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Attorneys for Plaintiff
OTTO BOCK HEALTHCARE LP

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
SOUTHERN DIVISION

OTTO BOCK HEALTHCARE LP,

Plaintiff,

v.

ÖSSUR HF. and ÖSSUR AMERICAS,
INC.,

Defendants.

Case No. SACV13-891-CJC (ANx)

**FIRST AMENDED
COMPLAINT**

Plaintiff Otto Bock HealthCare LP ("Otto Bock"), by and through its attorneys, alleges for its Complaint against Össur Hf. and Össur Americas, Inc. (together, "Össur") as follows:

NATURE OF THE ACTION

Otto Bock brings this action to recover damages and obtain injunctive and other relief arising from Össur's infringement of Otto Bock's U.S Patent No.

ORIGINAL

FILED
2013 AUG -8 PM 12:42
CLERK U.S. DISTRICT COURT
CENTRAL DISTRICT OF CALIF.
SANTA ANA

1 6,726,726 B2 (the “’726 Patent”) and Össur’s breach of a settlement agreement
2 between Otto Bock and Össur Hf. reached in a previous federal district court action
3 brought by Otto Bock for infringement of the ’726 Patent (the “July 2012
4 Settlement Agreement”). Otto Bock is the owner and developer of patented
5 technology relating to vacuum-controlled artificial limb prosthetics. Otto Bock’s
6 claims arise out of Össur’s manufacture and offer for sale of vacuum pump systems
7 that infringe the ’726 Patent, and Össur’s corresponding breach of its agreement not
8 to make, use, sell, offer for sale, or import any products or goods that fall within the
9 claims of the ’726 Patent.

10 PARTIES

11 1. Plaintiff Otto Bock is a limited partnership organized and existing
12 under the laws of Minnesota, with its principal place of business in Minneapolis,
13 Minnesota. Otto Bock HealthCare GmbH, a parent company of Otto Bock, was
14 founded in Germany in 1919. Otto Bock HealthCare GmbH researches, designs,
15 develops, manufactures, and sells products to help people increase and retain their
16 physical independence, including unique and patented vacuum-controlled artificial
17 limb prosthetics. Otto Bock, which was founded in the United States in 1958, is the
18 leading manufacturer and distributor of vacuum-controlled artificial limb
19 prosthetics in the United States.

20 2. Upon information and belief, Defendant Össur Hf. is a corporation
21 organized and existing under the laws of Iceland, with a principal place of business
22 at Grjothals 5, Reykjavik 110, Iceland.

23 3. Upon information and belief, Defendant Össur Americas, Inc. is a
24 corporation organized and existing under the laws of the State of California, with a
25 principal place of business at 27501 Town Centre Drive, Foothill Ranch, California.
26 Upon information and belief, Össur Americas, Inc. is a wholly owned subsidiary of
27 Össur Hf.
28

JURISDICTION AND VENUE

4. This Court has jurisdiction over Otto Bock's claims for infringement of the '726 Patent arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has supplemental jurisdiction over Otto Bock's claims for breach of the July 2012 Settlement Agreement pursuant to 28 U.S.C. § 1367(a), because those claims are so related to Otto Bock's claim for infringement of the '726 Patent that they form part of the same case or controversy and derive from a common nucleus of operative facts.

6. This Court has personal jurisdiction over Össur Hf. because, on information and belief, Össur Hf. has sufficient contacts with this judicial district and Össur Hf. regularly conducts business within this judicial district. Upon information and belief, Össur Hf. directly or through its agents distributes, offers for sale or license, sells or licenses, and advertises its products and services within the State of California and this judicial district, has purposefully availed itself of the privileges and benefits of the laws of the State of California, and committed acts of patent infringement during the course of its business in this judicial district.

7. This Court has personal jurisdiction over Össur Americas, Inc. because it has its principal place of business in this judicial district.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c), and (d) and 1400(b).

OTTO BOCK'S CLAIMS OF INFRINGEMENT AND BREACH

The '726 Patent

9. In the late 1990s, Carl Caspers, the inventor of the '726 Patent, originated the idea of a vacuum-controlled artificial limb for amputees. Caspers, who is a transtibial amputee, was focused on developing improved prosthesis technology. He believed that such vacuum technology would address significant issues of comfort, prosthesis fit and safety experienced by amputees on a day-to-

1 day basis, including issues related to loss of residual limb volume due to weight-
2 bearing pressures.

3 10. Caspers continued his innovative work. He has been rewarded with
4 several United States patents, including the '726 Patent. On April 27, 2004, the
5 '726 Patent entitled "Vacuum Apparatus and Method for Managing Residual Limb
6 Volume in an Artificial Limb" was duly and legally issued by the United States
7 Patent and Trademark Office.

8 11. Caspers sought to commercialize his inventions and started his own
9 company, which became Caspers-Schneider Technologies, Inc. d/b/a TEC Interface
10 Systems, Inc. In 2003, Otto Bock agreed to buy the assets of TEC Interface,
11 including its patents. As part of that transaction, the application that led to the '726
12 Patent, then owned by TEC Interface, was assigned to Otto Bock, and the '726
13 Patent issued to Otto Bock U.S. Otto Bock is the sole owner by valid assignment of
14 all right and title to the '726 Patent. A true and correct copy of the '726 Patent is
15 attached as Exhibit 1.

16 12. The invention of the '726 Patent is incorporated into Otto Bock's
17 prostheses, the Harmony and Triton Harmony vacuum systems. These systems are
18 manufactured and sold in the United States by Otto Bock. The different Harmony
19 vacuum systems, including the Triton Harmony Foot/vacuum combination, have
20 achieved success in the marketplace and are considered one of the most beneficial
21 suspension-type prostheses for lower limb amputees.

22 ***The Prior Litigation***

23 13. On or about March 19, 2012, Otto Bock filed a complaint in the United
24 States District Court for the District of Utah, captioned *Otto Bock HealthCare LP v.*
25 *Evolution Industries, Inc.*, Case No. 2:12-cv-00267-DN (the "Prior Litigation"), for
26 infringement of the '726 Patent. The accused products were a vacuum-controlled
27 artificial limb prosthetics system. On information and belief, Össur Hf. is the
28 parent company and owner of Evolution Industries ("Evolution").

1 14. In or around July, 2012, Otto Bock and Össur Hf./Evolution agreed to
2 settle the Prior Litigation pursuant to the terms of the July 2012 Settlement
3 Agreement. In Article 6 of the July 2012 Settlement Agreement, Össur Hf. agreed
4 that, “for a period equating to the life of the [’726] Patent, it shall not, directly or
5 indirectly make, have made, use, sell, offer for sale, or import any products or
6 goods that fall within the claims of the [’726] Patent, as ultimately determined by a
7 court of law.”

8 15. In Article 6 of the July 2012 Settlement Agreement, Össur Hf. further
9 “acknowledge[d] the validity and enforceability of the [’726] Patent.” In the same
10 article, Össur Hf. agreed that should it subsequently contest the validity of the
11 patent, Otto Bock had the right: a) at its sole option and sole discretion, to
12 immediately terminate the accompanying license agreement attached to the
13 Agreement as Exhibit B, more fully described in paragraph 17 of this First
14 Amended Complaint, and b) to recover its reasonable attorney’s fees and costs in
15 defending against any unsuccessful challenge to the validity of the ’726 Patent.

16 16. The Parties to the July 2012 Settlement Agreement, including Össur
17 Hf., agreed that each would cause “all Affiliates to comply with the provisions of
18 this Agreement.” “Affiliates” was defined to include “subsidiaries.” Therefore, the
19 July 2012 Settlement Agreement is binding on Össur Americas.

20 17. Although Otto Bock also granted a license to Evolution, that license
21 was limited to specifically identified valve products. Further, Otto Bock expressly
22 stated that it did not grant “any express or implied, exclusive or nonexclusive,
23 license to Össur or any Össur Affiliate, customer or supplier of Össur....”

24 18. The July 2012 Agreement contained, in Article VI, mutual releases
25 that were contingent in part on “compliance with the obligations contained in this
26 Agreement.” The voluntary dismissal of the case by Otto Bock was made without
27 prejudice.

28 19. On or about March 8, 2013, Otto Bock filed a notice of voluntary

1 dismissal without prejudice in the Prior Litigation.

2 ***Össur's Infringement***

3 20. Upon information and belief, Össur Hf. and Evolution did cease
4 manufacturing the products at issue in the Prior Litigation. But notwithstanding its
5 agreement not to manufacture any vacuum pump system that infringes any claim of
6 the '726 Patent, following the July 2012 Settlement Agreement, Össur Hf. has
7 begun manufacturing new vacuum pump systems that infringe claims of the '726
8 Patent.

9 21. Upon information and belief, Össur Hf. is currently manufacturing and
10 selling and/or importing at least the following infringing products under its "Unity"
11 Vacuum System line: Unity Vacuum System for Re-Flex Rotate and Unity
12 Vacuum System for Re-Flex Shock (the "Unity Foot Products"), both of which are
13 sold together with Össur Hf.'s Iceross Seal-In V liner, and a valve kit containing a
14 Unity Valve.

15 22. Also upon information and belief, Össur Americas is importing, using,
16 offering for sale and/or selling since mid-April 2013 at least the following
17 infringing products: the Unity Foot Products, both of which are sold together with
18 Össur Hf.'s Iceross Seal-In V liner, and a valve kit containing a Unity Valve.

19 23. Beginning in or around September, 2012, Otto Bock GmbH and Össur
20 Hf. communicated regarding the '726 Patent and Össur Hf.'s Unity Foot Products
21 that it planned to introduce in the United States. Össur Hf. suggested that it had a
22 work-around of the '726 Patent but was open to a possible "collaboration." Össur
23 Hf. also provided a drawing of its proposed products, but it was insufficient to
24 compare to the claims of the '726 Patent. Otto Bock determined that this matter
25 was of such importance to its business that it had to investigate Össur's activities.
26 On May 3, 2013, Otto Bock placed an order for Össur's Unity Foot, valve, and
27 Iceross liner, and Össur shipped these products on May 7, 2013. Otto Bock
28 completed its investigation and filed a Complaint.

1 ***Össur's Repudiation of the July 2012 Settlement Agreement***

2 24. On June 12, 2013, Otto Bock filed the original Complaint in this
3 Action. The Complaint contained paragraphs 14-17 above, referring to terms of the
4 July 2012 Settlement Agreement.

5 25. On or about July 18, 2013, counsel for Össur wrote a letter to counsel
6 for Otto Bock, claiming that by filing the Complaint that referenced terms of the
7 July 2012 Settlement Agreement in paragraphs 14-17, Otto Bock had materially
8 breached that Agreement. Counsel for Össur claimed that this alleged material
9 breach "discharges Össur and Evolution of their previous duties and obligations
10 under the [July 2012] Settlement Agreement, which Össur deems to be no longer
11 effective."

12 26. On or about July 19, 2013, Össur filed its Answer and Counterclaims
13 in this Action. In its Answer and Counterclaims, Össur again took the position that
14 Otto Bock's filing of the original Complaint constituted a material breach of the
15 July 2012 Settlement Agreement that relieved Össur of its duties and obligations
16 under that Agreement. Össur further took the position that the July 2012 Settlement
17 Agreement was no longer effective.

18 27. Further, in the Aforesaid Answer and Counterclaims, Össur asserted a
19 Second Claim For Relief, seeking a declaratory judgment of the invalidity of one or
20 more claims of the '726 Patent. Pursuant to Article 6 of the Agreement, more fully
21 set forth in paragraph 15 and 17 above, this assertion gave Otto Bock the right, inter
22 alia, to terminate License Agreement to Evolution which is Exhibit B to the July
23 2012 Settlement Agreement.

24 **FIRST CAUSE OF ACTION**

25 ***Patent Infringement***

26 28. Otto Bock hereby realleges and incorporates by reference each and
27 every allegation set forth in paragraphs 1 through 27 above.

28 29. Otto Bock has not licensed or otherwise authorized either of the Össur

1 entities to use the '726 Patent to make, use, offer for sale, sell or import into the
2 United States the Unity Foot Products.

3 30. On information and belief, Össur Americas, Inc. has directly
4 infringed, and continued to directly infringe one or more claims of the '726 Patent
5 in violation of 35 U.S.C. § 271(a), by testing and demonstrating the aforesaid Unity
6 Foot Products to entities such as doctors, hospitals, rehabilitation centers,
7 prosthetists, and amputees.

8 31. On information and belief, Össur Hf. has had actual knowledge of the
9 '726 Patent since at least March 19, 2012, the date of the filing of the complaint for
10 infringement of the '726 Patent against its subsidiary, Evolution Industries, which
11 led to the July 2012 Settlement Agreement. Further, on information and belief,
12 Össur Americas, Inc. had had actual knowledge of the '726 Patent since in or about
13 July 2012, because the July 2012 Settlement Agreement required Össur Hf. to cause
14 its subsidiaries to comply with the terms of the Agreement, including without
15 limitation, the covenant not to infringe the '726 Patent.

16 32. On information and belief, the Össur entities have contributorily
17 infringed the '726 Patent and continue to contributorily infringe one or more claims
18 of the '726 Patent in the United States in violation of 35 U.S.C. § 271(c) by
19 importing, offering to sell and selling the aforesaid Unity Foot products, which are
20 material to practicing the invention of the '726 Patent, with knowledge that they are
21 especially made for use in the infringement of the '726 Patent, and are not staple
22 articles of commerce suitable for substantial noninfringing use.

23 33. On information and belief, Össur Hf. has actively induced and
24 continues to actively induce infringement of one or more claims of the '726 Patent
25 in the United States in violation of 35 U.S.C. § 271(b) by inducing a) Össur
26 Americas, Inc. to infringe claims of the '726 Patent by providing Unity Foot
27 Products and marketing and sales support to enable Össur Americas, Inc. to sell,
28 offer for sale and use in the United States Unity Foot Products, together with

1 Iceross Seal-In V liners, and valve kits containing Unity Valves and b) end-users to
2 directly infringe the '726 Patent in the United States by importing, selling and
3 offering for sale Unity Foot Products together with Iceross Seal-In V liners and
4 valve kits containing Unity Valves . Össur Hf. intentionally took the aforesaid
5 actions that induced Össur Americas, Inc. and end-users to directly infringe claims
6 of the '726 Patent. Össur Hf. has awareness of the '726 Patent and knew or was
7 willfully blind to the fact that its actions would cause direct infringement by end-
8 users.

9 34. On information and belief, Össur Americas, Inc. has actively induced,
10 and continues to actively induce end users of its Unity Foot Products to directly
11 infringe the '726 Patent in the United States in violation of 35 U.S.C. § 271(b) by
12 importing, selling and offering for sale Unity Foot Products together with Iceross
13 Seal-In V liners, and accompanying valve kits containing Unity Valves. Össur
14 Americas, Inc. intentionally took the aforesaid actions that induced end-users to
15 directly infringe claims of the '726 Patent. Össur Americas has awareness of the
16 '726 Patent and knew or was willfully blind to the fact that its actions would cause
17 direct infringement by end users.

18 35. Upon information and belief, the Össur entities' infringement of
19 claims of Otto Bock's '726 Patent has been and will continue to be willful, wanton
20 and deliberate.

21 36. Otto Bock is damaged and irreparably injured by Össur's infringing
22 activities and will continue to be so damaged and irreparably injured unless and
23 until Össur's infringing activities are enjoined by this court.

24 SECOND CAUSE OF ACTION

25 *Breach of Contract*

26 37. Otto Bock hereby realleges and incorporates by reference each and
27 every allegation set forth in paragraphs 1 through 35 above.

28 38. Otto Bock and Össur Hf. entered into a written contract referred to as

1 the July 2012 Settlement Agreement that, *inter alia*, resulted in the dismissal
2 without prejudice of the Prior Litigation.

3 39. The July 2012 Settlement Agreement is also binding on Össur
4 Americas, Inc. as an "Affiliate" of Össur Hf.

5 40. The July 2012 Settlement Agreement is a valid and enforceable
6 contract.

7 41. Otto Bock has performed its obligations under the July 2012
8 Settlement Agreement.

9 42. As set forth above, by their actions infringing claims of the '726
10 Patent, the Össur entities have breached their obligations under the July 2012
11 Settlement Agreement.

12 43. As a direct result of the Össur entities' breaches of the July 2012
13 Settlement Agreement, Otto Bock has suffered damages and other harm.

14 44. Otto Bock has suffered, and will continue to suffer, substantial and
15 irreparable damage to its position in the market, business reputation, and good will
16 for which Otto Bock has no adequate remedy at law, as well as losses in an amount
17 to be determined.

18 **THIRD CAUSE OF ACTION**

19 ***Breach of Contract***

20 45. Otto Bock hereby realleges and incorporates by reference each and
21 every allegation set forth in paragraphs 1 through 41 above.

22 46. As set forth in paragraph 26 above, because of the Össur entities'
23 actions in asserting a Second Claim For Relief of Invalidity of the '726 Patent,
24 Otto Bock now has the unfettered right to terminate the License Agreement to
25 Evolution which is Exhibit B to the July 2012 Settlement Agreement.

26 47. As set forth in paragraphs 23-25 above, by their actions repudiating the
27 July 2012 Settlement Agreement, the Össur entities have breached the July 2012
28 Settlement Agreement.

48. As set forth in paragraph 18 above, as a result of the breach by the Össur entities, Otto Bock may refile its patent infringement litigation against Evolution and may seek past damages. Össur and Evolution are also not entitled to the benefit of the Release of Article 6 of the Agreement.

49. As a direct result of the Össur entities' breach of the July 2012 Settlement Agreement, Otto Bock has suffered damages and other harm.

50. Otto Bock has suffered, and will continue to suffer, substantial and irreparable damage to its position in the market, business reputation, and good will for which Otto Bock has no adequate remedy at law, as well as losses in an amount to be determined.

PRAYER FOR RELIEF

WHEREFORE, Otto Bock prays for judgment as follows:

A. An entry of judgment that the '726 Patent is valid and enforceable;

B. An entry of judgment holding the Össur entities liable for infringement of one or more claims of the '726 Patent and for breach of the July 2012 Settlement Agreement;

C. An entry of judgment that the July 2012 Settlement Agreement is valid and enforceable;

D. An entry of judgment holding that Otto Bock did not breach the July 2012 Settlement Agreement by filing the Complaint in this action and that in any event, the conduct of Otto Bock about which Össur complains cannot qualify as a material breach sufficient to justify Össur's repudiation of that Agreement;

E. An entry of judgment holding that Otto Bock has the unfettered right to a) terminate the License Agreement which is Exhibit B to the July 2012 Settlement Agreement, and b) refile its case against Evolution for infringement of the '726 Patent and seek all past damages for Evolution's infringement, and that Össur and Evolution are not entitled to the benefit of the Release of Article 6 of the July 2012 Settlement Agreement.

1 F. An order preliminarily and permanently enjoining the Össur entities,
2 their officers, agents, representatives, employees, attorneys and affiliated
3 companies, their assigns and successors in interest, and those persons in active
4 concert or participation with them, from continued acts of infringement of the '726
5 Patent;

6 G. An order preliminarily and permanently enjoining the Össur entities,
7 their officers, agents, representatives, employees, attorneys and affiliated
8 companies, their assigns and successors in interest, and those persons in active
9 concert or participation with them, from continued actions in breach of the July
10 2012 Settlement Agreement;

11 H. An order awarding Otto Bock all damages adequate to compensate for
12 the Össur entities' infringement of the '726 Patent, and in no event less than a
13 reasonable royalty for the Össur entities' acts of infringement, and for breach of the
14 July 2012 Settlement Agreement, together with prejudgment and post-judgment
15 interest;

16 I. Trebling of damages under 35 U.S.C. § 284 in view of the willful and
17 deliberate nature of the Össur entities' infringement of the '726 Patent, together
18 with prejudgment and post-judgment interest;

19 J. Actual damages suffered by Otto Bock as a result of the Össur entities'
20 breach of the July 2012 Settlement Agreement, in an amount to be proven at trial,
21 together with prejudgment and post-judgment interest, and any attorney's fees and
22 costs recoverable under Article 6 of the July 2012 Settlement Agreement;

23 K. An order awarding Otto Bock its costs and attorney's fees pursuant to
24 35 U.S.C. § 285; and

25 L. Any and all other legal and equitable relief as may be available under
26 the law and which the Court may deem proper.

27 **DEMAND FOR A JURY TRIAL**

28 Otto Bock hereby demands a jury trial on all issues so triable under the law

1 as provided by Rule 38(b) of the Federal Rules of Civil Procedure.

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3 Dated: August 7, 2013

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14 Attorneys for Plaintiff
OTTO BOCK HEALTHCARE LP

Exhibit 1



US006726726B2

(12) **United States Patent**
Caspers

(10) Patent No.: **US 6,726,726 B2**
(45) Date of Patent: **Apr. 27, 2004**

(54) **VACUUM APPARATUS AND METHOD FOR MANAGING RESIDUAL LIMB VOLUME IN AN ARTIFICIAL LIMB**

(75) Inventor: Carl A. Caspers, Avon, MN (US)

(73) Assignee: Otto Bock Healthcare LP, Minneapolis, MN (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: 09/785,714

(22) Filed: Feb. 16, 2001

(65) Prior Publication Data

US 2001/0005798 A1 Jun. 28, 2001

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/492,406, filed on Jan. 27, 2000, now Pat. No. 6,508,842, which is a continuation-in-part of application No. 09/325,297, filed on Jun. 3, 1999, now abandoned, and a continuation-in-part of application No. 09/534,274, filed on Mar. 23, 2000, now Pat. No. 6,554,868, which is a continuation-in-part of application No. 09/325,297, filed on Jun. 3, 1999, now abandoned.

(51) Int. Cl.⁷ A61F 2/80

(52) U.S. Cl. 623/34

(58) Field of Search 623/34, 36, 37

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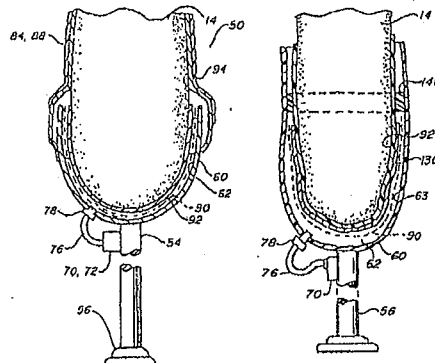
Primary Examiner—David H. Willse

(74) Attorney, Agent, or Firm—Faegre & Benson, LLP

(57) **ABSTRACT**

A hypobarically-controlled artificial limb for amputees includes a single socket with a volume and shape to receive a substantial portion of the residual limb. A liner with a volume less than the residual limb is donned over the residual limb, with the liner tensioned into a total contact relationship with the residual limb. A sealed cavity is formed between the socket and the liner. A vacuum source is connected to the socket cavity thereby drawing the residual limb and liner into firm and total contact with the socket. To compensate for some air leakage past the seal, there is a mechanism to maintain the vacuum in the cavity.

23 Claims, 11 Drawing Sheets



US 6,726,726 B2

Page 2

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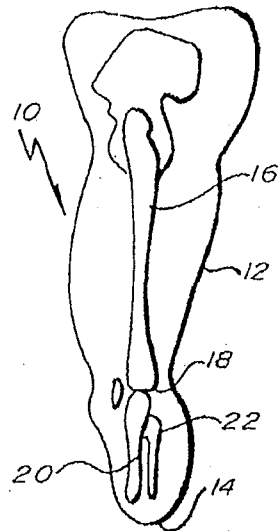


Fig. 1.

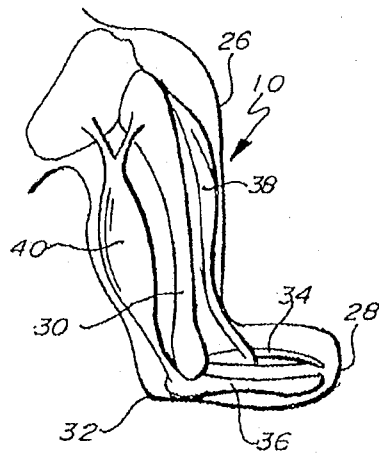


Fig. 2.

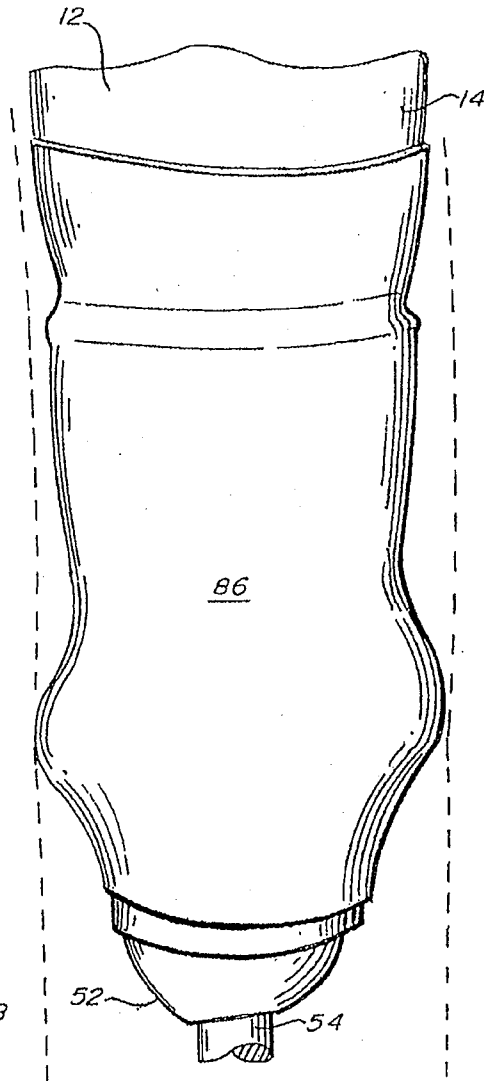


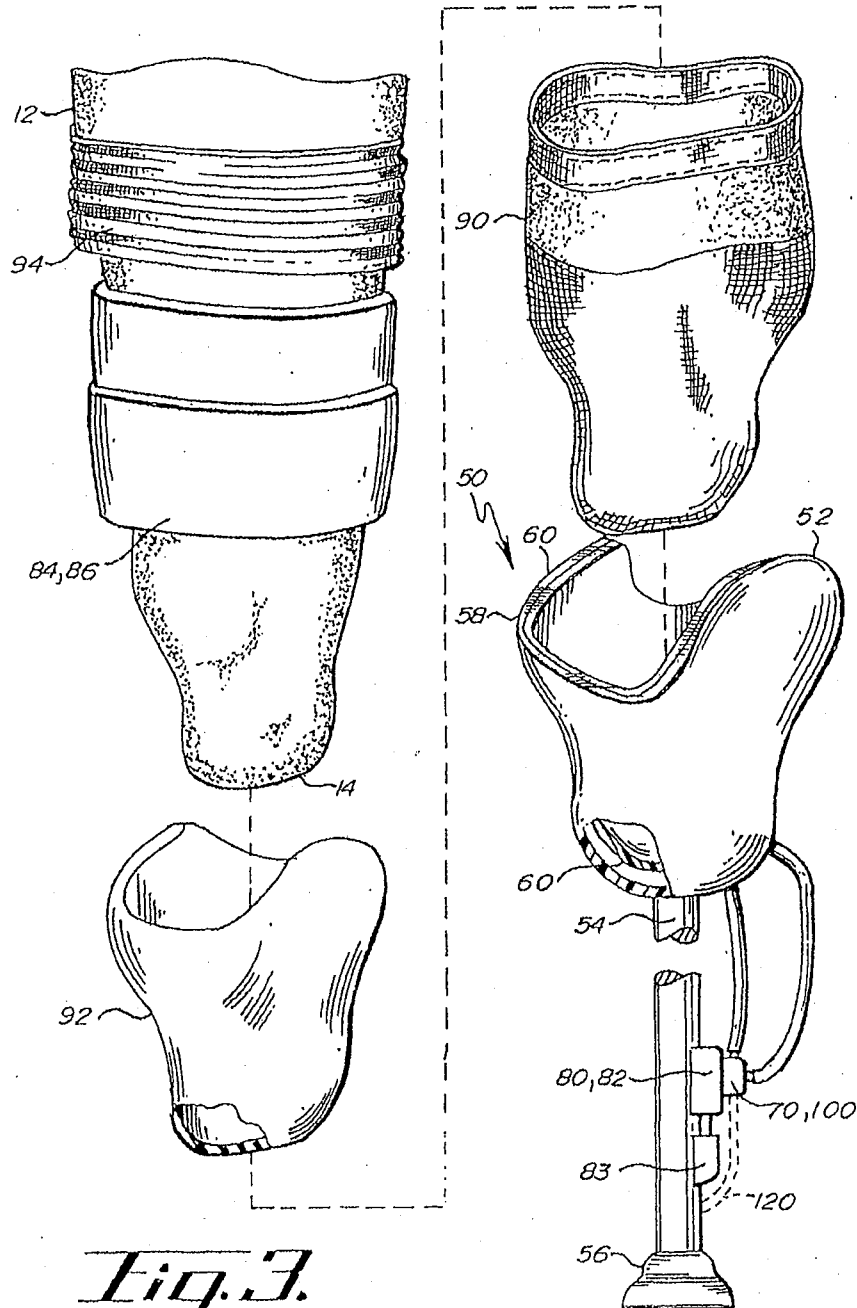
Fig. 3.

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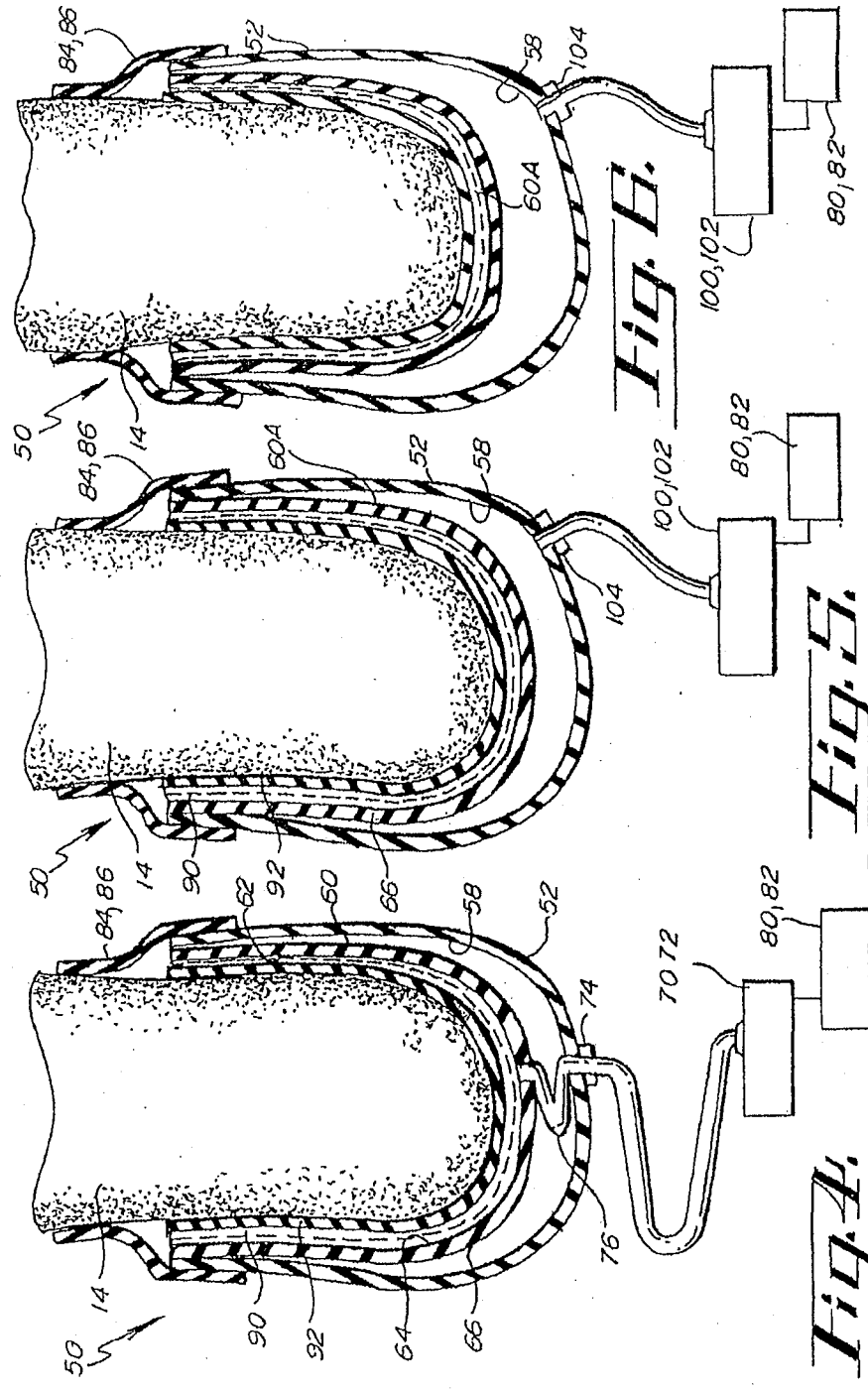


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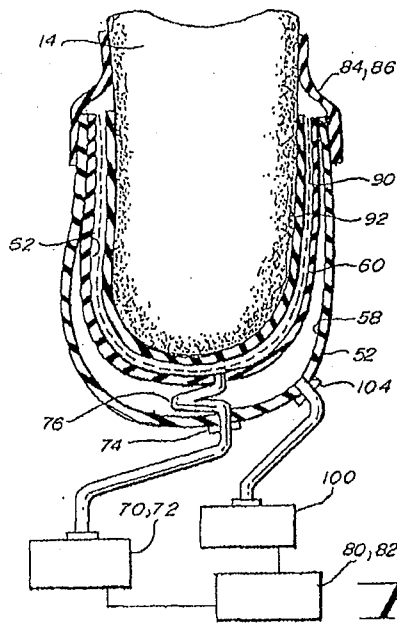


Fig. 7.

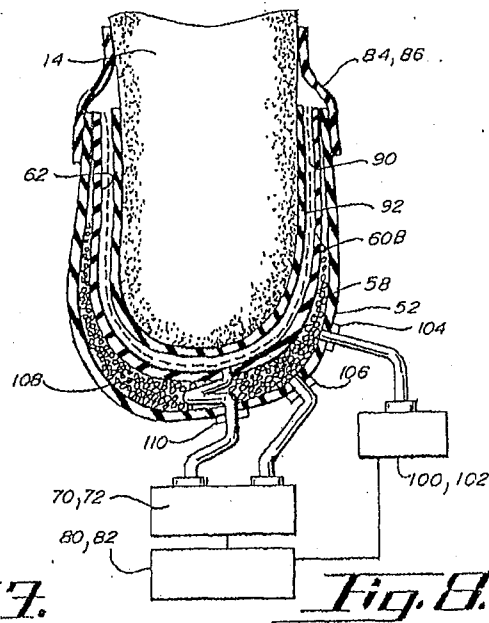


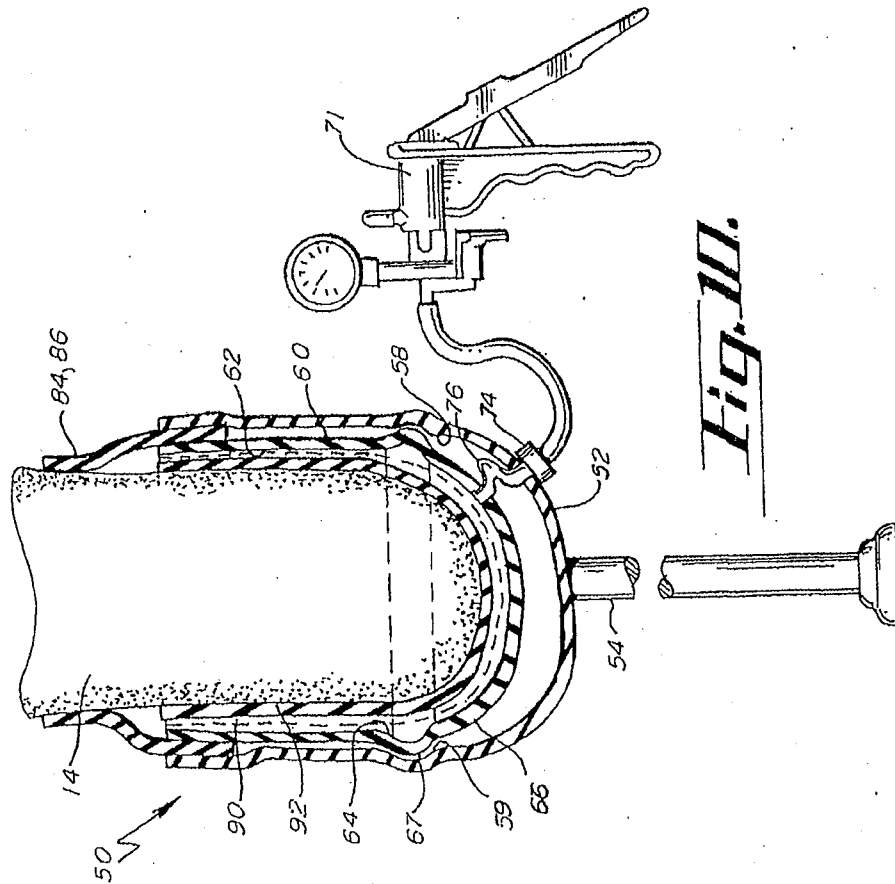
Fig. 8.

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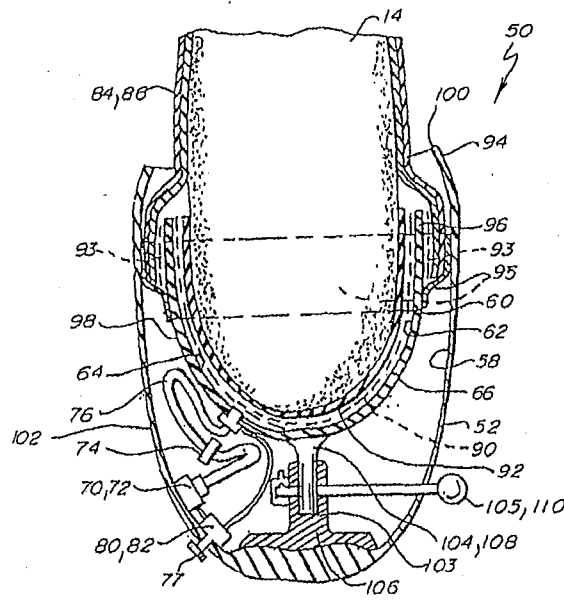


Fig. 11.

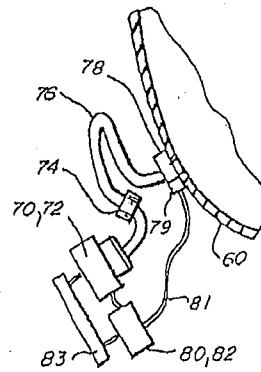


Fig. 12.

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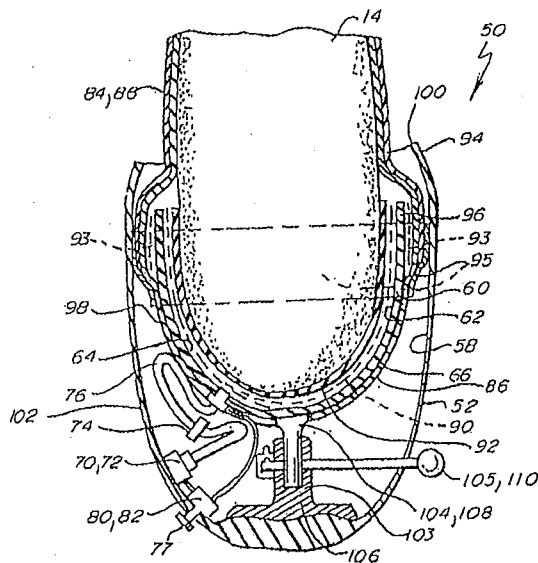


Fig. 13.

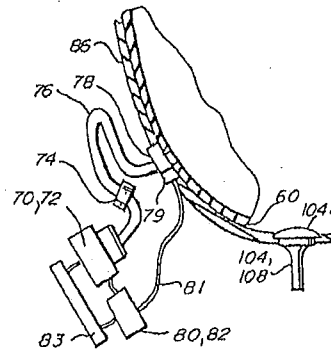


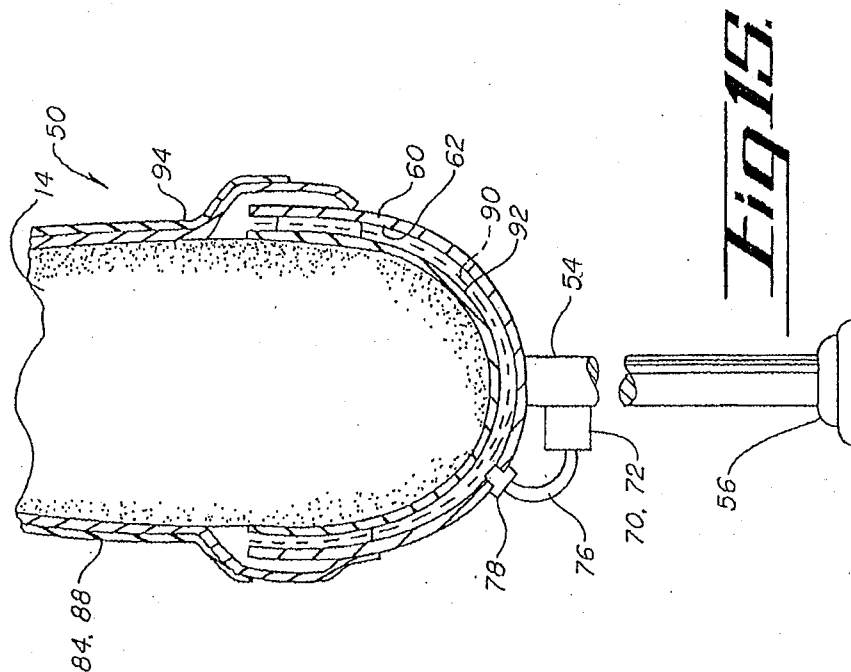
Fig. 14.

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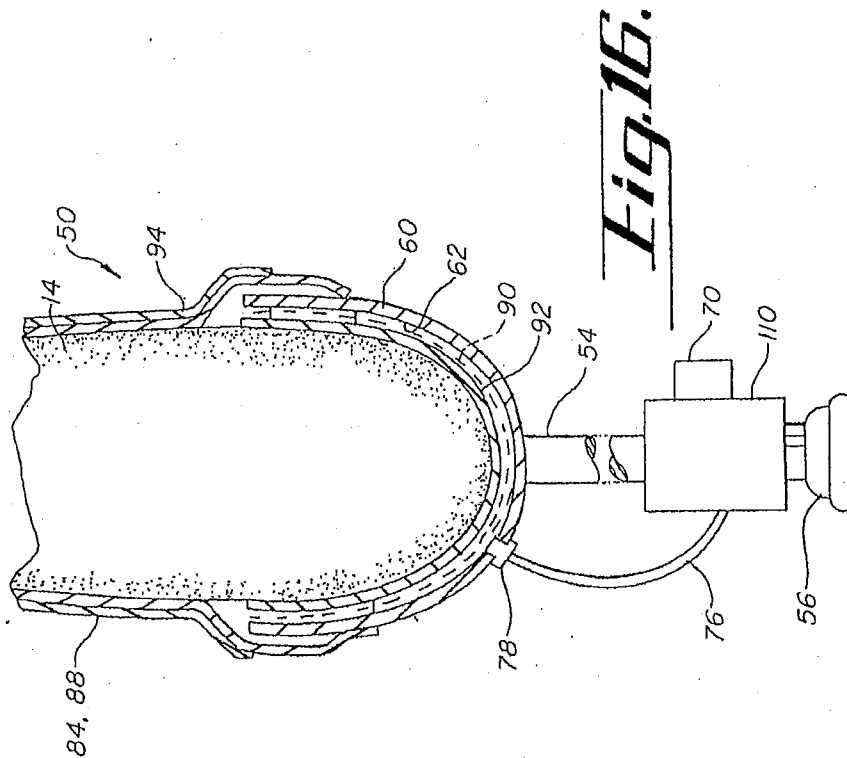


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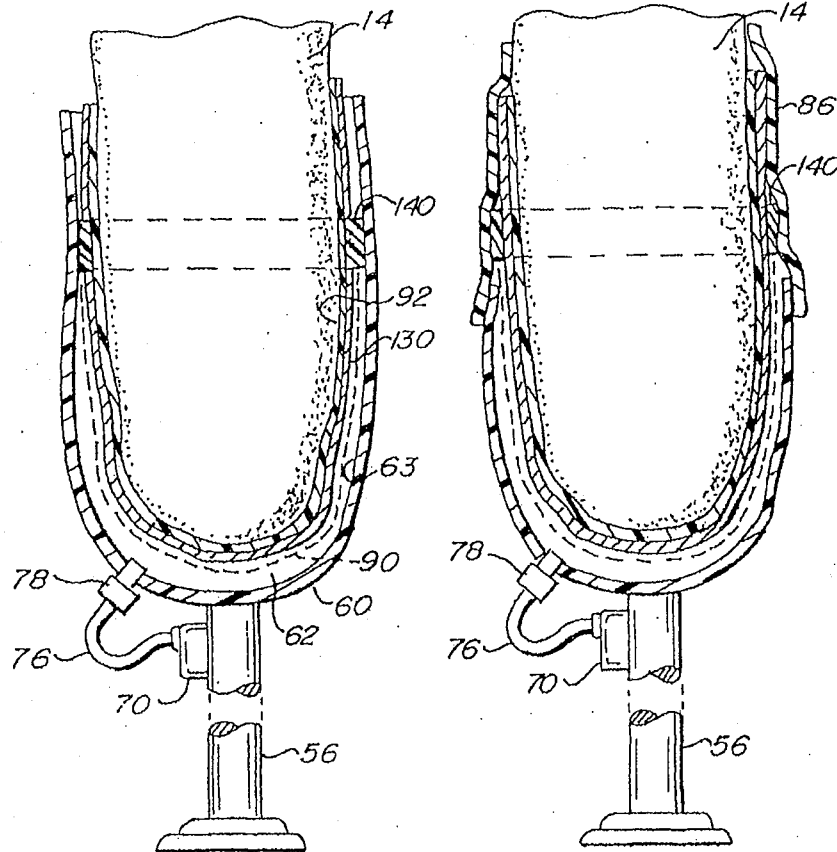


Fig. 18.

Fig. 17.

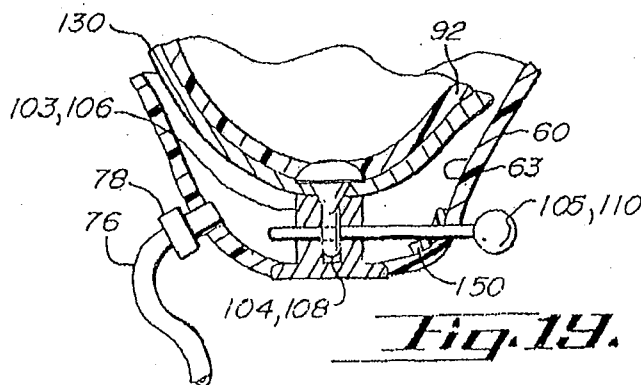


Fig. 19.

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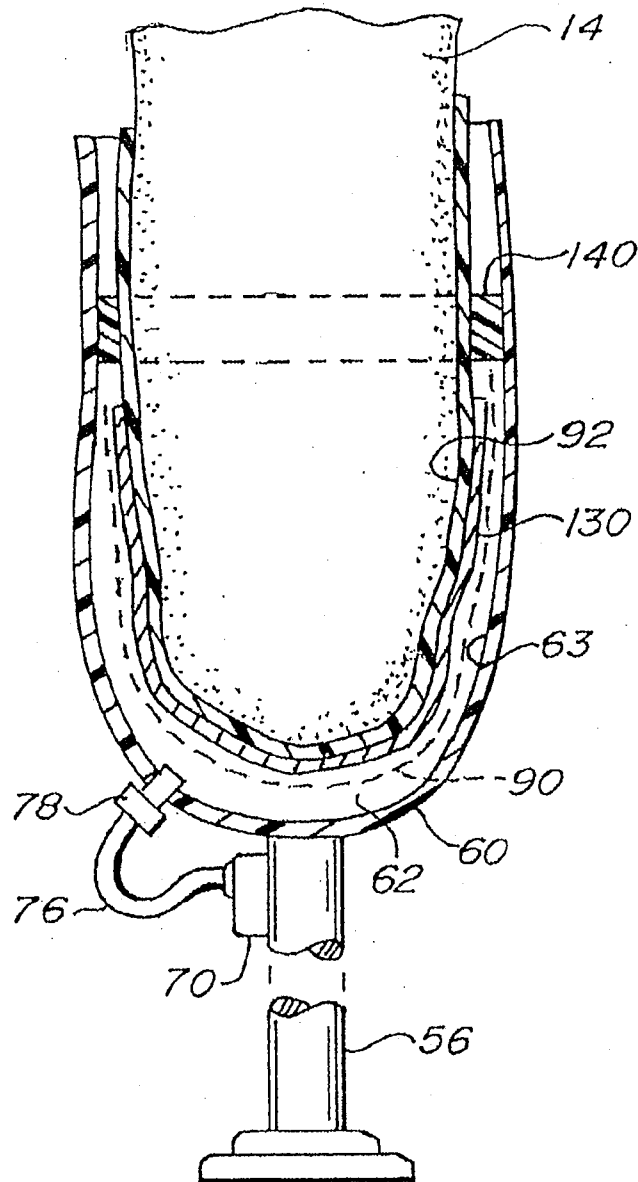


Fig. 20.

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VACUUM APPARATUS AND METHOD FOR MANAGING RESIDUAL LIMB VOLUME IN AN ARTIFICIAL LIMB

This application is a continuation-in-part of U.S. patent application Ser. No. 09/492,406, filed Jan. 27, 2000, which is a continuation-in-part of U.S. patent application Ser. No. 09/325,297, filed Jun. 3, 1999, now abandoned, and a continuation-in-part of U.S. patent application Ser. No. 09/534,274, filed Mar. 23, 2000, which is also a continuation-in-part of U.S. patent application Ser. No. 09/325,297, filed Jun. 3, 1999, now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to prosthetic devices and more particularly to a hypobarically-controlled artificial limb for amputees and to a method for preventing loss of residual limb volume due to weight-bearing pressures.

An amputee is a person who has lost part of an extremity or limb such as a leg or arm which commonly may be termed as a residual limb. Residual limbs come in various sizes and shapes with respect to the stump. That is, most new amputations are either slightly bulbous or cylindrical in shape while older amputations that may have had a lot of atrophy are generally more conical in shape. Residual limbs may further be characterized by their various individual problems or configurations including the volume and shape of a stump and possible scar, skin graft, bony prominence, uneven limb volume, neuroma, pain, edema or soft tissue configurations.

Referring to FIGS. 1 and 2, a below the knee residual limb 10 is shown and described as a leg 12 having been severed below the knee terminating in a stump 14. In this case, the residual limb 10 includes soft tissue as well as the femur 16, knee joint 18, and severed tibia 20 and fibula 22. Along these bone structures surrounded by soft tissue are nerve bundles and vascular routes which must be protected against external pressure to avoid neuromas, numbness and discomfort as well as other kinds of problems. A below the knee residual limb 10 has its stump 14 generally characterized as being a more bony structure while an above the knee residual limb may be characterized as including more soft tissue as well as the vascular routes and nerve bundles.

Referring to FIG. 2, amputees who have lost a part of their arm 26, which terminates in a stump 28 also may be characterized as having vascular routes, nerve bundles as well as soft and bony tissues. The residual limb 10 includes the humerus bone 30 which extends from below the shoulder to the elbow from which the radius 34 and ulna 36 bones may pivotally extend to the point of severance. Along the humerus bone 30 are the biceps muscle 38 and the triceps muscle 40 which still yet may be connected to the radius 34 and the ulna, 36, respectively.

In some respects, the residual limb amputee that has a severed arm 26 does not have the pressure bearing considerations for an artificial limb but rather is concerned with having an artificial limb that is articulable to offer functions typical of a full arm, such as bending at the elbow and grasping capabilities. An individual who has a paralyzed limb would also have similar considerations wherein he or she would desire the paralyzed limb to having some degree of mobility and thus functionality.

Historically, artificial limbs typically used by a leg amputee were for the most part all made out of wood such as an Upland Willow. The limbs were hand carved with sockets for receiving the stump 14 of the residual limb 10. Below the socket would be the shin portion with the foot below the

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shin. These wooden artificial limbs were covered with rawhide which often were painted. The sockets of most wood limbs were hollow as the limbs were typically supported in the artificial limb by the circumferential tissue adjacent the stump 14 rather than at the distal end of the stump 14.

Some artificial limbs in Europe were also made from forged pieces of metal that were hollow. Fiber artificial limbs were also used which were stretched around a mold after which they were permitted to dry and cure. Again, these artificial limbs were hollow and pretty much supported the residual limb about the circumferential tissue adjacent the stump 14.

All of these various artificial limbs have sockets to put the amputee's stump 14 therein. There are generally two categories of sockets. There are hard sockets wherein the stump goes right into the socket actually touching the socket wall without any type of liner or stump sock. Another category of sockets is a socket that utilizes a liner or insert. Both categories of sockets typically were opened ended sockets where they had a hollow chamber in the bottom and no portion of the socket touched the distal end of the stump 14. So, the stump was supported about its circumferential sides as it fits against the inside wall of the sockets.

These types of sockets caused a lot of shear force on the stump 14 as well as had pressure or restriction problems on the nerve bundles and vascular flow of fluid by way of the circumferential pressure effect of the socket on the limb. This pressure effect could cause a swelling into the ends of the socket where an amputee may develop severe edema and draining nodules at the end of their stump 14.

With time, prosthetists learned that by filling in the socket's hollow chamber and encouraging a more total contact with the stump and the socket, the swelling and edema problems could be eliminated. However, the problematic tissue configurations, such as bony prominences, required special consideration such as the addition of soft or pliable materials to be put into the socket.

Today, most artificial limbs are constructed from thermoset plastics such as polyester resins, acrylic resins, polypropylenes and polyethylenes, which are perhaps laminated over a nylon stockinette which also may be impregnated by the various resins.

In the past, most artificial limbs were suspended from the amputee's body by some form of pulley, belt or strap suspension often used with various harnesses and perhaps leather lacers or lacings. Another method of suspending artificial limbs is known as the wedge suspension wherein an actual wedge is built into the socket which is more closed at its top opening. The wedge in the socket cups the medial femoral condyle or knuckle at the abductor tubical. Yet another form of suspension is referred to as the shuttle system or a mechanical hookup or linkup wherein a thin suction liner is donned over the stump that has a docking device on the distal end which mechanically links up with its cooperative part in the bottom of the socket chamber. Sleeve suspensions were also used wherein the amputee may use a latex rubber tube which forms into a rubber-like sleeve which would be rolled on over both the top of the artificial limb and onto the amputee's thigh. The sleeve suspensions have been used in combination with other forms of suspensions techniques.

Both the use of a positive pressure system and the use of a negative pressure system (or hypobaric closed chamber) have been utilized in the field of prosthetics. At one time, for pressure systems "inflatable inner tubes" were used to fit

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into sockets. Presently, there are pneumatic "bags" which are strategically placed over what people consider to be good weight-bearing areas to increase pressure to help accommodate for volume changes within the socket.

The problem with this is that it is a very specific pressure and creates atrophy and loss of tissue dramatically over these high pressure areas. None of these systems employs positive pressure distributed over the total contact area between the residual limb and the artificial limb socket to accommodate volume changes within the socket.

The negative pressure aspects have been utilized for a closed chamber in that a socket is donned by pulling in with a sock, pulling the sock out of the socket and then closing the opening with a valve. This creates a seal at the bottom and the stump is held into the socket by the hypobaric seal.

The older systems were initially started in Germany. They were an open-ended socket, meaning there was an air chamber in the bottom of the socket. This did not work particularly well because it would cause swelling of the residual limb into the chamber created by the negative draw of suspending the weight of the leg and being under a confined area. This would lead to significance edema which would be severe enough to cause stump breakdown and drainage.

It was later discovered in America that total contact was essential between the residual limb and the socket and once you had total contact the weight was distributed evenly or the suspension was distributed over the whole surface of the limb rather than just over the open chamber portion of the socket.

The human body as a whole is under approximately one atmosphere of pressure at sea level. It keeps and maintains a normal fluid system throughout the body. When an amputee dons a prosthesis and begins taking the pressures of transmitting the weight of the body through the surface area of the residual limb to the bone, there is increased pressure on the residual limb equal to one atmosphere plus whatever additional pressures are created by weight bearing. This increased pressure causes the eventual loss of fluids within the residual limb to the larger portion of the body which is under less pressure. This loss of fluids causes the volume of the residual limb to decrease during the day. It varies from amputee to amputee, but it is a constant among all amputee and the more "fleshy" and the softer the residual limb, the more volume fluctuation there will be. The greater the weight and the smaller the surface area, the greater the pressures will be and the more "swings" there will be in fluids. In the past, the amputee had to compensate for this volume decrease by removing the artificial limb and donning additional stump socks to make up for the decreased residual limb volume.

U.S. Pat. No. 5,888,230 discloses the use of a vacuum pump connected between the limb and a liner. However, this invention is essentially inoperable because the liner will conform to the stump at all times, by an interference fit, so that there is no space between the residual limb and the liner against which to draw a vacuum. In any case, the patent does not disclose application of vacuum to the socket cavity in such a manner as to draw the residual limb firmly and totally against the interior of the socket. Instead, the patent discloses the use of shims between the liner and the socket. Without total contact between the residual limb and the socket, the limb may swell into the space between the limb and the socket. Also, the patent does not disclose the use of vacuum to prevent reduction in volume of the artificial limb due to weight-bearing pressures.

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While some of these devices addressed some of the problems associated with prosthetics, none of the artificial limbs, liners and socket, individually or in combination, offered a prosthesis that presented a total contact relationship with the residual limb; absorbed and dissipated shear, shock and mechanical forces transmitted to the limb tissues by the artificial limb; controlled residual limb volume; and used negative pressure as a locking device to hold the residual limb into the socket.

There is a need for an improved hypobarically-controlled artificial limb that will offer total contact relationship with the residual limb; absorb and dissipate shock, mechanical and shear forces typically associated with ambulation, twisting and turning and weight bearing with an artificial limb; control residual limb volume by way of even weight distribution; use negative pressure as a locking device to hold the residual limb into the socket without causing swelling of the residual limb into the socket; and control residual limb volume changes by a negative pressure system. Ideally, the vacuum system should be automatically regulated.

U.S. Pat. No. 5,549,709 discloses several embodiments of a hypobarically-controlled artificial limb. However, all of these embodiments required two sockets: an outer socket and an inner socket. Applicant has found that the present invention offers improved performance without the requirement for two sockets. A single socket works equally well or better than two sockets. Also, this patent does not disclose a mechanism for maintaining vacuum in the presence of air leakage into the socket.

It has been found that it is essentially impossible to maintain a perfect, airtight seal between the residual limb and the sockets disclosed in U.S. Pat. No. 5,549,709, with the result that slow air leakage into the sockets diminishes the vacuum in the sockets. With the reduction in vacuum, the beneficial effects of the vacuum also slowly diminish. Consequently, there is a need for a means for maintaining the vacuum in the socket cavity in the presence of some air leakage past the seal.

SUMMARY OF THE INVENTION

A hypobarically-controlled artificial limb for amputees includes a single socket with a volume and shape to receive a substantial portion of the residual limb. A sealed cavity is formed between the socket and the residual limb. The wearer may use a liner over the residual limb for comfort. A vacuum source is connected to a vacuum valve connected to the cavity to suspend the artificial limb from the residual limb and to control and minimize volumetric and fluid changes within the residual limb. To compensate for some air leakage past the seal, there is a mechanism to maintain the vacuum in the cavity. A method for preventing the loss of residual limb volume due to weight-bearing pressures includes the steps of: inserting the residual limb into a socket with a cavity; making a seal between the residual limb and the socket; applying a vacuum to the socket cavity to thereby draw the residual limb into firm and total contact with the socket; maintaining the vacuum in the socket cavity in the presence of some leakage past the seal; and opposing the loss of body fluids from the residual limb due to weight-bearing pressures, by means of 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.

A principle object and advantage of the present invention is that it uses vacuum within the artificial limb socket to suspend the artificial limb from the residual limb.

Another object and advantage of the present invention is that it uses vacuum within the artificial limb socket to assist in socket fit and minimizes volumetric limb changes within the socket.

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Another object and advantage of the present invention is that it uses vacuum within the socket to lock the residual limb into the socket while preventing negative draw within the socket from causing swelling of the residual limb into the socket.

Another object and advantage of the present invention is that it uses vacuum within the socket to oppose the loss of fluids from the residual limb caused by weight-bearing pressures.

Another object and advantage of the present invention is that the vacuum may be created by a pump with a mechanical or motor drive.

Another principal object and advantage of the present invention is that it may comprise only a single socket, rather than two sockets, simplifying construction and reducing cost and complexity.

Another principal object and advantage of the present invention is that it includes a mechanism that can be used to maintain vacuum in the cavity between the residual limb or liner and the socket as air leaks into the cavity.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevational view of the tissue and skeletal structure of an amputee's residual limb;

FIG. 2 is a side elevational view of a residual limb in the form of an amputated arm showing the skeletal and muscular structure of the residual limb;

FIG. 3 is an exploded elevational view of the residual limb donning the polyurethane sleeve, stretchable nylon sleeve, liner, nylon sheath and socket of an artificial limb;

FIG. 4 is a cross-section of the artificial limb in FIG. 3, which is a first embodiment of the artificial limb;

FIG. 5 is a cross-section of the artificial limb similar to FIG. 4, showing a second embodiment of the artificial limb;

FIG. 6 is the same as FIG. 5, but showing compression of the inner socket under the influence of positive air pressure;

FIG. 7 is a cross-section of the artificial limb showing a third embodiment of the artificial limb;

FIG. 8 is a cross-section of the artificial limb showing a fourth embodiment of the artificial limb;

FIG. 9 is an elevational view of the polyurethane sleeve and second stretchable nylon sleeve rolled over the socket and residual limb with clothing shown in broken outline;

FIG. 10 is a cross-section of the artificial limb showing a fifth embodiment of the artificial limb;

FIG. 11 is a cross-section of the artificial limb showing a sixth embodiment of the artificial limb;

FIG. 12 is a detailed view of the vacuum mechanism in FIG. 11;

FIG. 13 is a cross-section of the artificial limb showing a seventh embodiment of the artificial limb;

FIG. 14 is a detailed view of the vacuum mechanism and suspension sleeve of FIG. 13;

FIG. 15 is a cross-section of the artificial limb showing an eighth embodiment of the artificial limb; and

FIG. 16 is a cross-section of the artificial limb showing a ninth embodiment of the artificial limb.

FIG. 17 is a cross section of the artificial limb showing a liner with an annular seal.

FIG. 18 is a cross-section of the artificial limb showing a second embodiment of the liner of FIG. 17.

FIG. 19 is a partial cross-section of the artificial limb showing a third embodiment of the liner of FIG. 17.

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FIG. 20 is a partial cross-section of the artificial limb showing a fourth embodiment of the liner of FIG. 17.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The drawings show a number of different embodiments of an apparatus and method for managing the volume of a residual limb within an artificial limb, by applying a vacuum source to the artificial limb cavity. It will be seen that application of the vacuum to the cavity draws the residual limb (which may be encased in a liner) firmly and totally against the socket, thereby preventing swelling of the residual limb into the socket, because there is no open chamber into which the residual limb may be drawn by the vacuum. Importantly, application of the vacuum to the cavity also opposes the loss of fluids from the residual limb due to weight-bearing pressures.

FIGS. 3 and 4 show one embodiment of the apparatus 50 of the present invention. The hypobarically-controlled artificial limb 50 includes an outer socket 52, shin 54, and foot 56. The outer socket 52 has a volume and shape to receive a substantial portion of the residual limb 14 with a space 58 therebetween.

The apparatus 50 further includes a flexible inner socket 60 with a cavity 62 with a volume and shape for receiving a substantial portion of the residual limb 14 and fitting in the space 58 between the outer socket 52 and the residual limb 14. The inner socket 60 has an inner surface 64 opposing the residual limb 14 and an outer surface 66 opposing the outer socket 52.

A vacuum source 70 may conveniently be attached to the shin or pylon 54. The vacuum source 70 may preferably be a mechanical or motor-driven pump 72. The vacuum source 70 may be connected to a power source 83, which may be a battery.

A vacuum valve 74 is suitably connected to the vacuum source 70. The vacuum valve 74 may preferably be disposed on the outer socket 52. A vacuum tube 76 connects the vacuum valve 74 to the cavity 62. It will be seen that the vacuum source will cause the residual limb 14 to be drawn into firm contact with the inner surface 64 of the inner socket 60.

The hypobarically-controlled artificial limb 50 also includes a regulator means 80 for controlling the vacuum source 70. Preferably, the regulator means 80 may be a digital computer 82. Alternately, the regulator means may be a vacuum regulator. The regulator means 80 is connected to a power source 83, which may be a battery.

A seal means 84 makes an airtight seal between the residual limb 14 and the outer socket 52. Preferably, the seal means 84 is a nonfoamed, nonporous polyurethane suspension sleeve 86 which rolls over and covers the outer socket 52 and a portion of the residual limb 14. Alternatively, the seal means 84 may be any type of seal which is airtight.

The hypobarically-controlled artificial limb 50 may also include a thin sheath 90 between the residual limb 14 and the inner surface 64 of the inner socket 60. As vacuum is applied to the cavity 62, the sheath 90 will allow the vacuum to be evenly applied throughout the cavity 62. Without the sheath 90, the residual limb 14 might "jack up" against the inner surface 64 and form a seal which might prevent even application of the vacuum to the cavity 62. The sheath 90 may also be used to assist the amputee into a smooth and easy fitting into the inner socket 60. The sheath 90 is preferably made of thin knitted nylon.

The apparatus 50 may also include a nonfoamed, nonporous polyurethane liner 92 receiving the residual limb 14 and

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disposed between the sheath 90 and the residual limb 14. The liner 92 provides a total-contact hypobaric suction, equal weight distribution socket liner. The liner 92 readily tacks up to the skin of the residual limb 14 and provides total contact with the limb 14. The liner 92 absorbs and dissipates shock, mechanical and shear forces typically associated with ambulation.

The hypobarically-controlled artificial limb 50 may also include a stretchable nylon second sleeve 94 for rolling over and covering the suspension sleeve 86 to prevent clothing from sticking to and catching the suspension sleeve 86.

Referring to FIG. 3, the polyurethane tubular sleeve 86 may be appreciated alone and in combination with the urethane liner 92 together with the optional nylon sheath 90 and second stretchable nylon sleeve 94.

More specifically, the amputee takes the stretchable nylon second sleeve 94, suitably made of a spandex-like material and rolls it up over the stump 14 to the upper portions of the residual limb suitably as the thigh of a leg 12. Next, the polyurethane sleeve 86 is also rolled upwardly over the residual limb 10. Thereafter, the liner 92 is optionally donned.

Next, the amputee may optionally utilize the nylon sheath 90 which is suitably of a non-stretching, thin, friction reducing nylon. As stated, this sheath 90 optionally may be used to assist the amputee into a smooth and easy fitting into the inner socket 60. Alternatively, the sheath 90 may be avoided and the liner 92 simply inserted into the inner socket 60 of the artificial limb 50.

Next, the amputee simply grasps the rolled over portion of the polyurethane sleeve 86 and rolls it over a substantial portion of the outer socket 52. The sleeve 86 makes an airtight seal between the residual limb 14 and the outer socket 52.

As can be appreciated, the polyurethane sleeve 86 is tacky. Consequently, the stretchable nylon second sleeve 94 may be utilized and rolled over the polyurethane sleeve 86.

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 (ideally ten to twenty five inches).

It will be seen that the vacuum within the inner socket 60 will cause the hypobarically-controlled artificial limb 50 to be suspended from the residual limb 14. The vacuum will lock the residual limb 14 into the inner socket 60 without causing swelling of the residual limb into the socket, because of the total contact of the residual limb 14 with the inner socket 60. That is, there is no open chamber between the residual limb 14 and the inner socket 60 which would draw on the residual limb.

As the volume of the residual limb 14 decreases during the day due to weight-bearing pressures, the regulator means 80 may appropriately adjust the vacuum source 70 to draw the residual limb 14 more firmly against the inner socket 60 and thus compensate for the loss of residual limb volume. The vacuum may also partially or completely oppose the loss of fluids from the residual limb caused by weight-bearing pressures.

A second embodiment of the apparatus 50 is shown in FIGS. 5 and 6. The second embodiment of the apparatus 50 is as described above, with the exception that the inner

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socket 60A is compressible as well as being flexible. Instead of a vacuum source, the second embodiment has a positive air pressure source 100, which may preferably be a motor-driven pump 102. The regulator means 80, which may be a digital computer 82, controls the positive air pressure source 100. The regulator means and positive air pressure source 100 are connected to a power source 83, which may be a battery. A positive pressure valve 104 connects the space 58 to the positive air pressure source 100, for compressing the inner socket 60A as the volume of the residual limb decreases.

It will be seen that as the volume of the residual limb 14 decreases during the day due to weight-bearing pressures, the regulator means 80 may control the positive air pressure source 100 to cause air pressure to compress the inner socket 60A to compensate for the decreased volume of the residual limb, as shown in FIG. 6.

A third embodiment of the hypobarically-controlled artificial limb 50 is shown in FIG. 7. The third embodiment is a combination of the first and second embodiments described above.

The mechanical motor-driven pump 72 may act as both the vacuum source 70 and the positive air pressure source 100. The regulator means 80, vacuum source 70 and positive air pressure source 100 are connected to a power source (not shown), which may be a battery.

The vacuum source 70, under control of the regulator means 80, will compensate for reduced residual limb volume up to a certain point. From that point on, the regulator means 80 will cause the positive air pressure source 100 to further compensate for reduced residual limb volume as described above. The third embodiment thus uses both vacuum and positive air pressure working together to lock the residual limb 14 into the inner socket 60 and reduce socket volume to compensate for fluid loss in the residual limb 14. The exact point at which the changeover is made between vacuum compensation and positive air pressure compensation is controlled by the regulator means 80, which as described may be a digital computer appropriately programmed for the socket environment.

A fourth embodiment of the apparatus 50 is shown in FIG. 8. The fourth embodiment is like the first embodiment, but includes two vacuum valves: a first vacuum valve 106 and a second vacuum valve 110, both connected to the vacuum source 70. The first vacuum valve 106 connects the vacuum source 70 to the space 58. The space 58 contains a semi-compressible material 108, such as polystyrene beads, as disclosed in U.S. Pat. No. 4,828,325, herein incorporated by reference.

To don the artificial limb 50, the amputee proceeds as described above. After inserting the residual limb 14 (with optional coverings) into the inner socket 60B, which is both compressible and expandable, and rolling the suspension sleeve 86 over the outer socket 52, the amputee activates the regulator means 80, causing the vacuum source 70 to apply a vacuum to the space 58. This causes the material 108 to lock mechanically together into a rigid mass, conforming to the shape of the residual limb 14. The inner socket 60B may expand slightly under the weight of the residual limb 14 and under the influence of vacuum.

It will be seen that the semi-compressible molding material 108 can be molded to the contours of the residual limb 14 without using a custom-building process to produce a custom socket. The outer socket 52 may appropriately occur in standard sizes, such as small, medium, and large. The inner socket 60B may also occur in standard sizes such as

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small, medium, and large. Adaptation of the inner socket 60B to the contours of the residual limb 14 occurs through solidifying the material 108 under the influence of vacuum.

The second vacuum valve 110 connects the vacuum source 70 to the cavity 62 as previously described, for locking the residual limb 14 into the inner socket 60B.

The fourth embodiment may also include a positive air pressure source 100 as previously described, to adjust the size of the inner socket 60B to compensate for decreased residual limb volume.

The fourth embodiment may also include a thin sheath 90, liner 92, and second sleeve 94, as previously described.

The positive air pressure source 100 may also be used for shock absorption and a dynamic response in the ankle and foot sections of the artificial limb 50, by means of a connection 120.

A fifth embodiment of the hypobarically-controlled artificial limb 50 is shown in FIG. 10. This embodiment is the same as the first embodiment shown in FIG. 4, with some changes. First, vacuum source 71 may be a hand-operated vacuum pump 71 which may remove air from the cavity 62 down to approximately 10-25 inches of mercury. A suitable hand-operated vacuum pump is marketed under the trademark MITY VAC II® by Neward Enterprises, Inc. of Cucamonga, Calif.

The fifth embodiment also includes the seal means 84 which preferably consists of a non-foamed, nonporous polyurethane suspension sleeve 86 for rolling over and covering a portion of the residual limb 14. A portion of the seal means 86 is adapted to be disposed between the outer socket 52 and the inner socket 60. The sleeve may be made of any of a variety of air-imperious elastomers.

The fifth embodiment, shown in FIG. 10 also includes a mechanical interlock 67, 59 for interlocking the inner socket 62 with the outer socket 52. Preferably, the mechanical interlock consists of a first detent 67 in the inner socket 62 and a second detent 59 in the outer socket 52. The first detent 67 engages the second detent 59 to lock the inner socket 60 into the outer socket 52.

A sixth embodiment of the apparatus of the present invention is shown in FIGS. 11 and 12. The sixth embodiment is like the first embodiment shown in FIG. 4, with some changes.

First, the inner socket is specifically intended to be removably from the outer socket. To provide a positive mechanical connection between the inner socket and outer socket and yet allow the inner socket to be easily removed, the sixth embodiment includes a mechanical interlock 103 engaging the inner socket 60 and the outer socket 52. Preferably, the mechanical interlock may be an extension 104 which is attached to the inner socket 60 and a docking device 106 attached to the outer socket 52 and receiving the extension 104, and a locking mechanism 105 engaging the extension 104 and the docking device 106.

The extension may be any sort of protrusion from the inner socket, such as a bulge or tab. Preferably, the extension 104 comprises a shuttle pin 108.

The locking mechanism may be any sort of member which engages both the extension 104 and the docking device 106, such as a screw, wire, or pin. Preferably, the locking mechanism 105 comprises a second pin 110 which extends outside the outer socket 52 as to be accessible.

Second, the sixth embodiment includes two thin sheaths, rather than one. A first inner sheath 90 may preferably be disposed between the residual limb 14 and the inner surface

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64 of the inner socket 60. As vacuum is applied to the cavity 62, the inner sheath 90 will allow the vacuum to be evenly applied throughout the cavity 62. Without the inner sheath 90, the residual limb 14 might "tack up" against the inner surface 64 and form a seal which might prevent even application of the vacuum to the cavity 62. The inner sheath 90 may also be used to assist the amputee into a smooth and easy fitting into the inner socket 60.

An outer sheath 93 is preferably disposed between the suspension sleeve 86 and the inner socket 60, thereby preventing the suspension sleeve from tacking to the inner socket 60. Such tacking would cause friction between the inner socket 60 and the sleeve 86 which would cause the sleeve to wear out. Such tacking might also cause restrictions in the movement of the residual limb. The outer sheath 93 also protects the suspension sleeve 86 from being damaged by friction with the inner socket 60.

The sixth embodiment also preferably includes an adhesive pressure tape 95 adapted to cover the outer sheath 93, suspension sleeve 86, and the second sleeve 94 and sealing the outer sheath 93, suspension sleeve 86, and the second sleeve 94 to the inner socket 60. The tape 95 locks all of these layers to the inner socket so that they do not come loose during movement.

In the sixth embodiment, the suspension sleeve 86 goes between the inner socket 60 and the outer socket 52, so that the sleeve 86 is protected from damage.

In the sixth embodiment, the inner socket 60 has a rigid lower portion 98 and a substantially flexible upper portion 96. The rigid lower portion assists in weight-bearing while the substantially flexible upper portion allows for movement of the residual limb 14. As the knee is bent from fully straight to fully flexed, the width of the knee changes rather significantly and in a hard, non-flexible socket brim, there can be excessive pressure on the residual limb 14. The substantially flexible upper portion 96 makes the artificial limb 50 more comfortable and more adaptive to these changes. For the same reason, the outer socket 52 has a rigid lower portion 102 and a substantially flexible upper portion 100.

Preferably, the top edge of the inner socket 60 is below the top edge of the outer socket 52 so that the sleeve 86 is protected from impact. Preferably, the top edge of the inner socket 60 may be $\frac{3}{16}$ inch below the top edge of the outer socket 52.

The sixth embodiment includes extensive modifications to the vacuum system.

First, a vacuum fitting 78 has been added to the inner socket 60 to attach the vacuum tube 76. The vacuum fitting 78 allows the attachment of a vacuum sensor 79 adapted to sense the amount of vacuum in the cavity 62 and a sensor lead 81 is attached to the sensor 79 connecting the sensor 79 to the regulator means 80, thus conveying the sensed vacuum to the regulator means 80.

A vacuum valve 74 is placed between the cavity 62 and the vacuum source 70 to maintain vacuum in the cavity 62. Typically, the vacuum valve 74 is a one-way valve or non-return valve.

In the sixth embodiment, the vacuum source 70, vacuum tube 76, vacuum valve 74, regulator means 80, and power source 83 are all attached to the outer socket 52 in the space 58 between the outer socket 52 and inner socket 60. In this way, these delicate components are protected against being damaged by impact. Because of the placement of the regulator means 80 within the outer socket 52, a vacuum control 77 is provided extending outside the outer socket 52 to allow manual control of the regulator means 80.

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The amputee dons the sixth embodiment in a manner similar to that earlier described, with some modifications. First, the outer sheath 93 is put on the residual limb 14 after rolling the suspension sleeve 86 upward over the residual limb and before donning the liner 92. After donning the inner sheath 90 over the liner 92, the amputee inserts the residual limb 14 into the inner socket 60. Next, the outer sheath 93, suspension sleeve 86, and second sleeve 94 are rolled down over the inner socket 60, and the adhesive pressure tape 95 is applied. Next, the wearer sets the regulator means 80 to an appropriate vacuum level by means of the vacuum control 77, and connects the vacuum tube 76 to the vacuum fitting 78. The inner socket 60 is then placed within the outer socket 52 so that the shuttle pin 108 engages the docking device 106 and the locking pin 110 is set to engage the shuttle pin 108 and the docking device 106, providing a positive mechanical interlock.

A seventh embodiment of the hypobarically-controlled artificial limb of the present invention is shown in FIG. 13. The seventh embodiment is similar to the sixth embodiment, with some changes.

First, the mechanical interlock 103 does not engage the inner socket 60. Instead, the mechanical interlock engages the outer socket 52 and the suspension sleeve 86. To accomplish this, the suspension sleeve 86 covers the entire inner socket 60, and the suspension sleeve 86 has the extension 104 or shuttle pin 108 embedded in the suspension sleeve at the distal end of the suspension sleeve, as shown in FIG. 14. Preferably, the extension 104 has a portion 104A embedded in the suspension sleeve. This portion 104A may be a disk or umbrella 104A. The extension 104 then engages the docking device 106 as previously described.

Second, the suspension sleeve 86 is modified to support the additional weight imposed on the suspension sleeve 86 due to the outer socket 52 and artificial limb. In particular, the suspension sleeve 86 is fabricated from a material which allows circumferential expansion but resists longitudinal stretching under the weight of the artificial limb. Such a material is described in U.S. Pat. No. 5,571,208, herein incorporated by reference.

The sleeve 86 preferably contains fabric threads which may be oriented circumferentially around the sleeve. The threads preferably are comprised of double-knit polyurethane. The threads may also include nylon. The threads permit the sleeve 86 to expand circumferentially so that the sleeve may be slipped onto the residual limb 14 and so that the lower portion may be slipped over the inner socket 52. The threads are preferably connected together with cross-links, which also may be preferably comprised of polyurethane. The cross-links and threads form a matrix which allows circumferential expansion but resists longitudinal stretching under the weight of the artificial limb. By example, the sleeve 86 may have a 4-to-1 ratio of circumferential stretch relative to longitudinal stretch.

The sleeve 86 may have a portion above the inner socket 52 which is manufactured of material which allows both vertical and horizontal stretching, to increase flexibility.

An eighth embodiment of the hypobarically-controlled artificial limb of the present invention is shown in FIG. 15.

Unlike earlier embodiments, the artificial limb 50 of the eighth embodiment has only a single socket 60 rather than inner and outer sockets and is thus considerably simpler.

The socket 60 has a volume and shape to receive a substantial portion of the residual limb 14 with a cavity 62 therebetween.

A nonfoamed, nonporous polyurethane liner 92 is preferably adapted to receive the residual limb 14 and to be disposed between the residual limb 14 and the socket 60.

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A vacuum source 70 is connected to the cavity 62 by a vacuum valve 78, thereby drawing the residual limb 14 into firm contact with the socket 60.

A seal means 84 makes a seal between the residual limb 14 and the socket 60 to minimize air leakage into the cavity 62. It has been found that it is impossible to make a perfect seal, with the result that air leakage can occur at rates up to 30 cc per minute. As air leaks into the cavity 62, it is necessary to activate the vacuum source 70 to restore vacuum in the cavity. Furthermore, it has been found that when the vacuum in the cavity is about 5 inches of mercury, the residual limb may lose up to 6 to 15% of its volume during the day, whereas if the vacuum in the cavity is 10-25 inches of mercury, the residual limb loses only about 1% of its volume during the day.

To minimize the time that the vacuum source, such as a vacuum pump 72, needs to run to maintain vacuum in the cavity, a ninth embodiment of the artificial limb 50 is shown in FIG. 16. The ninth embodiment is the same as the eighth embodiment, but a vacuum reservoir 110 is added between the vacuum source 70 and the vacuum valve 78. The vacuum reservoir 110 has a volume substantially larger than the cavity 62. Suitably, the vacuum reservoir may have a volume of 2 gallons or 9000 cc while the volume of the cavity 62 may be only about 100 cc or even less.

It will be seen that as air leaks into the cavity 62, the air will be pulled into the vacuum reservoir 110, thereby maintaining the vacuum in the cavity 62.

When the vacuum in the reservoir 110 reaches a certain minimum threshold, the vacuum source 70 may be activated to restore vacuum to the vacuum reservoir 110. The vacuum source 70 may be activated either manually or by a regulator means (not shown).

The artificial limb 50 typically includes a shin or pylon 54 and a foot 56, as shown in FIG. 3. Preferably, the vacuum reservoir 110 is attached to the shin 54 between the socket 60 and the foot 56. However, the vacuum reservoir may also be carried separately, as for example in a backpack. Depending on the placement of the vacuum reservoir 110, a vacuum tube 76 may be necessary to connect the vacuum reservoir 110 to the vacuum valve 78.

If the volume of the vacuum reservoir 110 is about 9000 cc and air leaks into the cavity 62 at about 75 cc per minute, it will be seen that the intervals between activation of the vacuum source 70 can be up to about 120 minutes.

The artificial limb 50 of the eighth and ninth embodiments may preferably further comprise the following.

An inner sheath 90 may be adapted to be disposed between the liner 92 and the socket, to ensure even distribution of vacuum in the cavity 62, as earlier described. Preferably, the inner sheath 90 may be thin knitted nylon. The sheath 90 may also be affixed to the outside of the liner 92.

The seal means 84 is preferably a nonfoamed, nonporous polyurethane suspension sleeve 86 for rolling over and covering the socket 60 and a portion of the artificial limb 14, as earlier described.

A stretchable nylon second sleeve 94 for rolling over and covering the suspension sleeve 86 may be added to prevent clothing from sticking to and catching on the suspension sleeve 86, as earlier described.

The vacuum source 70 is preferably a motor or mechanical driven vacuum pump 72, as earlier described. A vacuum tube 76 may be necessary to connect the vacuum pump 72 to the vacuum valve 78, depending on the placement of the vacuum pump 72.

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The vacuum source 70 may also be a weight-actuated vacuum pump and shock absorber as disclosed in U.S. Patent application Ser. No. 09/534,274, filed Mar. 23, 2000 and herein incorporated by reference.

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 Ser. No. 09/534,274, may be employed.

Applicant has found that many of the embodiments discussed earlier share a common problem. The vacuum which holds the residual limb (and liner) in firm contact with the socket tends to cause edema and blistering at the point on the residual limb where the suspension sleeve contacts the residual limb. This problem occurs because the vacuum (perhaps $7\frac{1}{2}$ pounds of negative pressure) in cavity 62 draws against the suspension sleeve 86 at the point where the suspension sleeve 86 contacts the skin of the residual limb. However, because the liner 92 often has an outer fabric cover 130 to prevent the liner from adhering to the socket 60 or clothing, the suspension sleeve cannot make a good seal at the point where it contacts the outer fabric cover 120. This has left the residual limb as the only point at which to make the seal.

FIG. 17 shows one solution to this problem. The liner 92 is improved by adding an annular seal 140 extending outwardly from the fabric cover 130. The annular seal, which may be made from the same material as the inner layer 92 of the liner, is adapted to sealingly engage the suspension sleeve 86, producing a seal against the vacuum in cavity 62 at the point of contact with the suspension sleeve 86. Therefore, the vacuum in cavity 62 now draws against the annular seal 130 rather than against the skin of the residual limb 14.

An alternative solution to the above problem is shown in FIG. 18. Here, the annular seal 140 does not make contact with the suspension sleeve 86, but rather makes contact with the inner wall 63 of the socket 60, and makes a seal at that point. No suspension sleeve is used in this variation, it being found that sufficient holding force is provided by the vacuum in cavity 62.

A second alternative is shown in FIG. 19. This alternative is like that of FIG. 18, with the exception that a mechanical interlock 103 is provided which is adapted to interlock with the socket 60. Preferably, as shown, the mechanical interlock 103 comprises a shuttle pin 108 adapted to connect the liner 92 with the socket 60, and a locking mechanism 105 such as a second pin 110 extending through the socket 60 to the exterior of the socket 60 for access by the amputee as earlier described. More particularly, the liner 92 may have an extension 104 or shuttle pin 108 embedded in the liner at the distal end of the liner. Preferably, the extension 104 has a portion 104A which may be a disk or umbrella which engages a docking device 106 as earlier described.

To keep air from entering the cavity 62, the invention of FIG. 19 also preferably includes a locking mechanism seal 150 adapted to engage the inner wall 63 of the socket 60 about the locking mechanism 105. The seal 150 could alternatively be on the outer surface of the socket 60.

Another alternative is shown in FIG. 20. Here, the fabric cover 130 stops below the annular seal 140. The annular seal 140 may also be made of the same material as the liner 92.

A very important advantage, in all of the above embodiments, is the use of vacuum within the socket to prevent fluids from migrating out of the distal end of the residual limb due to weight-bearing pressures. Although the exact mechanism is not precisely known at this time, Appli-

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cant believes this limb vacuum volume management system to function as follows.

Application of a vacuum to the socket cavity 62 sucks the liner 92 tightly against the inner wall of the socket 60. The liner has a tight interference fit with the residual limb 14, so that the residual limb is also butted tightly up against the inner wall of the socket. During the weight-bearing phase of walking, the wearer's body weight will force the limb and liner even more tightly against the inner wall of the socket. However, during the non-weight-bearing phase, or swing phase, of walking, the weight of the artificial limb will have a tendency to cause the socket 60 to pull away from the liner 92. This is prevented by the vacuum in the socket cavity. Because the vacuum keeps the liner tightly opposed to the inner wall of the socket, this tendency will also cause the liner 92 to pull away from the residual limb, creating a small, partial vacuum between the liner 92 and the residual limb 14. This small, partial vacuum, perhaps on the order of 2 inches of mercury, will then oppose the migration of fluids out of the residual limb.

In order for this beneficial effect of vacuum to occur, the vacuum in the socket cavity 62 needs to be at least about 10 to 25 inches of mercury. At this level of vacuum, it has been found that the residual limb loses only about 1% of its volume during the day.

The present invention may be embodied in other specific forms without departing from the spirit or essential attributes thereof, and it is therefore desired that the present embodiment be considered in all respects as illustrative and not restrictive, reference being made to the appended claims rather than to the foregoing description to indicate the scope of the invention.

What is claimed:

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:

- (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;
- (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;
- (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;
- (d) a seal means for sealing the socket cavity;
- (e) a means to maintain a vacuum in the socket cavity, in the presence of some air leakage past the seal means; and
- (f) further comprising a thin sheath between the liner and the socket, to assist the even distribution of vacuum in the cavity about the liner;

wherein application of the vacuum source of the socket cavity prevents the loss of residual limb volume due to weight-bearing pressures.

2. The apparatus of claim 1, wherein a vacuum of at least ten inches of mercury is maintained in the cavity.

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3. The apparatus of claim 1, wherein the socket has a single wall.

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.

5. The apparatus of claim 1, wherein the liner is of a nonfoamed, nonporous polyurethane.

6. The apparatus of claim 1, wherein the seal means further comprises an annular seal between the liner and the socket.

7. The 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.

8. The apparatus of claim 1, wherein the means to maintain the vacuum in the cavity further comprises a vacuum reservoir having a volume substantially larger than the cavity.

9. The apparatus of claim 1, wherein the vacuum source and the means to maintain the vacuum in the cavity further comprise a weight-actuated vacuum pump.

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 causing swelling of the residual limb into the socket, the apparatus comprising:

(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;

(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;

(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

(d) a seal means for sealing the socket cavity; 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%.

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.

12. The apparatus of claim 11, wherein a vacuum of at least ten inches of mercury is maintained in the cavity.

13. The apparatus of claim 11, wherein the vacuum source is a vacuum pump and the means to maintain the vacuum in

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the cavity is a regulator, and further comprising a power source for the vacuum pump and the regulator.

14. The apparatus of claim 11, wherein the means to maintain the vacuum in the cavity further comprises a vacuum reservoir having a volume substantially larger than the cavity.

15. The apparatus of claim 11, wherein the vacuum source and the means to maintain the vacuum in the cavity further comprise weight-actuated vacuum pump.

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.

17. The apparatus of claim 10, wherein the liner is of a nonfoamed, nonporous polyurethane.

18. The apparatus of claim 10, wherein the seal means further comprises an annular seal between the liner and the socket.

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.

20. A method for preventing the loss of residual limb volume due to weight-bearing pressures in an artificial limb, comprising the steps of:

(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;

(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;

(c) sealing the socket cavity;

(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;

(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

(f) opposing the loss of body fluids from the residual limb due to weight-bearing pressures, by means of 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.

21. The method of claim 20, wherein the liner is of a non-foamed, non-porous polyurethane.

22. The method of claim 20, wherein the socket has a single wall.

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.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 6,726,726 B2
DATED : April 27, 2004
INVENTOR(S) : Carl A. Caspers

Page 1 of 1

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 14,

Line 65, after "mercury" insert -- below ambient --

Signed and Sealed this

Twenty-fourth Day of August, 2004

A handwritten signature in black ink, appearing to read "Jon W. Dudas". The signature is written in a cursive, flowing style. Below the signature is a horizontal line.

JON W. DUDAS
Director of the United States Patent and Trademark Office

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CERTIFICATE OF SERVICE

I declare that I am employed with the law firm of Morrison & Foerster LLP, whose address is 707 Wilshire Boulevard, Los Angeles, California 90017-3543. I am not a party to the within cause, and I am over the age of eighteen years.

I further declare that on August 8, 2013, I served a copy of:

FIRST AMENDED COMPLAINT

☒ **BY U.S. MAIL [Fed. Rule Civ. Proc. rule 5(b)]** by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid, addressed as follows, for collection and mailing at Morrison & Foerster LLP, 707 Wilshire Boulevard, Los Angeles, California 90017-3543 in accordance with Morrison & Foerster LLP's ordinary business practices.

I am readily familiar with Morrison & Foerster LLP's practice for collection and processing of correspondence for mailing with the United States Postal Service, and know that in the ordinary course of Morrison & Foerster LLP's business practice the document(s) described above will be deposited with the United States Postal Service on the same date that it (they) is (are) placed at Morrison & Foerster LLP with postage thereon fully prepaid for collection and mailing.

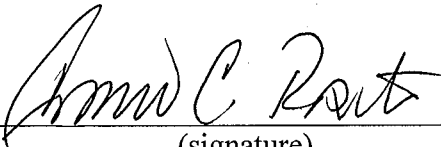
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I declare under penalty of perjury that the foregoing is true and correct.

Executed at Los Angeles, California, this 8th day of August, 2013.

Connie C. Rosete
(typed)


(signature)