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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SMITH & NEPHEW INC., WRIGHT MEDICAL GROUP, INC. AND WRIGHT
MEDICAL TECHNOLOGY, INC.
Petitioners

v.

BONUTTI SKELETAL INNOVATIONS, LLC
Patent Owner of U.S. Patent No. 7,806,896 to Peter M. Bonutti

IPR Trial No. IPR2013-00629, Consolidated

PETITIONER'S REPLY

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I. INTRODUCTION

As set forth in the Petition and recognized in the Decision on Institution, the following Grounds disclose each limitation of claim 1 of the '896 patent (the challenged claim): (1) Delp with Turner or Scorpio; and (2) Stulberg with Turner or Scorpio. Petition at pp. 27-37, 43-47, *Smith & Nephew, Inc. v. Bonutti Skeletal Innovations, LLC*, IPR2013-00629 Paper 1 ("Petition"); *see also* Decision on Institution at p. 27, *Smith & Nephew, Inc. v. Bonutti Skeletal Innovations, LLC*, IPR2013-00629 Paper 9, (Feb. 28, 2014) ("Decision on Institution").

In its response, BSI does not dispute that all of the challenged claim limitations are present in at least one of Petitioner's cited prior art references. Instead, BSI's lone argument for validity in this regard is that the two guide surfaces described in Scorpio are supposedly one continuous guide surface that is wider than the implant. This argument is incorrect. In the Scorpio reference, the person of skill in the art would understand that a metal divider separates the two distinct guide surfaces that are used for different cuts. Moreover, BSI does not dispute that Turner discloses a guide surface and that this guide surface is less than the transverse dimension of the implant.

Because BSI cannot dispute that all of the elements of claim 1 of the '896 patent were known in the prior art, BSI's instead argues in its Response that a person of skill would lack motivation to combine the proffered references. This

argument also lacks merit. Smith & Nephew's Petition demonstrated the reasons why a person of ordinary skill in the art would have been motivated to combine the teaching of small guide surfaces that reduce trauma (Turner and Scorpio), with the teaching of computer-assisted surgical techniques that further reduce trauma, improve surgical outcomes by eliminating intramedullary ("IM") and extramedullary ("EM") alignment rods, and improve the accuracy of surgical procedures (Delp and Stulberg). Petition at pp. 34-36, 45-46. This motivation is consistent with the fundamental tenet that a person of ordinary skill at the time of the invention would follow—do no harm. BSI's attempt to suggest that a person of skill—a medical doctor in this case—would not be motivated to reduce trauma to his or her patient has no legal, factual, or practical basis. Moreover, because BSI presented no evidence of secondary considerations, it has failed to identify any evidence to rebut Smith & Nephew's *prima facie* demonstration of obviousness.

Finally, BSI's Response makes three arguments directed to irrelevant inquiries. First, BSI cannot save its claim by arguing that features such as reduced instrumentation size or small incision length that are "described" in the specification ***but not recited in the challenged claim*** are "novel." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1565 (Fed. Cir. 1991) ("The invention is defined by the claims.") (internal quotation marks omitted)). Second, contrary to clear Federal Circuit precedent, BSI argues that the claim is patentable because it alleges that the

actual devices disclosed in the prior art references are not physically combinable.

Third, also contrary to Federal Circuit precedent, BSI argues that each of the references is, in and of itself, flawed in some way that prevents it from being part of an obviousness combination.

When BSI's irrelevant inquiries are placed to the side, the essential elements of the Petition are un rebutted: every element of the claimed invention was disclosed in the prior art, and a person of skill in the art would be motivated to combine these teachings to achieve reduced trauma for patients. Accordingly, the claim is invalid as obvious and should be rejected.

II. BSI DOES NOT DISPUTE THAT ALL ELEMENTS OF THE CHALLENGED CLAIM WERE IN THE PRIOR ART

Claim 1 recites a preamble and six limitations. The Petition demonstrates that every element of claim 1 is disclosed by both: (1) the combination of Delp with Turner or Scorpio; and (2) the combination of Stulberg with Turner or Scorpio. Petition at pp.27-37, 43-47. There is no dispute that *every single one* of claimed limitations was known in the prior art.

As discussed in Section III below, BSI instead disputes whether the Scorpio reference discloses limitation 1(f), reciting “attaching a replacement portion of the knee to the cut surface, the replacement portion having a transverse dimension that is larger than a transverse dimension of the guide surface.” ’896 patent, cl. 1 (Ex.

1001). But BSI does not dispute that Turner, a separate combination reference, squarely discloses this limitation. *See, e.g.*, Smith & Nephew, Inc. v. Bonutti Skeletal Innovations, LLC, IPR2013-00629, Paper 17, at pp. 30-32 (“Resp.”); *see also* Aug. 25, 2014, Schoifet Tr. at 167:6-20, 168:12-15, 169:8-23 (“Schoifet Dep.”) (Ex. 1031). BSI’s failure to dispute Turner’s disclosure of limitation 1(f) is particularly conspicuous because both Smith & Nephew’s Petition and the Decision on Institution cite Turner for this limitation. Petition at pp. 32-33; Decision on Institution at pp. 12-13.

Thus, notwithstanding its (incorrect) arguments regarding Scorpio, BSI has not disputed, and cannot dispute, that each and every element of the challenged claim was known in the prior art in at least one reference cited by Petitioner.

III. SCORPIO DISCLOSES A GUIDE SURFACE SMALLER THAN AN IMPLANT

The only disputed disclosure in the prior art is whether the Scorpio guide discloses limitation 1(f), “a guide surface” that has a transverse dimension less than the transverse dimension of the replacement portion. BSI is unable to challenge Scorpio’s teaching of this limitation without resorting to both: (1) a clear misstatement of Scorpio’s actual disclosure; and (2) argument inconsistent with both the Board’s claim construction and the ’896 patent specification.

As described in the Petition and acknowledged in the Board's Decision on Institution, the Scorpio guide includes two guide surfaces, a left guide surface and a right guide surface. Petition at pp. 33-34; Decision on Institution at pp. 13-14. When considered independently, each of these two guide surfaces has a transverse dimension less than the transverse dimension of the implant. Petition at pp. 33-34; Decision on Institution at 17-18. BSI does not dispute this. Instead, BSI argues, based on a commercial embodiment of the Scorpio reference ("Scorpio Product"), that Scorpio's left guide surface and the right guide surface, which are separated by a metal divider, should somehow be considered to be a single, continuous guide surface. *See, e.g.*, Resp. at p. 20. As an initial matter, BSI's argument should be rejected because it is based on the Scorpio Product, not the Scorpio reference. *See* 35 U.S.C. § 311 (Petitioner may request cancellation "only on the basis of prior art consisting of patents or printed publications"). Even if the Scorpio Product were considered, however, BSI's argument should be rejected for multiple reasons.

First, it is undisputed that the left and right Scorpio guide surfaces are separated by a solid metal divider positioned between them. Resp. at 36 (admitting there is a "central metal portion" between the left and right slots). As a result, a surgeon cannot cut along the full length of both the left guide surface and the right guide surface without: (1) removing the blade when it reaches the center divider; and (2) reinserting the blade on the other guide surface. *See* Sep. 3, 2013,

Declaration of Jay Mabrey M.D., ¶ 13 (“Mabrey Reply Decl.”) (Ex. 1023). This alone confirms that Scorpio discloses two guide surfaces, each of which meets limitation 1(f). BSI points out that in the Scorpio Product the solid metal divider is a truncated triangle that ends just before the back edge of the cutting guide. Resp. at p. 20; Schoifet Dep. at 141:4-7; 10-18 (Ex. 2031). However, this is irrelevant because it does not change how the person of skill in the art would understand the separate guide surfaces were used. The *de minimis* space¹ between the back edge of the divider and the back edge of the guide cannot overcome the fact that the two guide surfaces are separated by a metal divider and cannot be used to make a single, continuous cut without removing the blade from one slot and reinserting it into the other slot. Mabrey Reply Decl. ¶ 13 (Ex. 1023).

Second, under the Board's construction, Scorpio meets the limitation of the claim because it includes two guide surface rather than, as BSI contends, a single “guide surface” that extends the width of the cutting guide. The Board construed the term “guide surface” to mean “a surface that guides a cutting instrument.” Decision on Institution at 9. The *de minimis* space between the back edge of the

¹ Dr. Mabrey determined the size of the missing apex of the truncated triangle of the Scorpio Product and it was approximately 1 mm wide by 0.5 mm deep.

Mabrey Reply Decl. ¶ 14 (Ex. 1023).

divider and the back edge of the guide in the Scorpio Product—the space that in BSI's view links the left to the right guide surfaces—does not guide the cutting instrument and therefore is not itself a “guide surface.” *See* Mabrey Reply Decl. ¶¶ 14-16 (Ex. 1023). Thus, contrary to BSI's position, Scorpio does not disclose “a single continuous guide surface that extends across the entire cutting guide.” *See, e.g.,* Resp. at p. 20 (emphasis omitted). Instead, Scorpio discloses two separate guide surfaces separated by a metal divider and a non-guide surface space.

Third, BSI's argument that Scorpio “would not function” without a single continuous guide surface spanning the left and right guide surfaces is unsupported and plainly incorrect. In his declaration, Dr. Schoifet declaration offers the conclusory statement that “Scorpio would not function as an anterior resection guide if the center metal piece in front of the guide surface extended all of the way to the bone side of the guide surface.” Schoifet Decl. ¶ 77 (Ex. 2004) (emphasis in original). At his deposition, however, Dr. Schoifet could not confirm this, and his only opinion was that if the metal divider were extended all the way to the bone side, the guide “may very well be a nonfunctioning cutting guide.” Schoifet Dep. at 150:8-15, 150:25-151:6, 151:15-154:2; 154:21-155:6 (Ex. 1031). Dr. Schoifet also admitted he was unable to render an opinion whether the cut could be performed using only one of the two slots. Schoifet Dep. at 146:3-147:3 (Ex. 1031). By contrast, Dr. Mabrey performed a test using the Scorpio product that

demonstrated that the anterior resection cut can be performed using *solely* one of the two guide surfaces *without* the *de minimis* space behind the divider. This is consistent with what a person of skill in the art would understand from reading the Scorpio Technique Guide that there are two separate guides surfaces for two different cuts. Mabrey Reply Decl. ¶¶ 17-21 (Ex. 1023). These tests demonstrate that Dr. Schoifet's conclusory statement does not accurately describe Scorpio.

IV. BSI FAILS TO OVERCOME PETITIONER'S SHOWING OF MOTIVATION TO COMBINE THE REFERENCES

A. A Person Of Ordinary Skill Would Be Motivated To Reduce Trauma

In the Petition, Smith & Nephew demonstrated that a person of ordinary skill in the art would have been motivated to combine the computer-assisted techniques in Delp and Stulberg with the teaching of small guide surfaces in Turner and Scorpio. Petition at pp. 34-36, 45-46. Delp and Stulberg each teach computer-assisted techniques that improve the accuracy of mechanical instruments, like the instruments taught in Turner and Scorpio. *Id.* Therefore, a person of skill in the art would have been motivated to combine the teachings of either Delp or Stulberg with both Turner and Scorpio to improve their accuracy. *Id.*; *see also* Schoifet Dep. at 178:12-17 (admitting accuracy is important for total knee replacement surgeries). The person of ordinary skill in the art would have been motivated to improve the accuracy of surgical instrumentation because doing so creates more

accurate cuts that reduce unnecessary trauma to the patient and improve surgical outcomes. Mabrey Reply Decl. ¶¶ 9, 43 (Ex. 1023).

Likewise, a person of ordinary skill in the art would have been motivated to combine Turner's and Scorpio's teachings of small guide surfaces with the computer-assisted techniques taught in Delp and Stulberg. Petition at pp. 34-36, 45-46. Reducing the size of cutting guide surfaces and bulky alignment instrumentation was a known solution for reducing trauma. *See, e.g.*, Delp '018, col. 22, ll. 45-50 ("smaller jigs" allow "a smaller incision to be made," which "will result in a less invasive procedure, and will lead to a shorter rehabilitation time, thereby reducing costs, morbidity, and patient complaints") (Ex. 1004).

In its Response, BSI repeatedly argues that a person of ordinary skill in the art would not have been motivated to reduce trauma by combining these teachings, and that doing so relies on improper hindsight reasoning. *See, e.g.*, Resp. at pp. 40, 54. This argument should be rejected. As Dr. Mabrey explains:

[T]he motivation of every orthopedic surgeon, and indeed every doctor, is to first do no harm. Accordingly, a doctor chooses the techniques that will minimize any and all side effects . . . while still providing the best possible outcome for the patient. Therefore, the motivation of a person of skill in the art of orthopedic surgery is always to design/develop the most efficient and least invasive technique possible to achieve the desired outcome.

Mabrey Reply Decl. ¶ 9 (Ex. 1023). A person of ordinary skill in the art would have been motivated to combine the small guide surfaces taught in Turner and Scorpio with the computer-assisted techniques in Delp and Stulberg to develop smaller instruments that could be used to operate through smaller incisions.

Mabrey Reply Decl. ¶ 22 (Ex. 1023). As Patentee admitted when arguing for patentability of a related application that claimed the same priority date as the challenged patent “[r]educing incision size is . . . *always a major motivation* for *any* surgical procedure.” File History for U.S. Patent No. 8,133,229 to Bonutti, June 18, 2009 Office Action Response (“’3229 File History”) at p. 20 (emphasis added) (Ex. 1024); *see also* Delp ’018, col. 22, ll. 45-50 (“smaller jigs” allow “a smaller incision to be made,” which “will result in a less invasive procedure, and will lead to a shorter rehabilitation time, thereby reducing costs, morbidity, and patient complaints”) (Ex. 1004).

Dr. Schoifet’s testimony to the contrary should be given little or no weight. As Dr. Schoifet admitted at his deposition, he had no experience with instrument design or computer-assisted techniques in the 2000 to 2003 timeframe, and he has never used computer-assisted techniques in actual surgical procedures because he “didn’t feel . . . that computer-assisted added much to the technique or outcomes.” Schoifet Dep. at 51:24-52:7, 62:10-15, 66:8-10, 67:9-22; *see also id.* at 51:11-53:2, 54:13-55:4 (Ex. 1031). By contrast, Dr. Mabrey, who has performed over 500

computer-assisted total knee replacements, helped design and develop a computer-assisted TKA system that would eliminate mechanical alignment from 2000-2003, and has been involved with the computer-assisted surgical techniques, including techniques for TKA, since the mid-1990's. Mabrey Reply Decl. ¶ 37 (Ex. 1023).

A person of ordinary skill therefore would have been motivated to reduce trauma by eliminating mechanical alignment, as taught in Delp and Stulberg, combined with smaller guide surfaces, as shown in Turner or Scorpio.

B. BSI Offers No Evidence Of Secondary Considerations

BSI has not presented any evidence of secondary considerations, and thus has not presented any evidence to rebut the *prima facie* case of obviousness. For example, although BSI argues that unclaimed features like a smaller incision and a smaller cutting guide reduce trauma, *see* Reply at pp. 2-3, BSI does not argue that this is an unexpected result. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). The method of the challenged claim is precisely such a predictable result. A person of ordinary skill in the art would have expected to reduce patient trauma using smaller guide surfaces (such as Scorpio or Turner), and by replacing bulky mechanical alignment devices with more accurate and less invasive computer-assisted techniques (such as Delp or Stulberg). Mabrey Reply Decl. ¶¶ 22, 37-41, 43-50 (Ex. 1023); '3229

File History at p. 20 (“[r]educing incision size is . . . always a major motivation for any surgical procedure”) (Ex. 1024); Delp ’018, col. 22, ll. 45-50 (known benefit of using “smaller jigs” is to allow “a smaller incision to be made,” which “will result in a less invasive procedure, and will lead to a shorter rehabilitation time, thereby reducing costs, morbidity, and patient complaints”) (Ex. 1004).

C. BSI's Remaining Arguments For Non-Obviousness Are Legally Deficient

BSI cannot dispute that every element of the challenged claim was disclosed in the prior art. Accordingly, BSI's Response focuses on three legally irrelevant arguments in an effort to rebut Petitioner's *prima facie* case of obviousness: (1) that the references fail to disclose things that are ***not claimed***, but instead are merely “described” in the specification; (2) that the prior art devices could not be physically combined; and (3) that individual references do not disclose every claimed element. None of these arguments withstands scrutiny.

1. Unclaimed Features Are Irrelevant

BSI first argues that the challenged claim is not obvious because the references lack disclosure of un-claimed elements but that are “described” in the specification. For example, BSI argues that the “’896 patent describes the use of reduced size cutting guides,” Resp. at p. 2 (emphasis added), and that according to the specification, “[b]y using reduced size cutting guides, ‘the size of the

incision . . . can be reduced.” Resp. at p. 3 (citing '896 patent col. 18, ll. 36-38); *see also* Resp. at p. 42 (arguing that the person of skill in the art would not look to the combined references of the Petition for disclosure suggesting that cutting guide size should be reduced).

Despite BSI's focus on these statements in the specification, however, the challenged claim simply does not recite “reduced size cutting guides” or “reduced size incisions.” *See* '896 patent, cl. 1 (Ex. 1001). Rather, the challenged claim relates to the size of a “guide surface” and is silent about incision length. *Id.*; Mabrey Reply Decl. ¶ 4 (Ex. 1023). This is for a good reason. As Petitioner separately demonstrated, BSI's other claims that actually recite these features are anticipated and/or obvious in view of the prior art, and BSI disclaimed those challenged claims. *See, e.g.*, Petition for *Inter Partes* Review of U.S. Patent No. 6,702,821, IPR2013-00620, Paper 1 at p. 31-32, 44-48 (demonstrating how Turner and Scorpio disclose and render obvious challenged claim purportedly directed at small guides) (Ex. 1025); Notice Regarding Filing of Disclaimer of a Claim in a Patent, IPR2013-00620, Paper 8 (Ex. 1026); Decision on Institution for *Inter Partes* Review of U.S. Patent No. 7,749,229, IPR2013-00605, Paper 9 at pp. 13, 17, 20 (recognizing the prior art discloses challenged claim purportedly directed to small incisions) (Ex. 1027); Notice Regarding Filing of Disclaimer of a Challenged Claim in a patent, IPR2013-00605, Paper 11 (Ex. 1028).

Even if the unclaimed features that the '896 patent "describes" were novel, they are irrelevant to the patentability of the challenged claim. It is the scope of what BSI actually chose to claim that determines obviousness. *Vas-Cath Inc.* 935 F.2d at 1565 ("The invention is defined by the claims.") (internal quotation marks omitted). Thus, BSI's repeated arguments that Petitioner's references do not concern smaller incisions or smaller cutting guides, *see, e.g.*, Resp. at pp. 11, 13, 17, and 21, have no bearing on the relevant question of whether those references disclose the claimed elements (and they do).

BSI similarly focuses on unclaimed and irrelevant features when it asserts that Turner is "crude," "primitive," and "no more than a rough reference for what is essentially a 'free-hand' or 'eyeball' cut." *See, e.g.*, Resp. at pp. 24-26 and 29-30. Even if these assertions were true, they are irrelevant.

First, such considerations are irrelevant to the obviousness analysis because the challenged claim does not recite any limitation specifying the accuracy of the cut. *See* '896 Patent at claim 1 (Ex. 1001). Indeed, BSI has conceded that Figure 54 of the '896 patent is an embodiment of claim 1. Resp. at p. 8. A comparison of Turner to Figure 54 demonstrates that both guides operate in the same manner—a guide surface without slots. *Compare* Turner, Fig. 8 (Ex. 1008) *with* '896 Patent, Fig. 54 (Ex. 1001). As a result, in both cases a surgeon guides a blade along a guide surface to cut the bone without the aid of a cutting slot to hold the blade in

place. Thus, even if cutting accuracy were relevant to the challenged claim (and it is not), Turner's accuracy is consistent with what the '896 patent discloses.

Second, BSI's criticism of Turner as "crude" and "primitive" is not only irrelevant, it is incorrect. Turner's technique resulted in life changing pain relief and mobility, and the person of skill in the art would have recognized it to be a significant advance in TKA that formed the basis of the modern TKA. Mabrey Reply Decl. ¶ 27 (Ex. 1023).

2. Physical Combinability Is Not the Standard

BSI next argues that the references could not be physically combined, and therefore cannot render the claim obvious. For example, BSI argues Stulberg cannot be combined with Turner or Scorpio because the latter's figures do not depict physically identical cutting guides. *See, e.g.*, Resp. at pp. 25-26 (arguing "the cutting guide of Turner is designed to make an entirely different distal cut" than the exemplary cutting guide of Stulberg); 32-33 (arguing Scorpio's anterior resection guide is "designed to make an entirely different cut on the femur" than the exemplary cutting guide of Stulberg). BSI similarly argues that Turner and Scorpio cannot be combined with Stulberg because they show different cuts on the femur than Stulberg does. *See, e.g.*, Resp. at pp. 26, 28, 30, and 31-32.

The Federal Circuit has rejected such arguments. "The obviousness inquiry does not ask 'whether the references could be physically combined but whether the

claimed inventions are rendered obvious by the teachings of the prior art as a whole.”” *In re Chevalier*, 500 Fed. App’x 932, 934 (Fed. Cir. 2013) (quoting *In re Etter*, 756 F.2d 852, 859 (Fed. Cir. 1985) (en banc)); *see also In re Mouttet*, 686 F.3d 1322, 1332 (Fed. Cir. 2012) (“obviousness based on teachings from multiple references does not require an actual, physical substitution of elements”); *Orthopedic Equip. Co., Inc. v. United States*, 702 F.2d 1005, 1013 (Fed. Cir. 1983) (“Claims may be obvious in view of a combination of references, even if the features of one reference cannot be substituted physically into the structure of the other reference.”); *In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983).

Turner and Scorpio teach small guide surfaces, and Delp and Stulberg teach computer-assisted surgical techniques that eliminate IM and EM alignment rods. As demonstrated in the Petition and as discussed above in section IV.A-B, it would have been obvious to a person of skill to combine these teachings, regardless of whether the exemplary cutting guides disclosed by Delp and Stulberg are physically identical to the cutting guides shown in Turner and Scorpio. Mabrey Reply Decl. ¶¶ 39, 45, 48-50 (Ex. 1023).

BSI additionally argues that Scorpio is not physically combinable with Stulberg or Delp because the guide in Scorpio purportedly must be used with an IM alignment rod. Resp. at p. 33. This argument is legally irrelevant because Stulberg and Delp teach how to eliminate IM alignment rods. *See, infra* § IV.C.3.

BSI's argument is also factually wrong. The physical guide shown in Scorpio could be secured to the bone and aligned without an IM alignment rod using the teachings of Stulberg or Delp. Mabrey Reply Decl. ¶ 44 (Ex. 1023).

BSI also argues that the physical guide shown in Turner is too inaccurate to combine with the computer-assisted techniques of Delp and Stulberg. Resp. at p. 27. This argument once again runs afoul of the Federal Circuit's clear precedent that physical combination is not relevant to obviousness. *Chevalier*, 500 Fed. App'x at 934; *Etter*, 756 F.2d at 859; *Moultet*, 686 F.3d at 1332. It further ignores the uncontroverted fact that Delp and Stulberg teach that computer-assisted techniques can be combined with mechanical guides like Turner specifically to improve their accuracy. Resp. at pp. 29, 53 (admitting Delp and Stulberg teach computer-assisted techniques that improve the accuracy of mechanical instrumentation); Mabrey Reply Decl. ¶¶ 39, 47 (Ex. 1023).

In short, BSI's arguments that the references would not or could not be combined physically are contrary to the standard for obviousness. "Nothing . . . requires [the challenger] to prove obviousness by starting with a prior art commercial embodiment and then providing motivation to alter that commercial embodiment 'What matters is the objective reach of the claim.'" *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 737 (Fed. Cir. 2013) (quoting *KSR* 550 U.S. at 419). Here, the references disclose the claimed elements in a way that

would be understood and combined by a person of skill, and would cover the objective reach of the claim. The claim is obvious.

3. BSI Improperly Argues Against The References Individually

In its last arguments, BSI attempts to discount Stulberg's and Delp's express teaching of how to eliminate the use of IM and EM alignment rods by alleging that the devices disclosed by Scorpio and Turner use such rods. This argument fails for two reasons: (1) it misstates the references; and (2) it incorrectly focuses on what individual references disclose instead of what a person of ordinary skill would understand from the combination of the references as a whole.

First, BSI wrongly argues against combining Turner with either Stulberg or Delp because Turner is supposedly "an extramedullary mounted cutting guide." Resp. at p. 28. BSI's does not and cannot include the words "alignment rod" in this argument because Turner does not use an EM *alignment* rod. Mabrey Reply Decl. ¶¶ 33-36 (Ex. 1023). Instead, Turner's cutting guide has a bar that allows the surgeon to hold the cutting guide in place during the surgery. *Id.* Because this bar does not perform any form of "aligning," it is not an alignment rod. *Id.*; *see also* Schoifet Dep. at 71:9-19, 114:7-16 (admitting EM rods are aligned with two or more anatomical landmarks). BSI's suggestion that Turner is inconsistent with eliminating an "extramedullary alignment rod" is misplaced.

Second, BSI concedes that Stulberg and Delp each teach the elimination of IM and EM alignment rods through the use of computer-assisted techniques. Resp. p. at 29 (“Stulberg provides a femoral cutting guide which is positioned and mounted without an intramedullary or extramedullary alignment rod.”); 53 (Delp “specifically states that its system ‘eliminates the need for intramedullary and extramedullary alignment guides’” (citing Delp Article at 55)). Despite this admission, BSI improperly argues that when Turner or Scorpio (which BSI alleges use such devices) is combined with Stulberg or Delp, the combined procedure would use an IM or an EM alignment rod. Resp. at pp. 31, 44, 51, 56. That argument makes no sense. If Delp and Stulberg each teach how to perform computer-assisted techniques without such alignment rods, as they plainly do, no rational person of skill would conclude that Delp or Stulberg could only be used with such alignment rods. BSI’s argument that, despite this core teaching, a person of skill would still use such rods when combining Scorpio or Turner should be rejected. *See* Mabrey Reply Decl. ¶¶ 37-40, 44, 49 (Ex. 1023).

BSI persists that, even though Stulberg teaches replacing alignment rods with computer-assisted alignment, a person of skill in the art might not have followed this core teaching of Stulberg because the reference also includes a figure that shows an EM alignment rod. Resp. at p. 31. This is a red herring. As BSI admits, this figure depicts a tibial cut, not a femoral cut as claimed in claim 1. *Id.*

Use of an EM alignment rod for cutting the tibia (shin bone) is irrelevant because the challenged claim relates to cuts on the femur (thigh bone). '896 patent at claim 1 (Ex. 1001). There is no dispute Stulberg teaches performing femoral cuts without an IM or EM alignment rod.

In light of the clear teaching of Stulberg and Delp regarding the elimination of alignment rods, BSI's arguments that Turner or Scorpio somehow require the use of such rods improperly focuses on individual references instead of the overall combinations. In re Merck & Co., Inc., 800 F.2d 1091, 1097 (Fed. Cir. 1986) ("Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references."). The combination of Stulberg and Turner and the combination of Delp and Turner each teach eliminating IM and EM alignment rods and render the claim obvious.

V. CONCLUSION

Claim 1 of the '896 patent is unpatentable and should be cancelled.

Respectfully submitted,

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LIST OF EXHIBITS FOR
Petitioner's Reply, IPR2013-00629

<u>Exhibit</u>	<u>Description</u>
1001	U.S. patent No. 7,806,896 (“’896 patent”)
1002	Declaration of Jay Mabrey, M.D., M.B.A. (“Mabrey Declaration” or “Mabrey Decl.”)
1003	Scott L. Delp, <i>et al.</i> , “Computer Assisted Knee Replacement,” 354 Clinical Orthopaedics and Related Research (1998) (“Delp Article”)
1004	U.S. Patent No. 5,871,018 (“Delp ’018”)
1005	S. David Stulberg, <i>et al.</i> , “Computer-Assisted Total Knee Replacement Arthroplasty,” 10(1) Operative Techniques in Orthopaedics (Jan. 2000) (“Stulberg”)
1006	Klaus Radermacher, <i>et al.</i> , “Computer Assisted Orthopaedic Surgery With Image Based Individual Templates,” 354 Clinical Orthopaedics and Related Research (1998) (“Radermacher Article”)
1007	International Patent Application Publication No. WO 93/25157 to Radermacher (“Radermacher ’157”)
1008	Roderick H. Turner, Richard Matzan, and Yousif I. Hamati, “Geometric and Anametric Total Knee Replacement,” <i>in</i> Total Knee Replacement (A.A. Savastano, M.D. ed. 1980) (“Turner”)
1009	Stryker Howmedica Osteonics, “Scorpio Single Axis Total Knee System: Passport A.R. Surgical Technique” (“Scorpio”)
1010	The New Oxford American Dictionary (2d ed. 2005)
1011	Webster’s New College Dictionary (2007)
1012	The American Heritage College Dictionary (3d ed. 1993)
1013	U.S. Patent No. 4,502,483 (“Lacey ’483”)

<u>Exhibit</u>	<u>Description</u>
1014	'896 patent file history, Response dated April 30, 2007
1015	'896 patent file history, Office Action dated March 25, 2009
1016	'896 patent file history, Response dated October 9, 2007
1017	'896 patent file history, Response dated March 22, 2010
1018	Smith & Nephew, "Genesis Unicompartmental Knee System," 1994
1019	U.S. Patent No. 5,282,803 ("Lackey '803")
1020	Richards Manufacturing Co., Inc., "Richards Intracondylar Knee" (1979) ("Richards")
1021	Peter A. Keblish, Jr., M.D., "Surgical Techniques in the Performance of Unicompartmental Arthroplasties," 8(3) Operative Techniques in Orthopaedics, pp. 134-145 (July 1998) ("Keblish")
1022	Exhibit 2007 with annotations made by Dr. Schoifet
1023	Reply Declaration Jay D. Mabrey, MD, MBA Regarding U.S. Patent No. 7.806,896 ("Mabrey Reply Decl.")
1024	File History for U.S. Patent No. 8,133,229 to Bonutti, June 18, 2009, Office Action Response ("'3229 File History")
1025	Petition for <i>Inter Partes</i> Review of U.S. Patent No. 6,702,821, IPR2013-00620, Paper 1
1026	Notice Regarding Filing of Disclaimer of a Claim in a Patent, IPR2013-00620, Paper 8
1027	Decision on Institution for <i>Inter Partes</i> Review of U.S. Patent No. 7,749,229, IPR2013-00605, Paper 9
1028	Notice Regarding Filing of Disclaimer of a Challenged Claim in a patent, IPR2013-00605, Paper 11
1029	Matthew D. Skolnick, Mark B. Coventry, and Duane M. Ilstrup, "Geometric Total Knee Arthroplasty," 58-A(6) Bone & Joint Surgery pp. 749-53 (Sept. 1976) ("Skolnick")

<u>Exhibit</u>	<u>Description</u>
1030	Photos from Aug. 11, 2014 demonstration of the use of a Scorpio Anterior Resection Cutting Guide
1031	Transcript of Aug. 25, 2014, Deposition of Scott Schoifet, M.D. with Errata
1032	Lacey Condylar Total Knee System Surgical Procedure (Dow Corning Wright) ("Lacey Guide")
1033	Steven H. Stern, "Surgical Exposure in Total Knee Arthroplasty," <i>in</i> 2 Knee Surgery pp. 1289-1302 (Freddie H. Fu <i>et. al</i> eds. 1994) ("Stern")
1034	"Minimally Invasive Solution: The M/G Unicompartmental Knee Minimally Invasive Surgical Technique" (Zimmer, Inc. 2000) ("Zimmer Guide")
1035	P.M. Bonutti and M.A. Kester, "Unicompartmental Knee Arthroplasty: a US Experience" <i>in</i> Unicompartmental Knee Arthroplasty pp. 260-66 (Ph. Cartier <i>et. al</i> eds. 1997) ("Bonutti 1997")
1036	Aaron A. Hofmann, Rodney L. Plaster, and Louis E. Murdock, "Subvastus (Southern) Approach for Primary Total Knee Arthroplasty," 269 Clinical Orthopaedics and Related Research pp. 70-77 (Aug. 1991) ("Hofmann")

CERTIFICATE OF SERVICE

I hereby certify that on September 3, 2014, I caused a true and correct copy of the foregoing materials:

- Petitioner's Reply
- Exhibits 1022-1036
- Petitioner's List of Exhibits

to be served by email, as previously agreed between the parties, on the following counsel of record for Patent Owner:

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