UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

STRYKER CORPORATION and WRIGHT MEDICAL TECHNOLOGY, INC. Petitioners,

v.

OSTEOMED LLC, Patent Owner

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Case IPR2022-00191

U.S. Patent No. 9,763,716

PETITION FOR INTER PARTES REVIEW

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### **EXHIBITS**

Exhibit	Description
1001	U.S. Patent No. 9,763,716
1002	Declaration of Professor Kenneth A. Gall, Ph.D
1003	CV of Professor Kenneth A. Gall, Ph.D.
1004	Prosecution History of U.S. Patent No. 8,529,608
1005	Slater WO 2007/131287
1006	Falkner U.S. 2005/00171544
1007-1009	Not used
1010	Duncan US2009/0228048
1011	Grady US2005/0010226
1012	Amended Scheduling Order, OsteoMed LLC v. Stryker Corp., No. 1:20-cv-6821(N.D. Ill. Jun. 16, 2021), ECF. No. 48.
1013	Scheduling Order, OsteoMed LLC v. Wright Medical Tech., Inc., No. 1:20-cv-01621-RGA (D. Del. Aug. 4, 2021), ECF. No. 40.
1014	Tr. of Hr'g on Mot. to Transfer, OsteoMed LLC v. Wright Medical Tech., Inc., No. 1:20-cv-01621-RGA (D. Del. Apr. 14, 2021), ECF. No. 27
1015	Strnad (US2007/0239163)
1016	U.S. Provisional Application No. 16/035,270 filed March 10, 2008
1017	Prosecution History of U.S. Patent No. 9,351,776
1018	Prosecution History of U.S. Patent No. 9,763,716
1019	Not used
1020	Merriam-Webster's Medical Dictionary 51 (2006)
1021-1024	Not used
1025	Prosecution History of Duncan U.S. Patent Application No. 12/400,071 ("Duncan Non-provisional")

Petitioners Stryker Corporation and Wright Medical Technology, Inc. respectfully petition for *inter partes* review of Claims 15 and 21 of U.S. Patent No. 9,763,716 ("the 716 patent"), which is purportedly assigned to OsteoMed LLC ("Patent Owner"). Patent Owner separately sued Petitioners for infringing the 716 patent in the Northern District of Illinois and in the District of Delaware. On October 11, 2021, Patent Owner served its infringement contentions against Petitioner Wright Medical alleging, for the first time, infringement of claims 15 and 21 of the 716 patent. In this Petition, review is sought of only the newly asserted claims.

### I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

#### A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

Petitioner Wright Medical Technology, Inc. is a wholly-owned subsidiary of Petitioner Stryker Corporation. Stryker Corporation is the real party-in-interest.

#### B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

The 716 patent is one of four related patents entitled "Bone Plate with a Transfixation Screw Hole," all of which have been asserted against Petitioner Stryker in the following litigation pending in the Northern District of Illinois: *OsteoMed LLC v. Stryker Corporation*, Case No. 1:20-cv-06821, filed November 17, 2020. As of the date of this Petition, the litigation is in its infancy. Fact discovery opened on July 6, 2021. (EX1012). According to the current scheduling order, and assuming no extensions are granted, no claim construction hearing will take place

until after April 1, 2022 at the earliest. (EX1012). Opening expert reports are due on August 5, 2022, at the earliest, depending on when the claim construction ruling is issued. (EX1012). No trial has been scheduled and dispositive motions are not expected to be filed until after November 4, 2022. (EX1012).

The same four related patents, including the 716 patent, have also been asserted against Petitioner Wright Medical in the following litigation pending in the District of Delaware: *OsteoMed LLC v. Wright Medical Technology, Inc.*, Case No. 1:20-cv-1621, filed November 27, 2020. As of the date of this Petition, the litigation is also in its infancy. (EX1013). The Delaware court has indicated that this case will follow behind the Illinois case. (EX1014).

The related patents include U.S. Patent Nos. 8,529,608 ("the 608 patent"), 9,351,776 ("the 776 patent"), and 10,245,085 ("the 085 patent"), all of which claim priority to the 608 patent. Petitioners earlier petitioned for *inter partes* review of claims 1-6, 8-14 and 17 of the 608 patent in IPR2021-01450, claims 1-6 and 8-13 of the 776 patent in IPR2021-01451, claims 1-6, 8-13, and 16-19 of the 716 patent in IPR2021-01452, and claims 1-9 of the 085 patent in IPR2021-01453. The earlier petitions addressed all of the claims asserted by OsteoMed against Stryker in OsteoMed's initial infringement contentions, served on July 20, 2021 in the Illinois litigation.

On October 11, 2021, OsteoMed served its initial infringement contentions against Wright Medical in the Delaware litigation. In addition to claims already addressed in the earlier IPRs, OsteoMed further asserted claim 16 of the 608 patent, claim 15 of the 776 patent, and claims 15 and 21 of the 716 patent. Newly asserted claims 15 and 21 of the 716 patent are the subject of the present IPR, while newly asserted claim 16 of the 608 patent is the subject of IPR2022-00189 and newly asserted claim 15 of the 776 patent is the subject of IPR2022-00190. IPR2022-00189 and IPR2022-00190 are filed simultaneously with the present Petition.

### C. Lead And Back-Up Counsel Under 37 C.F.R. §42.8(b)(3)

Petitioners provide the following designation of counsel.

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### D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Please address all correspondence to the lead counsel at the address provided

in Section I.C of this Petition. Petitioners also consent to electronic service by email

at: <u>Stryker-Wright-IPR@mcandrews-ip.com</u>.

#### E. Payment of Fees (37 C.F.R. §§ 42.15(a) and 42.103(a))

The USPTO is authorized to charge Deposit Account No. 13-0017 for fees in 37 C.F.R. § 42.15(a) and any additional fees.

#### F. Grounds for Standing (37 C.F.R. § 42.104(a))

The 716 patent is available for *inter partes* review and Petitioners are not barred or estopped from requesting *inter partes* review on the grounds identified in this Petition.

#### II. OVERVIEW OF CHALLENGE AND RELIEF REQUESTED

Pursuant to 35 U.S.C. §§ 311-319, Petitioners request *inter partes* review of Claims 15 and 21 ("the Challenged Claims") of the 716 patent on the grounds below and request that each claim be found unpatentable. Additional support for each ground is set forth in the Declaration of Kenneth A. Gall, Ph.D. (EX1002), which demonstrates the knowledge of a person of ordinary skill in the art ("POSITA") at the time of the invention.

#### A. Prior Art Relied Upon

Exhibit 1005: Slater WO 2007/131287 ("Slater"), published on November 22, 2007. Slater is §102(b) prior art.

Exhibit 1006: Falkner U.S. 2005/00171544 ("Falkner"), published on August 4, 2005. Falkner is §102(b) prior art.

**Exhibit 1010:** Duncan U.S. 2009/0228048 A1 ("Duncan"), published on September 10, 2009, was filed on March 9, 2009 as U.S. Patent Application No. 12/400,071 (EX1025, "Duncan Non-Provisional") and claims priority to U.S. Provisional Application No. 60/606,334 (EX1016, "Duncan Provisional"), which was filed on March 10, 2008.

The content of the Duncan Non-Provisional is identical or substantially identical to Duncan (as published), including the same abstract, figures, claims, and fifty-four paragraphs of written description. (*Compare* EX1010 *with* EX1025, STROST00012623-12650; EX1002, ¶100). The Duncan Non-Provisional, having been later published pursuant to 35 U.S.C. § 122(b), is therefore available as prior art under pre-AIA 35 U.S.C. § 102(e)(1) with a priority date of at least March 9, 2009.

To the extent OsteoMed attempts to claim an invention date earlier than March 9, 2009, the Duncan Publication is also available as prior art under pre-AIA 35 U.S.C. § 102(e)(1) as of March 10, 2008, the date the provisional application was filed. As described in detail in the Gall Declaration, the Duncan Provisional (1) fully supports the relevant subject matter relied upon herein within the meaning of 35 U.S.C. § 112(1), and (2) describes and enables representative claims of Duncan. (Ex. 1002, ¶¶101-102). Moreover, Petitioners have included parallel citations to Duncan and the Duncan Provisional in their invalidity analysis. (*See infra* at Section

VI.B.2). Duncan is therefore entitled to the priority date of the Duncan Provisional.

MPEP § 2136.03 pt. III (citing Amgen Inc. v. Sanofi, 872 F.3d 1367, 1380 (Fed. Cir.

2017); Dynamic Drinkware, LLC v. Nat'l Graphics, Inc., 800 F.3d 1375 (Fed. Cir.

2015)). Accordingly, Duncan is prior art to the 716 patent at least under pre-AIA 35

U.S.C. §102(e)(1) with a priority date of March 10, 2008. Duncan was not of record

during the prosecution of the 716 patent.

#### **B.** Grounds for Challenge

Petitioners request cancellation of the Challenged Claims on the following grounds:

Ground	Proposed Grounds for Rejection
1	Claims 15 and 21 are anticipated by Slater
2	Claims 15 and 21 are obvious over Falkner in view of Duncan

#### III. THE 716 PATENT

### A. Priority Date of the 716 Patent

The 716 patent was filed on May 5, 2016, and is a continuation of the 776 patent, filed on August 30, 2013, which is a continuation of the 608 patent, filed on April 28, 2009. The alleged priority date of the 716 patent is April 28, 2009.

### B. Subject Matter of the 716 Patent (EX1001)

The 716 patent is directed to a bone plate used with a transfixation screw for securing the bones of a joint together. (EX1001, 1:35-38).

Figure 2 illustrates bone plate 100 being used in conjunction with a transfixation screw 150 to repair a failed metatarsophalangeal joint in the foot. (EX1001, 4:25-27). In accordance with the 716 patent, transfixation screw 150 is



inserted through transfixation screw hole 102 into a first bone 104a and a second bone 104b. (EX1001, 4:39-43). Figure 3 illustrates that the bone plate 100 includes at least one attachment point 128 for attaching first end 126a to first bone 104a, and at least one attachment point 128 for attaching second end 126b to second bone 104b. (EX1001, 7:44-48). The bone plate 100 further includes a bridge portion disposed between the first end and the second end to span across joint 106. (EX1001, 7:48-50). "Since bridge portion 130 is configured to span across joint 106, it is typically defined by an unbroken section of spine 124 that is free of voids such as positioning holes or screw holes that could potentially reduce the bending strength of bridge portion 130." (EX1001, 8:28-32). In the claimed embodiments, bridge portion 130

includes "a thickened section 136 of bone plate 100 to increase the bending strength of bridge portion 130." (EX1001, 8:33-35).

Figures 2 and 3 also illustrate that the bone plate 100 further includes flared hips 148 adjacent to angled transfixation screw hole 102. (EX1001, 10:27-29). The 716 patent explains that, "to help a surgeon precisely position the entry point for transfixation screw 150 onto a desired location on bone 104a, the entry point for transfixation screw 150 (e.g., the center of the bottom side of transfixation screw hole 102) may reside directly in between the widest portion of flared hips 148. Accordingly, by positioning the widest portion of hips 148 directly adjacent to the desired location for transfixation screw 150 on bone 104a, the surgeon may confidently position the entry point for transfixation screw 150 at the desired location, even when the entry point is out of sight. Flared hips 148 may also increase the strength of bone plate 100 around transfixation screw hole 102, lessening the chance of plate deformation or breakage." (EX1001, 10:43-56).

#### C. Prosecution History of the 716 Patent (EX1018)

#### 1. Prosecution History of the 608 Parent Patent

On April 28, 2009, Patent Owner filed its original application with claims generally directed to a system including a bone plate and a transfixation screw for securing two discrete bones together across a joint. (EX1004, OSTEOMED 0001591-1632.)

The Examiner rejected original application claims 1-15 under § 102(b) as anticipated by Grady US2005/0010226 (EX1011) and rejected original claims 11 and 16 as unpatentable over Grady in view of Strnad. (EX1004. OSTEOMED 0001764-65). Without amending the claims, Patent Owner attempted to distinguish Grady on the basis that "Grady discloses a bone plate dimensioned and configured for internal fixation of two portions of a single bone, which has been fractured" and that Grady "merely shows a screw passing through a single bone" instead of "at a trajectory configured to pass through two bones," as claimed. (EX1004, OSTEOMED 0001796) (emphasis in original). With respect to claim 16, Patent Owner argued that Strnad disclosed an orthopedic plate having asymmetric lobes and thus did not disclose the elements of claim 16. (EX1004, OSTEOMED 0001798). The Examiner thereafter issued a Final Rejection, noting that Grady could be used with a two bone fracture, and that Strnad expressly discloses that "the plate may be straight, or even symmetrical from the top view." (EX1004, OSTEOMED 0001819-21).

Thereafter, Patent Owner amended the independent claims to emphasize that the first and second ends of the plate comprise inner surfaces configured to substantially conform with a geometry of a first bone and second bone. (EX1004, OSTEOMED\_0001836, OSTEOMED\_0001839). Patent Owner then re-argued that "Grady merely discloses a bone plate dimensioned and configured for fixing two

portions of a single bone" and did not include the first and second inner surfaces configured to substantially conform with a geometry of a first and second bone as newly claimed. (EX1004, OSTEOMED-0001844-47).

Once again, the Examiner rejected the claims as anticipated by Grady, stating that Grady teaches a bone plate conforming to the surface of the bone. (EX1004, OSTEOMED\_0001858-59). The Examiner also maintained his rejection of claims 11 and 16 as unpatentable over Grady in view of Strnad. (EX1004, OSTEOMED\_0001860-61).

In response, Patent Owner amended independent claim 1 to recite "at least a portion of said bridge portion having a thickness greater than at least a portion of the thickness of either the first end or the second end" and to specify that the transfixation screw extends through the first discrete bone, through the joint, and into the second discrete bone "so as to absorb tensile load when the second discrete bone is loaded relative to the first discrete bone thereby transferring tensile load from the second discrete bone, through the screw into said head and said bridge portion." (EX1004, OSTEOMED 0001879-80, OSTEOMED 0001886-87). Patent Owner made similar amendments independent claim 11. to (EX1004, OSTEOMED 0001881). Following these amendments, the claims were allowed without further discussion. (EX1004, OSTEOMED 0001892-99).

#### 2. Prosecution History of the 716 Patent

The continuation application that issued as the 716 patent was filed on May 5, 2016. The original patent application included three independent claims generally directed to a system including a bone plate and a transfixation screw for securing two discrete bones together across a joint (application claim 1) and a plate with a transfixation screw hole for securing bones together across a joint (application claim 1) and a plate with a claims 11 and 17). (EX1018, OSTEOMED\_0002352-56).

On May 16, 2016, the Patent Owner filed a first preliminary amendment under 37 C.F.R. § 1.115. (EX1018, OSTEOMED\_0002379-87). In relevant part, the Patent Owner amended original claim 1 removing the language "once the plate is placed across the joint." (EX1018, OSTEOMED\_0002381). On March 9, 2017, the Patent Office issued its first office action. The Examiner rejected original claims 1-15 on the ground of nonstatutory double patenting as being unpatentable over claims 1-10 of the 608 patent and over claims 1-15 of the 776 patent. (EX1018, OSTEOMED\_0002418-23).

On June 9, 2017, the Patent Owner responded to the Examiner's March 9, 2017 rejection by filing a terminal disclaimer related to the 608 and 776 patents. (EX1018, OSTEOMED\_0002447-55). On July 12, 2017, the Examiner issued a Notice of Allowance. (EX1018, OSTEOMED\_0002461).

### D. The Challenged Claims of the 716 Patent

Challenged claims 15 and 21 are identical, except for the independent claims

from which they each depend. The challenged claims recite as follows:

Claims 15 and 21 of the 716 Patent		
15.1/21.11	The plate of claim [10/16], further comprising a first flared hip on a first side of the plate and a second flared hip on a second side of the plate,	
15.2/21.2	the flared hips comprising two generally parabolic wings extending laterally from the spine and being symmetrically opposed to one another about the transfixation screw hole.	

Challenged claims 15 and 21 depend from independent claims 10 and 16, respectively, which recite:

Claims 10 and 16 of the 716 Patent		
10.P/16.P	A plate for securing two discrete bones together across an intermediate joint, comprising:	
10.1/16.1	an elongate spine having: a first end comprising: at least one fixation point for attaching the first end to a first discrete bone on a first side of a joint; and a first inner surface configured to substantially conform with a geometry of the first bone;	
10.2/16.2	a second end comprising: at least one fixation point for attaching the second end to a second discrete bone on a second side of the	

<sup>&</sup>lt;sup>1</sup> For ease of reference and presentation, Petitioners have separately numbered each element of the asserted dependent claims, including the elements of the underlying independent claims.

	joint; and a second inner surface configured to substantially conform with a geometry of the second bone; and
10.3/16.3	a bridge portion disposed between the first end and the second end; and
10.4/16.4	a transfixation screw hole disposed along the spine, the transfixation screw hole comprising an inner surface configured to direct a transfixation screw through the transfixation screw hole such that the transfixation screw extends alongside the bridge portion at a trajectory configured to pass through a first position on the first bone and a second position on the second bone, enabling said screw to absorb tensile load when the second bone is loaded permitting transfer of the tensile load through said screw into said bridge,
10.5/16.5	wherein at least a portion of said bridge portion and said transfixation screw hole has a [depth/thickness] greater than at least a portion of said first and second ends.

Independent claims 10 and 16 of the 716 patent are the subject of IPR2021-1452, which was filed on August 30, 2021. Petitioners rely on the same analysis set forth in IPR2021-1452 explaining that claims 10 and 16 of the 716 patent are anticipated by both Slater and Falkner. In the present Petition, Petitioners set forth an analysis of how dependent claims 15 and 21 are anticipated by Slater (Ground 1) and rendered obvious by Falkner in view of Duncan (Ground 2). For the convenience of the Board and because challenged claim 15 depends on independent claim 10 while challenged claim 21 depends on independent claim 16, Petitioners also include the previous analysis of claims 10 and 16.

#### E. Level of Skill in the Art

A POSITA at the time of the alleged invention would be an individual having at least a bachelor's degree in engineering with at least two years of experience in the field, such as experience with the design of surgical implants, or a clinical practitioner with a medical degree and at least two years of experience as an orthopedic surgeon. (EX1002, ¶35-39).

#### **IV. CLAIM CONSTRUCTION**

Claim terms should generally be construed according to their ordinary and customary meaning, which is the meaning they would have to a POSITA at the time of invention, in light of the specification and file history. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). Where the construction of specific terms is not necessary to resolve the issues before the Board, the Board need not construe those terms, "leaving that question to a later forum where the issue is determinative." *Leo Pharm. Prods. v. Rea*, 726 F.3d 1346, 1353 (Fed. Cir. 2013); *see also Nidec v. Zhongshan*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (noting that the Board need only construe terms "that are in controversy, and only to the extent necessary to resolve the controversy").

Petitioners have applied the ordinary and customary meaning of each claim term throughout the Petition in light of the 716 patent specification and file history. In particular, Petitioner clarifies that the claim term "flared hips" from claims 15 and

21 means "a widened section of the bone plate." This is supported by the 716 specification, which expressly states that "[f]lared hips may generally be defined by a widened section of bone plate 100." (EX1001 at 10:29-30). The 716 specification further notes that the flared hips are "adjacent to transfixation screw hole 102." (EX1001 at 10:27-29).

#### V. SUMMARY OF THE PRIMARY PRIOR ART REFERENCES

Challenged claims 15 and 21 of the 716 patent claims are directed to features well known in the art prior to its priority date of April 28, 2009. The prior art references relied upon herein are directed to the same field as the 716 patent, namely, bone plates for use in fusing bone parts in the extremities (feet or hands), and thus are analogous art. (EX1002, ¶¶84-85, 90-92, 97-98, 161). Petitioners are not aware of any secondary considerations supporting a finding of nonobviousness.

#### A. Slater

Slater, entitled "Ankle Fusion Plate," is directed to a plate for immobilizing a joint by fusion of the adjacent bones ("arthrodesis"). (EX1005, Abstract). While Slater describes a bone plate for ankle fusion, the reference specifically contemplates that its invention "may be applied to the repair/fusion of other bones requiring axial alignment." (EX1005, 6:34-7:2).

The Slater plate includes a first end (30) and a second end (5) having inner surfaces that "conform to the typical geometry of the anatomical region." (EX1005,



9:10-12). In particular, the first end 30 comprises at least one opening (33, 34, 35) configured to allow fixation screws (36, 37, 38) to pass through to attach to the tibia 4. The second end 5 comprises at least one opening (11, 12) configured to allow fixation screws (9, 10) to pass through to attach to the talus 3. Portion 20 of the plate includes an

opening 26 and a formation 27 configured to allow a screw 25 to be implanted at an angle within a predetermined allowable angular range to pass through tibia 4 and talus 3. (EX1005, 11:19-22).

Slater discloses that "the plate depth changes at different locations. Preferably, the depth at the beginning and end points of the Lshaped contour over the ankle joint in the second region will be at its maximum thickness." (EX1005, 8:31-35). "The plate will taper at least one but preferably two



different points of the plate. (EX1005, 9:3-4). As can be seen at left, the unbroken portion of the plate that spans the ankle joint is thickened.

During the prosecution of the PCT application corresponding to the 608 parent patent, Slater was cited by the International Search Authority ("ISA") as disclosing the subject matter of original application claims 1-5, 10-14 and subsequently cited by Patent Owner during prosecution of the 776 and 716 patents. (EX1004, OSTEOMED 0002153; OSTEOMED 0001738-41; EX1017, EX1018, OSTEOMED 0002402). However, the Examiner did not rely on Slater during the prosecution of any of the patents, nor did he substantively address the international search report. The Office materially erred in failing to consider Slater as the basis for any prior art rejection, especially after Patent Owner amended its 608 patent claims to require that the claimed "bridge portion" has a thickness greater than at least a portion of either or both of said first and second ends," a feature that is clearly described in Slater, as discussed above, in the context of a bone plate for use across a joint. (See Section III.C.1).

#### B. Falkner

Falkner is directed to a bone plate with toothed aperture for use in fixing bone fractures or to fuse bones across a joint. (EX1006, ¶¶21, 27-29). Falkner was not cited during the prosecution of the 716 patent, and thus was not considered by the Office.

Falkner teaches a bone plate 22 that "may be sized and shaped to conform to particular portions of a bone (or bones)." (EX1006, ¶¶33-34). Falkner further



discloses that the "plate 22 may span a joint, such as joint 30 between tibia 26 and talus 32, among others." (EX1006,  $\P21$ ). The Falkner plate includes a first end (first plate portion 34) and a second end (second plate portion 36) secured to the bone(s) using bone screws that "may be placed into bone from any suitable number of openings of the bone plate." (EX1006,  $\P23-24$ , 36-38). Threaded fastener 42 extends angularly through a bone fracture or a

joint. (EX1006,  $\P$ 24). Falkner further recognizes that "[t]hickness may be varied within the plates," recognizing that the plate can be "thicker to increase structural stability," and that "plates may be thicker and thus stronger in regions where they may not need to be contoured...." (EX1006,  $\P$ 35).

#### C. Duncan

Duncan is directed to a joint fixation system including precontoured and angled joint fixation plates that allow for easier and more reliable fusion of joints in the hand. (EX1010, ¶13; EX1016, ¶11). Duncan was not cited during the prosecution of the 716 patent or any of its predecessor patents, and thus was not considered by the Office.

As shown in Figure 2, Duncan discloses a bone plate comprising an elongated

plate having screw holes (16, 18, 22, 26, 28, 32) at both the proximal (24) and distal (34) sections of the plate. (EX1010, ¶42; EX1016, ¶28). Duncan explains that screw holes 16, 18, 28, and 32 can be configured to accommodate locking or nonlocking screws. (*Id.*). Moreover, Duncan discloses that screw 62 is angled distally when inserted in the third screw hole 22 while screw 64 is angled proximally when inserted in the fourth screw hole 16. (EX1010, ¶44; EX1016, ¶30). The Duncan bone plate is "widened laterally at an intermediate section 72 where the proximal section 24 and the distal section 34 of the joint fixation plate 12 are connected such that neither



of the third screw 62 and the fourth screw 64 will interfere with the other when inserted into the proximal phalanx 13 and the intermediate phalanx 14." (EX1010, ¶45; EX1016, ¶31).

### VI. THERE IS A REASONABLE LIKELIHOOD THAT CLAIMS 15 AND 21 ARE UNPATENTABLE

#### A. Ground 1: Slater Anticipates Challenged Claims 15 and 21

For the reasons set forth below, Slater anticipates challenged claims 15 and 21.

### 1. Slater Discloses Every Element of Independent Claims 10 and 16

Challenged claims 15 and 21 are identical except that claim 15 depends from independent claim 10, and claim 21 depends from independent claim 16 of the 716 patent. Independent claims 10 and 16 are identical except for the last claim element, where the claim terms "depth" and "thickness" are substituted for each other. To avoid redundancy, Petitioners will analyze independent claims 10 and 16 together. As shown below, in the accompanying Declaration, and in earlier-filed IPR2021-1452, Slater discloses all elements of claims 10 and 16 of the 716 patent. (EX1002, ¶¶107-118; 125-136).

# a. Preamble (claims 10 and 16): *"a plate for securing two discrete bones together across an intermediate joint"*

To the extent the preamble is limiting, Slater includes a plate for securing two discrete bones together across an intermediate joint. (EX1002,  $\P\P108$ , 126).

Slater is directed to an ankle fusion plate for arthrodesis. (EX1005, Abstract). "Arthrodesis" means "the surgical immobilization of a joint so that the bones grow solidly together." (EX1020, p. 51).

Figure 1 of Slater illustrates (1) a fusion plate 1 being used to secure three discrete bones (tibia 4, talus 3, and calcaneous 28) across two joints and (2) an

alternate embodiment where fusion plate 1 is used to secure two discrete bones (tibia 4 and talus 3, within the oval annotated into Figure 1) together across a single joint between the two bones. (EX1005, 12:3-4, 6:17-7:2, 7:19-21, 8:3, 8:13-28, 9:28-30, 11:1-4, 12:3-10, 13:5-9, 14:1-



30, 11:1-4, 12:3-10, 13:5-9, 14:1-8, 15:12-16, 16:6-9, 16:28-30, 17:3-10, 20:14-16, 21:6-20, 26:14-23, 22:17-23:13, 23:24-25, 23:26-24:7).

### b. 10.1/16.1: "an elongate spine having: a first end comprising..."

As shown in Figures 1, 5, and 6, Slater discloses a bone plate comprising an elongate spine having a first end (proximal end of portion 30 (of plate 1) or proximal end of portion 95 (of plate 80)) comprising at least one fixation point (fixation points 35, 34, 33 or fixation points 98, 99) for attaching the first end (proximal end of portion 30 or proximal end of portion 95) to a first discrete bone (tibia 4) on a first side of a joint. (EX1002, ¶¶109-110, 127-128; EX1005, 12:22-23 (illustrated in Fig. 2) ("Openings 33, 34 and 35 are preformed and receive a first preferably countersunk

screw type such as that shown in figure 3."), 13:28-30 (illustrated in Fig. 5) ("Portion 95 includes openings 98 and 99 which receive fastening screws each preferably in the same orientation and which engage the tibia."), Fig. 6).



(EX1005, Figs. 1, 5-6).

Moreover, as shown in Figure 1, the first inner surface (31 or 96) is configured to substantially conform with a geometry of the first bone (tibia 4). (EX1002,  $\P$ ¶111, 129).



(EX1005, Fig. 1).

For example, Slater expressly discloses "the plates are configured to **generally conform to the anatomic contours** of the ankle joint." (EX1005, 9:14-15; 9:15-18, 11:28-29, 12:21-22, 13:27-28,15:12-14, 16:32-34, 17:2-3, 23:15-17). Slater even includes a claim that expressly recites a kit "wherein the **plate geometry** is arranged to at least partially **conform to the shape of the anatomy of bones** to which the plate is fixed." (EX1005, 23:15-17).

### c. 10.2/16.2: "a second end comprising..."

As shown in Figures 1 and 6, the second end in Slater (distal end of portion 5 or 81) includes at least one fixation point (11, 12 or 84, 85) for attaching the second end (distal end of portion 5 or 81) to a second discrete bone (talus 3) on a second side of a joint. (EX1002, ¶¶112, 130; EX1005, 11:8-10, 13:10-12).



(EX1005, Figs. 1, 6).

In addition, as shown in Figure 1, the second end in Slater (distal end of portion 5 or 81) includes a second inner surface (8 or 83) configured to substantially conform with a geometry of the second bone (talus 3). (EX1002,  $\P$ ¶113, 131).



(EX1005, Fig. 1).

As discussed above, Slater expressly discloses that the various portions of the plate "will preferably resemble and conform to the typical geometry of the anatomical region" and that "the plates are configured to generally conform to the anatomic contours of the ankle joint." (EX1005, 9:8-15, 11:7-8, 13:9-10, 14:19-22, 16:32-34, 17:2-3, 23:15-17).



As shown in Figures 1, 6, and 7, Slater includes a bridge portion (portions of 5 and 20 or portions of 81 and 90) disposed between the first end (proximal end of portion 30 or portion 95) and the second end (distal end of portion 5 or portion 81). (EX1002, ¶¶114, 132).





(EX1005, Figs. 1, 6, 7).

#### e. 10.4/16.4: "a transfixation screw hole disposed..."

As shown in Figures 1, 6 and 7, Slater includes a transfixation screw hole (opening 26 or 93) disposed along the spine. (EX1002, ¶¶115, 133).



<sup>(</sup>EX1005, Figs. 1, 6, 7).

While Slater does not explicitly identify openings 26 and 93 as "transfixation screw holes," Slater's disclosure makes it clear that openings 26 and 93 each receive a fixation screw that passes through those openings so that the screw is implanted at an angle. (EX1005, 11:19-21, 13:21-24).

As shown in Figures 1 and 7, Slater includes a transfixation screw hole (26 or 93) that comprises an inner surface (unnumbered in Slater's drawings) configured

to direct the transfixation screw (25) through the transfixation screw hole such that the transfixation screw extends alongside the bridge portion (portions of 5 and 20 or portions of 81 and 90) at a trajectory configured to pass through a first position on the first bone (tibia 4) and a second position on the second bone (talus 3) once the plate (1 or 80) is placed across the joint. (EX1002, ¶¶116, 134; EX1005, 11:19-25, 13:21-25). Figure 1 shows three separate exemplary angles for the transfixation screw 25, including one example where the screw 25 passes through a first position on a first discrete bone (tibia 4) and a second position on a second discrete bone (talus 3). (EX1002, ¶¶116, 134).



(EX1005, Figs. 1, 7).

In Slater, when the fixation screw (25) advances through the opening (26) and into the second bone (talus 3), the second bone (talus 3) is loaded relative to the first discrete bone (tibia 4), and tensile load is transferred from the second bone (talus 3), through the screw (25) and into the bridge portion (portions of 5 and 20 or portions of 81 and 90) of the plate. (EX1002, ¶¶117, 135). This transfer occurs because the threads on the screw and the portion of the screw head that abuts the inner surface of the screw hole act essentially as a vise to the second bone and the plate, with the first bone held in between. (EX1002, ¶¶117, 135; EX1005, 11:19-25, 12:32-13:3, 13:21-24).

### f. 10.5/16.5: "wherein at least a portion of said bridge portion and said transfixation screw hole has a [depth/thickness]..."

The term "depth" appears nowhere in the specification or prosecution history of the 716 patent other than in the claims. However, the patent specification repeatedly discusses the "thickness" of the disclosed bone plate. (EX1001, 8:32-52). In light of the teachings of the 716 patent as set forth in the specification and prosecution history, a POSITA would understand that the claim term "depth" to refer to the "thickness" of the bone plate. (EX1002, ¶118, 136).

In any event, Slater uses the terms "depth" and "thickness" interchangeably to refer to "the dimension measured from the bone engaging face to an opposite outer face." (EX1005, 8:31-35; 9:2-3; 9:5-9). Slater specifically discloses that the portion

of the plate adjacent the ankle joint will preferably be the thickest part of the plate (with the greatest depth), while the portions towards the ends of the plate may be thinner. (EX1005, 8:25-26, 8:32-9:6). Slater recognizes that the plate should be at its "maximum thickness" at the "region that the highest loading will occur in normal use." (EX1005, 14:19-23). Dependent claim 29 expressly recites a kit "wherein the plate thickness varies at different locations and wherein the portion of the plate which lays over the ankle joint has maximum thickness." (EX1005, 34:17-19).

As shown in Figures 5 and 7, at least a portion of Slater's bridge portion (portions of 5 and 20 or portions of 81 and 90) and the portion of the plate including the transfixation screw hole (26 or 93) have a depth or thickness greater than at least a portion of said first and second ends (proximal end of portion 30 or 95, distal end of portion 5 or 81). (EX1002, ¶¶118, 136).



(EX1005, Figs. 5, 7). Indeed, the first and second ends of the Slater bone plate are tapered. As such, both the bridge portion and the portions of the plate surrounding the transfixation screw hole have a greater depth (thickness) than "at least a portion

of" the tapered ends. (EX1002, ¶¶118, 136; EX1005, Figs. 5, 7, 8:25-26, 8:32-9:6, 14:19-23, 24:17-19).

### 2. Dependent Claims 15 and 21

As discussed above, Slater discloses each and every element of independent claims 10 and 16 of the 716 patent. Slater also discloses each and every element of dependent claims 15 and 21, and thus anticipates claims 15 and 21 under 35 U.S.C. § 102. (EX1002, ¶¶120,138).

### a. 15.1/21.1: "The plate of claim [10/16], further comprising a first flared hip on a first side of the plate and a second flared hip on a second side of the plate"

As shown below, Figure 2 of Slater shows a front elevation view of plate 1 further comprising a first flared hip on a first side of the plate 1 and a second flared hip on a second side of the plate 1. (EX1002, ¶122-123, 138; EX1005, 12:12-25, Fig. 2).



### b. 15.2/21.2: "the flared hips comprising two generally parabolic wings extending laterally from the spine and being symmetrically opposed to one another about the transfixation screw hole"

As shown in Figure 2, the flared hips of Slater comprise two generally parabolic wings extending laterally (sideways) from the elongate spine. (EX1002, ¶¶124, 138). As can be seen relative to the center line shown in Figure 2, the flared hips are symmetrically opposed to one another about the transfixation screw hole 27. (EX1002, ¶¶124, 138).



### B. Ground 2: Falkner in View of Duncan Renders Obvious Claims 15 and 21 of the 716 Patent

For the reasons set forth below, challenged claims 15 and 21 are rendered obvious by Falkner in view of Duncan.

### 1. Falkner Discloses Every Element of Independent Claims 10 and 16

As an initial matter and as shown below, in the accompanying Declaration, and in earlier-filed IPR2021-1452, Falkner discloses every element of independent claims 10 and 16 of the 716 patent. (EX1002, ¶¶139-151, 163-174).

### a. Preamble: "a plate for securing two discrete bones together across an intermediate joint"

To the extent the preamble is limiting, Falkner discloses a system 20 for securing two discrete bones (tibia 26 and talus 32) together across an intermediate joint 30 between the tibia 26 and talus 32. (EX1002, ¶¶141, 164).

While Figure 1 of Falkner shows an exemplary system for fixing bones, the Falkner

disclosure expressly contemplates that "the bone plate may be positioned on and/or in any suitable <u>bone(s)</u> to span any natural or artificial discontinuity within a bone or between bones. In the present illustration, plate 22 is secured to a distal end (metaphyseal) region of a tibia bone 26 and spans fracture 28. <u>In other examples, plate 22 may span</u> <u>a joint, such as joint 30 between tibia 26 and talus 32,</u> <u>among them.</u>" (EX1006, ¶21) (emphasis added); (EX1006, ¶¶27-29, 62).



### b. 10.1/16.1: "an elongate spine having: a first end comprising..."

As shown in Figures 1 and 2, Falkner discloses a bone plate 22 comprising an elongate spine (22) having a first end comprising at least one fixation point (50) for attaching the first end to a first discrete bone (tibia 26) on a first side of a joint (30). (EX1002, ¶¶142-143, 165-166).



(EX1006, Figs. 1, 2).

For example, Falkner explains that "[e]ach bone plate portion may define one or more openings for receiving fasteners, such as bone screws, that secure the plate portions to bone." (EX1006, ¶19). Falkner further explains with respect to Figure 2 that external portion 34 "<u>may include a first set of one or more openings 50</u>, a second set of one or more openings 52, and an oblique opening 44 disposed between the first and second sets." (EX1006, ¶68; ¶¶19, 23, 33, 36, 39, 44).

As discussed in Section VI.B.1.a., Falkner specifically contemplates that "plate 22 may span a joint, such as joint 30 between tibia 26 and talus 32." (EX1006, ¶21). In that situation, the plate 22 would be placed across the joint 30 and bone screws 40 may be placed into the first discrete bone (tibia 26) through the openings 50 at the first end of the plate 22. (EX1002, ¶¶143, 166).

As shown in Figure 1, the first end of Falkner includes a first inner surface configured to substantially conform with a geometry of the first bone (tibia 26). (EX1002, ¶¶144, 167; EX1006, ¶42, Fig. 1).



Falkner specifically discloses that "[t]he

external plate portion may be contoured to follow an exterior surface of the bone." (EX1006, ¶23). Falkner further explains that "[t]he bone plates (or exterior plate portions, see Section II) may include inner (bone-facing) and outer (bone-opposing) surfaces. One or both of these surfaces may be contoured generally to follow an exterior surface of a target bone (or bones) for which a bone plate is intended, so that the bone plate maintains a low profile and fits onto the bone(s). For example, the inner surface of a plate (or of an exterior plate portion) may be generally complementary in contour to the bone surface." (EX1006, ¶34). To the extent that the Falkner plate 22 spans joint 30, the first inner surface would be configured to substantially conform with a geometry of the first bone (tibia 26). (EX1002, ¶144, 167). Of course, if the plate 22 was used to span a different joint, Falkner teaches that the first inner surface would substantially conform with a geometry of the first bone of that particular joint "so that the bone plate maintains a low profile and fits onto the bone(s)." (EX1006, ¶34).

#### c. 10.2/16.2: "a second end comprising..."

As shown in Figures 1 and 2, Falkner discloses a bone plate 22 comprising an elongate spine having a second end comprising at least one fixation point (52, seen in Fig. 2) for attaching the second end to a second bone (talus 32) on a second side of the joint 30. (EX1002, ¶145, 168; EX1006, ¶21, 36, 39). ).



(EX1006, Figs. 1-2).

Similar to the discussion above relating to the first end, Falkner explains that external portion 34 "may include a first set of one or more openings 50, <u>a second</u> <u>set of one or more openings 52</u>, and an oblique opening 44 disposed between the first and second sets." (EX1006, ¶68). If the Falkner plate was used to span a joint between tibia 26 and talus 32 (as specifically contemplated at ¶¶21, 27-29, 62), the plate 22 would be placed across the joint 30 and bone screws 40 may be placed into first discrete bone (tibia 26) through the openings 50 at the first end of the plate 22

and a bone screw 40 may be placed into the second discrete bone (talus 32) through the opening 52 at the second end of the plate 22. (EX1002,  $\P$ 145, 168).

Falkner discloses that its second end comprises a second inner surface configured to substantially conform with a geometry of the second bone (talus 32) when the plate is used to span a joint. (EX1002, ¶¶146, 169; EX1006, Fig. 1).



Falkner expressly contemplates that "[t]he external plate portion may be contoured to follow an exterior surface of the bone." (EX1006, ¶23; ¶¶34, 42). When Falkner is configured to span a joint between two discrete bones, the plate would be placed across the joint and the second inner surface would be configured to substantially conform with a geometry of the second bone (talus 32). (EX1002, ¶¶146, 169).

#### d. 10.3/16.3: "a bridge portion disposed between the first end and the second end"

As shown in Figures 1 and 2, Falkner includes a bridge portion disposed between the first end and the second end. (EX1002,  $\P$ 147, 170; EX1006,  $\P$ 22, 28, 29, 31, 33, 35, 44, 45, 54, 68, 69).



(EX1006, Figs. 1-2).

e. 10.4/16.4: "a transfixation screw hole disposed..."

As shown in Figure 2, Falkner discloses a transfixation screw hole (44) disposed along the spine (22), the transfixation screw hole comprising an inner surface configured to direct a transfixation screw (42) through



the screw hole (44). (EX1002, ¶¶148-149, 171-172; EX1006, Fig. 2, ¶¶68, 71-72, 78).

When the Falkner bone plate is configured to span a joint 30 such as tibia 26 and talus 32, then the oblique opening 44 is a transfixation screw hole comprising

an inner surface configured to direct a transfixation screw 42 through the oblique opening 44 such that the transfixation screw 42 extends alongside the bridge portion at a trajectory configured to pass through a first position on the first bone (tibia 26) and a second position on the second bone (talus 32). (EX1002, ¶¶149, 172; EX1006, ¶¶21, 27, 28, 29).



In that configuration, when the second bone (talus 32) is loaded, tensile load



is transferred through the screw and into the bridge portion of the plate. (EX1002, ¶¶150, 173). For example, Falkner explains that "[w]ith the head of the screw engaged with the external plate portion, further rotation of screw 42 and thus further advancement of threaded region 64 into/through the aperture applies a tension to the plate." (EX1006, ¶¶70, 71).

### f. 10.5/16.5: "wherein at least a portion of said bridge portion and said transfixation screw hole has a [depth/thickness]..."

At least a portion of the Falkner bridge portion and the transfixation screw hole has a depth or thickness greater than at least a portion of said first and second ends. (EX1002, ¶¶151, 174). As discussed above in Ground 1, a person of ordinary skill in the art at the time of the invention would understand that the claim term "depth" refers to the "thickness" of the bone plate. (EX1002, ¶¶118, 136, 151, 174).

According to Falkner, "[t]he thickness of the bone plates may be defined by the distance between the inner and outer surfaces of the plates. The thickness of the plates may vary between plates and/or within the plates, according to the intended use." (EX1006, ¶35). Falkner expressly recognizes that "[t]hickness may be varied within the plates" and that "the plates may become thinner as they extend over protrusions" or "where soft tissue irritation is a greater concern," such as at the ends of the plate, or "thicker to increase structural stability." (EX1006, ¶¶32, 35). "In this way, the plates may be thicker and thus stronger in regions where they may not need to be contoured, such as along the shaft of the bone." (EX1006, ¶35).

As can be seen in Figure 1, at least a portion of the bridge portion and the transfixation screw hole (44) has a depth or thickness greater than at least a portion of said first and second ends. (EX1006, Fig. 1). In particular, the second end is described in the specification as an "internal portion" and is thinner at the end to



further contemplates reducing the thickness of the bone plate to minimize irritation of soft tissue in regions such as the "first end" of the plate. (EX1002, ¶¶151, 174; EX1006, ¶¶32, 35). Thus, Falkner teaches that the bridge portion and the portions of the plate surrounding the transfixation screw hole have a depth or thickness greater than at least a portion of the first and second ends. (EX1002, ¶¶151, 174).

In any event, as discussed in Section III.C., during the prosecution of the 608 parent patent, Patent Owner amended claim 1 to include the language "at least a portion of said bridge portion having a thickness greater than at least a portion of the thickness of either the first end or the second end" and amended claim 11 to include the language "wherein at least a portion of said bridge portion and said transfixation screw hole has a thickness greater than at least a portion of said first and second ends." (EX1004, OSTEOMED 0001879, OSTEOMED 0001881). In explaining

its amendments, Patent Owner represented that "the amended claims further recite that at least a portion of the bridge portion has a thickness greater than at least the portion of the thicknesses of either the first or second end," thus confirming that the amended claims were intended to have the same scope, at least with respect to the comparison of thicknesses between the bridge portion and either the first or second end. (EX1004, OSTEOMED 0001886).

#### 2. Dependent Claims 15 and 21

As discussed above, Falkner discloses each and every element of independent claims 10 and 16 of the 716 patent. Moreover, Duncan discloses each and every element of dependent claims 15 and 21, which recite that the claimed bone plate further comprises "a first flared hip on a first side of the plate and a second flared hip on a second side of the plate, the flared hips comprising two generally parabolic wings extending laterally from the spine and being symmetrically opposed to one another about the transfixation screw hole." (EX1002, ¶153, 176). Both Duncan and Falkner are directed to bone plates for use in fusing joints in the extremities (hands, feet, wrists, and ankles) and are thus analogous art. (EX1002, ¶161); In re Clay, 966 F.2d 656, 659 (Fed. Cir. 1992) ("If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his invention.").

As discussed below, dependent claims 15 and 21 are rendered obvious by Falkner in view of Duncan. (EX1002, ¶152-162, 175-176).

Duncan describes a joint fixation system useful for joints in the hand, including a bone plate having screw holes in its proximal and distal sections (24, 34). (EX1010, ¶42; EX1016, ¶28). The bone plate includes an angled proximal screw hole 22 and an angled distal screw hole 26 so that one screw is angled proximally when inserted into a distal screw hole and another screw is angled distally when inserted in a proximal screw hole. (EX1010, ¶44; EX1016, ¶30). As shown in Figure 2, the Duncan bone plate is "widened laterally" at an intermediate section 72 where the proximal section 24 and the distal section 34 are connected. (EX1010, ¶45; EX1016, ¶31).

As shown in annotated Figure 2, the intermediate section 72 of the bone plate includes a first flared hip on a first side of the plate and a second flared hip on a second side of the plate. (EX1002, ¶156, 176). The flared hips comprise two generally parabolic wings extending laterally from the spine (similar to flared hips 148 shown



in Figure 3 of the 716 patent). (EX1002, ¶¶156, 176). The flared hips are symmetrically opposed to one another about either the two angled screw holes 22, 26, or, when combined with Falkner, the transfixation screw hole (oblique opening 44 of Falkner). (EX1002, ¶¶156, 176).

As described in the Gall Declaration, it would have been obvious to a person of ordinary skill in the art at the time of the invention to combine the teaching of symmetrically flared hips of Duncan with the plate disclosed by Falkner. (EX1002, ¶¶158-162, 176). A person of ordinary skill in the art at the time of the invention would have understood that, in addition to selecting an appropriate material for the bone plate, bone plates can be strengthened by making the bone plate thicker and/or wider to counteract areas that experience high stress. (EX1002, ¶158).

Duncan explains that the joint fixation plate 12 is widened laterally at the intermediate section 72 such that neither the third screw 62 nor the fourth screw 64 "will interfere with the other when inserted into the proximal phalanx 13 and the intermediate phalanx 14." (EX1010, ¶45; EX1016, ¶31). As can be seen from Figure 2, however, even if the intermediate section 72 was not widened, the third screw 62 and fourth screw 64 would not interfere with one another. (EX1002, ¶157; EX1010, Fig. 2; EX1016, Fig. 2). A person of ordinary skill in the art would understand that widening the bone plate in the intermediate section 72 functions to

strengthen the bone plate in the area around the third and fourth screw holes 22, 26. (EX1002, ¶158; EX1006, ¶35; EX1010, ¶45; EX1016, ¶31).

Falkner discloses a bone plate that may be used to "span a joint, such as joint 30 between tibia 26 and talus 32, among others." (EX1006, ¶21). Falkner discloses screw 42 as being received in oblique opening 44 and threaded into toothed aperture 24 to provide intra-plate tension. (EX1006, ¶71). A person of ordinary skill in the art would understand that the inclusion of an angled hole such as oblique opening 44 in the plate results in more bone plate material being hollowed out of the plate as compared with perpendicular holes. (EX1002, ¶159). As a result, the area around the angled screw hole may require additional strength. (EX1002, ¶159).

While Falkner does not specifically disclose the use of flared hips symmetrically opposed to one another around an angled screw hole, Falkner acknowledges that its plates may be thicker and thus stronger in particular regions, and that the length and/or width of the bone plates may be varied according to intended use. (EX1006, ¶¶33, 35). A person of ordinary skill in the art would understand that, in addition to thickening the bone plate in the area around the angled screw hole, the bone plate can be widened in the area around the angled screw hole in order to provide additional support. (EX1002, ¶¶160, 161); *see KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) ("[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would

improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill."). Because the Falkner plate may be used on the medial side of the ankle, a person of ordinary skill in the art would have been motivated to further strengthen the bone plate while minimizing any patient discomfort by, for example, widening the area around the angled screw hole. (EX1002, ¶160).

Similarly, a person of ordinary skill in the art would have been motivated to choose a symmetric, parabolic shape for widening the Falkner bone plate to ensure that the stresses around the transfixation screw hole are evenly distributed. (EX1002, ¶162). Such a parabolic shape may be positioned around the angled screw hole in a manner in which the widest part of the parabolas coincide with the region that spans the joint, which helps the surgeon visualize how to position the plate over the joint. (EX1002, ¶162). A person of ordinary skill in the art would have had a reasonable expectation of success in combining the flared hips of Duncan with the Falkner plate to achieve the predictable result of strengthening the bone plate and providing visual cues to the surgeon to position the strongest part of the plate over the joint. (EX1002, ¶162); see, e.g., Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 1367 (Fed. Cir. 2008) (stating that the combination of references would yield what one would expect from such an arrangement because adding the elements of the second reference to the first reference would give the "resulting design exactly the same benefit" as the second reference); *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1241 (Fed. Cir. 2010) ("It is simply a matter of common sense that the sleeve used in Down, in a towing attachment quite similar to [the claims at issue], could be combined with [prior art a barbell lock] to address the known problem[s] [in the field].").

# VII. THE BOARD SHOULD REACH THE MERITS OF THIS PETITIONA. 35 U.S.C. § 325(d) Does Not Favor Denial of Institution

The Board applies a two-part framework in considering whether to exercise its discretion to deny institution under § 325(d). *Advanced Bionics, LLC v, Med-El Elektromedizinische Gerate GmbH*, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Fed. 13, 2020) (precedential). Institution should not be denied under § 325(d) because the same or substantially the same prior art and arguments presented in this Petition were not previously presented to the Office.

For example, while Slater was buried among the almost 200 prior art references presented to the Office during prosecution of the parent application, it were not substantively addressed by the Office or discussed by Patent Owner. *See* Section V.A. Neither Falkner nor Duncan was before the Office during prosecution of the 716 patent. Under these circumstances, the Board has declined to exercise its discretion to deny institution. *See, e.g., Cellco Partnership v. Huawei Device Co.,* IPR2020-01117, Paper 10 at 13 (P.T.A.B. Feb. 3, 2021) ("[T]he fact that Wen was

not the basis of rejection weighs strongly against exercising our discretion to deny institution under 35 U.S.C. § 325(d)."); *Apple Inc. v. Qualcomm Inc.*, IPR2018-01315, Paper 7 at 25 (P.T.A.B. Jan. 18, 2019) ("The fact that neither AAPA nor Majcherczak was the basis of rejection weighs strongly against exercising our discretion to deny under 35 U.S.C. § 325(d)"). *See also Oticon Medical AB v. Cochlear Limited*, IPR2019-00975, Paper 15 at 20 (P.T.A.B. Oct. 16, 2019) (precedential) (declining to exercise institution where one prior art reference was new and noncumulative).

Moreover, the present Petition is not redundant of Petitioners' earlier-filed petition for *inter partes* review of the 716 patent in IPR-2021-01452. Petitioners' earlier-filed petition challenges claims 1-6, 8-13, and 16-19, which were asserted by Patent Owner against Petitioner Stryker in the underlying Illinois litigation. Recently, on October 11, 2021, Patent Owner served preliminary infringement contentions against Petitioner Wright Medical in the co-pending district court litigation in Delaware, asserting many of the same claims asserted against Petitioner Stryker, with the addition of newly asserted claims 15 and 21 of the 716 patent. The present Petition challenges only the newly asserted claims, which includes limitations directed to "flared hips," a feature not included in any of the previously asserted claims. The Board should decline to exercise its discretion under § 325(d) because the claims challenged in the present Petition are different than the claims

challenged in the earlier petition. *See Netflix, Inc. v. Realtime Adaptive Streaming LLC*, IPR2018-01630, Paper 13 at 9 (P.T.A.B. Apr. 19, 2019) (declining to exercise discretion under § 325(d) because "the claims challenged in the different petitions are not the same."); *Volkswagen Grp. v. Carucel Invs., L.P.*, IPR2019-01573, Paper 7 at 5 (P.T.A.B. Jan. 22, 2020) ("We are, instead, persuaded by Petitioner's argument that a second petition was warranted by Patent Owner's delayed assertion of claims 56–59."); *see also Ford Motor Co. v. Paice LLC*, IPR2015-00799, Paper 11 at 6–7 (P.T.A.B. Nov. 9, 2015) (declining to exercise discretion because the later petition challenges different dependent claims from the same patent).

The present Petition raises new prior art and arguments that are unique to claims 15 and 21 ("... a first flared hip on a first side of the plate and second flared hip on a second side of the plate, the flared hips comprising two generally parabolic wings extending laterally from the spine and being symmetrically opposed to one another about the transfixation screw hole"). Here, Duncan was not included in any of the grounds for invalidating the claims challenged in the first petition. In contrast, the present Petition relies on Falkner in view of Duncan as a grounds for rendering obvious claims 15 and 21. While both the earlier petition and the present Petition include anticipation arguments based on Slater and Falkner with respect to independent claims 10 and 16, the present arguments relating to dependent claims 15 and 21 are not redundant of any of the arguments addressed in the earlier petition.

Because this Petition challenges newly asserted claims that were not challenged in the first petition, this is a situation where "the Board recognizes that there may be circumstances in which more than one petition may be necessary. . ." Trial Practice Guide Update, pg. 26. *See also Fisher & Paykel Healthcare Ltd. v. ResMed Ltd.*, IPR2017-01789, Paper 7 at 16 (P.T.A.B. Jan. 25, 2018) (declining to exercise discretion where petitioner challenged different claims that included an "additional limitation sufficiently significant to warrant addressing the merits of this Petition"). Thus, the Board should not exercise its discretion to deny this Petition under 35 U.S.C. § 325(d).

#### B. 35 U.S.C. § 314(a) Does Not Favor Denial of Institution

The decision whether to exercise discretion to deny institution under Section 314(a) is based on "a balanced assessment of all relevant circumstances in the case, including the merits." PTAB Consolidated Trial Practice Guide at 58 (Nov. 2019).

### 1. The *General Plastics* Factors Weigh Against Discretionary Denial

The Board has identified several factors that are relevant to its determination of whether to exercise its discretion to deny institution under § 314(a). *General Plastics Indus. Co. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19 at 16 (P.T.A.B. Sept. 6, 2017) (precedential). As set forth below, the *General Plastics* factors weigh against a discretionary denial.

### a. Factor 1: whether the same petitioner previously filed a petition directed to the same claims of the same patent

As discussed above, Petitioners have not previously challenged claims 15 and 21 of the 716 patent, which were first asserted by Patent Owner against Petitioner Wright Medical on October 11, 2021 and which have never been asserted by Patent Owner against Petitioner Stryker. As such, this factor weighs against discretionary denial. See Xilinx, Inc. v. Analog Devices, Inc., IPR2020-01564, Paper 12 at 11 (P.T.A.B. Mar. 15, 2021) ("We determine that factor 1 does not weigh in favor of denying institution because Petitioner challenges claims not previously challenged and we are not persuaded that Petitioner reasonably could have known without benefit of the infringement contentions to include all challenged claims in one or both of the first two filed petitions."); Volkswagen, IPR2019-01573, Paper 7 at 6-7 (finding that Factor 1 weighs against discretionary denial where challenged claims in the second petition "are still different claims that Patent Owner chose to assert in the district court after Petitioner filed the [earlier] petition").

# b. Factor 2 (knowledge of the prior art asserted in the second petition) and Factor 4 (length of time elapsed between learning of prior art and filing second petition)

Factors 2 and 4 are at worst neutral, and do not weigh in favor of discretionary denial, because the present Petition challenges different claims than those challenged in the earlier petition. *See Ingenico Inc. v. Ioengine, LLC*, IPR2019-00929, Paper 16 at 54-56 (P.T.A.B. Sept. 26, 2019) (finding that factors 2 and 4 do not support

discretionary denial where different claims were challenged in later petition using some of the same prior art references as in earlier petition).

### c. Factor 3: whether petitioner already received POPR or institution decision from first petition

Factor 3 weighs against discretionary denial because Patent Owner has not yet filed a POPR in the earlier petition, nor has the Board issued any institution decision. As such, "Petitioner[s] had no opportunity to use Patent Owner's preliminary responses or the Board's decisions as a roadmap for formulating its challenges." *Ingenico*, IPR2019-00929, Paper 16 at 55.

### d. Factor 5: whether the petitioner provides adequate explanation for the time elapsed between filings of multiple petitions directed to the same claims of the same patent

Factor 5 does not apply here because this is the first petition directed to challenged claims 15 and 21of the 716 patent. *See, e.g., Ingenico*, IPR2019-00929, Paper 16 at 56 ("because Petitioner has not filed multiple petitions directed to the same claims of the same patent, Petitioner was not required to provide an explanation for the time elapsed between the petitions."). Indeed, the present Petition was filed in response to Patent Owner's new infringement assertion of challenged claims 15 and 21 of the 716 patent on October 11, 2021. Petitioners were first notified of this new infringement assertion through Patent Owner's initial infringement contentions, which were served on Petitioner Wright Medical in the underlying Delaware

litigation more than a month <u>after</u> Petitioners filed the earlier IPR2021-01452 petition. *See Mercedes-Benz USA, LLC v. Carucel Invs., L.P.*, IPR2019-01441, Paper 8 at 20 (P.T.A.B. Mar. 3, 2020) ("we determine that Petitioner's description of the circumstances necessitating a second petition…has provided 'adequate explanation for the time elapsed between the filings of multiple petitions' under *General Plastics* Factor 5.").

#### e. Factors 6 (finite resources of the Board) and 7 (requirement under § 316(a)(11) to issue final determination not later than 1 year after institution)

*General Plastics* factors 6 and 7 are at worst neutral, and do not favor denial of institution.

Challenged claims 15 and 21 depend on independent claims 10 and 16, respectively, which were the subject of IPR2021-01452. Thus, while claims 15 and 21 include limitations related to "flared hips" that are nowhere addressed in the earlier petition, Petitioners recognize that there is overlap in subject matter to the extent that claims 10 and 16 are addressed in both petitions.<sup>2</sup> Due to the overlapping

<sup>&</sup>lt;sup>2</sup> Petitioners note that they are not separately challenging claims 10 and 16 in the present Petition but, by necessity, must address those claims in their discussion of dependent claims 15 and 21. The Trial Practice Guide does not allow Petitioners

arguments and evidence, instituting on both petitions "will at most create a small amount of additional effort by the parties and the Board." *Xilinx*, IPR2020-01564, Paper 12 at 13. Moreover, Petitioners are amenable to consolidation of the present IPR with IPR2021-01452 under 35 U.S.C. § 315(d) to conserve the Board's resources and to prevent needless costs incurred by the parties. *See Mercedes-Benz* USA, IPR2019-01441, Paper 8 at 20. Consolidation would not prejudice Patent Owner because Petitioners have not gained any advantage from filing two separate petitions challenging the 716 patent. *See Mercedes-Benz USA*, *LLC v. Carucel Investments*, *L.P.*, IPR2019-01644, Paper 9 at 35 (P.T.A.B. Mar. 26, 2020). Indeed, Patent Owner's decision to belatedly assert challenged claims 15 and 21 necessitated the current Petition.

Based on a review of the *General Plastics* factors, the Board should decline to exercise its discretion to deny the present Petition under §314(a).

#### 2. The *Fintiv* Factors Weigh Against Discretionary Denial

Similarly, an examination of the *Fintiv* factors weighs strongly <u>against</u> discretionary denial of institution under 35 U.S.C. § 314(a). *See, e.g., Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020) (precedential).

to simply incorporate by reference its earlier arguments relating to independent claims 10 and 16 as presented in IPR2021-01452. *See* 37 C.F.R. § 42.6(a)(3).

While there is co-pending litigation in Illinois and Delaware, both cases are in their infancy such that a final written decision would issue long before any trial takes place. (EX1012, EX1013).

#### a. Factor 1: Likelihood of a Stay

None of the parties to the district court proceedings has requested a stay. As such, this factor is neutral. *See, Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 15 at 12 (P.T.A.B. May 13, 2020) (informative) ("*Fintiv II*").

#### b. Factor 2: Proximity of Trial Date

No trial date has been set in either case. (EX1012; EX1013). As such, this factor weighs against discretionary denial. *See Google LLC v. Uniloc 2017 LLC*, IPR2020-00441, Paper 13 at 35 (P.T.A.B. Jul. 17, 2020).

#### c. Factor 3: Investment in the Parallel Proceeding

The two litigation matters are in their infancy such that any investment in them has been minimal. As discussed in Section I.B., discovery only recently began on July 6, 2021 in both cases, and no claim construction hearing is expected to take place in Illinois until April 2022, at the earliest. (EX1012). The Delaware court indicated that the Illinois case will go first and that Delaware is "completely jammed with cases, and it's been aggravated by the pandemic. And you know, this case is going to sit" because of the enormous backlog of cases in that district. (EX1014, 17:10-12, 32:7-10). To date, no substantive orders have been issued in either case

relating to the 716 patent. This fact weighs against discretionary denial. *See Nvidia Corp. v. Invensas Corp.*, IPR2020-00602, Paper 11 at 27 (P.T.A.B. Sept. 3, 2020).

Moreover, Petitioners diligently filed the present Petition within five weeks of being served infringement contentions in the Delaware case (October 11, 2021), when Petitioner Wright Medical learned for the first time that Patent Owner added a claim of patent infringement based on dependent claims 15 and 21 of the 716 patent. This fact weighs against discretionary denial. *Cellco Partnership*, IPR2020-01117, Paper 10 at 22.

### d. Factor 4: Overlap in Issues

While Petitioner Stryker's recently-served invalidity contentions include the prior art addressed in the Petition, Petitioners agree that, upon institution, they will not pursue the invalidity grounds in the litigation that are included in this Petition and upon which trial is instituted.<sup>3</sup> Such agreement mitigates any "concerns of inefficiency and the possibility of conflicting decisions," and thus weighs against discretionary denial. *See, e.g., Sand Revolution II*, Paper 24 at 11; *Peloton* 

<sup>&</sup>lt;sup>3</sup> Both Petitioners expressly reserve the right to pursue other grounds of invalidity as consistent with 35 U.S.C. § 315 and the relevant case law. *E.g., Sand Revolution II, LLC v. Continental Intermodal Group – Trucking LLC*, IPR2019-01393, Paper 24 at 11 (P.T.A.B. June 16, 2020) (informative).

Interactive, Inc. v. Icon Health & Fitness, Inc., IPR2021-00342, Paper 14 at 14-16 (P.T.A.B. Jul. 7, 2021).

#### e. Factor 5: Petitioner and Defendant Same Party

Patent Owner OsteoMed is the plaintiff in the parallel district court proceedings. Petitioner Wright Medical is the defendant in the Delaware case. Petitioner Stryker is the defendant in the Illinois case, along with wholly owned subsidiary Howmedica Osteonics Corp. Because the Office is likely to reach the merits before either district court does, this factor weighs against discretionary denial. *See, e.g., Nvidia Corp. v. Tessera Advanced Techs., Inc.*, IPR2020-00708, Paper 9 at 17 (P.T.A.B. Sept. 2, 2020).

#### f. Factor 6: Other Circumstances

Petitioners diligently filed the present Petition within the 1-year window and within five weeks of learning which claims OsteoMed is asserting against Petitioner Wright Medical. Moreover, Petitioners have established a reasonable likelihood that they will prevail with respect to the challenged claims with an anticipatory reference and an obviousness challenge. Where, as here, the merits of the challenges presented in the Petition are strong, this factor favors institution. *Cellco Partnership*, IPR2020-01117, Paper 10 at 26-27.

Five of the *Fintiv* factors (2-6) weigh against the exercise of discretion to deny institution, while one factor (1) is neutral. Here, the nascent state of the parallel

district court proceedings combined with the strength of Petitioners' showing of

unpatentability strongly favor institution of *inter partes* review. Id., Paper 10 at 27.

#### VIII. CONCLUSION

Petitioners respectfully request institution of *inter partes* review of Claims 15 and 21 of the 716 patent.

Respectfully submitted,

Dated: November 17, 2021

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#### **CERTIFICATE OF WORD COUNT**

I hereby certify that this Petition complies with the word count limit of 37 CFR § 42.24. The argument sections of this Petition (Introduction, Section I.F. (Grounds for Standing), and Sections II-VIII) have a total of 10,671, less than 14,000 words, as measured by Microsoft Word<sup>TM</sup>.

Dated: November 17, 2021

<u>/s/ Sharon A. Hwang</u> Sharon A. Hwang Registration No. 39,717

#### **CERTIFICATE OF SERVICE**

I hereby certify that true and correct copies of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 9,763,716 (IPR2022-00191) was served on November 17, 2021, via pre-paid, overnight Express Mail to the correspondence address of record for the subject patent pursuant to 37 C.F.R. § 42.105:

K&L Gates LLP – Chicago P.O. Box 1135 Chicago, IL 60690

An electronic courtesy copy was sent via email to:

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Counsel for OsteoMed in OsteoMed LLC v. Stryker Corporation, Case No. 1:20cv-06821, and OsteoMed LLC v. Wright Medical Technology, Inc., Case No. 1:20-cv-1621.

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