

EXHIBIT 2003

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION**

Spinelogik, Inc.,	)	
	)	
	)	
Plaintiff,	)	Case No. 2:23-cv-00529-JRG
	)	
v.	)	
	)	
Globus Medical, Inc.	)	
	)	
Defendant.	)	
	)	

DEFENDANT’S INVALIDITY CONTENTIONS

Pursuant to the Docket Control Order (D.I. 22), and Eastern District of Texas Local Patent Rule 3-3, Defendant Globus Medical, Inc. (“Defendant” or “Globus”), hereby serves the following Invalidity Contentions for U.S. Patent Nos. 8,460,385 (the “’385 patent”) and 9,730,805 (the “’805 patent”) (collectively, the “Asserted Patents”). Invalidating references will be produced by Globus concurrently with these Invalidity Contentions.

I. Introduction

These Invalidity Contentions are based on information currently available to Globus. Continuing investigation and discovery may alter this disclosure. Globus reserves the right to supplement or amend these Invalidity Contentions, if necessary, based on developments in this action, including, without limitation, by identifying additional prior art and additional theories of invalidity, in response to Plaintiff Spinelogik, Inc.’s (“Plaintiff” or “Spinelogik”) amended infringement contentions, Spinelogik’s responses to discovery requests, or any assertion of additional claims by Spinelogik. Globus also reserves the right to object to any assertion of additional claims.

A. Asserted Patents and Asserted Claims

Spinelogik asserted the following claims in its Infringement Contentions:

Asserted Patent	Asserted Claim(s)
'385 patent	1, 2, 7, and 9
'805 patent	1, 5, ¹ 11, 15, 16, and 17

These Invalidity Contentions address only those claims asserted by Spinelogik in the Infringement Contentions. Globus intends to supplement these Invalidity Contentions in the event Spinelogik is allowed to assert any additional claims.

B. Priority of Asserted Claims

In its Infringement Contentions, Spinelogik contended that the priority date for each of the Asserted Claims² of the '385 patent is February 15, 2010 and each of the Asserted Claims of the '805 patent is October 18, 2012. Based on Spinelogik's contention, Globus has therefore applied those respective priority dates when assessing the validity of the Asserted Claims. Nothing herein should be construed, however, to imply that each of the Asserted Claims has written description support in the Asserted Patents and/or any earlier patents or applications to which the Asserted Patents claim priority.

¹ Spinelogik does not include claim 6 of the '805 patent in its list of Asserted Claims in the cover document of its Preliminary Infringement Contentions. See Prelim. Infringement Contentions at 1. Thus, Globus presumes this claim is not being asserted. However, in the infringement claim charts accompanying Spinelogik's Preliminary Infringement Contentions, Spinelogik has included claim 6. Globus therefore has incorporated claim 6 into these Invalidity Contentions, the accompanying invalidity claim charts, and into the meaning "Asserted Claims" as used herein. Claim 6, like the other Asserted Claims, is invalid for the reasons set forth more fully below.

² Spinelogik's Preliminary Infringement Contentions actually state "The priority date of each of the '385 Patent . . . [and] each of the '805 Patent" is the above-referenced dates. See Prelim. Infringement Contentions at 1. Globus has inferred that Spinelogik is referring to "each of the *asserted claims*" of those patents. To the extent Spinelogik is only referring to certain claims, Globus reserves the right to address any different priority dates later asserted by Spinelogik, including the timeliness of any such assertion.

Globus reserves the right to amend these Invalidity Contentions in the event Spinelogik claims priority to an earlier application, asserts an earlier conception or reduction to practice date than the priority application filing date, changes the alleged priority dates, or the Court determines that the Asserted Patents are not entitled to claim priority to earlier provisional or non-provisional applications.

C. Claim Construction Considerations

Claim construction has not yet occurred. As such, Globus reserves the right to modify, amend, and/or supplement these Invalidity Contentions following claim construction rulings, to the extent permitted by the Court. Globus also reserves the right to modify, amend, and/or supplement these Invalidity Contentions based on Spinelogik's clarification of its asserted claim constructions, including any adopted by Globus in its Infringement Contentions or any amendments thereto.

For the purposes of these Invalidity Contentions, Globus acknowledges that the Court may provide a specific construction for the terms within the Asserted Claims. To the extent Globus has asserted that portions of the prior art invalidate the Asserted Claims based on constructions seemingly applied by Spinelogik, Globus is explicitly not adopting or admitting to the accuracy or propriety of that construction. Globus reserves the right to propose any claim construction it deems appropriate and to contest any claim construction it considers inappropriate, regardless of the apparent constructions applied in these Invalidity Contentions. Additionally, any application of the prior art to the Asserted Claims is not an admission or waiver of an argument pursuant to 35 U.S.C. § 112. Globus specifically reserves the right to argue that certain claim terms, phrases, and elements within the Asserted Claims are indefinite, lack written description, are not enabled, and/or are otherwise invalid under 35 U.S.C. § 112.

D. Spinelogik's Infringement Contentions

Globus provides these Invalidity Contentions in accordance with the Docket Control Order (D.I. 22). Globus does so, however, without waiving its right to receive full, complete, and detailed infringement contentions in compliance with Local Patent Rule 3-1. Spinelogik's Infringement Contentions are deficient in many ways, including: (1) Spinelogik failed to identify where each element of each asserted claim is found within each accused product, relying on arrows and nondescript shapes to point to purportedly relevant structures, without any analysis stating, with specificity, which portions of the accused products meet the asserted claims; (2) Spinelogik identifies the same structure as both the "driving member" and "delivery mechanism" in its infringement claim charts, however, these claim terms have separate meanings and, as such, Spinelogik has failed to identify a structure corresponding to each claim limitation; (3) Spinelogik incorrectly asserts expiration dates in 2029 for the Asserted Patents when both patents are already expired; (4) Spinelogik seems to rely on overly broad constructions of the asserted claim terms to demonstrate infringement, although those constructions are not supported by the claim language and intrinsic record; and (5) Spinelogik's Local Patent Rule 3-2 document production is deficient in that it does not include any conception and reduction to practice documents as required by the Local Rules.

Because Spinelogik has not provided its allegations regarding infringement with reasonable particularity, Globus is forced to guess as to what Spinelogik believes the Asserted Claims cover. As such, Globus has provided differing prior art references and combinations, in the alternative, to encompass the potential infringement arguments that Spinelogik may proffer. If and when Spinelogik is required to provide more detailed, and clear, infringement contentions, Globus reserves the right to revise, amend, and/or supplement these Invalidity Contentions accordingly. Globus reserves the right to move to compel more detailed contentions.

E. Ongoing Discovery and Disclosure

Discovery in this case is in its early stages and Globus' investigation, including Globus' search for prior art, is ongoing. Globus reserves the right to amend or modify these Invalidity Contentions based on additional information obtained through discovery or other means pursuant to Fed. R. Civ. P. 26(e).

II. Invalidity Contentions

Globus contends that each of the Asserted Claims is invalid as anticipated and/or rendered obvious by the prior art, for lack of written description support, and/or for indefiniteness. Globus reserves the right to respond to any allegations of secondary considerations of non-obviousness set forth by Spinelogik or its expert witness(es) in accordance with the schedule set by the Court for expert reports and discovery.

A. Identification of Prior Art – 35 U.S.C. §§ 102 and 103 (pre-AIA)

The following prior art, alone or in combination with the knowledge of a person of ordinary skill in the art, admitted prior art, prior art of record in the prosecution of the Asserted Patents and related applications, and/or the additional prior art references discussed below and in **Exhibits A-1 through A-14** and **B-1 through B-8**, would have invalidated and/or rendered obvious one or more Asserted Claims of the Asserted Patents. In addition, Globus expressly incorporates by reference all prior-art references cited within the Asserted Patents and their file histories. Globus reserves the right to identify or rely on additional or different references based on Spinelogik's amended assertions and/or arguments as to the priority date(s) of the Asserted Claims.

Prior Art	Filing Date	Date of Issuance or Publication	Exhibit No.
U.S. Patent No. 8,075,593, entitled "Interspinous Implants and Methods for Implanting Same," to Harold Hess ("Hess")	January 30, 2008 (claims priority to May 1, 2007)	December 13, 2011	A-1

Prior Art	Filing Date	Date of Issuance or Publication	Exhibit No.
U.S. Patent No. 7,985,255, entitled “Implant Subsidence Control,” to Robert S. Bray (“Bray ’255”)	October 12, 2005	July 26, 2011	A-2; B-4
U.S. Patent No. 7,942,903, entitled “Bi-Directional Fixating Transvertebral Body Screws and Posterior Cervical and Lumbar Interarticulating Joint Calibrated Stapling Devices for Spinal Fusion,” to Ahmnon D. Moskowitz, et al. (“Moskowitz”)	August 21, 2007 (claims priority to April 12, 2005)	May 17, 2011	A-3; B-3
U.S. Patent Pub. No. 2002/0147450, entitled “Anterior Plating System and Method,” to Jean-Charles LeHuec, et al. (“LeHuec”)	November 6, 2001	October 10, 2002	A-4
U.S. Patent No. 6,214,005, entitled “Spinal Column Retaining Apparatus,” to Edward C. Benzel (“Benzel”)	August 28, 1998 (claims priority to August 31, 1996)	April 10, 2001	A-5
U.S. Patent Pub. No. 2006/0235409, entitled “Flanged Interbody Fusion Device,” to Jason Blain (“Blain”)	March 13, 2006	October 19, 2006	A-6
U.S. Patent No. 6,447,546, entitled “Apparatus and Method for Fusing Opposing Spinal Vertebrae,” to Dale G. Bramlet, et al. (“Bramlet”)	August 11, 2000	September 10, 2002	A-7
U.S. Patent No. 9,408,715, entitled “Arcuate Fixation Member,” to Thomas Donner, et al. (“Donner”)	April 15, 2010 (claims priority to April 15, 2009)	August 9, 2016	A-8; B-2
U.S. Patent Pub. No. 2013/0150968, entitled “Anchoring Device and System for an Intervertebral Implant, Intervertebral Implant and Implantation Instrument,” to Hervé Dinville, et al. (“Dinville”)	PCT filed December 31, 2009	June 13, 2013	A-9; B-8
U.S. Patent No. 8,167,949, entitled “Hydrostatic Interbody,” to Jeffrey Tyber, et al. (“Tyber”)	January 25, 2008	May 1, 2012	A-10
U.S. Patent No. 8,328,872, entitled “Intervertebral Fusion Implant,” to William E. Duffield, et al. (“Duffield”)	September 2, 2008	December 11, 2012	A-11
Synthes SynFix-LR Stand Alone Anterior Lumbar Interbody Fusion System (“Synthes SynFix”)	N/A	2006	A-12; B-5

Prior Art	Filing Date	Date of Issuance or Publication	Exhibit No.
RSB Spine, LLC's InterPlate™ System ("RSB InterPlate")	N/A	2006	A-13; B-7
U.S. Patent No. 8,172,854, entitled "Attachable Instrument Guide with Detachable Handle," to Jason Blain ("Blain '854")	July 18, 2008 (claims priority to July 19, 2007)	May 8, 2012	B-1
U.S. Patent No. 8,343,219, entitled "Intersomatic cage, intervertebral prosthesis, anchoring device and implantation instruments" was invented by Jérôme Allain, Jean Lombard, Jeff Phelps, Pierce D. Nunley, Charles Gordon, Vincent J. Leone, and Michael M.D. Hisey ("Allain")	June 6, 2008	January 1, 2013	B-6; A-14

The identified prior art may also provide background and context pertinent to the teachings and interpretations of the prior art and is indicative of the relevant state of the art and knowledge of one of ordinary skill in the art at the time of the alleged invention of the Asserted Patents. The prior art demonstrates, for example, the lack of inventiveness of the alleged invention of the Asserted Patents and provides teachings, suggestions, and motivations to combine. The identified prior art is exemplary and not intended to limit the scope of what a person of ordinary skill in the art would have understood at the time of alleged invention.

Certain parts of the identified prior art may inherently or implicitly disclose elements of the Asserted Claims. Globus reserves the right to rely on inherency and secondary documentation to demonstrate the invalidity of the Asserted Claims based on these inherent or implicit disclosures within the identified prior art references. Moreover, Globus may rely on additional evidence, including expert testimony, to establish the express, implicit, or inherent disclosure of certain elements of the prior art, or the knowledge of a person of ordinary skill in the art, to establish the invalidity of the Asserted Claims. Globus further reserves the right to rely on additional evidence,

including expert testimony, to establish that the disclosures or identified prior art are enabled and/or to explain the meaning of any terms used within the disclosures of the identified prior art.

Additionally, discovery is ongoing and Globus anticipates that additional discovery, including third party discovery, may reveal prior art systems that invalidate the asserted claims of the Asserted Patents. Globus has specifically identified the Synthes SynFix system and RSB InterPlate system (*see* Exs. A-12-13; B-5; B-7) but expects additional system art to be revealed as discovery progresses. For example, Medtronic, Stryker, SeaSpine, Zimmer Biomet, and UCLA developed spinal implant systems that may invalidate the Asserted Patents. *See, e.g.*, Medtronic SOVEREIGN™ spinal system, [Press Releases | Medtronic](#) and [Medtronic Sofamor Danek SOVEREIGN. IBF w/ Screws. Lumbar/T-Lumbar. SCREW. Catalog #7975525 \(catablog.com\)](#); Stryker Reflex Hybrid System, [Cervical Reflex Hybrid ACP Implant : Stryker \(archive.org\)](#); SeaSpine Sonoma Spinal Implant, [SeaSpine Sonoma | Video \(ghostproductions.com\)](#); Zimmer BioMet dynamic stabilization transition system, [Zimmer Spine Introduces New Rigid to Dynamic Stabilization Transition System – Zimmer Biomet](#); Zimmer Biomet Trinica lumbar plate system, [Zimmer Spine's New Lumbar Plate System Allows for Greater Intraoperative Flexibility – Zimmer Biomet](#) and [06.01353.012 Trinica Select ATO ST English.indd \(thespinemarketgroup.com\)](#); UCLA spinal stenosis device, [New device to treat spinal stenosis offered at UCLA \(youtube.com\)](#). Additional investigation and third-party discovery into these prior art systems is required. Globus will supplement and amend these contentions, as appropriate, to the extent additional system art is identified.

B. Exhibits A-1 through B-8

The attached Exhibits identify where, specifically, each limitation of each Asserted Claim is found in each item of prior art. The Exhibits may refer to combinations of prior art and where the requisite claim element may be found in a combined reference. While Globus has endeavored

to thoroughly demonstrate the citations where each element or limitation of the Asserted Claims may be found in each prior art reference, each and every disclosure of the same element or limitation within the same prior art reference is incorporated herein. Globus reserves the right to rely on other portions of the identified prior art references to support its claims and/or defenses.

Any reference within an Exhibit to a figure incorporates by reference the figure itself and any description of that figure in a reference. Additionally, many of the identified prior art references are related to, or counterparts of, patent applications and issued patents that cover substantially the same subject matter and similar disclosures. Any citation to or quotation from these prior art references should be understood to encompass any parallel citation to the same subject matter in related or corresponding applications or patents.

As previously explained, the disclosures within these Exhibits are based on Globus' understanding of the claim constructions as they are applied by Spinelogik, or may be applied by Spinelogik in the future, even though Globus does not necessarily agree with those constructions and reserves the right to dispute them.

C. Invalidity of the Asserted Patents Under 35 U.S.C. § 102 (pre-AIA)

A patent claim is invalid if the claimed invention was known or used by others in this country or patented or described in a printed publication in this or a foreign country before the invention thereof by the patent applicant. *See* 35 U.S.C. § 102(a) (pre-AIA). Additionally, a patent claim is invalid if “the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.” *Id.* § 102(b) (pre-AIA). A patent may also be invalid under 35 U.S.C. § 102 (pre-AIA) if, for example, the invention was described in an application for patent filed by another in the United States before the invention by the patent

applicant (*id.* § 102(e)) or if “the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it” (*id.* § 102(g)(2)).

Anticipation of a patent requires a “single prior art reference [that] discloses, either expressly or inherently, each limitation of the claim.” *In re Cruciferous Sprout Lit.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002). Thus, even if a single prior art reference does not expressly teach each limitation of a claim, that claim may still be anticipated. *Id.* An inherent disclosure may be found where “the natural result flowing from the operation as taught would result in the performance of the questioned function.” *King Pharm., Inc. v. Eon Labs., Inc.*, 616 F.3d 1267, 1275 (Fed. Cir. 2010). “[I]nherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure.” *Abbott Labs. v. Baxter Pharm. Prods. Inc.*, 471 F.3d 1363, 1368 (Fed. Cir. 2006). Moreover, the anticipation analysis “indisputably allows for some flexibility” such as considering whether a person of ordinary skill in the art would “at once envisage” the claimed invention. *Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1069-70 (Fed. Cir. 2017); *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381-82 (Fed. Cir. 2015).

Below, Globus has identified prior art references that anticipate the Asserted Claims. These references teach every limitation of each Asserted Claim either expressly or implicitly. Explanations of how the prior art anticipates the Asserted Claims appear in the attached Exhibits, which identify specifically where each limitation of each asserted claim is found in each item of prior art. To the extent an Exhibit references a potential combination with one of the below-identified prior art references to invalidate a particular claim limitation, that combination is discussed as a § 103 alternative to § 102 invalidation.

Exhibit	Asserted Patent	Prior Art
A-1	'385 patent	Hess

Exhibit	Asserted Patent	Prior Art
A-2	'385 patent	Bray '255
A-3	'385 patent	Moskowitz
A-4	'385 patent	LeHuec
A-5	'385 patent	Benzel
A-8	'385 patent	Donner
A-14	'385 patent	Allain
B-1	'805 patent	Blain '854
B-2	'805 patent	Donner
B-3	'805 patent	Moskowitz
B-4	'805 patent	Bray '255
B-5	'805 patent	Synthes SynFix
B-6	'805 patent	Allain
B-7	'805 patent	RSB InterPlate
B-8	'805 patent	Dinville

D. Invalidity of the Asserted Patents Under 35 U.S.C. § 103 (pre-AIA)

A patent claim is invalid as obvious “if the differences between the subject matter . . . patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103 (pre-AIA). To determine whether a patent claim is obvious, a court considers: (1) the level of ordinary skill in the art; (2) the scope and content of the prior art; (3) any differences between the prior art and the claim; and (4) objective indicia of non-obviousness, sometimes referred to as “secondary considerations.” *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). To “determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue,” a court should “look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). A patent may be obvious if, *inter alia*, there was a “known problem for which there was an obvious solution encompassed by the patent’s claims” or the combination of the patent’s claims was “obvious to try.” *Id.* at 419-

421. “[I]nherency may supply a missing claim limitation in an obviousness analysis.” *Par Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1194-95 (Fed. Cir. 2014). If the natural result flowing from practicing the teachings of a reference would result in the claimed attribute, the reference renders the attribute obvious, even without expressly reciting it. *Id.* at 1194. Additionally, the Supreme Court has held that inventions arising from ordinary innovation and skill or common sense are not patent-eligible. *See KSR Int’l Co.*, 550 U.S. 402, 419-22, 427-28.

To the extent a claim or limitation is deemed to be not exactly met by an item of prior art, Globus contends that the difference would have been obvious to a person of ordinary skill in the art and within the knowledge of one skilled in the art at the time of alleged invention. Thus, the claimed invention would have been obvious both in light of the single reference alone and/or in light of the combined references.

1. Identified Combinations of Prior Art References

Below and in the Exhibits, Globus has identified combinations of the identified prior art references that invalidate the Asserted Claims. By so combining, Globus does not admit or concede that the element is not expressly or inherently disclosed in the primary reference described in the Exhibit. Explanations of how the prior art renders the asserted claims obvious appear in the attached Exhibits, which identify specifically where each limitation of each asserted claim is found in each item of prior art. Globus expressly intends to combine one or more prior art items identified in the attached Exhibits with each other to address any further contentions from Spinelogik that a particular prior art reference purportedly lacks one or more elements of an Asserted Claim.

Exhibit(s)	Asserted Patent	Prior Art Combination
A-1	'385 patent	Hess alone
A-8	'385 patent	Donner alone
A-2 in view of A-1, A-8, or A-9	'385 patent	Bray '255 alone and/or in view of Hess, Donner, Allain, or Dinville

Exhibit(s)	Asserted Patent	Prior Art Combination
A-3 in view of A-1, A-8, or A-9	'385 patent	Moskowitz alone and/or in view of Hess, Donner, Allain, or Dinville
A-4 in view of A-1, A-8, or A-9 and/or A-2, A-3, A-5, or A-6	'385 patent	LeHuec alone and/or in view of Hess, Donner, Allain, or Dinville, and/or in further view of Bray '255, Moskowitz, Benzel, or Blain
A-5 in view of A-1, A-8, or A-9 and/or A-2, A-3, or A-4	'385 patent	Benzel alone and/or in view of Hess, Donner, Allain, or Dinville, and/or in further view of Bray '255, Moskowitz, or LeHuec
A-6 in view of A-1, A-8, or A-9 and/or A-2, A-3, A-4	'385 patent	Blain alone and/or in view of Hess, Donner, Allain, or Dinville, and/or in further view of Bray '255, Moskowitz, or LeHuec
A-7 in view of A-1, A-8, or A-9 and/or A-2, A-3, A-5, or A-6	'385 patent	Bramlet alone and/or in view of Hess, Donner, Allain, or Dinville, and/or in further view of Bray '255, Moskowitz, Benzel, or Blain
A-9 in view of A-1, A-2, A-3, A-5, A-6, or A-8	'385 patent	Dinville alone and/or in view of Hess, Bray '255, Moskowitz, Benzel, Blain, or Donner
A-10 in view of A-1, A-8, or A-9 and/or A-2, A-3, or A-4	'385 patent	Tyber alone and/or in view of Hess, Donner, Allain, or Dinville and/or in further view of Bray '255, Moskowitz, or LeHuec
A-11 in view of A-1, A-8, or A-9 and/or A-2, A-3, A-5, or A-6	'385 patent	Duffield alone and/or in view of Hess, Donner, Allain, or Dinville and/or in further view of Bray '255, Moskowitz, Benzel, or Blain
A-12 in view of A-1, A-8, or A-9 and/or A-2, A-3, A-5, or A-6	'385 patent	Synthes SynFix alone and/or in view of Hess, Donner, Allain, or Dinville and/or in further view of Bray '255, Moskowitz, Benzel, or Blain

Exhibit(s)	Asserted Patent	Prior Art Combination
A-13 in view of A-1, A-8, or A-9 and/or A-2, A-3, A-4, A-5, or A-6	'385 patent	RSB InterPlate alone and/or in view of Hess, Donner, Allain, or Dinville and/or in further view of Bray '255, Moskowitz, LeHuec, Benzel, or Blain
A-14	'385 patent	Allain alone
B-1 in view of B-2, B-6, or B-8	'805 patent	Blain '854 alone and/or in view of Donner, Dinville, or Allain
B-2	'805 patent	Donner alone
B-3 in view of B-2, B-6, or B-8	'805 patent	Moskowitz alone and/or in view of Donner, Dinville, or Allain
B-4 in view of B-2, B-6, or B-8	'805 patent	Bray '255 alone and/or in view of Donner, Dinville, or Allain
B-5 in view of B-2, B-6, or B-8	'805 patent	Synthes SynFix alone and/or in view of Donner, Dinville, or Allain
B-6	'805 patent	Allain alone
B-7 in view of B-2, B-6, or B-8	'805 patent	RSB InterPlate alone and/or in view of Donner, Dinville, or Allain
B-8	'805 patent	Dinville alone

2. Rationale and Motivation to Combine

One of ordinary skill in the art, at the time of the purported inventions of the Asserted Claims, would have been motivated to combine the teachings of these references, for at least the reasons set forth herein, disclosed in the attached Exhibits, within the prior art references themselves, and based on the knowledge of one of ordinary skill in the art at the time of alleged invention. At the time of the alleged inventions of the Asserted Claims, a person of ordinary skill in the art would have held a bachelor's of science degree in mechanical, biomechanical, or biomedical engineering as well as at least three years of experiencing designing, developing, and/or utilizing orthopedic implants and/or spinal interbody devices. More experience would compensate for less formal education, and vice versa.

The cited prior art relates to common objectives and general subject matter and share other commonalities, including the types of equipment, products, and/or approaches used. For example, the prior art references are directed specifically towards spinal implants and related devices. These references are therefore within the field of the Asserted Patents and are directed to similar subject matter within that field. A person of ordinary skill in the art would have been motivated to combine the teachings of the references to enhance the operability and efficacy of spinal implants. Further, some of the prior art references explicitly or implicitly reference each other, share common authors or inventors, and/or were developed at common companies, schools, or organizations, which would have motivated one of skill in the art to combine them. Additionally, the references, and any products, devices, or processes described in the references, existed, and/or were invented in the same time period providing further motivation for combination.

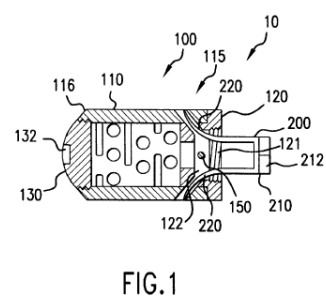
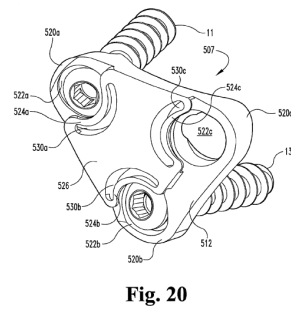
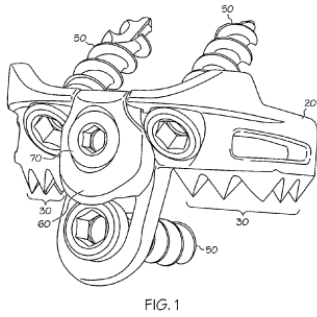
A person of ordinary skill in the art at the time of the alleged invention of the Asserted Patents would have been motivated to combine the below-identified prior art references, and have a reasonable expectation of success in doing so, because each combination would have been merely: (1) a combination of prior art elements according to known methods to yield predictable results; (2) a simple substitution of one known element for another to obtain predictable results; (3) a use of a known technique to improve similar devices in the same way; (4) an application of a known technique to a known device ready for improvement to yield predictable results; (5) obvious to try; and/or (6) known work in one field of endeavor prompting variations of it for use in either the same field or a different field based on design incentives or other market forces since the variations are predictable to one of ordinary skill in the art.

i. A POSITA would have been motivated to combine references disclosing spinal implants with straight channels with those disclosing curved channels ('385 Patent)

All of the prior art references disclose spinal implantation devices that utilize anchoring members to fuse with a first and second vertebrae. Additionally, each reference discloses a channel that is traversed by the anchoring member to reach the respective vertebrae. Claim 1 of the '385 patent requires that these channels are “curved.”

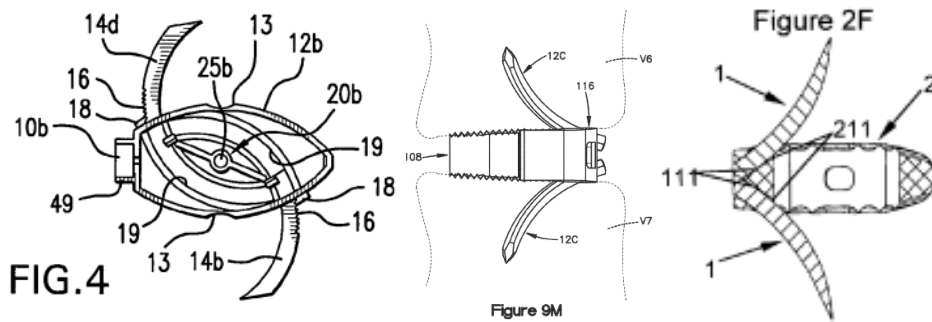
Claim construction has not yet begun and Globus expects that there may be a dispute between the Parties regarding the meaning of a “curved channel,” as evidenced by Spinelogik’s apparent interpretation in the Infringement Contentions. To the extent that the term “curved” channel is given a very broad construction—in-line with Spinelogik’s apparent interpretation—the above-cited prior art references all disclose a curved channel. To the extent the term “curved” channel is given a narrower construction—in-line with the patent specification, claim language, and prosecution history—certain prior art references only disclose straight channels that do not include the claimed curvature. A POSITA, however, would have been motivated to combine these references with prior art references, such as Hess, Donner, Allain, and Dinville, that teach the use of a curved channel.

Bray '255, Moskowitz, LeHuec, Benzel, Blain, Bramlet, Tyber, Duffield, Synthes SynFix, and RSB InterPlate all teach the use of a straight channel through which an anchoring member may pass to enter a spinal vertebra, as exemplified in the attached claim charts. Examples of the straight channels disclosed in these references are shown below:



(Bray, Fig. 1; LeHuec, Fig. 20; Bramlet, Fig. 1). These references do not, however, explicitly teach a *curved* channel, traversed by a curved anchoring member.

A POSITA would have been familiar with known prior art at the time of invention, including Hess, Donner, and Dinville, that teach a curved channel, as shown below:



(Hess, Fig. 4; Donner, Fig. 9M; Dinville, Fig. 2F; *see also* Allain, Figs. 11A-D). Prior to February 15, 2010, curved channels—like those taught by the '385 patent—were well-known in the art. *See also, e.g.,* Allain, Figs. 10A, 11A. Thus, the combination of art teaching curved channels with the art teaching straight channels would merely be a combination of known elements according to methods known to a POSITA at the time of alleged invention. As is evident by the figures above, modifying the straight channels disclosed in Bray '255, Moskowitz, LeHuec, Benzel, Blain, Bramlet, Tyber, Duffield, Synthes SynFix, or RSB InterPlate to instead utilize the curved channels taught by Hess, Donner, Allain, or Dinville would be a simple substitution of one known element for another.

Moreover, a POSITA would have expected this combination to yield predictable results. One of the main concerns with spinal implants prior to 2010 was retaining the anchoring members within the vertebrae and fusion device to prevent the implant shifting before the vertebrae properly healed. *See, e.g.*, Bramlet at 1:34-37 (explaining “shifting of the implant between the adjacent vertebrae during the initial stabilization period . . . can lead to discomfort and serious consequences for the patient); Dinville at [0002] (“there is a risk that the implant will shift in the intervertebral space due to forces imposed when the patient moves”). A POSITA would have recognized that curved channels would help to stabilize the implant by more evenly distributing these forces in multiple directions, as opposed to a straight channel.

Another common problem with spinal fusion implants prior to 2010 was preventing backout of the bone screws or anchoring members. For example, as explained by Blain in 2006:

In existing spinal fusion implants there have also been problems with loosening and backing out of screws into the patient’s throat area. Backout is the exhibited tendency of bone screws, which affix the bone plate to the bone(s), to loosen with respect to both the plate and bone, resulting in poor fixation, fusion and ultimately, healing. Essentially, this loosening of the bone screw causes the screw to work itself out of the bone into which it is implanted. This results in the bone plate before poorly fixed in place thus becoming devoid of its fixation capabilities. Usually, backout is caused by the chronic stress of bodily movement. While such loosening can be benign if limited in scope, it may lead to complications such as complete failure of the fixation device or incomplete bone fusion. Backout is particularly prevalent in areas of high bodily stress and movement, such as the spine.

Blain at [0095]. The issue of backout was well-known in the art and prior inventors attempted to mitigate the risks of backout in various ways. *See* Blain at [0096] (“To avoid backout and its associated problems, current systems utilize secondary locking screws, locking collars or other secondary locking devices that hold the bone screws in place after deployment within the bone); *see also, e.g.*, Bray ’255, Moskowitz, Benzel (all teaching a recess within the channel to lock the bone screw into place); Bramlet, Duffield, and Hess (teaching a locking mechanism to hold the

anchoring members into place to prevent backward movement); *see also* '385 patent (disclosing the use of a recess in the channel to prevent backout). A POSITA would have recognized, as taught in the prior art, that curved channels would also have assisted in preventing backout of the anchoring members. A POSITA would have known that straight channels and straight anchoring members have a tendency to backout due to compressive forces on the spine. *See* Blain at [0095]; *see also* Donner at 1:44-51. Utilizing curved channels and curved anchoring members, therefore, allows the spinal implant to better distribute those forces in multiple directions, leaving the anchoring members less prone to backout.

Based on the knowledge of a POSITA and teachings of a prior art, then, combining the spinal implant systems taught by Bray '255, Moskowitz, LeHuec, Benzel, Blain, Bramlet, Duffield, Tyber, Synthes SynFix, or RSB InterPlate with the curved channels taught by Hess, Donner, Allain, or Dinville would have been obvious to try in order to provide a way to better avoid backout. As evidenced by the disclosures of Hess, Donner, Allain, and Dinville, implementing curved channels in a spinal fusion implant was a known technique and Bray '255, Moskowitz, LeHuec, Benzel, Blain, Bramlet, Duffield, Tyber, Synthes SynFix, and RSB InterPlate all teach similar spinal fusion implant devices utilized for the same purposes. Accordingly, a POSITA would have been motivated to combine each of Bray '255, Moskowitz, LeHuec, Benzel, Blain, Bramlet, Duffield, Tyber, Synthes SynFix, or RSB InterPlate with Hess, Donner, Allain, or Dinville.

ii. A POSITA would have been motivated to combine references disclosing only spinal implants with those disclosing a driving member ('385 Patent)

Prior to 2010, a POSITA would have known that a spinal implant device comprising anchoring members that attach to spinal vertebrae would necessarily require the use of a “driving member” to drive the anchoring member into the respective vertebrae. As such, most of the cited

prior art references teach the use of a “driving member”. *See* Hess; Bray ’255; Moskowitz; Donner; LeHuec; Bramlet; Dinville; Duffield; Synthes SynFix; RSB InterPlate. Some of the prior art references, however, do not explicitly disclose the “driving member” and how it connects, and disconnects, from the implant device anchoring members. *See* Benzel; Blain; Tyber. Benzel, Blain, and Tyber each teach the use of bone screws—corresponding to the claimed “anchoring members”—and further teach that they are screwed into a patient’s vertebrae. *See* Benzel at 11:51-53; Blain at [0022]; Tyber at 4:55-63. A POSITA would have understood that some kind of “driving member” must be used to screw the bone screws into the vertebral body. Thus, the disclosure of a “driving member” is obvious based on the teachings of Benzel, Blain, Tyber, Synthes SynFix, and RSB InterPlate alone.

Alternatively, a POSITA would have found it obvious to combine Benzel, Blain, Tyber, Synthes SynFix, or RSB InterPlate with any of the prior art references that do teach a driving member to drive bone screws into a patient’s spine, including Bray ’255, Moskowitz, or LeHuec. These references each teach the use of “driving member” that is configured to screw the bone screws into the patient’s vertebrae as is anticipated in the disclosures and teachings of Benzel, Blain, Tyber, Synthes SynFix, and RSB InterPlate. Utilizing a driving member—such as a screw driver, hammer, or other tool—to attach a bone screw to a human spine was well-known in the art. *See* Bray ’255; Moskowitz; LeHuec; Duffield; *see also* Hess; Donner; Bramlet. Thus, a POSITA would have found the proposed combinations to merely be a combination of known prior art elements, utilizing known methods, to achieve the predictable result of attaching the bone screws to the patient’s spine and holding the spinal implant in place. This would have been nothing more than a known, and necessary, technique to achieve the goal of implanting the fusion device into a patient’s spine.

The Parties have not yet engaged in claim construction to determine the proper construction of the term “driving member” as it is claimed in the ’385 and ’805 patents. Additionally, because Spinelogik appears to conflate the meaning of “driving member” with “delivery mechanism” (*see* ’805 patent claim charts attached to Spinelogik’s Infringement Contentions), it is not entirely clear how Spinelogik is interpreting this term. However, the plain language of the claim does not appear to limit the term “driving member” to a specific device and only requires that it be “configured to drive the anchoring member into the corresponding vertebral body and decouple from the anchoring member.” ’385 patent, cl. 7. As such, for the purposes of these invalidity contentions, Globus has interpreted the term “driving member” to encompass any such device or structure that is configured to attach the anchoring members to spinal vertebrae.

iii. A POSITA would have been motivated to combine references disclosing spinal implants utilizing anchoring members with those disclosing recesses in the channels (’385 Patent)

All of the prior art references disclose spinal implantation devices that utilize anchoring members to fuse with a first and second vertebrae. Additionally, each reference discloses some kind of locking mechanism to prevent the anchoring members from backing out, as discussed more fully above. Like the ’385 patent, many of the prior art references disclose a recess within the channels to retain the anchoring members in place. *See* Hess; Bray ’255; Moskowitz; Donner; Benzel; Blain. Certain references, however, do not explicitly teach the inclusion of a recess in the channel to lock the anchoring members in place. *See* LeHuec; Bramlet; Tyber; Dinville; Duffield; Synthes SynFix; RSB InterPlate. Instead of a recess within a channel, for example, LeHuec teaches the use of a locking plate (shown in Figure 8b below) that is placed on the implant device after the bone screws are attached to the spine to prevent screw backout:

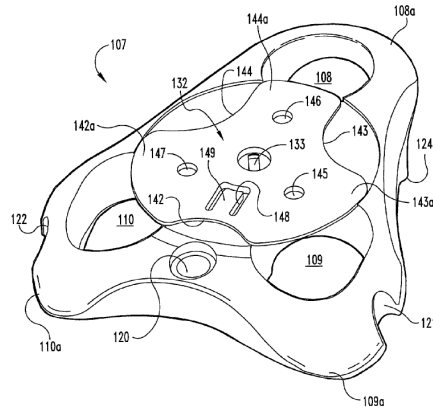


Fig. 8b

Bramlet discloses a “self-locking” end cap that accomplishes the same goal. *See* Bramlet at 6:29-35. Duffield similarly teaches a screw back out prevention mechanism. *See* Duffield at 3:25-29. Tyber does not explicitly disclose a mechanism for preventing backout of the bone screws.

A POSITA would have found it obvious to combine the spinal fusion implant devices taught by LeHuec, Bramlet, Dinville, Duffield, Tyber, Synthes SynFix, or RSB InterPlate with the channel recess feature as disclosed in Bray '255, Moskowitz, Benzel, or Blain³. This would have been a combination of prior art elements, known in the art prior to 2010, to yield the same, predictable result. As explained with regard to the use of “curved channels” to prevent backout, a POSITA would have been motivated to add a recess within the channel to provide another level of support to maintain the anchoring members within the vertebrae. Moreover, combining LeHuec, Bramlet, or Duffield with one of the references that teaches the recessed channel would have been obvious as a simple substitution of known elements—substituting a backing cap with a recess in the channel. This would have also been an attractive option because it would require one less step

³ Alternatively, a POSITA would have found it obvious to combine the teachings of Bramlet or Dinville with Hess or Donner, which disclose a recess within a curved channel to retain a curved anchoring member. Like Hess and Donner, Bramlet and Dinville disclose a curved anchoring member (as opposed to a straight bone screw). A POSITA would have found this combination obvious for the same reasons as discussed herein.

(adding a backing cap) as the recess would be built into the implant device itself. Thus, the recess channel would be a design incentive and likely more cost efficient as it requires less material and resources.

As noted for the previous terms, claim construction has not yet occurred. To the extent Spinelogik is construing the “recess” term in a manner that is not encompassed by the prior art or proposed combinations, Globus reserves the right to amend its combinations, and the accompanying motivation to combine, in response.

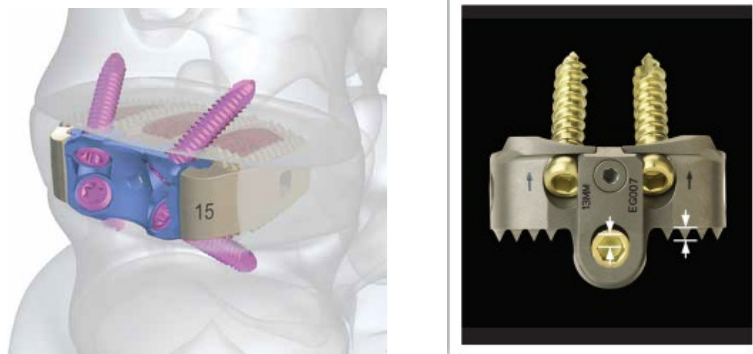
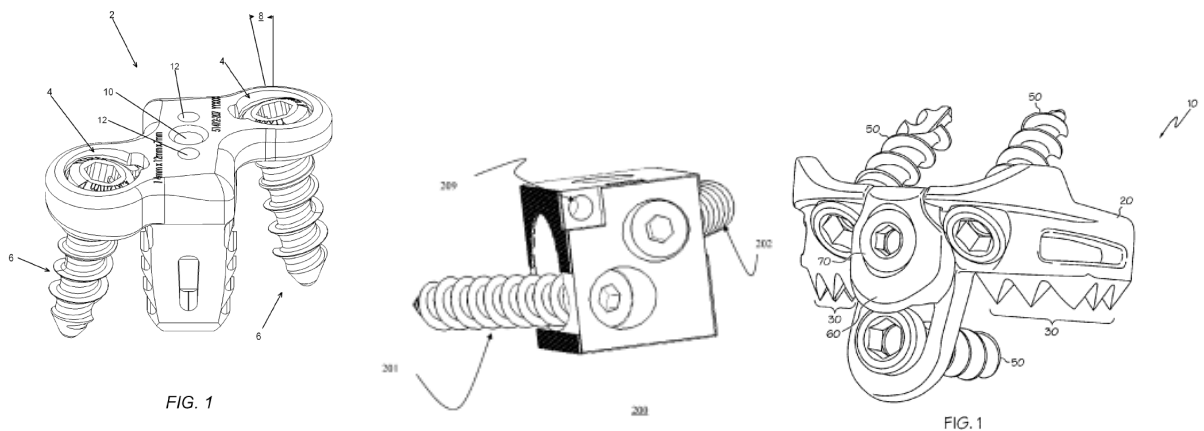
iv. A POSITA would have been motivated to combine references disclosing spinal implants with straight channels with those disclosing curved channels ('805 Patent)

All of the prior art references disclose each of the elements of the asserted independent claims of the '805 patent; that is, spinal fusion members for positioning between two vertebral bodies, a delivery device, and a plurality of anchoring members for securing the fusion member to the vertebral bodies. All of the references also disclose that the spinal fusion members include a plurality of channels. Dependent claims 5 and 16 require that each channel of the fusion member be curved.

Claim construction has not yet begun and Globus expects that there may be a dispute between the Parties regarding the meaning of “curved,” as evidenced by Spinelogik’s apparent interpretation in the Infringement Contentions. To the extent that the term “curved” channel is given a very broad construction—in-line with Spinelogik’s apparent interpretation—the above-cited prior art references all disclose a curved channel. To the extent the term “curved” channel is given a narrower construction—in-line with the patent specification, claim language, and prosecution history—certain prior art references only disclose straight channels that do not include the claimed curvature. A POSITA, however, would have been motivated to combine these

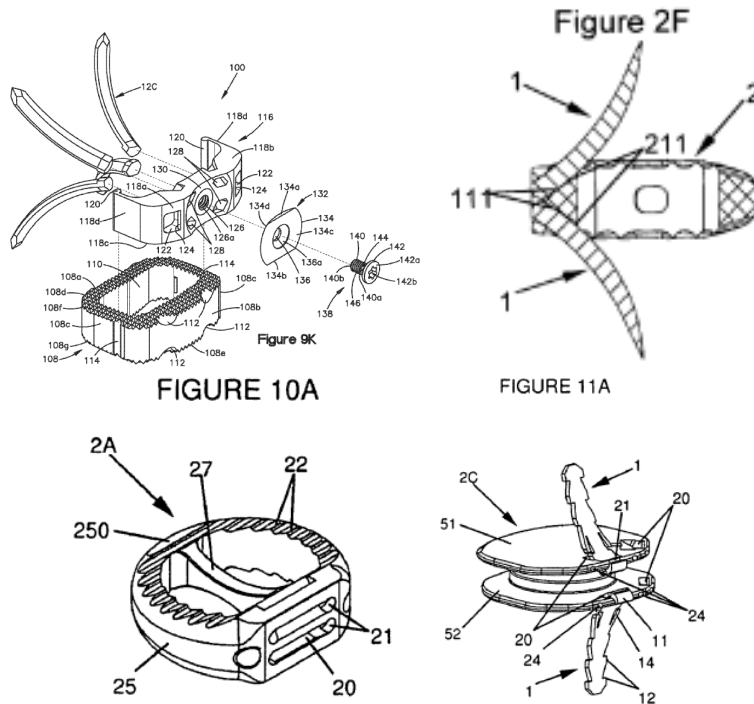
references with prior art references, such as Donner, Dinville, or Allain that teach the use of a curved channel.

Blain '854, Moskowitz, Bray '255, Synthes SynFix, and RSB InterPlate all teach the use of a straight channel through which an anchoring member may pass to enter a spinal vertebra, as exemplified in the attached claim charts. Examples of the straight channels disclosed in these references are shown below:



Blain '854, Fig. 1; Moskowitz, Fig. 2C; Bray '255, Fig. 1; Synthes SynFix Brochure; RSB InterPlate Brochure. These references do not, however, explicitly teach that each channel of the fusion member is *curved*.

A POSITA would have been familiar with known prior art at the time of the invention, including Donner, Dinville, and Allain, that teach a curved channel, as shown below:



Donner at Fig. 9K; Dinville, Fig. 2F; Allain, Figs. 10A, 11A. Prior to October 18, 2012, and indeed, as discussed with respect to the '385 patent, prior to February 15, 2010, curved channels were well-known in the art. *See also, e.g.,* Hess, Fig. 4. Thus, the combination of art teaching curved channels with the art teaching straight channels would merely be a combination of known elements according to methods known to a POSITA at the time of alleged invention. As is evident by the figures above, modifying the straight channels disclosed in Blain '854, Moskowitz, Bray '255, Synthes SynFix, and RSB InterPlate to instead utilize the curved channels taught by Donner, Dinville, or Allain would be a simple substitution of one known element for another. Likewise, for the reasons detailed in Section II.D.2.i, *supra*, a POSITA would be motivated to utilize curved channels to better distribute compressive forces in multiple directions and to prevent the independent anchoring members from backing out, and would find such a substitution or combination obvious to try. Moreover, as discussed in Allain, curved channels and corresponding curved anchoring members advantageously permit for insertion along a longitudinal axis of the implant “in such a manner that the anchoring device may be implanted in the vertebral plate of a

vertebra by presenting its longitudinal axis substantially along the plane of the intervertebral space, where the anchoring device is inserted, by use of the instrument, through a slot located in at least one peripheral wall of the cage or on at least one plate of the intervertebral disc prosthesis to penetrate into at least one vertebral plate.” Allain at Abstract.

E. Invalidity of the Asserted Claims – 35 U.S.C. § 112

Globus asserts that certain Asserted Claims are invalid for failure to satisfy the written description requirement, invalid for lack of enablement, and/or invalid for indefiniteness. Globus’ arguments relating to 35 U.S.C. § 112 are made in the alternative to any potential claim construction arguments and are not—and should not be taken as—admissions regarding the construction or scope of the claims of the Asserted Patents. Globus reserves the right to amend these contentions in the future, as claim construction may raise additional invalidity arguments pursuant to 35 U.S.C. § 112.

**1. Invalidity by Failure to Satisfy the Enablement Requirement
(35 U.S.C. § 112, first paragraph)**

The Asserted Claims are invalid under 35 U.S.C. § 112, first paragraph, for failing to satisfy the enablement requirement. “The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” *U.S. v. Teletronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988); *MagSil Corp. v. Hitachi Glob. Storage Techs.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012) (“To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’”) (quoting *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997)).

The Federal Circuit utilizes an eight-factor test (non-limiting) that is considered when determining whether a claim term fails for enablement. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Those factors include:

- (1) The breadth of the claims;
- (2) The nature of the invention;
- (3) The statue of the prior art;
- (4) The level of one of ordinary skill;
- (5) The level of predictability in the art;
- (6) The amount of direction provided by the inventor;
- (7) The existence of working examples; and
- (8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Id. Lack of enablement means, at the time the patent application was filed the specification would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *See Storer v. Clark*, 860 F.3d 1340, 1350 (Fed. Cir. 2017).

Globus asserts that certain of the Asserted Claims are invalid for failure to meet the enablement requirement. Specifically, the following claim terms are not enabled by the disclosures in the patent specification in which they appear. At least some of these terms appear in every independent claim and are incorporated into each dependent claim. Thus, each Asserted Claim is invalid under 35 U.S.C. § 112 (pre-AIA), first paragraph, for violating the enablement requirement.

Asserted Patent	Claim Term(s) Lacking Enablement	Claim Nos.
'805 patent	“preventing decoupling of the fusion member from the penetrated vertebral body”	1, 11

2. Invalidity by Indefiniteness (35 U.S.C. § 112, second paragraph)

The Asserted Claims are invalid under 35 U.S.C. § 112, second paragraph, as they are indefinite. According to the Supreme Court, “a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). The Asserted Claims are invalid as indefinite under 35 U.S.C. § 112, second paragraph, for failing to point out and distinctly claim the subject matter which the inventor regards as the patented invention. Specifically, the following claim terms are indefinite.

Asserted Patent	Indefinite Claim Term(s)	Claim Nos.
'385 patent	“curved channel”	1
'385 patent	“[first / second] cross-sectional plane along a [first / second] path”	1
'385 patent	“driving member”	7
'805 patent	“driving member”	15
'805 patent	“curved”	5

III. Conclusion

For the reasons described herein and in the attached exhibits, Globus contends that all Asserted Claims of the Asserted Patents are invalid.

Dated: May 6, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on May 6th, 2024, the above Invalidity Contentions and accompanying documents were served on counsel for Plaintiff via e-mail.

/s/ James R. Anderson

James R. Anderson