

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION**

MEDSHAPE, INC., and TRILLIANT SURGICAL
LLC, (d/b/a ENOVIS FOOT AND ANKLE)

Plaintiff,

v.

ARTHREX, INC.

Defendant.

Civil Action No. 6:24-cv-151

Jury Trial Demanded

**DEFENDANT’S FIRST AMENDED DISCLOSURE OF PRELIMINARY INVALIDITY
CONTENTIONS**

Defendant Arthrex, Inc. (“Defendant” or “Arthrex”) hereby serves its first amended disclosure of Preliminary Invalidity Contentions pursuant to the Scheduling Order (Dkt. No. 46) and the Local Patent Rules of the Western District of Texas. Defendant provides its Preliminary Invalidity Contentions as to Claims 1–10 of U.S. Patent No. 7,985,222 and 1–3, 5 and 7–10 of U.S. Patent No. 8,491,583 (the “Asserted Claims”), which have been asserted against Defendant by Plaintiffs Medshape, Inc. and Trilliant Surgical LLC (d/b/a Enovis Foot and Ankle) (collectively, “Enovis” or “Plaintiffs”).

I. RESERVATIONS

A. General Reservations

Defendant relies on and incorporates by reference, as if originally set forth herein, all invalidity or unenforceability positions, and all associated prior art and arguments, raised during the prosecution of the ’222 and ’583 Patents (“Asserted Patents”) and any continuations, continuations-in-part, divisional patents, parent patents or foreign counterparts thereof. Moreover, Defendant reserves the right, to the extent permitted by the Court and the applicable statutes and

rules, to supplement these Preliminary Invalidity Contentions based on prior art currently known to Plaintiff, including any prior art identified or provided to Plaintiffs by any third party.

Moreover, Defendant further reserves the right to amend or supplement these disclosures and the corresponding document production should Plaintiff: 1) provide any information that it failed to provide in its Infringement Contentions; 2) amend its Infringement Contentions in any way; or 3) attempt to rely on any information at trial, in a hearing or during a deposition which it failed to provide in its Infringement Contentions.

Defendant provides the information below, as well as the accompanying production of documents, for the sole purpose of complying with Local Patent Rules. The information provided shall not be deemed an admission regarding the scope of any claims or the proper construction of those claims or any terms contained therein. Nothing contained in these Preliminary Invalidity Contentions should be understood or deemed to be an express or implied admission or contention with respect to the proper construction of any terms in the Asserted Claim, or with respect to the alleged infringement of that claim.

B. Ongoing Discovery

Discovery is ongoing and Defendant has not yet completed its search for and analysis of relevant prior art, which will include taking discovery from Plaintiffs and/or third parties. As such, Defendant reserves the right to revise, amend, and/or supplement the information provided herein, including identifying, charting, and relying on additional references, should Defendant's further search and analysis yield additional information or references, consistent with the Local Patent Rules and the Federal Rules of Civil Procedure.

Defendant's contentions concerning the invalidity of the asserted claims may also change depending upon the Court's construction of the asserted claims, any findings as to the priority date of the asserted claims and/or positions that Plaintiffs or their expert witness(es) may take concerning claim construction, infringement and/or invalidity. Prior art not included in this disclosure, whether or not now known to Defendant, may therefore become relevant as the case

and discovery progresses, and Defendant may amend or supplement the Invalidity Contentions accordingly.

Furthermore, Defendant is currently unaware of the extent, if any, to which Plaintiffs will contend that limitations of the claims at issue are not disclosed in the art identified by Defendant, and the extent to which Plaintiffs will contend that elements not disclosed in the specifications of the Asserted Patents and related applications would have been known to persons of ordinary skill in the art at the relevant time. To the extent that an issue arises with any such limitations, Defendant reserves the right to identify other references that would have made such limitations obvious in view of the relevant disclosures.

C. Claim Construction

Defendant does not waive the right to contest any claim constructions or to take positions during claim construction proceedings that have yet to occur that may be inconsistent with the Invalidity Contentions herein. Defendant also reserves the right to amend or supplement these Preliminary Invalidity Contentions in the event that the claims are construed differently at some point in the future.

Defendant does not necessarily adopt Plaintiffs' positions on the scope or construction of the claims. In certain instances, Defendant has applied the claims to the prior art in view of Plaintiffs' allegations, admissions or positions for purposes of these contentions only. As such, Defendant's Preliminary Invalidity Contentions are not adoptions or admissions by Defendant as to the accuracy of Plaintiffs' allegations, admissions or positions. Accordingly, these contentions are made in the alternative, are not necessarily intended to be consistent with each other or other contentions and should not be otherwise construed.

Defendant expressly reserves the right to take positions with respect to future claim construction or infringement issues that are inconsistent with, or even contradictory to, the claim construction or infringement positions expressed or implied in the Preliminary Invalidity Contentions set forth herein.

D. Plaintiffs' Infringement Contentions

Defendant submits these Preliminary Invalidity Contentions without waiving any argument about the sufficiency or substance of Plaintiffs' Infringement Contentions. Indeed, Plaintiffs' disclosures of Preliminary Infringement Contentions are incomplete or deficient in that Plaintiffs have failed to specifically identify where the recited element of each claim is found within each Accused Instrumentality. These Preliminary Invalidity Contentions are based in whole or in part on the Defendant's present understanding of the Asserted Claims and Plaintiffs' apparent positions as to the scope of the Asserted Claims as applied in its infringement contentions. Defendant reserves the right to modify or add additional contentions in light of any amendment made by Plaintiffs. Furthermore, any such amendment may lead to further grounds for invalidity; therefore, Defendant specifically reserves the right to modify, amend or supplement its Preliminary Invalidity Contentions as Plaintiffs modify, amend or supplement their disclosures, produce documents in discovery or otherwise amend their contentions.

II. IDENTIFICATION OF PRIOR ART

In addition to the prior art identified in the Asserted Patents and their prosecution histories, Defendant intends to rely upon the prior art identified below and in the attached Appendices A-1 to A-15 and A-100 ('222 Patent) and Appendices B-1 to B-5 and B-100 ('583 Patent). Defendant identifies each item of prior art based on currently available information and reserves the right to amend the information provided and/or provide further information as it becomes known.

Defendant's identification of patents and publications as prior art here and in the attached Appendices under 35 U.S.C. §§ 102 and 103 includes the patents and publications themselves, as well as the use, sale and/or offer for sale of any products, devices and systems described. Although Defendant's investigation continues, information available to date indicates that such products, devices and systems were known or used in the United States before the alleged invention of the claimed subject matter of the Asserted Claims and/or were invented by another who did not abandon, suppress or conceal before the alleged invention of the claimed subject matter of the Asserted Claims. Upon information and belief, these prior art products, devices and systems and

their associated references anticipate and/or render obvious each of the Asserted Claims. Defendant further intends to rely on inventor admissions concerning the scope of the prior art relevant to the Asserted Patents found in, inter alia, the prosecution history of the Asserted Patents and any related patents, patent applications and/or reexaminations; any deposition testimony of the named inventor of the Asserted Patents; and the papers and evidence submitted by Plaintiff in conjunction with this litigation.

Prior Art References and Patents

Reference	Filing Date	Publication/Issue Date
US 3,786,806 (“Johnson”)	Nov. 22, 1972	Jan. 22, 1974
US 4,275,717 (“Bolesky”)	July 27, 1979	Jun. 30, 1981
US 4,959,064 (“Engelhardt”)	Oct. 7, 1988	Sep. 25, 1990
US 5,035,712 (“Hoffman”)	Jun. 12, 1990	Jul. 30, 1991
US 5,190,546 (“Jervis”)	Apr. 9, 1991	Mar. 2, 1993
US 5,505,734 (“Caniggia”)	Oct. 5, 1994	Apr. 9, 1996
US 5,601,572 (“Middleman”)	Jun. 7, 1995	Feb. 11, 1997
US 5,766,218 (“Arnott”)	Oct. 1, 1996	Jun. 16, 1998
US 5,797,913 (“Dambreville”)	Feb. 10, 1997	Aug. 25, 1998
US 5,876,434 (“Flomenblit”)	Aug. 12, 1997	Mar. 2, 1999
US 5,964,770 (“Flomenblit ‘770”)	Sep. 30, 1997	Oct. 21, 1999
US 6,273,888 (“Justis ‘888”)	Sep. 29, 1999	Aug. 14, 2001

US 6,293,949 (“Justis”)	Mar. 1, 2000	Sep. 25, 2001
US 6,579,293 (“Chandran”)	Aug. 2, 2000	June 17, 2003
US 6,592,559 (“Pakter”)	Dec. 9, 1999	July 15, 2003
US 6,685,708 (“Monassevitch”)	Feb. 28, 2001	Feb. 03, 2004
US 7,410,488 (“Si Janna”)	Feb. 18, 2005	Aug. 12, 2008
US 7,789,979 (“Dooley”)	May 2, 2003	Sep. 7, 2010
US 7,850,623 (“Griffin”)	Oct. 27, 2005	Dec. 14, 2010
US 2001/0012939 (“Wahl”)	Mar. 20, 2001	Aug. 9, 2001
US 2002/0052568 (“Houser”)	Sep. 27, 2001	May 2, 2002
US 2003/0208211 (“Kortenbach”)	May 1, 2002	Nov. 6, 2003
US 2004/026561 (“Cheung”)	Apr. 19, 2004	Dec. 30, 2004
US 2005/0107791 (“Manderson”)	Nov. 14, 2003	May 19, 2005
US 2005/0171539 (“Braun”)	Jan. 30, 2004	Aug. 4, 2005
US 2005/0203518 (“Harms”)	Mar. 8, 2005	Sep. 15, 2005
US 2005/0216007 (“Woll”)	Mar. 29, 2004	Sep. 29, 2005
US 2005/0240190 (Gall ’190”)	Apr. 21, 2005	Oct. 27, 2005
US 2006/0129247 (“Brown”)	Feb. 9, 2006	Jun. 15, 2006
US 2006/0200141 (“Janna”)	Feb. 18, 2005	Sep. 7, 2006

US 2006/0229617 (“Meller”)	Sep. 23, 2005	Oct. 12, 2006
US 2006/0264954 (“Sweeney”)	Apr. 6, 2006	Nov. 23, 2006
US 2007/0213725 (“Hack”)	Mar. 10, 2006	Sep. 13, 2007
US 2007/0225716 (“Deffenbaugh”)	Mar. 24, 2006	Sep. 27, 2007
US 2007/0233104 (“Metzinger”)	Mar. 31, 2006	Oct. 4, 2007
US 2007/0270855 (“Partin”)	Apr. 6, 2007	Nov. 22, 2007
US 2007/0288097 (“Hurowitz”)	Mar. 30, 2007	Dec. 13, 2007
US 2008/0161805 (“Saravia”)	Nov. 21, 2007	Jul. 3, 2008
US 2009/0062796 (“Parks”)	May 10, 2007	Mar. 5, 2009
US 2010/0065606 (“Stopek”)	Oct. 25, 2007	Mar. 18, 2010
EP 1011464 (“Beyar”)	Mar. 6, 1998	Jan. 23, 2008
EP 1582161 (“Coati ‘161”)	Mar. 31, 2004	Oct. 5, 2005
FR2787313 (“Moulin ’313”)	Dec. 17, 1998	Jun. 23, 2003
FR2794019 (“Moulin ’019”)	May 26, 1999	Dec. 1, 2000
KR20040002891	Sep. 30, 2003	Jan. 7, 2004
JP1997010224 (“Hitoshi”)	Jun. 30, 1995	Jan. 14, 1997
RU 26288 (“Plotkin”)	Jun. 13, 2002	Nov. 27, 2002
WO02/078555 (“Von Hoffman”)	Mar. 29, 2002	Oct. 10, 2002

WO2005/039425 (“Franck”)	Oct. 25, 2004	May 6, 2005
WO2005/094705 (“Coati”)	Mar. 31, 2005	Oct. 13, 2005
WO2006120355 (“Brodsky”)	May 12, 2006	Nov. 16, 2006
Berson et al., <i>Evaluation of Compression in Intramedullary Hindfoot Arthrodesis</i> , Foot & Ankle Int’l. Vol. 23, 11 (2002): 992-5 (“Berson”)	N/A	2002
Biscarini et al., <i>Enhanced Properties for Biomedical Applications</i> , Enhanced Nitinol Properties for Biomedical Applications. Recent Patents on Biomedical Eng., vol. 1, issue 3, 180-196. (“Biscarini”)	N/A	2008
Colgrove et al., <i>Ankle Arthrodesis: Combined Internal-External Fixation</i> , Foot & Ankle Int’l, vol. 22, issue 2, 92-97. (“Colgrove”)	N/A	2001
Duerig et al., <i>Engineering Aspects of Shape Memory Alloys</i> , Butterworth-Heinemann (“Duerig 1990”)	N/A	1990
Duerig et al., <i>The Use of Superelasticity in Medicine</i> . Metall. 50, 569-74 (“Duerig 1996”)	N/A	1996
Duerig et al., <i>An overview of superelastic stent design. Minimally invasive therapy & allied technologies: MITAT: Official J. of the Society for Minimally Invasive Therapy</i> vol. 9, 3-4. 235-46 (“Duerig 2000”)	N/A	2000
Duerig, <i>The Use of Superelasticity in Modern Medicine</i> . MRS Bulletin 27, 101–104. (“Duerig 2002”)	N/A	Feb. 2002
Kapanen et al., <i>Effect of nickel-titanium shape memory alloy on bone formation</i> . Biomaterials vol. 22, 18: 2475-80 (“Kapanen 2001”)	N/A	2001
Kasai, <i>Superelastic Ti–Ni Alloy Wire Intramedullary Nails for Metastatic Femoral Pathologic Fracture: A case report</i> . J. Surgical Oncology, Vol. 83, 2, 123-127. (“Kasai 2003”)	N/A	2003
Kauffman et al., <i>The Story of Nitinol: The Serendipitous Discovery of the Memory Metal and Its Applications</i> . The Chemical Educator. 2. 1-21. (“Kauffman”)	N/A	1996
Kirk-Othmer, <i>Encyclopedia of Chemical Technology</i> , 3 rd Ed., Vol. 20 (“Kirk-Othmer 1982”)	N/A	1982

Kirk-Othmer, <i>Encyclopedia of Chemical Technology</i> , 4 th Ed., Vol. 21 (“Kirk-Othmer 1997”)	N/A	1997
Mann et al., <i>Tibiototalcaneal Arthrodesis: A Biomechanical Analysis of the Rotational Stability of the Biomet Ankle Arthrodesis Nail</i> . <i>Foot & Ankle Int'l.</i> , Vol. 22, 9: 731-3 (“Mann 2001”)	N/A	2001
Mantovani, <i>Shape Memory Alloys: Properties and Biomedical Applications</i> , <i>JOM</i> 52, 36-44 (“Montavani”)	N/A	Oct. 2000
Muckley et al., <i>Concept of Tibiototalcaneal Fusion with a IIIrd Generation Intramedullary Nail</i> , https://www.researchgate.net/publication/228472535 (“Muckley 2006”)	N/A	Jun. 2006
Muckley, et al., <i>Biomechanical Evaluation of Primary Stiffness of Tibiototalcaneal Fusion with Intramedullary Nails</i> . <i>Foot & Ankle Int'l.</i> , 28(2):224-231 (“Muckley 2007”)	N/A	2007
Mueckley, <i>Biomechanical Evaluation of Primary Stiffness of Tibiotalar Arthrodesis with an Intramedullary Compression Nail and Four Other Fixation Devices</i> . <i>Foot & Ankle Int'l.</i> , vol. 27,10: 814-20 (“Mueckley 2006”)	N/A	2006
Niinimaki, <i>Tibiototalcaneal Arthrodesis with a Compressive Retrograde Intramedullary Nail: A Report of 34 Consecutive Patients</i> . <i>Foot & ankle Int'l.</i> , vol. 28, 4, 431-34. (“Niinimaki 2007”)	N/A	2007
Otsuka, <i>Shape Memory Materials</i> , Cambridge University Press. (“Otsuka”)	N/A	1998
Poncet, <i>Nitinol Medical Device Considerations</i> . SMST-2000: Proceedings Int'l. Conference Shape Memory and Superelastic Tech., 441-455 (“Poncet”)	N/A	2000
Ryhanen, <i>Biocompatibility Evaluation of Nickel-Titanium Shape Memory Metal Alloy</i> , Diss., Oulu: University of Oulu (“Ryhanen”)	N/A	1999
Ryhanen, et al., <i>Bone healing and mineralization, implant corrosion, and trace metals after nickel–titanium shape memory metal intramedullary fixation</i> . <i>J. Biomedical Materials Research</i> , vol. 47, 4: 472-80 (“Ryhanen II”)	N/A	1999

Stoeckel, <i>The Shape Memory Effect – Phenomenon, Alloys and Applications</i> . Proceedings of Shape Memory Alloys for Power Systems, EPRI, 1-13 (“Stoeckel”)	N/A	1995
Tyber, <i>Mechanical Behavior of Materials For Reconstructive Bioengineering Applications</i> . Thesis, University of Colorado (“Tyber”)	N/A	2005
van der Wijst, <i>Shape Memory Alloys featuring Nitinol</i> . TU Eindhoven, 62 (“van der Wijst”)	N/A	1992
Wayman, <i>Some Applications of Shape Memory Alloys</i> . JOM 32: 129-137 (“Wayman”)	N/A	Jun. 1980

Prior Art Systems

System	Date	Entities/Persons Involved
Depuy Memory Staple <i>See, e.g., (i) K964226 510(k)Summary; and (ii) Rethnam et al. Mechanical characteristics of three staples commonly used in foot surgery, J. Foot and Ankle Res. 2, 5 (2009)</i>	In or around 1997	Depuy
OSStaple (originally cleared as part of the Memograph Staple System) <i>See, e.g., (i) K993714 510(k)Summary; (ii) Jefferson, Local biotech firm ramping up for private placement, San Antonio Business Journal (Mar. 30, 2001); (iii) Lorek, Institution fosters growth in small but high-paying sector; Biotech ambitions; Texas Research Park is home to many startups out to become giants, San Antonio Express-News (May 13, 2003); (iv) Vanore, The OSStaple (2002); and (v) Russell, Design Considerations for Nitinol Bone Staples, J. of Materials Eng. and Performance 18, 831–835 (2009).</i>	In or around 2000	Biomedical Enterprises, Inc.

OSSplate (originally cleared as part of the Memograph Staple System) <i>See, e.g.,</i> (i) K993714 510(k) Summary; (ii) K061385 510(k) Summary (iii) Jefferson, Local biotech firm ramping up for private placement, San Antonio Bus. J. (Mar. 30, 2001); and (iv) Vanore, The OSStaple (2002).	In or around 2000	Biomedical Enterprises, Inc.
Shape Memory Bone Plate <i>See, e.g.,</i> Machado, et al., Medical Applications of shape memory alloys, Brazilian journal of medical and biological research Vol. 36, 6 (2003): 683-91	In or around 2001	TBD
T2 Ankle Arthrodesis Nail <i>See, e.g.,</i> (i) K01519590 510(k) Summary; (ii) T2 Ankle Arthrodesis Nail At-A-Glance Guide; and (iii) T2 Ankle Arthrodesis Nail Operative Technique	In or around 2005	Stryker / Howmedical Osteonics Corp.
Panta Nail <i>See, e.g.,</i> (i) Panta Surgical Technique (Integra); and (ii) Panta Arthrodesis Nail Surgical Technique (Newdeal)	In or around 2006	Integra LifeSciences Corporation / Newdeal

III. CHARTS SETTING FORTH WHERE IN THE PRIOR ART REFERENCES EACH ELEMENT OF THE ASSERTED CLAIM(S) ARE FOUND

Defendant's prior art charts for the Asserted Claims are attached as Appendices A-1 to A-15 and A-100 ('222 Patent) and Appendices B-1 to B-5 and B-100 ('583 Patent). The charts identify where in the prior art reference each claim element is found. In addition to the attached charts, Defendant also intends to rely on admissions and statements concerning the scope of the prior art found in the specification and/or prosecution history of the '222 and '583 patents. Defendant also reserves the right to rely on any evidence, including without limitation, deposition testimony, admissions or other statements concerning the scope of the prior art in this or any other litigation, legal proceeding or post-grant review proceeding concerning the '222 and '583 patents, and specifically incorporate by reference any and all evidence in IPR2025-00053 filed by Defendant challenging the claims of the '222 patent.

In the charts, Defendant has identified portions of the references that are believed to disclose the limitations of the Asserted Claims. Defendant reserves the right to rely on the entirety of each prior art reference for purposes of establishing invalidity under 35 U.S.C. §§ 102 or 103. Defendant may rely on all or a subset of the references depending on the Court's claim constructions, Plaintiffs' arguments and Defendant's further investigations. Defendant's contentions are in no way an admission or suggestion that a specific reference does not independently anticipate the asserted claims under 35 U.S.C. § 102. Defendant further reserves all rights to supplement, amend and/or modify its preliminary prior art charts based on any information or prior art discovered during the course of this litigation.

Defendant's claim charts cite to particular teachings and/or disclosures of the prior art as applied to features of the asserted claims. However, persons of ordinary skill in the art may view an item of prior art in the context of other publications, literature, products and technical knowledge. As such, Defendant reserves the right to rely on uncited portions of the prior art references, related file histories, other publications and testimony as aids in understanding and interpreting the cited portions, as providing context to them, and as additional evidence that the prior art discloses a claim element. Defendant further reserves the right to rely on uncited portions of the prior art references, related file histories, other publications and testimony to establish that a person of ordinary skill in the art would have been motivated to combine certain of the cited references so as to render the claims obvious.

The references discussed in the claim charts may disclose the elements of the Asserted Claims explicitly and/or inherently. As discussed further below, they may also be relied on to show the state of the art in the relevant time frame. Defendant is also unaware of the extent to which Plaintiffs will contend that elements of the asserted claims are not disclosed in the prior art identified by Defendant. To the extent such an issue arises, Defendant reserves the right to supplement their charts and/or identify other references that would render any such element obvious.

Defendant has only produced claim charts for those claims that are currently asserted according to Plaintiffs' Infringement Contentions. If Plaintiffs revise their Infringement Contentions to include additional claims, Defendant expressly reserves the right to supplement the claim charts.

A. Statement Regarding Anticipation and/or Obviousness

Each of the Asserted Claims is anticipated by and/or obvious in view of at least one or more items of prior art, including those identified above in Section II, alone or in combination. Defendant's claim charts, attached as Exhibits A-1 to A-15 ('222 Patent) and B-1 to B-5 ('583 Patent), identify examples of prior art that anticipate and/or render obvious each Asserted Claim. Those claim charts are identified in the following table:

Reference	Claim Chart
Hoffman	A-1
Monassevitch	A-2
Jervis	A-3
Justis	A-4
Moulin '313	A-5
Moulin '019	A-6
Von Hoffman/	A-7
Houser	A-8
Engelhardt	A-9
Dambreville	A-10
OSSstaple	A-11
Shape Memory Bone Plate	A-12
Depuy Memory Staple	A-13
OSSplate	A-14
Bolesky	A-15

Caniggia	B-1
Hack	B-2
Bolesky	B-3
T2 Ankle Arthrodesis Nail	B-4
Gall '190	B-5

To the extent that a primary reference (as identified in charts A-1 to A-15 and B-1 to B-5) is deemed not to anticipate a claim for failing to teach or suggest one or more limitations of that claim, Defendant contends that the claim would nonetheless have been obvious to a person of ordinary skill in the art at the time of the invention in view of the prior art reference itself.

Defendant also identifies exemplary secondary references in Appendices A-100 and B-100. To the extent that a primary reference is deemed not to by itself render obvious a claim for failing to teach or suggest one or more limitations of that claim, the claim would nonetheless have been obvious to a person of ordinary skill in the art at the time of the invention by the combination of the primary reference with one or more other primary references, one or more of the secondary references and/or the knowledge of someone skilled in the art disclosing the missing claim limitation. For example, a person of ordinary skill in the art would have been motivated to combine any reference in Appendices A-1 through A-15 with any other reference(s) in A-1 through A-15 or Appendix A-100. Likewise, a person of ordinary skill in the art would have been motivated to combine any reference in Appendices B-1 through B-5 with any other reference(s) in B-1 through B-5 or Appendix B-100. Such combinations would be achieved, for example, by merely combining the disclosures described in the respective claim charts for each reference.

In the following tables, Defendant identifies preliminary and exemplary combinations of prior art that render obvious the Asserted Claims of the '222 and '583 Patent:

'222 Patent Claim No.	Exemplary Invalidity Grounds under 35 U.S.C. § 103
1	Hoffman alone or in combination with Monassevitch, Jervis, Justis Moulin '313, Moulin '019, Von Hoffman, Houser, Engelhardt, Dambreville, the OSStaple, the Shape Memory Bone Plate, OSSplate,

	Bolesky, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Kapanen, Otsuka and/or van der Wijst Monassevitch alone or in combination with Hoffman, Jervis, Justis, Moulin '313, Moulin '019, Von Hoffman, Houser, Engelhardt, Dambreville, the OSStaple, the Shape Memory Bone Plate, OSSplate, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Kapanen, Otsuka and/or van der Wijst Jervis alone or in combination with Hoffman, Monassevitch, Justis, Moulin '313, Moulin '019, Von Hoffman, Houser, Engelhardt, Dambreville, the OSStaple, the Shape Memory Bone Plate, OSSplate, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Kapanen, Otsuka and/or van der Wijst Justis alone or in combination with Hoffman, Monassevitch, Jervis, Moulin '313, Moulin '019, Von Hoffman, Houser, Engelhardt, Dambreville, the OSStaple, the Shape Memory Bone Plate, OSSplate, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Kapanen, Otsuka and/or van der Wijst Moulin '313 alone or in combination with Hoffman, Monassevitch, Jervis, Justis, Moulin '019, Von Hoffman, Houser, Engelhardt, Dambreville, the OSStaple, the Shape Memory Bone Plate, OSSplate, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Kapanen, Otsuka and/or van der Wijst Moulin '019 alone or in combination with Hoffman, Monassevitch, Jervis, Justis, Moulin '313, Von Hoffman, Houser, Engelhardt, Dambreville, the OSStaple, the Shape Memory Bone Plate, OSSplate, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Kapanen, Otsuka and/or van der Wijst Von Hoffman alone or in combination with Hoffman, Monassevitch, Jervis, Justis, Moulin '313, Moulin '019, Houser, Engelhardt,
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	Dambreville, the OSStaple, the Shape Memory Bone Plate, OSSplate, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Kapanen, Otsuka and/or van der Wijst Houser alone or in combination with Hoffman, Monassevitch, Jervis, Justis, Moulin '313, Moulin '019, Von Hoffman, Engelhardt, Dambreville, the OSStaple, the Shape Memory Bone Plate, OSSplate, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Kapanen, Otsuka and/or van der Wijst Engelhardt alone or in combination with Hoffman, Monassevitch, Jervis, Justis, Moulin '313, Moulin '019, Von Hoffman, Houser, Dambreville, the OSStaple, the Shape Memory Bone Plate, OSSplate, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Kapanen, Otsuka and/or van der Wijst Dambreville alone or in combination with Hoffman, Monassevitch, Jervis, Justis, Moulin '313, Moulin '019, Von Hoffman, Houser, Engelhardt, the OSStaple, the Shape Memory Bone Plate, OSSplate, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Kapanen, Otsuka and/or van der Wijst OSStaple alone or in combination with Hoffman, Monassevitch, Jervis, Justis, Moulin '313, Moulin '019, Von Hoffman, Houser, Engelhardt, Dambreville, Depuy Memory Staple, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Kapanen, Otsuka and/or van der Wijst Shape Memory Bone Plate alone or in combination with Hoffman, Monassevitch, Jervis, Justis, Moulin '313, Moulin '019, Von Hoffman, Houser, Engelhardt, Dambreville, OSSplate, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Kapanen, Otsuka and/or van der Wijst Depuy Memory Staple alone or in combination with Hoffman, Monassevitch, Jervis, Justis, Moulin '313, Moulin '019, Von Hoffman, Houser, Engelhardt, Dambreville, the OSStaple, OSSplate, Wayman,
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	Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Kapanen, Otsuka and/or van der Wijst OSSplate alone or in combination with Hoffman, Monassevitch, Jervis, Justis, Moulin '313, Moulin '019, Von Hoffman, Houser, Engelhardt, Dambreville, Depuy Memory Staple, Wayman, Kauffman, Duerig 1990, 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Kapanen, Otsuka and/or van der Wijst. Bolesky alone or in combination with Hoffman, Monassevitch, Jervis, Justis, Moulin '313, Moulin '019, Von Hoffman, Houser, Engelhardt, Dambreville, the OSSStaple, the Shape Memory Bone Plate, OSSplate, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Kapanen, Otsuka and/or van der Wijst.
2	<i>See grounds of claim 1</i>
3	<i>See grounds of claim 1</i>
4	<i>See grounds of claim 3</i>
5	<i>See grounds of claim 1</i>
6	<i>See grounds of claim 1</i>
7	<i>See grounds of claim 1</i>
8	<i>See grounds of claim 1</i>
9	<i>See grounds of claim 1</i>
10	<i>See grounds of claim 1</i>

'583 Patent Claim No.	Exemplary Invalidity Grounds under 35 U.S.C. § 103
1	Caniggia alone or in combination with Hack, Bolesky, T2 Ankle Arthrodesis Nail, Gall '190, Coati, Si Janna, the Panta Nail, Berson, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Griffin, Muckley 2006, Tyber, Hoffman, Kirk-Othmer 1982, Kirk-

	Othmer 1997, Stoeckel, Sweeney, Partin, Kapanen, Van der Wijst, Otsuka, Stopek and/or Kortenbach Hack alone or in combination with Caniggia, Bolesky, T2 Ankle Arthrodesis Nail, Gall '190, Coati, Si Janna, the Panta Nail, Berson, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Griffin, Muckley 2006, Tyber, Hoffman, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Sweeney, Partin, Kapanen, Van der Wijst, Otsuka, Stopek and/or Kortenbach Bolesky alone or in combination with Caniggia, Hack, T2 Ankle Arthrodesis Nail, Gall '190, Coati, Si Janna, the Panta Nail, Berson, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Griffin, Muckley 2006, Tyber, Hoffman, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Sweeney, Partin, Kapanen, Van der Wijst, Otsuka, Stopek and/or Kortenbach T2 Ankle Arthrodesis Nail alone or in combination with Caniggia, Hack, Bolesky, Gall '190, Coati, Si Janna, the Panta Nail, Berson, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Griffin, Muckley 2006, Tyber, Hoffman, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Sweeney, Partin, Kapanen, Van der Wijst, Otsuka, Stopek and/or Kortenbach Gall '190 alone or in combination with Caniggia, Hack, Bolesky, T2 Ankle Arthrodesis Nail, Coati, Si Janna, the Panta Nail, Berson, Wayman, Kauffman, Duerig 1990, Duerig 1996, Duerig 2000, Duerig 2002, Ryhanen, Ryhanen II, Mantovani, Poncet, Pakter, Dooley, Griffin, Muckley 2006, Tyber, Hoffman, Kirk-Othmer 1982, Kirk-Othmer 1997, Stoeckel, Sweeney, Partin, Kapanen, Van der Wijst, Otsuka, Stopek and/or Kortenbach
2	<i>See grounds of claim 1</i>
3	<i>See grounds of claim 1</i>
5	<i>See grounds of claim 1</i>
7	<i>See grounds of claim 1</i>
8	<i>See grounds of claim 1</i>
9	<i>See grounds of claim 1</i>
10	<i>See grounds of claim 1</i>

The Scheduling Order does not require Defendant to disclose in these Preliminary Invalidity Contentions any contentions regarding the teaching, suggestion and/or motivation to combine such references. Nevertheless, as a non-limiting, exemplary disclosure, Defendant states that a combination of any of the identified references would have been obvious because such references would have been combined using: known methods to yield predictable results; known techniques in the same way; a simple substitution of one known and equivalent element for another to obtain predictable results; and/or a general teaching, suggestion or motivation in the prior art. In addition, it would have been obvious to try combining the prior art references identified herein because there were only a finite number of predictable solutions and/or because known work in one field of endeavor prompted variations based on predictable design incentives and/or market forces either in the same field or a different one. Moreover, the combination of the prior art references identified herein would have been obvious because the combination is a known potential option with a reasonable expectation of success.

Further evidence that there would have been a motivation to combine the prior art references identified herein includes the interrelated teachings of multiple prior art references; the effects of demands known to the design community or present in the marketplace; the existence of a known problem for which there was an obvious solution encompassed by the Asserted Claims; the existence of a known need or problem in the field of the endeavor at the time of the alleged invention(s); and the background knowledge that would have been possessed by a person having ordinary skill in the art.

In addition, the motivation to combine the teachings of the prior art references disclosed herein is found in the references themselves and (1) the nature of the problem being solved; (2) the express, implied and inherent teachings of the prior art; (3) the knowledge of persons of ordinary skill in the art; (4) the fact that the prior art is generally directed towards similar systems; (5) the fact that much of the prior art is specifically directed at solutions for solving similar types of problems; and/or (6) the predictable results obtained in combining the different elements of the prior art.

Further, any reference or combination of references that anticipates or makes obvious an asserted independent claim also makes obvious any asserted claim dependent from that independent claim because every limitation of each dependent claim was known by a person of ordinary skill at the time of the alleged invention, and it would have been obvious to combine those known limitations with the independent claims at least as a matter of common sense and routine work.

B. State of the Art

The references identified above, whether or not expressly cited in the attached Appendices, may also be relied on to show the state of the art in the relevant timeframe. For example, the references may be used to illustrate, among other things, that (i) the superelastic and/or pseudoeelastic properties of shape memory materials, including Nitinol, were well known before the priority dates of the Asserted Patents; (ii) it was understood that shape memory materials such as Nitinol have an austenite finish temperature; (iii) it was well known that stressing or stretching a shape memory material at or above its austenite finish temperature would result in creating stress-induced martensite; (iv) before the priority date of the Asserted Patents, shape memory materials like Nitinol were being used for various medical devices and were understood as being one of the materials of choice for such devices; (v) it was well known that the function and design of medical devices can be improved by utilizing the superelastic and/or pseudoelastic properties of shape memory materials such as Nitinol; and (vi) intramedullary medical devices were known and used to provide contracting forces between a patient's bones, such as in a TTC fusion procedure.

This prior art identification is only exemplary and is not in any way intended to limit the scope of what one of ordinary skill in the art would have understood at the relevant time period of the alleged inventions or the breadth of the state of the art to which the alleged inventions of the Asserted Patents relate. Defendant reserves the right to rely upon additional prior art, information, testimony and/or knowledge to demonstrate what one of ordinary skill in the art would have understood prior to the date of the alleged invention of the Asserted Claims.

Defendant may further rely upon the admitted prior art disclosed in the Asserted Patents, including the references cited during prosecution of the Asserted Patents. Defendants may also rely on certain prior art technologies and/or prior art references as describing or indicating the state of the art as known to a person of skill in the art at the time of the alleged invention. These include all technologies and references cited in the Asserted Patents and related patent applications and/or raised during any proceedings before the U.S. Patent and Trademark Office. Defendants may rely on articles, publications, textbooks and/or physical devices to establish the state of the art at the time of the alleged inventions, including the points discussed above or for any other industry knowledge at the time.

**IV. AN IDENTIFICATION OF ANY LIMITATIONS THE DEFENDANT
CONTENDS ARE INDEFINITE OR LACK WRITTEN DESCRIPTION UNDER
SECTION 112**

Defendant hereby identifies grounds of invalidity based on lack of written description or enablement under 35 U.S.C. § 112 ¶1 and/or indefiniteness under 35 U.S.C. § 112 ¶2. Defendant reserves the right to supplement or amend these contentions based on Plaintiffs' representations during the course of the litigation (including during claim construction) and following any claim construction rulings of the Court.

These contentions shall not be construed as an admission that any claim construction advanced by Defendant in this case is in any way inconsistent, flawed or erroneous. Nor should these contentions prevent Defendant from advancing claim construction and/or non-infringement positions in lieu of, or in addition to, invalidity positions. Further, these contentions shall not be construed as an admission of or acquiescence to Plaintiffs' purported construction of the claim language or of other positions advanced by complainant during the course of this litigation. Defendant's Preliminary Invalidity Contentions under 35 U.S.C. § 112 may depend, in part, on the Court's claim construction as well as Plaintiffs' alleged scope of the asserted claims. Consequently, Defendant identifies only the issues under 35 U.S.C. § 112 of which they are presently aware.

A. 35 U.S.C. § 112, First Paragraph: Lack of Enablement / Written Description

To comply with the enablement requirement of 35 U.S.C. § 112(a), the patent specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Courts consider multiple factors to determine whether experimentation is undue, including: “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

To comply with the written description requirement of 35 U.S.C. § 112, the patent specification must describe an invention in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention. *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997). Further, to satisfy the written description requirement, the disclosure of the patent must “convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [the inventor] was in possession of the invention.” *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). “An applicant demonstrates that he was in possession of the invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the invention.” *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). “[T]he written description inquiry looks to the four corners of the specification to discern the extent to which the inventor(s) had possession of the invention as broadly claimed. The knowledge of ordinary artisans may be used to inform what is actually in the specification, but not to teach limitations that are not in the specification, even if those limitations would be rendered obvious by the disclosure in the specification.” *Rivera v. Int’l Trade Comm’n*, 857 F.3d 1315, 1322-23 (Fed. Cir. 2017) (citations omitted).

The Asserted Claims are invalid for failure to enable and/or provide a written description of the alleged invention as required by 35 U.S.C. § 112. A person skilled in the art would not be

able to make and use the claimed inventions by reading the specification. For example, the asserted patents fail to sufficiently describe or enable at least the following limitations:

Patent Claim	Term(s)
'222 All Asserted Claims	The patent specification fails to enable and/or provide written description support for any single embodiment that supports all the limitations of any asserted claim. In addition, the specification fails to enable or provide written description support for an intramedullary nail that practices all the limitations of any asserted claim. As such, to the extent that Plaintiff seeks to interpret any claim of the '222 patent as encompassing an intramedullary nail, such claim is invalid for lack of enablement and/or written description. <i>See, e.g.</i> 1/24/11 Final Rejection (Examiner stating: "Applicant's disclosure, as originally filed, does not provide support for the method steps of 'fixing a first portion of the intramedullary nail to the first bone element; after fixing the first portion, creating a stress-induced martensitic phase in a responsive portion of the intramedullary nail, ... ; and after creating the stress-induced martensitic phase, fixing a second portion of the intramedullary nail to the second bone element of the patient, wherein the responsive portion is disposed between the first portion and the second portion'" ... "Applicant's disclosure as originally filed ... provides support for the claimed method steps with an elongate element, not an intramedullary nail."). The specification also fails to enable or provide written description support for a method of using the claimed bone device as in claim 1, where the step of creating/stretching is performed after inserting. During prosecution, in response to a §112 reject of claim 47 (which ultimately issued as claim 1) for not having support for the step "<i>after inserting the bone device</i>, creating in a responsive portion of the bone device at least a partial transformation into a stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis," Applicant deleted the "<i>after inserting the bone device</i>" language from the claim. <i>See</i> 2-18-10 Non-Final Rejection; 8-19-10 Response. As such, to the extent Plaintiff interprets any claim of the '222 patent as encompassing stretching (and/or creating a partial transformation into a stress-induced martensitic phase via stretching) after inserting the bone device, such claim is invalid for lack of enablement and/or written description.

'222, Claim 1	after performing the stretching, fixing the second portion of the bone device to the second bone fragment
'222, Claim 3	before performing the stretching, fixing the bone device to the first bone fragment
'222, Claim 4	holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the bone device to the first bone fragment is performed
'222, Claim 5	holding the shape memory alloy at a temperature greater than the austenite finish temperature of the shape memory alloy while the stretching is performed
'222, Claim 6	holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the second portion is performed
'222, Claim 7	inserting the bone device into the second bone fragment is performed while the responsive portion is substantially in an austenitic phase
'222, Claim 8	inserting the bone device into the first bone fragment is performed while the responsive portion is substantially in an austenitic phase
'583, Claim 1	wherein the non-linear contracting element is adapted to provide compression between the separate bones of the ankle joint through moving the distal anchor element within the encasement toward the proximal end of the encasement
'583, Claim 1	wherein the non-linear contracting element comprises a shape memory alloy adapted to exhibit a pseudo-elastic stress-strain response over a pseudo-elastic range of expansive strain imparted to the non-linear contracting element based on the distal anchor element being moved distally with respect to the proximal anchor element;
'583, Claim 3	wherein the access port is adapted such that the distal bone screw interface may be accessed in configurations of the non-linear contracting element having the pseudo elastic range of expansive strain
'583, Claim 3	wherein the non-linear contracting element is adapted such that the first pseudo-elastic range of expansive strain provides through the encasement compressive forces between the separate bones of the ankle joint
'583, Claim 7	wherein the shape memory alloy is further adapted to comprise only either an austenite crystalline phase or a rhombohedral crystalline phase before the distal anchor element is moved within the encasement

'583, Claim 8	wherein the shape memory alloy is further adapted not to contain a martensite crystalline phase before the distal anchor element is moved within the encasement
'583, Claim 9	wherein the pseudo-elastic range of expansive strain is between about one millimeter absolute strain and about an eight millimeter absolute strain
'583, Claim 10	wherein the non-linear contracting element is adapted to exhibit a non-linear engineering stress-strain response above about 1 millimeter of absolute strain

B. 35 U.S.C. § 112, Second Paragraph: Indefiniteness

The claims of a patent must “particularly point out and distinctly claim the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112. A claim is invalid as indefinite if it is not sufficiently precise to permit a potential competitor to determine whether or not it is infringing. *Morton Int’l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed. Cir. 1993). Specifically, “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. 891, 901 (2014). Furthermore, when a claim includes a term of degree, the patent “must provide ‘some standard of measuring that degree’ such that the claim language provides ‘enough certainty to one of skill in the art when read in context of the invention.’” *GE Lighting Solutions, LLC v. Lights of Am., Inc.*, 663 Fed. App’x. 938, 940 (Fed. Cir. 2016); *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 214). For terms of degree, “the patent must provide that additional information in the form of ‘objective boundaries.’” *Id.* And the Federal Circuit’s “case law is clear that the objective boundaries requirement applies to terms of degree.” *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1364 (Fed. Cir. 2018). Finally, to comply with 35 U.S.C. § 112, claims must “positively recite structural relationships” between the essential elements of the claimed invention. *In re Collier*, 397 F.2d 1003, 1005 (C.C.P.A. 1968); *Courtesy Prods., L.L.C. v. Hamilton Beach Brands, Inc.*, No. 13-2012-SLD, 2015 U.S. Dist. LEXIS 155572, at *8 (Nov. 18, 2015).

At least the following limitations of the Asserted Claims fail to particularly point out and distinctly claim the subject matter which the applicant regards as his invention, as required by 35 U.S.C. § 112:

Patent Claim	Term(s)
'222, Claim 1	fixing the second portion of the bone device to the second bone fragment
'222, Claim 2	wherein stretching the bone device is performed with the bone device substantially in an austenitic phase
'222, Claim 3	fixing the bone device to the first bone fragment
'222, Claim 4	holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the bone device to the first bone fragment is performed
'222, Claim 7	inserting the bone device into the second bone fragment is performed while the responsive portion is substantially in an austenitic phase
'222, Claim 8	inserting the bone device into the first bone fragment is performed while the responsive portion is substantially in an austenitic phase
'583, Claim 1	wherein the non-linear contracting element is adapted to provide compression between the separate bones of the ankle joint through moving the distal anchor element within the encasement toward the proximal end of the encasement
'583, Claim 1	wherein the non-linear contracting element comprises a shape memory alloy adapted to exhibit a pseudo-elastic stress-strain response over a pseudo-elastic range of expansive strain imparted to the non-linear contracting element based on the distal anchor element being moved distally with respect to the proximal anchor element
'583, Claim 3	wherein the access port is adapted such that the distal bone screw interface may be accessed in configurations of the non-linear contracting element having the pseudo elastic range of expansive strain
'583, Claim 3	wherein the non-linear contracting element is adapted such that the first pseudo-elastic range of expansive strain provides through the encasement compressive forces between the separate bones of the ankle joint
'583, Claim 9	wherein the pseudo-elastic range of expansive strain is between about one millimeter absolute strain and about an eight millimeter absolute strain

'583, Claim 10	wherein the non-linear contracting element is adapted to exhibit a non-linear engineering stress-strain response above about 1 millimeter of absolute strain
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V. IDENTIFICATION OF ANY CLAIMS THE DEFENDANT CONTENDS ARE DIRECTED TO INELIGIBLE SUBJECT MATTER UNDER SECTION 101

To be eligible for patent protection, an invention must claim a “new and useful process, machine, manufacture, or composition of matter.” 35 U.S.C. § 101. The Supreme Court has long held that certain exceptions to this provision exist: laws of nature, natural phenomena and abstract ideas. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354 (2014) (citing *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013)). Thus, patent claims that recite a relationship that is the product of natural processes are unpatentable natural laws. *See Genetic Techs. Ltd. v. Lab Corp. of Am. Holdings*, No. 12-1736-LPS-CJB, 2014 U.S. Dist. LEXIS 122780, at *9 (D. Del. Sept. 3, 2014) (citing *Mayo*, 132 S. Ct. at 129 (“‘Law of nature’ is defined broadly: ‘[A] patent that ... describes [a relationship that is the consequence of entirely natural processes] sets forth a natural law.’”)). The asserted claims of the ’222 patent are invalid under 35 U.S.C. § 101 for claiming ineligible subject matter.

Identification of the alleged abstract idea, law of nature, and/or natural phenomenon in each challenged claim. The asserted claims of the ’222 patent are directed to the law of nature or natural phenomenon of creating stress-induced martensite in a shape memory material by stretching the material at a temperature above the material’s austenite finish temperature. As in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 71, 132 S. Ct. 1289 (2012), the claimed methods amount to “nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.” *Id.* As in *Mayo*, “[s]imply appending conventional steps, specified at a high level of generality” is not enough to supply an inventive concept. *Id.* at 1300. As such, each of the asserted claims of the ’222 patent is directed to an unpatentable law of nature or natural phenomenon.

Identification of each claim element alleged to be well-understood, routine, and/or conventional. Defendant contends that each of the following elements in the asserted claims of the '222 patent are well-understood, routine, and/or conventional:

- inserting a bone device having a longitudinal axis into a first bone fragment and a second bone fragment, wherein the inserting causes a first portion of the bone device to contact the first bone fragment and causes a second portion of the bone device to contact the second bone fragment, the second portion different from the first portion (claim 1)
- a shape memory alloy having an austenite finish temperature (claim 1)
- creating in a responsive portion of the bone device at least a partial transformation into a stress-induced martensitic phase via stretching the responsive portion along the longitudinal axis (claim 1)
- after performing the stretching, fixing the second portion of the bone device to the second bone fragment (claim 1)
- the creating is performed at a temperature greater than the austenite finish temperature of the shape memory alloy (claim 1)
- stretching the bone device is performed with the bone device substantially in an austenitic phase (claim 2)
- before performing the stretching, fixing the bone device to the first bone fragment (claim 3)
- holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the bone device to the first bone fragment is performed (claim 4)
- holding the shape memory alloy at a temperature greater than the austenite finish temperature of the shape memory alloy while the stretching is performed (claim 5)
- holding the responsive portion above the austenite finish temperature of the shape memory alloy while the fixing the second portion is performed (claim 6)

- wherein inserting the bone device into the second bone fragment is performed while the responsive portion is substantially in an austenitic phase (claim 7)
- inserting the bone device into the first bone fragment is performed while the responsive portion is substantially in an austenitic phase (claim 8)
- the first portion comprises the shape memory alloy (claim 9)
- second portion comprises the shape memory alloy (claim 10)

Identification of prior art for the contention that claim elements are well-understood, routine, and/or conventional, to the extent not duplicative of 102/103 prior art contentions:
Exemplary prior art showing that the above-recited claim elements are well-understood, routine, and/or conventional is identified in Section II above, as well as Appendices A-1 to A-15 and A-100.

VI. ACCOMPANYING DOCUMENT PRODUCTION

A. Prior Art Referenced in These Contentions

Defendant previously produced the prior art referenced in these Preliminary Invalidity Contentions as ART_00000001-ART_00003623 and ART_00004124-ART_00004137. Defendant is hereby supplementing this production with the '222 patent IPR Petition (IPR2025-00053) and related documents.

B. Technical Documents

Defendant previously produced, to the extent available and identified after a reasonable search, technical documents sufficient to show the operation of the accused products as ART_00003624-ART_00004123.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that this document and accompanying exhibits were served upon counsel of record for Plaintiff on November 6, 2024 via electronic service.

/s/ Steven M. Lubezny
Steven M. Lubezny