Petitioner supports its challenges with a declaration, executed October 18, 2013, by Robert G. Watkins, IV, MD ("Watkins Declaration") (Ex. 1015), a declaration, executed October 12, 2013, by Daniel Schwartz, Ph.D ("Schwartz Declaration") (Ex. 1016), and a declaration, executed October 10, 2013, by David Hacker ("Hacker Declaration") (Ex. 1017).

wire" through the patient's tissue to the target site. *Id.* at 6:51-59. Then, tissue dilators of increasing diameter are advanced over the K-wire to the target site, so as to sequentially distract, that is, open up, an initial pathway through the tissue to the site. *Id.* at 6:65-7:23.

Once the initial pathway through the tissue is formed, an operative corridor for performing the surgery may be prepared by advancing a set of retractor blades into the tissue opening, and attaching the blades to a pivot linkage. *Id.* at 8:15-30; *see also* Figs. 8, 32 (showing pivot linkage 14, and attached retractor blades 90, 92). The pivot linkage has handle-like pivot arms that allow the surgeon to spread the tissue-distracting elements farther apart. *See id.* at Fig. 8 (showing pivot arms 60, 62, 64, and 66).

The '356 patent explains that the "the retractor blades 90, 92 may be locked in a desired position by tightening the respective nuts 82, 86 of the locking assemblies 32, 34." *Id.* at 8:28-30 (bolding omitted); *see also* Fig. 8. In a preferred embodiment, the retractor blades accommodate a locking member 36 that extends distally from the blades and has a narrowed distal region 110 that enters the intervertebral disc space and engages the adjacent vertebrae, thus stabilizing the position of the overall apparatus during surgery. *See id.* at 8:31-43; *also* Fig. 11. Once an operative corridor is established, the surgeon can perform surgical procedures, such as installing a spinal fusion implant. *Id.* at 6:31-35.

The '356 patent discloses that any of the tissue-distracting instruments, including dilators and retractor blades, may be equipped with stimulation electrodes that allow the surgeon to monitor the location of nerves in the patient, so as to avoid and not damage the nerves during surgery. *See id.* at 9:40-59. The electrodes emit a stimulation signal that,

when sufficiently close to a nerve, causes an innervation response in the muscle associated with the nerve. *Id.* at 9:51-57. Response to the stimulation signal may be monitored visually, by a twitch in the muscle, or detected using an electromyography (EMG) system, which includes electrodes positioned on the patient's muscles. *Id.* at 9:60-10-23, 11:14-32. The nerve-monitoring EMG system disclosed by the '356 patent includes stimulating and detecting electrodes connected to a control unit which has a touch screen display that controls the system and provides information to the surgeon. *See id.* at 10:24-11:48; *also* Fig. 12.

Claim 21, the only independent claim Petitioner challenges in this proceeding, reads as follows:

> 21. A system for accessing a spinal disc of a lumbar spine through an operative corridor, comprising:
>
> a distraction assembly to create a tissue distraction corridor to a lumbar spine, wherein said distraction assembly comprises: an elongate penetration member deliverable to a spinal disc along a lateral, trans-psoas path to the lumbar spine such that a distal tip region of the elongate penetration member penetrates into an annulus of a spinal disc in the lumbar spine, and at least two dilators of sequentially larger diameter deliverable to the spinal disc along the lateral, trans-psoas path to the lumbar spine, a first dilator of the at least two dilators having a lumen configured to slidably receive the elongate penetration member, at least one of said at least two dilators including a stimulation electrode to deliver electrical stimulation for nerve monitoring when said stimulation electrode is positioned in the lateral, trans-psoas path to the lumbar spine; and

> a retraction assembly comprising a plurality of retractor blades that enlarge the tissue distraction corridor to thereby form an operative corridor along the lateral, trans-psoas path to the lumbar spine when the plurality of retractor blades are delivered to the lumbar spine, the retraction assembly further comprising a blade holder apparatus that is configured to releasably lock with the plurality of retractor blades,
>
> wherein when the plurality of retractor blades enlarge the tissue distraction corridor to form the operative corridor along the lateral, trans-psoas path to the lumbar spine, the operative corridor is dimensioned so as to pass an implant through the operative corridor along the lateral, trans-psoas path to the lumbar spine.

Id. at 18:60-19:24.

II. ANALYSIS

A. Claim Construction

The Board interprets claims using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b); *see also* Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). Under that standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech. Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth with reasonable clarity, deliberateness, and precision. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

1. "lateral trans-psoas path to the lumbar spine"

Petitioner contends that this language is a functional recitation of a particular use of the claimed system, and thus should be given no patentable weight in the system claim 21. Pet. 8. Patent Owner contends that this language is pervasive in claim 21, "impart[s] structural requirements limiting the claimed structures to those that are specifically designed and constructed to define, enlarge, and dimension the trans-psoas operative corridor as recited in claim 21," and, thus, should not be ignored. Prelim. Resp. 19-20.

"It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (citations omitted). We agree with Petitioner that the language at issue recites an intended use of the claimed apparatus.

Specifically, claim 21 recites that the elongate penetration member and dilators of the claimed surgical system are "deliverable" to the spinal disc along a trans-psoas path to the lumbar spine. Ex. 1018, 18:64-66, 19:2-4. The remaining references to the trans-psoas path explain the function of the electrodes, the function of the retractor blades, and the dimension of the corridor, when the apparatus is deployed in that pathway. *See id.* at 19:7-24.

Thus, the recitations in claim 21 regarding the trans-psoas path do not describe the structure of the elements of the claimed system. Accordingly, in construing claim 21, we attribute to the intended use recitations no particular structural limitations, beyond an ability to be used in, or follow, a trans-psoas path, in the manner recited in the claim.

2. "rounded distal tip of a narrowed tip portion"

Claim 25 of the '356 patent depends ultimately from claim 21, through claims 22 and 24, and states that each extension member that extends from the retractor blades "has a smallest width at a rounded distal tip of the narrowed tip portion." Ex. 1018, 19:43-44.

Petitioner contends that the "specification of the '356 patent does not describe an extension member having a rounded distal tip of a narrowed tip portion," and that this limitation "means that any portion of a narrowed tip of the extension member has a rounded shape." Pet. 9

Petitioner does not, however, cite credible evidence to support its construction. According to the proffered construction, roundedness may be judged solely by cross-section, which would mean that a sharply pointed object with a round cross-section, such as a screw or nail, would be construed as a having a rounded distal tip. We are not persuaded that Petitioner's proffered construction is reasonable. Accordingly, we construe the "rounded distal tip" requirement of claim 25 according to its plain language, as requiring the distal tip of the extension to have a curved surface which is not jagged or sharply pointed.

3. Other terms

All other terms in claims 21, 22, 24-26, 30, and 33-37 are given their ordinary and customary meanings as would be understood by an ordinarily skilled artisan, and need not be construed expressly at this time.

B. Effective Filing Date of the '356 Patent

The '356 patent claims priority to U.S. Provisional Application No. 60/392,214 (Ex. 1019, "the '214 application"), filed June 26, 2002. Ex. 1018, col. 1, ll. 10-13. Petitioner contends that the '356 patent is not

entitled to the benefit of the '214 application's filing date, because the '214 application does not provide descriptive support for the blade holder apparatus being configured to releasably lock with the plurality of retractor blades, recited in claim 21. Pet. 12.

Patent Owner contends that, based on images and handwritten notations in the '214 application, the blade holder apparatus recited in claim 21 is adequately described in the '214 application. Prelim. Resp. 13-16.

We find that, on the current record, Petitioner has the better position.

When a petition identifies specific features and claims allegedly lacking support in earlier-filed applications, we consider whether the patent owner makes a sufficient showing of entitlement to an earlier filing date, in a manner commensurate in scope with the specific contentions made by the petitioner. *See Polaris Wireless, Inc. v. TruePosition, Inc.*, Case IPR2013-00323, Paper 9, 29 (PTAB 2013). To establish descriptive support for a claim, "the written description must include all of the limitations . . ., or the [proponent] must show that any absent text *is necessarily comprehended in the description provided* and would have been so understood at the time the patent application was filed." *Hyatt v. Boone*, 146 F.3d 1348, 1354-55 (Fed. Cir. 1998) (emphasis added).

Here, claim 21 of the '356 patent recites "a blade holder apparatus that is configured to releasably lock with the plurality of retractor blades." Ex. 1018, 19:16-18. Although Patent Owner urges that the images from the '214 application (including the original version of image "142sen.jpg" from the '241 application) "plainly show nuts and bolts that releasably lock the retractor blades to the blade holder apparatus," Prelim. Resp. 14, Patent Owner does not direct us to, nor do we see, any clear or specific mention of

nuts or bolts in the supporting disclosure of the ’214 application. Moreover, we are not persuaded, based on the actual images, that the features in the images designated as nuts and bolts would necessarily be comprehended as nuts and bolts.

Patent Owner argues that the handwritten notations on pages 9 and 11 of the notes following page 25 of the ’214 application state that retractor blades are locked in place. *See* Prelim. Resp. 15. Patent Owner does not explain, however, why an ordinarily skilled artisan would have necessarily comprehended that disclosure as describing the releasably locking blade holder apparatus recited in claim 21 of the ’356 patent.

In sum, on the current record, Patent Owner does not dissuade us from agreeing with Petitioner that the ’214 application does not provide descriptive support for the blade holder apparatus configured to releasably lock with the plurality of retractor blades, recited in claim 21 of the ’356 patent. Accordingly, on this record, we determine that the ’356 patent is not entitled to the benefit of the ’214 application’s filing date.

C. Asserted Grounds of Unpatentability

1. Obviousness of claims 21, 30, 33, and 34 over Cistac, Obenchain, Kelleher, and Mathews

Petitioner’s position, essentially, is that an ordinarily skilled artisan would have considered it obvious to equip the dilators and retractor blades of the surgical system described by Cistac with the nerve-monitoring electrodes taught by Kelleher. *See* Pet. 25-26, 30-31. Petitioner cites Obenchain as evidence that the trans-psoas path to the lumbar spine was known to be a suitable surgical approach to the lumbar spine. *Id.* at 34. Petitioner cites Mathews as evidence that an ordinarily skilled artisan would

have considered it obvious to configure minimally invasive surgical instruments intended for lumbar spine surgery to be dimensioned so as to allow surgical implants to pass through them. *Id.* at 36-37.

Having reviewed Petitioner's contentions and supporting evidence regarding the proposed ground of obviousness of claims 21, 30, 33, and 34 over Cistac, Obenchain, Kelleher, and Mathews, as well as Patent Owner's arguments and evidence traversing the proposed ground, we determine that Petitioner has shown a reasonable likelihood of prevailing in accordance with 35 U.S.C. § 314.

Cistac discloses that, "[t]o create a percutaneous access, as is required in a lumbar discectomy for example, it is known to insert tubular cannulas into the body and to arrange additional instruments on these by means of a positioning plate or by means of a positioning sleeve . . . ." Ex. 1002, 1. To that end, Cistac discloses a "device for creating a percutaneous access into a body, with two retractor blades which together form an access channel . . . ." *Id*. As seen in Figure 2 of Cistac, the two retractor blades 26 are semicircular in cross section. *Id.* at Fig. 2.

As required by claim 21, Cistac discloses that its device includes a blade holder apparatus that releasably locks with the retractor blades. *See id.* at 5 ("The retractor blades can be held releasably on the carrying elements, such that it is possible for retractor blades that are suitable for the specific operation to the secured on the carrying elements.").

As also required by claim 21, Cistac discloses that, for initial access into the patient, its system includes an elongate penetration member, in the form of a wire, and at least two dilators of sequentially larger diameter deliverable to a spinal disc.

Id. at 12.

Cistac explains that, after removing the initially inserted wire and tube, the two semicircular retractor blades cooperatively "define a tubular access into the interior of the body, the size of which access can be increased by pivoting of the holding arms, for which purpose it suffices to actuate the adjusting screw 7." *Id.* at 12-13; *also* Fig. 2. Cistac discloses that the diameter of the retractor blades "can be of the order of 15 mm . . . ." *Id.* at 14.

Although Cistac does not describe its dilators as having the nerve-monitoring stimulation electrodes required by claim 21 of the '356 patent, Kelleher discloses the desirability of including such electrodes on devices used in spinal surgery. Ex. 1003, 1. In particular, Kelleher discloses, "it is especially important to sense the presence of spinal nerves when performing spinal surgery, since these nerves are responsible for the control of major body functions." *Id.* Kelleher also discloses that "a downside of . . . minimally invasive surgical procedures [is] that they tend to offer a somewhat reduced visibility of the patient's tissues during the surgery. Accordingly, the danger of inadvertently contacting and/or severing a patient's nerves can be increased." *Id.*

Kelleher thus discloses a nerve detection system that has "an electrode or electrodes positioned on the distal end of the surgical tool or probe, with an electromyographic system used to detect whether a spinal nerve is positioned adjacent to the surgical tool or probe." *Id.* at 4. Kelleher explains:

> A conclusion is made that the surgical tool or probe is positioned adjacent to a spinal nerve when a neuro-muscular (e.g.: EMG) response to a stimulus pulse emitted by the electrode or electrodes on the surgical tool or probe is detected (at a distant myotome location, such as on the patient's legs) at or below certain neuro-muscular response onset values (i.e.: pre-determined current intensity levels) for each of the plurality of spinal nerves.

Id.

Kelleher discloses that in "preferred aspects, the surgical tool or probe may be introduced into the patient in a minimally invasive cannulated approach." *Id.* at 2. Kelleher further discloses that its electrified probes "can be any manner of surgical tool, including (electrified) cannulae through which other surgical tools are introduced into the patient." *Id.* at 16.

We agree with Petitioner, on the present record, that an ordinarily skilled artisan, advised by Kelleher of the desirability of equipping surgical instruments with electrodes to detect nerves during spinal surgery when using a minimally invasive cannulated approach, would have been prompted to equip Cistac's dilators with the stimulating electrodes required by claim 21 of the '356 patent, in order to allow the surgeon to detect and avoid spinal nerves when using Cistac's cannulated surgical system. In view of Mathews' teaching of the desirability of delivering implants through a spine-accessing minimally invasive operative corridor, *see* Ex. 1005, 5:50-6:16, we also agree with Petitioner that, as required by claim 21, an ordinarily skilled artisan would, on the current record, have ensured that the operative corridor created by Cistac's system be dimensioned to permit implant passage.

As to the intended use of the system recited in claim 21, as discussed above, we attribute to the intended use recitations no particular structural limitations, beyond an ability to be used in, or follow, a trans-psoas path, in the manner recited in the claim. Because Cistac's instruments are sized for minimally invasive access to the lumbar spine, *see* Ex. 1002, 1, 12-14, we are persuaded, on the current record, that those instruments would be capable of the intended use recited in claim 21. Moreover, although Obenchain focuses on approaches other than a trans-psoas path, *see* Ex. 1004, 1:48-66, Obenchain discloses, nonetheless, that minimally invasive surgery of the lumbar spine can use a trans-psoas approach:

> If desired, the surgery may traverse through the psoas muscle. . . . [F]or example, where the patient has extensive abdominal adhesions, it may be preferred to use a lateral puncture of the abdomen to avoid bowel perforation, and entry into the disc space is lateral, [traversing] the psoas muscle, or immediately in front of it.

Id. at 6:22-31.

In sum, given the teachings of Cistac, Obenchain, Kelleher, and Mathews, we determine that Petitioner has shown a reasonable likelihood of prevailing in its obviousness challenge to claim 21 of the '356 patent, based on those references. Having reviewed Petitioner's arguments and evidence (Pet. 30, 38-39), we determine further that Petitioner has shown a reasonable likelihood of prevailing in its obviousness challenge to dependent claims 30, 33, and 34, based on Cistac, Obenchain, Kelleher, and Mathews.

Patent Owner's arguments do not persuade us that Petitioner has failed to establish a reasonable likelihood of prevailing in accordance with 35 U.S.C. § 314, as to claims 21, 30, 33, and 34. Although Patent Owner

contends that the translation of Cistac is unreliable because of inconsistencies between the drawings in the original document as compared to the translation, and because of a defective certificate of translation, Prelim. Resp. 16-18, Patent Owner does not direct us to any specific evidence suggesting that the actual text of the translation is inaccurate. We also note that Petitioner has, with Patent Owner's acquiescence, entered a substitute exhibit addressing the translation declaration deficiencies asserted by Patent Owner. *See* Paper 11, *generally*; *see also* Ex. 1002, (Declaration of Charles E. Sitch in support of Cistac translation, including perjury warning).

Regarding Patent Owner's contention that the Watkins and Schwartz Declarations lack adequate credibility and are based on hindsight (*see, e.g.* Prelim. Resp. 3-4, 23-24, 30), as evidenced by the discussion above, we are nevertheless persuaded that Petitioner has shown a reasonable likelihood that an ordinarily skilled artisan would have considered claims 21, 30, 33, and 34 obvious, on the current record, based solely on the teachings of the cited references.

Patent Owner also contends that the decades-earlier knowledge of both the lateral approach and nerve monitoring techniques, allegedly acknowledged in the Schwartz Declaration, demonstrates the unobviousness of the claimed invention, because the combination of nerve-monitoring and the trans-psoas approach was not made until the disclosure of the '356 patent. Prelim. Resp. 3-4. We first note, however, that Kelleher's, May 31, 2001, disclosure of nerve monitoring during lumbar spinal surgery, is relatively close in time to the June 26, 2002, date of the earliest priority date claimed by the '356 patent.

Moreover, "the mere passage of time without the claimed invention is not evidence of nonobviousness." *Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d* 1317, 1325 (Fed. Cir. 2004) (citation omitted). Thus, as our reviewing court's predecessor explained, an allegation of a long-felt but unsolved problem in the art "is not evidence of unobviousness unless it is shown . . . that the widespread efforts of skilled workers having knowledge of the prior art had failed to find a solution to the problem." *In re Allen*, 324 F.2d 993, 997 (CCPA 1963) (citing *Toledo Pressed Steel Co. v. Standard Parts, Inc.*, 307 U.S. 350, 356 (1939)). Patent Owner does not direct us to any specific evidence that skilled workers tried and failed to make the combination of elements recited in the challenged claims.

As to Patent Owner's contentions that Obenchain, for a number of reasons, teaches away from using a trans-psoas pathway when performing lumbar spine surgery, *see* Prelim. Resp. 18-27, we again note Obenchain's express disclosure that a trans-psoas pathway may be preferred in certain circumstances. *See* Ex. 1004, 6:22-31 ("If desired, the surgery may traverse through the psoas muscle. . . . [I]t may be preferred to use a lateral puncture of the abdomen to avoid bowel perforation, and entry into the disc space is lateral, [traversing] the psoas muscle, or immediately in front of it.").

Thus, although it might be true that Obenchain focuses on other access pathways to the lumbar spine, *see id.* at 1:48-66, and in one embodiment directs practitioners to avoid dissecting the psoas, *see id.* at 7:41-43, we are not persuaded that Obenchain, when viewed as a whole, disparages the psoas-traversing pathway such that an ordinary artisan would having been taught away from using that approach. *See DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009) ("A

reference does not teach away . . . if it merely expresses a general preference for an alternative invention but does not 'criticize, discredit, or otherwise discourage' investigation into the invention claimed.") (citing *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004)). Similarly, although surgeons may "have not felt comfortable with dissecting the psoas muscle because of the presence of the lumbar plexus" (Ex. 2004, 428), given Obenchain's disclosure of the preference for the trans-psoas pathway in certain circumstances, we are not persuaded that an ordinarily skilled artisan would have been discouraged from that surgical approach.

We acknowledge Obenchain's disclosure that the outer diameter of the cannula used in its minimally invasive procedures is "important," and that "[i]t has been found that a sleeve having a maximum exterior cross-sectional dimension of about 10 mm, and preferably between about 5 or about 9 mm is quite suitable for lumbar discectomy and many other procedures." Ex. 1004, 3:46-54 (bolding omitted). We also acknowledge that Cistac's retractors create an initial operative corridor on the order of 15 millimeters. *See* Ex. 1002, 14. However, because Obenchain does not state expressly that cannulas larger than 10 millimeters would be unsuitable or undesirable in its methods, we are not persuaded that Obenchain would have suggested that Cistac's only slightly larger instruments would be unsuitable in a trans-psoas approach.

Moreover, although Patent Owner urges that Obenchain suggests traversing a region of the psoas without a significant danger of encountering nerves, Prelim. Resp. 22, given Kelleher's general teaching of the dangers of damaging nerves during minimally invasive spinal surgery, Ex. 1003, 1, we are not persuaded that Obenchain teaches away from including nerve

monitoring electrodes on Cistac's dilator sleeves. We also are not persuaded, for the reasons discussed above, that Kelleher fails to suggest equipping Cistac's dilators with nerve-monitoring electrodes. Indeed, as noted above, Kelleher suggests that its electrodes would be desirable on "any manner of surgical tool." *Id.* at 16.

Patent Owner also contends that Petitioner failed to consider evidence of secondary considerations of non-obviousness regarding Patent Owner's "XLIF" ("eXtreme Lateral Interbody Fusion") system, including praise by competitors (*see* Ex. 2001, 9; Ex. 2002, 3), commercial success (*see* Ex. 2002, 3*;* Ex. 2003, 10), skepticism (*see* Ex. 2002, 21), and copying (*see* Ex. 2001, 8; Ex. 2002, 8; Ex. 2003, 17). Prelim. Resp. 31-36. We have reviewed the evidence presented by Patent Owner. Although Patent Owner asserts that the "XLIF" system is a commercial embodiment protected by the '356 patent, Prelim. Resp. 1, on the current record, Patent Owner has not advanced any clear or specific evidence explaining what the XLIF system is precisely, such that it is clear which features, if any, of the challenged claims, are part of the XLIF system. It is, therefore, not clear, on the current record, that any of the alleged secondary indicia of non-obviousness relate to the surgical system recited in the challenged claims.

In sum, after considering Patent Owner's arguments, we are still persuaded that the Petitioner has demonstrated a reasonable likelihood of prevailing in accordance with 35 U.S.C. § 314 as to its obviousness challenge of claims 21, 30, 33, and 34, over Cistac, Obenchain, Kelleher, and Mathews.

2. Obviousness of claims 22 and 24-26 over Cistac, Obenchain, Kelleher, Mathews, and Koros;

Petitioner relies on Cistac, Obenchain, Kelleher, and Mathews, for the teachings discussed above, and cites Koros as evidence that an ordinarily skilled artisan would have considered it obvious to include, on the retractor blades of Cistac, extension members having the features required by claims 22, 24 and 25, as well as a light emitting device encompassed by claim 26. *See* Pet. 27-29.

Having reviewed Petitioner's contentions and supporting evidence regarding this proposed ground of unpatentability, as well as Patent Owner's arguments, we determine that Petitioner has shown a reasonable likelihood of prevailing in accordance with 35 U.S.C. § 314 as to claims 22 and 24, but not as to claims 25 and 26.

Koros discloses "an improved retractor such as a lumbar fusion laminectomy retractor and distractor that has adjustable length blades and guides for accommodating a plurality of fixation screws and a light pipe." Ex. 1006, 2:42-46. Koros explains that, once its retractor blades are properly positioned, "a pair of screws can be slid down the pair of tubular guides [in the retractor blades] and then screwed into adjacent vertebrae on opposite sides of the diseased lumbar disc." *Id.* at 4:41-43. Koros discloses that using more than one fixation screw is "advantageous to provide stability and improve support for the distractor system." *Id.* at 6:57-58.

We agree with Petitioner that an ordinarily skilled artisan, advised by Koros of the desirability of slidably attaching fixation screws to retractor blades used in lumbar spinal surgery, on the current record, would have been prompted to add that feature to Cistac's retractor blades. We, therefore, are

persuaded that Petitioner has shown a reasonable likelihood of prevailing in this obviousness challenge to claim 22, which recites extension members that slidably and releasably engage with the retractor blades, and in which the extension members extend from the distal portion of the blades to engage with the lumbar spine. *See* Ex. 1018, 19:25-32. Moreover, as seen in Figures 1 and 5 of Koros, the fixation screws have a narrowed tip portion that is smaller than a proximal region of the screws, thus meeting the requirements of claim 24.

In response, Patent Owner argues that an ordinarily skilled artisan would not have considered it possible to slide retractor blades having Koros's guides safely over Cistac's initial tissue-distracting sheaths. *See* Prelim. Resp. 38-40. Moreover, Patent Owner argues, in addition to being unreliable, the Watkins Declaration does not testify that there was any known way to add fixation screws and tubular guides to Koros's retractor blades. *Id.* at 40-42.

We are not persuaded, however, that it was unreasonable, based on the references' teachings, to find that the level of skill in this art was such that a practitioner of ordinary skill would have been able to modify Cistac's semicircular blades to incorporate Koros's screw guides, and still allow deployment over the initial distraction sheaths. The fact that Koros was able to modify its retractor blades to have the guides suggests that other retractor blades, such as those described by Cistac, would have been amenable to such modification as well.

Patent Owner also argues that adding Koros's fixation screws and guides to Cistac's retractor blades would have rendered Cistac unsatisfactory for its intended purpose, because Cistac is directed to a device whose

position can be changed at any time during the operation. Prelim. Resp. 41. We are not persuaded, however, that an ordinarily skilled artisan would have viewed the advantage of positional stability during surgery, taught by Koros, to be antithetical to the adjustability taught by Cistac. Indeed, Koros describes adjusting its retractor blades before locking them into place. *See* Ex. 1006, 5:1-4 ("Another optional but preferred feature of the invention is the inclusion of a lock mechanism to fix *the adjusted position* of the blades so they will not move during an operation." (Emphasis added.)).

In sum, after considering Patent Owner's arguments, we are still persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing in accordance with 35 U.S.C. § 314, as to claims 22 and 24.

As to claims 25 and 26, however, we determine that Patent Owner has the better position. Claim 25 depends from claim 24, and requires the extension members to have "a smallest width at a rounded distal tip of the narrowed tip portion." Ex. 1018, 19:43-44. As discussed above, we interpret "rounded distal tip" to mean that the distal tip of the extension member has a curved surface which is not jagged or sharply pointed. In contrast, the distal tips of the fixation screws 83 shown in Figures 1 and 5 of Koros are not shown as having curved surfaces, but instead are sharply pointed.

Accordingly, we determine that Petitioner has not shown a reasonable likelihood of prevailing as to claim 25. Because claim 26 depends from claim 25, and therefore includes all of the limitations of claim 25, we also determine that Petitioner has not shown a reasonable likelihood of prevailing as to claim 26.

3. Obviousness of claims 22 and 24-26 over Cistac, Obenchain, Kelleher, Mathews, Koros, and Michelson

Petitioner advances a second obviousness ground of unpatentability against claims 22 and 24-26, relying on Cistac, Obenchain, Kelleher, Mathews, and Koros for the teachings discussed above, and additionally relying on Michelson. Pet. 41-43. Petitioner cites Michelson as evidence that an ordinarily skilled artisan would have considered it obvious to include, either in addition to Koros's fixation screws, or as a substitute for the screws, an extension member described by Michelson. *See id.* at 42.

Michelson discloses, for use in minimally invasive cannulated lumbar surgery, an extension member attached to a sleeve that slides over the outside of the cannula, the extension member extending into the disc space to maintain the distraction of the adjacent vertebrae. *See* Ex. 1007, 5:53-55; 10:47-11:25. As seen in Figure 7A of Michelson, the extension member 148 has a tapered tip with a curved surface.

Given the fact that Koros describes the fixation screws of its device as stabilizing the positions of the adjacent vertebrae for surgery, however, *see, e.g.*, Ex. 1006, 3:60-62, 6:55-58, we are not persuaded by Petitioner that an ordinarily skilled artisan would have been prompted to add Michelson's additional stabilization element to Koros's apparatus. As to the proposed substitution of Michelson's extension for the fixation screws of Koros, Petitioner has not explained convincingly how Cistac's blades or Koros's guides would have been reconfigured to accommodate Michelson's extension element, which slides over the outside of the operative corridor-forming cannula, rather than along guides on the inner faces of the retractor blades, as taught by Koros.

Accordingly, we are not persuaded that Petitioner has explained convincingly how or why Michelson would have prompted an ordinary artisan to modify the device suggested by Cistac, Obenchain, Kelleher, Mathews, and Koros, to have retractor blades with the features required by claim 22. We, therefore, determine that Petitioner has not shown a reasonable likelihood of prevailing in accordance with 35 U.S.C. § 314 in its obviousness challenge to claim 22, and its dependent claims 24-26, over Cistac, Obenchain, Kelleher, Mathews, Koros, and Michelson.

4. Obviousness of claim 35 over Cistac, Obenchain, Kelleher, Mathews, and NIM Guide

Petitioner relies on Cistac, Obenchain, Kelleher, and Mathews for the teachings discussed above, and cites NIM Guide as further evidence that an ordinarily skilled artisan would have considered it obvious to include, in Kelleher's EMG nerve monitoring system, a video touch screen display to convey to a user the information provided by Kelleher's system, which includes the information required by claim 35. *See* Pet. 31, 39.

Claim 35, which depends from claim 21 through claim 34, requires the nerve monitoring system to "display[] to a user a numeric stimulation threshold value required to obtain the electromyographic activity in at least one of said muscle myotomes along with the myotomes levels being monitored." Ex. 1018, 20:34-37.

As noted above, Kelleher's system determines that a surgical instrument is adjacent to a spinal nerve when an EMG response to an electric stimulus emitted by the electrode on the instrument is detected at a distant myotome location on the patient's muscles "at or below certain neuro-muscular response onset values (i.e.: pre-determined current intensity levels)

for each of the plurality of spinal nerves." Ex. 1003, 4. As Kelleher explains, these thresholds are displayed for the electrodes/myotomes being monitored. *See id.* at 15 ("As noted these values represent the baseline or initial nerve status for each nerve corresponding to one of the myotome locations. This baseline onset current level may be displayed as a fixed value on a bar gra[ph] of LEDs such as shown in Fig. 8A or 8B."). We agree with Petitioner that Kelleher's nerve monitoring system displays the information required by claim 35.

For these reasons, we determine that Petitioner has shown a reasonable likelihood of prevailing in accordance with 35 U.S.C. § 314 in its obviousness challenge to claim 35 over Cistac, Obenchain, Kelleher, Mathews, and NIM Guide.

5. Obviousness of claims 36 and 37 over Cistac, Obenchain, Kelleher, Mathews, NIM Guide, and Jones

Petitioner relies on Cistac, Obenchain, Kelleher, and Mathews, for the teachings discussed above, and again cites NIM Guide as evidence that an ordinarily skilled artisan would have considered it obvious to include, in Kelleher's EMG nerve monitoring system, a video touch screen display. *See* Pet. 31-32, 39-41. Petitioner cites Kelleher and NIM Guide as evidence that an ordinarily skilled artisan would have considered the control unit and patient module recited in claim 36 to be obvious components of a nerve monitoring system, and cites Jones as evidence that an ordinarily skilled artisan would have considered it obvious to connect the electrodes of such a device to the patient module using a harness, as also recited in claim 36. *Id.* at 32-33. Petitioner contends that Kelleher's system includes the features required by claim 37. *Id.* at 40-41.

NIM Guide describes a system "for intraoperative use during surgeries in which a motor nerve is at risk due to unintentional manipulation. The NIM-Response records electromyographic (EMG) activity from muscles innervated by the affected nerve." Ex. 1013, 1. The NIM Guide system includes a video touch screen display that conveys information to the user. *Id.* at 2.

Jones describes the use of an electrode harness for connecting a plurality of sensing electrodes deployed on a patient to a monitoring device. Ex. 1008, abstract.

Given these teachings, we agree with Petitioner that an ordinarily skilled artisan, on the current record, would have considered NIM Guide's video touch screen and Jones' electrode harness obvious components of the nerve monitoring system described by Kelleher. We also agree that Kelleher's system includes the control unit and connected patient module required by claim 36. *See* Ex. 1003, Fig. 7 (showing EMG Input Stage 142, which receives inputs from the sensing electrodes 128-138 on the patient, connected ultimately to Controller 118). We, thus, determine that, based on the current record, the cited references teach or suggest a nerve monitoring system having all of the features of claim 36. Regarding claim 37, as noted, Kelleher's controller 118 receives output from sensor electrodes 128-138, and processes the output for ultimate display. *See* Ex. 1003, Fig. 7; *also id.* at 23-24.

Accordingly, we are persuaded that Petitioner has shown a reasonable likelihood of prevailing in accordance with 35 U.S.C. § 314 in its obviousness challenge to claims 36 and 37 over Cistac, Obenchain, Kelleher, Mathews, NIM Guide, and Jones.

6. Obviousness of claims 21, 30, and 33-37 over Branch, Obenchain, Blewett, and Onimus

Petitioner's position, essentially, is that an ordinarily skilled artisan would have considered it obvious to equip the dilators and retractor blades of the surgical system described by Branch with the nerve-monitoring electrodes taught by Blewett. *See* Pet. 46-48. Petitioner cites Obenchain as evidence that the trans-psoas path was known to be a suitable surgical approach to the lumbar spine. *Id.* at 45. Petitioner cites Onimus as evidence that an ordinarily skilled artisan would have considered it obvious to use releasable locking assemblies to secure Branch's retractor blades to its blade holder assembly. *Id.* at 44-45.

Having reviewed Petitioner's contentions and supporting evidence regarding the proposed ground of obviousness of claims 21, 30, and 33-37 over Branch, Obenchain, Blewett, and Onimus, as well as Patent Owner's arguments traversing the proposed ground, we determine that Petitioner has shown a reasonable likelihood of prevailing in accordance with 35 U.S.C. § 314.

Branch discloses "instruments and methods for performing percutaneous surgery, including spinal surgeries that include . . . implant insertion, for example. The surgery is performed through a working channel or passageway through skin and tissue of the patient provided by a retractor." Ex. 1009, 2:32-38. Branch discloses that the retractor "can be used with any surgical approach to the spine, including anterior, posterior, posterior mid-line, lateral, postero-lateral, and/or antero-lateral approaches, and in other regions besides the spine." *Id.* at 2:46-50. Branch discloses a blade holder apparatus 140 that is used to manipulate the retractor blades.

Id. at Fig. 13. Branch discloses that initial access to the spine is obtained using one or more guidewires, corresponding to the elongate penetration member of claim 21 of the '356 patent, as well as the sequentially larger dilators required by claim 21. *Id.* at 6:47-57.

Although Branch does not disclose that at least one of its dilators has the stimulation electrode required by claim 21, Blewett discloses, for use in spinal surgery, a nerve monitoring system which includes such electrodes on the surgical instruments. Ex. 1010, 3. Blewett explains that, in one embodiment, the surgical instrument may be a "dilating instrument and . . . the control unit determines at least one of proximity and direction between a nerve and the instrument based on the identified relationship between the neuromuscular response and the stimulation signal." *Id.*

We agree with Petitioner that an ordinarily skilled artisan, advised by Blewett of the desirability of equipping surgical instruments with electrodes to detect nerves during spinal surgery when using a minimally invasive techniques, would have been prompted to equip Branch's dilators with stimulating electrodes as required by claim 21 of the '356 patent, in order to allow the surgeon to detect and avoid spinal nerves.

As to claim 21's requirement that the retractor blades be locked releasably with the blade holder apparatus, we note Onimus's disclosure that snap-fitting or screwing retractor blades to a holding apparatus was known to be a useful feature on devices for providing surgical access to the spine. *See* Ex. 1012, 9. Accordingly, we also agree with Petitioner that, on this record, an ordinarily skilled artisan would have been prompted to include that feature on Branch's device. As to the intended use of the system recited in claim 21, Branch expressly states that its system may be used to access

the spine from a lateral approach, Ex. 1009, 2:46-50, and Obenchain discloses that a lateral trans-psoas approach to the lumbar spine may be preferable in certain circumstances. Ex. 1004, 6:22-31.

In sum, given the teachings of Branch, Obenchain, Blewett, and Onimus, we are persuaded that Petitioner has shown a reasonable likelihood of prevailing in its obviousness challenge to claim 21 of the '356 patent, based on those references. Having reviewed Petitioner's arguments and evidence (Pet. 48-49, 55-57), we are persuaded further that Petitioner has shown a reasonable likelihood of prevailing in its challenge to dependent claims 30 and 33-37, based on Branch, Obenchain, Blewett, and Onimus.

After considering Patent Owner's arguments, we are still persuaded that, on the current record, Petitioner has demonstrated a reasonable likelihood of prevailing in this challenge. As noted above, we are not persuaded, on the current record, that the '356 patent is entitled to the benefit of the June 26, 2002, filing date of the '214 application. Thus, because Branch's filing date, June 26, 2002, and Blewett's publication date, January 23, 2003, pre-date the earliest priority date to which the '356 patent is entitled, June 23, 2003, we agree with Petitioner that Branch qualifies as prior art to the '356 patent under 35 U.S.C. § 102(e), and Blewett constitutes prior art under § 102(a).

Patent Owner argues that Obenchain, for essentially the same reasons advanced above in relation to the challenges based on Cistac and Kelleher, teaches away from using a lateral trans-psoas pathway when performing lumbar spine surgery. *See* Prelim. Resp. 45-49. Patent Owner also argues that the proposed ground based on Branch and Blewett is deficient because it fails to take into account the evidence of objective indicia of non-

obviousness advanced previously in the context of the challenges based on Cistac and Kelleher. *Id.* at 49-50. For the reasons discussed above, we do not find these arguments persuasive.

In sum, we are persuaded that, on the current record, Petitioner has shown a reasonable likelihood of prevailing in accordance with 35 U.S.C. § 314, as to its obviousness challenge of claims 21, 30, and 33-37, over Branch, Obenchain, Blewett, and Onimus.

7. Obviousness of claims 22 and 24-26 over Branch, Blewett, Obenchain, Onimus, and Koros

Similar to the first challenge of claims 22 and 24-26 based on Cistac and Koros, discussed above, in this challenge Petitioner cites Koros as evidence that an ordinary artisan would have considered it obvious to include, on the retractor blades of Branch, extension members having the features required by claims 22, 24, and 25. *See* Pet. 47-48.

We agree with Petitioner that an ordinarily skilled artisan, advised by Koros of the desirability of slidably attaching fixation screws to retractor blades used in lumbar spinal surgery, *see* Ex. 1006, 2:42-46, 4:41-43, would have been prompted to add that feature to Branch's retractor blades. We are, therefore, persuaded that Petitioner has shown a reasonable likelihood of prevailing in its obviousness challenge to claim 22 based on Branch, Blewett, Obenchain, Onimus, and Koros. Moreover, as seen in Figures 1 and 5 of Koros, the fixation screws have a narrowed tip portion that is smaller than a proximal region of the screws, thus, meeting the requirements of claim 24.

In traversing this challenge, Patent Owner reiterates the arguments discussed above in relation to the ground based on Cistac and Koros. *See*

Prelim. Resp. 50-54. For the reasons discussed above, we do not find these arguments persuasive, as to claims 22 and 24.

As to claims 25 and 26, however, as also discussed above, we are not persuaded that the pointed distal tips of Koros's fixation screws 81, *see* Ex. 1006, Figs. 1 and 5, meet claim 25's requirement of having a rounded distal tip. We, therefore, determine that Petitioner has not shown a reasonable likelihood of prevailing as to claim 25, or its dependent claim 26.

8. Obviousness of claims 22 and 24-26 over Branch, Blewett, Obenchain, Koros, Onimus, and Michelson

Similar to the challenge discussed above based on Cistac, Koros, and Michelson, in this challenge Petitioner cites Michelson as evidence that an ordinarily skilled artisan would have considered it obvious to include, either in addition to Koros's fixation screws, or as a substitute for the screws, an extension member described by Michelson. Pet. 58-59. For the reasons discussed above relating to the first ground relying on Michelson, however, we are not persuaded that Petitioner has explained convincingly why an ordinarily skilled artisan would have been prompted to add Michelson's additional stabilization element to Koros's already stabilized apparatus. As to the proposed substitution of Michelson's extension for the fixation screws of Koros, as also discussed above, we are not persuaded that Petitioner has explained convincingly how Branch's blades or Koros's guides would have been reconfigured to accommodate Michelson's extension element, which slides over the outside of the operative corridor-forming cannula, rather than along guides on the inner faces the retractor blades, as taught by Koros.

Accordingly, because we are not persuaded that Petitioner has explained persuasively how or why Michelson would have prompted an

ordinarily skilled artisan to modify a device suggested by Branch, Blewett, Obenchain, Koros, and Onimus to have retractor blades with the features required by claim 22, we determine that Petitioner has not shown a reasonable likelihood of prevailing in its obviousness challenge to claims 22 and 24-26 over Branch, Blewett, Obenchain, Koros, Onimus, and Michelson.

III. CONCLUSION

For the foregoing reasons, we are persuaded that Petitioner has demonstrated that there is a reasonable likelihood that it would prevail regarding claims 21, 22, 24, 30, and 33-37 of the '356 patent. Accordingly, we institute an *inter partes* review of claims 21, 22, 24, 30, and 33-37 based on the following grounds:

(1) Claims 21, 30, 33, and 34 under 35 U.S.C. § 103(a) as obvious over Cistac, Obenchain, Kelleher, and Mathews;

(2) Claims 22 and 24 under 35 U.S.C. § 103(a) as obvious over Cistac, Obenchain, Kelleher, Mathews, and Koros;

(3) Claim 35 under 35 U.S.C. § 103(a) as obvious over Cistac, Obenchain, Kelleher, Mathews, and NIM Guide;

(4) Claims 36 and 37 under 35 U.S.C. § 103(a) as obvious over Cistac, Obenchain, Kelleher, Mathews, NIM Guide, and Jones;

(5) Claims 21, 30, and 33-37 under 35 U.S.C. § 103(a) as obvious over Branch, Obenchain, Blewett, and Onimus; and

(6) Claims 22 and 24 under 35 U.S.C. § 103(a) as obvious over Branch, Blewett, Obenchain, Onimus, and Koros.

Whether to institute review on a ground which may be redundant is strictly a matter of Board discretion and not a right or entitlement of either party. Notwithstanding Patent Owner's urging the Petition advances redundant grounds, we institute review of claims 21, 22, 24, 30, and 33-37 on the alleged grounds of obviousness detailed above.

Petitioner has not demonstrated that there is a reasonable likelihood that it would prevail regarding claims 25 and 26 of the '356 patent. The Board has not made a final determination on the patentability of the challenged claims.

IV. ORDER

For the reasons given, it is

ORDERED that *inter partes* review is instituted as to claims 21, 22, 24, 30, and 33-37 of the '356 patent on the grounds listed in the Conclusion, above. No other ground is authorized;

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '356 patent is hereby instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial; and

FURTHER ORDERED that an initial conference call with the Board is scheduled for 2 PM Eastern Time on April 30, 2014. The parties are directed to the Office Trial Practice Guide, 77 Fed. Reg. 48,756, 48,765-66 (Aug. 14, 2012) for guidance in preparing for the initial conference call, and should be prepared to discuss any proposed changes to the Scheduling Order entered herewith and any motions the parties anticipate filing during the trial.

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