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Fusion Orthopedics, LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Extremity Medical, LLC,

Plaintiff/Counter-Defendant,

vs.

Fusion Orthopedics, LLC,

Defendant/Counterclaimant.

No. CV-22-00723-PHX-GMS

**DEFENDANT FUSION
ORTHOPEDICS LLC'S INVALIDITY
CONTENTIONS**

Extremity Medical, LLC
EXHIBIT 2007
Fusion Orthopedics v. Extremity Medical
Case IPR2023-00894

I. INTRODUCTION

Pursuant to the Court’s Scheduling Order dated December 16, 2022 (Dkt. No. 49), Defendant Fusion Orthopedics, LLC (“Defendant” or “Fusion”) hereby submits its Invalidity Contentions regarding U.S. Patent No. 11,298,166 the following patents (“the ‘166 Patent”). Plaintiff Extremity Medical, LLC. (“Plaintiff” or “Treace”) alleges in its January 6th, 2023 Infringement Contentions that Defendant infringe claims 1-8 and 10-15 of the ‘166 Patent (collectively, the “Asserted Claims”):

As discussed throughout these Invalidity Contentions, Defendant contends that each Asserted Claim is invalid under at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 115.¹ The Asserted Claims are invalid under 35 U.S.C. §§ 102, 103 as anticipated by and/or as obvious in view of the prior art. An identification of the prior art relied upon in these Invalidity Contentions is provided in the table below.

The Asserted Claims are anticipated by the following prior art references under 35 U.S.C. § 102, as shown in the attached Exhibits A1-A8.

Exh.	Anticipatory Reference	Short Cite
A1	U.S. Patent No. 4,827,917	Brumfield
A2	French Patent No. FR2861576A1	Cognet
A3	U.S. Patent No. 4,622,959	Marcus
A4	U.S. Patent Application Pub. No. US2008/0015587	Munoz
A5	Omega3 System Hansson Twin Hook Operative Technique	Omega3
A6	U.S. Patent Application Pub. No. US2006/0206044	Simon
A7	PCT Application No. WO 2008/003433 A1	Van Rhee
A8	Tibiototalcalcaneal Fusion Using the VersaNail Surgical Technique	VersaNail

The Asserted Claims are rendered obvious by the prior art references listed above as well as the additional references listed below, and combinations thereof, under 35 U.S.C. § 103, as shown in the attached Exhibit B.

¹ Nothing in these Invalidity Contentions constitutes an admission of validity as to any other non-asserted claims of the ‘166 Patent.

Exh.	Anticipatory Reference	Short Cite
B	U.S. Patent Application Pub. No. US2003/0187447	Ferrante
B	Chinese Patent No. CN2513533Y	Zuojun

The primary claim charts attached as Exhibits A1 - A8 demonstrate how various prior art references anticipate and/or render obvious the Asserted Claims. The obviousness contentions are in the alternative to the anticipation contentions and should not be construed to suggest that any primary reference does not anticipate. The secondary claim chart attached as Exhibit B provides example disclosures of certain claim elements from various prior art references that can be combined with the primary references from Exhibits A1 - A8 to render the Asserted Claims obvious.

Defendant further contends that various Asserted Claims of the '166 Patent are invalid under 35 U.S.C. § 112 for failure to satisfy the enablement, written description, and/or definiteness requirements, invalid under 35 U.S.C. § 101 for failure to claim patentable subject matter, and invalid under at least 35 U.S.C. §§ 101 and 115 based on improper inventorship.

II. RESERVATION OF RIGHTS

Defendant reserves the right to supplement and/or amend these Invalidity Contentions based on the Court's claim construction, should Plaintiff supplement and/or amend its Infringement Contentions or otherwise alter its theory of the case, or as otherwise permitted by the Court.

Defendant's Invalidity Contentions reflect its present knowledge and understanding of Plaintiff's Infringement Contentions regarding the Asserted Claims, and are based on Defendant's current knowledge, understanding, and belief as to the facts and information available as of the date of these Invalidity Contentions. Defendant has not yet completed its investigation, discovery, nor analysis of matters relating to the invalidity of the Asserted Claims, including, without limitation, invalidity due to public use, on-sale, and/or public availability statutory bars and based on improper inventorship. In addition, Defendant's search for prior art is ongoing. Accordingly, Defendant reserves the right to amend,

1 modify, and supplement, without prejudice, these Invalidity Contentions as additional
2 information is discovered or otherwise identified or appreciated, including testimony about
3 the scope and content of the claimed inventions and the state of the prior art.

4 Defendant submits these Invalidity Contentions without waiving its position that
5 Plaintiff's Infringement Contentions do not adequately identify with sufficient specificity
6 the basis for Plaintiff's contention that any Accused Instrumentality meets the limitations
7 of any of the Asserted Claims. Nothing stated herein is or shall be treated as an admission
8 or suggestion that Defendant agrees with Plaintiff regarding either the scope of any
9 Asserted Claim nor the claim constructions advanced directly or implicitly by Plaintiff's
10 Infringement Contentions or in any other pleading, discovery request or response, or
11 written or verbal communications between the parties. Additionally, nothing in these
12 Invalidity Contentions shall be treated as an admission that any Accused Instrumentality
13 meets any limitation of the Asserted Claims. Further, these Invalidity Contentions are not
14 and should not be construed as a representation that no other persons have discoverable
15 information, that no other documents, data compilations, or tangible things exist that may
16 be used to support Defendant's claims or defenses, nor that no other legal theories or factual
17 bases will be pursued.

18 In the absence of a claim construction order from the Court, Defendant's Invalidity
19 Contentions are based in whole or in part on its present understanding of the Asserted
20 Claims and Plaintiff's apparent construction of those claims in its Infringement
21 Contentions. However, Plaintiff's Infringement Contentions contradict the teaching of the
22 '166 Patent, contradict the understanding of the claim terms by a person of ordinary skill,
23 and are vague and conclusory concerning how certain claim limitations supposedly read
24 on the Accused Instrumentality. Thus, Defendant is unable to discern Plaintiff's position
25 regarding the construction or interpretation of numerous claim limitations and has provided
26 these Invalidity Contentions based in part on its present understanding of Plaintiff's
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1 apparent constructions. Accordingly, Defendant's Invalidity Contentions may reflect
2 alternative positions as to claim construction and scope of the Asserted Claims.

3 Defendant's Invalidity Contentions do not necessarily represent Defendant's
4 agreement nor view as to the meaning of any claim term contained therein, and Defendant
5 may disagree with Plaintiff's interpretation of the meaning of terms and phrases in the
6 Asserted Claims. In particular, by asserting grounds of invalidity based on Plaintiff's
7 apparent claim construction or any other particular claim construction, Defendant is neither
8 adopting those constructions nor admitting to their accuracy. Further, Defendant's
9 Invalidity Contentions do not necessarily represent Defendant's agreement or view as to
10 whether any claim preamble is limiting. Defendant will disclose its claim construction
11 positions in accordance with the deadlines set forth in the Court's Scheduling Order.

12 Defendant also anticipates that the Court's construction of claim terms may
13 significantly affect the scope of the Asserted Claims. Therefore, Defendant reserves the
14 right to supplement, without prejudice, these Invalidity Contentions as appropriate
15 depending upon the Court's construction of the Asserted Claims, any findings as to the
16 priority date of the '166 Patent, and positions that Plaintiff or its expert witnesses may take
17 concerning claim interpretation, infringement, or invalidity issues.

18 Defendant reserves the right to supplement or amend these Invalidity Contentions
19 with additional positions on anticipation or obviousness in response to any allegation by
20 Plaintiff that any of the prior art, or any combination of prior art, does not disclose one or
21 more elements of the Asserted Claims.

22 In addition, Defendant reserves the right to supplement these Invalidity Contentions
23 with additional prior art and/or arguments should Plaintiff allege that any Asserted Claim
24 is entitled to a priority date earlier than the date alleged in Plaintiff's Infringement
25 Contentions.

III. PRIORITY DATES FOR THE ASSERTED CLAIMS

The '166 Patent, on its face, claims priority to prior applications including an earliest claim of priority to June 23, 2008. Defendant disputes whether any Asserted Claim is entitled to any priority date earlier than the filing date of the application for the '166 Patent (App. No. 17/323,923), which was filed May 18, 2021, and in particular whether the Asserted Claims are entitled to the filing date of either the provisional application No. 1/132,932 or to the subsequent non-provisional application 12/456,808, both of which the '166 Patent purports to claim priority. Plaintiff has not yet established that any of the Asserted claims are entitled to an effective filing date earlier than May 18, 2021, and Defendants reserve the right to challenge any earlier date to which Plaintiff later claims as priority for the Asserted Claims.

IV. INVALIDITY UNDER 35 U.S.C. §§ 102 AND 103

The Asserted Claims are invalid as anticipated by the prior art under 35 U.S.C. § 102 and/or as obvious in view of the prior art under 35 U.S.C. § 103. The primary claim charts attached as Exhibits A1 - A8 demonstrate how various prior art references anticipate and/or render obvious the Asserted Claims. In particular, each primary claim chart (Ex. A1 - A8) provides examples of where a particular prior art reference discloses, either expressly or inherently, and/or renders obvious, each element of the Asserted Claims. The obviousness contentions are in the alternative to the anticipation contentions and should not be construed to suggest that any primary reference does not anticipate. The secondary claim chart attached as Exhibit B provides example disclosures of certain claim elements from various prior art references that can be combined with the primary references from Exhibits A1 - A8 to render the Asserted Claims obvious. Each primary reference in Exhibits A1 - A8 can be combined with (i) other primary references in Exhibits A1 - A8; (ii) secondary references in Exhibit B; (iii) other prior art references identified throughout these Invalidity Contentions and/or in Exhibit A; and/or (iv) a combination thereof.

Defendant has endeavored to cite to the most relevant portions of the identified prior art. However, other portions of the identified prior art may additionally disclose, either

1 expressly or inherently, and/or render obvious one or more elements or limitations of the
2 Asserted Claims. While Defendant has identified example citations from each reference
3 for each claim element, each and every disclosure of the same element in the reference is
4 not necessarily identified. The lack of a citation for an element should not be deemed an
5 admission that the element is not disclosed or is not inherent in the reference. In an effort
6 to focus the issues, Defendant is identifying only exemplary portions of cited references.
7 Defendant reserves the right to rely on uncited portions of the identified prior art to
8 establish the invalidity of the Asserted Claims. Moreover, Defendant reserves the right to
9 rely on uncited portions of the identified prior art, other prior art, references that show the
10 state of the art (irrespective of whether such references themselves qualify as prior art to
11 the '166 Patent), and/or expert testimony to provide context to or aid in understanding the
12 cited portions of the identified prior art.

13 Where Defendant cites to a particular drawing or figure in the accompanying charts,
14 the citation encompasses the description of the drawing or figure, as well as any text
15 associated with the drawing or figure. Similarly, where Defendant cites to particular text
16 concerning a drawing or figure, the citation encompasses that drawing or figure as well.

17 Defendant reserves the right to rely on any identified piece of prior art individually
18 to anticipate all of the Asserted Claims and/or to render obvious all of the Asserted Claims
19 in view of the knowledge of one of ordinary skill in the art or in combination with other
20 references identified herein.

21 To the extent these Invalidity Contentions identify any prior art patents and/or
22 printed publications under pre-AIA 35 U.S.C. § 102(a) or (b), or (e), Defendant may also
23 rely on those patents and/or printed publications as evidence that the described invention
24 was in public use, on sale, or otherwise available to the public under pre-AIA 35 U.S.C. §
25 102(a) or (b).

26 Certain prior art references inherently disclose elements of the Asserted Claims.
27 Defendant reserves the right to rely on inherency to demonstrate the invalidity of the
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1 Asserted Claims. Moreover, certain prior art references may inherently disclose certain
2 elements of the Asserted Claims as construed by Plaintiff. Defendant may rely on cited or
3 uncited portions of the prior art, other documents, and expert testimony to establish the
4 inherency of certain features of the prior art to invalidate the Asserted Claims. Defendant
5 also reserves the right to rely on any reference identified in these Invalidity Contentions or
6 any other reference to prove that the prior art references herein are enabled or to explain
7 the meaning of a term used in any reference.

8 To the extent that Plaintiff argues that a piece of prior art does not disclose an
9 element or limitation, Defendant reserves the right to rely on any combination of the prior
10 art disclosed in these Invalidity Contentions, including the prior art identified in Exhibits
11 A1 - A8, and B, the Applicant's admitted prior art, the knowledge of those skilled in the
12 art, and/or other prior art to show that it would have been obvious to include the allegedly
13 missing element or limitation.

14 The reasons or motivation to combine the prior art would include, for example, the
15 fact that the prior art is all in the field of fixation devices for bone fusion in orthopedic
16 surgical procedures such as osteosynthesis or arthrodesis, and one of ordinary skill in the
17 art performing these types of procedures, would be motivated to investigate the various
18 existing surgical techniques, methods, and medical devices/equipment relating to fixation
19 devices for bone fusion (e.g., as described in the prior art identified herein) to address their
20 particular needs. The combinations and modifications of the prior art to invalidate the
21 Asserted Claims would have arisen from ordinary skill or common sense, or would have
22 been obvious to try or otherwise predictable.

23 A person of ordinary skill would have been motivated to combine the identified
24 prior art based on the nature of the problem to be solved, the teachings of the prior art, and
25 the knowledge of persons of ordinary skill in the art. Design incentives and other market
26 forces would have also prompted those combinations and modifications. In particular, there
27 were many different types of fixation devices known to those of ordinary skill in the art at
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1 the time of the alleged invention, and it would have been obvious to combine elements or
2 features of different bone fixation devices and techniques.

3 For example, one of ordinary skill in the art would have been motivated to combine
4 elements of existing bone fixation devices and techniques according to known methods to
5 yield predictable results, perform simple substitutions of one known element of bone
6 fixation devices for another to obtain predictable results, use known techniques and
7 features of bone fixation devices to improve similar devices in the same way, apply known
8 techniques and features for bone fixation/fusion to known bone fixation devices ready for
9 improvement to yield predictable results, and choose from, evaluate, or try a finite number
10 of identified, predictable solutions for bone fixation with a reasonable expectation of
11 success.

12 As another example, known work in the field of bone fixation, and in other fields
13 involving fixation devices or hardware (e.g., construction, woodworking, manufacturing
14 and assembly, etc.), prompts variations in the field of bone fixation based on design
15 incentives and other market forces, as those variations would have been predictable to one
16 of ordinary skill in the art. For example, with respect to surgical procedures in the prior art
17 that involve bone fixation and/or fusion, there were well-recognized design needs and
18 market pressures to perform bone fusion/fixation in a flexible, easy-to-use, and
19 reproducible manner, tailor/adapt the fusion/fixation of bones to the unique needs of each
20 patient (e.g., fuse bones of varying sizes, shapes, and areas of the body with varying levels
21 and directions of pressure/force, angles, orientations, alignments, etc.), achieve
22 reproducible intraoperative and post-operative bone fusion/fixation results (e.g., strong
23 fusion with no infections or complications from wounds or otherwise), reduce operating
24 time and recovery time (e.g., via easy-to-use fixation devices that require minimal time to
25 apply in procedures, minimal invasiveness, etc.), and improve overall patient outcomes.
26 As a result, based on these design incentives and market forces, it would have been obvious
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1 to create variations of bone fixation devices based on concepts from the same field or from
2 other fields involving fixation devices or hardware.

3 As another example, the prior art references identified herein provide various
4 teachings, suggestions, and motivations that would have led one of ordinary skill in the art
5 to modify and/or combine the prior art to arrive at the claimed invention.

6 Moreover, some pieces of prior art refer to or discuss other pieces of prior art,
7 illustrating the close technical relationship among the prior art. To the extent any piece of
8 prior art refers to or discusses other pieces of prior art, either expressly or inherently, it
9 would have been obvious to combine those pieces of prior art for that reason. Similarly, it
10 would have been obvious to combine multiple pieces of prior art that originate from the
11 same author(s) or inventor(s).

12 Defendant contends that the Asserted Claims are obvious because they merely
13 arrange old elements, with each performing the same function that had been known, to
14 perform and yield no more than what one of ordinary skill would expect from such an
15 arrangement. Because there were a finite number of predictable solutions in the art of
16 fixation devices for bone fusion in orthopedic surgical procedures, it would have been
17 obvious to a person of ordinary skill in the art to pursue the known options. A person
18 skilled in the art of procedures such as osteosynthesis and arthrodesis would have been
19 familiar with all the claim elements that the Applicant used to distinguish the prior art
20 during prosecution. The identified prior art references merely use those familiar elements
21 for their primary or well-known purposes and in a manner well within the ordinary level
22 of skill in the art. Accordingly, common sense and the knowledge of the prior art render
23 the Asserted Claims invalid as well.

24 With respect to the state of the art at the time of the alleged invention of the Asserted
25 Claims, many different types of fixation devices for fusion of bones were well-known to
26 those of skill in the art at the time of the alleged inventions. One of ordinary skill in the
27 art would have found it obvious to combine and/or modify prior art involving various
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1 orthopedic surgical procedures for fixing fused bones with concepts from other prior art in
2 the same or similar field.

3 Various additional exemplary combinations and modifications, and reasons or
4 motivations to implement those combinations and modifications, are provided below.

5 In addition to the prior art identified below and the accompanying invalidity claim
6 charts, Defendant also reserves the right to rely on other references disclosed or
7 incorporated by reference in these Invalidity Contentions; the “Background of the
8 Invention” and other relevant portions of the ‘166 Patent and its related patents; the file
9 histories of the ‘166 Patent and its related patents, including the references cited during
10 prosecution; and other evidence, including fact and expert testimony about that evidence,
11 to prove that the Asserted Claims are anticipated and/or rendered obvious under 35 U.S.C.
12 §§ 102 and 103.

13 **A. Brumfield**

14 The Brumfield reference is U.S. Patent No. 4,827,917 issued to David L. Brumfield
15 (“Brumfield”) on May 9, 1989, and filed on December 30, 1986. Brumfield qualifies as
16 prior art under at least pre-AIA 35 U.S.C. § 102(a), (b), and (e). The chart attached hereto
17 as Exhibit A1 provides examples of where Brumfield discloses, either expressly or
18 inherently, each element of the Asserted Claims, thereby anticipating those claims.

19 To the extent Plaintiff asserts that Brumfield does not anticipate the Asserted
20 Claims, it would have been obvious to combine or modify Brumfield with concepts from
21 other prior art to render the Asserted Claims obvious, including, without limitation, other
22 prior art identified in Exhibit B and/or throughout these Invalidity Contentions, because all
23 of that prior art relates to fixation devices used in orthopedic surgical procedures to
24 promote the fusion of bones, such as osteosynthesis or arthrodesis. For example, with
25 respect to any claim element that Plaintiff contends is not expressly or inherently disclosed
26 by Brumfield, Brumfield can be combined with any prior art reference in Exhibit B having
27 disclosure for that claim element to render the claim obvious. In particular, Brumfield can
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1 be combined with Cognet, Marcus, Munoz, Omega3, Simon, Van Rhee, VersaNail,
2 Ferrante, and/or Zuojun.

3 One of ordinary skill in the art would have been motivated to combine or modify
4 Brumfield in the manner described above because Brumfield and the above-referenced
5 prior art from Exhibit B are all directed towards fixation devices used in orthopedic surgical
6 procedures to promote the fusion of bones, and it would have been obvious to combine or
7 modify the fixation devices disclosed in Brumfield using concepts from prior art in the
8 same field.

9 As described above, one of ordinary skill in the art would not have limited themselves
10 to a specific device, method, or technology when making modifications or improvements
11 to Brumfield, but would have modified Brumfield with the concepts set forth in various
12 prior art solutions of the time. This would have been a result of ordinary skill and common
13 sense and would have been obvious to try and predictable. Moreover, design incentives
14 and other market forces would have prompted those endeavors.

15 **B. Cognet**

16 The Cognet reference is French Patent No. FR2861576A1 to Jean Michael Cognet
17 (“Cognet”), filed October 31, 2003, published May 6, 2005. Cognet qualifies as prior art
18 under at least pre-AIA 35 U.S.C. § 102(a), (b), and (e). The chart attached hereto as Exhibit
19 A2 provides examples of where Cognet discloses, either expressly or inherently, each
20 element of the Asserted Claims, thereby anticipating those claims. The chart in Exhibit A2
21 refers to portions of the Cognet reference as well as an English translation of the reference,
22 both of which are being produced by Defendant in conjunction with these Invalidity
23 Contentions.

24 To the extent Plaintiff asserts that Cognet does not anticipate the Asserted Claims,
25 it would have been obvious to combine or modify Cognet with concepts from other prior
26 art to render the Asserted Claims obvious, including, without limitation, other prior art
27 identified in Exhibit B and/or throughout these Invalidity Contentions, because all of that
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1 prior art relates to fixation devices used in orthopedic surgical procedures to promote the
2 fusion of bones, such as osteosynthesis or arthrodesis. For example, with respect to any
3 claim element that Plaintiff contends is not expressly or inherently disclosed by Cognet,
4 Cognet can be combined with any prior art reference in Exhibit B having disclosure for
5 that claim element to render the claim obvious. In particular, Cognet can be combined with
6 Brumfield, Marcus, Munoz, Omega3, Simon, Van Rhee, VersaNail, Ferrante, and/or
7 Zuojun.

8 One of ordinary skill in the art would have been motivated to combine or modify
9 Cognet in the manner described above because Cognet and the above-referenced prior art
10 from Exhibit B are all directed towards fixation devices used in orthopedic surgical
11 procedures to promote the fusion of bones, and it would have been obvious to combine or
12 modify the fixation devices discloses in Cognet using concepts from prior art in the same
13 field.

14 As described above, one of ordinary skill in the art would not have limited themselves
15 to a specific device, method, or technology when making modifications or improvements
16 to Cognet, but would have modified Cognet with the concepts set forth in various prior art
17 solutions of the time. This would have been a result of ordinary skill and common sense
18 and would have been obvious to try and predictable. Moreover, design incentives and other
19 market forces would have prompted those endeavors.

20 **C. Marcus**

21 The Marcus reference is U.S. Patent No. 4,622,959 issued to Randall E. Marcus
22 (“Marcus”) on November 18, 1986, filed March 5, 1985. Marcus qualifies as prior art under
23 at least pre-AIA 35 U.S.C. § 102(a), (b), and (e). The chart attached hereto as Exhibit A3
24 provides examples of where Marcus discloses, either expressly or inherently, each element
25 of the Asserted Claims, thereby anticipating those claims.

26 To the extent Plaintiff asserts that Marcus does not anticipate the Asserted Claims,
27 it would have been obvious to combine or modify Marcus with concepts from other prior
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1 art to render the Asserted Claims obvious, including, without limitation, other prior art
2 identified in Exhibit B and/or throughout these Invalidity Contentions, because all of that
3 prior art relates to fixation devices used in orthopedic surgical procedures to promote the
4 fusion of bones, such as osteosynthesis or arthrodesis. For example, with respect to any
5 claim element that Plaintiff contends is not expressly or inherently disclosed by Marcus,
6 Marcus can be combined with any prior art reference in Exhibit B having disclosure for
7 that claim element to render the claim obvious. In particular, Marcus can be combined
8 with Brumfield, Cognet, Munoz, Omega3, Simon, Van Rhee, VersaNail, Ferrante, and/or
9 Zuojun.

10 One of ordinary skill in the art would have been motivated to combine or modify
11 Marcus in the manner described above because Marcus and the above-referenced prior art
12 from Exhibit B are all directed towards fixation devices used in orthopedic surgical
13 procedures to promote the fusion of bones, and it would have been obvious to combine or
14 modify the fixation devices disclosed in Marcus using concepts from prior art in the same
15 field.

16 As described above, one of ordinary skill in the art would not have limited themselves
17 to a specific device, method, or technology when making modifications or improvements
18 to Marcus, but would have modified Marcus with the concepts set forth in various prior art
19 solutions of the time. This would have been a result of ordinary skill and common sense
20 and would have been obvious to try and predictable. Moreover, design incentives and other
21 market forces would have prompted those endeavors.

22 **D. Munoz**

23 The Munoz reference is U.S. Patent Application Publication No. 2008/0015587 to
24 Felipe Lopez-Oliva Munoz (“Munoz”), filed May 23, 2007, priority date May 24, 2006,
25 published January 17, 2008. Munoz qualifies as prior art under at least pre-AIA 35 U.S.C.
26 § 102(a), (b), and (e). The chart attached hereto as Exhibit A4 provides examples of where
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1 Munoz discloses, either expressly or inherently, each element of the Asserted Claims,
2 thereby anticipating those claims.

3 To the extent Plaintiff asserts that Munoz does not anticipate the Asserted Claims,
4 it would have been obvious to combine or modify Munoz with concepts from other prior
5 art to render the Asserted Claims obvious, including, without limitation, other prior art
6 identified in Exhibit B and/or throughout these Invalidity Contentions, because all of that
7 prior art relates to fixation devices used in orthopedic surgical procedures to promote the
8 fusion of bones, such as osteosynthesis or arthrodesis. For example, with respect to any
9 claim element that Plaintiff contends is not expressly or inherently disclosed by Munoz,
10 Munoz can be combined with any prior art reference in Exhibit B having disclosure for
11 that claim element to render the claim obvious. In particular, Munoz can be combined with
12 Brumfield, Cognet, Marcus, Omega3, Simon, Van Rhee, VersaNail, Ferrante, and/or
13 Zuojun.

14 One of ordinary skill in the art would have been motivated to combine or modify
15 Munoz in the manner described above because Munoz and the above-referenced prior art
16 from Exhibit B are all directed towards fixation devices used in orthopedic surgical
17 procedures to promote the fusion of bones, and it would have been obvious to combine or
18 modify the fixation devices disclosed in Munoz using concepts from prior art in the same
19 field.

20 As described above, one of ordinary skill in the art would not have limited themselves
21 to a specific device, method, or technology when making modifications or improvements
22 to Munoz, but would have modified Munoz with the concepts set forth in various prior art
23 solutions of the time. This would have been a result of ordinary skill and common sense
24 and would have been obvious to try and predictable. Moreover, design incentives and other
25 market forces would have prompted those endeavors.

1 **E. Omega3**

2 The Omega3 reference is a printed publication authored by Stryker Corporation
3 entitled, "Omega3 System Hansson Twin Hook Operative Technique" ("Omega3") and
4 published in 2006. Omega3 qualifies as prior art under at least pre-AIA 35 U.S.C. § 102(a)
5 and (b). The Omega3 reference is also evidence that may be used to establish that the
6 Omega3 Hip Fracture System in combination with the Hansson Twin Hook was in use or
7 known prior to the purported invention of the '166 Patent in accordance with pre-AIA 35
8 U.S.C. § 102(a) and/or in public use or on sale in the U.S. more than one year before the
9 earliest effective filing date of the '166 Patent. The chart attached hereto as Exhibit A5
10 provides examples of where Omega3 discloses, either expressly or inherently, each element
11 of the Asserted Claims, thereby anticipating those claims.

12 To the extent Plaintiff asserts that Omega3 does not anticipate the Asserted Claims,
13 it would have been obvious to combine or modify Omega3 with concepts from other prior
14 art to render the Asserted Claims obvious, including, without limitation, other prior art
15 identified in Exhibit B and/or throughout these Invalidity Contentions, because all of that
16 prior art relates to fixation devices used in orthopedic surgical procedures to promote the
17 fusion of bones, such as osteosynthesis or arthrodesis. For example, with respect to any
18 claim element that Plaintiff contends is not expressly or inherently disclosed by Omega3,
19 Omega3 can be combined with any prior art reference in Exhibit B having disclosure for
20 that claim element to render the claim obvious. In particular, Omega3 can be combined
21 with Brumfield, Cognet, Marcus, Munoz, Simon, Van Rhee, VersaNail, Ferrante, and/or
22 Zuojun.

23 One of ordinary skill in the art would have been motivated to combine or modify
24 Omega3 in the manner described above because Omega3 and the above-referenced prior
25 art from Exhibit B are all directed towards fixation devices used in orthopedic surgical
26 procedures to promote the fusion of bones, and it would have been obvious to combine or
27 modify the fixation devices discloses in Omega3 using concepts from prior art in the same
28 field.

1 As described above, one of ordinary skill in the art would not have limited themselves
2 to a specific device, method, or technology when making modifications or improvements
3 to Omega3, but would have modified Omega3 with the concepts set forth in various prior
4 art solutions of the time. This would have been a result of ordinary skill and common sense
5 and would have been obvious to try and predictable. Moreover, design incentives and other
6 market forces would have prompted those endeavors.

7 **F. Simon**

8 The Simon reference is U.S. Patent Application Publication No. 2006/0206044 to
9 William H. Simon ("Simon"), filed August 1, 2003, priority date August 10, 2002,
10 published September 14, 2006. Simon qualifies as prior art under at least pre-AIA 35
11 U.S.C. § 102(a), (b), and (e). The chart attached hereto as Exhibit A6 provides examples
12 of where Simon discloses, either expressly or inherently, each element of the Asserted
13 Claims, thereby anticipating those claims.

14 To the extent Plaintiff asserts that Simon does not anticipate the Asserted Claims, it
15 would have been obvious to combine or modify Simon with concepts from other prior art
16 to render the Asserted Claims obvious, including, without limitation, other prior art
17 identified in Exhibit B and/or throughout these Invalidity Contentions, because all of that
18 prior art relates to fixation devices used in orthopedic surgical procedures to promote the
19 fusion of bones, such as osteosynthesis or arthrodesis. For example, with respect to any
20 claim element that Plaintiff contends is not expressly or inherently disclosed by Simon,
21 Simon can be combined with any prior art reference in Exhibit B having disclosure for that
22 claim element to render the claim obvious. In particular, Simon can be combined with
23 Brumfield, Cognet, Marcus, Munoz, Omega3, Van Rhee, VersaNail, Ferrante, and/or
24 Zuojun.

25 One of ordinary skill in the art would have been motivated to combine or modify
26 Simon in the manner described above because Simon and the above-referenced prior art
27 from Exhibit B are all directed towards fixation devices used in orthopedic surgical
28

1 procedures to promote the fusion of bones, and it would have been obvious to combine or
2 modify the fixation devices disclosed in Simon using concepts from prior art in the same
3 field.

4 As described above, one of ordinary skill in the art would not have limited themselves
5 to a specific device, method, or technology when making modifications or improvements
6 to Simon, but would have modified Simon with the concepts set forth in various prior art
7 solutions of the time. This would have been a result of ordinary skill and common sense
8 and would have been obvious to try and predictable. Moreover, design incentives and other
9 market forces would have prompted those endeavors.

10 **G. Van Rhee**

11 The Van Rhee reference is PCT Application No. WO 2008/003433 A1 to Ryszard
12 Van Rhee (“Van Rhee”), filed June 29, 2007, priority date January 7, 2006, published
13 January 10, 2008. Van Rhee qualifies as prior art under at least pre-AIA 35 U.S.C. § 102(a),
14 (b), and (e). The chart attached hereto as Exhibit A7 provides examples of where Van Rhee
15 discloses, either expressly or inherently, each element of the Asserted Claims, thereby
16 anticipating those claims. The chart in Exhibit A7 refers to portions of the Van Rhee
17 reference as well as an English translation of the reference, both of which are being
18 produced by Defendant in conjunction with these Invalidity Contentions.

19 To the extent Plaintiff asserts that Van Rhee does not anticipate the Asserted Claims,
20 it would have been obvious to combine or modify Van Rhee with concepts from other prior
21 art to render the Asserted Claims obvious, including, without limitation, other prior art
22 identified in Exhibit B and/or throughout these Invalidity Contentions, because all of that
23 prior art relates to fixation devices used in orthopedic surgical procedures to promote the
24 fusion of bones, such as osteosynthesis or arthrodesis. For example, with respect to any
25 claim element that Plaintiff contends is not expressly or inherently disclosed by Van Rhee,
26 Van Rhee can be combined with any prior art reference in Exhibit B having disclosure for
27 that claim element to render the claim obvious. In particular, Van Rhee can be combined
28

1 with Brumfield, Cognet, Marcus, Munoz, Omega3, Simon, VersaNail, Ferrante, and/or
2 Zuojun.

3 One of ordinary skill in the art would have been motivated to combine or modify
4 Van Rhee in the manner described above because Van Rhee and the above-referenced prior
5 art from Exhibit B are all directed towards fixation devices used in orthopedic surgical
6 procedures to promote the fusion of bones, and it would have been obvious to combine or
7 modify the fixation devices disclosed in Simon using concepts from prior art in the same
8 field.

9 As described above, one of ordinary skill in the art would not have limited themselves
10 to a specific device, method, or technology when making modifications or improvements
11 to Van Rhee, but would have modified Simon with the concepts set forth in various prior
12 art solutions of the time. This would have been a result of ordinary skill and common sense
13 and would have been obvious to try and predictable. Moreover, design incentives and other
14 market forces would have prompted those endeavors.

15 **H. VersaNail**

16 The VersaNail reference is a printed publication authored by Stryker Corporation DePuy
17 Ace (or DePuy Orthopedics) a Johnson & Johnson company entitled, “Tibiototalcaneal
18 Fusion Using the VersaNail Surgical Technique” (“VersaNail”) and published in 2002.
19 VersaNail qualifies as prior art under at least pre-AIA 35 U.S.C. § 102(a) and (b). The
20 VersaNail reference is also evidence that may be used to establish that the VersaNail
21 System was in use or known prior to the purported invention of the ‘166 Patent in
22 accordance with pre-AIA 35 U.S.C. § 102(a) and/or in public use or on sale in the U.S.
23 more than one year before the earliest effective filing date of the ‘166 Patent. The chart
24 attached hereto as Exhibit A8 provides examples of where VersaNail discloses, either
25
26
27
28

1 expressly or inherently, each element of the Asserted Claims, thereby anticipating those
2 claims.

3 To the extent Plaintiff asserts that VersaNail does not anticipate the Asserted
4 Claims, it would have been obvious to combine or modify VersaNail with concepts from
5 other prior art to render the Asserted Claims obvious, including, without limitation, other
6 prior art identified in Exhibit B and/or throughout these Invalidity Contentions, because all
7 of that prior art relates to fixation devices used in orthopedic surgical procedures to
8 promote the fusion of bones, such as osteosynthesis or arthrodesis. For example, with
9 respect to any claim element that Plaintiff contends is not expressly or inherently disclosed
10 by VersaNail, VersaNail can be combined with any prior art reference in Exhibit B having
11 disclosure for that claim element to render the claim obvious. In particular, VersaNail can
12 be combined with Brumfield, Cognet, Marcus, Munoz, Omega3, Simon, Van Rhee,
13 Ferrante, and/or Zuojun.

14 One of ordinary skill in the art would have been motivated to combine or modify
15 VersaNail in the manner described above because VersaNail and the above-referenced
16 prior art from Exhibit B are all directed towards fixation devices used in orthopedic surgical
17 procedures to promote the fusion of bones, and it would have been obvious to combine or
18 modify the fixation devices disclosed in VersaNail using concepts from prior art in the
19 same field.

20 As described above, one of ordinary skill in the art would not have limited themselves
21 to a specific device, method, or technology when making modifications or improvements
22 to VersaNail, but would have modified VersaNail with the concepts set forth in various
23 prior art solutions of the time. This would have been a result of ordinary skill and common
24 sense and would have been obvious to try and predictable. Moreover, design incentives
25 and other market forces would have prompted those endeavors.

1 **I. Ferrante**

2 The Ferrante reference is U.S. Patent Application Publication No. 2003/0187447 to
3 Joseph Ferrante, et. al. (“Ferrante”), filed April 7, 2003, priority date April 16, 2001,
4 published October 2, 2003. Ferrante qualifies as prior art under at least 35 U.S.C. § 103 in
5 combination with the other references previously identified and described in Exhibits A1-
6 A8 and/or Exhibit B.

7 It would have been obvious to combine or modify Ferrante with concepts from other
8 prior art to render the Asserted Claims obvious, including, without limitation, other prior
9 art identified in Exhibit B and/or throughout these Invalidity Contentions, because all of
10 that prior art relates to fixation devices used in orthopedic surgical procedures to promote
11 the fusion of bones, such as osteosynthesis or arthrodesis. For example, with respect to
12 any claim element that Plaintiff contends is not expressly or inherently disclosed by
13 Ferrante, Ferrante can be combined with any prior art reference in Exhibit B having
14 disclosure for that claim element to render the claim obvious. In particular, Ferrante can
15 be combined with Brumfield, Cognet, Marcus, Munoz, Omega3, Simon, Van Rhee,
16 VersaNail and/or Zuojun.

17 One of ordinary skill in the art would have been motivated to combine or modify
18 Ferrante in the manner described above because Ferrante and the above-referenced prior
19 art from Exhibit B are all directed towards fixation devices used in orthopedic surgical
20 procedures to promote the fusion of bones, and it would have been obvious to combine or
21 modify the fixation devices disclosed in Ferrante using concepts from prior art in the same
22 field.

23 As described above, one of ordinary skill in the art would not have limited themselves
24 to a specific device, method, or technology when making modifications or improvements
25 to Ferrante, but would have modified Ferrante with the concepts set forth in various prior
26 art solutions of the time. This would have been a result of ordinary skill and common sense
27 and would have been obvious to try and predictable. Moreover, design incentives and other
28 market forces would have prompted those endeavors.

1 **J. Zuojun**

2 The Zuojun reference is Chinese Patent No. CN2513533Y to Zhang Zuojun, et. al.,
3 filed December 25, 2001, published October 2, 2002. The chart in Exhibit B refers to
4 portions of the Zuojun reference as well as an English translation of the reference, both of
5 which are being produced by Defendant in conjunction with these Invalidity Contentions.
6 Zuojun qualifies as prior art under at least 35 U.S.C. § 103 in combination with the other
7 references previously identified and described in Exhibits A1-A8 and/or Exhibit B.

8 It would have been obvious to combine or modify Zuojun with concepts from other
9 prior art to render the Asserted Claims obvious, including, without limitation, other prior
10 art identified in Exhibit B and/or throughout these Invalidity Contentions, because all of
11 that prior art relates to fixation devices used in orthopedic surgical procedures to promote
12 the fusion of bones, such as osteosynthesis or arthrodesis. For example, with respect to
13 any claim element that Plaintiff contends is not expressly or inherently disclosed by
14 Zuojun, Zuojun can be combined with any prior art reference in Exhibit B having
15 disclosure for that claim element to render the claim obvious. In particular, Zuojun can be
16 combined with Brumfield, Cognet, Marcus, Munoz, Omega3, Simon, Van Rhee, VersaNail
17 and/or Ferrante.

18 One of ordinary skill in the art would have been motivated to combine or modify
19 Zuojun in the manner described above because Ferrante and the above-referenced prior art
20 from Exhibit B are all directed towards fixation devices used in orthopedic surgical
21 procedures to promote the fusion of bones, and it would have been obvious to combine or
22 modify the fixation devices discloses in Zuojun using concepts from prior art in the same
23 field.

24 As described above, one of ordinary skill in the art would not have limited themselves
25 to a specific device, method, or technology when making modifications or improvements
26 to Zuojun, but would have modified Zuojun with the concepts set forth in various prior art
27 solutions of the time. This would have been a result of ordinary skill and common sense
28

1 and would have been obvious to try and predictable. Moreover, design incentives and other
2 market forces would have prompted those endeavors.

3 **K. Admitted Prior Art**

4 Defendant reserves the right to rely on inventor or applicant admissions concerning
5 the scope of the prior art relevant to the ‘166 Patent or related patents found in, *inter alia*,
6 the specification and/or prosecution histories of the ‘166 Patent or related patents and/or
7 patent applications, any testimony or declarations of the named inventors concerning the
8 ‘166 Patent or related patents, and any papers or evidence submitted by Plaintiff in
9 connection with this litigation, any other pending or future litigation brought by Plaintiff
10 involving the ‘166 Patent or related patents, or *inter partes* review proceedings involving
11 the ‘166 Patent or related patents.

12 For example, statements made by the Applicant in the specification and/or during
13 prosecution of the ‘166 Patent and their related patents and/or applications, such as in the
14 “Background of the Invention” section that describes the related art known to the
15 Applicant, are admissions that can be relied upon for both anticipation and obviousness
16 determinations, regardless of whether the admitted prior art would otherwise qualify as
17 prior art under the statutory categories set forth in 35 U.S.C. § 102. *See* MPEP §§
18 608.01(c), 2129.

19 To the extent Plaintiff contends that the Asserted Claims are not invalid as
20 anticipated by and/or obvious in view of the prior art under 35 U.S.C. §§ 102 and 103,
21 Defendant reserves the right to rely on the applicant’s “Admitted Prior Art” to demonstrate
22 the invalidity of the Asserted Claims.

23 **L. The Knowledge of One of Ordinary Skill in the Art**

24 To the extent that Plaintiff contends that any particular feature of the Asserted
25 Claims is a novel aspect of the Asserted Claims, Defendant reserves the right to illustrate
26 that the particular feature was widely known, understood, and implemented by those of
27 ordinary skill in the art at the time of the alleged inventions, and that it would have been
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1 obvious to combine and/or modify the prior art identified throughout these Invalidity
2 Contentions with the knowledge of one of ordinary skill in the art.

3 Defendant reserves the right to illustrate this knowledge using any of the prior art
4 references identified herein, which provides an exemplary identification of prior art
5 evidencing the state of the art at the time of the alleged inventions. Defendant also may
6 establish what was known to a person having ordinary skill in the art through treatises,
7 published industry standards and/or other publications, products, medical procedures,
8 and/or testimony.

9 Defendant also reserves the right to contend that it would have been obvious to
10 modify any of the prior art identified by these Invalidity Contentions to render the Asserted
11 Claims invalid in view of the knowledge of one of ordinary skill in the art.

12 **V. INVALIDITY UNDER 35 U.S.C. § 112**

13 Certain Asserted Claims are invalid for failing to comply with the written
14 description, enablement, and/or definiteness requirements under 35 U.S.C. § 112, as
15 described below.

16 The specifications of the ‘166 Patent does not provide adequate written description
17 support for certain claims,² whether based on the proper claim scope or the overbroad claim
18 scope advanced in Plaintiff’s Infringement Contentions. 35 U.S.C. § 112 ¶ 1 requires the
19 specification to contain “a written description of the invention.” To fulfill the written
20 description requirement, the specification “must clearly allow persons of ordinary skill in
21 the art to recognize that the inventor invented what is claimed.” *Ariad Pharm., Inc. v. Eli*
22 *Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (citation omitted). To satisfy the written
23 description requirement, “the applicant must ‘convey with reasonable clarity to those
24 skilled in the art that, as of the filing date sought, he or she was in possession of the
25 invention,’ and demonstrate that by disclosure in the specification of the patent.” *Carnegie*
26 *Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008) (quoting

27
28 ² This is also true of the priority application(s) referred to in the ‘166 Patent.

1 *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991)). The ‘166 Patent
2 fails to satisfy the written description requirement for certain claims for at least the reasons
3 described below.

4 Additionally, the specification of the ‘166 Patent does not enable the scope of
5 certain claims,³ whether based on the proper claim scope or the overbroad claim scope
6 advanced in Plaintiff’s Infringement Contentions. 35 U.S.C. § 112 ¶ 1 requires the
7 specification to describe “the manner and process of making and using [the invention], in
8 such full, clear, concise, and exact terms as to enable any person skilled in the art to which
9 it pertains, or with which it is most nearly connected, to make and use the [invention].”
10 The enablement requirement is separate from and in addition to the written description
11 requirement. *Ariad*, 598 F.3d at 1344. This “requirement is satisfied when one skilled in
12 the art, after reading the specification, could practice the claimed invention without undue
13 experimentation.” *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003)
14 (citation omitted); see *Wyeth & Cordis Corp. v. Abbott Laboratories*, 720 F.3d 1380 (Fed.
15 Cir. 2013). The ‘166 Patent fails to satisfy the enablement requirement for certain claims
16 for at least the reasons described below.

17 Further, certain claims of the ‘166 Patent are invalid for failing to comply with the
18 definiteness requirement of 35 U.S.C. § 112 ¶ 2.⁴ 35 U.S.C. § 112 ¶ 2 requires that a patent
19 claim “particularly point[] out and distinctly claim[] the subject matter which the applicant
20 regards as his invention.” Claim terms that fail to inform those skilled in the art “with
21 reasonable certainty...about the scope of the invention” fail the definiteness requirement
22 of § 112 ¶ 2. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). The
23 patent laws of the United States prohibit claiming an invention through functional terms as
24 a way to capture every way of performing a function. Claim terms that recite an invention

25 ³ This is also true of the priority application(s) referred to in the ‘166 Patent.

26 ⁴ Defendant notes that its charting of a prior art reference for a claim or limitation that
27 Defendant contends is invalid for lack of definiteness in no way represents an admission
28 or concession that the scope of the claim or limitation is definite or ascertainable.

using functional terms are invalid as indefinite, except for those adequately claimed and supported in accordance with 35 U.S.C. § 112 ¶ 6. Under 35 U.S.C. § 112 ¶ 6, an element in a claim may be expressed as “a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.” “The standard [for determining whether § 112 ¶ 6 applies] is whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure.” *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015). Although use of the word “means” in a claim creates a “presumption that [§ 112 ¶ 6] applies,” “[w]hen a claim term lacks the word ‘means,’ the presumption can be overcome and [§ 112 ¶ 6] will apply if the challenger demonstrates that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function.” *Id.* (internal quotations omitted). Certain claims of the ‘166 Patent are indefinite for at least the reasons described below.

The following chart identifies claims of the ‘166 Patent that are invalid for failing to comply with the written description, enablement, and/or definiteness requirements under 35 U.S.C. § 112. In particular, certain claims are invalid based on lack of written description at least because the specifications of the ‘166 Patent fail to provide adequate written description support for the claim elements identified in the chart. Certain claims are invalid based on lack of enablement at least because the specifications Of the ‘166 Patent fail to enable the claim elements identified in the chart. Certain claims are invalid based on indefiniteness at least because the claim elements identified in the chart fail to satisfy the definiteness requirement. Further, any claim that depends, directly or indirectly, from one of the invalid claims identified in the chart below is also invalid under 35 U.S.C. § 112 based on the same grounds.

Claim(s)	Claim Element	§ 112 Invalidity Grounds
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1	1	wherein the first angle is in the range of about 0 degrees to about 90 degrees	Indefinite Lack of Written Description Lack of Enablement
2	1, 12	wherein the second angle is in the range of about 0 degrees to about 90 degrees	Indefinite Lack of Written Description Lack of Enablement
3	1, 12	wherein the second bore axis is substantially perpendicular to the third longitudinal axis	Indefinite Lack of Written Description Lack of Enablement
4	2, 6, 13	wherein the head portion of the first member resides at least partially within the first bore	Indefinite Lack of Written Description
5	5	wherein the first aperture of the third member is aligned on the first bore axis	Indefinite
6	4	torque transmitting aperture	Indefinite Lack of Enablement
7	1, 12	wherein there are no threads adjacent to the second aperture of the third member	Indefinite Lack of Written Description
8	1, 12	longitudinal axis	Indefinite Lack of Written Description
9	1, 12	a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis, wherein the first member comprises a shaft portion having an external surface and a head portion having an exterior surface	Indefinite Lack of Written Description
10	1, 12	a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis, wherein the second member comprises a shaft having an external surface	Indefinite Lack of Written Description
11	1, 12	shaft	Indefinite Lack of Written Description
12	1, 12	shaft portion	Indefinite Lack of Written Description
13	1, 12	a third member comprising a third elongated body extending along a straight line from a first end to a second end along a third longitudinal axis	Indefinite Lack of Written Description
14	1, 10, 12	a first end	Indefinite Lack of Written Description
15	1, 12	a second end	Indefinite Lack of Written Description
16	1, 12	a first thread	Indefinite Lack of Written Description

1, 12	a first thread height	Indefinite Lack of Written Description
1, 12	external surface	Indefinite Lack of Written Description
1, 7, 12	exterior surface	Indefinite Lack of Written Description
1-3, 5, 7, 9, 12, 13	bore	Indefinite Lack of Written Description

As an illustrative example of the above, Claims 1 and 12 of the '166 Patent each recite “wherein the second angle is in the range of about 0 degrees to about 90 degrees” and Claim 1 also includes the phrase “wherein the first angle is in the range of about 0 degrees to about 90 degrees”. The claims are unclear and ambiguous both as to the scope of these terms and their particular meaning. It is unclear from the claim language and the specification which particular angle is being referenced by the claim. And because the range of angles is sufficiently broad, they could potentially encompass any angle such that these claims lack sufficient written description, are not enabled, and/or are indefinite for failing to inform those skilled in the art with reasonable certainty about the scope of the invention.

As another example, Claims 1 and 12 of the '166 Patent lack sufficient written description, are not enabled, and/or are indefinite for failing to inform those skilled in the art with reasonable certainty about the scope of the invention based on various claim terms, such as (among others) “wherein the second bore axis is substantially perpendicular to the third longitudinal axis”, for example, at least because such terms are not defined with sufficient specificity and/or are defined ambiguously in the '166 Patent.

As another example, Claims 2, 6 and 13 of the '166 Patent lack sufficient written description, are not enabled, and/or are indefinite for failing to inform those skilled in the art with reasonable certainty about the scope of the invention based on various claim terms, such as (among others) “wherein the head portion of the first member resides at least partially within the first bore”, for example, at least because such terms are not defined with sufficient specificity and/or are defined ambiguously in the '166 Patent.

1 As another example, Claims 1 and 12 of the '166 Patent lack sufficient written
2 description, are not enabled, and/or are indefinite for failing to inform those skilled in the
3 art with reasonable certainty about the scope of the invention based on the claim terms
4 “shaft” and “shaft portion” at least because such terms do not appear anywhere in the
5 specification of the '166 Patent.

6 As another example, Claims 1-3, 5, 7, 9, 12 and 13 of the '166 Patent lack sufficient
7 written description, are not enabled, and/or are indefinite for failing to inform those skilled
8 in the art with reasonable certainty about the scope of the invention based on the claim
9 term, “bore” at least because such term does not appear anywhere in the specification of
10 the '166 Patent.

11 Defendant reserves the right to amend or supplement its asserted grounds of
12 invalidity under 35 U.S.C. § 112 as additional information is discovered or otherwise
13 identified or appreciated.

14 **VI. PATENT-INELIGIBLE SUBJECT MATTER UNDER 35 U.S.C. § 101**

15 Defendant's asserted bases for invalidity under 35 U.S.C. § 101 are based on its
16 investigation thus far. Defendant reserves its right to amend or otherwise modify its
17 asserted bases for invalidity under 35 U.S.C. § 101 based on its review of additional
18 documents and evidence, including, without limitation, additional information concerning
19 the state of the art and level of one of ordinary skill in the art at the relevant time. Further,
20 Defendant reserves the right to assert additional arguments of invalidity under 35 U.S.C. §
21 101 based on the claim construction process, Plaintiff's proposed claim constructions, any
22 supplement to Plaintiff's infringement contentions, Plaintiff's expert reports, or other
23 positions taken by Plaintiff. A more detailed basis for § 101 invalidity positions will be set
24 forth in Defendant's expert reports, pleadings, and/or motions.

25 Certain Asserted Claims are not patent eligible under 35 U.S.C. § 101 because they
26 are directed to laws of nature, natural phenomena, and/or abstract ideas, which have been
27 held as ineligible for patent protection. See, e.g., *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*,

1 573 U.S. 208 (2014). For example, claims 1 and 12 of the ‘166 Patent recite “An assembly
2 for bone fusion” which is also an element of each of the dependent Asserted Claims (2-8,
3 10, 11, and 13-15). Each of these claims recite a law of nature or natural phenomena – the
4 biological process of the fusion of two bones or parts of a bone.

5 Accordingly, all of the Asserted Claims are invalid under 35 U.S.C. § 101 for
6 claiming ineligible subject matter.

7 **VII. ADDITIONAL INVALIDITY POSITIONS**

8 Precise identification of all of the bases upon which the Asserted Claims are invalid
9 and/or unenforceable, including failure to disclose the best mode, improper inventorship,
10 and the judicially-created non-statutory obviousness-type double patenting doctrine, are
11 likely to be revealed only after further developments in the case, including fact and expert
12 discovery. Defendant reserves the right to amend or supplement these Invalidity
13 Contentions to address any additional invalidity arguments that become apparent in view
14 of any relevant facts and information revealed during discovery or to otherwise seek to
15 invalidate the Asserted Claims on any basis.

16 **VIII. DOCUMENT PRODUCTION**

17 Concurrently with service of these Invalidity Contentions, Defendant is producing
18 copies of prior art and other relevant documents.
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1 Dated: February 17th, 2023

Respectfully submitted,

2
3 /s/ Corby R. Vowell

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22 *Fusion Orthopedics, LLC*
23
24
25
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28

CERTIFICATE OF SERVICE

I hereby certify that, on February 17th, 2023, all counsel of record who have appeared in this case are being served with a copy of the foregoing via e-mail.

/s/ Corby R. Vowell

Exhibit A2

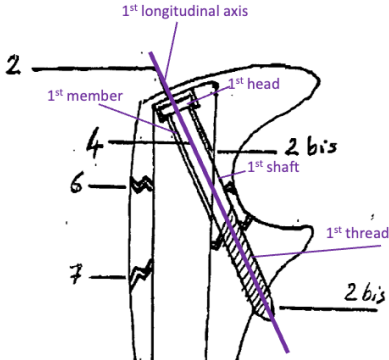
Claim Chart for Cognet¹ and Cognet English²

¹ FR2861576, Cognet, published 5/6/2005

² Machine translation into English of FR2861576, Cognet, published 5/6/2005

'166 Patent

Exhibit A2: Cognet

No.	Claim 1	Cognet
1a	1. An assembly for bone fusion, comprising:	See, e.g.: The osteosynthesis device described above is associated with an ancillary intended to facilitate the fitting of said material and in particular to carry out the screwing by automatic aiming. 71 The device according to the invention is particularly intended for the treatment of olecranon fractures. (Cognet English, 69-72) Furthermore, this limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
1b	a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis, wherein the first member comprises a shaft portion having an external surface and a head portion having an exterior surface, said first member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft portion;	See, e.g.:  (Cognet, Fig. 1 – cropped) Furthermore, this limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
1c	a second member comprising a second	See, e.g.,

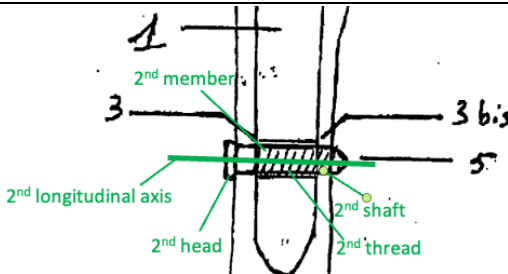
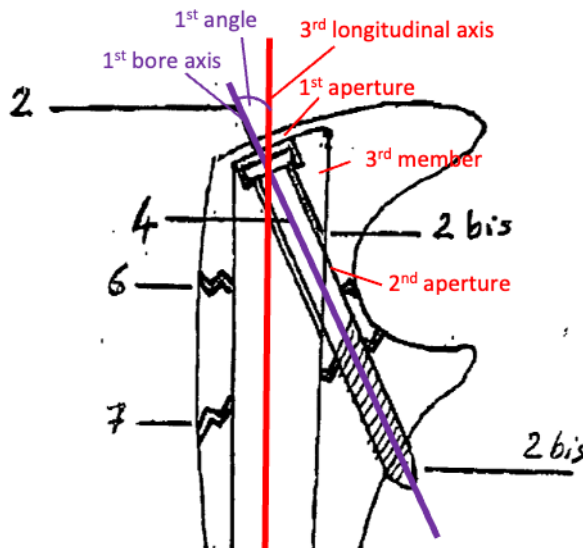
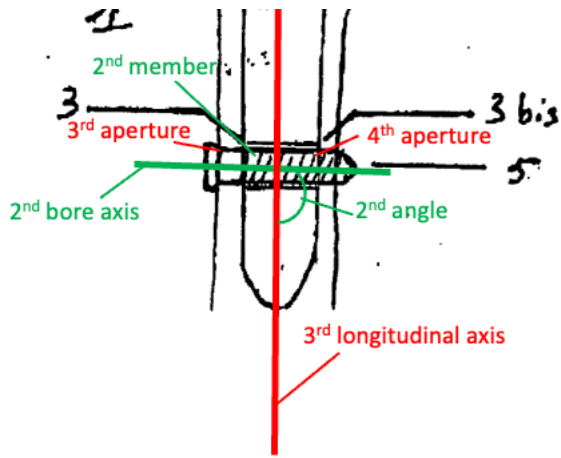
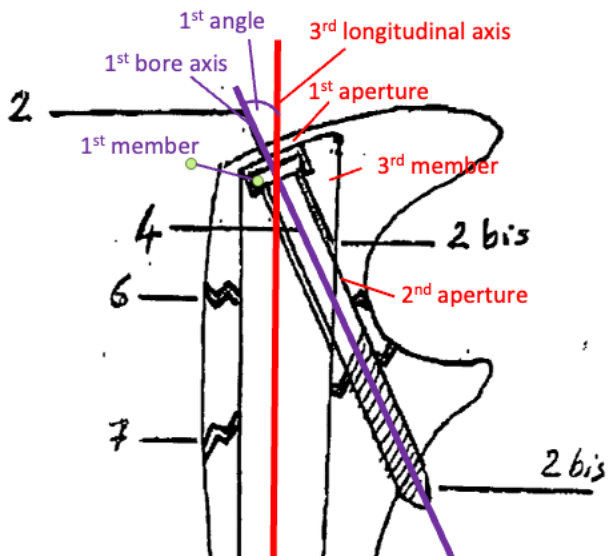
	elongated body extending from a first end to a second end along a second longitudinal axis, wherein the second member comprises a shaft having an external surface, said second member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft;	 (Cognet, Fig. 1 – cropped) Furthermore, this limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant’s Invalidity Contentions.
1d	a third member comprising a third elongated body extending along a straight line from a first end to a second end along a third longitudinal axis, wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body, and a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member, wherein the first bore comprises an interior surface at the first aperture, wherein there are	See, e.g.:  (Cognet, Fig. 1 – cropped)

Exhibit A2: Cognet

	no threads adjacent to the second aperture on the exterior surface of the third member, and wherein the third longitudinal axis and the first bore axis define a first angle,	The proximal and distal part of this screw is smooth and has no threads; this is the part in contact with the nail. (Cognet English, 61-62) ... a nail traversed by at least two screws allowing the anchoring of this nail in the bone. The nail can be solid or hollow. If the nail is solid, it has tunnels allowing the screws to pass through it. If the nail is hollow, it has holes allowing the screws to pass through it. (Cognet English, 25-28) Furthermore, this limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
1e	wherein the third member further comprises a third aperture on the exterior surface of the third member, and a second bore extending along a second bore axis from the third aperture to a fourth aperture on an exterior surface of the third member, wherein the third longitudinal axis and the second bore axis define a second angle,	See, e.g.:  (Cognet, Fig. 1 – cropped) Furthermore, this limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.

1f	wherein the first member couples to the third member by inserting the first end of the first member into the first aperture, through the first bore, and out of the second aperture,	<i>See, e.g.:</i> An orifice or tunnel is present at the top of the nail and follows an oblique descending path, in the direction of the coronoid process. This oblique descending path is intended to receive a screw according to a passage from the proximal part towards the distal part which allows the bone anchoring of the nail and the compression of the fracture site. (Cognet English, 30-34)  (Cognet, Fig. 1 – cropped) Furthermore, this limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant’s Invalidity Contentions.
1g	wherein the second member couples to the third member by inserting	<i>See, e.g.:</i> This nail also has at least one orifice or a tunnel located at the distal part of the nail,

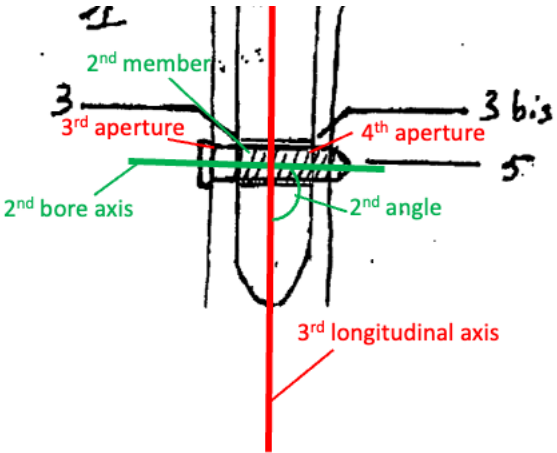
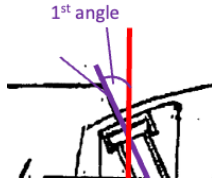
	the first end of the second member into the third aperture, through the second bore, and out of the fourth aperture,	perpendicular to the axis of the latter, and intended to receive a screw which allows the bone anchoring of the nail, (Cognet English, 35-37)  (Cognet, Fig. 1 – cropped) Furthermore, this limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant’s Invalidity Contentions.
1h	wherein the first angle is in the range of about 0 degrees to about 90 degrees,	See, e.g.:  (Cognet, Fig. 1 – cropped)

Exhibit A2: Cognet

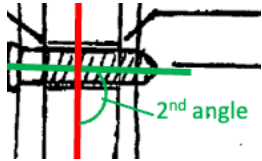
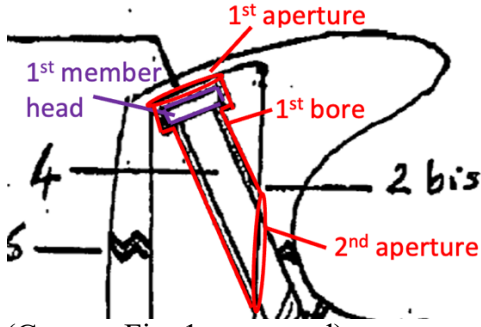
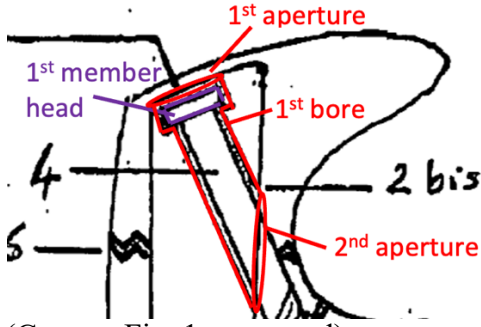
		Furthermore, this limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
1i	wherein the second angle is in the range of about 0 degrees to about 90 degrees, and	<i>See, e.g.:</i>  (Cognet, Fig. 1 – cropped) This nail also has at least one orifice or a tunnel located at the distal part of the nail, perpendicular to the axis of the latter, and intended to receive a screw which allows the bone anchoring of the nail, (Cognet English, 35-37) Furthermore, this limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
1j	wherein the second bore axis is substantially perpendicular to the third longitudinal axis.	<i>See, e.g.:</i> This nail also has at least one orifice or a tunnel located at the distal part of the nail, perpendicular to the axis of the latter, and intended to receive a screw which allows the bone anchoring of the nail, (Cognet English, 35-37)
No.	Claim 2	Cognet
2a	2. The assembly of claim 1,	<i>See</i> Claim 1, above.
2b	wherein the head portion of the first member resides	<i>See, e.g.:</i>

Exhibit A2: Cognet

	at least partially within the first bore.	 (Cognet, Fig. 1 – cropped) Furthermore, this limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant’s Invalidity Contentions.
No.	Claim 3	Cognet
3a	3. The assembly of claim 2,	See Claim 2, above.
3b	wherein the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture.	See, e.g.: The top of the screw has a head, with a diameter larger than the diameter of the body of the screw and than the tunnel (2) through which the screw passes, which makes it possible to stop the progression of the screw in its tunnel and to obtain a compression effect at the level of the fracture site. (Cognet English, 62-65)

		 (Cognet, Fig. 1 – cropped) Furthermore, this limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant’s Invalidity Contentions.
No.	Claim 4	Cognet
4a	4. The assembly of claim 3,	See Claim 3, above.
4b	wherein the head portion of the first member comprises a torque transmitting aperture.	See, e.g.: This limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant’s Invalidity Contentions.
No.	Claim 5	Cognet
5a	5. The assembly of claim 1,	See Claim 1, above.
5b	wherein the first aperture of the third member is aligned on the first bore axis.	See, e.g.:

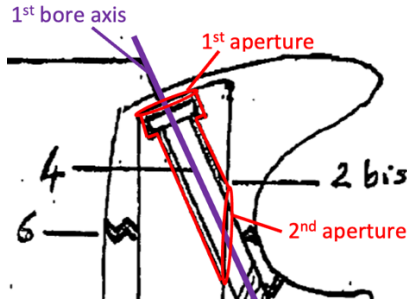
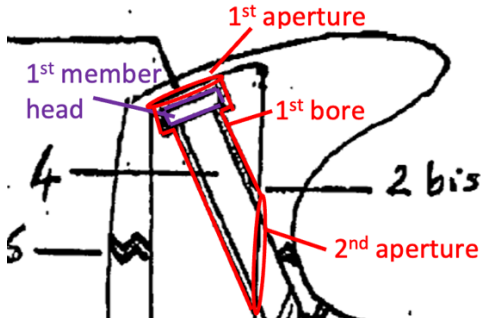
		 (Cognet, Fig. 1 – cropped) Furthermore, this limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant’s Invalidity Contentions.
No.	Claim 6	Cognet
6a	6. The assembly of claim 5,	See Claim 5, above.
6b	wherein the head portion of the first member resides at least partially within the first bore.	See, e.g.:  (Cognet, Fig. 1 – cropped) The top of the screw has a head, with a diameter larger than the diameter of the body of the screw and than the tunnel (2) through which the screw passes, which makes it possible to stop the progression of the screw in its tunnel and to obtain a compression effect at the level of the fracture site.

Exhibit A2: Cognet

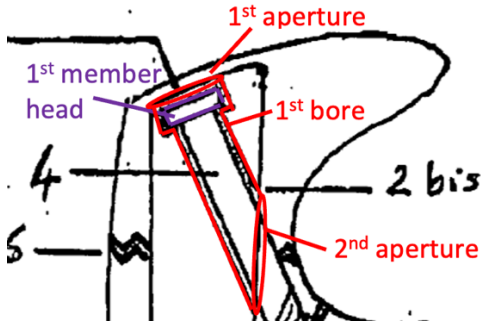
		(Cognet English, 62-65) Furthermore, this limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
No.	Claim 7	Cognet
7a	7. The assembly of claim 6,	See Claim 6, above.
7b	wherein the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture.	See, e.g.: The top of the screw has a head, with a diameter larger than the diameter of the body of the screw and than the tunnel (2) through which the screw passes, which makes it possible to stop the progression of the screw in its tunnel and to obtain a compression effect at the level of the fracture site. (Cognet English, 62-65)  (Cognet, Fig. 1 – cropped) Furthermore, this limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
No.	Claim 8	Cognet

Exhibit A2: Cognet

8a	8. The assembly of claim 1,	<i>See</i> Claim 1, above.
8b	wherein the head portion of the first member is tapered.	<i>See, e.g.:</i> This limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
No.	Claim 10	Cognet
10a	10. The assembly of claim 1	<i>See</i> Claim 1, above.
10b	wherein the first end of the first member includes a self-tapping edge for removing bone material.	<i>See, e.g.:</i> This limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
No.	Claim 11	Cognet
11a	11. The assembly of claim 10,	<i>See</i> Claim 1, above.
11b	wherein the first end of the second member includes a self-tapping edge for removing bone material.	<i>See, e.g.:</i> This limitation would have been obvious in view of Cognet alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
No.	Claim 12	Cognet
12a	12. An assembly for bone fusion, comprising:	<i>See</i> Claim 1, above.
12b	a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis, wherein the first member	<i>See, e.g.:</i> Same as 1b

Exhibit A2: Cognet

	comprises a shaft portion having an external surface and a head portion having an exterior surface, said first member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft portion;	
12c	a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis, wherein the second member comprises a shaft having an external surface, said second member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft;	Same as 1c
12d	a third member comprising a third elongated body extending along a straight line from a first end to a second end along a third longitudinal axis, wherein the third	Same as 1d

Exhibit A2: Cognet

	member comprises a first aperture at a terminal end of the first end of the third elongated body, and a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member, wherein the first bore comprises an interior surface at the first aperture, wherein there are no threads adjacent to the second aperture on the exterior surface of the third member, and wherein the third longitudinal axis and the first bore axis define a first angle,	
12e	wherein the third member further comprises a third aperture on the exterior surface of the third member, and a second bore extending along a second bore axis from the third aperture to a fourth aperture on an exterior surface of the third member, wherein the third longitudinal axis and the	Same as 1e

Exhibit A2: Cognet

	second bore axis define a second angle,	
12f	wherein the first member couples to the third member by inserting the first end of the first member into the first aperture, through the first bore, and out of the second aperture,	Same as 1f
12g	wherein the second member couples to the third member by inserting the first end of the second member into the third aperture, through the second bore, and out of the fourth aperture,	Same as 1g
12h	wherein the second angle is in the range of about 0 degrees to about 90 degrees, and	Same as 1i
12i	wherein the second bore axis is substantially perpendicular to the third longitudinal axis.	Same as 1j
No.	Claim 13	Cognet
13a	13. The assembly of claim 12,	See Claim 1, above.
13b	wherein the head portion of the first member resides	See, e.g.: Same as 2b

Exhibit A2: Cognet

	at least partially within the first bore.	
No.	Claim 14	Cognet
14a	14. The assembly of claim 13,	<i>See</i> Claim 14, above.
14b	wherein the head portion of the first member is tapered.	See, e.g.: Same as 8b
No.	Claim 15	Cognet
15a	15. The assembly of claim 12,	<i>See</i> Claim 16, above.
15b	wherein the head portion of the first member is tapered.	See, e.g.: Same as 8b

Exhibit A6

Claim Chart for Simon¹

¹ US 2006/0206044 Simon, published September 14, 2006

'166 Patent

Exhibit A6: Simon

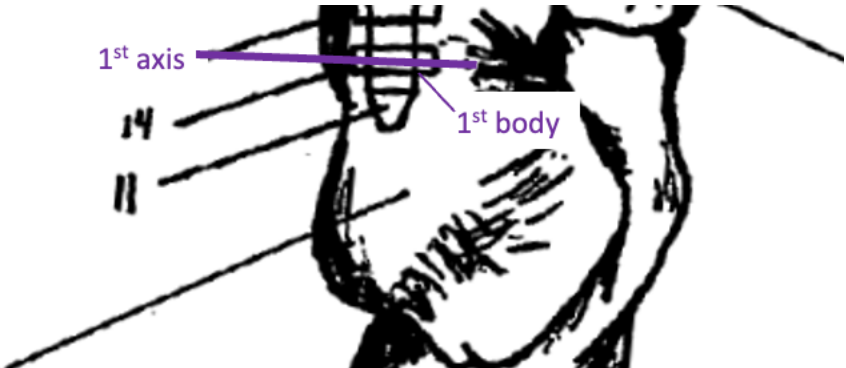
No.	Claim 1	Simon
1a	1. An assembly for bone fusion, comprising:	See, e.g.: The present invention specifically relates to the fusion, and eventual rejuvenation of the bones in the mid-foot region... (Simon, [0045]) This is one method for securing, fusing, and repairing the medial cuneiform and navicular bones and represents one embodiment of the present invention. (Simon, [0045])
1b	a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis, wherein the first member comprises a shaft portion having an external surface and a head portion having an exterior surface,	See, e.g.:  (Simon, Fig. 1 - cropped) The talus bone 1 makes up the lower part of the ankle joint where the proximal end 11 of the implant or intramedullary nail 10 is attached with at least one fastener (or locking screw, with two depicted in FIG. 1, 14 & 15). (Simon, [0053])

Exhibit A6: Simon

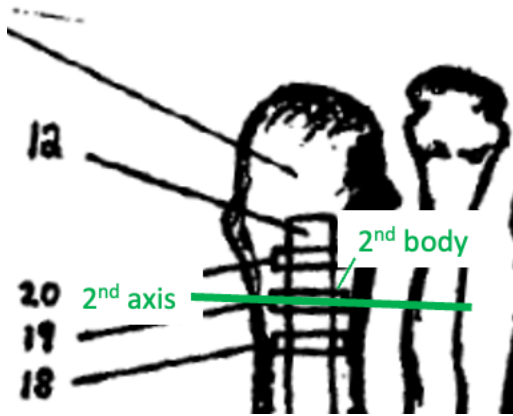
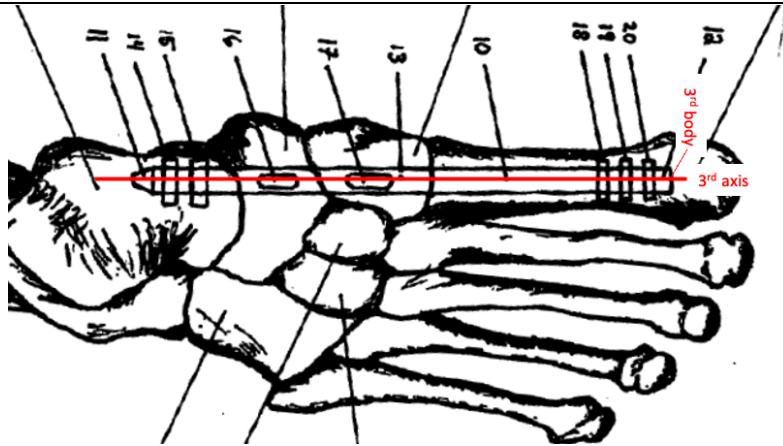
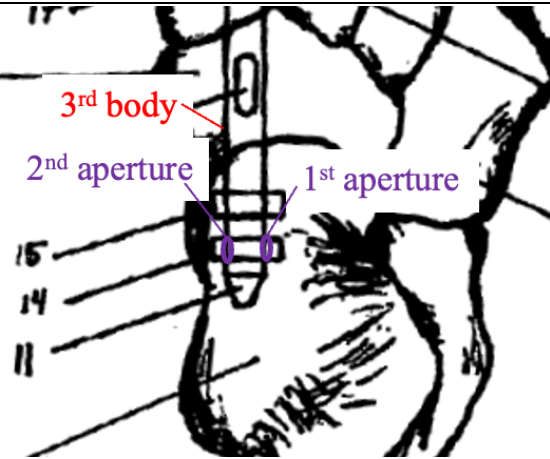
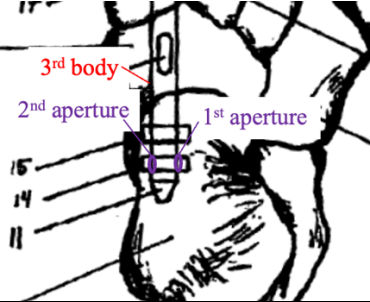
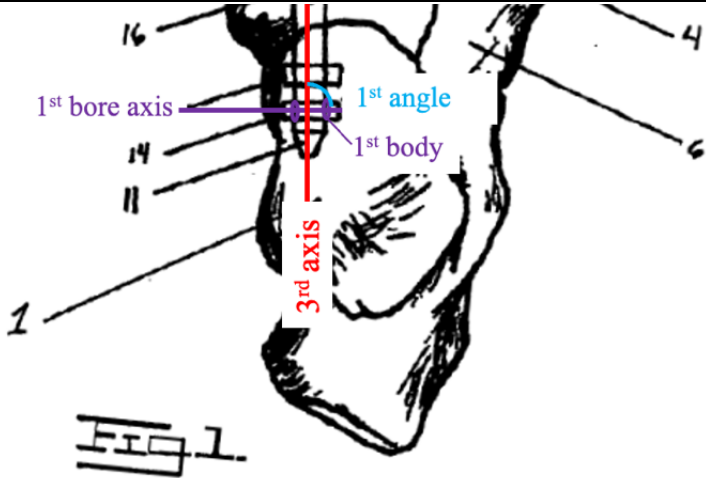
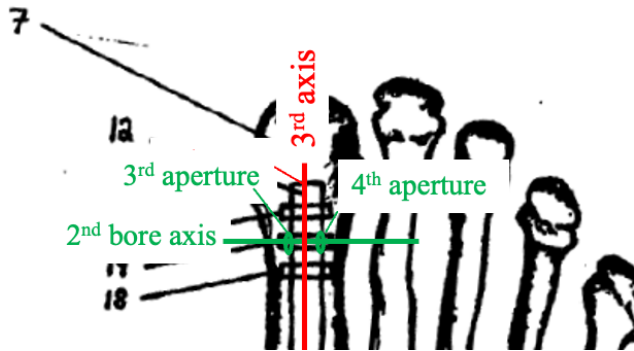
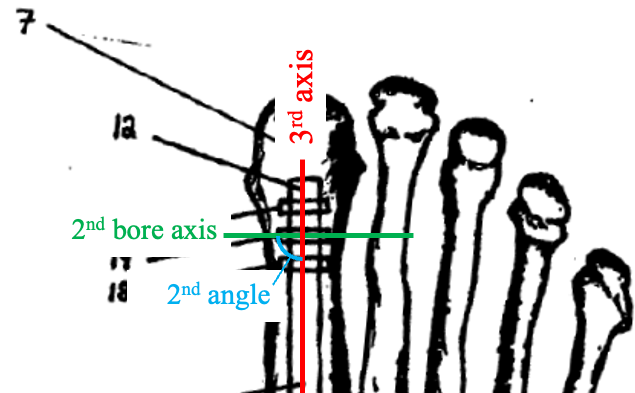
		Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
1b(i)	said first member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft portion;	The talus bone 1 makes up the lower part of the ankle joint where the proximal end 11 of the implant or intramedullary nail 10 is attached with at least one fastener (or locking screw, with two depicted in FIG. 1, 14 & 15). (Simon, [0053]) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
1c	a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis, wherein the second member comprises a shaft having an external surface,	<i>See, e.g.,</i>  (Simon, Fig. 1 – cropped) Finally, the first metatarsal 7 is the bone that makes up the big toe in the human foot, where the distal end 12 of the intramedullary nail 10 is attached by way of at least one fastener (or locking screw, with three depicted in FIG. 1, 20, 19, & 18). (Simon, [0053])

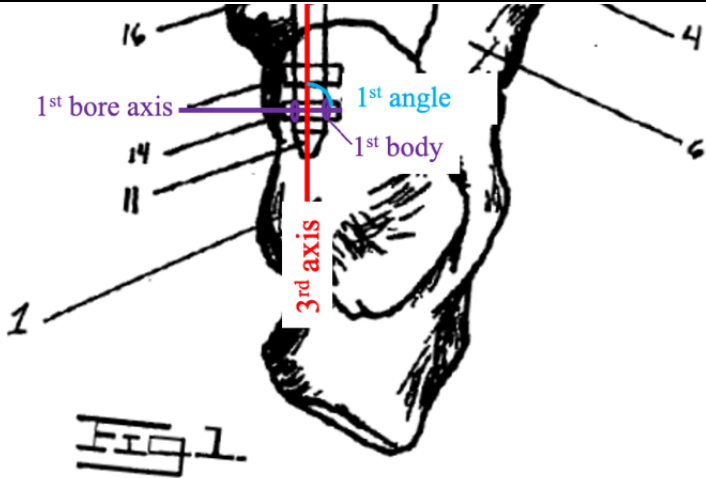
Exhibit A6: Simon

		Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
1c(i)	said second member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft;	Finally, the first metatarsal 7 is the bone that makes up the big toe in the human foot, where the distal end 12 of the intramedullary nail 10 is attached by way of at least one fastener (or locking screw, with three depicted in FIG. 1, 20, 19, & 18). (Simon, [0053]) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
1d	a third member comprising a third elongated body extending along a straight line from a first end to a second end along a third longitudinal axis,	 (Simon, Fig. 1 - rotated) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.

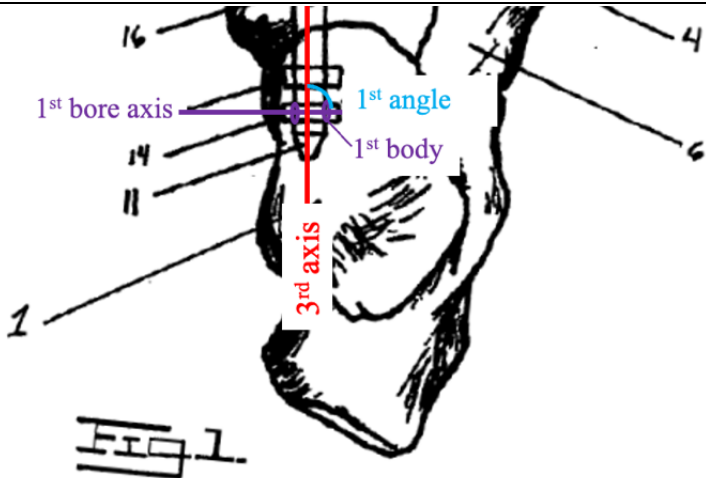
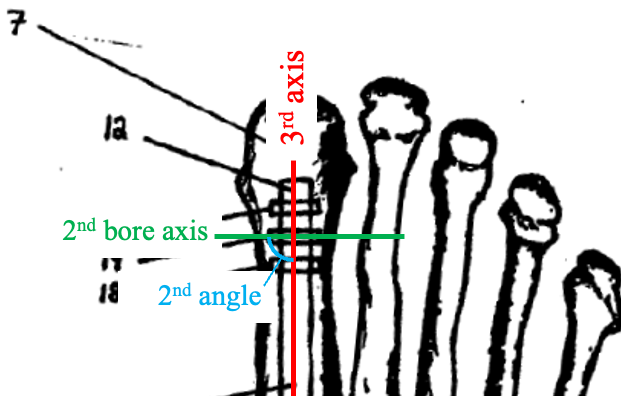
1d(i)	wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body, and a first bore extending along a first bore axis from the first aperture to a second aperture on an exterior surface of the third member,	 (Simon, Fig. 1 – cropped) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant’s Invalidity Contentions.
1d(ii)	wherein the first bore comprises an interior surface at the first aperture,	The nail ideally would have a number of proximal and distal fastener holes (transfixation or interlocking holes) for securing the IM medial column nail to the appropriate osseous cortical structures of the foot. (Simon, [0046]) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant’s Invalidity Contentions.
1d(iii)	wherein there are no threads adjacent to the second aperture on the exterior surface of the third member, and	

		(Simon, Fig. 1 – cropped) [0056] FIG. 3 is an x-ray picture taken following an experimental procedure to insert an implant into a patient's foot with two fasteners at both the proximal and distal ends. The procedure, performed in March of 2000, is being followed-up to determine the effectiveness of the newly adapted treatment. This is the only procedure to date ever performed of its kind. Such a procedure is an embodiment of the present invention. Furthermore, this limitation would have been obvious in view of '044 Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
1d(iv)	wherein the third longitudinal axis and the first bore axis define a first angle,	 (Simon, Fig. 1 – cropped) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.

1e	wherein the third member further comprises a third aperture on the exterior surface of the third member, and a second bore extending along a second bore axis from the third aperture to a fourth aperture on an exterior surface of the third member,	 (Simon, Fig. 1 – cropped) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant’s Invalidity Contentions.
1e(i)	wherein the third longitudinal axis and the second bore axis define a second angle,	 (Simon, Fig. 1 – cropped) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant’s Invalidity Contentions.

1f	wherein the first member couples to the third member by inserting the first end of the first member into the first aperture, through the first bore, and out of the second aperture,	 (Simon, Fig. 1 – cropped) The proximal portion of the nail may have a tapered tip to aid in insertion, and at least one fastener hole (ideally two) for the insertion of fasteners to fixate the neck of the talus to the implant or nail. (Simon, [0046]) [0057] The implant was an small intramedullary (Smith & Nephew) nail intended for insertion in a longer bone. The fasteners were locking screws inserted into the transfixation holes and also into the talus and first metatarsal bones. Such a device is an embodiment of the present invention. (Simon, [0056]-[0057]) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant’s Invalidity Contentions.
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1g	wherein the second member couples to the third member by inserting the first end of the second member into the third aperture, through the second bore, and out of the fourth aperture,	(Simon, Fig. 1 – cropped) The distal portion has at least one fastener hole (ideally three) for the insertion of fasteners to fixate the nail to the first metatarsal. (Simon, [0046]) the eleventh step involves insertion of at least one fastener (or locking screw, with three depicted in FIG. 1, 20, 19, & 18) into the distal fastener hole(s) and also into the first metatarsal. The same process of percutaneously inserting the fasteners as noted above for the proximal end can be replicated here. Fasteners may be optionally included in slots 16 for the navicular bone 2 and 17 for the medial cuneiform 3, depending upon the condition of either of these two bones. (Simon, [0055]) [0057] The implant was an small intramedullary (Smith & Nephew) nail intended for insertion in a longer bone. The fasteners were locking screws inserted into the transfixation holes and also into the talus and first metatarsal bones. Such a device is an embodiment of the present invention. (Simon, [0056]-[0057])
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1h	wherein the first angle is in the range of about 0 degrees to about 90 degrees,	 (Simon, Fig. 1 – cropped) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant’s Invalidity Contentions.
1i	wherein the second angle is in the range of about 0 degrees to about 90 degrees, and	 (Simon, Fig. 1 – cropped)

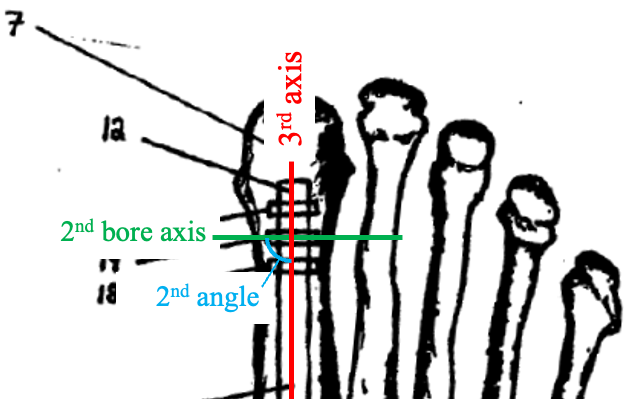
		Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
1j	wherein the second bore axis is substantially perpendicular to the third longitudinal axis.	 (Simon, Fig. 1 – cropped) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
No.	Claim 2	Simon
2a	2. The assembly of claim 1,	See Claim 1, above.
2b	wherein the head portion of the first member resides at least partially within the first bore.	See, e.g., Such transverse fastener holes or slots are used for insertion of fasteners (including interlocking cortical screws or transfixation screws), which ideally may be attached to the first metatarsal and talus bones to secure the nail in place. (Simon, [0039]) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
No.	Claim 3	Simon

Exhibit A6: Simon

3a	3. The assembly of claim 2,	<i>See</i> Claim 2, above.
3b	wherein the exterior surface of the head portion of the first member abuts the interior surface of the first bore at the first aperture.	<i>See, e.g.,</i> Such transverse fastener holes or slots are used for insertion of fasteners (including interlocking cortical screws or transfixation screws), which ideally may be attached to the first metatarsal and talus bones to secure the nail in place. (Simon, [0039]) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
No.	Claim 4	Simon
4a	4. The assembly of claim 3,	<i>See</i> Claim 3, above.
4b	wherein the head portion of the first member comprises a torque transmitting aperture.	Such transverse fastener holes or slots are used for insertion of fasteners (including interlocking cortical screws or transfixation screws), which ideally may be attached to the first metatarsal and talus bones to secure the nail in place. (Simon, [0039]) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
No.	Claim 5	Simon
5a	5. The assembly of claim 1,	<i>See</i> Claim 1, above.

Exhibit A6: Simon

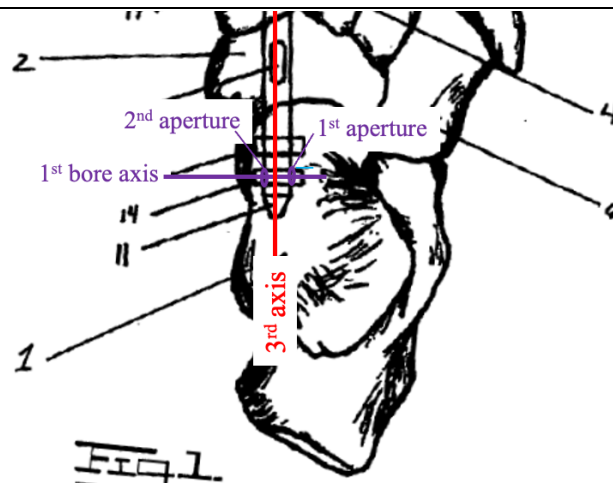
5b	wherein the first aperture of the third member is aligned on the first bore axis.	 (Simon, Fig. 1 – cropped) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant’s Invalidity Contentions.
No.	Claim 6	Simon
6a	6. The assembly of claim 5,	See Claim 5, above.
6b	wherein the head portion of the first member resides at least partially within the first bore.	Same as 2b
No.	Claim 7	Simon
7a	7. The assembly of claim 6,	See Claim 6, above.
7b	wherein the exterior surface of the head portion of the first member abuts the interior	Same as 3b

Exhibit A6: Simon

	surface of the first bore at the first aperture.	
No.	Claim 8	Simon
8a	8. The assembly of claim 1,	<i>See</i> Claim 1, above.
8b	wherein the head portion of the first member is tapered.	<i>See, e.g.,</i> Such transverse fastener holes or slots are used for insertion of fasteners (including interlocking cortical screws or transfixation screws), which ideally may be attached to the first metatarsal and talus bones to secure the nail in place. (Simon, [0039]) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
No.	Claim 10	Simon
10a	10. The assembly of claim 1	<i>See</i> Claim 1, above.
10b	wherein the first end of the first member includes a self-tapping edge for removing bone material.	<i>See, e.g.,</i> Such transverse fastener holes or slots are used for insertion of fasteners (including interlocking cortical screws or transfixation screws), which ideally may be attached to the first metatarsal and talus bones to secure the nail in place. (Simon, [0039]) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
No.	Claim 11	Simon
11a	11. The assembly of claim 10,	<i>See</i> Claim 10, above.
11b	wherein the first end of the second member	<i>See, e.g.,</i>

Exhibit A6: Simon

	includes a self-tapping edge for removing bone material.	Such transverse fastener holes or slots are used for insertion of fasteners (including interlocking cortical screws or transfixation screws), which ideally may be attached to the first metatarsal and talus bones to secure the nail in place. (Simon, [0039]) [0008] Several nails exist with fasteners or locking screws that are much longer in shape, described as lag screws, jigs, or nail heads, which further prevent the rotation of separated bones. Other nails have spacers to absorb stress associated with repetitive, natural impact. All such devices are focused on securing bone fragments during the process of fracture healing. Other methods for attaching the nail to the bone including the use of longitudinal pins, or the use of cement injected through a cannula in a nail to secure one end to the nail. (Simon, [0008]) Furthermore, this limitation would have been obvious in view of Simon alone or in combination with references identified in Exhibit B regarding this limitation. The motivations to combine these references are described in further detail in Defendant's Invalidity Contentions.
No.	Claim 12	Simon
12a	12. An assembly for bone fusion, comprising:	Same as 1a
12b	a first member comprising a first elongated body extending from a first end to a second end along a first longitudinal axis, wherein the first member comprises a shaft portion having an external surface and a head portion having an exterior surface, said first member further comprising a first thread having a first	See, e.g.: Same as 1b

Exhibit A6: Simon

	thread height extending radially outward from the external surface of said shaft portion;	
12c	a second member comprising a second elongated body extending from a first end to a second end along a second longitudinal axis, wherein the second member comprises a shaft having an external surface, said second member further comprising a first thread having a first thread height extending radially outward from the external surface of said shaft;	Same as 1c
12d	a third member comprising a third elongated body extending along a straight line from a first end to a second end along a third longitudinal axis, wherein the third member comprises a first aperture at a terminal end of the first end of the third elongated body, and a first bore extending along a first bore axis from the	Same as 1d

Exhibit A6: Simon

	first aperture to a second aperture on an exterior surface of the third member, wherein the first bore comprises an interior surface at the first aperture, wherein there are no threads adjacent to the second aperture on the exterior surface of the third member, and wherein the third longitudinal axis and the first bore axis define a first angle,	
12e	wherein the third member further comprises a third aperture on the exterior surface of the third member, and a second bore extending along a second bore axis from the third aperture to a fourth aperture on an exterior surface of the third member, wherein the third longitudinal axis and the second bore axis define a second angle,	Same as 1e
12f	wherein the first member couples to the third member by inserting the first end of the first	Same as 1f

Exhibit A6: Simon

	member into the first aperture, through the first bore, and out of the second aperture,	
12g	wherein the second member couples to the third member by inserting the first end of the second member into the third aperture, through the second bore, and out of the fourth aperture,	Same as 1g
12h	wherein the second angle is in the range of about 0 degrees to about 90 degrees, and	Same as 1i
12i	wherein the second bore axis is substantially perpendicular to the third longitudinal axis.	Same as 1j
No.	Claim 13	Simon
13a	13. The assembly of claim 12,	<i>See</i> Claim 12, above.
13b	wherein the head portion of the first member resides at least partially within the first bore.	See, e.g.: Same as 2b
No.	Claim 14	Simon
14a	14. The assembly of claim 13,	<i>See</i> Claim 13, above.

Exhibit A6: Simon

14b	wherein the head portion of the first member is tapered.	See, e.g.: Same as 8b
No.	Claim 15	Simon
15a	15. The assembly of claim 12,	<i>See</i> Claim 12, above.
15b	wherein the head portion of the first member is tapered.	See, e.g.: Same as 8b