

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GLOBUS MEDICAL, INC.,
Petitioner,

v.

DEPUY SYNTHES PRODUCTS, LLC,
Patent Owner.

Case IPR2015-00111
U.S. Patent No. 8,623,057

**PATENT OWNER'S PRELIMINARY RESPONSE
PURSUANT TO 37 C.F.R. § 42.107**

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Statement of Material Facts in Dispute

Petitioner, Globus Medical, Inc. (“Globus”), did not submit a statement of material facts in its Petition. Accordingly, no response is due pursuant to 37 C.F.R. § 42.23(a), and no facts are admitted.

Patent Owner's Exhibit List

Exhibit Number	Contents
2001	Index Volume, <i>Encyclopedia of Polymer Sci. & Eng'g</i> ("Elastomers, Synthetic") (1990)
2002	DePuy Synthes Products, LLC v. Globus Medical, Inc., Case No. 1:14-cv-00011-RGA (U.S. District Ct., Dist. of Del.), Dkt. No. 44 (Joint Claim Construction Chart)
2003	Sept. 3, 2013 Reasons for Allowance

Pursuant to 35 U.S.C. § 313 and 37 C.F.R. § 42.107, DePuy Synthes Products, LLC (“Synthes” or “Patent Owner”) hereby submits its Preliminary Response to the Petition for *inter partes* review (“IPR”) of U.S. Patent No. 8,623,057 (the “’057 Patent”) filed by Globus Medical, Inc. (“Globus” or “Petitioner”). Globus bases its Petition on a single Ground 1: “Claims 23-32 and 46-55 are rendered obvious under 35 U.S.C. § 103 by U.S. Pat. No. 7,931,675 B2, issued Apr. 26, 2011 to Panjabi et al. (‘Panjabi,’ hereinafter) and U.S. Pub. No. 2004/0143264 A1, published Jul. 22, 2004 to McAfee (‘McAfee,’ hereinafter).” (Pet. at 3; Pet. Exs. 1002, 1005.) The Petition fails to show that there is a “reasonable likelihood” that any of claims 23-32 and 46-55 of the ‘057 Patent are unpatentable. 35 U.S.C. § 314(a).

I. INTRODUCTION

There are numerous reasons why the Board should deny institution of IPR and reject Globus’ Petition – a Petition founded on a primary reference that Globus admits does not disclose multiple limitations present in every challenged claim. Indeed, there are two threshold reasons for dismissal that obviate the need even to consider the substance of Globus’ obviousness challenge. First, even assuming all facts Globus has alleged are true, Globus has failed to and cannot carry its burden of proving that the proffered primary reference – U.S. Patent No. 7,931,675 (‘Panjabi’), which serves as the basis for Globus’ one and only ground for

unpatentability – is actually prior art. Second, Globus has failed to and cannot carry its burden of proving that the priority date for Synthes’ ’057 Patent is not in fact earlier than March 3, 2005, and in particular that Panjabi precedes that priority date. And third, even if Globus could overcome these threshold deficiencies, Globus comes nowhere near establishing a reasonable likelihood that one of ordinary skill would modify Panjabi in the multiple separate ways that Globus concedes would be necessary to arrive at Synthes’ claimed invention.

- ***Globus has not carried its burden of proving that Panjabi, on which Globus bases its entire challenge, is prior art.***

Globus has failed to prove that its primary reference, Panjabi, is prior art under 35 U.S.C. § 102(e). Globus itself contends that the effective filing date for the ’057 Patent is at least as early as March 3, 2005. (Pet. at 3.) Panjabi, however, issued from an application filed on June 23, 2005. Thus, based upon the filing date of its utility application, Panjabi is not prior art to the ’057 Patent under Section 102(e). Although Panjabi does claim priority to a provisional application filed on June 23, 2004, Globus has failed to demonstrate that Panjabi qualifies as prior art under Section 102(e) based upon the Panjabi provisional application. Globus does not cite to any disclosure in that provisional application or compare it to the issued version of Panjabi to demonstrate that the relied upon disclosure was carried forward from the provisional application into the issued Panjabi patent. In fact,

Globus did not mention the Panjabi provisional in its Petition and did not attach it as an exhibit to its Petition. These failures are fatal to Globus' Petition because Globus has not demonstrated that its primary reference – Panjabi – is prior art to the '057 Patent. Without Panjabi, Globus cannot support its one and only ground for unpatentability.

- ***Globus has not carried its burden of proving that the effective filing date for the claims of the '057 Patent is not in fact earlier than March 3, 2005.***

Even if Globus could rely on the June 23, 2004 provisional filing date of Panjabi (which it cannot), Panjabi still is not prior art because Globus has not met its burden to establish that the effective filing date for the '057 Patent claims is no earlier than March 3, 2005. The '057 Patent claims priority to several ancestral applications including U.S. Serial App. No. 10/798,014 (the "'014 Application") filed on March 10, 2004 – which pre-dates the Panjabi provisional. Globus did not even mention these prior applications nor did it identify any disclosures in these prior applications lacking written description or enabling support for the issued '057 Patent claims. Globus' conclusory assertion that those claims are not entitled to an effective filing date earlier than March 3, 2005 is insufficient, and thus, Globus' Petition fails as a matter of law.

- ***Even if Panjabi were prior art, Globus has not established that it would have been obvious to modify Panjabi in multiple ways to reach the claimed invention.***

Globus' one and only ground for unpatentability rests solely on the combination of Panjabi in view of U.S. Pub. No. 2004/0143264 ("McAfee"). (Pet. at 3.) But Globus admits that Panjabi fails to disclose a large number of claim limitations – which are recited in every challenged claim. McAfee does not fill these gaps, because it fails to supply many of the claim limitations missing from Panjabi. Because neither Panjabi nor McAfee discloses all of the limitations of the challenged claims, and because Globus does not rely on any other references, Globus is left without "patents or printed publications" to support its obviousness case: as a result, Globus' Petition must fail. 35 U.S.C. § 311(b).

Even if Panjabi and McAfee disclosed all the claim limitations, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007). Globus has failed to demonstrate that a person of ordinary skill in the art would have been motivated to combine the disclosures of Panjabi with those of McAfee to arrive at each of the claim limitations, and that one of ordinary skill would reasonably expect the modified device to work for its intended purpose. Globus instead relies only on conclusory argument, which is insufficient.

Accordingly, for the foregoing and other reasons explained in more detail below, the Board should not institute IPR in this matter.

II. THE PATENTED INVENTION

The spinal implants claimed in the ‘057 Patent provide a novel and effective way to combat serious back pain – “one of the most expensive diseases afflicting industrialized societies.” (Pet. Ex. 1002, col. 1, ll. 26-27. *See also* Pet. Ex. 1001 (‘057 Patent), col. 1, ll. 34-37.) Because no two patients’ bodies are alike, finding a common solution to back pain has been a complex problem. (Pet. Ex. 1001 (‘057 Patent), col. 3, ll. 7-11.)

Many types of spinal implants other than the claimed implants exist, but they have certain limitations. For example, “[c]onventional methods of spinal fixation utilize a rigid spinal fixation device to support an injured spinal part and prevent movement of the injured part”; these methods include inflexible rods or metal plates inserted adjacent to a patient’s injured spinal column held in place with screws inserted into the vertebrae. (*Id.*, col. 1, l. 58 – col. 2, l. 23.) Because these implants result in rigid fixation, they generally “prevent normal movement of the spinal column,” which can cause “further complications and abnormalities.” (*Id.*, col. 2, ll. 1-23.)

Other implants that use non-metallic substances may provide a greater degree of spinal flexibility, but the design of these implants is “not well suited to

provide varying levels of flexibility to provide optimum results for each individual candidate.” (*Id.*, col. 3, ll. 8-11.)

The spinal implants of the present invention are unique in that they provide both flexibility and stabilization. The claimed implants generally include: a “first” rigid portion having an outer surface configured to be “secured within” a first bone screw assembly; a “second” rigid portion; a “longitudinally compressible spacer” comprising a rigid portion having an outer surface configured to be secured within a second bone screw assembly, and non-rigid, first and second “elastomeric” portions; and a “flexible member” running through the components of the longitudinally compressible spacer and connected to the “first” and “second” rigid portions of the implant. (*Id.*, claims 23, 46.) As the specification explains, the “compressibility and elasticity” of the elastomeric spacer portions allow for “stabilized motion” of the spacer, at once allowing the implant to respond to forces imposed by the patient’s body and resisting a degree of movement that could threaten spinal stability. (*Id.*, col. 27, ll. 49-64; *id.*, col. 29, ll. 39-54.) The surgeon inserts the implant through the patient’s back and connects it to the spine by at least two bone screws implanted in the patient’s vertebrae. (*Id.*, col. 16, ll. 61-64; Fig. 53 (showing the implant with two bone screws implanted in the spine).)

III. THE BOARD SHOULD REJECT GLOBUS' PETITION BECAUSE
GLOBUS HAS NOT DEMONSTRATED THAT THE PANJABI
REFERENCE IS PRIOR ART

The Board should reject Globus' Petition in the first instance because the primary reference on which the Petition rests – Panjabi – does not qualify as prior art. Globus' proposed ground of unpatentability is obviousness based upon the combination of Panjabi with McAfee. (Pet. at 3.) Globus' reliance on Panjabi is fundamental: Globus relies on only Panjabi for at least one limitation in every challenged claim.¹

Globus has failed to establish, however, that Panjabi qualifies as prior art under 35 U.S.C. § 102(e). Globus contends that **March 3, 2005** is the effective filing date for the '057 Patent claims, and it “submits that Panjabi [U.S. Pat. No. 7,931,675 B2] is prior art to the '057 Patent under 35 U.S.C. § 102(e).” (Pet. at 3.)

¹ Although Globus' claim chart for claim 29 cites both Panjabi and McAfee, claim 29 depends from claims 27 and 23, both of which contain limitations for which Panjabi is the only reference cited. (See Pet. at 32 (claim 29), 29-30 (claim 27), 13-17 (claim 23).) Similarly, although Globus' claim chart for claim 53 cites both Panjabi and McAfee, claim 53 depends from claims 46-52, all of which contain limitations for which Panjabi is the only reference cited. (See *id.* at 53 (claim 53), 36-52 (claims 46-52).)

Panjabi, however, issued from a utility application filed on **June 23, 2005**, which post-dates March 3, 2005. (Pet. Ex. 1002 at [22].) Globus must therefore establish that Panjabi is entitled to the June 23, 2004 filing date of the Panjabi provisional application. (*Id.* at [60].) Because Globus has not met its burden to do so, Panjabi does not qualify as prior art under Section 102(e) and Globus cannot carry its burden of demonstrating a “reasonable likelihood” of proving unpatentability for any challenged claim of the ‘057 Patent.

A. Legal Standard for Establishing That A Reference
Is Entitled to The Filing Date of Its Provisional Application

The Federal Circuit has identified two prerequisites for relying on a provisional filing date for a U.S. patent for prior art purposes under 35 U.S.C. § 102(e). First, an “important limitation” is that the provisional application must provide written description support for the claim limitations that are allegedly disclosed therein. *See In re Giacomini*, 612 F.3d 1380, 1383 (Fed. Cir. 2010). Second, the disclosures in the provisional application must have been “carried forward” into the issued patent. *Id.*

These two requirements exist in IPRs, where a petitioner wishing to establish that a U.S. patent has an effective § 102(e) date for prior art purposes to an underlying provisional application – like Globus here – bears the burden of demonstrating by a “preponderance of the evidence” that both requirements are

met. *Dynamic Drinkware LLC v. Nat'l Graphics, Inc.*, Case IPR2013-00131, Paper No. 42, 2014 WL 4628897, at *3-4 (PTAB Sept. 12, 2014) (*citing* *Giacomini* and *Ex Parte Yamaguchi*, 88 U.S.P.Q.2d 1606, 1613-14 (BPAI 2008) (precedential) (Examiner properly cited to provisional application for relied-upon disclosure and established that the disclosure was carried forward to the patent reference to support Section 102(e) rejection)). *See also* *Cisco Sys., Inc. v. Constellation Techs. LLC*, Case IPR2014-00914, Paper No. 11, 2015 WL 66520, at *13 (PTAB Jan. 2, 2015) (“A petitioner has the burden of proof to establish that a reference that serves as the basis of a ground of unpatentability asserted in an *inter partes* review qualifies as prior art.”).

To support its position that Panjabi qualifies as prior art under 35 U.S.C. § 102(e), Globus must demonstrate that it relies on “subject matter from [Panjabi] that is present in and supported by its provisional.” *Dynamic Drinkware*, 2014 WL 4628897, at *4.² Specifically, Globus must “compare the portions of [the Panjabi]

² In *Dynamic Drinkware*, the Board instituted IPR but later rejected the petitioner’s validity challenges that were based on a provisional application because the challenger failed to provide the proper “analysis of common subject matter required by *Yamaguchi* and *Giacomini*.” *Id.* A review of the IPR docket indicates that the patent owner did not raise this priority date issue in its (*Continued*)

patent relied on by [Globus] to the [Panjabi] provisional, to demonstrate that those portions were carried over from the provisional,” such that the disclosures sought to be relied upon are prior art as of the provisional application’s filing date. *Id.* See also *Human Genome Sciences, Inc. v. Immunex Corp.*, 83 U.S.P.Q.2d 1286, at *1, *3 (BPAI 2006); *Oracle Corp. v. Clouding IP, LLC*, Case IPR2013-00099, Paper No. 10, 2013 WL 5970190, at *7 (PTAB May 1, 2013) (holding that petitioner could rely on provisional filing date because it “provide[d] detailed explanations as to how each claim limitation is met by each of [the issued patent] and the [provisional] application”).

Just last month in *Cisco Systems*, the Board reaffirmed these requirements and held that the petitioner failed to make a sufficient showing that a reference qualified as prior art under 35 U.S.C. § 102(e) based on the date of its prior-filed provisional applications. Specifically, the Board rejected the petitioner’s attempt to rely on the provisional filing dates when the petitioner had no “sufficient or credible explanation as to how the disclosures in the [provisional applications] provide sufficient written description support for the features in [the proposed prior art reference] relied upon by [petitioner].” *Cisco Sys.*, 2015 WL 66520, at *13.

Preliminary Response, as Synthes is doing here. (Case IPR2013-00131, Paper No. 15, July 30, 2013.)

B. Globus Has Failed To Meet Its Burden

Globus has failed to provide the Board with the necessary showing to establish that the prior art date for Panjabi under 35 U.S.C. § 102(e) is the date of the Panjabi provisional application. Globus' one and only statement concerning the prior art status of Panjabi is that "Petitioner submits that Panjabi is prior art to the '057 Patent under 35 U.S.C. § 102(e)." (Pet. at 3). That statement alone, however, fails to meet Globus' dual burden to establish that it relies on subject matter from the Panjabi provisional application, and that the disclosures relied upon were carried over from that application.

Globus has not compared the portions of the issued Panjabi patent on which Globus relies to the Panjabi provisional application, to show that those portions it is relying on were carried over from the provisional application to the issued patent. Rather, in every instance throughout its Petition, Globus cites only to the disclosure found in the Panjabi patent. (*See, e.g.*, Pet. at 13-17, 36-39 (citing Panjabi patent for each claim).) Globus never mentions the Panjabi provisional. Globus provides no citations to the Panjabi provisional and makes no attempt to show that the provisional application contains the disclosure Globus relies upon from the Panjabi patent.

Critically, Globus does not attach the provisional as an exhibit anywhere in its papers, precluding its use. See 35 U.S.C. § 312(a)(3)(A) (requiring Globus to

attach copies of all prior art references relied upon). This omission alone is fatal to Globus' Petition. *See Ariosa Diagnostics, Inc. v. Illumina, Inc.*, Case IPR2014-01093, Paper No. 14, 2015 WL 153677, at *6-7 (PTAB Jan. 8, 2015) (petitioner failed to demonstrate that a reference should have a prior art date under 35 U.S.C. § 102(e) as of the date of an earlier continuation application because petitioner failed to submit a copy of the prior-filed application as an exhibit to the petition).

This situation is similar to *Marvell Semiconductor, Inc. v. Intellectual Ventures I LLC*, Case IPR2014-00547, Paper No. 19, Decision at 3-5 (PTAB Jan. 14, 2015), where the Board recently denied a petition to institute trial. In *Marvell*, the petitioner – like Globus here – needed to establish that the patent reference was prior art under 35 U.S.C. § 102(e) as of the filing date of the provisional application. And in *Marvell*, the petitioner – like Globus here – not only failed to provide the requisite showing that the disclosure it was relying upon from the issued patent was present in and carried over from the provisional application, but the petitioner also failed to include a copy of the provisional application as an exhibit to support the petition. *Id.* The Board held that each omission provided support to deny petitioner its claim that the reference should have a Section 102(e) prior art date as of the date of the provisional application, and denied instituting trial based upon that reference. *Id.*

Globus appears to have presumed, without any evidence, that it may rely on the filing date of the Panjabi provisional. But as Petitioner, Globus “has the burden of proof to establish that it is entitled to the requested relief,” 37 C.F.R. § 42.20(c), by providing the evidentiary basis to show that the reference it relies on is actually prior art. Having failed to meet that burden, Globus cannot rely on the Panjabi provisional application’s filing date, and it is left without the primary prior art reference in support of its obviousness challenges. Without it, Globus’ Petition lacks a “reasonable likelihood” of success and must fail. 35 U.S.C. § 314(a).

IV. THE BOARD SHOULD REJECT GLOBUS’ PETITION
BECAUSE IT FAILS TO ESTABLISH THAT THE ‘057 PATENT’S
EFFECTIVE DATE IS NO EARLIER THAN MARCH 3, 2005

Even assuming Globus was entitled to rely upon the provisional filing date of Panjabi, its Petition suffers from yet another fatal defect relating to priority dates. There is no dispute between the parties that the effective filing date for the ‘057 Patent claims is at least as early as March 3, 2005: Globus has put forth no evidence or argument to contend otherwise. (Pet. at 3: “The Petitioner submits that the earliest effective filing date for the claim inventions within the ‘057 Patent is March 3, 2005.”) Globus has failed to establish, however, that the effective filing date cannot be *earlier* than March 3, 2005, in light of the fact that the ‘057 Patent claims the benefit of several earlier applications, including an original parent application filed on December 5, 2003. (Pet. Ex. 1001 (‘057 Patent) at

[63].) Once again, Globus ignores its obligation to demonstrate which of multiple possible priority dates controls. This is critical, because even if Globus were somehow entitled to rely on the June 23, 2004 filing date of Panjabi's provisional application (and it should not be permitted to do so), that date may nonetheless be insufficient to qualify Panjabi as prior art.

As the petitioner, it is Globus' duty to establish an effective filing date for the '057 Patent by specifically identifying those claim limitations lacking § 112 support in prior ancestral applications. Although "the Patent Owner is not presumed to be entitled to the earlier filing dates of ancestral applications which do not share the same disclosure," "the issue first has to be raised by the Petitioner in its petition, by identifying, specifically, the features, claims, and ancestral applications allegedly lacking § 112, first paragraph, written description and enabling disclosure support for the claims based on the identified features."

Polaris Wireless, Inc. v. TruePosition, Inc., Case IPR2013-00323, Paper No. 9, 2013 WL 8563953, at *17 (PTAB Nov. 15, 2013). Only if the petitioner first "specifically" identifies the ancestral applications allegedly lacking written description and enabling support for the claims, does the patent owner "[t]hen...ha[ve] to make a sufficient showing of entitlement to earlier filing date or dates, in a manner that is commensurate in scope with the specific points and contentions raised by Petitioner." *Id.*

In *Hewlett-Packard Co. v. MCM Portfolio, LLC*, Case IPR2013-00217, Paper No. 10, 2013 WL 8595889, at *5-6 (PTAB Sept. 10, 2013), for example, the petitioner asserted that the challenged claims were entitled to an effective date later than the date of the earliest application of which the patent claimed a benefit. Because the petitioner supported that assertion with nothing other than conclusory attorney argument and conclusory expert testimony, the Board rejected it and declined to institute IPR on the basis of any references that post-dated the earliest application listed in the patent. *Id.*

Globus comes nowhere near meeting these important standards. Simply stating that “the earliest effective filing date for the claim inventions within the ‘057 Patent is March 3, 2005, which is the filing date of patent application No. 11/072,886³” (Pet. at 3), does not satisfy Globus’ burden to “identify[], specifically, the features, claims, and ancestral applications allegedly lacking § 112, first paragraph, written description and enabling disclosure support for the claims based on the identified features.” *Polaris*, 2013 WL 8563953, at *17. Globus has not provided any “specific points and contentions” to support a claim

³ The ‘057 Patent is a continuation of U.S. Patent Application No. 11/705,953, which is a continuation-in-part of U.S. Patent Application No. 11/072,866. (Pet. Ex. 1001 (‘057 Patent) at [63].)

that the patent's effective filing date can stretch back no farther than March 3, 2005 – such as, say, to the March 10, 2004 filing date of the '014 Application – which means that Globus has failed to present a proper framework to which Synthes can then respond. *Id.* (requiring a response “in a manner that is commensurate in scope with the specific points and contentions raised by Petitioner”).⁴ Because Globus has not met its burden to establish that the effective filing date for the '057 Patent cannot precede March 3, 2005 – indeed, that it cannot precede June 23, 2004, the filing date of the Panjabi provisional – Globus has also not met its burden to demonstrate that Panjabi is prior art.

V. THE BOARD SHOULD REJECT GLOBUS' PETITION BECAUSE GLOBUS FAILS TO DEMONSTRATE THAT NUMEROUS CLAIM LIMITATIONS ARE DISCLOSED IN, OR WOULD BE OBVIOUS MODIFICATIONS OF, THE CITED REFERENCES

Putting aside the threshold deficiencies that doom Globus' Petition, the Petition fails on substantive grounds, as well. It does not establish that the two references in its one and only ground for unpatentability teach or suggest each and every claim limitation in Synthes' claims. It does not provide sufficient rationales for one of ordinary skill to cure the many deficiencies in Panjabi through McAfee

⁴ Synthes does not concede that any limitations in the issued patent claims are missing from the disclosures in, for example, the '014 Application, filed March 10, 2004.

to arrive at the claimed invention. It does not even address the reasonable expectation of success of making multiple modifications to Panjabi. Globus failed to meet its burden.

Lacking the necessary evidence, Globus relies on faulty claim constructions, and conclusory attorney argument and expert testimony instead of the disclosures in its so-called prior art references. Ultimately, Globus is left with nothing more than impermissible hindsight, relying on Synthes' patent claims as a blueprint for its many modifications to Panjabi that purportedly render the claimed invention obvious.

A. Globus Provides No Evidence That It Would Have Been Obvious To Modify Panjabi with Respect to Specific Claim Limitations⁵

Globus concedes that Panjabi does not disclose multiple limitations present in independent claims 23 and 46 (and therefore in every claim challenged in the

⁵ Although Synthes need not (and will not) address every claim limitation addressed in the Petition, Synthes does not concede at this point that any claim limitations are disclosed in any prior art references cited by Globus, or that those references are prior art. Synthes also does not concede that any claim construction addressed in the Petition is correct.

Petition). (Pet. at 18-19, 40-41.) Specifically, Globus concedes (*id.*) that Panjabi does not expressly disclose:

- a first elastomeric spacer portion;
- a second elastomeric spacer portion;
- the first rigid portion having an outer surface configured to be secured within a first bone screw assembly;
- the spacer rigid portion having an outer surface configured to be secured within a second bone screw assembly;
- the flexible member being connected to the first and second rigid portions; and
- the spacer rigid portion having an inner bore of larger diameter than the outer surface of the flexible member.

At times Globus contends that the McAfee reference discloses those limitations missing from Panjabi. At other times, as discussed herein, Globus appears to concede that neither Panjabi nor McAfee discloses certain claim limitations. But Panjabi and McAfee are the only two “patents or printed publications relied upon” that Globus identified pursuant to 37 C.F.R. § 42.104(b)(2) and upon which Globus relies for its patentability challenge. (Pet. at 3.) If neither reference discloses the claim limitation in question, Globus has no obviousness case.

Synthes turns now to five specific limitations in every challenged claim, and five additional limitations in certain dependent claims, that are missing from both Panjabi and McAfee. Specifically, Synthes will demonstrate that the following claim limitations cannot be found in either of Globus' references:

- a first elastomeric spacer portion;
- a second elastomeric spacer portion;
- the first rigid portion having an outer surface configured to be secured within a first bone screw assembly;
- the spacer rigid portion having an outer surface configured to be secured within a second bone screw assembly;
- the flexible member being connected to the first and second rigid portions;
- the first rigid portion being metallic;
- the second rigid portion being metallic;
- the spacer metallic portion being metallic;
- a first elastomeric spacer portion comprising polycarbonate urethane;
and
- a second elastomeric spacer portion comprising polycarbonate urethane.

1. First and second “elastomeric” spacer portions

Globus has not established that either Panjabi or McAfee teaches first and second “elastomeric” spacer portions, which limitations are present in all of the challenged claims. (Pet. at 24, 45; Pet. Ex. 1001 (‘057 Patent), claims 23-32, 46-55.)

a. Globus’ claim construction is incorrect

Globus’ analysis of this claim limitation begins with an incorrect claim construction. The correct construction of “elastomeric” is “polymer having elastic qualities.” This construction comports with the term’s plain and ordinary meaning to a person of ordinary skill in the art in light of the patent’s specification. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). Globus erroneously contends that “elastomeric” means “something capable of being deformed and able to return to its original condition,” which ignores the polymeric quality of the term. (Pet. at 5.)

Synthes’ construction is consistent with the intrinsic evidence. The ‘057 Patent’s specification identifies as suitable elastomers “silicone, polyurethane, polycarbonateurethane and silicone-urethane copolymers” – all polymers with elastic qualities. (Pet. Ex. 1001 (‘057 Patent), col. 23, ll. 35-38.) Rather than defining “elastomer” to embrace all elastic substances regardless of whether they are polymeric, the specification makes a distinction between elastomers and non-

polymeric substances such as metal springs. In discussing one embodiment of the invention, for example, the specification indicates that a “resilient element” of the implant may consist of “any of a variety of medical grade elastomers” *or*, in “alternative embodiments,” “may be implemented as a helical metal spring.” (*Id.*, col. 32, ll. 26-42.) Only elastomers were claimed (*id.*, claims 23, 46), which establishes that “elastomeric” excludes metal springs, and thus that “elastomeric” does not refer to any and all resilient materials without regard to their polymeric qualities.

Even beyond the patent’s specification, one of ordinary skill in the art would have recognized that elastomers have polymeric qualities. *See, e.g.*, Index Volume, *Encyclopedia of Polymer Sci. & Eng’g* 106 (“Elastomers, Synthetic”) (1990) (Patent Owner’s Ex. 2001, p. 3) (“Elastomers are derived from natural rubber and synthetic polymers with rubberlike properties.”). Consistent with both the intrinsic and extrinsic record, Globus and Synthes agreed in co-pending district court litigation that the term “elastomeric” in the ‘057 Patent meant “polymer having elastic qualities.” (Case No. 1:14-cv-00011-RGA, Doc. 44 at 1 (Patent Owner’s Ex. 2002, p. 1).)

In its IPR Petition, however, Globus advances a different construction that ignores the polymeric aspect of the term: “something capable of being deformed and able to return to its original condition.” (Pet. at 5.) Globus concedes that this

construction is not the meaning that the term would have to a person of ordinary skill in the art, and submits without any evidentiary basis that “the inventors did not intend that elastomeric be understood as those skilled in the material science arts would appreciate.” (*Id.*) It is not surprising that Globus cites no intrinsic or extrinsic evidence to support its contention, because there is none, and indeed, the intrinsic evidence described above contradicts its contention.

Globus has offered no reason for the Board to depart from the general rule that the proper meaning for a claim term is its “ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure.” *See Iron Dome LLC v. Chinook Licensing DE LLC*, Case IPR2014-00674, Paper No. 10, 2014 WL 5239771, at *3 (PTAB Oct. 10, 2014). Even under the Board’s broadest reasonable interpretation standard, Globus has put forth no evidence to support its construction. As a result, the Board should not adopt it.

- b. An elastomeric spacer portion is not disclosed in either of Globus’ references

Neither Panjabi nor McAfee discloses “elastomeric” spacer portions under the correct construction of this term. Panjabi’s springs (Pet. at 16, 38-39) simply do not qualify under the correct construction of “elastomeric” because the springs are not polymeric. Indeed, Globus admits that Panjabi does not expressly disclose

elastomeric spacer portions even under Globus' erroneous construction: as one of the many claim limitations missing from Panjabi, Globus identifies "the springs 230 and 232, also disclosed as resilient members, corresponding to the claimed first and second elastomeric portions of the compressible spacer, being made from elastomeric materials." (Pet. at 18-19, 40-41.) Globus nowhere contends that Panjabi inherently discloses the limitation.

Globus also fails to identify any disclosure in McAfee teaching or suggesting this limitation, in its claim charts (*id.* at 16, 38-39) or anywhere in its Petition. As the '057 Examiner explained in her Reasons for Allowance, "McAfee fails to disclose elastomeric portions." (Sept. 3, 2013 Reasons for Allowance (Patent Owner's Ex. 2003, p. 2).)

Without Panjabi or McAfee – the only two references identified in the Petition per 37 C.F.R. § 47.104(b)(2) – Globus has not cited to any patents or printed publications supporting the obviousness of this claim limitation. As a result, Globus cannot establish a "reasonable likelihood" of showing that any of the challenged claims is unpatentable: "A petitioner in an inter partes review may request to cancel as unpatentable 1 or more claims of a patent...only on the basis of prior art consisting of patents or printed publications." 35 U.S.C. § 311(b).

c. Globus' simple substitution argument is conclusory

Globus cannot rely on testimony in Dr. McAfee's Declaration for its argument that a person of ordinary skill in the art would have substituted elastomeric spacer portions in place of Panjabi's spacer portions (Pet. at 24, 45), because this Declaration is not a patent or printed publication, and therefore, it cannot form the basis of an IPR obviousness challenged. 35 U.S.C. § 311(b).

Globus is trying to fill gaps in its analysis not with prior art but with its expert's say-so. Even on its merits, though, Dr. McAfee's Declaration does not establish a reasonable likelihood of proving that the elastomeric limitation is found in the prior art. Although Dr. McAfee identifies, in Paragraph 19 of his Declaration, certain elastomeric materials that he claims "would be used" in spacers (Pet. Ex. 1007, ¶ 19; Pet. at 24, 45), that assertion cannot establish that elastomeric spacers were an obvious choice to a person of ordinary skill in the art for at least the following two reasons.

First, Dr. McAfee's testimony is devoid of underlying facts or data, and should therefore receive no weight. *See* 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight."). The Federal Circuit does not credit expert testimony devoid of underlying facts or data:

The expert failed to explain how specific references could be combined, which combination(s) of elements in specific references would yield a predictable result, or how any specific combination would operate or read on the asserted claims. Rather, the expert's testimony on obviousness was essentially a conclusory statement that a person of ordinary skill in the art would have known, based on the "modular" nature of the claimed components, how to combine any of a number of references to achieve the claimed inventions. This is not sufficient and is fraught with hindsight bias.

ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc., 694 F.3d 1312, 1327 (Fed. Cir. 2012). *See also Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1373-74 (Fed. Cir. 2008). Dr. McAfee's "testimony" suffers from these same deficiencies. Dr. McAfee does not explain why elastomers "would be used," what functionality they would have, what advantages or disadvantages they might bring to the spinal implant, whether using elastomers would yield a predictable result, or what that predictable result would be.⁶

⁶ Dr. McAfee also discusses "elastomers" or "elastic materials" in Paragraphs 21 and 29 of his Declaration, but Globus does not cite those Paragraphs in its Petition. And in any event, Paragraphs 21 and 29 are just as devoid of evidentiary support as is Paragraph 19.

Second, even if Dr. McAfee did properly buttress his assertion, it would not support Globus' argument that "a POSITA would find it obvious to substitute one material for another," which is the crux of Globus' obviousness challenge. (Pet. at 24, 45.) A "simple substitution" argument cannot rely, as it does here, on nothing more than the existence of two allegedly substitutable elements in the prior art: instead, there must be evidence that establishes "*why* the alleged combination would be a 'simple' substitution achieving 'predictable results.'" *TRW Auto. US LLC v. Magna Elecs. Inc.*, Case IPR2014-00258, Paper No. 16, 2014 WL 2965895, at *10 (PTAB June 26, 2014). "[P]redictability is a touchstone of obviousness," and it requires not only an "expectation that prior art elements are capable of being physically combined, but also that the combination would have worked for its intended purpose." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1326 (Fed. Cir. 2009).

As noted, neither Dr. McAfee's Declaration nor Globus' Petition identifies any evidence that could explain why the use of elastomers would achieve predictable results – or what those predictable results would be. Not only is Dr. McAfee silent on predictability, but he also admits that the prior art teaches away from elastomers, stating that certain elastomers would have disadvantages not present with metals: for example, Dr. McAfee states that "[t]he disadvantages [of materials such as PCU (polycarbonate urethane, an elastomer)] are the increased

infection rate of a woven material, [and] the spine is not as rigidly held so there is more potential for neurologic compression due to great spinal movement.” (Pet. Ex. 1007, ¶ 13.) Neither Globus nor Dr. McAfee explains why a person of ordinary skill in the art would disregard these differences when the reaction of a spinal implant to the body’s movement is important to the implant’s functionality. (Pet. Ex. 1001 (‘057 Patent), col. 28, ll. 41-54 (describing the movement of the device in response to external forces when it is fixed to the spine); Pet. Ex. 1002, col. 3, ll. 37-41 (noting the interplay between movement of the spine and movement of the attached spinal stabilization device), col. 6, ll. 5-9 (noting the movement of the device as the spine bends forward or backward).) Indeed, rather than citing to patents or printed publications that would cause a person of ordinary skill in the art to make the elastomeric substitution, Dr. McAfee appears to be testifying as to his *own* view, whether or not that view finds support in the kinds of references on which the Board can institute IPR.

Globus does not even rely upon or cite to any patents or printed publications establishing the use of elastomeric spacers in spinal stabilization procedures. The Board should not consider Dr. McAfee’s discussion of the use of polycarbonate urethane in the “Dynesys” device because Globus has failed to rely upon and provide any patent or printed publication describing the Dynesys device to qualify it as prior art. *See* 35 U.S.C. § 311(b). *See also Capsugel Belgium NV v. Innercap*

Techs., Inc., Case IPR2013-00331, Paper No. 9, 2013 WL 8595288, at *8-9 (PTAB Dec. 9, 2013) (rejecting obviousness challenge based on pharmaceutical product because product was not a “patent or printed publication”); *A.R.M., Inc. v. Cottingham Agencies Ltd.*, Case IPR 2014-00671, Paper No. 10, 2014 WL 5112102, at *4-5 (PTAB Oct. 3, 2014). In any event, Dr. McAfee’s Declaration does not account for Dynesys’ shortcomings, which the inventors of the ‘057 Patent recognized. (See Pet. Ex. 1001 (‘057 Patent), col. 2, ll. 60-67.)

To the extent Globus attempts to use Dr. McAfee’s Declaration as evidence of “common knowledge” that elastomeric spacer portions would have been obvious, Globus once again ignores that IPRs may be instituted only on the basis of patents or printed publications, not “common knowledge.” 35 U.S.C. § 311(b). Even so, “the Board cannot simply reach conclusions based on its own understanding or experience—or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings.” *In re Zurko*, 258 F.3d 1379, 1386 (Fed. Cir. 2001). “[G]eneral conclusions about what is ‘basic knowledge’ or ‘common sense’” are no “replacement for documentary evidence for core factual findings in a determination of patentability.” *K/S HIMPP v. Hear-Wear Techs., LLC*, 751 F.3d 1362, 1366 (Fed. Cir. 2014). No such “concrete,” “documentary” evidence exists here. For all these reasons, Globus has not demonstrated that

Panjabi or McAfee, alone or in combination, teaches first and second “elastomeric” spacer portions.

2. First rigid portion and spacer rigid portion having an outer surface configured to be “secured within” pedicle screw assemblies

Globus has not established that Panjabi or McAfee teaches the claimed first rigid portion or the claimed spacer rigid portion having an outer surface configured to be “secured within” a pedicle screw assembly, which limitations are present in all of the challenged claims. (Pet. at 19-21, 41-42; Pet. Ex. 1001 (‘057 Patent), claims 23-32, 46-55.)

- a. “first rigid portion”

Globus concedes that Panjabi does not expressly disclose a first rigid portion having an outer surface configured to be secured within a pedicle screw assembly (Pet. at 18-19, 40-41), and it does not argue that Panjabi inherently discloses the limitation. Globus’ position concerning McAfee’s disclosures on this limitation is unclear, but regardless, the disclosure does not exist.

Globus suggests that McAfee discloses an “in-line” anchoring system pursuant to which a longitudinal rod “tracks over” the perpendicular pedicle screw. (Pet. at 15, 37.) But McAfee never discloses whether the longitudinal rod has an outer surface configured to be “secured within” the assembly housing the pedicle screw: this is the spatial relationship claimed by the ‘057 Patent. (Pet. Ex. 1001

(‘057 Patent), claims 23, 46.) Thus, Globus has not demonstrated that McAfee expressly teaches or suggests Synthes’ “secured within” limitation or that McAfee’s “in-line” structure would be modified to do so. Globus also cannot satisfy the “necessarily present” standard for inherency because McAfee’s pedicle screw could pass through the rigid portion rather than the other way around – this is simply unknown based on McAfee’s disclosure. Because neither Panjabi nor McAfee discloses the claimed limitation, Globus’ challenge should be rejected.

Globus seemingly attempts to rely on other references that allegedly disclose in-line anchoring systems. (Pet. at 20, 42 (citing Pet. Exs. 1010-14).) Because Globus did not identify these references as “patents or printed publications relied upon” under 37 C.F.R. § 47.104(b)(2) (Pet. at 3), or make any attempt to establish that they are prior art, the Board should disregard them. Globus also has not identified “the portions of the references alleged to teach or suggest the limitations of the challenged claims,” improperly placing the burden on the Board to sift through references to which Globus has only generally referred. *Fid. Nat’l Info. Servs., Inc. v. Datatrans Corp.*, Case IPR2014-00489, Paper No. 9, 2014 WL 4059220, at *6 (PTAB Aug. 13, 2014). The burden always remains on Globus, and not on the Board, to identify disclosures in prior art patents or printed publications that establish the obviousness of particular claim limitations. 37 C.F.R. § 42.20(c).

Even if Globus could rely on these additional references, and even if Globus had properly identified the disclosures in those references that supplied the claim limitations missing from Panjabi and McAfee, Globus still has not established, as it must, that a person of ordinary skill would have a rationale for combining Panjabi and McAfee with the teachings of those additional references to arrive at Synthes' claimed invention. *See Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009).

To the extent Globus argues that this is a matter of “simple substitution” based on common knowledge, Globus has failed here just as it did earlier. As with the “elastomeric” limitation, Globus does not explain why one of ordinary skill would modify Panjabi so that it had a first rigid portion with an outer surface configured to be secured within a pedicle screw assembly, or why that modification would yield “predictable results.” *TRW Auto.*, 2014 WL 2965895, at *10. Nor does Globus identify an “expectation that...the combination would have worked for its intended purpose.” *DePuy Spine*, 567 F.3d at 1326. Indeed, Panjabi extensively promotes the advantages of its “off-set” anchoring system (Pet. Ex. 1002 at col. 1, ll. 17-24; col. 3, ll. 10-16; col. 3, ll. 27-31; Figs. 8, 9, 11-13), and Globus provides no evidence of how changing Panjabi's device to an in-line system and otherwise modifying its screw connections would affect the performance of the device – a device used in the human body, where it reacts to

biomechanical forces. As with the “elastomeric” limitation, Globus’ simple substitution argument here is ultimately based on attorney argument.

Globus attempts to avoid its failure of proof by contending that just because “a given course of action has simultaneous advantages and disadvantages[, that] does not nullify modifying the teachings of one reference over another.” (Pet. at 21 (citing *Winner Int’l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000).) Although the disadvantages of using an in-line screw connection may not necessarily “nullify” a finding of obviousness, nor do they create one: Globus still has to make out a *prima facie* case of obviousness in the first place, which it has not done. Contrary to Globus’ implication, the Federal Circuit’s *Winner* decision does not excuse a challenger from demonstrating a motivation to combine teachings simply because the challenger can point to “simultaneous advantages and disadvantages” of those teachings – as is clear from *Winner*’s finding of no obviousness despite the existence of such advantages and disadvantages. *See Winner*, 202 F.3d at 1349-50.

b. “spacer rigid portion”

Globus also fails to demonstrate that either Panjabi or McAfee teaches or suggests a spacer rigid portion with an outer surface configured to be secured within the pedicle screw assembly. Globus concedes that Panjabi does not expressly disclose this limitation (Pet. at 18-19, 40-41), and Globus’ claim chart

does not cite any disclosure in McAfee for this limitation. (Pet. at 16, 38.) Nor does Globus rely on the additional references (Pet. Exs. 1010-14) that it cites in support of its analysis of the “first rigid portion” (which are improper in any event). (Pet. at 22-23, 44.)

Although Globus mentions Figures 2 and 3 in McAfee in the Analysis for Claim 23 and Analysis for Claim 46 sections of its Petition (*id.*), neither is sufficient. Figure 2 discloses an off-set anchoring system (which Globus contends would have to be modified to satisfy the claimed subject matter). And Figure 3 discloses an in-line anchoring system without any disclosure of the precise spatial relationship between the spacer metallic portion and the pedicle screw assembly. (Pet. Ex. 1005, Figs. 2, 3.)

Without Panjabi or McAfee, Globus cannot rely on Dr. McAfee’s Declaration – which is neither a prior art patent nor printed publication – to establish obviousness. 35 U.S.C. § 311(b). Even if it could, Paragraph 14 of Dr. McAfee’s Declaration, which Globus cites (Pet. at 22-23, 44), is insufficient. (Pet. Ex. 1005, ¶ 14.) As with the “first rigid portion,” it does not cite any evidence backing up Dr. McAfee’s assertions about in-line systems. *See* 37 C.F.R. § 42.65(a) (expert testimony that does not disclose underlying facts is entitled to little or no weight). Globus thus has not demonstrated that Panjabi or McAfee,

alone or in combination, discloses a spacer metallic portion with an outer surface configured to be secured within a pedicle screw assembly.

3. Flexible member “connected” to
the first rigid portion and the second rigid portion

Globus has not demonstrated that Panjabi or McAfee teaches a flexible member “connected” to both the first and second rigid portions of the device, which limitation is present in all of the challenged claims. (Pet. at 21, 43; Pet. Ex. 1001 (‘057 Patent), claims 23-32, 46-55.) Globus concedes that Panjabi does not expressly disclose this feature, and Globus does not contend that McAfee discloses it either expressly or inherently. (Pet. at 18-19, 21, 40-41, 43.) Nor does Globus contend anywhere in its Petition that it would have been obvious to modify Panjabi to make a flexible member connected to the first and second rigid portions of the device. Globus’ only argument, that Panjabi inherently discloses the feature, lacks evidentiary support.

To support its argument that Panjabi inherently discloses a flexible member connected to both a first and second rigid portion, Globus cites to one part of Panjabi’s specification that says nothing about whether, or to what degree, a flexible member is connected to any other portion of the device: Panjabi discloses an “alignment pin” that “extends from” the “first attachment member” and “includes an abutment member 256 at its free end 258.” (Pet. Ex. 1002, col. 13, ll.

6-10. *See also* Pet. at 15, 37 (relying on this disclosure from Panjabi.) Even assuming, as Globus contends, that Panjabi’s “alignment pin” is the claimed “flexible member,” Panjabi’s “first attachment member” is the claimed “first rigid portion,” and Panjabi’s “abutment member” is the claimed “second rigid portion,” then all Panjabi really discloses is a flexible member that “extends from” the first rigid portion and “includes” a second rigid portion.”⁷ An object that “extends from” the first rigid portion, however, is not necessarily “connected” to that first rigid portion. Although an object that “extends from” a structure *may* be connected to that structure, “[t]he mere fact that a certain thing *may* result from a given set of circumstances is not sufficient [to establish inherency.]” *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). *See also In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981) (same). Similarly, an object that “includes” point B is not necessarily “connected” to Point B.

Globus cites nothing in Panjabi that bridges these gaps. Globus cannot, once again, fill the gaps by relying on Dr. McAfee’s Declaration. 35 U.S.C. § 311(b). Even if it could, Dr. McAfee does not even opine on the meaning of the Panjabi

⁷ Synthes accepts Globus’ contentions here – and any other contention that certain structures disclosed by Panjabi correspond to claim limitations of the claimed device – for argument’s sake only, and does not concede that Globus is correct.

disclosure that Globus cites, even though he opines on the meaning of many others. This leaves attorney argument as the only support for Globus' claim that "a POSITA would conclude that the alignment pin 250 is directly secured to the attachment member 260 and abutment member 256." (Pet. at 21, 43.) Attorney argument cannot satisfy Globus' burden.

4. "Metallic" nature of the "first rigid portion,"
"second rigid portion" and "spacer rigid portion"

Globus has not demonstrated that Panjabi or McAfee teaches either a first rigid portion or second rigid portion that is "metallic" – as required by dependent claims 30 and 48 – or a spacer rigid portion that is "metallic" – as required by dependent claims 31 and 50. (Pet. at 32-35, 47-48, 50-51; Pet. Ex. 1001 ('057 Patent), claims 30, 31, 48, 50.)

a. "Second rigid portion" that is metallic

Starting with the claimed "second rigid portion," neither Panjabi nor McAfee discloses its metallic quality, either expressly or inherently: the sole prior art support Globus lists is a passage from Panjabi that says nothing about metal (Pet. at 32, 47), and the Analysis for Claim 30 and Analysis for Claim 48 in the body of Globus' Petition do not cite McAfee at all (*id.* at 33, 48). Because Globus has not cited to any patents or printed publications supporting the obviousness of

this claim limitation, Globus cannot establish a “reasonable likelihood” of succeeding. *See* 35 U.S.C. § 311(b).

Globus’ only support for its argument that the metallic nature of the second, metallic rigid portion would have been obvious, is its assertion that “the likely preferred material would be titanium” – an assertion Globus backs up by citing Paragraph 11 of Dr. McAfee’s Declaration. (*Id.* at 33, 48.) Dr. McAfee’s Declaration is neither a prior art patent nor a prior art printed publication, and therefore cannot support an IPR obviousness challenge. 35 U.S.C. § 311(b). In any event, Paragraph 11 of Dr. McAfee’s Declaration contains a single sentence about titanium’s flexibility and does not support the sentence with citations to any evidence (much less a patent or printed publication). (Pet. Ex. 1007, ¶ 11.) Paragraph 11 of the Declaration, then, and the assertion in the Petition relying on it, should be entitled to no weight. *See* 37 C.F.R. § 42.65(a).⁸

Finally, Globus has offered no rationale concerning why a person of ordinary skill in the art would modify Panjabi’s device to make its “abutment

⁸ Paragraph 11 of the Declaration does cite to one article, but that article does not discuss any benefits of using titanium or other metals in a spinal implant: indeed, the article says nothing about any portion of a spinal implant being metallic. (Pet. Ex. 1009, cited in Pet. Ex. 1007, ¶ 11.)

member” (which Globus equates with the claimed second rigid portion) metallic.

See Procter & Gamble, 566 F.3d at 994. Globus thus has not demonstrated that Panjabi or McAfee, alone or in combination, discloses a “second rigid portion” that is metallic.

b. “Spacer rigid portion” that is metallic

Globus’ arguments on the “spacer rigid portion” fare no better. Globus concedes that neither Panjabi nor McAfee discloses a spacer portion that is metallic, either expressly or inherently: Globus’ citations to Panjabi say nothing about the spacer rigid portion being metal, and Globus has no citations to McAfee. (Pet. at 34-35, 50-51). As with “second rigid portion,” Globus’ obviousness challenge to “spacer rigid portion” finds no support in any patents or printed publications. *See* 35 U.S.C. § 311(b).

Even if it did, Globus has not established a motivation to modify Panjabi to include a metallic spacer portion. Globus’ attempt to supply that motivation in Paragraph 11 of Dr. McAfee’s Declaration (Pet. at 34-35, 50-51) is misplaced for the reasons explained above: the Declaration is not a competent basis for an IPR challenge, and in any event Paragraph 11 cites no evidence to support its

conclusions.⁹ Globus’ assertion that “the functionality of the second attachment member 266 (spacer metallic portion) is to secure the implant to the pedicle screw” (*id.*), even if relevant to the question of motivation, is also not supported by citations to any evidence. The Panjabi citations in Globus’ claim chart do not speak to whether Panjabi’s “second attachment member” serves to secure the implant to the pedicle screw. (Pet. at 34, 50.)

Globus cannot establish the obviousness of the “metallic” limitation by contending that a person of ordinary skill “understands that there are a finite number of materials acceptable for use in the body.” (Pet. at 34, 50.) Globus appears to be relying on the Supreme Court’s statement that “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.” *KSR*, 550 U.S. at 421. But Globus does not identify a “design need or market pressure to solve a

⁹ Although Dr. McAfee opines in Paragraph 28 of his Declaration that “the second attachment member 266 would tend to be metal material” (Pet. Ex. 1007, ¶ 28), Globus does not rely on that paragraph in its Petition (Pet. at 34-35, 50-51), and even if it did, Paragraph 28 is just as devoid of citations to evidence as is Paragraph 11.

problem” that would have caused a person of ordinary skill to look beyond the disclosures in Panjabi and choose a metallic spacer portion. Moreover, as the Federal Circuit explained, *KSR*’s statement quoted above “posits a situation with a finite, and in the context of the art, small or easily traversed, number of options that would convince an ordinarily skilled artisan of obviousness.” *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008).

Paragraph 11 of Dr. McAfee’s Declaration, on which Globus relies (Pet. at 34-35, 50-51), identifies various materials that could be used in spinal implants but does not characterize the listed materials as a closed set. (Pet. Ex. 1007, ¶ 11.) Dr. McAfee does not state that the materials he identifies are the only options, does not state how many such additional options there might be, or whether the complete set of options would be “easily traversed.” Globus’ assertion of a “finite number of materials acceptable for use” is thus conclusory attorney argument that cannot sustain an obviousness challenge. *See KSR*, 550 U.S. at 418. Globus has not demonstrated that Panjabi or McAfee, alone or in combination, discloses a “spacer metallic portion.”

c. “First rigid portion” that is metallic

Globus’ arguments on the claimed “first rigid portion” suffer from similar deficiencies. Globus concedes that Panjabi does not expressly disclose the metallic quality of this element, so it relies on a combination of Panjabi with McAfee,

which discloses a “rod sleeve” with a metal casing. (Pet. at 33-34, 47-48.) The disclosure of a metal casing as one option does not render its use obvious – especially when Globus’ declarant has identified several alleged disadvantages to using metal. (Pet. Ex. 1007, ¶¶ 11-12.)¹⁰ As with the other claim limitations, Globus must provide evidence that a person of ordinary skill in the art would have been motivated to modify Panjabi’s device so that its first rigid portion is metallic. *See Procter & Gamble*, 566 F.3d at 994. And as with the other claim limitations, Globus has not done so.

Although Globus asserts that “[t]itanium is a metal that will allow this technology achieve [*sic*] the needed functionality” (Pet. at 33, 47), Globus has not properly identified that “functionality” or the way that titanium would achieve it. Globus cites Panjabi 12:2-19 to support its claim that “the functionality of the first attachment member is to secure the stabilization device 210 to a vertebra via a

¹⁰ Globus once again notes that “a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate any or all reasons to combine teachings.” (Pet. at 21 (citing *Winner*, 202 F.3d at 1349 n.8).) For the reasons explained above, this assertion is irrelevant even if true, because it does not excuse Globus from demonstrating a motivation to modify Panjabi so that it has a first rigid portion that is metallic. (*See supra* at V.A.2.a.)

pedicle screw” (Pet. at 33, 47), but Panjabi 12:2-19 does not speak to the functionality of Panjabi’s first attachment member: if anything, it speaks to the functionality of the pedicle screws, which are a different portion of the device. (Pet. Ex. 1002, col. 12, ll. 2-19.) Even if that portion of Panjabi established that the functionality of the “first attachment member” is to secure the device to the vertebra, Globus cites no evidence that titanium would achieve that functionality. Its sole support is Paragraph 11 of Dr. McAfee’s Declaration (Pet. at 33, 47), which, as noted, is neither a patent nor a printed publication, and consists of conclusory testimony that should be disregarded.

Finally, Globus once again contends that a person of ordinary skill in the art “understands that there are a finite number of materials acceptable for use in the body.” (Pet. at 33, 47.) But Globus does not identify a “design need or market pressure to solve a problem” that would have caused a person of ordinary skill to look beyond the disclosures in Panjabi and choose a metallic rigid portion. *KSR*, 550 U.S. at 421. And while Paragraphs 11-13 and 19 of Dr. McAfee’s Declaration (Pet. at 33, 47) identify various materials that could be used in spinal implants, they do not characterize the listed materials as a closed set. (Pet. Ex. 1007, ¶¶ 11-13, 19.) Dr. McAfee does not state that the materials he identifies are the only options, does not state how many such additional options there might be, or whether the complete set of options would be “easily traversed.” Globus’ assertion

of a “finite number of materials acceptable for use” remains conclusory attorney argument that cannot sustain an obviousness challenge. *See KSR*, 550 U.S. at 418. Globus has not demonstrated that Panjabi or McAfee discloses a “first, metallic rigid portion.”

5. The first and second elastomeric spacer
portions “compris[ing] polycarbonate urethane”

Globus has not demonstrated that Panjabi or McAfee teaches first and second elastomeric spacer portions that “comprise polycarbonate urethane,” which limitations are present in dependent claims 32 and 54. (Pet. at 35, 54; Pet. Ex. 1001 (‘057 Patent), claims 32, 54.)

Neither Panjabi nor McAfee discloses first and second elastomeric spacer portions comprising polycarbonate urethane, either expressly or inherently: the sole prior art support Globus lists in its claim chart are passages from Panjabi that say nothing about polycarbonate urethane (Pet. at 35, 54 (citing Panjabi Abstract and col. 3, ll. 55-65)), and the Analysis for Claim 32 and Analysis for Claim 54 in the body of Globus’ Petition do not cite Panjabi or McAfee at all (*id.* at 35, 54). Because Globus has not cited to any patents or printed publications supporting the obviousness of this claim limitation, Globus cannot establish a “reasonable likelihood” of succeeding. *See* 35 U.S.C. § 311(b).

Globus cannot cure this deficiency through Dr. McAfee's Declaration (Pet. at 35, 54), which is neither a patent nor printed publication. 35 U.S.C. § 311(b). Moreover, Dr. McAfee's mere mention of polycarbonate urethane ("PCU") as a possible material for a spacer (Pet. Ex. 1007, ¶ 19) does not establish that polycarbonate urethane was an obvious choice. Dr. McAfee does not supply the necessary motivation for a person of ordinary skill in the art to modify Panjabi's implant to include first and second elastomeric spacer portions comprising polycarbonate urethane – as opposed to some other material. *See Procter & Gamble*, 566 F.3d at 994. Globus has not demonstrated that Panjabi or McAfee, alone or in combination, discloses first and second elastomeric spacer portions comprising polycarbonate urethane.

B. Globus Provides No Evidence That
The Claimed Invention As A Whole Would Have Been Obvious

Even if Globus had shown that the prior art disclosed all of the *individual* claim limitations addressed above, which Globus concedes are not disclosed in Panjabi, there is another, critical defect in Globus' Petition: Globus has not shown that the claimed invention *as a whole* would have been obvious in light of the disclosures in Panjabi and McAfee. Indeed, the sheer number of modifications to Panjabi reveals Globus' hindsight reconstruction.

“An invention is not obvious just ‘because all of the elements that comprise the invention were known in the prior art;’ rather a finding of obviousness at the time of invention requires a ‘plausible rational [sic] as to why the prior art references would have worked together.’” *Broadcom Corp. v. Emulex Corp.*, 732 F.3d 1325, 1335 (Fed. Cir. 2013). *See also Grain Processing Corp. v. Am. Maize-Products Co.*, 840 F.2d 902, 907 (Fed. Cir. 1988). When an accused infringer such as Globus claims that various claim limitations are spread out among various prior art references, it must show that a “skilled artisan would have a reasonable expectation of success” in combining those references to achieve the claimed invention.” *Procter & Gamble*, 566 F.3d at 994. Without showing that the prior art created such a reasonable expectation of success, all Globus has done is to use “the inventor’s own path” as a route to obviousness: “that is hindsight.” *Ostuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012).

Globus’ Petition fails to address whether a person of ordinary skill in the art would have been motivated to make all of the required modifications to Panjabi or how one modification would affect the others. Globus’ declarant opined that “the features recited in claims of the ‘057 Patent were well-known” (Pet. Ex. 1007, ¶ 5), but even if that were true (which it is not), it could not establish obviousness because it does not speak to the reasons why a person of ordinary skill in the art would have combined those features – to wit, the reasons why a person of ordinary

skill in the art would have taken Panjabi's device, changed its first attachment member, second attachment member and abutment member to make them metallic, changed certain portions of its spacer to make them elastomeric, changed its alignment pin so that it is connected to the first attachment member and abutment member, changed its first and second attachment member so that they have an outer surface configured to be secured within bone screw assemblies, *and* made the other required modifications to Panjabi to reach the claimed device. *KSR*, 550 U.S. at 418.

Nor does Globus address whether a person of ordinary skill in the art would have reasonably expected that each of the modified portions of Panjabi's device would have worked together for the intended purpose set out by the '057 Patent. Indeed, Globus does not even mention the issue.

The reason for this omission is clear – a reasonable expectation of success is lacking. The '057 Patent is directed to a multi-element spinal stabilization system for use in the human body, where it will have to react to biomechanical forces placed on it every minute of every day. (Pet. Ex. 1001 ('057 Patent), claim 23, 46 & col. 29, ll. 43-54.) Even Panjabi and McAfee recognized that changing the elements of their spinal implants could affect the implants' biomechanical properties. McAfee, for example, notes that the change from an off-set to an in-line screw anchoring system could affect torque and change the forces that the

patient's bones put on the implant. (Pet. Ex. 1005 at [0020], [0037], [0044].)

Panjabi also focused on the resistance created by the springs in its device – springs that Globus contends would have to be modified to reach the claimed invention. (Pet. Ex. 1002 at col. 3, ll. 41-49; col. 6, ll. 51-57; col. 7, ll. 60-64; col. 9, ll. 54-58; col. 10, ll. 6-10.)

Globus has not proven (or even alleged) that these modifications would create an implant that works for the intended purpose of the '057 Patent. For example, Globus has not proven (or even alleged) that a modified Panjabi implant with metallic rigid portions and elastomeric spacer portions would work for the intended purpose of the '057 Patent. Globus has not proven (or even alleged) that a modified Panjabi implant with an outer surface of certain portions configured to be “secured within” pedicle screw assemblies would work for that intended purpose. The list goes on, but the upshot is clear: this Petition does not establish reasonable expectation of success. Indeed, the large number of modifications that would be required suggests that one of ordinary skill would not reasonably expect success— which is perhaps why Globus skirts this dispositive issue.

VI. OBJECTIVE INDICIA OF NON-OBVIOUSNESS

Globus' Petition does not address objective indicia (“secondary considerations”) of non-obviousness. If the Board institutes proceedings, then Patent Owner will submit objective evidence of non-obviousness.

VII. CONCLUSION

For the foregoing reasons, the Board should reject Globus' Petition in its entirety and not institute proceedings in this matter.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, David R. Bailey, hereby certify that on this 5th day of February, 2015, the foregoing PATENT OWNER'S PRELIMINARY RESPONSE PURSUANT TO 37 C.F.R. § 42.107 was served on the following by email:

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