IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of: BONUTTI, et al.

§ § § Petition for *Inter Partes* Review U.S. Patent No. 7,955,286

Issued: June 7, 2011

Attorney Docket No.: 026027.0000

§ Customer No.: 111393 Title: ELBOW ORTHOSIS

§ Real Party in Interest: Lantz Medical, Inc.

PETITION FOR INTER PARTES REVIEW

Pursuant to the provisions of 35 U.S.C. §§ 311-319, Lantz Medical, Inc. ("Petitioner") hereby petitions the Patent Trial and Appeal Board to institute an inter partes review of Claims 26-31 and 33 of United States Patent No. 7,955,286 ("the '286 Patent") (Exhibit 1001) that issued on June 7, 2011 to Boris P. Bonutti, Peter M. Bonutti, Kevin R. Ruholl, and Glen A. Phillips, resulting from U.S. Patent Application No. 11/687,679, filed on March 19, 2007. According to USPTO records, the '286 patent is currently assigned to Bonutti Research, Inc. ("Patentee").

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I. COMPLIANCE WITH REQUIREMENTS FOR A PETITION FOR INTER PARTES REVIEW

A. Certification that U.S. Patent No. 7,955,286 May Be Contested by Petitioner

Petitioner certifies it is not barred or estopped from requesting *inter partes* review ("IPR") of U.S. Patent No. 7,955,286 (the '286 patent) (Exhibit 1001). Neither Petitioner, nor any party in privity with Petitioner, has filed a civil action challenging the validity of any claim of the '286 patent. The '286 patent has not been the subject of a prior IPR by Petitioner or a privy of Petitioner.

Petitioner also certifies this petition for IPR review is filed within one year of the date of service of a Complaint (Exhibit 1003) alleging infringement of a patent. Petitioner was served with a Complaint alleging infringement of the '286 patent on April 22, 2014, which led to *Bonutti Research, Inc. et al v. Lantz Medical, Inc.*, Civil Action No. 1:14-cv-00609 in the United States District Court, Southern District of Indiana.

Because the date of this petition is less than one year from April 22, 2014, this petition complies with 35 U.S.C. § 315(b).

B. Fee for Inter Partes Review (§ 42.15(a))

The Director is authorized to charge the fee specified by 37 CFR § 42.15(a) to Deposit Account No. 506567.

C. Mandatory Notices (37 CFR § 42.8(b))

1. Real Party in Interest (§ 42.8(b)(1))

The real party in interest of this petition pursuant to § 42.8(b)(1) is Lantz Medical, Inc. ("Lantz") located at 7750 Zionsville Road, #800, Indianapolis, Indiana 46268.

2. Other Proceedings ($\S 42.8(b)(2)$)

The '286 patent is not the subject of any civil actions other than *Bonutti Research, Inc. et al v. Lantz Medical, Inc.*, Civil Action No. 1:14-cv-00609. However, Petitioner is contemporaneously filing requests for IPR of U.S. Patent Nos.: 7,112,179 (Claim 26); 7,404,804 (Claim 7); and 8,784,343 (Claims 1-4).

3. Designation of Lead and Backup Counsel

	Lead Counsel	Backup Counsel
Name	Jacque R. Wilson	Cedric D'Hue
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4. Service Information $(\S42.8(b)(4))$

Service on Petitioner may be made by mail or hand delivery to Lead Counsel, Jacque R. Wilson at Carson Boxberger LLP, 301 W. Jefferson Blvd., Suite 200, Fort Wayne, IN 46802. Mr. Wilson's fax number is (260) 423-4329.

Service may be made by mail or hand delivery to Backup Counsel, Cedric D'Hue at D'Hue Law LLC, P.O. Box 421972, Indianapolis, IN 46242-1972. Mr. D'Hue's fax number is (202) 446-2951.

II. RELIEF REQUESTED

Petitioner requests IPR of Claims 26-31 and 33 of the '286 patent on the grounds set forth below, and requests that the Claims be found unpatentable. An explanation of how the Claims are unpatentable is provided below, including where each element can be found in the prior art publications and the relevance of the prior art references.

III. IDENTIFICATION OF CLAIMS BEING CHALLENGED (§ 42.104(b))

Claims 26-31 and 33 of the '286 patent are unpatentable. Each claim is anticipated pursuant to 35 U.S.C. § 102(a) and (b).

Specifically, Claims 26-31 and 33 of the '286 patent are anticipated pursuant to 35 USC § 102(a) and (b) by U.S. Patent No. 2,832,334, issued: April 29, 1958 (Exhibit 1008); U.S. Patent No. 5,399,154, issued on March 21, 1995 (Exhibit 1009); and the TenoStretch device (Exhibit 1010) which was sold by Robert Kaiser to three companies at least as early as November 21, 2003 (Exhibit 1010). The '334 patent and '154 patent were issued and the TenoStretch was sold more than one year before the earliest effective filing date of the '286 patent, and Patentee failed to cite any of these references to the USPTO during prosecution of the '286 patent.

Petitioner's proposed construction of the contested claims, the evidence relied upon, and the precise reasons why the claims are unpatentable are provided below. The evidence relied upon in this petition is attached and listed in the List of Exhibits.

IV. BACKGROUND INFORMATION ON THE '286 PATENT

U.S. Patent No. 7,955,286 ("the '286 Patent") issued from U.S. Patent Application Serial Number 11/687,679. The earliest possible effective filing date of the '286 patent is March 20, 2006. The '286 Patent includes three independent claims and thirty claims dependent from these independent claims. The independent claim at issue is Claim 26, which was originally filed as Claim 51. During prosecution, the Claim was rejected and modified to include the specific language of "an extension member movably coupled to the first arm member, wherein the extension member is configured to at least one of increase and decrease a range of motion of the orthosis" to overcome a 35 U.S.C. § 102(b) anticipation rejection by U.S. patent number 5,683,351 of Kaiser, et al.

Claims 26-31 and 33 of the '286 patent states,

(26) An orthosis for stretching tissue around a joint of a patient connecting a first body portion and a second body portion, the orthosis compromising: a first arm member for coupling to the first body portion and defining a curved path; a second arm member for coupling to the second body portion and operatively coupled to the first arm member; the second arm member movable along the curved path, to rotate the second body portion about an axis of rotation of the joint; and an extension member movably coupled to the first arm member, wherein the extension member is configured to at least one of increase and decrease a range of motion of the orthosis.

- (27) An orthosis in accordance with Claim 26 wherein at least a portion of the curved path includes an arcuate path.
- (28) An orthosis in accordance with Claim 26 wherein a first end of the second arm member is selectively movable along the curved path to rotate the second body portion about the axis of rotation of the joint.
- (29) An orthosis in accordance with Claim 26 wherein the first arm member is positioned within an orthosis plane substantially orthogonal to the axis of rotation of the joint.
- (30) An orthosis in accordance with Claim 26 further comprising a drive assembly operatively coupled to the second arm member.
- (31) An orthosis in accordance with Claim 30 wherein the drive assembly comprises a gear rotatably mounted on the first arm member.
- (33) An orthosis in accordance with Claim 26 further comprising a spring member connected to at least the second arm member for dynamically stretching the tissue.

V. DEFINITION OF A PERSON OF ORDINARY SKILL IN THE ART

"A person of ordinary skill in the art at the time of the invention of the . . . ['286 patent] . . . would be an occupational therapist, physical therapist, mechanical engineer, and/or biomedical engineer with three to five years of experience designing or evaluating the design of orthotics." (Exhibit 1005, page 4)

VI. LEGAL STANDARD FOR CLAIM CONSTRUCTION IN IPR

A claim subject to IPR is given its "broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b). The broadest reasonable construction should be determined, in part, by taking into account the subject matter Patentee contends infringes the claims and the constructions Patentee has advanced in litigation. Also, if Patentee contends terms in the claims should be read to have a special meaning, those contentions should be disregarded unless Patentee also amends the claims compliant with 35 U.S.C. § 112 to make them expressly correspond to those contentions. *See* 77 Fed. Reg. 48764 at II.B.6 (August 14, 2012); cf. *In re Youman*, 679 F.3d 1335, 1343 (Fed. Cir. 2012).

Thus, Petitioner suggests, for the sake of rational analysis only, that the "broadest reasonable" construction to be applied in this proceeding for these

limitations is at least as broad as what Patentee is asserting in the pending litigation, which construction is presented below.

VII. CONSTRUCTION OF TERMS IN THE '286 PATENT

A. Orthosis

Dr. Rogge opines that "one of ordinary skill in the art at the time of the invention would have readily understood that the term 'orthosis' would indicate 'an external orthopedic appliance, as a brace or splint that prevents or assists movement of the spine or limbs." Dr. Rogge further opines that the phrase "for stretching tissue around a joint of a patient connecting a first body portion and a second body portion serves to clarify the function of the 'orthosis' for the patent, but does not redefine the term to mean 'a device designed or constructed to stretch tissue around a joint." (Exhibit 1005, page 21).

B. "a first arm member for coupling to the first body portion and defining a curved path"

In the '286 patent, the claim term "a first arm member for coupling to the first body portion and defining a curved path" is found in Claims 26-31 and 33.

Patentee's expert opines in the above referenced litigation that to the extent that the phrase is necessary to construe, "the definition of 'a first arm member for coupling to the first body portion and defining a curved path' should be 'a first member for connecting to a first body portion and defining a curved line of travel." (Exhibit 1006, page 37)

C. "Operatively coupled"

In the '286 patent, the claim term "operatively coupled" is found in Claims 26 and 30.

Patentee's expert opines in the above referenced litigation that to the extent that the phrase is necessary to construe, "the definition of 'operatively coupled' should be 'connected so as to operate in an intended manner." (Exhibit 1006, page 38)

D. "movable along the curved path"

In the '286 Patent, the claim term "movable along the curved path" is found in Claims 26 and 28.

Patentee's expert opines in the above referenced litigation that to the extent that the phrase is necessary to construe, "the definition of 'moveable along the curved path' should be 'adapted to move along the curved line of travel." (Exhibit 1006, page 39)

E. "curved path"

In the '286 Patent, the claim term "curved path" is found in Claims 26, 27, and 28.

Patentee's expert opines in the above referenced litigation that to the extent that the phrase is necessary to construe, "the definition of 'curved path' should be 'curved line of travel." (Exhibit 1006, page 40)

F. "drive assembly"

In the '286 Patent, the claim term "drive assembly" is found in Claims 30 and 31. Claims 30 and 31 are dependent claims (depending from Claim 26).

Patentee's expert opines in the above referenced litigation that to the extent that the phrase is necessary to construe, "the definition of 'drive assembly' should be 'an assembly designed or constructed to transfer power from one part to another." (Exhibit 1006, page 42)

VIII. CLAIM CHART FOR '286 PATENT

CLAIM PRIOR ART

26. An orthosis for stretching tissue around a joint of a patient connecting a first body portion and a second body portion, the orthosis comprising:	Fig. 1 • U.S. Patent 5,399,154, Abstract
a first arm member for coupling to the first body portion and defining a curved path;	 U.S. Patent 2,832,334, Fig. 1(10)(17) (29) U.S. Patent 5,399,154, Fig. 1 (16) (20) (108) Kaiser Medical TenoStretch (Exhibit 1010 at Exhibit K, element 1)

a second arm member for coupling U.S. Patent 2,832,334, Fig. 1(11)(29) to the second body portion and U.S. Patent 5,399,154, Fig. 1 (18) operatively coupled to the first arm (106)(16)member. • Kaiser Medical TenoStretch (Exhibit 1010 at Exhibit K, element 3) the second arm member movable U.S. Patent 2,832,334, Figs 1, 2, and 3 along the curved path, to rotate the U.S. Patent 5,399,154, Fig. 3 second body portion about an axis Kaiser Medical TenoStretch (Exhibit of rotation of the joint; 1010 at Exhibit K, element 4) and extension member an U.S. Patent 2,832,334, Fig. 2(12)(13) movably coupled to the first arm U.S. Patent 5,399,154, Fig. 6 (106) (110) member, wherein the extension (114)member is configured to at least Kaiser Medical TenoStretch (Exhibit one of increase and decrease a 1010 at Exhibit K, element 5) range of motion of the orthosis. 27. An orthosis in accordance with U.S. Patent 2,832,334, Fig. 1(28)(29) claim 26 wherein at least a portion U.S. Patent 5,399,154, Fig. 1(16) and of the curved path includes an Fig. 3 arcuate path. Kaiser Medical TenoStretch (Exhibit 1010 at Exhibit K, elements 6 and 8) 28. An orthosis in accordance with Kaiser Medical TenoStretch (Exhibit claim 26 wherein a first end of the 1010 at Exhibit K, element 4) second arm member is selectively U.S. Patent 5,399,154, Fig. 3 movable along the curved path to U.S. Patent 2,832,334, Figs. 1, 2, and 3 rotate the second body portion about the axis of rotation of the joint. 29. An orthosis in accordance with U.S. Patent 2,832,334, Figs. 1, 2, and 3 claim 26 wherein the first arm U.S. Patent 5,399,154, Fig. 1; Fig. 3 • member is positioned within an Kaiser Medical TenoStretch (Exhibit plane substantially orthosis 1010 at Exhibit K) orthogonal to the axis of rotation of the joint.

- 30. An orthosis in accordance with U.S. Patent 2,832,334, Col. 3, ll. 11-17; claim 26 further comprising a and Fig. 4 drive assembly operatively U.S. Patent 5,399,154, Figs. 2-4 (26)(28) coupled to the second arm and Col. 3, 11. 24-28 member. Kaiser Medical TenoStretch (Exhibit 1010 at Exhibit K, elements 3, 4, 8, 9, and 10) 31. An orthosis in accordance with U.S. Patent 2,832,334, Fig. 4 (36), (45) claim 30 wherein the drive U.S. Patent 5,399,154, Col. 3, ll. 63-65 assembly comprises a gear Kaiser Medical TenoStretch (Exhibit rotatably mounted on the first arm 1010 at Exhibit K, element 9) member. U.S. Patent 2,832,334, Col. 3, 11 8-10; 33. An orthosis in accordance with claim 26 further comprising a Fig. 4(53) spring member connected to at U.S. Patent 5,399,154, Col. 3, 11. 40-42; least the second arm member for Fig. 2 (50)
- IX. PRECISE REASONS FOR RELIEF FOR CLAIMS 26-31 AND 33 OF THE '286 PATENT

dynamically stretching the tissue.

A. U.S. Patent No. 2,832,334 (Exhibit 1008) Anticipates Claims 26-31 and 33 of the '286 Patent.

Kaiser Medical TenoStretch (Exhibit

1010 at Exhibit K, element 10)

- 1. Background of U.S. Patent No. 2,832,344 (Exhibit 1008)
- U.S. Patent No. 2,832,334 (Exhibit 1008) discloses a "therapeutic device for use in manipulative treatment of joints of the human body." (Exhibit 1008, Title). The '334 patent issued on April 29, 1958, more than one year before the earliest effective filing date of the '286 patent. However, Patentee for the '286 patent failed

to provide this publically available reference to the USPTO. Thus, the '334 patent (Exhibit 1008) is previously undisclosed prior art to the '286 patent at least pursuant to 35 U.SC. § 102 (a) and (b). Moreover, Claims 26-31 and 33 of the '286 patent are invalid in view of the '334 patent (Exhibit 1008), which, as demonstrated below, anticipates every element of Claims 26-31 and 33 of the '286 patent.

2. The '334 Patent Anticipates Claim 26 of the '286 Patent.

Claim 26 of the '286 patent recites "an orthosis for stretching tissue around a joint of a patient connecting a first body portion and a second body portion, the orthosis." Using Patentee's analysis of this Claim (Exhibit 1007), the '334 patent (Exhibit 1008) discloses this element of Claim 26 of the '286 patent at Col. 1, ll. 12-15; Fig. 1. (Exhibit 1011, ¶ 20)

Claim 26 of the '286 patent further recites "a first arm member for coupling to the first body portion and defining a curved path." Using Patentee's analysis of this Claim (Exhibit 1007), the '334 patent (Exhibit 1008) discloses this element of Claim 26 of the '286 patent at Fig. 1 (10)(17)(29). (Exhibit 1011, ¶ 21)

Claim 26 of the '286 patent further recites "a second arm member for coupling to the second body portion and operatively coupled to the first arm member." Using Patentee's analysis of this Claim (Exhibit 1007), the '334 patent

(Exhibit 1008) discloses this element of Claim 26 of the '286 patent at Fig. 1(11)(29). (Exhibit 1011, ¶ 22)

Claim 26 of the '286 patent further recites "the second arm member movable along the curved path, to rotate the second body portion about an axis of rotation of the joint." Using Patentee's analysis of this Claim (Exhibit 1007), the '334 patent (Exhibit 1008) discloses this element of Claim 26 of the '286 patent at Figs. 1, 2, and 3. (Exhibit 1011, ¶ 23)

Claim 26 of the '286 patent further recites "and an extension member movably coupled to the first arm member, wherein the extension member is configured to at least one of increase and decrease a range of motion of the orthosis." Using Patentee's analysis of this Claim (Exhibit 1007), the '334 patent (Exhibit 1008) discloses this element of Claim 26 of the '286 patent at Fig. 2(12)(13). (Exhibit 1011, ¶24)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 26 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 26 of the '286 patent. (Exhibit 1011, ¶25)

3. The '334 Patent Anticipates Claim 27 of the '286 Patent.

Claim 27 of the '286 patent recites "An orthosis in accordance with claim 26 wherein at least a portion of the curved path includes an arcuate path." Using Patentee's analysis of this Claim (Exhibit 1007), the '334 patent (Exhibit 1008) discloses this element of Claim 27 of the '286 patent at Fig. 1 (28)(29). (Exhibit 1011, ¶27)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 27 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 27 of the '286 patent. (Exhibit 1011, ¶28)

4. The '334 Patent Anticipates Claim 28 of the '286 Patent.

Claim 28 of the '286 patent recites "An orthosis in accordance with claim 26 wherein a first end of the second arm member is selectively movable along the curved path to rotate the second body portion about the axis of rotation of the joint." Using Patentee's analysis of this Claim (Exhibit 1007), the '334 patent (Exhibit 1008) discloses this element of Claim 28 of the '286 patent at Figs. 1, 2, and 3. (Exhibit 1011, ¶30)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 28 of the '286 patent is identical to the analysis proposed by Patentee to

demonstrate that Petitioner's commercial product is covered by Claim 28 of the '286 patent. (Exhibit 1011, ¶31)

5. The '334 Patent Anticipates Claim 29 of the '286 Patent.

Claim 29 of the '286 patent recites "An orthosis in accordance with claim 26 wherein the first arm member is positioned within an orthosis plane substantially orthogonal to the axis of rotation of the joint." Using Patentee's analysis of this Claim (Exhibit 1007), the '334 patent (Exhibit 1008) discloses this element of Claim 29 of the '286 patent at Figs. 1, 2, and 3. (Exhibit 1011, ¶33)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 29 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 29 of the '286 patent. (Exhibit 1011, ¶34)

6. The '334 Patent Anticipates Claim 30 of the '286 Patent.

Claim 30 of the '286 patent recites "An orthosis in accordance with claim 26 further comprising a drive assembly operatively coupled to the second arm member." Using Patentee's analysis of this Claim (Exhibit 1007), the '334 patent (Exhibit 1008) discloses this element of Claim 30 of the '286 patent at Col. 3, lines 11-17 and Fig. 4. (Exhibit 1011, ¶36)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 30 of the '286 patent is identical to the analysis proposed by Patentee to

demonstrate that Petitioner's commercial product is covered by Claim 30 of the '286 patent. (Exhibit 1011, ¶37)

7. The '334 Patent Anticipates Claim 31 of the '286 Patent.

Claim 31 of the '286 patent recites "An orthosis in accordance with claim 30 wherein the drive assembly comprises a gear rotatably mounted on the first arm member." Using Patentee's analysis of this Claim (Exhibit 1007), the '334 patent (Exhibit 1008) discloses this element of Claim 31 of the '286 patent at Fig. 4 (36)(45). (Exhibit 1011, ¶39)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 31 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 31 of the '286 patent. (Exhibit 1011, ¶40)

8. The '334 Patent Anticipates Claim 33 of the '286 Patent.

Claim 33 of the '286 patent recites "An orthosis in accordance with claim 26 further comprising a spring member connected to at least the second arm member for dynamically stretching the tissue." Using Patentee's analysis of this Claim (Exhibit 1007), the '334 patent (Exhibit 1008) discloses this element of claim 33 of the '286 patent at Col. 3, lines 8-10; Fig. 4 (53). (Exhibit 1011, ¶42)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 33 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 33 of the '286 patent. (Exhibit 1011, ¶43)

Based on the foregoing, a reasonable likelihood exists that Petitioner will prevail in its challenge of at least one Claim of the '286 patent. The USPTO should, thus, initiate IPR proceedings and find Claims 26-31 and 33 of the '286 patent invalid pursuant to 35 U.S.C. § 102 (a) and/or (b).

B. U.S. Patent No. 5,399,154 (Exhibit 1009) Anticipates Claims 26-31, and 33 of the '286 Patent.

1. Background of U.S. Patent No. 5,399,154 (Exhibit 1009)

U.S. patent no. 5,399,154 (Exhibit 1009) discloses a "range-of-motion splint." (Exhibit 1009, Abstract). The '154 patent issued on May 28, 1996, more than one year before the earliest effective filing date of the '286 patent. However, Patentee for the '286 patent failed to provide this publically available reference to the USPTO. Thus, the '154 patent (Exhibit 1009) is previously undisclosed prior art to the '286 patent at least pursuant to 35 U.SC. § 102 (a) and (b). Moreover, Claims 26-31 and 33 of the '286 patent are invalid in view of the '154 patent (Exhibit 1009), which, as demonstrated below, anticipates every element of Claims 26-31 and 33 of the '286 patent.

2. The '154 Patent Anticipates Claim 26 of the '286 Patent.

Claim 26 of the '286 patent recites "an orthosis for stretching tissue around a joint of a patient connecting a first body portion and a second body portion, the orthosis." Using Patentee's analysis of this Claim (Exhibit 1007), the '154 patent (Exhibit 1009) discloses this element of Claim 26 of the '286 patent at Abstract. (Exhibit 1011, ¶ 45)

Claim 26 of the '286 patent further recites "a first arm member for coupling to the first body portion and defining a curved path." Using Patentee's analysis of this Claim (Exhibit 1007), the '154 patent (Exhibit 1009) discloses this element of Claim 26 of the '286 patent at Fig. 1 (16)(20)(108). (Exhibit 1011, ¶ 46)

Claim 26 of the '286 patent further recites "a second arm member for coupling to the second body portion and operatively coupled to the first arm member." Using Patentee's analysis of this Claim (Exhibit 1007), the '154 patent (Exhibit 1009) discloses this element of Claim 26 of the '286 patent at Fig. 1 (18)(106)(16). (Exhibit 1011, ¶ 47)

Claim 26 of the '286 patent further recites "the second arm member movable along the curved path, to rotate the second body portion about an axis of rotation of the joint." Using Patentee's analysis of this Claim (Exhibit 1007), the '154 patent

(Exhibit 1009) discloses this element of Claim 26 of the '286 patent at Fig. 3. (Exhibit 1011, ¶ 48)

Claim 26 of the '286 patent further recites "and an extension member movably coupled to the first arm member, wherein the extension member is configured to at least one of increase and decrease a range of motion of the orthosis." Using Patentee's analysis of this Claim (Exhibit 1007), the '154 patent (Exhibit 1009) discloses this element of Claim 26 of the '286 patent at Fig. 6 (106)(110)(114). (Exhibit 1011, ¶ 49)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 26 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 26 of the '286 patent. (Exhibit 1011, ¶ 50)

3. The '154 Patent Anticipates Claim 27 of the '286 Patent.

Claim 27 of the '286 patent recites "An orthosis in accordance with claim 26 wherein at least a portion of the curved path includes an arcuate path." Using Patentee's analysis of this Claim (Exhibit 1007), the '154 patent (Exhibit 1009) discloses this element of Claim 27 of the '286 patent at Fig. 1 (16) and Fig. 3. (Exhibit 1011, ¶ 52)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 27 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 27 of the '286 patent. (Exhibit 1011, ¶ 53)

4. The '154 Patent Anticipates Claim 28 of the '286 Patent.

Claim 28 of the '286 patent recites "An orthosis in accordance with claim 26 wherein a first end of the second arm member is selectively movable along the curved path to rotate the second body portion about the axis of rotation of the joint." Using Patentee's analysis of this Claim (Exhibit 1007), the '154 patent (Exhibit 1009) discloses this element of Claim 28 of the '286 patent at Fig. 3. (Exhibit 1011, ¶ 55)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 28 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 28 of the '286 patent. (Exhibit 1011, ¶ 56)

5. The '154 Patent Anticipates Claim 29 of the '286 Patent.

Claim 29 of the '286 patent recites "An orthosis in accordance with claim 26 wherein the first arm member is positioned within an orthosis plane substantially orthogonal to the axis of rotation of the joint." Using Patentee's

analysis of this Claim (Exhibit 1007), the '154 patent (Exhibit 1009) discloses this element of Claim 29 of the '286 patent at Fig. 1 and Fig. 3. (Exhibit 1011, ¶ 58)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 29 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 29 of the '286 patent. (Exhibit 1011, ¶ 59)

6. The '154 Patent Anticipates Claim 30 of the '286 Patent.

Claim 30 of the '286 patent recites "An orthosis in accordance with claim 26 further comprising a drive assembly operatively coupled to the second arm member." Using Patentee's analysis of this Claim (Exhibit 1007) the '154 patent (Exhibit 1009) discloses this element of Claim 30 of the '286 patent at Figs. 2-4 (26)(28) and Col. 3, lines 24-28. (Exhibit 1011, ¶ 61)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 30 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 30 of the '286 patent. (Exhibit 1011, ¶ 62)

7. The '154 Patent Anticipates Claim 31 of the '286 Patent.

Claim 31 of the '286 patent recites "An orthosis in accordance with claim 30 wherein the drive assembly comprises a gear rotatably mounted on the first arm

member." Using Patentee's analysis of this Claim (Exhibit 1007), the '154 patent (Exhibit 1009) discloses this element of Claim 31 of the '286 patent at Col. 3, lines 63-65. (Exhibit 1011, ¶ 64)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 31 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 31 of the '286 patent (Exhibit 1011, ¶ 65)

8. The '154 Patent Anticipates Claim 33 of the '286 Patent.

Claim 33 of the '286 patent recites "An orthosis in accordance with claim 26 further comprising a spring member connected to at least the second arm member for dynamically stretching the tissue." Using Patentee's analysis of this Claim (Exhibit 1007), the '154 patent (Exhibit 1009) discloses this element of claim 33 of the '286 patent at Col. 3, lines 40-42 and Fig. 2 (50). (Exhibit 1011, ¶ 67)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 33 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 33 of the '286 patent. (Exhibit 1011, \P 68)

Based on the foregoing, a reasonable likelihood exists that Petitioner will prevail in its challenge of at least one Claim of the '286 patent. The USPTO

should, thus, initiate IPR proceedings and find Claims 26-31 and 33 of the '286 patent invalid pursuant to 35 U.S.C. § 102 (a) and/or (b).

C. The TenoStretch (Exhibit 1010) anticipates Claims 26-31, and 33 of the '286 Patent.

1. Background of the TenoStretch (Exhibit 1010)

Kaiser Medical developed the TenoStretch (Exhibit 1010) orthosis device at least as early as June 2002. (Exhibit 1010, ¶ 3, 5, and 6). Kaiser Medical offered the device for sale to the public at least as early as the Annual Meeting for the American Academy of Orthopedic Surgeons ("AAOS") from February 5-9, 2003 (Exhibit 1010, ¶ 7). Kaiser Medical, in fact, sold the TenoStretch device to at least three companies from November 2003 to December 2003 (Exhibit 1010, ¶ 10, 12, and 15) and delivered actual products to at least two companies no later than March 2004. (Exhibit 1010, ¶18). One of the companies to whom Kaiser Medical delivered the TenoStretch device, Omni Motion, included a photograph of the TenoStretch device in a sales brochure (Exhibit 1010, ¶21 and 22) distributed in at least Nevada and California.

Thus, the TenoStretch orthosis device is previously undisclosed prior art to the '286 patent at least pursuant to 35 U.SC. § 102 (a) and (b). Moreover, Claims 26-31 and 33 of the '286 patent are invalid in view of the TenoStretch which, as

demonstrated below, anticipates every element of Claims 26-31 and 33 of the '286 patent.

2. The TenoStretch (Exhibit 1010) Anticipates Claim 26 of the '286 Patent.

Claim 26 of the '286 patent recites "an orthosis for stretching tissue around a joint of a patient connecting a first body portion and a second body portion, the orthosis." Using Patentee's analysis of this Claim (Exhibit 1007), the TenoStretch (Exhibit 1010) discloses this element of Claim 26 of the '286 patent at Exhibit K. (Exhibit 1011, ¶ 70)

Claim 26 of the '286 patent further recites "a first arm member for coupling to the first body portion and defining a curved path." Using Patentee's analysis of this Claim (Exhibit 1007), the TenoStretch (Exhibit 1010) discloses this element of Claim 26 of the '286 patent at Exhibit K, element 1. (Exhibit 1011, ¶ 71)

Claim 26 of the '286 patent further recites "a second arm member for coupling to the second body portion and operatively coupled to the first arm member." Using Patentee's analysis of this Claim (Exhibit 1007), the TenoStretch (Exhibit 1010) discloses this element of Claim 26 of the '286 patent at Exhibit K, element 3. (Exhibit 1011, ¶ 72)

Claim 26 of the '286 patent further recites "the second arm member movable along the curved path, to rotate the second body portion about an axis of

rotation of the joint." Using Patentee's analysis of this Claim (Exhibit 1007), the TenoStretch (Exhibit 1010) discloses this element of Claim 26 of the '286 patent at Exhibit K, element 4. (Exhibit 1011, ¶ 73)

Claim 26 of the '286 patent further recites "and an extension member movably coupled to the first arm member, wherein the extension member is configured to at least one of increase and decrease a range of motion of the orthosis." Using Patentee's analysis of this Claim (Exhibit 1007), the TenoStretch (Exhibit 1010) discloses this element of Claim 26 of the '286 patent at Exhibit K, element 5. (Exhibit 1011, ¶ 74)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 26 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 26 of the '286 patent. (Exhibit 1011, ¶75)

3. The TenoStretch (Exhibit 1010) Anticipates Claim 27 of the'286 Patent.

Claim 27 of the '286 patent recites "An orthosis in accordance with claim 26 wherein at least a portion of the curved path includes an arcuate path." Using Patentee's analysis of this Claim (Exhibit 1007), the TenoStretch (Exhibit 1010) discloses this element of Claim 27 of the '286 patent at Exhibit K, elements 6 and 8. (Exhibit 1011, ¶ 77)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 27 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 27 of the '286 patent. (Exhibit $1011, \P 78$)

4. The TenoStretch (Exhibit 1010) Anticipates Claim 28 of the '286 Patent.

Claim 28 of the '286 patent recites "An orthosis in accordance with claim 26 wherein a first end of the second arm member is selectively movable along the curved path to rotate the second body portion about the axis of rotation of the joint." Using Patentee's analysis of this Claim (Exhibit 1007), the TenoStretch (Exhibit 1010) discloses this element of Claim 28 of the '286 patent at Exhibit K, element 4, in that the arm members are rotatably movable relative to one another along a "curved path" as that phrase is defined by Patentee's expert. (Exhibit 1011, ¶ 80)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 28 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 28 of the '286 patent. (Exhibit 1011, ¶ 81)

5. The TenoStretch (Exhibit 1010) Anticipates Claim 29 of the '286 Patent.

Claim 29 of the '286 patent recites "An orthosis in accordance with claim 26 wherein the first arm member is positioned within an orthosis plane substantially orthogonal to the axis of rotation of the joint." Using Patentee's analysis of this Claim (Exhibit 1007), the TenoStretch (Exhibit 1010) discloses this element of Claim 29 of the '286 patent at Exhibit K, as the arm members are perpendicular to the axis of rotation of the device. (Exhibit 1011, ¶ 83)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 29 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 29 of the '286 patent. (Exhibit 1011, ¶ 84)

6. The TenoStretch (Exhibit 1010) Anticipates Claim 30 of the'286 Patent.

Claim 30 of the '286 patent recites "An orthosis in accordance with claim 26 further comprising a drive assembly operatively coupled to the second arm member." Using Patentee's analysis of this Claim (Exhibit 1007), the TenoStretch (Exhibit 1010) discloses this element of Claim 30 of the '286 patent at Exhibit K, elements 3, 4, 8, 9, 10. (Exhibit 1011, ¶ 86)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 30 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 30 of the '286 patent. (Exhibit $1011, \P 87$)

7. The TenoStretch (Exhibit 1010) Anticipates Claim 31 of the '286 Patent.

Claim 31 of the '286 patent recites "An orthosis in accordance with claim 30 wherein the drive assembly comprises a gear rotatably mounted on the first arm member." Using Patentee's analysis of this Claim (Exhibit 1007) the TenoStretch (Exhibit 1010) discloses this element of Claim 31 of the '286 patent at Exhibit K, element 9. (Exhibit 1011, ¶ 89)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim 31 of the '286 patent is identical to the analysis proposed by Patentee to demonstrate that Petitioner's commercial product is covered by Claim 31 of the '286 patent. (Exhibit 1011, ¶ 90)

8. The TenoStretch (Exhibit 1010) Anticipates Claim 33 of the '286 Patent.

Claim 33 of the '286 patent recites "An orthosis in accordance with claim 26 further comprising a spring member connected to at least the second arm member for dynamically stretching the tissue." Using Patentee's analysis of this

Claim (Exhibit 1007) the TenoStretch (Exhibit 1010) discloses this element of

Claim 33 of the '286 patent at Exhibit K, element 10. (Exhibit 1011, ¶ 92)

As shown in the attached Exhibit 1007, this anticipation analysis of Claim

33 of the '286 patent is identical to the analysis proposed by Patentee to

demonstrate that Petitioner's commercial product is covered by Claim 33 of the

'286 patent. (Exhibit 1011, ¶ 93)

Based on the foregoing, a reasonable likelihood exists that Petitioner will

prevail in its challenge of at least one Claim of the '286 patent. The USPTO

should, thus, initiate IPR proceedings and find Claims 26-31 and 33 of the '286

patent invalid pursuant to 35 U.S.C. § 102(a) and/or (b).

X. CONCLUSION

Because a reasonable likelihood exists that Petitioner will prevail in its

challenge of at least one Claim of the '286 patent, in light of the above-referenced

prior art, the USPTO should initiate IPR proceedings and find the '286 patent

invalid pursuant to 35 U.S.C. § 102(a) and/or (b).

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CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of April, 2015 a true and complete copy of the above and foregoing was served via certified mail/return receipt requested:

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