Filed on behalf of Össur hf and Össur Americas, Inc.
By: Brenton R. Babcock
Nicholas M. Zovko
KNOBBE, MARTENS, OLSON & BEAR, LLP
2040 Main Street, 14th Floor
Irvine, CA 92614
Tel.: (949) 760-0404
Fax: (949) 760-9502
Email: BoxOssur@knobbe.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ÖSSUR HF AND ÖSSUR AMERICAS, INC.,
Petitioners

v.

OTTO BOCK HEALTHCARE LP,
Patent Owner

U.S. Patent 6,726,726 to Caspers
Appl. No. 09/785,714 filed Feb. 16, 2001
Issued Apr. 27, 2004
Title: VACUUM APPARATUS AND METHOD FOR
MANAGING RESIDUAL LIMB VOLUME IN AN ARTIFICIAL LIMB

IPR Trial No. TBD

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 6,726,726 PURSUANT TO 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *ET SEQ.*

TABLE OF CONTENTS

Page No.

EXHIBIT LIST ..... Exhibit List, Pages 1-4

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1) 1

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1) 1

B. Related Matters Under 37 C.F.R. § 42.8(b)(2) 1

C. Lead and Back-up Counsel Under 37 C.F.R. § 42.8(b)(3) 1

D. Service Information Under 37 C.F.R. § 42.8(b)(4) 2

II. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(a) 2

III. SUMMARY OF ISSUE PRESENTED 2

IV. INTRODUCTION 3

V. STATEMENT OF PRECISE RELIEF REQUESTED 10

VI. SUMMARY OF THE ’726 PATENT 11

A. Brief Description 11

B. Prosecution History 12

1. Prior Caspers Patent Application Families 12

2. The ’726 Patent Family 13

C. Issued Claims 16

VII. LEVEL OF ORDINARY SKILL IN THE ART 17

VIII. CLAIM CONSTRUCTION 17

A. Apparatus Claims 18

B. Method Claims 22

IX. SCOPE AND CONTENT OF THE PRIOR ART 25

A. Caspers ’906 Discloses Almost All Of The Claims’ Limitations 26

TABLE OF CONTENTS
(*cont'd*)

Page No.

B. Single-Socket Vacuum Sockets Were Well-Known In The Art.....27

1. Caspers '208 discloses a single-socket vacuum socket providing "total contact" between the residual limb, a liner, and the socket 28

2. Slemker discloses a single-socket vacuum socket that creates vacuum in the socket with a pump 29

3. Takidani discloses a single-socket vacuum socket that creates and maintains vacuum in the socket cavity 29

4. Caspers '208, Slemker, and Takidani are not cumulative 30

C. A Person Of Ordinary Skill In The Art Would Have Combined The Teachings Of Caspers '906 With Those Of Either Caspers '208, Slemker, Or Takidani 31

D. Haberman Teaches Solid Ring Seals To Seal Socket Cavities 33

1. The urethane Haberman "Ring" is structurally identical to the narrow urethane ring "annular seal" 33

2. The silicone Haberman "Ring" is structurally equivalent to the narrow nonfoamed, nonporous polyurethane ring "annular seal" 34

X. PROPOSED REJECTIONS 36

A. Claims 1-5, 7, 10-13, 16-17, And 19-23 Are Unpatentable Under 35 U.S.C. § 103(a) As Obvious Over Caspers '906 In View Of Either Caspers '208 (Ground 1), Slemker (Ground 3), Or Takidani (Ground 5).....36

B. Claims 6 And 18 Are Unpatentable Under 35 U.S.C. § 103(a) As Obvious Over Caspers '906 In View Of Either Caspers '208 (Ground 2), Slemker (Ground 4), Or Takidani (Ground 6), And Haberman 55

TABLE OF CONTENTS
(*cont'd*)

Page No.

XI. SECONDARY CONSIDERATIONS, EVEN IF PRESENT, FAIL TO OVERCOME THE STRONG EVIDENCE OF OBVIOUSNESS 57

A. No Unexpected Results 58

B. No Commercial Success 58

XII. THE PROPOSED REJECTIONS RAISE NEW ISSUES IN WHICH ÖSSUR WILL LIKELY PREVAIL 59

XIII. CONCLUSION 60

TABLE OF AUTHORITIES

Page No(s).

Altiris, Inc. v. Symantec Corp.,
318 F.3d 1363 (Fed. Cir. 2003) 18, 19

Cole v. Kimberly-Clark Corp.,
102 F.3d 524 (Fed. Cir. 1996) 18

Leapfrog Enters. Inc. v. Fisher-Price Inc.,
485 F.3d 1157 (Fed. Cir. 2007) 57

In re Morris,
127 F.3d 1048 (Fed. Cir. 1997) 15

Newell Cos., Inc. v. Kenney Mfg. Co.,
864 F.2d 757 (Fed. Cir. 1988) 57

O.I. Corp. v. Tekmar Co. Inc.,
115 F.3d 1576 (Fed. Cir. 1997) 22

In re Roberts,
470 F.2d 1399 (C.C.P.A 1973).....23

Seal-Flex, Inc. v. Athletic Track & Court Constr.,
172 F.3d 836 (Fed. Cir. 1999) 22, 23, 24

Syntex LLC v. Apotex, Inc.,
407 F.3d 1371 (Fed. Cir. 2005) 58

In re Trans Texas Holdings Corp.,
498 F.3d 1290 (Fed. Cir. 2007) 17, 18

TriMed, Inc. v. Stryker Corp.,
514 F.3d 1256 (Fed. Cir. 2008) 18

In re Yamamoto,
740 F.2d 1569 (Fed. Cir. 1984) 18

TABLE OF AUTHORITIES
(*cont'd*)

Page No(s).

OTHER AUTHORITIES

35 U.S.C. § 102 ..... passim

35 U.S.C. § 103 ..... passim

35 U.S.C. § 112 ..... passim

35 U.S.C. § 311 1

35 U.S.C. § 312 1

35 U.S.C. § 313 1

35 U.S.C. § 314 ..... 1, 59, 60

35 U.S.C. § 315 1

35 U.S.C. § 316 1

35 U.S.C. § 317 1

35 U.S.C. § 318 1

35 U.S.C. § 319 1

37 C.F.R. § 42.8 ..... 1, 2

37 C.F.R. § 42.10 1

37 C.F.R. § 42.15 60

37 C.F.R. § 42.100 *et seq.* 1, 17

37 C.F.R. § 42.104 2

EXHIBIT LIST

Exhibit No.	Description
1001	Declaration of Steven A. Gard, Ph.D., in Support of Petition for *Inter Partes* Review of U.S. Patent No. 6,726,726
1002	Curriculum vitae of Steven A. Gard, Ph.D.
1003	List of documents reviewed by Steven A. Gard, Ph.D.
1004	U.S. Patent No. 6,726,726 to Caspers ("the '726 patent")
1005	File wrapper for U.S. Patent No. 6,726,726
1006	U.S. Patent No. 5,735,906 to Caspers ("Caspers '906")
1007	File wrapper for U.S. Patent No. 5,735,906
1008	U.S. Patent No. 5,571,208 to Caspers ("Caspers '208")
1009	U.S. Patent No. 5,702,489 to Slemker ("Slemker")
1010	Japanese Patent JP-07 155343 and English translation thereof ("Takidani")
1011	Louis J. Haberman, "Silicone-Only Suspension (SOS) with Socket-Loc and the Ring for the Lower Limb," Journal of Prosthetics and Orthotics, Vol. 1, No. 1, 2-14 (1995) ("Haberman"), *available at* http://www.oandp.org/jpo/library/printArticle.asp?printArticleId=1995_01_002
1012	U.S. Patent No. 5,549,709 to Caspers ("Caspers '709")
1013	File wrapper for U.S. Patent App. No. 09/325,297 ("the '297 application")
1014	U.S. Patent No. 5,258,037 to Caspers ("the '037 patent")

Exhibit No.	Description
1015	U.S. Patent No. 5,534,034 to Caspers ("the '034 patent")
1016	U.S. Patent No. 6,508,842 to Caspers ("the '842 patent")
1017	U.S. Patent No. 6,554,868 to Caspers ("the '868 patent")
1018	Excerpts from file wrapper for U.S. Patent App. No. 10/808,982 ("the '982 application")
1019	U.S. Patent No. 708,685 to White
1020	German Patent DE 745,981
1021	U.S. Patent No. 980,457 to Toles ("Toles")
1022	U.S. Patent No. 6,231,616 to Helmy ("Helmy")
1023	Unity™ - Sleeveless Vacuum, *available at* https://www.ossur.com/?PageID=17800
1024	Iceross Seal-In® V Transtibial, *available at* http://www.oandp.com/edge/advertisers/ossur/E-Ossur_Iceross_Apr13.pdf
1025	English language portion of Harmony Instructions for Use, *available at* http://www.ottobock.com/cps/rde/xbcr/ob_us_en/04020441.1D_HarmonyP2_HD_IFU.pdf
1026	Otto Bock Harmony Certification Course Manual, *available at* http://www.ottobock.com/cps/rde/xchg/ob_us_en/hs.xsl/14904.html
1027	Memorandum of Points and Authorities in Support of Otto Bock's Motion for Preliminary Injunction, dated July 23, 2013
1028	Declaration of James Jay Martin in Support of Otto Bock's Motion for Preliminary Injunction, dated July 24, 2013

Exhibit No.	Description
1029	Össur's Memorandum of Points and Authorities in Support of Opposition to Plaintiff's Motion for Preliminary Injunction, dated August 5, 2013
1030	Declaration of Steven A. Gard, Ph.D. in Support of Össur's Opposition to Plaintiff's Motion for Preliminary Injunction, dated August 5, 2013
1031	Reply Memorandum of Points and Authorities in Support of Plaintiff's Motion for Preliminary Injunction, dated August 12, 2013
1032	Reply Declaration of James Jay Martin in Support of Otto Bock's Motion for Preliminary Injunction, dated August 12, 2013
1033	Order Denying Plaintiff's Motion for Preliminary Injunction, dated August 22, 2013
1034	Appeal Brief for Plaintiff-Appellant Otto Bock HealthCare LP, dated September 30, 2013
1035	Appeal Brief for Defendants-Appellees Össur hf and Össur Americas, Inc., dated November 1, 2013
1036	U.S. Patent No. 6,726,726 with disclosure repeated from U.S. Patent No. 5,735,906 highlighted
1037	Mount Nittany Health, "Healthsheet," published February 16, 2009, *available at* http://www.mountnittany.org/articles/healthsheets/4818.
1038	"Unity™ Sleeveless Vacuum. Now Available for Vari-Flex®," O&P Edge advertisement, September 2013, *available at* http://www.oandp.com/edge/advertisers/ossur/E-Ossur_Unity_QC_13Sept.pdf.

Exhibit No.	Description
1039	U.S. Patent Publication No. 2013/0289741 to Halldorsson, et al., entitled "Prosthetic Device, System and Method for Increasing Vacuum Attachment."
1040	U.S. Patent Publication No. 2013/0053982 to Halldorsson, entitled "Suspension Liner with Seal Component."

Össur hf and Össur Americas, Inc. (collectively, "Össur" or "Petitioner") request *inter partes* review in accordance with 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq.* of Claims 1-7, 10-13, and 16-23 of U.S. Patent No. 6,726,726 ("the '726 patent"), which issued on April 27, 2004 and is purportedly owned by Otto Bock HealthCare LP ("Otto Bock" or "Patent Owner").

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

The following mandatory notices are provided as part of this Petition:

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

Össur hf and Össur Americas, Inc. are the real parties-in-interest.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

The '726 patent has been asserted in co-pending litigation captioned *Otto Bock HealthCare LP v. Össur hf and Össur Americas, Inc.*, Case No. SACV13-00891-CJC (ANx) (C.D. Cal.) (the "Litigation"). Össur and Otto Bock are parties to the Litigation. Otto Bock served its initial complaint in the Litigation on or about June 20, 2013, and its first amended complaint on or about August 13, 2013.

C. Lead and Back-up Counsel Under 37 C.F.R. § 42.8(b)(3)

Pursuant to 37 C.F.R. §§ 42.8(b)(3) and 42.10(a), Össur provides the following designation of counsel:

Lead Counsel	Back-up Counsel
Brenton R. Babcock (Reg. No. 39,592) 2brb@knobbe.com Postal and Hand-Delivery Address: 2040 Main St., 14th Fl. Irvine, CA 92614 Telephone: (949) 760-0404 Facsimile: (949) 760-9502	Nicholas M. Zovko (Reg. No. 61,557) 2nmz@knobbe.com Postal and Hand-Delivery Address: 2040 Main St., 14th Fl. Irvine, CA 92614 Telephone: (949) 760-0404 Facsimile: (949) 760-9502

Petitioner's Lead Counsel is Brenton R. Babcock, USPTO Registration

No. 39,592, of Knobbe, Martens, Olson & Bear, LLP. Petitioner's Back-up Counsel is Nicholas M. Zovko, Registration No. 61,557, also of Knobbe Martens.

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Please address all correspondence to lead counsel and back-up counsel at the addresses shown above. Össur also consents to electronic service by email to: BoxOssur@knobbe.com.

II. GROUNDS FOR STANDING UNDER 37 C.F.R. § 42.104(a)

Össur certifies that the '726 patent is available for *inter partes* review and that Össur is not barred or estopped from requesting *inter partes* review challenging the patent claims on the grounds identified in this petition. The present petition is being filed within one year of service of the complaint against Petitioner in the Litigation.

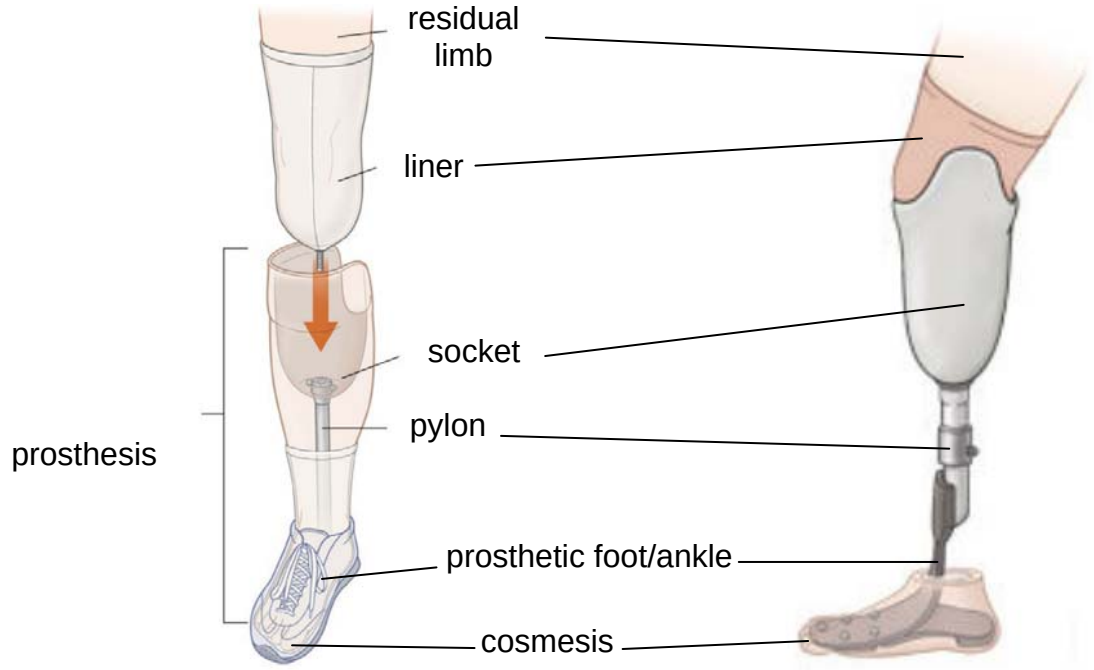
III. SUMMARY OF ISSUE PRESENTED

This petition primarily presents the Board with the following issue: The '726 patent claims apparatuses and methods relating to vacuum-controlled artificial limb prostheses for amputees. U.S. Patent No. 5,706,906, which is prior art under 35 U.S.C. § 102(b), expressly discloses every limitation of the '726 patent's independent claims other than, arguably, a single socket. However, the '726 patent acknowledges that single sockets were well-known and prevalent components of vacuum sockets. And prior patent applications by the '726 patent's named inventor, Carl Caspers, are directed to single-socket vacuum sockets. Thus, would a vacuum socket with one socket, instead of two sockets, have been obvious to a person having ordinary skill in the art in the 1999 time frame?

IV. INTRODUCTION

Össur is a global leader in the area of non-invasive orthopaedics. Össur provides innovative products and technologies in the fields of prosthetics, orthotics, bracing and supports, and compression therapy to improve the mobility of people throughout the world.

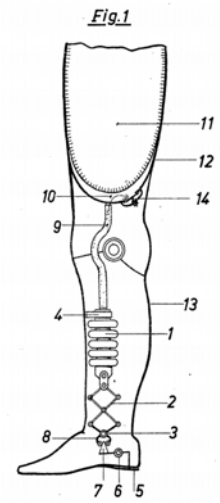
This petition is directed generally to lower-limb prosthetics, and more particularly to mechanical devices that are used to replace a portion of a patient's leg, either above the patient's knee (a "transfemoral" or "above-knee" prosthesis) or below the patient's knee (a "transtibial" or "below-knee" prosthesis). The basic components of a prosthesis are illustrated generically in the figure below:



In general, the patient places his or her residual limb into a protective and cushioning liner, which is then inserted into a socket (sometimes called "donning" the socket). The bottom of the socket is firmly connected to a pylon, which in turn is attached to a prosthetic ankle and/or foot. The prosthetic foot is covered by a

cosmesis designed to provide a more cosmetic foot-like appearance and to assist the patient in wearing conventional footwear.

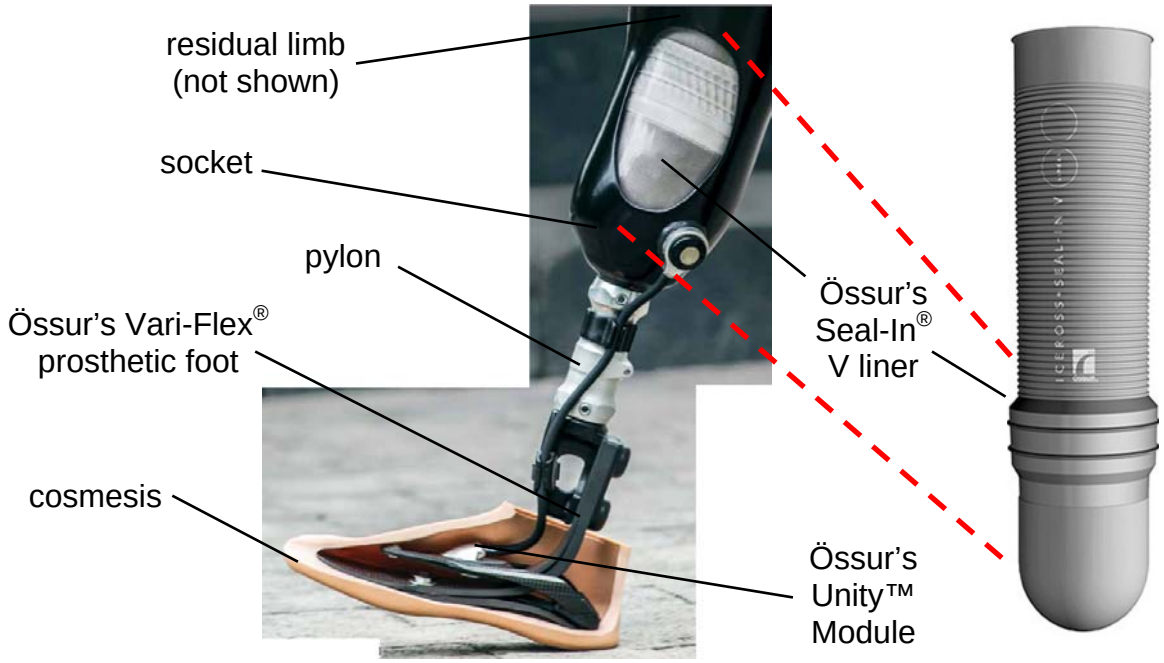
This petition focuses on apparatuses and methods used to firmly secure the patient's liner-covered residual limb into the socket. In centuries past, straps, cinches, suspenders, and the like were used. The idea of creating a vacuum inside the socket to secure the patient's residual limb dates back some 70 years to at least the World War II era. *See* Ex. 1001 ¶¶ 137-41. For example, a German patent to Spitzfadem issued in 1943 discloses an artificial limb that creates vacuum suspension in the socket using a weight-actuated mechanical vacuum pump:



Ex. 1020 at Fig. 1 (Spitzfadem)

Many other vacuum suspension technologies have been developed over the intervening decades. *See, e.g.*, *id.* ¶¶ 107, 144-58. To advance the state of the art in vacuum suspension technology, Össur developed several innovative products, including its Unity™ module, Seal-In® V liner, and Vari-Flex® foot modules. These products can be used with a third-party socket to create a vacuum-assisted artificial lower limb. Below are images of Össur's Unity™ pump module attached to a Vari-Flex® foot module, with Össur's Seal-In® V silicone liner in the blown-up

image on the right. *See also* Exs. 1023-1024, 1038.



Össur has applied for several patents for its novel Unity™ module and Seal-In® V liner. Össur's innovative Unity™ module creates vacuum suspension in the socket using a lightweight elastomeric membrane pump that is activated by movement of the heel and does not require a preexisting vacuum chamber. Össur's Seal-In® V liner seals the cavity of the socket using a unique membrane seal that provides a secure seal using a dual-seal mechanism on its outer surface and Volume Adaptive Blades that adjust to volume and pressure changes by the residual limb on its interior. *See generally* Exs. 1039-1040.

Several months after Össur introduced the Unity™ system, Otto Bock sued Össur for allegedly infringing the '726 patent. Otto Bock sells a line of vacuum-assisted artificial limbs under its "Harmony" product line. Ex. 1025. The Harmony system creates vacuum in the socket using a dual-function mechanical pump and shock absorber. Ex. 1025 at 3-4; Ex. 1017 at 27 (Col. 15:2-4).

Precursors to the Harmony system were originally developed by Carl Caspers in the mid-to-late 1990's. Ex. 1026 at 5. The first Harmony pump and shock absorber was introduced commercially by Caspers and his company TEC Interface Technologies ("TEC") around 1999. *Id.* at 6. In 2003, Otto Bock purchased TEC and adopted the Harmony product line. *Id.* at 8.

Otto Bock's Harmony system includes a liner, a sheath, a socket with a valve, an outer suspension sleeve for sealing the socket cavity, and a Harmony combination piston/cylinder pump and shock absorber. Ex. 1026 at 9. For example, Otto Bock's Harmony P2 and HD products are dual-function piston/ cylinder pumps and shock absorbers that are integral components of the pylon between the socket and foot module. Ex. 1025 at 3-4; Ex. 1026 at 27-29.

Below are images of Caspers' original dual-function pump and shock absorber (left) and Otto Bock's Harmony P2 and HD dual-function pumps and shock absorbers (right).

Caspers filed at least eleven utility patent applications relating to vacuum-assisted sockets in the 1990's and early 2000's. Each of these eleven applications belongs to one of three distinct patent "families" based on their respective priority chains. No single application in any one family claims priority to another application in a different patent family.

Caspers' first family of applications is directed to polymer liners and sleeves that offer a "total contact relationship with the [amputee's] residual limb" and provide "hypobaric suction suspension" when used with a single socket. *See, e.g.*, Ex. 1008 at Cols. 3:40-43, 10:47-11:48. This family claims priority to an application filed in July 1990, and concludes with the Caspers '208 patent, which issued in November 1996.

Caspers' second family of applications begins with the Caspers '709 patent, filed in July 1995, and is directed to a vacuum socket with inner and outer sockets, a vacuum source and valve used to draw the residual limb into firm contact with the inner socket, a regulator means with a power source for controlling the vacuum source, and a means for making an airtight seal between the residual limb and socket. Ex. 1012 at Col. 8:66-9:21. Caspers filed two related applications, one of which issued in April 1998 as the Caspers '906 patent. Ex. 1006.

Caspers' third family of applications begins in June 1999 with the '297 application. Ex. 1013. The '297 application, now abandoned, is directed to a vacuum socket of the second family that uses the single socket of the first family. The '297 application includes substantial overlapping disclosure with patents in the second Caspers family, but does not claim priority to any earlier-filed patent. One of at least four subsequently-filed CIP applications claiming priority to the '297 application issued as the '726 patent. Ex. 1004.

The '726 patent claims essentially the same vacuum socket disclosed in the prior art Caspers '906 patent, which issued more than one year before the earliest effective date of the '726 patent. The only arguable difference is that the '726

patent recites an apparatus having a "single socket" instead of an apparatus having an "inner socket" and an "outer socket."[1] Single sockets, however, were common in the prior art. Ex. 1001 ¶¶ 136-43. Caspers himself acknowledges that single sockets were well-known in the art at the time of the alleged inventions. *See, e.g.*, Ex. 1006 at Col. 4:6-40. Indeed, Caspers' first family of patent applications is directed to polymer liners and sleeves for use with single-socket vacuum sockets. *See, e.g.*, Ex. 1008; Ex. 1001 ¶¶ 143-48. Further, the Slemker and Takidani references both disclose single-socket vacuum sockets that include components such as vacuum pumps and mechanisms to maintain vacuum in the socket cavity. Exs. 1009 and 1010; Ex. 1001 ¶¶ 149-158.

A person having ordinary skill in the art would have understood that inner and outer sockets could be easily replaced with a conventional single socket. Ex. 1001 ¶¶ 159-61. As such, a person having ordinary skill in the art would have been motivated to substitute a more common single socket for the more complicated inner and outer sockets of the Caspers '906 vacuum socket. *Id.* ¶ 162. Additionally, it would have been obvious to try a simpler single socket with the Caspers '906 vacuum socket to, for example, use a more conventional socket or accommodate preferences of amputees for single sockets. *Id.* Thus, Claims 1-5, 7, 10-13, 16-17, and 19-23 of the '726 patent would have been obvious over Caspers '906 in view of either Caspers '208, Slemker, or Takidani. *Id.* ¶¶ 143-163.

---

[1] As discussed in Section VI.B *infra*, at least one embodiment in Caspers '709 and Caspers '906 discloses the inner and outer socket molded together into a single "rigid mass." *See, e.g.*, Ex. 1004 at Cols. 8:41-9:3.

The claims of the '726 patent recite means-plus-function and step-plus-function limitations, and thus are governed by 35 U.S.C. § 112, ¶ 6. Indeed, Otto Bock has acknowledged in the pending Litigation that the claims recite limitations invoking 35 U.S.C. § 112, ¶ 6. The district court has also determined that the claims recite limitations invoking 35 U.S.C. § 112, ¶ 6.

For example, Claims 1 and 10 recite a "means for sealing the socket cavity." Claims 6 and 18 further recite that this means-plus-function limitation comprises an "annular seal between the liner and the socket." The structure described in the specification corresponding to the "annular seal" includes a narrow nonfoamed, nonporous polyurethane (or "urethane") ring with a rectangular cross section that fully contacts the socket. Ex. 1004 at Col. 13:24-34; 13:36-40; 13:60-62; Fig. 18.

Narrow ring seals were well-known in the prior art. Ex. 1001 ¶¶ 165-67. For example, the Haberman reference teaches the use of a narrow "Ring" with a rectangular cross section as an improved way of sealing a socket cavity. Ex. 1011 at 8-9; Ex. 1001 ¶¶ 168-71. The Haberman urethane "Ring" is structurally identical to the narrow urethane ring "annular seal" of the '726 patent. Ex. 1001 ¶¶ 172-73. Similarly, the preferred Haberman silicone "Ring" is structurally equivalent to the narrow polyurethane ring "annular seal." *Id.* ¶¶ 174-77. Thus, Claims 6 and 18 would have been obvious over Caspers '906 in view of either Caspers '208, Slemker, or Takidani, and Haberman. *Id.* ¶¶ 178-80.

As discussed above, Össur's Unity™ Module and Seal-In® V liner create and maintain vacuum in the socket and seal the socket cavity in a fundamentally different way than Otto Bock's Harmony system, which Otto Bock alleges

practices the '726 patent's claims. Indeed, the district court recently determined in the Litigation that Össur's products do not satisfy, *inter alia*, the "means for sealing" limitation because they do not have an equivalent structure to the narrow polyurethane ring disclosed in the '726 patent's written description. Ex. 1033 at 7-8. In addition to Össur's non-infringement of the '726 patent, Össur has filed this petition because the identified claims of the '726 patent are also invalid as at least obvious over the prior art. Össur therefore respectfully requests that the Board institute an *inter partes* review and determine that Claims 1-7, 10-13, and 16-23 of the '726 patent are unpatentable under at least 35 U.S.C. § 103(a).

V. STATEMENT OF PRECISE RELIEF REQUESTED

Össur respectfully requests that the Board cancel Claims 1-7, 10-13, and 16-23 of the '726 patent based on the following grounds for unpatentability:

Ground 1: Claims 1-5, 7, 10-13, 16-17, and 19-23 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Pat. No. 5,735,906 to Caspers ("Caspers '906") in view of U.S. Pat. No. 5,571,208 to Caspers ("Caspers '208").

Ground 2: Claims 6 and 18 are unpatentable under 35 U.S.C. § 103(a) as obvious over Caspers '906 in view of Caspers '208 and a 1995 article by Louis J. Haberman in the Journal of Prosthetics and Orthotics ("Haberman").

Ground 3: Claims 1-5, 7, 10-13, 16-17, and 19-23 are unpatentable under 35 U.S.C. § 103(a) as obvious over Caspers '906 in view of U.S. Pat. No. 5,702,489 ("Slemker").

Ground 4: Claims 6 and 18 are unpatentable under 35 U.S.C. § 103(a) as obvious over Caspers '906 in view of Slemker and Haberman.

Ground 5: Claims 1-5, 7, 10-13, 16-17, and 19-23 are unpatentable under 35 U.S.C. § 103(a) as obvious over Caspers '906 in view of Japanese patent JP-07155343 ("Takidani").

Ground 6: Claims 6 and 18 are unpatentable under 35 U.S.C. § 103(a) as obvious over Caspers '906 in view of Takidani and Haberman.

Detailed claim charts are provided *infra* in Section X. The claim charts provide examples of why the claims are unpatentable under the grounds identified above. The charts also identify examples of where each claim limitation is found in the prior art patents and publications, and the relevance of those references.

Additional explanation and support for each ground of rejection is included in the Declaration of Steven A. Gard, Ph.D. *See, e.g.*, Ex. 1001 ¶¶ 181-225. Dr. Gard is the Executive Director at the Northwestern University Prosthetics-Orthotics Center ("NUPOC") and an Associate Professor at the Feinberg School of Medicine. Dr. Gard is also a Research Health Scientist with the Jesse Brown VA Medical Center in Chicago. Dr. Gard has established his professional career investigating lower-limb prostheses and orthoses, and the gait patterns of users of lower-limb prostheses and orthoses. *See, e.g.*, *id.* ¶¶ 2-9.

VI. SUMMARY OF THE '726 PATENT

A. Brief Description

The '726 patent describes a vacuum socket for amputees that incorporates a vacuum source to draw the residual limb into firm and total contact with the socket. The '726 patent's claims recite two means-plus-function limitations that invoke 35 U.S.C. § 112, ¶ 6: (1) a "means for sealing the socket cavity"; and (2) a

"means to maintain [a] vacuum in the [socket] cavity." Ex. 1001 ¶¶ 50-70. The '726 patent's claims also recite analogous step-plus-function limitations. *Id.* ¶¶ 71-91. The '726 patent discloses that by using its vacuum source to draw the residual limb into firm and total contact with the socket, the vacuum socket opposes the loss of body fluids from the residual limb due to weight-bearing pressures. *See* Ex. 1004 at Col. 14:3-20; Ex. 1001 ¶¶ 29-31, 106-07.

B. Prosecution History

1. Prior Caspers Patent Application Families

Caspers' first family of applications in the early 1990's, which concluded with the Caspers '208 patent, is directed to polymer liners and sleeves that offer total contact with the residual limb and provide "hypobaric suction suspension" in ***single-socket*** vacuum sockets. Ex. 1008 at Col. 3:40-43; Exs. 1014-1015; Ex. 1001 ¶¶ 100, 143-48. Caspers' second family of applications in the mid-1990's incorporates the polymer liners and sleeves from Caspers' first family of applications into ***double-socket*** vacuum sockets with an outer socket and flexible inner socket, a vacuum source and valve, a means for making an airtight seal between the residual limb and outer socket, and a means for maintaining vacuum in the socket. *See, e.g.*, Ex. 1012 at Col. 8:66-9:21; Ex. 1006 at Col. 9:29-50; *see also* Ex. 1001 ¶¶ 101, 117-35. In this second family of applications, Caspers acknowledges that single-socket vacuum sockets—such as those described in the Caspers '208 patent—were well-known in the field, but characterized the "custom-building process" for single sockets as "expensive, time-consuming, and requir[ing] the constant attention of a skilled prosthetist." Ex. 1012 at Col. 4:27-

29; Ex. 1006 at Col. 4:32-34. In view of this purported problem, Caspers' second family of applications, in particular the Caspers '709 and Caspers '906 patents, claim a double socket and recite a "generic artificial limb socket which can be fitted to the contours of the residual limb without the need for a lengthy, expensive custom-molding process." Ex. 1012 at Col. 4:30-33; Ex. 1006 at Col. 4:35-37.

2. <u>The '726 Patent Family</u>

On June 3, 1999, Caspers began a third family of applications by filing the '297 application. The '297 application lacks continuity with, and therefore does not claim priority to, any earlier Caspers applications. Caspers has filed at least four CIP applications claiming priority to the '297 application. Exs. 1004, 1016-1018. One of these applications eventually issued as the '726 patent. Ex. 1004.

The applications in this third Caspers family are directed to the vacuum socket of the ***second*** Caspers family, but recite claims replacing the inner and outer sockets for a single socket of the ***first*** Caspers family. *See* Ex. 1001 ¶¶ 102, 160-62. The '726 patent includes (1) all ten figures of Caspers '906; (2) substantial portions of the "background" and "summary of the invention" sections of Caspers '906; (3) virtually all of the "description of the preferred embodiment" section of Caspers '906; and (4) many claims similar to the claims of Caspers '906. *See* Ex. 1030 at 37:23-27; *see also* Ex. 1001 ¶¶ 126-27. For example, Claim 1 of the '726 patent recites a liner, a socket, a vacuum source, and two means-plus-function limitations that invoke 35 U.S.C. § 112, ¶ 6. Ex. 1005 at 55; Ex. 1001, ¶¶ 50-70. Other than the substitution of a single socket (from the first Caspers family) for inner and outer sockets (from the second Caspers family), this claim mirrors

Claims 1-4 of Caspers '906. Ex. 1001 ¶¶ 134.

During prosecution of the '726 patent, Caspers emphasized that the maintenance of a vacuum in the socket between "10 to 25 inches mercury" so that "the residual limb loses only about 1% of its volume during the day," and ***not*** the substitution of a single socket for inner and outer sockets, was "the result of [Caspers'] inventive activities." Ex. 1005 at 163-64. However, because Caspers '906 discloses "maintain[ing] a vacuum [in the socket] in the range of 0 to 25 inches of mercury," the patent examiner found that this vacuum level was inherently disclosed by Caspers '906, and rejected the claims of the '726 as either anticipated and/or obvious over Caspers '906. *Id.* at 213; Ex. 1004 at Col. 7:20-27. Caspers acquiesced to the examiner's rejection, and then argued that the Caspers '906 patent purportedly did not disclose "1) a single socket; or 2) a means to maintain a vacuum in the socket cavity." Ex. 1005 at 220-21 (excerpted below):

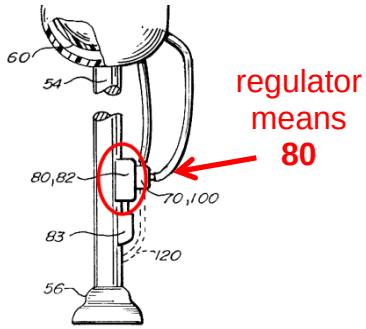
> Second, Caspers '906 does not disclose a means to maintain a vacuum in the socket cavity in the presence of some air leakage past the seal means. Comparing the instant application with Caspers '906, the Examiner will note that the disclosure of this limitation was added to the application that matured into Caspers '906 as a result of Applicant's experience. The added material appears at page 20, third full paragraph and following.

Caspers' response statees that no "means to maintain vacuum" is disclosed in Caspers '906. However, the '726 patent indicates that "regulator means 80" may be used to maintain vacuum in the socket. *Id.* at 51 (excerpted below):

> To maintain the vacuum in the cavity, either a regulator means 80, a vacuum reservoir 110, or a weight-actuated vacuum pump and shock absorber as disclosed in U.S. Patent application Serial No. 09/534,274, may be employed.

And Caspers '906 discloses and describes the same "regulator means 80." *See*,

e.g., Ex. 1006 at Fig. 3, Col. 7:21-44 (excerpted below).



The amputee then sets the regulator means **80** to cause the vacuum source **70** to apply vacuum through the vacuum valve **74** and vacuum tube **76** to the cavity **62**. Enough vacuum is applied to cause the residual limb (with optional coverings) to be drawn firmly against the inner surface **64** of the inner socket **60**, which is flexible. The vacuum source **70** may preferably maintain a vacuum in the range of 0 to 25 inches of mercury.

But for Caspers' mischaracterization of the Caspers '906 patent, it is unclear whether the examiner would have allowed the patent application. *See* Ex. 1005 at 256. During prosecution of the '297 application, the examiner asserted that in one embodiment of Caspers '709, the disclosed inner and outer sockets function as a single socket when molded together into a "rigid mass," and thus fully anticipate a limitation reciting a "single socket." Ex. 1013 at 52; Ex. 1012 at Col. 8:35-43. This disclosure also appears in Caspers '906. Ex. 1006 at Col. 8:43-51.

Indeed, the same patent examiner, David H. Willse, has maintained to this day that this embodiment in Caspers '709 functions as a single socket. For example, in the '982 application, which Otto Bock is currently prosecuting, the examiner rejected pending claims reciting "only a single prosthetic socket" as being anticipated by Caspers '709. *See, e.g.*, Ex. 1018 at 261-62, 270. Citing *In re Morris*, 127 F.3d 1048, 1055-56 (Fed. Cir. 1997) for the proposition that "a *single* unit may involve multi-piece structures held in a fixed relationship," the examiner determined that the inner and outer sockets of Caspers '709 "may collectively be viewed as a single socket because they are held together in a fixed relationship so as to define a custom socket molded to the contours of a residual limb." *Id.*

(emphasis in original). The examiner also rejected pending claims in the '982 application reciting "a single, monolithic socket" as obvious, noting that to replace the double sockets of Caspers '709 with a single socket "would have been an ***obvious step backward*** . . . in order to provide a thinner (albeit more expensive, if customized) structure to facilitate the donning of clothing, for example, and/or to accommodate an amputee not requiring a customized socket." *Id.* at 257-58, 270-71 (emphasis added).

In response to the rejection for obviousness, Caspers submitted an affidavit from an individual asserting that "there is nothing in the teachings of Caspers ['709] that suggests, teaches or would logically imply replacing any of the double socket embodiments disclosed by Caspers ['709] with a prosthetic device having 'only a single socket.'" *Id.* at 290-91. However, the examiner remains unconvinced, finding no "technical jump" from "double-socket design" to single-socket technology that "was well known and old." *Id.* at 296 (excerpted below).

> is whether the *converse* is true: Is there a technical jump from said "double socket design" to a monolithic form? The latter was clearly prevalent in the art, as evidenced by the previously referenced background discussion of Caspers '709 (column 1, line 53, to column 2, line 31), and there would have been plenty of motivation to provide ubiquitous, inexpensive, and/or factory-made alternatives that are more familiar to amputees and prosthetists.

C. <u>Issued Claims</u>

The '726 patent has 23 claims, which include three independent claims. Independent Claims 1 and 10 recite apparatuses for managing residual limb volume in an artificial limb; independent Claim 20 recites a method for preventing

the loss of residual limb volume due to weight-bearing pressures in an artificial limb. Ex. 1004 at Col. 14:34-65, 15:23-49, 16:23-47; Ex. 1001 ¶¶ 29-34, 39-41.

The dependent claims recite additional limitations. For example, Claims 6 and 18 further limit the scope of a functional limitation in Claims 1 and 10 that invokes § 112, ¶ 6 (a "means for sealing the socket cavity") to corresponding structure of a narrow ring "annular seal" described, for example, at Col. 13:24-41 (Fig. 18, element 140). Claims 4 and 16 further limit the "means for sealing" to the "nonfoamed, nonporous polyurethane suspension sleeve" disclosed, for example, at Col. 6:50-52. Claims 7 and 13 further limit the scope of a functional limitation in Claims 1 and 11 that invokes § 112, ¶ 6 (a "means to maintain [a] vacuum") to corresponding structure of the "regulator means" generically disclosed, for example, at Col. 6:43-48. *See* Ex. 1001 ¶¶ 35-38, 42-48.

VII. LEVEL OF ORDINARY SKILL IN THE ART

In the field relevant to lower-limb prosthetic vacuum sockets, the person having ordinary skill in the art at the time of the claimed invention is someone who had obtained a Bachelor's degree in engineering (mechanical, electrical, bio/biomedical, or the like), or the equivalent, and 1-2 years of professional experience working with lower limb prosthetics, in the 1999 time frame. *See* Ex. 1001 ¶¶ 25-28.

VIII. CLAIM CONSTRUCTION

The claim terms in the '726 patent are presumed to take on their ordinary and customary meaning based on the broadest reasonable interpretation of the claim language. *See* 37 C.F.R. § 42.100(b); *see also In re Trans Texas Holdings*

Corp., 498 F.3d 1290, 1298 (Fed. Cir. 2007) (stating that "[c]laims are given 'their broadest reasonable interpretation, consistent with the specification, in reexamination proceedings'") (citing *In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984)). Össur does not believe that any special meanings apply to the claim terms. Accordingly, the claim terms should be given their broadest reasonable interpretation in light of the specification as commonly understood by a person having ordinary skill in the art. Össur's position regarding the scope of the claims should not be taken as an assertion regarding the appropriate claim scope in other adjudicative forums where a different standard of claim construction and/or claim interpretation may apply.

A. <u>Apparatus Claims</u>

Claims 1-7, 10-13, and 16-19 include terms presumed to invoke 35 U.S.C. § 112, ¶ 6, because these claim terms use the language "means for" or "means to" and recite a corresponding function without reciting sufficient structure, material, or acts to perform the recited function. *See, e.g.*, *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531 (Fed. Cir. 1996). The presumption cannot be rebutted because the limitations in Claims 1-7, 10-13, and 16-19 do not recite the structure necessary to perform the recited functions. *See TriMed, Inc. v. Stryker Corp.*, 514 F.3d 1256, 1259-60 (Fed. Cir. 2008) (*rev'd and remanded on other grounds*) ("Sufficient structure exists when the claim language specifies the exact structure that performs the functions in question without need to resort to other portions of the specification or extrinsic evidence for an adequate understanding of the structure."); *see also Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1376 (Fed.

Cir. 2003).[2]

Össur and Otto Bock agree that the "means for sealing" and "means to maintain" limitations invoke § 112, ¶ 6. *See, e.g.*, Ex. 1028 at 26-27, 39, 41; Ex. 1034 at 22 (Otto Bock's appeal brief) ("[T]he asserted claims [Claims 6, 9, 15, and 18] recite means-plus-function limitations."). The district court in the related Litigation has also determined that the claims invoke § 112, ¶ 6. Ex. 1033 (order denying Otto Bock's motion for preliminary injunction) at 5:25-6:10.

The means-plus-function limitations recited in Claims 1-7, 10-13, and 16-19 are identified in the table below, along with their corresponding function and structure as described in the specification of the '726 patent.[3] Ex. 1001 ¶¶ 50-70.

---

[2] In the alternative, if the broadest reasonable interpretation of a "means for sealing" and/or a "means to maintain" were such that § 112, ¶ 6 is not invoked, these elements would not necessarily be limited to the structures described in the specification. Under such an interpretation (which is not correct), it is axiomatic that a person having ordinary skill in the art would still have found the prior art references relied upon in this petition to fully disclose the above elements in these claim limitations. Ex. 1001 ¶ 50 n.1.

[3] Claims 2, 3, and 5 depend from Claim 1. Claim 12 depends from Claim 11. Claims 17 and 19 depend from Claim 10. Accordingly, the analysis for the "means for sealing" and "means to maintain" limitations in Claims 1, 10, and 11 also applies to Claims 2, 3, 5, 12, 17, and 19.

Claims 1 and 10: Means-Plus-Function Claim Limitations
a seal <u>means for sealing</u> the socket cavity **Function**: sealing the socket cavity. **Structure**: • a nonfoamed, nonporous polyurethane suspension sleeve 86, which rolls over and covers the socket and a portion of the residual limb[4]; **<u>or</u>** • a narrow nonfoamed, nonporous polyurethane ring, or a narrow urethane ring, with a rectangular cross section (as depicted by element 140) that fully contacts (a) the liner (or the liner's fabric cover) and the socket; or (b) the liner's fabric cover and the suspension sleeve.[5]

Claims 1 and 11: Means-Plus-Function Claim Limitations
a <u>means to maintain</u> [<u>a</u>] <u>vacuum</u> in the [socket] cavity **Function**: maintaining a vacuum in the socket cavity. **Structure**: • a regulator means 80 for controlling the vacuum source[6];

[4] *See* Ex. 1004 at Cols. 6:49-54, 7:31-38, 8:54-55, 9:27-30, 10:17-23, 11:3-9, 11:32-56, 12:4-6, 12:55-58, Figs. 3-11, 13, 15-16.

[5] *See id.* at Cols. 6:66-7:1 ("nonfoamed, nonporous polyurethane liner"), 13:61-62 ("same material as the liner"); Cols. 7:12-15 ("urethane liner"), 13:61-62 ("same material as the liner"); Figs. 18 and 20, Col. 13:60-62 (contacts liner and socket); Col. 13:24-40 (contacts fabric cover and socket); Fig. 17, Col. 13:24-34 (contacts fabric cover and suspension sleeve).

[6] Ex. 1004 at Cols. 6:43-45, 7:39-41, 7:56-61, 8:4-8, 8:12-17, 8:24-37,

Claims 1 and 11: Means-Plus-Function Claim Limitations
• a vacuum reservoir 110[7]; **<u>or</u>** • a weight-actuated vacuum pump and shock absorber as disclosed in U.S. Patent App. No. 09/534,274 (the '868 patent)[8].

Claims 4 and 16: Means-Plus-Function Claim Limitations
wherein the <u>seal means</u> further comprises a nonfoamed, nonporous polyurethane suspension sleeve for rolling over and covering the socket and a portion of the residual limb **Function**: sealing the socket cavity. **Structure**: a nonfoamed, nonporous polyurethane suspension sleeve 86, which rolls over and covers the socket and a portion of the residual limb[9].

Claims 6 and 18: Means-Plus-Function Claim Limitations
wherein the <u>seal means</u> further comprises an annular seal between the liner and the socket **Function**: sealing the socket cavity. **Structure**: a narrow nonfoamed, nonporous polyurethane ring, or a narrow urethane ring, with a rectangular cross section (as depicted by element 140) that fully contacts the liner and the socket[10].

8:55-57, 10:53-54, 10:60-67, 11:10-12, 13:5-8, Figs. 3-8, 11-14.

[7] *Id.* at Cols. 12:19-47, 13:5-8, Fig. 16.

[8] *Id.* at Col. 13:5-8.

[9] *See supra* note 4.

[10] Ex. 1004 at Cols. 6:67-7:1 ("nonfoamed, nonporous polyurethane

Claims 7 and 13: Means-Plus-Function Claim Limitations
wherein the vacuum source is a vacuum pump and the <u>means to maintain the vacuum</u> in the cavity is a regulator, and further comprising a power source for the vacuum pump and the regulator
Function: maintaining the vacuum in the socket cavity.
Structure: a regulator means 80 for controlling the vacuum source[11].

B. <u>Method Claims</u>

Claims 20-23 recite "[a] method for preventing the loss of residual limb volume due to weight-bearing pressures in an artificial limb, comprising the steps of . . . ." Ex. 1004 at Col. 16:23-47. 35 U.S.C. § 112, ¶ 6 provides that "[a]n" element in a claim for a combination may expressed as a means or ***step for*** performing a specified function without the recital of structure, material, or ***acts*** in support thereof." (emphases added). The Federal Circuit has instructed that the term "steps" may "refer to the generic description of elements of a process," and the term "acts" may "refer to the implementation of such steps." *O.I. Corp. v. Tekmar Co. Inc.*, 115 F.3d 1576, 1583 (Fed. Cir. 1997).

Claims 20-23 do not appear to presumptively invoke 35 U.S.C. § 112, ¶ 6 because they do not use the phrase "steps for." Nevertheless, Claims 20-23 are properly construed as step-plus-function claims because they merely claim the

---

liner"), 13:61-62 ("same material as the liner"); Cols. 7:12-15 ("urethane liner"), 13:61-62 ("same material as the liner"); Figs. 18 and 20, Col. 13:60-62 (contacts liner and socket).

[11] *See supra* note 6.

underlying function without the recitation of any acts for performing that function. *See Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 172 F.3d 836, 849 (Fed. Cir. 1999) (Rader, C.J., concurring); *see also In re Roberts*, 470 F.2d 1399 (C.C.P.A 1973) (applying 35 U.S.C. § 112, ¶ 6 to the element "reducing the coefficient of friction to below about 0.40").[12]

For example, element (d) of Claim 20 recites: "sealing the socket cavity." Ex. 1004 at Col. 16:35. This limitation recites the function of "sealing" without providing any specific acts necessary to perform that function. Caspers chose to omit a prepositional phrase, such as "sealing the socket cavity *by rolling over and covering the outer socket and a portion of the residual limb with a nonfoamed, nonporous polyurethane suspension sleeve*," which may have provided the acts necessary to perform the function of "sealing the socket cavity." Without such recitation of specific acts, however, this element must also be construed under 35 U.S.C. § 112, ¶ 6. *See Seal-Flex*, 172 F.3d at 850 ("If a claim element recites only an underlying function without acts for performing it, then § 112, ¶ 6 applies even without express step-plus-function language."); *see also* Ex. 1001 ¶¶ 71-81.

---

[12] In the alternative, if the broadest reasonable interpretation of the steps of "sealing the socket cavity" and/or a "maintaining a vacuum in the socket cavity" were such that § 112, ¶ 6 is not invoked, these steps would not necessarily be limited to the acts described in the specification. Under such an interpretation (which is not correct), it is axiomatic that a person having ordinary skill in the art would still have found the prior art references relied upon in this petition to fully disclose the above steps in these claim limitations. Ex. 1001 ¶ 75 n.11.

Similarly, element (e) of Claim 20 recites: "maintaining a vacuum in the socket cavity to at least ten inches of mercury below ambient, in the presence of some air leakage into the socket cavity." Ex. 1004 at Col. 16:40-42. This limitation recites a function ("*maintaining a vacuum* . . . to at least ten inches of mercury below ambient") without providing any specific acts necessary to perform that function. "Maintaining a vacuum" describes ***what*** the step ultimately accomplishes rather than ***how*** maintaining such a vacuum is accomplished. *See Seal-Flex*, 172 F.3d at 849-50; Ex. 1001 ¶¶ 71-76, 82-91.

The step-plus-function limitations recited in Claims 20-23 are identified in the table below, along with their corresponding function and acts described in the specification of the '726 patent.[13] Ex. 1001 ¶ 91.

Claim 20: Step-Plus-Function Claim Limitations
<u>sealing the socket cavity</u>
Function: sealing the socket cavity.
Specific acts for performing the function:
• rolling over and covering the outer socket and a portion of the residual limb with a nonfoamed, nonporous polyurethane suspension sleeve 86[14]; **<u>or</u>**
• using a nonfoamed, nonporous polyurethane ring, or a narrow urethane ring, with a rectangular cross section (as depicted by element 140) to fully contact

[13] The analysis for the "sealing the socket cavity" and "maintaining a vacuum in the socket cavity to at least ten inches of mercury below ambient" limitations in Claim 20 also applies to Claims 21-23, which depend from Claim 20.

[14] *See supra* note 4.

Claim 20: Step-Plus-Function Claim Limitations
(a) the liner (or the liner's fabric cover) and the socket; or (b) the liner's fabric cover and the suspension sleeve[15].
<u>maintaining a vacuum</u> in the socket cavity to at least ten inches of mercury below ambient, in the presence of some air leakage into the socket cavity **Function**: maintaining a vacuum in the socket cavity to at least ten inches of mercury below ambient, in the presence of some air leakage into the socket cavity. **Specific acts for performing the function**: • controlling the application of vacuum by the vacuum source with a regulator means 80[16]; • attaching a vacuum reservoir 110 between the socket and foot or carrying the reservoir separately, and activating the reservoir 110 either manually or by a regulator means[17]; **<u>or</u>** • attaching a weight-actuated vacuum pump and shock absorber as disclosed in U.S. Patent Ser. No. 09/534,274 (the '868 patent) between the socket and the pylon, and actuating the vacuum pump by applying a vertical load on the shock absorber[18].

IX. SCOPE AND CONTENT OF THE PRIOR ART

The Caspers '906 patent expressly discloses nearly all of the limitations of

---

[15] *See supra* note 5.

[16] *See supra* note 6.

[17] *See supra* note 7.

[18] *See supra* note 8.

the '726 patent's claims except for, arguably, a single socket. The Caspers '208 patent discloses a single-socket vacuum socket that suspends the residual limb using a polymer liner, the polymer liner offering a "total contact" relationship between the limb, the liner, and the single socket. Slemker and Takidani disclose single-socket vacuum sockets that use vacuum pumps to create and to maintain vacuum in the socket cavity, respectively. Haberman discloses several liners modified to include narrow rings with rectangular cross sections around the liner. One Haberman "Ring" constructed of urethane is identical to the narrow urethane ring "annular seal" disclosed in the '726 patent. Another Haberman "Ring" constructed of silicone is structurally equivalent to the narrow polyurethane ring "annular seal" disclosed in the '726 patent.

Accordingly, Caspers '906 in view of either Caspers '208, Slemker, or Takidani, disclose every limitation of the '726 patent's independent claims and most of its dependent claims. Caspers '906 in view of either Caspers '208, Slemker, or Takidani, and Haberman disclose the limitations of the remaining claims at issue in this petition.

A. <u>Caspers '906 Discloses Almost All Of The Claims' Limitations</u>

The Caspers '906 patent issued on April 7, 1998, which is more than one year before the earliest claimed priority date of the '726 patent. Caspers '906 is therefore prior art to the '726 patent under 35 U.S.C. § 102(b).

As discussed above, Caspers '906 includes substantial common disclosure with the '726 patent. For instance, Caspers '906 discloses, *inter alia*, a vacuum socket with inner and outer sockets, a liner, a thin sheath, a vacuum source for

drawing the residual limb and liner into firm contact with the inner surface of the inner socket, a means for making an airtight seal between the limb and the inner socket, and a means to maintain the vacuum in the socket to a level between 0 and 25 inches of mercury. *See, e.g.*, Ex. 1006 at Cols. 9:30-59, Col. 7:20-44; Ex. 1001 ¶¶ 121-35. According to Caspers '906, use of the vacuum socket prevents negative draw within the socket from causing swelling of the residual limb into the socket and opposes the loss of fluids from the residual limb caused by weight-bearing pressures. *See, e.g.*, Ex. 1006 at Col. 4:63-5:4; Ex. 1001 ¶ 133.

In short, Caspers '906 expressly discloses every limitation of the independent claims of the '726 patent except for, arguably, a single socket. Ex. 1001 ¶ 135; *see supra* note 1.

B. <u>Single-Socket Vacuum Sockets Were Well-Known In The Art</u>

As the '726 patent acknowledges, single sockets were well-known in the art. Ex. 1006 at Col. 1:57-2:38; Ex. 1001 ¶¶ 136-43. Otto Bock also admits that single sockets were preferred by most transtibial (below-knee) and transfemoral (above-knee) amputees. Ex. 1001 ¶¶ 103, 136. Additionally, Caspers '208 demonstrates that by the time frame of the alleged inventions, vacuum suspension of a residual limb in a single socket using a liner having "total contact" with the limb and socket was common. Ex. 1001 ¶¶ 143-48. Slemker demonstrates vacuum pumps were used to create vacuum in single sockets and suspend residual limbs in those single sockets. Ex. 1001 ¶¶ 143, 149-53. Takidani demonstrates specialized pump devices were used not only to create, but to *maintain* vacuum in single-socket vacuum sockets. *Id.* ¶¶ 143, 154-58.

As such, a person having ordinary skill in the art would have been motivated to substitute a single socket, such as those disclosed in either Caspers '208, Slemker, or Takidani, for the inner and outer sockets of Caspers '906. *Id.* ¶¶ 159-63, 184-93, 200-02, 211-13. Indeed, with just two prevalent socket configurations for amputees, replacing the double socket of Caspers '906 with a single socket would have been obvious to a person having ordinary skill in the art. *Id.*

1. Caspers '208 discloses a single-socket vacuum socket providing "total contact" between the residual limb, a liner, and the socket

Caspers '208 issued on November 5, 1996, and is therefore prior art to the '726 patent under 35 U.S.C. § 102(b). Caspers '208 is incorporated by reference into the '726 patent. Ex. 1004 at Col. 11:36-38. Caspers '208 discloses a near-identical single socket, liner, sleeve, and sheath combination to that of Caspers '726 in order to create vacuum suspension by "total contact" between the limb, liner, and single socket. Ex. 1008 at Fig. 21; Ex. 1001 at ¶¶ 143-46. In particular, Caspers '208 discloses a polyurethane[19] liner and sleeve having a "total contact relationship with the residual limb." Ex. 1008 at Cols. 3:40-42; 8:42-48. After donning the "urethane liner," the amputee optionally dons a thin, nylon sheath. *Id.* at Cols. 10:50-51, 10:60-62. The sheath assists the amputee into a smooth and easy fitting into the single socket. *Id.* at Col. 10:65-67. The outer surface of the liner contacts the socket to create a "total contact hypobaric suction, equal weight distribution socket liner." *Id.* at Cols. 9:30-33, 11:21-23. A polyurethane sleeve

[19] The Caspers '208 patent uses "urethane" as a shorthand or abbreviated term for "polyurethane". Ex. 1008 at Col. 8:42-50; Ex. 1001 ¶ 145.

on an upper portion of the limb rolls over and covers the outer part of the socket. *Id.* at Cols. 10:47-56; 11:42-45. *See* Ex. 1001 ¶¶ 145-46.

2. Slemker discloses a single-socket vacuum socket that creates vacuum in the socket with a pump

Slemker issued on December 30, 1997, and is therefore prior art to the '726 patent under 35 U.S.C. § 102(b). Slemker discloses a single-socket vacuum socket for receiving the residual limb of an amputee. Ex. 1009 at Col. 3:39-45; Ex. 1001 ¶ 150. An amputee may roll a silicone liner over the residual limb to protect the limb and provide a seal between the limb and the socket when the limb is "tightly fitted" in the socket. Ex. 1009 at Col. 5:53-57. A pump mechanism attached to a valve at the bottom of the socket evacuates air from the socket and draws the limb and liner into contact with the socket. *Id.* at Col. 6:22-30. Closing the valve at the bottom of the socket forms vacuum suction in the socket to secure the socket to the amputee's residual limb and liner. *Id.* at Col. 3:39-45.

3. Takidani discloses a single-socket vacuum socket that creates and maintains vacuum in the socket cavity

Takidani is a Japanese patent application that was published on June 20, 1995, and is therefore prior art to the '726 patent under 35 U.S.C. § 102(b). Takidani discloses an artificial leg with a single socket having a suction valve at its lower end. Ex. 1010 at 10, Figs. 1, 3; Ex. 1001 ¶ 155. The residual limb is inserted into the socket, and a pump attached to the socket evacuates air from the socket to ensure that the residual limb is "tightly fitted" into the socket's inner surface. Ex. 1010 at 10, Figs. 1, 3. Using an operating switch, suction pressure of

the pump can be adjusted, and vacuum in the socket can be maintained during walking. *Id.* at 11, Fig. 1. Takidani describes that when "fit between the amputated leg and the socket becomes loose by sweat and the like, suction pressure of the pump can be properly adjusted by the operating switch" in order to maintain vacuum in the socket cavity so that "the socket . . . does not come off." *Id.* at 11.

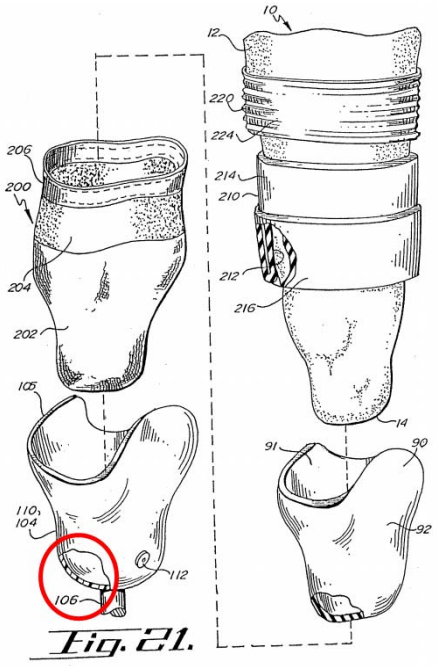
4. <u>Caspers '208, Slemker, and Takidani are not cumulative</u>

While Caspers '208, Slemker, and Takidani each disclose single-socket vacuum sockets, their disclosures are not cumulative. In particular, Caspers '208 discloses a single-socket vacuum socket that suspends the residual limb with a polymer liner that provides a "total contact relationship" with the limb and the socket. Slemker discloses a single-socket vacuum socket with a silicone liner that creates vacuum in the socket using a pump. In addition, as discussed in Section IX.C, *infra*, Slemker also provides express teaching, suggestion, and motivation for a person having ordinary skill in the art to substitute a single socket for the inner and outer sockets of Caspers '906. Takidani does not include the express teaching of Slemker, but specifically discloses a single-socket vacuum socket that maintains vacuum in the socket cavity while the prosthesis is being worn by the patient by use of an operating switch to control a pump attached to the socket cavity.

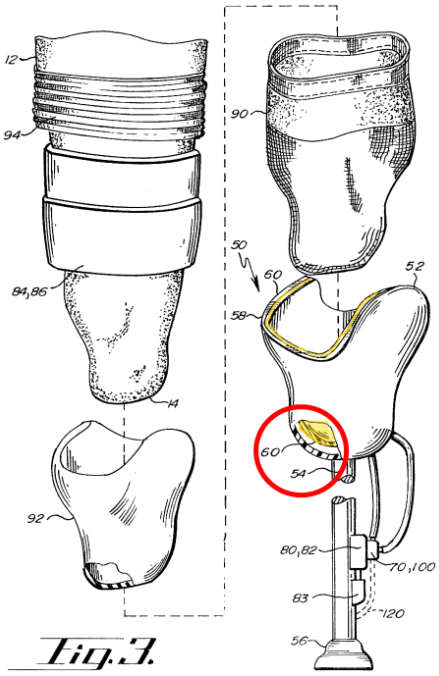
For at least these reasons, Caspers '208, Slemker, and Takidani emphasize the obviousness of using a single-socket with the vacuum socket of Caspers '906 in different ways, and petitioner believes separate grounds of unpatentability based on each reference are justified and appropriate. *See* Ex. 1001 ¶¶ 143, 164.

C. A Person Of Ordinary Skill In The Art Would Have Combined The Teachings Of Caspers '906 With Those Of Either Caspers '208, Slemker, Or Takidani

Caspers' prior patent applications demonstrate that he was well aware of single-socket vacuum sockets to suspend residual limbs by a total contact, equal weight distribution relationship between the limb, liner, and socket. Indeed, Caspers '208 discloses a near-identical socket, liner, sheath, and sleeve combination as Caspers '906, with a single socket instead of inner and outer sockets. Ex. 1001 ¶¶ 143-46.



Caspers '208
(single socket circled)



Caspers '906
(double socket circled)

Further, as explained by Dr. Gard, a person having ordinary skill in the art at the time of the claimed inventions would have been aware of single-socket vacuum sockets as an alternative to the inner and outer sockets of the Caspers '906 vacuum socket. Ex. 1001 ¶¶ 136-163. Otto Bock's purported technical expert in the Litigation also admits that "single socket prostheses are by far the most common

socket design being used today by lower limb prosthesis users, and that their usage in 1999 was similar or comparable." Ex. 1032 at 26:1-3.

Slemker would have also provided an express teaching, suggestion, and motivation for a person having ordinary skill in the art to substitute a single socket for the inner and outer sockets of Caspers '906. Slemker identifies several disadvantages of double-socket configurations in vacuum sockets, including alignment problems when replacing an inner socket and the long profile created by double sockets that can interfere with an amputee's range of movement:

> Another disadvantage with the above valve systems is the requirement of the two sockets. Besides the added time and expense of creating an inner socket in the first place, if the inner socket needs to be re-fabricated due to damage or needs to be re-fitted due to a change in the limb dimensions, the hole on the outer socket for the valve may no longer align with the valve projection protruding from the inner socket. Furthermore, two sockets can give the prosthesis a long profile; thus if the amputation is immediately above the knee, the prosthesis may undesirably extend the thigh portion beyond where the knee joint should be.

Ex. 1009 at Col. 2:29-39; Ex. 1001 ¶¶ 143, 151-53, 164.

Takidani provides evidence that a person having ordinary skill in the art would have recognized and understood that a single socket could be used with vacuum sockets that maintain vacuum in the socket cavity, such as the vacuum sockets of Caspers '906 and the '726 patent. Ex. 1001 ¶¶ 143, 155-57, 164.

Further, a person having ordinary skill in the art at the time of the alleged inventions would have understood that the inner and outer socket of the Caspers '906 vacuum socket could be replaced with a single socket without compromising the purported benefits of the Caspers '906 vacuum socket. Ex. 1001 ¶¶ 159-63. Caspers admits in the '726 patent that "single socket[s] work equally well or better

than two sockets" in the vacuum socket of the '709 patent (an application in the priority chain of Caspers '906). Ex. 1006 at Col. 4:20-28; *id.* ¶¶ 160-62. It would also have been obvious for a person having ordinary skill in the art to try a single socket with the vacuum socket of Caspers '906 to accommodate amputee preferences for single sockets. Ex. 1001 ¶ 163. As noted recently by the patent examiner during prosecution of the currently pending '982 application, single sockets "w[ere] clearly prevalent in the art . . . and there would have been plenty of motivation to provide ubiquitous, inexpensive, and/or factory-made alternatives that are more familiar to amputees and prosthetists." Ex. 1018 at 296. Indeed, replacing double sockets with a single socket "would have been an ***obvious step backward[s]***." *Id.* at 295-96 (emphasis added).

D. <u>Haberman Teaches Solid Ring Seals To Seal Socket Cavities</u>

Haberman is a 1995 article in the prominent Journal of Prosthetics & Orthotics that describes several liner-based structures to improve suction in vacuum socket cavities. Ex. 1011 at 1. The Haberman article is prior art under 35 U.S.C. § 102(b).

1. <u>The urethane Haberman "Ring" is structurally identical to the narrow urethane ring "annular seal"</u>

One of the seal structures described in Haberman, the "Ring," is a silicone or urethane liner modified to include a solid ring around the liner with a rectangular cross section and narrow vertical width of 4 cm (~1.5"). Ex. 1011 at 8. Haberman evaluated both silicone and urethane material for this "Ring." *Id.* at 12. The narrow "Ring" fully contacts the socket. *Id.* at 8, 14. The "Ring" structure

"maintain[s] a positive seal" between the limb and liner and the socket, even though it is not fully airtight. *Id.* Thus, the urethane Haberman "Ring" is structurally identical to the narrow urethane ring "annular seal" of the '726 patent. Ex. 1001 ¶¶ 170-73.

2. **The silicone Haberman "Ring" is structurally equivalent to the narrow nonfoamed, nonporous polyurethane ring "annular seal"**

Haberman also discloses a variant of the urethane "Ring" constructed of an injection-molded-silicone material. Ex. 1011 at 8-9. This silicone Haberman "Ring" is structurally *equivalent* to the narrow nonfoamed, nonporous polyurethane ring "annular seal" because it performs the same function of "sealing the socket cavity" in substantially the same way to achieve substantially the same result. Ex. 1001 ¶¶ 174-80.

For example, in the same way as the narrow ring "annular seal" of the '726 patent, the narrow silicone "Ring" seals the cavity by fully contacting the socket, "sealingly engag[ing]" and closing the gap between the liner and socket with a rectangular cross section shape. *Id.* ¶ 175. The solid and non-hollowed construction of the "Ring" resists deformation at a consistent level regardless of where and from what direction pressure is exerted against its outer and inner surfaces, allowing the "Ring" to maintain a suction seal and sufficient "holding force" at different positions of the limb and the socket, with or without additional structures contributing to the socket cavity seal. *Id.*; Ex. 1011 at 8-9. The "Ring" fully contacts the socket using a smooth outer surface with no irregularities in shape that could cause (1) small spatial gaps between the "Ring" and the socket, or

(2) areas of the outer surface where the "Ring" does not exert much pressure against the socket. Ex. 1011 at 8-9; Ex. 1001 ¶ 175. The solid, non-hollowed construction of the "Ring," together with its smooth outer surface and absence of irregular or curved shapes at its outer corners, minimizes vertical "pistoning" movement and potential loss of outer "Ring" surface contact with the socket, helping to maintain suction suspension in the cavity during walking and other movement. *Id.* Though the "high tear strength, high-grade silicone" material of the "Ring" is not identical to nonfoamed, nonporous polyurethane, in the same way it achieves "[e]xcellent silicone suction" at the point where it contacts the socket. Ex. 1011 at 4, 8-9, 11-12; Ex. 1001 ¶ 175. The silicone also "exhibit[s] flexibility and high elasticity," which allows the "Ring" to "absorb and dissipate[] shock [and] mechanical and shear forces typically associated with ambulation" in the same way as nonfoamed, nonporous polyurethane, thereby helping to maintain suction suspension in the cavity while walking. *Id.*; *see* Ex. 1004 at Col. 7:5-7.

Similarly, the narrow silicone Haberman "Ring" achieves the same result as the narrow nonfoamed, nonporous polyurethane ring "annular seal" of the '726 patent. Both the silicone "Ring" and the polyurethane "annular seal" prevent the "compromise of skin integrity" at the seal. Ex. 1011 at 8; Ex. 1004 at Col. 13:11-14; Ex. 1001 ¶ 176. Although neither the "Ring" nor the "annular seal" are fully airtight, they both maintain suction suspension and sufficient "holding force" of the liner within the cavity, with or without additional structures contributing to the socket cavity seal. Ex. 1011 at 8; Ex. 1004 at Col. 4:29-33; Ex. 1001 ¶ 176.

As demonstrated by Haberman, the use of a structure identical and/or

equivalent to the narrow ring "annular seal" of the '726 patent was well-known by the 1999 time frame. Ex. 1001 ¶¶ 168-80. Indeed, the narrow "Ring" of Haberman appears to be based on a liner from Caspers' own company at the time, TEC. Ex. 1011 at 8; Ex. 1001 ¶ 170. Haberman provides a teaching, suggestion, and motivation to a person having ordinary skill in the art to employ either a narrow urethane or silicone "Ring"—which are structurally identical and structurally equivalent to the narrow urethane and narrow nonfoamed, nonporous, polyurethane ring "annular seals" of the '726 patent, respectively—to seal the cavity between a liner and a single socket of either Caspers '208, Slemker, or Takidani, in the Caspers '906 vacuum socket. Ex. 1001 ¶¶ 168-80, 220-22, 224.

X. PROPOSED REJECTIONS

A. Claims 1-5, 7, 10-13, 16-17, And 19-23 Are Unpatentable Under 35 U.S.C. § 103(a) As Obvious Over Caspers '906 In View Of Either Caspers '208 (Ground 1), Slemker (Ground 3), Or Takidani (Ground 5)

As discussed in Section IX.A, *supra*, Caspers '906 discloses every limitation of the independent claims of the '726 patent except, arguably, for a "single socket." Further, Caspers '906 discloses every limitation of the dependent claims in Grounds 1, 3, and 5 except, arguably, for a single socket with "a single wall" (Claims 3 and 22). Other than one limitation in each of the independent claims and dependent Claims 3 and 22, the Claim Charts for Grounds 1, 3, and 5 are ***identical***. Instead of a *verbatim* repetition of disclosure by Caspers '906 for each Ground for Rejection, the Claim Charts herein incorporate multiple Grounds for Rejection where the proposed rejections differ between Grounds (*e.g.*, Claim 1(b), Claim 10(b), Claim 20(b), Claim 3, and Claim 22).

Claim 1	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
1. In an artificial limb for amputees who have a residual limb, an apparatus for managing residual limb volume, wherein application of a vacuum prevents loss of residual limb volume due to weight-bearing pressures and locks the residual limb to the artificial limb without causing swelling of the residual limb, the apparatus comprising:	Caspers '906 discloses a vacuum socket artificial limb for amputees who have a residual limb. Ex. 1006 at Col. 9:29-30; Ex. 1001 ¶ 127. The vacuum socket of Caspers '906 uses vacuum within the socket to lock the residual limb into the socket while preventing swelling of the residual limb into the socket. Ex. 1006 at Col. 4:63-67; Ex. 1001 ¶ 127. The vacuum within the socket also opposes the loss of fluids from the residual limb caused by weight-bearing pressures. Ex. 1006 at Col. 5:1-4; Ex. 1001 ¶ 133. This prevents the loss of residual limb volume. Ex. 1001 ¶ 133. For example, Caspers '906 teaches that the "vacuum source **70** may preferably maintain a vacuum in the range of 0 to 25 inches of mercury." Ex. 1006 at Col. 7:25-27. Thus, Caspers '906 discloses the range required to prevent loss of residual limb volume as indicated by Caspers in the '726 patent. Ex. 1001 ¶ 133; Ex. 1004 at Col. 14:22-25; *see also* Ex. 1005 at 213. *See* Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-83, 217.
(a) a flexible liner having a cavity with a volume less than that of the residual limb, whereby the liner is tensioned into a total contact relationship with the residual limb;	Caspers '906 discloses a nonfoamed, nonporous polyurethane liner receiving the residual limb that "readily tacks up to the skin of the residual limb 14 and provides total contact with the limb 14." Ex. 1006 at Col. 6:47-55; Ex. 1001 ¶ 128. *See* Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-83, 217.
(b) a single socket with a volume and shape to receive a substantial portion of the residual limb and the liner, the socket having a cavity adapted to receive the residual limb and the liner;	**<u>GROUND 1</u>: Caspers '906 in view of <u>Caspers '208</u>** Caspers '208 discloses a single-socket vacuum socket with a volume and shape to receive a substantial portion of the residual limb and the liner. *See* Figs. 21-24; Ex. 1001 ¶¶ 145-46. A "reduced positive model" of the residual limb and an enlarged "negative mold of the socket" are keyed together repeatedly "in the exact relationship[,] so that the liner may be repeatedly poured and shaped into the same shape" [as

Claim 1	Caspers '906 in view of either Caspers '208, Slemker, or Takidani
	the single socket]. Ex. 1008 at Cols. 7:6-65, 9:7-12; Ex. 1001 ¶ 146. After the liner and socket are fabricated, the residual limb is then fitted within the liner and the liner is placed in the socket so that the outer surface of the liner contacts the socket. Ex. 1008 at Cols. 11:2-3, 11:21-23; Ex. 1001 ¶ 146. After donning the "urethane liner," the amputee optionally dons a thin, nylon sheath over the liner. Ex. 1008 at Cols. 10:50-51, 10:60-62; Ex. 1001 ¶ 146. The sheath assists the amputee into a smooth and easy fitting into the single socket. Ex. 1008 at Col. 10:60-67; Ex. 1001 ¶ 146. A polyurethane sleeve on the upper portions of the limb rolls over and covers the outer portion of the socket, with its inside surface "tacking up" to the residual limb. Ex. 1008 at Cols. 10:47-59, 11:26-29, 11:42-45; Ex. 1001 ¶ 146. The outer surface of the liner contacts the socket to create a "total contact hypobaric suction, equal weight distribution socket liner" within the single socket. *See* Ex. 1008 at Cols. 3:32-35, 9:30-33, 11:21-23, Figs. 21-24; Ex. 1001 ¶ 146. *See* Sections VI.B, IX.B; *see also* Ex. 1001 ¶¶ 92, 94-97, 136-64, 181-85, 217. **<u>GROUND 3</u>: Caspers '906 in view of <u>Slemker</u>** Slemker discloses a vacuum socket with a single socket for receiving the residual limb of an amputee. *See* Ex. 1009 at Col. 6:40-42; Ex. 1001 ¶ 150. Before inserting the residual limb into the socket, the amputee rolls a silicone liner over the limb to protect the limb and provide a seal between the limb and the socket when the limb is tightly fitted in the socket. Ex. 1009 at Col. 5:53-58; Ex. 1001 ¶ 150. Operation of a pump mechanism attached to a valve at the bottom of the socket evacuates air from the socket and draws the limb and liner into the socket. Ex. 1009 at Col. 6:22-30; Ex. 1001 ¶ 150. The valve at the bottom of the socket is closed, forming vacuum suction in the socket to secure the socket to the amputee's residual limb and

Claim 1	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
	liner. *Id.* at Col. 3:39-45; Ex. 1001 ¶ 150. *See* Sections VI.B, IX.B; *see also* Ex. 1001 ¶¶ 92, 94-97, 136-64, 181-84, 186, 217. **<u>GROUND 5</u>: Caspers '906 in view of <u>Takidani</u>** Takidani discloses an artificial leg with a single socket. The socket has a suction valve at its lower end. Ex. 1010 at 10, Figs. 1, 3; Ex. 1001 ¶ 155. The residual limb is inserted "smoothly and tightly fitted" into the socket, and a pump attached to the socket evacuates air from the socket to ensure that the residual limb is tightly fitted into the socket's inner surface. Ex. 1010 at 10-11, Figs. 1, 3; Ex. 1001 ¶ 155. The amputee may don a "wrapping cloth" liner prior to inserting the limb into the socket. Ex. 1010 at 8, 11; Ex. 1001 ¶ 156. Using an operating switch, suction pressure of the pump can be adjusted, and vacuum in the socket can be maintained during walking. Ex. 1010 at 11 and Fig. 1; Ex. 1006 ¶ 155. *See* Sections VI.B, IX.B; *see also* Ex. 1001 ¶¶ 92, 94-97, 136-64, 181-84, 187, 217.
(c) a vacuum source connected to the socket cavity between the liner and the socket, wherein application of the vacuum source to the socket cavity draws the residual limb and liner into firm and total contact with the socket, thereby locking the residual limb to the socket without causing swelling of the residual limb into the socket;	Caspers '906 discloses a vacuum source connected to the socket between the liner and the socket by way of a vacuum valve and a vacuum tube. Application of the vacuum source "cause[s] the residual limb 14 to be drawn into firm contact with the inner surface 64 of the inner socket 60." Ex. 1006 at Col. 6:12-23 and Col. 3:61-63; Ex. 1001 ¶ 129. Further, enough vacuum is applied to draw the residual limb and its "optional coverings"—including the liner and the thin sheath—firmly against the socket. Ex. 1006 at Col. 7:22-25; Ex. 1001 ¶ 129. This locks the residual limb into the socket while preventing negative draw within the socket from causing swelling of the residual limb into the socket. Ex. 1006 at Col. 4:63-67; Ex. 1001 ¶ 129. *See* Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-83, 217.
(d) a seal means for	In view of the proper claim construction (*see supra*

Claim 1	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
sealing the socket cavity;	Section VIII.A), Caspers '906 discloses a nonfoamed, nonporous polyurethane suspension sleeve which rolls over and covers the outer socket and a portion of the residual limb, thereby sealing the socket cavity. Ex. 1006 at Cols. 6:30-34, 9:8-13; Ex. 1001 ¶ 130. *See* Sections VI.B, VIII.A, IX.A; *see also* Ex. 1001 ¶¶ 50-60, 70, 92-93, 99, 119-35, 181-83, 217.
(e) a means to maintain a vacuum in the socket cavity, in the presence of some air leakage past the seal means; and	In view of the proper claim construction (*see supra* Section VIII.A), Caspers '906 discloses a regulator means for controlling the vacuum source such as a digital computer or a vacuum regulator. Ex. 1006 at Col. 6:23-29; Ex. 1001 ¶ 131. The regulator causes the vacuum source to apply vacuum through the vacuum valve and vacuum tube to the cavity. The regulator causes the vacuum source to apply enough vacuum so that the residual limb—with any liners and/or sleeves—is drawn into firm contact with the socket. Further, the regulator causes the vacuum source to "maintain a vacuum [in the socket] in the range of 0 to 25 inches of mercury." Ex. 1006 at Col. 7:20-27; Ex. 1001 ¶ 131. As Caspers admitted: "It has been found that it is essentially impossible to maintain a perfect, airtight seal between the residual limb and the sockets disclosed in [Caspers '709], with the result that slow air leakage into the sockets diminishes vacuum in the sockets." Ex. 1004 at Col. 4:29-33; Ex. 1001 ¶ 130. Thus, air leakage is inherent in the vacuum socket disclosed in Caspers '906, which discloses the same means for sealing the socket cavity as Caspers '709. Ex. 1001 ¶ 130. *See* Sections VI.B, VIII.A, IX.A; *see also* Ex. 1001 ¶¶ 50-51, 61-70, 92-93, 99, 119-35, 181-83, 217.
(f) further comprising a thin sheath between the liner and the socket, to assist the even	Caspers '906 discloses a thin sheath between the liner and the inner socket. Ex. 1006 at Col. 7:3-9; Ex. 1001 ¶ 132. The thin sheath allows the vacuum to be evenly applied throughout the cavity. Ex. 1006 at Col.

Claim 1	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
distribution of vacuum in the cavity about the liner;	6:36-46; Ex. 1001 ¶ 132. *See* Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-83, 217.
wherein application of the vacuum source of the socket cavity prevents the loss of residual limb volume due to weight-bearing pressures.	Caspers '906 discloses that application of the vacuum source to the socket cavity opposes the loss of fluids from the residual limb caused by weight-bearing pressures. Ex. 1006 at Col. 5:1-4; Ex. 1001 ¶ 133. This prevents the loss of residual limb volume. Ex. 1001 ¶ 133. For example, Caspers '906 teaches that the "vacuum source **70** may preferably maintain a vacuum in the range of 0 to 25 inches of mercury." Ex. 1006 at Col. 7:25-27. Thus, Caspers '906 discloses the range required to prevent loss of residual limb volume as indicated by Caspers in the '726 patent. Ex. 1001 ¶ 133; Ex. 1004 at Col. 14:22-25 ("[I]t has been found that the residual limb loses only about 1% of its volume during the day" when the vacuum in the socket cavity is "at least about 10-25 inches of mercury."); *see also* Ex. 1005 at 213 ("limiting the loss of residual limb volume due to weight-bearing pressures to about 1% is believed to be inherent"). *See* Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-83, 217.

Claim 2	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
2. The apparatus of claim 1, wherein a vacuum of at least ten inches of mercury below ambient is maintained in the cavity.	Caspers '906 discloses a regulator means that maintains a vacuum of between 0 and 25 inches of mercury in the cavity. Ex. 1006 at Col. 7:25-27; Ex. 1001 ¶ 131. *See* Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-87, 194, 217.

Claim 3	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
3. The apparatus of claim 1, wherein the socket has a single wall.	**<u>GROUND 1</u>: Caspers '906 in view of <u>Caspers '208</u>** Caspers '208 discloses a single-socket vacuum socket with a single wall. *See, e.g.*, Ex. 1008 at Cols. 10:54-11:29; Figs. 21-24; Ex. 1001 ¶ 146. *See* Sections VI.B, IX.A, IX.B; *see also* Ex. 1001 ¶¶ 92, 94-97,

Claim 3	Caspers '906 in view of either Caspers '208, Slemker, or Takidani
	136-64, 181-85, 195, 217. **<u>GROUND 3</u>: Caspers '906 in view of <u>Slemker</u>** Slemker discloses a single-socket vacuum socket with a single wall. *See, e.g.*, Ex. 1009 at Col. 6:40-44, Fig. 1; Ex. 1001 ¶ 150. *See also* Sections VI.B, IX.A, IX.B; *see also* Ex. 1001 ¶¶ 92, 94-97, 136-64, 181-84, 186, 195, 217. **<u>GROUND 5</u>: Caspers '906 in view of <u>Takidani</u>** Takidani discloses a single-socket vacuum socket with a single wall. *See, e.g.*, Ex. 1010 at 10, Fig. 1; Ex. 1001 ¶ 155. *See* Sections VI.B, IX.A, IX.B; *see also* Ex. 1001 ¶¶ 92, 94-97, 136-64, 181-84, 187, 195, 217.

Claim 4	Caspers '906 in view of either Caspers '208, Slemker, or Takidani
4. The apparatus of claim 1, wherein the seal means further comprises a nonfoamed, nonporous polyurethane suspension sleeve for rolling over and covering the socket and a portion of the residual limb.	In view of the proper claim construction (*see supra* Section VIII.A), Caspers '906 discloses a nonfoamed, nonporous polyurethane suspension sleeve which rolls over and covers the outer socket and a portion of the residual limb, thereby sealing the socket cavity. Ex. 1006 at Cols. 6:30-34, 9:8-13; Ex. 1001 ¶ 130. See *Sections* VI.B, VIII.A, IX.A; see *also* Ex. 1001 ¶¶ 50-60, 70, 92-93, 99, 119-35, 181-87, 196, 217.

Claim 5	Caspers '906 in view of either Caspers '208, Slemker, or Takidani
5. The apparatus of claim 1, wherein the liner is of a nonfoamed, nonporous polyurethane.	Caspers '906 discloses a nonfoamed, nonporous polyurethane liner receiving the residual limb that "readily tacks up to the skin of the residual limb 14 and provides total contact with the limb 14." Ex. 1006 at Col. 6:47-55; Ex. 1001 ¶ 128. *See* Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-87, 197, 217.

Claim 7	Caspers '906 in view of either Caspers '208, Slemker, or Takidani
7. The	In view of the proper claim construction (*see supra* Section

Claim 7	Caspers '906 in view of either Caspers '208, Slemker, or Takidani
apparatus of claim 1, wherein the vacuum source is a vacuum pump and the means to maintain the vacuum in the cavity is a regulator, and further comprising a power source for the vacuum pump and the regulator.	VIII.A), Caspers '906 discloses that the vacuum source may be a vacuum pump. Ex. 1006 at Col. 6:13-14; Ex. 1001 ¶ 124. Caspers '906 also discloses a regulator means for controlling the vacuum source, such as a digital computer or a vacuum regulator. Ex. 1006 at Col. 6:23-29; Ex. 1001 ¶ 124. The regulator causes the vacuum source to apply vacuum through the vacuum valve and vacuum tube to the cavity. The regulator causes the vacuum source to apply enough vacuum so that the residual limb—with any liners and/or sleeves—is drawn into firm contact with the socket. Further, the regulator causes the vacuum source to "maintain a vacuum [in the socket] in the range of 0 to 25 inches of mercury." Ex. 1006 at Col. 7:20-27; Ex. 1001 ¶ 124. The regulator means is connected to a power source, which may be a battery. Ex. 1006 at Col. 6:24-29; Ex. 1001 ¶ 124. The vacuum pump is also connected to a power source, which may be a battery. Ex. 1006 at Col. 6:12-15; Ex. 1001 ¶ 124. *See* Sections VI.B, VIII.A, IX.A; *see also* Ex. 1001 ¶¶ 50-51, 61-70, 92-93, 99, 119-35, 181-87, 198, 217.

Claim 10	Caspers '906 in view of either Caspers '208, Slemker, or Takidani
10. In an artificial limb for amputees who have a residual limb, an apparatus for managing residual limb volume, the artificial limb having a socket, the socket having a cavity for insertion of the residual limb, wherein application of a vacuum to the cavity prevents loss of residual limb volume due to weight-bearing pressures and locks the residual limb to the socket without	Caspers '906 discloses a vacuum socket artificial limb for amputees who have a residual limb. Ex. 1006 at Col. 9:29-30; Ex. 1001 ¶ 127. A flexible inner socket has a cavity for with a volume and shape for receiving a substantial portion of the residual limb. Ex. 1006 at Col. 6:4-7; Ex. 1001 ¶ 123. The vacuum socket of Caspers '906 uses vacuum within the socket to lock the residual limb into the socket while preventing swelling of the residual limb into the socket. Ex. 1006 at Col. 4:63-67; Ex. 1001 ¶ 127. The vacuum within the socket also opposes the loss of fluids from the residual limb caused by weight-bearing pressures. Ex. 1006 at Col. 5:1-4; Ex. 1001 ¶ 133. This prevents the loss of residual limb volume. Ex. 1001 ¶ 133. For example, Caspers '906 teaches that the "vacuum source **70** may preferably maintain

Claim 10	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
causing swelling of the residual limb into the socket, the apparatus comprising:	a vacuum in the range of 0 to 25 inches of mercury." Ex. 1006 at Col. 7:25-27. Thus, Caspers '906 discloses the range required to prevent loss of residual limb volume as indicated by Caspers in the '726 patent. Ex. 1001 ¶ 133; Ex. 1004 at Col. 14:22-25; see also Ex. 1005 at 213. *See* Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-182, 199, 217.
(a) a flexible liner having a cavity with a volume less than that of the residual limb, whereby the liner is tensioned into a total contact relationship with the residual limb;	Caspers '906 discloses a nonfoamed, nonporous polyurethane liner receiving the residual limb that "readily tacks up to the skin of the residual limb **14** and provides total contact with the limb 14." Ex. 1006 at Col. 6:47-55; Ex. 1001 ¶ 128. *See* Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-82, 199, 217.
(b) a single socket with a single wall and with a volume and shape to receive a substantial portion of the residual limb and the liner, the socket having a cavity adapted to receive the residual limb and the liner;	**<u>GROUND 1</u>: Caspers '906 in view of <u>Caspers '208</u>** Caspers '208 discloses a single-socket vacuum socket with a volume and shape to receive a substantial portion of the residual limb and the liner. *See* Figs. 21-24; Ex. 1001 ¶¶ 145-46. The single socket has a single wall. *See, e.g.*, Ex. 1008 at Cols. 10:54-11:29; Figs. 21-25; Ex. 1001 ¶ 146. A "reduced positive model" of the residual limb and an enlarged "negative mold of the socket" are keyed together repeatedly "in the exact relationship[,] so that the liner may be repeatedly poured and shaped into the same shape" [as the single socket]. Ex. 1008 at Cols. 7:6-65, 9:7-12; Ex. 1001 ¶ 146. After the liner and socket are fabricated, the residual limb is then fitted within the liner and the liner is placed in the socket so that the outer surface of the liner contacts the socket. Ex. 1008 at Cols. 11:2-3, 11:21-23; Ex. 1001 ¶ 146. After donning the "urethane liner," the amputee optionally dons a thin, nylon sheath over the liner. Ex. 1008 at Cols. 10:50-51, 10:60-62; Ex. 1001 ¶ 146. The sheath assists the amputee into a smooth and easy fitting into the single socket. Ex. 1008 at

Claim 10	Caspers '906 in view of either Caspers '208, Slemker, or Takidani
	Col. 10:60-67; Ex. 1001 ¶ 146. A polyurethane sleeve on the upper portions of the limb rolls over and covers the outer portion of the socket, with its inside surface "tacking up" to the residual limb. Ex. 1008 at Cols. 10:47-59, 11:26-29, 11:42-45; Ex. 1001 ¶ 146. The outer surface of the liner contacts the socket to create a "total contact hypobaric suction, equal weight distribution socket liner" within the single socket. *See* Ex. 1008 at Cols. 3:32-35, 9:30-33, 11:21-23, Figs. 21-24; Ex. 1001 ¶ 146. *See* Sections VI.B, IX.B; *see also* Ex. 1001 ¶¶ 92, 94-97, 136-64, 181-82, 199-200, 217. **<u>GROUND 3</u>: Caspers '906 in view of <u>Slemker</u>** Slemker discloses a vacuum socket with a single socket for receiving the residual limb of an amputee. *See* Ex. 1009 at Col. 6:40-42; Ex. 1001 ¶ 150. The socket has a single wall. Ex. 1009 at Fig. 1, 12; Ex. 1001 ¶ 150. Before inserting the residual limb into the socket, the amputee rolls a silicone liner over the limb to protect the limb and provide a seal between the limb and the socket when the limb is tightly fitted in the socket. Ex. 1009 at Col. 5:53-58; Ex. 1001 ¶ 150. Operation of a pump mechanism attached to a valve at the bottom of the socket evacuates air from the socket and draws the limb and liner into the socket. Ex. 1009 at Col. 6:22-30; Ex. 1001 ¶ 150. The valve at the bottom of the socket is closed, forming vacuum suction in the socket to secure the socket to the amputee's residual limb and liner. *Id.* at Col. 3:39-45; Ex. 1001 ¶ 150. *See* Sections VI.B, IX.B; *see also* Ex. 1001 ¶¶ 92, 94-97, 136-64, 181-82, 199-200, 217. **<u>GROUND 5</u>: Caspers '906 in view of <u>Takidani</u>** Takidani discloses an artificial leg with a single socket. The socket has a single wall. *See, e.g.*, Ex. 1010 at 10, Fig. 1; Ex. 1001 ¶ 155. The socket has a

Claim 10	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
	suction valve at its lower end. Ex. 1010 at 10, Figs. 1, 3; Ex. 1001 ¶ 155. The residual limb is inserted "smoothly and tightly fitted" into the socket, and a pump attached to the socket evacuates air from the socket to ensure that the residual limb is tightly fitted into the socket's inner surface. Ex. 1010 at 10-11, Figs. 1, 3; Ex. 1001 ¶ 155. The amputee may don a "wrapping cloth" liner prior to inserting the limb into the socket. Ex. 1010 at 8, 11; Ex. 1001 ¶ 156. Using an operating switch, suction pressure of the pump can be adjusted, and vacuum in the socket can be maintained during walking. Ex. 1010 at 11 and Fig. 1; Ex. 1006 ¶ 155. *See* Sections VI.B, IX.B; *see also* Ex. 1001 ¶¶ 92, 94-97, 136-64, 181-82, 199-200, 217.
(c) a vacuum source connected to the socket cavity between the liner and the socket, wherein application of the vacuum source to the socket cavity draws the residual limb and liner into firm and total contact with the socket, thereby locking the residual limb to the socket without causing swelling of the residual limb into the socket; and	Caspers '906 discloses a vacuum source connected to the socket between the liner and the socket by way of a vacuum valve and a vacuum tube. Application of the vacuum source "cause[s] the residual limb 14 to be drawn into firm contact with the inner surface 64 of the inner socket 60." Ex. 1006 at Col. 6:12-23 and Col. 3:61-63; Ex. 1001 ¶ 129. Further, enough vacuum is applied to draw the residual limb and its "optional coverings"—including the liner and the thin sheath—firmly against the socket. Ex. 1006 at Col. 7:22-25; Ex. 1001 ¶ 129. This locks the residual limb into the socket while preventing negative draw within the socket from causing swelling of the residual limb into the socket. Ex. 1006 at Col. 4:63-67; Ex. 1001 ¶ 129. *See* Sections VI.B, IX.A; *see* also Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-82, 199, 217.
(d) a seal means for sealing the socket cavity;	In view of the proper claim construction (*see supra* Section VIII.A), Caspers '906 discloses a nonfoamed, nonporous polyurethane suspension sleeve which rolls over and covers the outer socket and a portion of the residual limb, thereby sealing the socket cavity. Ex. 1006 at Cols. 6:30-34, 9:8-13; Ex. 1001 ¶ 130. *See* Sections VI.B, VIII.A, IX.A; *see also* Ex. 1001 ¶¶ 50-60, 70, 92-93, 99, 119-35, 181-82, 199, 217.

Claim 10	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
wherein application of the vacuum source to the cavity also limits the loss of residual limb volume due to weight-bearing pressures to about 1%.	Caspers '906 discloses that application of the vacuum source to the socket cavity opposes the loss of fluids from the residual limb caused by weight-bearing pressures. Ex. 1006 at Col. 5:1-4; Ex. 1001 ¶ 133. This prevents the loss of residual limb volume. Ex. 1001 ¶ 133. For example, Caspers '906 teaches that the "vacuum source **70** may preferably maintain a vacuum in the range of 0 to 25 inches of mercury." Ex. 1006 at Col. 7:25-27. Thus, Caspers '906 discloses the range required to prevent loss of residual limb volume as indicated by Caspers in the '726 patent. Ex. 1001 ¶ 133; Ex. 1004 at Col. 14:22-25 ("[I]t has been found that the residual limb loses only about 1% of its volume during the day" when the vacuum in the socket cavity is "at least about 10-25 inches of mercury."); *see also* Ex. 1005 at 213 ("limiting the loss of residual limb volume due to weight-bearing pressures to about 1% is believed to be inherent"). *See* Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-82, 199, 217.

Claim 11	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
11. The apparatus of claim 10, further comprising a means to maintain vacuum in the cavity in the presence of some air leakage past the seal means.	In view of the proper claim construction (*see supra* Section VIII.A), Caspers '906 discloses a regulator means for controlling the vacuum source such as a digital computer or a vacuum regulator. Ex. 1006 at Col. 6:23-29; Ex. 1001 ¶ 131. The regulator causes the vacuum source to apply vacuum through the vacuum valve and vacuum tube to the cavity. The regulator causes the vacuum source to apply enough vacuum so that the residual limb—with any liners and/or sleeves—is drawn into firm contact with the socket. Further, the regulator causes the vacuum source to "maintain a vacuum [in the socket] in the range of 0 to 25 inches of mercury." Ex. 1006 at Col. 7:20-27; Ex. 1001 ¶ 131. As Caspers admitted: "It has been found that it is essentially impossible to maintain a perfect, airtight seal between the

Claim 11	Caspers '906 in view of either Caspers '208, Slemker, or Takidani
	residual limb and the sockets disclosed in [Caspers '709], with the result that slow air leakage into the sockets diminishes vacuum in the sockets." Ex. 1004 at Col. 4:29-33; Ex. 1001 ¶ 130. Thus, air leakage is inherent in the vacuum socket disclosed in Caspers '906, which discloses the same means for sealing the socket cavity as Caspers '709. Ex. 1001 ¶ 130. *See* Sections VI.B, VIII.A, IX.A; *see also* Ex. 1001 ¶¶ 50-51, 61-70, 92-93, 99, 119-35, 181-82, 199-200, 203-04, 217.

Claim 12	Caspers '906 in view of either Caspers '208, Slemker, or Takidani
12. The apparatus of claim 11, wherein a vacuum of at least ten inches of mercury is maintained in the cavity.	Caspers '906 discloses a regulator means that maintains a vacuum of between 0 and 25 inches of mercury in the cavity. Ex. 1006 at Col. 7:25-27; Ex. 1001 ¶ 131. See Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-82, 199-200, 203-05, 217.

Claim 13	Caspers '906 in view of either Caspers '208, Slemker, or Takidani
13. The apparatus of claim 11, wherein the vacuum source is a vacuum pump and the means to maintain the vacuum in the cavity is a regulator, and further comprising a power source for the vacuum pump and the regulator.	In view of the proper claim construction (*see supra* Section VIII.A), Caspers '906 discloses that the vacuum source may be a vacuum pump. Ex. 1006 at Col. 6:13-14; Ex. 1001 ¶ 124. Caspers '906 also discloses a regulator means for controlling the vacuum source, such as a digital computer or a vacuum regulator. Ex. 1006 at Col. 6:23-29; Ex. 1001 ¶ 124. The regulator causes the vacuum source to apply vacuum through the vacuum valve and vacuum tube to the cavity. The regulator causes the vacuum source to apply enough vacuum so that the residual limb—with any liners and/or sleeves—is drawn into firm contact with the socket. Further, the regulator causes the vacuum source to "maintain a vacuum [in the socket] in the range of 0 to 25 inches of mercury." Ex. 1006 at Col. 7:20-27; Ex. 1001 ¶ 124. The regulator means is connected to a power source, which may be a battery. Ex. 1006 at Col. 6:24-29; Ex. 1001 ¶ 124. The vacuum pump is also connected to a power source, which may be a battery. Ex. 1006 at Col. 6:12-15; Ex. 1001 ¶ 124. See *Sections* VI.B, VIII.A, IX.A; see *also* Ex. 1001 ¶¶ 50-51, 61-70, 92-93, 99,

Claim 13	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
	119-35, 181-82, 199-200, 203-04, 206, 217.

Claim 16	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
16. The apparatus of claim 10, wherein the seal means further comprises a nonfoamed, nonporous polyurethane suspension sleeve for rolling over and covering the socket and a portion of the residual limb.	In view of the proper claim construction (*see supra* Section VIII.A), Caspers '906 discloses a nonfoamed, nonporous polyurethane suspension sleeve which rolls over and covers the outer socket and a portion of the residual limb, thereby sealing the socket cavity. Ex. 1006 at Cols. 6:30-34, 9:8-13; Ex. 1001 ¶ 130. See *Sections* VI.B, VIII.A, IX.A; see *also* Ex. 1001 ¶¶ 50-60, 70, 92-93, 99, 119-35, 181-82, 199-200, 207, 217.

Claim 17	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
17. The apparatus of claim 10, wherein the liner is of a nonfoamed, nonporous polyurethane.	Caspers '906 discloses a nonfoamed, nonporous polyurethane liner receiving the residual limb that "readily tacks up to the skin of the residual limb 14 and provides total contact with the limb 14." Ex. 1006 at Col. 6:47-55; Ex. 1001 ¶ 128. *See* Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-82, 199-200, 208, 217.

Claim 19	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
19. The apparatus of claim 10, further comprising a thin sheath between the liner and the socket, to assist the even distribution of vacuum in the cavity about the liner.	Caspers '906 discloses a thin sheath between the liner and the inner socket. Ex. 1006 at Col. 7:3-9; Ex. 1001 ¶ 132. The thin sheath allows the vacuum to be evenly applied throughout the cavity. Ex. 1006 at Col. 6:36-46; Ex. 1001 ¶ 132. *See* Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-82, 199-200, 209, 217.

Claim 20	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
20. A method for preventing the loss of residual limb volume due to weight-bearing	Caspers '906 discloses a vacuum socket artificial limb for amputees who have a residual limb, and ways to prevent the loss of residual limb volume due to weight-bearing pressures. Ex. 1006 at Cols. 5:1-4,

Claim 20	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
pressures in an artificial limb, comprising the steps of:	9:29-30; Ex. 1001 ¶ 127. The vacuum within the socket opposes "the loss of fluids from the residual limb caused by weight-bearing pressures." Ex. 1006 at Col. 5:1-4; Ex. 1001 ¶ 133. This prevents the loss of residual limb volume. Ex. 1001 ¶ 133. For example, Caspers '906 teaches that the "vacuum source 70 may preferably maintain a vacuum in the range of 0 to 25 inches of mercury." Ex. 1006 at Col. 7:25-27. Thus, Caspers '906 discloses the range required to prevent loss of residual limb volume as indicated by Caspers in the '726 patent. Ex. 1001 ¶ 133; Ex. 1004 at Col. 14:22-25; *see also* Ex. 1005 at 213. *See* Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-82, 210, 217.
(a) inserting the residual limb into a flexible liner with a volume less than that of the residual limb, whereby the liner is tensioned into a total contact relationship with the residual limb;	Caspers '906 discloses a nonfoamed, nonporous polyurethane liner receiving the residual limb that "readily tacks up to the skin of the residual limb 14 and provides total contact with the limb 14." Ex. 1006 at Col. 6:47-55; Ex. 1001 ¶ 128. Caspers '906 discloses that the amputee may don the liner. Ex. 1006 at Col. 7:3-4; Ex. 1001 ¶ 123. *See* Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-82, 210, 217.
(b) inserting the residual limb and liner into a single socket having a volume and shape to receive the residual limb and the liner, the socket having a cavity into which the residual limb and liner are inserted;	**<u>GROUND 1</u>: Caspers '906 in view of <u>Caspers '208</u>** Caspers '208 discloses a single-socket vacuum socket with a volume and shape to receive a substantial portion of the residual limb and the liner. *See* Figs. 21-24; Ex. 1001 ¶¶ 145-46. A "reduced positive model" of the residual limb and an enlarged "negative mold of the socket" are keyed together repeatedly "in the exact relationship[,] so that the liner may be repeatedly poured and shaped into the same shape" [as the single socket]. Ex. 1008 at Cols. 7:6-65, 9:7-12; Ex. 1001 ¶ 146. After the liner and socket are fabricated, the residual limb is then fitted within the liner and the liner is placed in the socket so that the outer surface of the liner contacts the socket. Ex. 1008 at Cols. 11:2-3, 11:21-23; Ex. 1001 ¶ 146. After

Claim 20	Caspers '906 in view of either Caspers '208, Slemker, or Takidani
	donning the "urethane liner," the amputee optionally dons a thin, nylon sheath over the liner. Ex. 1008 at Cols. 10:50-51, 10:60-62; Ex. 1001 ¶ 146. The sheath assists the amputee into a smooth and easy fitting into the single socket. Ex. 1008 at Col. 10:60-67; Ex. 1001 ¶ 146. A polyurethane sleeve on the upper portions of the limb rolls over and covers the outer portion of the socket, with its inside surface "tacking up" to the residual limb. Ex. 1008 at Cols. 10:47-59, 11:26-29, 11:42-45; Ex. 1001 ¶ 146. The outer surface of the liner contacts the socket to create a "total contact hypobaric suction, equal weight distribution socket liner" within the single socket. *See* Ex. 1008 at Cols. 3:32-35, 9:30-33, 11:21-23, Figs. 21-24; Ex. 1001 ¶ 146. *See* Sections VI.B, IX.B; *see also* Ex. 1001 ¶¶ 92, 94-97, 136-64, 181-82, 210-11, 217. **<u>GROUND 3</u>: Caspers '906 in view of <u>Slemker</u>** Slemker discloses a vacuum socket with a single socket for receiving the residual limb of an amputee. *See* Ex. 1009 at Col. 6:40-42; Ex. 1001 ¶ 150. Before inserting the residual limb into the socket, the amputee rolls a silicone liner over the limb to protect the limb and provide a seal between the limb and the socket when the limb is tightly fitted in the socket. Ex. 1009 at Col. 5:53-58; Ex. 1001 ¶ 150. Operation of a pump mechanism attached to a valve at the bottom of the socket evacuates air from the socket and draws the limb and liner into the socket. Ex. 1009 at Col. 6:22-30; Ex. 1001 ¶ 150. The valve at the bottom of the socket is closed, forming vacuum suction in the socket to secure the socket to the amputee's residual limb and liner. *Id.* at Col. 3:39-45; Ex. 1001 ¶ 150. *See* Sections VI.B, IX.B; *see also* Ex. 1001 ¶¶ 92, 94-97, 136-64, 181-82, 210-11, 217. **<u>GROUND 5</u>: Caspers '906 in view of <u>Takidani</u>** Takidani discloses an artificial leg with a single

Claim 20	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
	socket. The socket has a suction valve at its lower end. Ex. 1010 at 10, Figs. 1, 3; Ex. 1001 ¶ 155. The residual limb is inserted "smoothly and tightly fitted" into the socket, and a pump attached to the socket evacuates air from the socket to ensure that the residual limb is tightly fitted into the socket's inner surface. Ex. 1010 at 10-11, Figs. 1, 3; Ex. 1001 ¶ 155. The amputee may don a "wrapping cloth" liner prior to inserting the limb into the socket. Ex. 1010 at 8, 11; Ex. 1001 ¶ 156. Using an operating switch, suction pressure of the pump can be adjusted, and vacuum in the socket can be maintained during walking. Ex. 1010 at 11 and Fig. 1; Ex. 1006 ¶ 155. *See* Sections VI.B, IX.B; *see also* Ex. 1001 ¶¶ 92, 94-97, 136-64, 181-82, 210-11, 217.
(c) sealing the socket cavity;	In view of the proper claim construction (*see supra* Section VIII.B), Caspers '906 discloses the step of rolling over and covering the outer socket and a portion of the residual limb with a nonfoamed, nonporous polyurethane suspension sleeve, thereby sealing the socket cavity. Ex. 1006 at Cols. 6:30-34, 9:8-13; Ex. 1001 ¶ 130. *See* Sections VI.B, VIII.B, IX.A; *see also* Ex. 1001 ¶¶ 71-81, 91-93, 99, 119-35, 181-82, 210, 217.
(d) applying a vacuum to the socket cavity between the liner and the socket, thereby drawing the residual limb and liner into firm and total contact with the socket;	Caspers '906 discloses a vacuum source connected to the socket between the liner and the socket by way of a vacuum valve and a vacuum tube. Application of the vacuum source "cause[s] the residual limb 14 to be drawn into firm contact with the inner surface 64 of the inner socket 60." Ex. 1006 at Col. 6:12-23 and Col. 3:61-63; Ex. 1001 ¶ 129. Further, enough vacuum is applied to draw the residual limb and its "optional coverings"—including the liner and the thin sheath—firmly against the socket. Ex. 1006 at Col. 7:22-25; Ex. 1001 ¶ 129. This locks the residual limb into the socket while preventing negative draw within the socket from causing swelling of the residual limb into the socket. Ex. 1006 at Col. 4:63-67; Ex. 1001 ¶

Claim 20	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
	129. *See* Sections VI.B, IX.A; *see* also Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-82, 210, 217.
(e) maintaining a vacuum in the socket cavity to at least ten inches of mercury below ambient, in the presence of some air leakage into the socket cavity; and	In view of the proper claim construction (*see supra* Section VIII.B), Caspers '906 discloses controlling the application of vacuum by the vacuum source with a regulator means, such as a digital computer or a vacuum regulator, thereby maintaining vacuum in the socket cavity to at least ten inches of mercury below ambient, in the presence of some air leakage into the socket cavity. *See*, *e.g.*, Ex. 1006 at Cols. 6:23-29, 7:20-27; Ex. 1001 ¶ 131. The regulator causes the vacuum source to apply vacuum through the vacuum valve and vacuum tube to the cavity. The regulator causes the vacuum source to apply enough vacuum so that the residual limb—with any liners and/or sleeves—is drawn into firm contact with the socket. Further, the regulator causes the vacuum source to "maintain a vacuum [in the socket] in the range of 0 to 25 inches of mercury." Ex. 1006 at Col. 7:20-27; Ex. 1001 ¶ 131. As Caspers admitted: "It has been found that it is essentially impossible to maintain a perfect, airtight seal between the residual limb and the sockets disclosed in [Caspers '709], with the result that slow air leakage into the sockets diminishes vacuum in the sockets." Ex. 1004 at Col. 4:29-33; Ex. 1001 ¶ 130. Thus, air leakage is inherent in the vacuum socket disclosed in Caspers '906, which discloses the same means for sealing the socket cavity as Caspers '709. Ex. 1001 ¶ 130. *See* Sections VI.B, VIII.B, IX.A; *see also* Ex. 1001 ¶¶ 71-76, 82-93, 99, 119-35, 181-82, 210, 217.
(f) opposing the loss of body fluids from the residual limb due to weight-bearing pressures, by means of	Caspers '906 discloses that vacuum within the socket draws the residual limb and its "optional coverings"—including the liner and the thin sheath—into firm contact with the inner socket, thereby opposing the loss of fluids from the residual limb caused by weight-

Claim 20	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
the total contact relationship of the liner with the residual limb and the vacuum drawing the liner into firm and total contact with the socket.	bearing pressures. Ex. 1006 at Col. 7:38-44; Ex. 1001 ¶¶ 129, 133. *See* Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-82, 210, 217.

Claim 21	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
21. The method of claim 20, wherein the liner is of a non-foamed, non-porous polyurethane.	Caspers '906 discloses a nonfoamed, nonporous polyurethane liner receiving the residual limb that "readily tacks up to the skin of the residual limb 14 and provides total contact with the limb 14." Ex. 1006 at Col. 6:47-55; Ex. 1001 ¶ 128. *See* Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-82, 210-11, 214, 217.

Claim 22	**Caspers '906 in view of either Caspers '208, Slemker, or Takidani**
22. The method of claim 20, wherein the socket has a single wall.	**<u>GROUND 1</u>: Caspers '906 in view of <u>Caspers '208</u>** Caspers '208 discloses a single-socket vacuum socket with a single wall. *See, e.g.*, Ex. 1008 at Cols. 10:54-11:29; Figs. 21-24; Ex. 1001 ¶ 146. *See* Sections VI.B, IX.A, IX.B; *see also* Ex. 1001 ¶¶ 92, 94-97, 136-64, 181-82, 210-11, 215, 217. **<u>GROUND 3</u>: Caspers '906 in view of <u>Slemker</u>** Slemker discloses a single-socket vacuum socket with a single wall. *See, e.g.*, Ex. 1009 at Col. 6:40-44, Fig. 1; Ex. 1001 ¶ 150. *See also* Sections VI.B, IX.A, IX.B; *see also* Ex. 1001 ¶¶ 92, 94-97, 136-64, 181-82, 210-11, 215, 217. **<u>GROUND 5</u>: Caspers '906 in view of <u>Takidani</u>** Takidani discloses a single-socket vacuum socket with a single wall. *See, e.g.*, Ex. 1010 at 10, Fig. 1; Ex. 1001 ¶ 155. *See* Sections VI.B, IX.A, IX.B; *see also* Ex. 1001 ¶¶ 92, 94-97, 136-64, 181-82, 210-11, 215, 217.

Claim 23	Caspers '906 in view of either Caspers '208, Slemker, or Takidani
23. The method of claim 20, further comprising the step of encasing the residual limb and the liner in a thin sheath to assist in the even distribution of vacuum about the liner.	Caspers '906 discloses a thin sheath between the liner and the inner socket. Ex. 1006 at Col. 7:3-9; Ex. 1001 ¶ 132. The thin sheath allows the vacuum to be evenly applied throughout the cavity. Ex. 1006 at Col. 6:36-46; Ex. 1001 ¶ 132. Caspers '906 further discloses, for example, that the amputee may encase the liner in the thin sheath before inserting the limb into the socket. Ex. 1006 at Col. 7:3-9; Ex. 1001 ¶ 123. *See* Sections VI.B, IX.A; *see also* Ex. 1001 ¶¶ 92-93, 99, 119-35, 181-82, 210-11, 216-17.

B. Claims 6 And 18 Are Unpatentable Under 35 U.S.C. § 103(a) As Obvious Over Caspers '906 In View Of Either Caspers '208 (Ground 2), Slemker (Ground 4), Or Takidani (Ground 6), And Haberman

Claim 6	Caspers '906 in view of either Caspers '208, Slemker, or Takidani, and Haberman
6. The apparatus of claim 1, wherein the seal means further comprises an annular seal between the liner and the socket.	In view of the proper claim construction (*see supra* Section VIII.A), Haberman discloses a narrow urethane ring with a rectangular cross section that fully contacts the liner and the socket. Ex. 1001 ¶¶ 168-73. In particular, Haberman discloses a urethane liner modified to include a solid ring around the liner with a rectangular cross section and narrow vertical width of 4 cm (~1.5"). Ex. 1011 at 8; Ex. 1001 ¶¶ 168-70. Haberman evaluated both silicone and urethane material for his "Ring." Ex. 1011 at 12; Ex. 1001 ¶ 172. The narrow "Ring" fully contacts the socket. Ex. 1011 at 8, 14; Ex. 1001 ¶ 173. The "Ring" structure "maintain[s] a positive seal" between the limb and liner and the socket, even though it is not fully airtight ("[a]ir still leaked around the grommet but did not interfere with suction suspension"). *Id.* Further, while the urethane variant of the Haberman "Ring" is structurally identical to the narrow urethane ring "annular seal" of the '726 patent, the preferred injection-molded-silicone "Ring" is also structurally *equivalent* to the narrow nonfoamed, nonporous polyurethane ring with a rectangular cross section that fully contacts the liner and the socket, because it performs the same function of "sealing the socket cavity" in substantially the same way to achieve

Claim 6	Caspers '906 in view of either Caspers '208, Slemker, or Takidani, and Haberman
	substantially the same result. Ex. 1001 ¶¶ 174-80. For example, in the same way as the narrow ring "annular seal" of the '726 patent, the Haberman "Ring" seals the cavity by fully contacting the socket, "sealingly engag[ing]" and closing the gap between the liner and socket with a rectangular cross section shape. *Id.* ¶ 175. The solid and non-hollowed construction of the "Ring" resists deformation at a consistent level regardless of where and from what direction pressure is exerted against its outer and inner surfaces, allowing the "Ring" to maintain a suction seal and sufficient "holding force" at different positions of the limb and the socket, with or without additional seal structures. *Id.*; Ex. 1011 at 8-9. The "Ring" fully contacts the socket using a smooth outer surface with no irregularities in shape that could cause (1) small spatial gaps between the "Ring" and the socket, or (2) areas of the outer surface where the "Ring" does not exert much pressure against the socket. Ex. 1011 at 8-9; Ex. 1001 ¶ 175. The solid, non-hollowed construction of the "Ring," together with its smooth outer surface and absence of irregular or curved shapes at its outer corners, minimizes vertical "pistoning" movement and potential loss of outer "Ring" surface contact with the socket, helping to maintain suction suspension in the cavity during walking and other movement. *Id.* Though the "high tear strength, high-grade silicone" material of the "Ring" is not identical to nonfoamed, nonporous polyurethane, in the same way it achieves "[e]xcellent silicone suction" at the point where it contacts the socket. Ex. 1011 at 4, 8-9, 11-12; Ex. 1001 ¶ 175. The silicone also "exhibit[s] flexibility and high elasticity," which allows the "Ring" to "absorb and dissipate[] shock [and] mechanical and shear forces typically associated with ambulation" in the same way as nonfoamed, nonporous polyurethane, thereby helping to maintain suction suspension in the cavity while walking. *Id.*; *see* Ex. 1004 at Col. 7:5-7. Similarly, the silicone Haberman "Ring" achieves the same result as the narrow nonfoamed, nonporous polyurethane ring "annular seal" of the '726 patent. Both the silicone "Ring" and the polyurethane "annular seal" prevent "the compromise of skin integrity" at the seal. Ex. 1011 at 8; Ex. 1004 at Col. 13:11-14; Ex. 1001 ¶ 176. Though neither the silicone "Ring" nor the polyurethane "annular seal" are fully airtight, they both maintain suction suspension and sufficient "holding force" of the liner within the cavity, with or without

Claim 6	Caspers '906 in view of either Caspers '208, Slemker, or Takidani, and Haberman
	additional structures contributing to the socket cavity seal. Ex. 1011 at 8; Ex. 1004 at Col. 4:29-33; *see* Ex. 1001 ¶ 176. *See supra* Sections VI.B, VIII.A, IX.A, I.X.D; *see also* Ex. 1001 ¶¶ 50-60, 70, 92-93, 98-99, 119-35, 181-87, 218-19, 217, 225.

Claim 18	Caspers '906 in view of either Caspers '208, Slemker, or Takidani, and Haberman
18. The apparatus of claim 10, wherein the seal means further comprises an annular seal between the liner and the socket.	See discussion and citations above in Claim 6. *See also* Ex. 1001 ¶¶ 199-200, 218, 223.

XI. SECONDARY CONSIDERATIONS, EVEN IF PRESENT, FAIL TO OVERCOME THE STRONG EVIDENCE OF OBVIOUSNESS

To overcome Össur's strong *prima facie* obviousness showing set forth above, Otto Bock may attempt to present alleged secondary considerations of nonobviousness. Although secondary considerations should be taken into account, they do not control the obviousness conclusion. *See Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988). In cases where a strong *prima facie* obviousness showing exists, the Federal Circuit has repeatedly held that even relevant secondary considerations supported by substantial evidence may not dislodge the primary conclusion of obviousness. *See, e.g.*, *Leapfrog Enters. Inc. v. Fisher-Price Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).

Össur addresses below the secondary considerations denominated as "unexpected results" and "commercial success." Össur reserves the right to supplement its positions regarding alleged secondary considerations as appropriate based on Otto Bock's potential arguments of purported non-obviousness and any alleged secondary considerations raised by Otto Bock or otherwise.

A. No Unexpected Results

The substitution of a single socket for the double-socket configuration in the vacuum socket of the Caspers '906 patent results in no change of the respective functions of each component. *See* Ex. 1001 ¶ 227. Caspers '208 demonstrates that single sockets could be used to achieve "total contact" suction suspension with the residual limb. Further, as stated in both Caspers '906 and the '726 patent, the vacuum socket, whether using a single- or double-socket configuration, "oppose[s] the loss of fluids from the residual limb caused by weight-bearing pressures." Ex. 1006 at Col. 5:2-4; Ex. 1004 at Col. 5:7-9. The straight-forward and obvious-to-try substitution of Caspers '906 with a single socket of either Caspers '208, Slemker, or Takidani, merely provides a single-socket configuration for the Caspers '906 vacuum socket. Ex. 1001 ¶ 227. Accordingly, the '726 patent fails to demonstrate any unexpected results from this ordinary and predictable combination of known prior art elements. *Id.* Thus, any purported advantages of the vacuum socket of the '726 patent would have been reasonably expected in view of the prior art. *Id.*

B. No Commercial Success

As discussed above, TEC and Otto Bock have sold vacuum sockets since at least the late 1990's. *See, e.g.*, Ex. 1026. Össur is unaware of any evidence that any alleged commercial success of such products has a nexus to the '726 patent's claims. Thus, any alleged commercial success would not support non-obviousness. *See, e.g, Syntex LLC v. Apotex, Inc.*, 407 F.3d 1371, 1383 (Fed. Cir. 2005).

XII. THE PROPOSED REJECTIONS RAISE NEW ISSUES IN WHICH ÖSSUR WILL LIKELY PREVAIL

An IPR petition must demonstrate "a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition." 35 U.S.C. § 314(a). This petition meets and exceeds that threshold. For at least the reasons explained herein, the alleged inventions of Claims 1-7, 10-13, and 16-23 of the '726 patent would have been obvious to a person having ordinary skill in the art at the time that the alleged inventions were made.[20]

This petition also addresses issues not previously considered by the patent examiner during examination of the application that became the '726 patent. For example, Caspers appears to have mischaracterized the disclosure of the Caspers '906 patent. Caspers stated unequivocally that "Caspers '906 does not disclose a means to maintain a vacuum in the socket cavity." Ex. 1005 at 221. However, Caspers '906 discloses a "regulator means 80 for controlling the vacuum source 70." *E.g.*, Ex. 1006 at Col. 6:24-26. In addition, in the pending Litigation between Össur and Otto Bock, Otto Bock and its purported expert witness recently acknowledged that the "means to maintain a vacuum" includes the "regulator means." Ex. 1028 at 27:14-19; Ex. 1031 at 7:22-25. Additionally, while Caspers '208, Slemker, and Takidani were of record during prosecution of the '726

---

[20] As discussed above, the examiner of the '726 patent has maintained in subsequent Caspers applications that the "single socket" limitation would not only have been obvious, but is also clearly anticipated by an embodiment disclosed in the Caspers '709 and Caspers '906 patents. Ex. 1018 at 316.

application, those references were not applied by the patent examiner. *See, e.g.*, Ex. 1005 at 77-78. Further, Caspers failed to provide the patent examiner with an English-language translation of Takidani, a reference originally published in the Japanese language. *Id.*

For at least these reasons, Össur is reasonably likely to prevail in challenging each of Claims 1-7, 10-13, and 16-23 of the '726 patent under 35 U.S.C. § 103 based on the prior art. Accordingly, this petition meets and exceeds the threshold requirements of 35 U.S.C. § 314(a).

XIII. CONCLUSION

Össur respectfully submits that this petition far exceeds the requisite showing of a reasonable likelihood that Claims 1-7, 10-13, and 16-23 of the '726 patent are unpatentable as obvious in view of the prior art. Thus, Össur requests that the Board grant *inter partes* review for each of those claims.

Össur authorizes the Patent and Trademark Office to charge any required fees, including the fee as set forth in 37 C.F.R. § 42.15(a) and any excess claim fees, to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: November 11, 2013

By: /Brenton R. Babcock/

Brenton R. Babcock (Reg. No. 39,592)
Nicholas M. Zovko (Reg. No. 61,557)
Customer No. 20,995
Attorneys for Petitioners
Össur hf and Össur Americas, Inc.
(949) 760-0404

CERTIFICATE OF SERVICE

I hereby certify that true and correct copies of the foregoing Össur hf and Össur Americas, Inc.'s Petition for Inter Partes Review of U.S. Patent No. 6,726,726 and Exhibits 1001-1040 were served on November 11, 2013, via FedEx Priority Overnight service to the correspondence address for the patent at issue, U.S. Patent No. 6,726,726:

Holland & Hart
222 South Main Street, Suite 2200
P.O. Box 11583
Salt Lake City, UT 84110

A courtesy copy was also served on counsel for the patent holder in the co-pending litigation captioned *Otto Bock HealthCare LP v. Össur hf and Össur Americas, Inc.*, Case No. SACV13-00891-CJC (ANx) (C.D. Cal.):

Charles S. Barquist
MORRISON & FOERSTER LLP
707 Wilshire Blvd.
Los Angeles, CA 90017-3543

Patricia A. Martone
Emily E. Huters
MORRISON & FOERSTER LLP
1290 Avenue of the Americas
New York, NY 10104-0050

Dated: November 11, 2013

/Brenton R. Babcock/
Brenton R. Babcock
Registration No. 39,592
Attorney for Petitioners
Össur hf and Össur Americas, Inc.

16255135