In the Matter of

CERTAIN DYNAMIC SEQUENTIAL GRADIENT COMPRESSION DEVICES AND COMPONENT PARTS THEREOF

Investigation No. 337-TA-335
Determination on Motion
for Temporary Relief

USITC PUBLICATION 2575

NOVEMBER 1992

United States International Trade Commission
Washington, DC 20436

UNITED STATES INTERNATIONAL TRADE COMMISSION

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UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

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CERTAIN DYNAMIC SEQUENTIAL GRADIENT COMPRESSION DEVICES AND COMPONENT PARTS THEREOF	)	Investigation No. 337-TA-335

NOTICE OF COMMISSION DECISION TO VACATE A PORTION OF AN INITIAL DETERMINATION CONCERNING TEMPORARY RELIEF AND TO DENY MOTION FOR TEMPORARY RELIEF

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to vacate a portion of the presiding administrative law judge's (ALJ's) initial determination (ID) denying temporary relief in the above-captioned investigation and not to vacate or modify the ID in other respects. The Commission's determination has the effect of denying the motion for temporary relief.

FOR FURTHER INFORMATION CONTACT: Marc A. Bernstein, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone 202-205-3087.

SUPPLEMENTARY INFORMATION: The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), and section 210.24 of the Commission's Interim Rules of Practice and Procedure (19 C.F.R. § 210.24).

On January 10, 1992, The Kendall Company ("Kendall") filed a complaint under section 337 alleging unfair acts in the importation and sale of certain dynamic sequential gradient compression devices ("SGCDs") and component parts thereof. The complaint alleged, inter alia, importation and sale of articles infringing certain claims of U.S. Letters Patent 4,029,087, which Kendall owns. Kendall concurrently moved for temporary relief. The Commission instituted an investigation of Kendall's complaint and provisionally accepted Kendall's motion for temporary relief. Notice of the Commission's actions was published in the Federal Register on February 20, 1992. 57 F.R. 6126. The notice named two respondents: Huntleigh Technology PLC, of Luton, Bedfordshire, England, and Huntleigh Technology, Inc., of Manalapan, N.J. (collectively "Huntleigh").

The ALJ conducted an evidentiary hearing on the temporary relief motion between March 18 and 23, 1992. All parties participated in the hearing. On

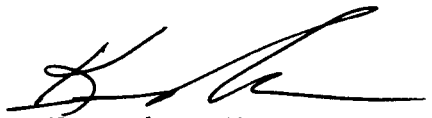
April 20, 1992, each party filed a memorandum with the Commission concerning the issues of remedy, the public interest, and respondents' bond, pursuant to Commission interim rule 210.24(e)(18)(ii). On April 28, 1992, the ALJ issued Order No. 4, designating the temporary relief phase of the investigation "more complicated."

On May 15, 1992, the ALJ issued an ID denying Kendall's motion for temporary relief. The ALJ found that Kendall had shown neither a reasonable likelihood that it would prevail on the merits nor that irreparable harm will occur in the absence of relief. With respect to Kendall's showing on the merits, the ID concluded that Kendall is unlikely to establish a violation of section 337 because: (1) claim 1 of the '087 patent is likely invalid for obviousness under 35 U.S.C. § 103; (2) claims 1 and 25 of the '087 patent are likely not infringed by respondents; and (3) Kendall is not likely to establish the existence of a domestic industry with respect to the '087 patent. The ID found no irreparable harm in light of the limited nature of competition between the Kendall SGCDs alleged to be covered by the '087 patent and the imported Huntleigh SGCDs alleged to infringe it and in view of the market strength and pricing practices of Kendall.

The Commission has determined to vacate the ID's discussion of the issue of obviousness under 35 U.S.C. § 103. It has determined not to modify or vacate the ID in any other respect. The ID's discussion on obviousness is neither necessary to its conclusion that Kendall is unlikely to establish a violation of section 337 nor dispositive of its determination that temporary relief should be denied. Consequently, the Commission's action not to modify or vacate the other portions of the ID has the effect of denying Kendall's motion for temporary relief.

Copies of the Commission opinion issued in connection with this temporary relief determination, the public disclosure version of the ID, and all other nonconfidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone 202-205-2000. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-252-1810.

By order of the Commission.



Kenneth R. Mason
Secretary

Issued: June 15, 1992

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of	)	
CERTAIN DYNAMIC SEQUENTIAL GRADIENT COMPRESSION DEVICES AND COMPONENT PARTS THEREOF	)	Investigation No. 337-TA-335

COMMISSION OPINION ON TEMPORARY RELIEF

I. BACKGROUND

On January 10, 1992, The Kendall Company ("Kendall") filed a complaint under section 337 alleging unfair acts in the importation and sale of certain dynamic sequential gradient compression devices ("SGCDs") and component parts thereof. The complaint alleged, inter alia, importation and sale of articles infringing certain claims of U.S. Letters Patent 4,029,087 ("the '087 patent"), which Kendall owns. Kendall concurrently moved for temporary relief.

The Commission instituted an investigation of Kendall's complaint and provisionally accepted Kendall's motion for temporary relief. Notice of the Commission's actions was published in the Federal Register on February 20, 1992.[1] The notice named two respondents: Huntleigh Technology PLC, of Luton, Bedfordshire, England, and Huntleigh Technology, Inc., of Manalapan, N.J. (collectively "Huntleigh").

The temporary relief motion was assigned to a presiding administrative law judge (ALJ), who conducted an evidentiary hearing on the motion between March 18 and 23, 1992. All parties and the Commission investigative attorneys

[1] 57 Fed. Reg. 6126 (February 20, 1992).

(IAs) participated in the hearing.

On May 15, 1992, the ALJ issued an initial determination (ID) denying Kendall's motion for temporary relief. The ALJ found that Kendall had shown neither a reasonable likelihood that it would prevail on the merits nor that irreparable harm will occur in the absence of relief. With respect to Kendall's showing on the merits, the ID concluded that Kendall is unlikely to establish a violation of section 337 because: (1) claim 1 of the '087 patent is likely invalid for obviousness under 35 U.S.C. § 103; (2) claims 1 and 25 of the '087 patent are likely not infringed by respondents; and (3) Kendall is not likely to establish the existence of a domestic industry with respect to the '087 patent. The ID found no irreparable harm in light of the limited nature of competition between the Kendall SGCDs alleged to be covered by the '087 patent and the imported Huntleigh SGCDs alleged to infringe it, and in view of the market strength and pricing practices of Kendall.

Kendall and the IAs have submitted comments alleging that the ID contains errors of law. Kendall contends that the ID should be reversed and that temporary relief should be granted; the IAs agree with the ALJ that temporary relief should be denied but nonetheless seek reversal of the ID's rulings on the issues of validity, infringement, and domestic industry. Huntleigh has filed responses to the comments of Kendall and the IAs, asserting that the ID should not be modified or vacated.

After consideration of the record in the temporary relief phase of this investigation, including the ID, the comments on the ID, and the responses to these comments, we have determined to vacate the ID's discussion of the issue of obviousness under 35 U.S.C. § 103. Our reasons for taking this action are described in section II below. We have determined not to modify or vacate the

ID in any other respect. The ID's discussion on obviousness is neither necessary to its conclusion that Kendall is unlikely to establish a violation of section 337 nor dispositive of its determination that temporary relief should be denied. Consequently, our action not to modify or vacate the other portions of the ID has the effect of denying Kendall's motion for temporary relief.

II. THE ID'S OBVIOUSNESS DISCUSSION

The ALJ concluded that respondents would likely prove claim 1 of the '087 patent invalid for obviousness under 35 U.S.C. § 103.[2] This conclusion was based largely on the ALJ's comparison of the claimed invention of the '087 patent and the prior art "as a whole."[3] The ALJ deemed six references to constitute the pertinent prior art. These were British Patent 1,310,492 ("the Flowtron patent"), U.S. Letters Patent 3,391,692 ("the Spielberg patent"), U.S. Letters Patent 2,781,041 ("the Weinberg patent"), British Patent Specification 403,859 ("the Höflinger specification"), U.S. Letters Patent 3,548,809 ("the Conti patent"), and U.S. Letters Patent 3,536,063 ("the Werding patent").

The ALJ first determined that each of the six prior art references discloses an elongated pressure sleeve for enclosing a portion of the patient's limb, means for filling the sleeve with a fluid, and means for emptying the sleeve during decompression. He also determined that most of the

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[2] Claim 1 of the '087 patent is described at pp. 9-11 of the ID. Familiarity with that description is assumed here.

[3] The ID's obviousness discussion also made findings on such issues as the scope of prior art, the level of ordinary skill in the art, and the so-called objective indicia of nonobviousness. See ID at 33-34, 40-41. We do not discuss these findings because our consideration of the obviousness issue is not dependent upon them.

prior art references disclose gradient compression. He additionally indicated that a number of the references disclose structures in which fluid pumped into the lowest chambers is distributed to subsequent chambers at decreasing pressure. The ALJ determined that the only teaching of claim 1 of the '087 patent missing from the prior art is maintenance of a pressure gradient throughout the compression cycle.[4]

The ALJ further determined that one of ordinary skill in the art would have known that in the closed multi-chambered devices disclosed in the prior art, the chambers would be at different pressures when the inflation cycle began but would reach equilibrium when the cycle completed. He further determined that one of ordinary skill would have known that (1) the compression cycle could be controlled by the use of a timing device and (2) using a timer to stop pumping before equilibrium would result in maintaining a pressure gradient throughout the compression cycle. Thus, the ALJ concluded, one with ordinary skill in the art "would have found it obvious to stop the pump before equilibrium, if he wanted to maintain a pressure gradient throughout the compression cycle, and to use a timer (or an equivalent control device) to do so, as is the case with the Figure 6 embodiment of the '087 patent."[5]

We have vacated the ID's obviousness analysis because it is not in accord with controlling law in two respects. First, the ALJ did not identify precisely which prior art reference or references render claim 1 of the '087 patent obvious. Nor did he conclude that the claim is obvious in light of any specified combination of those references. Instead, the ALJ discussed

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[4] ID at 39.

[5] ID at 42.

collectively the characteristics of the six prior art references and their differences from claim 1 of the '087 patent. He concluded that the '087 patent is obvious in light of "the prior art as a whole."[6]

We find no legal basis for comparing a claimed invention with collective or generic characteristics of the prior art. The authority cited in the ID, Panduit Corp. v. Dennison Manufacturing Co.,[7] does not support such an analysis. Panduit states that in obviousness analysis:

> Among legal standards for determining scope and content of the prior art, for example, are: a prior patent must be considered in its entirety, i.e., as a whole, including portions that would lead away from the invention in suit.[8]

Thus, it is prior patents, not the prior art generally, that must be viewed as a whole. Indeed, Panduit states expressly that patents cannot be viewed in conjunction to establish obviousness absent a suggestion to combine them:

> [E]lements of separate prior patents cannot be combined when there is no suggestion of such combination anywhere in those patents.[9]

The Federal Circuit has warned that in evaluating obviousness courts cannot "pick and choose among the individual elements of assorted prior art references to recreate the claimed invention, but rather [must] look for some teaching or suggestion in the references to support their use in the

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[6] ID at 42 n.19 (emphasis in original).

[7] 810 F.2d 1561 (Fed. Cir.), cert. denied, 481 U.S. 1052 (1987).

[8] Panduit, 810 F.2d at 1568 (emphasis in original).

[9] Panduit, 810 F.2d at 1568. Accord, Carella v. Starlight Archery & Pro Line Co., 804 F.2d 135, 140 (Fed. Cir. 1986); ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577 (Fed. Cir. 1984). See also Ex parte Clapp, 227 USPQ 972, 973 (PTO 1985) (reversing examiner's obviousness rejection based on "collective teachings of the references").

particular claimed combination."[10] The failure either to make an obviousness determination in the context of individual prior art references or to provide a rationale for using a group of references was a legal error.

Second, it appears that the ALJ might have misperceived the nature of the claimed invention he was evaluating for purposes of his obviousness analysis. Panduit states that --

> [a]nalysis [of obviousness] begins with a key legal question -- what is the invention claimed? Courts are required to view the claimed invention as a whole.[11]

Here the claimed invention at issue was claim 1 of the '087 patent. The ALJ's obviousness analysis, however, focused only on one specific preferred embodiment of the claimed invention -- the figure 6 embodiment. This is apparent from the ALJ's formulation of how the prior art must be modified to function in the same manner as claim 1:

> The only difference between the prior art and Claim 1 is that Claim 1 requires the maintenance of a pressure gradient throughout the compression cycle. In the case of the Figure 6 embodiment, this can only be achieved through the use of a timer or equivalent means to stop the compression cycle before the chambers reach equal pressure.[12]

Consequently, the ALJ examined the obviousness of introduction of a timer to stop the compression cycle before equilibrium. He concluded:

> Therefore, such a person would have found it obvious to stop the pump before equilibrium, if he wanted to maintain the pressure gradient throughout the compression cycle, and to use a timer (or an equivalent control device) to do so, as is the case with the Figure 6 embodiment of the '087 patent.[13]

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[10] Symbol Technologies, Inc. v. Opticon, Inc., 935 F.2d 1569, 1576 (Fed. Cir. 1991).

[11] Panduit, 810 F.2d at 1567 (emphasis in original).

[12] ID at 41-42.

[13] ID at 42 (emphasis in original).

However, it is the claims, not the specification, that define the invention.[14] "The claims, not particular embodiments, must be the focus of the obviousness inquiry."[15] The ALJ's obviousness discussion focuses on one characteristic of the figure 6 embodiment -- that its compression cycle must be stopped before equilibrium to maintain a pressure gradient throughout the compression cycle. This characteristic is not inherent in claim 1 and is not shared by all other claim 1 embodiments.[16] Consequently, the conclusion on the obviousness of the figure 6 embodiment fails to address the obviousness of the claimed invention -- claim 1 -- as a whole.

We therefore vacate the discussion of obviousness in section IV.B. of the ID.[17]

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[14] Sjolund v. Musland, 847 F.2d 1573, 1581-82 (Fed. Cir. 1988).

[15] Jackson Jordan, Inc. v. Plasser American Corp., 747 F.2d 1567, 1578 (Fed. Cir. 1984).

[16] The ALJ himself noted that, in the figure 1 embodiment of claim 1, the compression cycle need not be stopped before equilibrium to maintain gradience. See ID at 19. We note, however, that by our decision not to modify or vacate any portion of the ID other than the discussion of obviousness, we have rejected the arguments of Kendall and the IAs that claim 1 requires that a gradient be maintained throughout an indefinite compression cycle and that the ALJ improperly disregarded this requirement in construing the figure 6 embodiment.

[17] In light of our determination not to vacate or modify any other section of the ID, we do not and need not determine the obviousness issue de novo. We do not hold that the ALJ, as a matter of law, cannot find claim 1 obvious under a different analysis in any determination on permanent relief.

CERTAIN DYNAMIC SEQUENTIAL GRADIENT COMPRESSION DEVICES AND COMPONENT PARTS THEREOF

337-TA-335

CERTIFICATE OF SERVICE

I, Kenneth R. Mason, hereby certify that the attached COMMISSION OPINION ON TEMPORARY RELIEF was served upon Linda Odom, Esq. and Kent Stevens, Esq. and the following parties via first class mail, and air mail where necessary on June 23, 1992.

Kenneth R. Mason, Secretary
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CERTAIN DYNAMIC SEQUENTIAL GRADIENT COMPRESSION DEVICES AND COMPONENT PARTS THEREOF

337-TA-335

CERTIFICATE OF SERVICE

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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of CERTAIN DYNAMIC SEQUENTIAL GRADIENT COMPRESSION DEVICES AND COMPONENT PARTS THEREOF	Investigation No. 337-TA-335

INITIAL DETERMINATION
Administrative Law Judge Sidney Harris

Pursuant to the Notice of Investigation, 57 Fed. Reg. 6126 (February 20, 1992), this is the Administrative Law Judge's Initial Determination in the Matter of Certain Dynamic Sequential Gradient Compression Devices and Components Parts Thereof, U.S. International Trade Commission Investigation No. 337-TA-335. Commission Interim Rule 210.53(a).

The Administrative Law Judge hereby determines that there is no reason to believe that a violation of § 337 of the Tariff Act of 1930, as amended, has occurred in the importation of certain dynamic sequential gradient compression devices and component parts thereof by reason of infringement of claims 1, 2, 5, 8, 9, 11-13, 17-20, or 25 of U.S. Letters Patent 4,029,087, and that temporary relief is not warranted.

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of	)	
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INITIAL DETERMINATION
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The Administrative Law Judge hereby determines that there is no reason to believe that a violation of § 337 of the Tariff Act of 1930, as amended, has occurred in the importation of certain dynamic sequential gradient compression devices and component parts thereof by reason of infringement of claims 1, 2, 5, 8, 9, 11-13, 17-20, or 25 of U.S. Letters Patent 4,029,087, and that temporary relief is not warranted.

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FINDINGS OF FACT

I. INTRODUCTION

By publication in the Federal Register on February 20, 1992, the Commission gave notice of the institution of an investigation under section 337 of the Tariff Act of 1930, as amended, (19 U.S.C. § 1337) and provisional acceptance of motion for temporary relief pursuant to a complaint filed by Kendall Company, Mansfield, Massachusetts ("Complainant") on January 9, 1992. A supplement to the complaint was filed on January 28, 1992. The complaint, as supplemented, alleges violation of subsection (a)(1)(B)(i) of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain dynamic sequential gradient compression devices and component parts thereof by reason of infringement of claims 1, 2, 5, 8, 9, 11-13, 17-20, 25 and 27 of U.S. Letters Patent 4,029,087 and that there exists an industry in the United States as required by subsection (a)(2) Section 337. The complaint alternatively alleges unfair methods of competition in the importation of certain dynamic sequential gradient compression devices and component parts thereof in violation of subsection (a)(1)(A) of Section 337 by reason of infringement of U.S. Letters Patent 4,029,087, and other conduct. The complaint further alleges that the threat or effect of the asserted unfair methods of competition is to destroy or substantially injure the domestic industry. 57 Fed. Reg. 6126 (February 20, 1992).

The complaint requests that the Commission institute and investigation and, after a full investigation, issue a permanent general exclusion order and permanent cease and desist orders. Id.

The motion for temporary relief, which is limited to the alleged violation of subsection (a)(1)(B)(i) of section 337, requests that the

Commission issue a temporary exclusion order and temporary cease and desist orders prohibiting the importation into the sale within the United States after importation of infringing dynamic sequential gradient compression devices and component parts thereof, during the course of the Commission's investigation. Id.

On February 13, 1992, the Commission instituted an investigation to determine whether there is a violation of subsection (a)(1)(B)(i) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain dynamic sequential gradient compression devices and component parts thereof by reason of alleged infringement of claims 1, 2, 5, 8, 9, 11-13, 17-20, 25 or 27 of U.S. Letters Patent 4,029,087, and whether there exists an industry in the United States as required by subsection (a)(2) of section 337. Further, the Commission provisionally accepted the motion for temporary relief. Id.

The Commission named The Kendall Company the complainant and the following companies as respondents:

Huntleigh Technology, Inc.
Manalapna, New Jersey

Huntleigh Technology PLC
Luton, Bedfordshire
England

Linda C. Odom, Esq. and Sarah C. Middleton, Esq., Office of Unfair Import Investigations, were designated as the Commission Investigative Attorneys. Notice of Designation of Additional Commission Investigative Attorney (February 26, 1992).

Chief Administrative Law Judge Janet D. Saxon designated Administrative Law Judge Sidney Harris to preside over this investigation.

A preliminary conference in this investigation was conducted on February

20, 1992. Appearances were made on behalf of Complainant The Kendall Company, all Respondents and the Commission Investigative Staff.

On February 22, 1992, Complainant moved to amend the complaint to withdraw the allegation of infringement of claim 27. Motion Docket No. 335-2. This motion is hereby granted.

On March 16, 1992, Respondents moved in limine to exclude evidence relating to the establishment of a domestic industry. Motion Docket No. 335-4. On March 17, Complainant responded and stated it was not asserting, for purposes of the motion for temporary relief, that there is a prevention of establishment of a domestic industry. Accordingly, this motion was denied as moot at the prehearing conference. Tr. 15.

The hearing in the matter of Certain Dynamic Sequential Gradient Compression Devices and Components Parts Thereof commenced on March 18, 1992 and concluded on March 23, 1992.

This Initial Determination is based on the entire record of this proceeding. Proposed findings not herein adopted, either in form or in substance, are rejected as not being supported by the evidence or as involving immaterial matters.

The findings of fact include references to supporting evidentiary items in the record. Such references are intended to serve as guides to the depositions, exhibits, and testimony supporting the findings of fact; they do not necessarily represent complete summaries of the evidence supporting each finding. Some of the findings of fact are contained only in the opinion.

The following abbreviations are used in this Initial Determination:

CX - Complainant's Exhibit (followed by its number and the reference page(s)).

CPX - Complainant's Physical Exhibit

CRX - Complainant's Rebuttal Exhibit

RX - Respondent's Exhibit (followed by its number and the reference page(s)).

RPX - Respondent's Physical Exhibit

RRX - Respondent's Rebuttal Exhibit

SX - Staff Exhibit (followed by its number and the reference page(s)).

SPX - Staff Physical Exhibit

SRX - Staff Rebuttal Exhibit

ALJX- Administrative Law Judge's Exhibit

FF - Finding of Fact

Dep.- Deposition

Tr.- Transcript

II. STANDARDS GOVERNING THE GRANTING OF TEMPORARY RELIEF

In order to secure temporary relief the Complainant must show a reasonable likelihood that it will prevail on the merits, and that irreparable injury will occur in the absence of such relief. Certain Pressure Transmitters, Inv. 337-TA-304, at 18. Where a patentee makes a strong showing of likelihood of success by clearly establishing patent validity and continuing infringement, a rebuttable presumption of irreparable injury arises. Roper Corp. v. Litton Systems, Inc., 757 F.2d 1266, 225 U.S.P.Q. 345 (Fed Cir. 1985); Smith International, Inc v. Hughes Tool Co., 718 F.2d 1573, 219 U.S.P.Q. 686 (Fed. Cir. 1983).

In the absence of a strong showing of success on the merits, complainant must adduce specific facts establishing a reasonable likelihood it will prevail on the merits, and that the denial of temporary relief would result in

irreparable harm to the domestic industry. Pressure Transmitters at pp. 11-16. Where there is no reasonable probability that complainant will prevail on the merits, temporary relief should not be awarded. Smith International, 718 F.2d at 1578. If there is a reasonable likelihood that complainant will prevail on the merits, and irreparable injury will probably result, harm to respondents and to the public interest must also be balanced with the affirmative findings in deciding whether temporary relief is justified. Hybritech v. Abbott Laboratories, 849 F.2d 1446 (Fed. Cir. 1988); H.H. Robertson Co. v. United Steel Deck, Inc, 820 F.2d 384, 390 (Fed. Cir. 1987); However, if irreparable injury is not reasonably likely, temporary relief is not appropriate, and the balancing of harm is therefore unnecessary.

In this investigation there is no basis for concluding that complainant has made a strong showing that it will prevail on the merits. In prior cases such a showing involved admissions, or a failure to challenge validity, or prior adjudication of patent validity. Smith International, Inc. v. Hughes Tool Co., 718 F.2d 1573 (Fed. Cir. 1983). Neither prior adjudications, nor admissions, nor failure to contest validity, nor any other comparable factor indicating strong probability that the complainant will prevail on the merits is present in this case. On the contrary, the complainant's allegations raise serious questions concerning its ability to prevail on the merits. As discussed in further detail below, complainant's allegation of infringement of the means-plus-function claim which is at issue is based on an interpretation of the function of exhaust tube 80 depicted in the Figure 6 embodiment of the '087 patent that is wholly unsupported in the patent specification; and, the domestic industry allegations are principally based on the manufacture of devices which appear markedly different from (and work differently) than those

depicted in the embodiments (or their equivalents). Further, Respondents have come forward with at least one prior art reference not before the examiner which includes an embodiment of a sequentially filled, compression gradient device, raising substantial invalidity questions.

Consequently, the likelihood that the complainant will prevail on the merits is not strong, and it is complainant's burden to affirmatively establish facts which would show reasonable probability of prevailing on the merits, and reasonable likelihood of suffering irreparable injury in the absence of temporary relief.

III. INFRINGEMENT

A. Law Of Patent Infringement

A determination of whether the accused products infringe the claims of the '087 patent requires a two-step analysis. One must construe the claims, followed by reading them on the accused product. La Bounty Manufacturing, Inc. v. U.S. International Trade Commission, 867 F.2d 1572, 9 U.S.P.Q.2d 1995 (Fed. Cir. 1989), Autogiro Co. of America v. United States, 384 F.2d 391, 155 U.S.P.Q. 697 (Ct. Cl. 1967). Claims are construed in light of the specification, prosecution history, prior art and other claims in the patent. Specialty Composites v. Cabot Corp., 845 F.2d 981, 6 U.S.P.Q.2d 1601 (Fed. Cir. 1988). They are interpreted as they would be by one skilled in the relevant art and are given their usual and customary meaning in that art, unless it is apparent the inventor meant otherwise. Smithkline Diagnostics, Inc. v. Helena Laboratories Corp., 859 F.2d 878, 8 U.S.P.Q.2d 1468 (Fed. Cir. 1988). Ultimately, through this analysis, the scope and extent of the patent rights intended to be granted by the Patent and Trademark Office is determined. Autogiro Co. of America v. United States, supra; SRI

irreparable harm to the domestic industry. Pressure Transmitters at pp. 11-16. Where there is no reasonable probability that complainant will prevail on the merits, temporary relief should not be awarded. Smith International, 718 F.2d at 1578. If there is a reasonable likelihood that complainant will prevail on the merits, and irreparable injury will probably result, harm to respondents and to the public interest must also be balanced with the affirmative findings in deciding whether temporary relief is justified. Hybritech v. Abbott Laboratories, 849 F.2d 1446 (Fed. Cir. 1988); H.H. Robertson Co. v. United Steel Deck, Inc, 820 F.2d 384, 390 (Fed. Cir. 1987); However, if irreparable injury is not reasonably likely, temporary relief is not appropriate, and the balancing of harm is therefore unnecessary.

In this investigation there is no basis for concluding that complainant has made a strong showing that it will prevail on the merits. In prior cases such a showing involved admissions, or a failure to challenge validity, or prior adjudication of patent validity. Smith International, Inc. v. Hughes Tool Co., 718 F.2d 1573 (Fed. Cir. 1983). Neither prior adjudications, nor admissions, nor failure to contest validity, nor any other comparable factor indicating strong probability that the complainant will prevail on the merits is present in this case. On the contrary, the complainant's allegations raise serious questions concerning its ability to prevail on the merits. As discussed in further detail below, complainant's allegation of infringement of the means-plus-function claim which is at issue is based on an interpretation of the function of exhaust tube 80 depicted in the Figure 6 embodiment of the '087 patent that is wholly unsupported in the patent specification; and, the domestic industry allegations are principally based on the manufacture of devices which appear markedly different from (and work differently) than those

depicted in the embodiments (or their equivalents). Further, Respondents have come forward with at least one prior art reference not before the examiner which includes an embodiment of a sequentially filled, compression gradient device, raising substantial invalidity questions.

Consequently, the likelihood that the complainant will prevail on the merits is not strong, and it is complainant's burden to affirmatively establish facts which would show reasonable probability of prevailing on the merits, and reasonable likelihood of suffering irreparable injury in the absence of temporary relief.

III. INFRINGEMENT

A. Law Of Patent Infringement

A determination of whether the accused products infringe the claims of the '087 patent requires a two-step analysis. One must construe the claims, followed by reading them on the accused product. La Bounty Manufacturing, Inc. v. U.S. International Trade Commission, 867 F.2d 1572, 9 U.S.P.Q.2d 1995 (Fed. Cir. 1989), Autogiro Co. of America v. United States, 384 F.2d 391, 155 U.S.P.Q. 697 (Ct. Cl. 1967). Claims are construed in light of the specification, prosecution history, prior art and other claims in the patent. Specialty Composites v. Cabot Corp., 845 F.2d 981, 6 U.S.P.Q.2d 1601 (Fed. Cir. 1988). They are interpreted as they would be by one skilled in the relevant art and are given their usual and customary meaning in that art, unless it is apparent the inventor meant otherwise. Smithkline Diagnostics, Inc. v. Helena Laboratories Corp., 859 F.2d 878, 8 U.S.P.Q.2d 1468 (Fed. Cir. 1988). Ultimately, through this analysis, the scope and extent of the patent rights intended to be granted by the Patent and Trademark Office is determined. Autogiro Co. of America v. United States, supra; SRI

International v. Matsushita Electric Corp. of America, 775 F.2d 1107, 227 U.S.P.Q. 577 (Fed. Cir. 1985).

Claim 1 of the '087 patent[1] is written in large part as a "means-plus-function" claim as allowed by 35 U.S.C. § 112, ¶ 6 which provides:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

A means-plus-function claim is literally infringed if the accused process or device performs each of the claimed functions and each claimed function is performed by a means described in the specification or an equivalent of such means. In General Instrument Corp. v. U.S. International Trade Commission, 20 U.S.P.Q.2d 1161 (Fed. Cir. 1991), the Federal Circuit provided:

> "To meet a means-plus-function limitation literally, an accused device must (1) perform the identical function claimed for the means element, and (2) perform that function using the structure disclosed in the specification or an equivalent structure."
>
> 20 U.S.P.Q.2d at 1178

When an invention is claimed in means-plus-function form, the patentee is entitled to a "fair scope" of equivalents of the structures set forth in the embodiment, without setting forth a "catalogue" of alternative embodiments. Texas Instruments, Inc. v. U.S. International Trade Commission, 805 F.2d 1558, 231 U.S.P.Q. 833 (Fed. Cir. 1986). This does not mean, however, that a means-plus-function claim is infringed simply because the accused device incorporates any means for accomplishing the claimed function. To so hold would be contrary to the plain meaning of the statute. Section 112 ¶ 6

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[1] Claims 2, 5, 6, 9, 11-13, and 17-20 are dependent upon claim 1.

operates to limit the types of means which could literally satisfy the claim language by restricting them to the means set forth in the specification and their equivalents. As the court pointed out in Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 4 U.S.P.Q.2d 1737 (Fed. Cir. 1987):

> "[S]ection 112, paragraph 6, rules out the possibility that any and every means which performs the function specified in the claim literally satisfies that limitation. While encompassing equivalents of those disclosed in the specification, the provision, nevertheless, acts as a restriction on the literal satisfaction of a claim limitation.
>
> 4 U.S.P.Q.2d at 1739
> (original emphasis)

See also, Johnston v. IVAC Corp., 885 F.2d 1574, 12 U.S.P.Q.2d 1382 (Fed. Cir. 1989).

The standard for determining the scope of structural equivalents for purposes of Section 112, paragraph 6 was stated in General Instrument Corp. v. U.S. International Trade Commission, 20 U.S.P.Q.2d 1161 (Fed. Cir. 1991):

> [U]nder section 112, paragraph 6, the aids for determining a structural equivalent to the structure disclosed in the patent specification are the same as those used in interpreting any other claim language, namely, the specification, the prosecution history, other claims in the patent, and expert testimony.
>
> 20 U.S.P.Q.2d at 1179-1180
> (citations omitted)

Under Section 112, paragraph 6 structural equivalents may exist in the prior art. In this respect construction of a mean-plus-function claim is different than application of the doctrine of equivalents in which the range of equivalents is limited by the prior art. Also, because a patentee is free to be his own lexicographer and may use a term in a manner inconsistent with its ordinary meaning, analysis of the specification and prosecution history is important to proper claim construction. Hormone Research Foundation v. Genentech, Inc., 904 F.2d 1558, cert. denied, 111 S.Ct. 1434 (1991).

B. **Interpretation Of Claim 1 Of The '087 Patent**

1. **Claim 1**

Kendall asserts that Claim 1 of the '087 patent is infringed by Huntleigh's Flowplus device. Claim 1 provides:

> A device for applying compressive pressures against a patient's limb from a source of pressurized fluid comprising:
>
> an elongated pressure sleeve for enclosing a length of the patient's limb, said sleeve having a plurality of separate fluid pressure chambers progressively arranged longitudinally along the sleeve from a lower portion of the limb to an upper portion of the limb proximal the patient's heart relative said lower portion;
>
> means for filling said chambers from said source during periodic compression cycles while applying a greater pressure in each inflated lower chamber than the pressure in any upper inflated chamber to apply a compressive pressure gradient against the patient's limb by the sleeve which progressively decreases from said lower to upper limb portions throughout the compression cycles, said filling means including means for connecting the source to a lower first chamber in said sleeve;
>
> means for distributing fluid from said first chamber to progressively located upper chambers at progressively decreasing pressures; and
>
> means for emptying said chambers during periodic decompression cycles between said compression cycles.

Complainant bears the burden of establishing that the Flowplus device infringes Claim 1 of the '087 patent. Under Sea Industries, Inc. v. Dacor Corp., 833 F.2d 1551, U.S.P.Q. 2d 1772 (Fed. Cir. 1987). Accordingly, it must establish that the Flowplus device contains all the limitations set forth in Claim 1 as properly construed. Corning Glass Works v. Sumitomo Electric U.S.A., 868 F.2d 1251, 9 U.S.P.Q. 2d 1962 (Fed. Cir. 1989).

2. **The Means Described In The Specification Of The '087 Patent**

a. **"means for filling [fluid pressure] chambers ..."**

The specification of the '087 patent describes different embodiments of a

"device ... for applying compressive pressures against a patient's extremity of limb". The first embodiment, Figure 1, discloses an entire device with a sleeve connected to a timing device which is in turn connected to a source of pressurized gas. CX 9, Col. 2 lines 44 - 64. The timing device is also connected to an exhaust tube. CX 9, Col. 2 line 66. The specification makes clear that the timer controls the inflation and deflation of the sleeve:

> [T]he timing device 30 connects the source 28 of pressurized gas to the lowermost chamber 24a during periodic inflation or compression cycles when the sleeve is filled, and the timing device 30 connects the inflated lowermost chamber 24a of the sleeve 22 to the exhaust tube 36 during periodic deflation or decompression cycles, i.e., the interval between the inflation cycles, when the sleeve is emptied.
>
> CX 9, Col. 3 lines 5 - 12

b. **"while applying a greater pressure in each inflated lower chamber than the pressure in any upper inflated chamber to apply a compressive pressure gradient ... throughout the compression cycles ... "**

In the embodiments shown in Figures 1 and 5, the sleeve portion of the device has spring valves between the chambers which open to allow the passage of fluid only when a predetermined pressure differential is attained. Melrose, Tr. 590-592.[2] These valves will close if the pressure differential between the chambers drops below the predetermined level. Id. In this manner, these embodiments maintain the pressure in two adjacent chambers at different levels and thus maintain a compressive pressure gradient along the length of the sleeve throughout the compression cycle. Id.

Figure 6 of the '087 patent depicts an alternative embodiment of the sleeve portion of the device. The sleeve in Figure 6 utilizes flow restrictors between the chambers to create a pressure gradient. Melrose, Tr.

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[2] Dr. Denis Melrose, Respondents' expert witness, is the inventor of the heart-lung machine. Melrose, Tr. 558-560, RX 26.

593. This embodiment first fills the lowermost chamber, causing a pressure rise therein. Dye, Tr. 69. The restrictor tube between the lowermost chamber and the chamber immediately above it slightly impedes the passage of air into the second chamber. Id. This restriction causes the second chamber to fill more slowly than the first. As a result, the level of pressure applied by the second chamber lags behind the level applied by the first chamber. See, RX 171 at 38112-38114. Restrictor tubes in the walls between subsequent pairs of chambers also serve to impede the flow of air between them. Melrose, Tr. 593; CX 9, Figure 6. By utilizing progressively smaller restriction tubes in each chamber wall, the embodiment provides for greater pressure in each chamber than in the chamber above it. CX 9, Col. 6 lines 20-39. In this manner the embodiment in Figure 6 creates a gradience of pressure with the bottom of the sleeve exerting more pressure than the top. Id. This gradient will be maintained during at least the initial stages of compression. Melrose, Tr. 600-601. At some point after the compression cycle commences, the pressures in the chambers of the sleeve in the Figure 6 embodiment can reach equilibrium. Id. When the chambers reach equilibrium, the air flow will stop. Id.

Complainant and Staff assert that the exhaust tube 80 in Figure 6 serves as a bleed valve, allowing air to continuously exit the uppermost chamber, thus preventing the chambers from reaching equilibrium and maintaining a compressive pressure gradient throughout the compression cycle.[3] Indeed,

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[3] Complainant asserts that the Figure 6 embodiment and the accused Flowplus device apply a pressure gradient in accordance with Poiseuille's Law. Poiseuille's Law states that the pressure exerted against the wall of a tube by a fluid moving through it diminishes along the length of the tube provided the flow is laminar. RX 112. The pressure drop is directly proportional to the viscosity of the fluid, the length of the tube, and the fluid's velocity (continued...)

Complainant asserts that the only way that the embodiment in Figure 6 can maintain a compressive pressure gradient without restriction on the duration of the inflation cycle is if air is allowed to continuously flow through the device and out exhaust tube 80. Complainant's Posthearing Brief at 6-7.

The inventor's intention regarding exhaust tube 80 is reflected in the specification of the '087 patent. The only purpose set forth in the specification for tube 80 is to exhaust the sleeve at the end of the compression cycle. CX 9 Col. 6 lines 42-45.[4] The specification never refers to it as anything other than an "exhaust tube". There is no indication that the inventors intended to utilize the term "exhaust tube" in a manner different than its ordinary meaning, i.e., a tube for deflating the sleeve. Further, in order for exhaust tube 80 to maintain pressure gradience as a bleed valve, it would have to restrict the flow of air out of the uppermost chamber to a greater extent than the flow restrictor between the uppermost chamber and the next distal chamber. Were the tube to be as restrictive as

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[3](...continued)
through the tube. Id.

Complainant adduced no evidence demonstrating that the air flows through a Figure 6 embodiment or a Flowplus device in a laminar manner. Nor did Complainant adduce evidence that the viscosity of the air, the length of a Flowplus device, and the velocity of the air through a Flowplus device would account for the pressure gradient exhibited by a Flowplus device. Mr. Schild testified that Poiseuille's Law would relate to a pressure drop within the tubing connecting two chambers, but not to the difference in pressure applied by the chambers. Schild, Tr. 874. Mr. Dye was unable to describe Poiseuille's Law, but after reference to a physics textbook, agreed that it did not relate to the flow of fluids between chambers. Dye, Tr. 153-155. Further, Mr. Schild testified that he had never heard of anyone saying that Poiseuille's Law taught the use of a bleed valve to maintain pressure drops between chambers. Schild, Tr. 874. Accordingly, the Administrative Law Judge does not accept Complainant's assertion regarding Poiseuille's Law.

[4] The specification provides that the sleeve "may be deflated through an exhaust tube 80 connected to the uppermost chamber 24d, or in a manner as previously described". The manners "previously described" are depicted in Figures 1 and 5.

required to maintain gradience, it could not serve as an effective exhaust tube. Melrose, Tr. 611. In short, there is no evidence in the patent that the exhaust tube was to function in any manner other than as a port to deflate the sleeve at the end of the compression cycle.

There is no indication in the patent specification or prosecution history that exhaust tube 80 is intended to serve as a bleed valve to allow the maintenance of a pressure gradient throughout[5] the compression cycle. At no point in the specification is exhaust tube 80 described either as open during the compression cycle, or as contributing to the establishment of a pressure gradient along the length of the sleeve. Indeed, the specification gives no indication that the inventors had in their possession at the time they applied for the '087 patent an invention utilizing a continuous flow of air to maintain a pressure gradient. See, In re Wright, 866 F.2d 422, 424, 9 U.S.P.Q. 1649, 1651 (Fed. Cir. 1989) (one of the purposes of the specification is to clearly convey to one of ordinary skill in the art that the inventor had possession of the subject matter set forth in the claims at the time of the application).[6]

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[5] The specification of the '087 patent provides that the invention maintains a pressure gradient "during" each compression cycle (CX 9, Col 6 lines 33-42). In the course of the prosecution of the '087 patent's application, Claim 1 was amended to clarify that the invention maintained a gradient "throughout" each compression cycle (RX 155), i.e. at all points in time within the cycle. See discussion at 50.

[6] The circumstances surrounding Kendall's application for a Canadian patent support the conclusion that the inventors did not intend that exhaust tube 80 function to regulate gradience. The Canadian patent office rejected Kendall's application in view of U.S. Letters Patent No. 3,548,809, to Conti. Although the claim language in the Canadian patent was identical to Claim 1 of the '087, patent, in the face of a rejection of a claim identical to claim 1 of the '087 patent, Kendall narrowed its application to an embodiment which utilized spring valves. At that time (in March, 1980) Kendall did not assert that its invention maintained a pressure gradient by using exhaust tube 80 as

(continued...)

The testimony of Mr. John Dye, the co-inventor of the '087 device, together with the idea sheets of the other co-inventor, Mr. Howard Memhardt also reveal that tube 80 does not serve as a bleed valve. The notebook entry dated October 20, 1972, depicts a multichambered sleeve with the sleeves connected by tubes of decreasing diameter. RX 171 at 38112.[7] The entry states that the chambers "progressively inflate" and further states, "At the time that all chambers have come to an equal pressure the inlet valve would close and the exit valve would open", emptying the device.[8] Id., Dye, Tr. 133.

A further notebook entry dated November 20, 1972 describes an improvement on the October 20, 1972 idea and contains a drawing of a proposed device which is essentially identical to Figure 6. RX 171 at 38109. This drawing depicts a tube labeled "exhaust" exiting the uppermost chamber. RX 171 at 38109. It also refers to the October 20, 1972 entry and states that the idea disclosed in the current sheet substitutes ports in the chamber walls, for the tubing in the prior idea sheets. It does not indicate that the "exhaust" operates in a manner different from the "exit valve" depicted in the previous idea sheet,

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[6](...continued)
a bleed valve and that it was therefore patentable over the '809 patent. RX 154A. Complainant asserts that it has a Canadian patent No. 1,085,251, (CX 237) with respect to the Figure 6 embodiment. This patent is a counterpart of Claim 27 of the '087 patent, and not Claim 1. Because Complainant withdrew its allegation of infringement of Claim 27, no evidence was adduced regarding its construction. While Figure 6 may describe Claim 27, Claim 27 appears materially different than Claim 1.

[7] Exhibit 171 is a set of "idea sheets" authored by the co-inventor of the '087 device, Mr. Charles Memhardt. Mr. Dye spent "hundreds of hours" developing the project with Mr. Memhardt and acted as witness to several pages of Mr. Memhardt's notebook. Dye, Tr. at 124-130.

[8] The exhaust tubes as well as the inlet tube are shown in this idea sheet with an "X" over them, which is the conventional method of showing a valve. Dye, Tr. 235.

and described in the applicable text. Id. Therefore, it appears that in all the idea sheets the inventors intended what later became exhaust tube 80 to remain closed during the compression cycle, and to open only to deflate the device. Further, there is no objective evidence that the inventors made any changes in the invention between the dates of the idea sheets and the patent application date of October 28, 1975. Indeed, the drawing of Figure 6 in the patent specification is virtually identical to the conception and specific features shown in these idea sheets.

To function as an exhaust, tube 80 of necessity must be closed during the compression cycle, and open during the deflation of the sleeve. Melrose, Tr. 611. Staff argues that because exhaust tube 80 is described as a "tube", not a "valve", it is open at all times. Staff's Posthearing Brief at 8. However, Figure 6 depicts only the sleeve portion of the device and thus is not intended to illustrate a complete device. Tube 80 is drawn with jagged lines at the end, indicating that it continues to a location not depicted on the drawing, namely the exhaust control mechanism (e.g. a timer). The exhaust tube in the October 20, 1972 idea sheet continues to a valve and the November 20, 1972 idea sheet indicates that it also continues to a valve. RX 171 at 38109, 38112. Conventionally, an exhaust includes a method of closure when not in exhaust mode.

Complainant submitted the deposition testimony of Mr. Memhardt, the co-inventor and a former employee of Complainant, in support of its argument that tube 80 functions as a bleed valve which prevents equalization of pressure between the chambers and regulates gradience. Ordinarily, the deposition of an inventor/former employee of a complainant is not admissible by the complainant absent a showing of one of the exceptions set forth in Commission

Interim Rule 210.31(h). Complainant did not establish that one of the exceptions applied. However, Respondents did not object to the deposition's admission, but argue in their post-hearing filings that the testimony contained therein should be given little weight.

Mr. Memhardt's testimony upon which Complainant relies to support its argument that tube 80 is a bleed valve is not supported by objective corroboration. In his deposition, Mr. Memhardt stated that he built a prototype of the device depicted in Figure 6 in the patent. However Mr. Dye stated he never saw this prototype. Dye, Tr. 94.[9] In his deposition Mr. Memhardt testified that he had inflated the prototype with the exhaust tube open. However, Dr. Melrose testified that it could not be inflated to proper pressure unless the exhaust were closed during inflation. Melrose, Tr. 610-611.

In view of the fact that Mr. Dye has worked closely with Mr. Memhardt, and testified that he had never seen the Figure 6 prototype, and in view of the fact that neither in the idea sheets or other documentation is there any suggestion that tube 80 could prevent equilibrium among the chambers, or functions to regulate gradience, the Administrative Law Judge will rely on Dr. Melrose's testimony that such a device could not be inflated with an open exhaust tube and will not give weight to the above referenced deposition testimony of Mr. Memhardt. The Administrative Law Judge will rely only on

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[9] Further, when Respondents' counsel inquired into discussions Mr. Memhardt had with Complainant's counsel regarding tube 80, Complainant's counsel instructed him not to answer on the grounds of attorney-client privilege, despite the apparent absence of an attorney-client relationship. RPX 3 at 37-46. These questions appear not to be protected by the attorney-client privilege and should have been answered. A revelation of the discussion between Mr. Memhardt and complainant's counsel about the function of tube 80 could shed important light on complainants' contention concerning the function of tube 80.

those parts of the deposition which are corroborated by reliable documentation.[10]

Contrary to the assertions of Complainant, a device with a sleeve construction like that depicted in Figure 6 can maintain a pressure gradient throughout a compression cycle without a bleed valve. As noted, Figure 6 is not an embodiment of the entire invented device itself, but of only the internal structure of the sleeve portion. Indeed, the patent specifically provides "Another embodiment of the sleeve 22 of the present invention is illustrated in Figs. 6-8,..." CX 9, Col. 5 lines 53 - 54 (emphasis added). The complete compression device consists of a sleeve, pressurized gas source, and a timer. CX 9, Col. 2 lines 41-64. A complete functioning compression device incorporating the sleeve depicted in Figure 6 would necessarily incorporate the other components of the '087 patent which are described in more detail in the discussion regarding Figure 1, i.e. a source of pressurized gas and a timing device to control when inflation and deflation commence. One of ordinary skill in the art would know that as a Figure 6 sleeve filled with air, the flow restrictors between the chambers would create a pressure gradient along the length of the sleeve. This person would also know that the chambers in a Figure 6 sleeve would eventually reach equal pressure if the compression cycle were allowed to continue. Melrose, Tr. 600-601. At this point of equilibrium, air would cease flowing through the restrictors and there would be no pressure gradient. Melrose, Tr. 601. Accordingly, a person of ordinary skill would know that in order to maintain a pressure gradient "throughout the compression cycle" as called for in Claim 1, he would have to

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[10] If complainants intend to rely on Mr. Memhardt's testimony at the hearing on permanent relief, it should be presented live in accordance with the Commission's preference for live testimony.

utilize the timer described in the specification (or an equivalent) to halt the compression cycle before the chambers reach equal pressure. Melrose, Tr. 602-603.

Complainant further asserts that exhaust tube 80 must be construed as a bleed valve. This the Complainant alleges is because the patent does not teach a limitation upon the duration of the compression cycle, and the only way a pressure gradient can be maintained through an indeterminate cycle is by use of a bleed valve. The flaw in this argument is that there is no teaching of a particular duration of the compression cycle. Such a teaching is unnecessary because the duration of compression cycles vary based upon the medical condition of the patient and the philosophy of compressive treatment.[11] The patent teaches that the variability of the duration of the compression and decompression cycles is achieved through the use of a timer or its equivalent. Melrose, Tr. 602-603.

c. **"...including means for connecting the source to a lower first chamber in said sleeve;"**

In all of the embodiments depicted in the specification of the '087 patent, there is an inlet into the first chamber of the sleeve for fluid flowing from a source. Figures 1 and 5 depict a hose, 34, leading from the fluid source into the lowest portion of the sleeve. Because Figures 6, 9, 10 and 12 depict only the sleeve portion of the device, they do not show the hose leading to the sleeve from the source, although the sleeve in each of these depictions contains only one inlet.

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[11] Generally, lymphoedema is treated with devices that have longer compression cycles and higher compression pressures than devices designed to stimulate venous blood flow. Crosby, Tr. 413-414; Gilman, Tr. 444-447, Witko, Tr. 929.

d. **"means for distributing fluid from said first chamber to progressively located upper chambers at progressively decreasing pressures;**

The specification of the '087 patent depicts three means for distributing fluid from the first chamber of the sleeve to the upper chambers at progressively decreasing pressures. In the sleeve depicted in Figures 1 and 5, each chamber is connected to the adjacent chambers by small tubes inside of which are one-way spring valves. CX 9, Col. 3 lines 17-20. As fluid is pumped into the first chamber, the fluid pressure in that chamber increases. When the pressure is greater than the pressure in the second chamber by an amount determined by the spring valve, the fluid pushes open the spring valve and enters the second chamber. CX 9, Col. 3 lines 40-56. The spring valve remains open only as long as the pressure differential between the two chambers is equal to or higher than the predetermined level set by the valve. CX 9, Col. 3 lines 61-67. Similarly, a spring valve between the second and third chambers maintains a pressure differential between these chambers. CX 9, Col 4 lines 3-9. Thus, the pressure in the first chamber is always greater than the pressure in the second, which is always greater than the pressure in the third and so on up the sleeve resulting in a compressive pressure gradient. CX 9, Col. 4 lines 15-23.

The second embodiment in the specification of the '087 patent for performing this function is described in Figures 6 and 10. In this embodiment, the first chamber is separated from the second by a single flow restrictor, either a short length of tube (Figure 6) or a port or passageway in the chamber wall (Figure 10). The flow restrictor impedes the passage of fluid from the first chamber to the second so that while the chambers are filled simultaneously, they apply different pressures to the person's limb.

See discussion at 11. The single flow restrictor between the second and third chambers is of a narrower bore and further impedes the flow of fluid so that the second chamber applies a greater pressure than the third. The first chamber applies the greatest pressure and each subsequent chamber applies less pressure than the one before it. Thus, a compressive pressure gradient is achieved and will be maintained as long as fluid flow continues through the restrictors. CX 9 Col. 6 lines 9-19.

The third means utilizes several lengths of tube (Figure 9) or several passageways (Figure 12), all of equal bores, between the first and second chambers, with fewer tubes/passageways between subsequent pairs of chambers. The effect of decreasing the number of flow restrictors is the same as decreasing the size of a single flow restrictor. The pressure in the first chamber is greater than that in the second which is greater than that in the third and so on up the sleeve. CX 9 Col. 6 lines 46 - Col. 7 line 2.

e. "means for emptying said chambers during periodic decompression cycles between said compression cycles"

The uppermost chamber of Figure 6 has a tube (tube 80) which connects the chamber to the outside. The patent's specification provides that the sleeve "may be deflated through an exhaust tube 80 connected to the uppermost chamber 24d, or in a manner as previously described". CX 9, Col. 6 lines 43-45. The manners "previously described" emptied the sleeve's chambers either through a single exhaust tube connected to the lowermost chamber (Figure 1) or through multiple exhaust tubes, one extending from each chamber (Figure 5).

C. The Huntleigh Flowplus Device

Huntleigh's Flowplus device is a multi-chambered sleeve with flow restrictors between the chambers in the form of small diameter tubes. Melrose, Tr. 635-636. The first chamber (i.e., that chamber located around

the patient's foot) of the sleeve is connected to a pump. CPX 12. Air is pumped into the first chamber, and the interconnecting tubes between the chambers inflate them in sequence, the lower chambers filling first. Melrose, Tr. 635-636, Schild, Tr. 713-715. The interconnecting tubes restrict the flow of air from one chamber to the next, creating a compressive pressure gradient as in the Figure 6 embodiment. Id.

The Flowplus device maintains the compressive pressure gradient throughout the compression cycle through the use of a bleed valve in the uppermost chamber. Schild, Tr. 714. Air continually flows through the device, eventually exiting the uppermost chamber through the bleed valve. Id. This bleed valve prevents the chambers from coming to an equilibrium state and thus maintains the compressive pressure gradient along the length of the sleeve.

D. Kendall Has Not Demonstrated That It Is Likely To Prove That Huntleigh's Flowplus Device Infringes Claim 1

The Flowplus device performs all the functions claimed in Claim 1. It is comprised of an elongated pressure sleeve with a plurality of fluid pressure chambers. The sleeve is connected to a control unit which regulates the pumping of air into the lowermost chamber. The air which is pumped into the first chamber is distributed into the upper chambers at progressively decreasing pressures. Finally, the Flowplus device has a means for exhausting the air from the chambers between compression cycles.

The infringement analysis of a means-plus-function claim does not stop with the determination of whether the accused product performs the same functions as those set forth in the claim. The second step is to determine whether the accused product performs the claimed functions using the structure disclosed in the specification or an equivalent structure. General Instrument

Corp. v. U.S. International Trade Commission, 20 U.S.P.Q.2d 1161 (Fed. Cir. 1991). Indeed, it is legal error to simply compare the accused product to the claim alone; it must be compared to the structure disclosed in the specification. Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 4 U.S.P.Q.2d 1737 (Fed. Cir. 1987). Only if the accused product performs the claimed function through the use of an identical or equivalent structure does literal infringement hold. Id.

Equivalency of structure for purposes of Section 112, ¶ 6 is determined by reference to the aids utilized in claim interpretation, i.e., the specification, prosecution history, other claims in the patent, and expert testimony as appropriate. General Instrument, 20 U.S.P.Q.2d at 1179-1180, King Instrument Corp. v. Otari Corp., 767 F.2d 853, 226 U.S.P.Q. 402 (Fed. Cir. 1985).

The record does not support a conclusion that the structure of the Huntleigh Flowplus device is the same as or equivalent to the structure set forth in the '087 patent. The claim language requires that a compressive pressure gradient be maintained throughout the compression cycle. The '087 embodiments all maintain a compressive pressure gradient throughout the cycle by utilizing either a series of spring valves or a series of flow restrictors plus a timer. These embodiments maintain a pressure gradient throughout the compression cycle by stopping the flow of air into and through the device to prevent equalization of pressure between the chambers. Both the spring valves and the timer function in this manner. At no point during the prosecution history was it suggested that a compressive pressure gradient was maintained throughout the compression cycle in any other manner. In light of the specification, the prosecution history, and the testimony of Mr. Dye, the

proper scope of structural equivalents of these embodiments encompasses structures which maintain gradience by stopping the flow of air to prevent equalization of pressure between the chambers.

In contrast, the Flowplus device utilizes a bleed valve which maintains the compressive pressure gradient in a totally different manner. The bleed valve allows air to slowly escape from the uppermost chamber while this chamber is being inflated, in a more or less continuous fashion. There is no structure in the Flowplus device which halts the flow of air through the chambers. Thus, the Flowplus device prevents the establishment of equal pressure between the chambers by a continuous flow of air rather than stopping the air flow as is done in the '087 embodiments.[12]

The argument of Complainant and Staff that because Claim 1 is for a means that maintains a compressive pressure gradient "throughout the compression cycle", exhaust tube 80 in the Figure 6 embodiment must of necessity serve as a bleed valve, and thus maintain a compressive gradient by preventing equilibrium, constitutes a priori reasoning from a faulty hypothesis, without regard to the facts. A means-plus-function claim does not cover any and all embodiments which are capable of performing the claimed function. Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 4 U.S.P.Q.2d 1737 (Fed. Cir. 1987). Only the embodiments set forth in the specification (and their equivalents) are covered by the claim. Id. It is clear from the specification that the inventors intended the Figure 6 embodiment of the sleeve to attach to a timer (or equivalent means) which would maintain the compressive pressure gradient. There is nothing in the specification,

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[12] The Flowplus device has a timer which regulates the duration of the compression cycle, but this timer does not maintain the device's compressive pressure gradient.

prosecution history, other claims of the patent, or the expert testimony of Mr. Dye indicating that the inventors intended exhaust tube 80 to act as a bleed valve, or to in any way regulate gradience. Indeed, tube 80 is described only as a means for exhausting air out of the sleeve at the conclusion of the compression cycle. Interpreting the Figure 6 embodiment as incorporating a bleed valve in the guise of an exhaust tube would unduly broaden the scope of Claim 1.

The manner in which Huntleigh's bleed valve maintains a compressive pressure gradient throughout the compression cycle appears sufficiently different from the manner utilized by the '087 embodiments so as to remove it from the scope of structural equivalents of those embodiments.[13] Complainant argues that Figure 6 depicts the use of a bleed valve, thus bringing the Flowplus within the scope of Claim 1. In light of the Administrative Law Judge's determination that exhaust tube 80 does not regulate gradience and does not function as a bleed valve, and the failure of Complainant to demonstrate that a compression device with a bleed valve is the structural equivalent of Figure 6, Complainant has failed to establish that it is reasonably likely to prevail on the issue of infringement of Claim 1.

E. Kendall Has Not Demonstrated That It Is Reasonably Likely To Prove That Huntleigh's Flowplus Device Infringes Claim 25

Complainant has not adduced any evidence regarding the construction of Claim 25. The only evidence adduced regarding infringement of Claim 25 is a statement by Mr. Schild that the accused device has elements that corresponds to the elements in Claim 25. Schild, Tr. 746. This testimony, particularly

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[13] In its briefs and during the hearing, Complainant has not argued that a compression device utilizing a bleed valve to apply a compressive pressure gradient is the structural equivalent of the embodiment in Figure 6.

in the absence of evidence regarding the claim's construction, is insufficient to support a conclusion that it is reasonably likely that Camplainant can establish that Claim 25 is infringed.

IV. VALIDITY

Respondents assert that the '087 patent is invalid for anticipation under 35 U.S.C. § 102 and obviousness under 35 U.S.C. § 103.

A patent is presumed valid. 35 U.S.C. § 282. The statutory presumption of validity is based on a presumption that the Patent and Trademark Office performed its administrative duties correctly in issuing the patent. Lannom Mfg. Co., Inc. v. U.S. International Trade Commission, 799 F.2d 1572, 231 U.S.P.Q. 32 (Fed. Cir. 1986). This presumption requires one challenging the patent's validity to prove by clear and convincing evidence that the patent is invalid. Greenwood v. Hattori Seiko Co., Ltd., 900 F.2d 238, 14 U.S.P.Q.2d 1474 (Fed. Cir. 1990).

The presumption of validity places the burden of going forward and the ultimate burden of persuasion on the party challenging the patent's validity. It does not, however, relieve the movant for temporary relief of its burden of establishing a likelihood of success on the merits with respect to validity. Nutrition 21 v. United States, 930 F.2d 867, 18 U.S.P.Q.2d 1347 (Fed. Cir. 1991). Indeed, in Nutrition 21, the Federal Circuit held that because of the "extraordinary nature" of temporary relief, the movant must clearly establish a likelihood that the patent's validity will be upheld. 18 U.S.P.Q.2d at 1349.

A. Anticipation

1. Law Of Anticipation

Section 102(b) of Title 35 provides in relevant part:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country, ... more than one year prior to the date of the application for a patent in the United States.

In deciding whether a claim is invalid for anticipation, the trier of fact must identify the claim's elements, determine their meaning, and identify corresponding elements disclosed in the allegedly anticipating reference. Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick, 730 F.2d 1452, 221 U.S.P.Q. 481 (Fed. Cir. 1984). For a patent claim to be found invalid under § 102, every element of the claim must be literally present in the anticipating reference. Richardson v. Suzuki Motor Co., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989), Tyler Refrigeration v. Kysor Industrial Corp., 777 F.2d 687, 227 U.S.P.Q. 845 (Fed. Cir. 1985). The anticipating reference must show the claimed invention in as much detail as is contained in the claim. Richardson v. Suzuki Motor Co., Id. at 1920.

The anticipating reference must also satisfy the statutory requirement of a "publication". To serve as a publication for purposes of § 102(b), the reference must have been generally available. Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 15 U.S.P.Q.2d 1321 (Fed. Cir. 1990). The reference must have been accessible to the public interested in the relevant art. Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 7 U.S.P.Q.2d 1057 (Fed. Cir. 1988).

2. Claim 1 Of The '087 Patent Is Not Invalid For Anticipation

Claim 1 of the '087 patent provides:

A device for applying compressive pressures against a patient's limb from a source of pressurized fluid comprising:

an elongated pressure sleeve for enclosing a length of the patient's limb, said sleeve having a plurality of separate

fluid pressure chambers progressively arranged longitudinally along the sleeve from a lower portion of the limb to an upper portion of the limb proximal the patient's heart relative said lower portion;

means for filling said chambers from said source during periodic compression cycles while applying a greater pressure in each inflated lower chamber than the pressure in any upper inflated chamber to apply a compressive pressure gradient against the patient's limb by the sleeve which progressively decreases from said lower to upper limb portions throughout the compression cycles, said filling means including means for connecting the source to a lower first chamber in said sleeve;

means for distributing fluid from said first chamber to progressively located upper chambers at progressively decreasing pressures; and

means for emptying said chambers during periodic decompression cycles between said compression cycles.

A reference must describe all of the functions set forth in Claim 1 in order to anticipate the claim. Richardson v. Suzuki Motor Co., 9 U.S.P.Q.2d at 1920.

A review of the prior art alleged to be anticipatory follows:

a. British Patent No. 1,310,492

Respondents assert that British Patent No. 1,310,492 ("Flowtron Aire patent") anticipated the invention disclosed in the '087 patent and thus renders the patent invalid under 35 U.S.C. § 102(b).

The Flowtron Aire patent was issued on March 21, 1973. The patent is entitled "Apparatus For Activating Parts Of The Body". Its specification discloses that the apparatus is intended to mitigate medical problems, such as thrombosis[14], that arise when a patient is immobilized in bed. RX 30, Col. 1

[14] Thrombosis is defined as the formation of a thrombus. McGraw-Hill Dictionary of Scientific and Technical Terms 1928 (4th ed. 1989). A thrombus is a blood clot inside of an unbroken blood vessel. If it remains intact, it may damage tissue by restricting the tissue's oxygen supply. If it detaches from the wall of the vessel, it will travel through the circulatory system (continued...)

lines 11-30.

The invention disclosed in the Flowtron Aire patent is a multi-chambered device in which the chambers are connected together in series by "restricted passageways". RX 30, Col. 1 lines 31-37. The lowermost chamber is connected to a source of compressed gas by a supply tube. RX 30, Col. 2 lines 75-79. The device inflates the lowermost chamber first, and the restricted passageways cause the subsequent chambers to inflate in succession "to impart a cyclic force to said part of the body." RX 30, Col. 1 lines 37-40.

The sequential filling of a plurality of chambers as illustrated in the Flowtron Aire patent produces a pressure gradient against the patient's limb. As each chamber inflates, the pressure it exerts on the limb increases. There is a time delay between when each chamber reaches a certain pressure (i.e. sequential filling), and at any one point in time the first chamber will apply a greater pressure than the second chamber. Similarly, the second chamber will apply a greater pressure than the third and so on along the length of the sleeve.[15] Eventually, the chambers reach equal pressure at which point gradience will no longer exist.

The Flowtron Aire patent discloses a means for controlling when the compression cycle ends and the decompression cycle begins. RX 30, Col. 3 lines 24-38. This control shuts off the compression cycle and begins

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[14](...continued)
until it becomes lodged in a smaller blood vessel, completely cutting off circulation. This condition is called an embolism. Tortora and Anagnostakos, Principles of Anatomy and Physiology 451 (Harper and Row, 1981).

[15] The inventors of the '087 patent recognized that sequential filling of a plurality of chambers would apply a compressive pressure gradient against the patient's limb. In their idea sheets, the inventors of the '087 patent show their invention operating under these principles. The invention is described as having chambers which fill sequentially and thus apply a compressive pressure gradient. RX 171 at 38112, 38114.

decompression of the chambers when the air pressure in a cell which is connected to the air supply tube reaches a preset level. RX 30, Col. 3 lines 31-34.

The Flowtron Aire patent does not disclose a means for maintaining the pressure gradient throughout the compression cycle. Because of the sequential filling of the chambers, a pressure gradient is achieved during the compression cycle. While it may be possible to cut off the compression cycle before equilibrium and thus maintain gradience throughout a compression cycle, the Flowtron Aire patent neither discloses nor suggests such a feature.

Claim 1 of the '087 patent specifically provides that the invention maintains a pressure gradient throughout the compression cycle. This key limitation of the '087 patent - a limitation the PTO required before allowing the patent to issue - is not present in the Flowtron Aire patent.

b. U.S. Letters Patent No. 3,391,692

Respondents also assert that Claim 1 of the '087 patent is anticipated by U.S. Letters Patent No. 3,391,692 ("Spielberg patent"). The Spielberg patent was issued on July 9, 1968 and discloses a single-chamber device which is inflated from a source of pressurized gas. RX 44. The device has a series of broad straps which are wrapped around the patient's leg. RX 44, Col. 2 lines 43-54. The straps are wrapped tightly around the lower end of the limb and progressively more loosely around successive upper portions of the limb. Utilizing these straps in this manner results in each segment of the device's single chamber applying a different pressure to the limb with the greatest pressure applied at the lower end of the limb and the least pressure applied at the upper end. RX 44, Col. 2 lines 55-62. The Spielberg patent illustrates the use of a timer to regulate the compression/decompression

cycle, but does not teach the use of this timer to maintain gradience. RX 44, Col. 3 lines 8-21.

The Spielberg patent does not contain "a plurality of separate fluid pressure chambers" as set forth in Claim 1 of the '087 patent. The broad straps do not create a plurality of chambers out of the single chamber which is the device. Indeed, because the spaces between the straps are not wrapped against the patient's limb, there are no "walls" between the area under one strap and the area under the subsequent upper strap. Because the Spielberg device does not have a plurality of separate fluid pressure chambers, it also lacks the limitation requiring the distribution of fluid from the first chamber to the upper chambers under decreasing pressure so as to create a pressure gradient. Rather, the Spielberg patent creates a pressure gradient in a different manner, i.e. by varying the tightness with which the straps are wrapped around the patient's limb.

c. U.S. Letters Patent No. 2,781,041

Respondents assert that U.S. Letters Patent No. 2,781,041 ("Weinberg patent") anticipates Claim 1 of the '087 patent. The Weinberg patent was issued on February 12, 1957 and discloses a device with several independent "cells" which are inflated from a source of pressurized gas. RX 45, Col. 2 lines 30-35. Each cell in the Weinberg patent is filled with gas by an individual supply tube. RX 45, Col. 2 lines 54-56. There is no means by which one cell is connected with adjacent cells. RX 45, Figure 13. The Weinberg patent illustrates the use of a timer to regulate the compression/decompression cycle. RX 45, Col. 3 lines 19-21.

The Weinberg patent is missing at least two elements of the '087 patent. The cells of the Weinberg patent do not communicate with each other. Claim 1

of the '087 patent specifically claims means for distributing fluid from the most distal chamber to progressively located upper chambers. Because the Weinberg patent does not provide any means for the gas which is pumped into the most distal chamber to flow into the other chambers, it does not contain this element of Claim 1 of the '087 patent.

Further, the patent neither illustrates nor suggests that the device should be used to maintain a pressure gradient along the length of the patient's limb throughout the compression cycle. Indeed, it appears to teach away from a pressure gradient, providing:

> The continuously extending, long, inner inflatable member which bridges the abutting or adjoining ends of the shorter sequentially pressurized cells acts to equalize applied pressure between the cells and serves to prevent the creation of welts or "bamboo" effect on the arm or leg of the patient.
>
> RX 45, Col. 3 lines 43-48
> (emphasis added)

The Weinberg patent does not contain all of the elements of Claim 1 of the '087 patent.

d. Conclusion

The Flowtron Aire patent, Spielberg patent, and Weinberg patent each fail to disclose at least one limitation of Claim 1. Particularly, each of these references fails to disclose the maintenance of a pressure gradient throughout the compression cycle. For these reasons none of the cited references anticipates the '087 patent.

B. Obviousness

1. Law Of Obviousness

Under U.S. patent law, a person may not obtain a patent if the invention would have been obvious to one of ordinary skill in the art at the time it was made. Section 103 of Title 35, United States Code, provides:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

In Graham v. John Deere Co., 383 U.S. 1, 148 U.S.P.Q. 459 (1966), the Supreme Court set forth the approach by which a court is to determine whether a patent is invalid for obviousness:

> "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. ... Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy."
>
> 383 U.S. at 17-18

An obviousness analysis is conducted by comparing the prior art, evaluated as a whole, to the claimed invention taken as a whole. 35 U.S.C. § 103, Panduit Corp. v. Dennison Manufacturing Co., 810 F.2d 1561, 1 U.S.P.Q.2d 1593 (Fed. Cir. 1987). The scope of the prior art is that which is reasonably pertinent to the particular problem facing the inventor. Stratoflex, Inc. v. Aeroquip Corporation, 713 F.2d 1530, 218 U.S.P.Q. 871 (Fed. Cir. 1983). References which fall within one of the prior art categories set forth in 35 U.S.C. § 102 are also prior art for purposes of § 103. Baker Oil Tools, Inc. v. Geo Vann, Inc., 828 F.2d 1558, 4 U.S.P.Q.2d 1210 (Fed. Cir. 1987).

Respondents' burden of proving a patent invalid for obviousness is not reduced by the introduction of prior art which was not considered by the

United States Patent and Trademark Office ("PTO"). Uniroyal Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988). The introduction of such evidence may, however, facilitate the carrying of this burden. Id.

The comparison between the prior art and the claims at issue is conducted with reference to a hypothetical person of ordinary skill in the art. Such a person is presumed to be aware of all the pertinent prior art, but does not undertake to innovate. Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 227 U.S.P.Q. 293 (Fed. Cir. 1985).

A court must always consider objective evidence such as commercial success, failure of others, long-felt need, copying, and unexpected results before reaching a conclusion on whether a patent would have been obvious. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986), cert. denied, 107 S.Ct. 1606 (1987). Such evidence must be weighed along with the other factors of a Graham v. John Deere analysis. See, Truswal Systems Corp. v. Hydro-Air Engineering Inc., 813 F.2d 1207, 1212, 2 U.S.P.Q.2d 1034, 1038 (Fed. Cir. 1987) ("That evidence is 'secondary' in time does not mean that it is secondary in importance.") Commercial success of an invention will only be indicative of nonobviousness if there is a nexus between the success and the merits of the invention. Cable Electric Products, Inc. v. Genmark, Inc., 770 F.2d 1015, 226 U.S.P.Q. 881 (Fed. Cir. 1985).

2. Scope And Content Of The Prior Art

Messrs. Memhardt and Dye were employees of the Kendall Company in 1972. At this time they commenced work on a device which would enhance the flow of blood in the legs. RX 163, RX 171. The purpose of the device was to prevent the formation of thrombi in the veins of the calf. RX 171 at 38110. The

scope of the prior art therefore includes those prior art references which address the problem of moving body fluids such as blood.

The first embodiment of the invention claimed in the '087 patent was reduced to practice no later than C

C

C RX 171 at 38105.[16] Accordingly, a reference must have been published prior to this date in order to fall within the scope of the prior art.

A discussion of the references which allegedly render the '087 patent invalid for obviousness follows:

a. British Patent No. 1,310,492

The Flowtron Aire patent was described in full in the section of this initial determination addressing the alleged invalidity of the '087 patent for anticipation. In summary, it describes a multi-chambered device designed to

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[16] In their objections to Staff's proposed findings, Respondents assert that the patent's validity should be determined as of the application date (October 28, 1975) because Messrs. Dye and Memhardt "abandoned, suppressed or concealed" the invention during the intervening period. The Court of Appeals for the Federal Circuit has held that the doctrine of denying a patent to one who has abandoned, suppressed or concealed the invention does not apply "to mere delays in filing except in priority contests where the equities between claimants for the same invention may be fully evaluated". Panduit Corp. v. Dennison Mfg. Co., 774 F.2d 1082, 227 U.S.P.Q.337 (Fed. Cir. 1985), vacated and remanded, 475 U.S. 809, 229 U.S.P.Q. 478 (1986), on remand, 810 F.2d 1561, 1 U.S.P.Q.2d 1593 (Fed. Cir. 1987), cert. denied, 107 S.Ct. 2187 (1987). Because this case does not involve a contest between two claimants for the same invention, Respondents' argument that the invention was "abandoned, suppressed or concealed" is misplaced.

Respondents also assert in their objections to findings that there is no evidence that Mr. Memhardt tested a prototype of the Figure 6 embodiment. However, Respondents presented no argument in their briefs in support of the proposition that an inventor must demonstrate a reduction to practice of all embodiments set forth in his patent to obtain the benefit of an earlier invention date. Accordingly, for purposes of the motion for temporary relief, the Administrative Law Judge will adjudge the validity of the '087 patent as of C

apply a pressure gradient against the limb of a patient. Periods of compression are followed by periods of decompression to impart a "cyclic force" against the limb.

b. British Patent Specification No. 403,859

British Patent Specification No. 403,859 ("Höflinger specification") was published on January 4, 1934 and is entitled "Apparatus for Accumulating the Blood at a Desired Point of the Human Body". RX 40. It discloses a device which consists of a plurality of chambers which are connected to each other by small pipes. RX 40, Col. 1 lines 16-22. A "pressure medium" enters the first chamber and, after establishing a certain pressure therein, proceeds to fill the second chamber. RX 40, Col. 2 lines 89-95. Similarly, the medium does not enter the third chamber until the second chamber attains a certain pressure. RX 40, Col. 2 lines 95-100. The Höflinger specification teaches that this sequential filling of the chambers is performed through the use of flow restrictors:

> In order that this result may be achieved it is necessary to prevent the pressure medium from spreading from one chamber into the other without any impediment and to arrange for a suitable resistance to act as a hindrance.
>
> RX 40, Col. 2 lines 101-106

The Höflinger specification specifically teaches that the opening between the second chamber (b^2) and the third chamber (b^3) should be smaller than the opening between the first chamber (b^1) and the second chamber. RX 40, Col. 3 lines 8-14. The Höflinger specification also teaches that the purpose of decreasing the size of the flow restrictors is to increase the resistance met

by the fluid as it attempts to move from one chamber to the next,[17] thus causing the chambers to fill sequentially:

> Obviously, the nozzle opening which allows the passage of the pressure medium from chamber b^2 into chamber b^3 must be of smaller diameter than the nozzle openings which allows the passage of the pressure medium from the chamber b^1 into chamber b^2.
>
> The important point is this that the resistance which opposes the entering of the pressure medium into the chamber b^1 should be smaller than that which opposes its entering the chamber b^2 and that the resistance which the pressure medium has to overcome on entering chamber b^3 should be still greater than that which it has to overcome on entering chamber b^2.

RX 40, Col. 3 lines 8-24

The sequential filling of the chambers in the Höflinger device provides a compressive pressure gradient against the patient's limb in the same manner as the Flowtron Aire device and the embodiments in the '087 patent. By filling sequentially, the first chamber reaches a predetermined pressure level before the second chamber reaches that same pressure. Similarly, the second chamber reaches a predetermined level of pressure before the third chamber inflates to that level.

The Höflinger specification, however, does not disclose or suggest any method for avoiding ultimate equilibrium between the chambers, such as decompressing before equalization. Accordingly, in Höflinger there is no teaching that the pressure gradient produced by the sequential filling of the chambers is to be maintained throughout the compression cycle.

c. U.S. Letters Patent No. 3,548,809

U.S. Letters Patent No. 3,548,809 ("Conti patent") was issued on December

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[17] The Höflinger specification discloses the use of porous materials between the chambers as an alternative means for providing increased resistance between the chambers and thus sequentially filling the chambers. RX 40, Col. 3 lines 24-36.

22, 1970 and is entitled "Device For Stimulating The Flow Of Fluids In An Animal Body". RX 39. The Conti patent discloses a device which may be either single-chambered (Figure 4) or multi-chambered (Figures 6 and 8). RX 39. In the multi-chambered embodiment illustrated by Figure 6, the chambers are in communication with each other, with fluid entering the most distal portion of the device and exiting the least distal portion. The Conti patent discloses that the device is intended to be used with a timing mechanism which, after a predetermined time period, stops the compression cycle and commences the decompression of the device. RX 39, Col. 2 line 69 - Col. 3 line 2.

The Conti patent does not disclose the use of a pressure gradient in the embodiment which has the chambers in communication with each other (Figure 6). Indeed, the specification of the Conti patent states that one of the advantages of this embodiment is the ability to achieve "uniformity of pressure distribution" by having the size of the passageways through which the fluid flows increase from the lower chambers towards the upper chambers. CX 39, Col. 4 lines 39-44.

The Conti patent indicates that a pressure gradient occurs during the filling cycle in an embodiment which has independent chambers (Figure 8). The specification provides that fluid is not injected into an upper chamber until the pressure in the next lower chamber reaches a preset value:

> In this embodiment of the stimulator device according to the invention fluid under pressure is passed starting from the lower chamber reaches and the passing of fluid under pressure into the chamber immediately above the said lower chamber only when the pressure in the lower chamber reaches a desired value. This procedure is analogous for all of the chambers into which the interspace defined by the envelope 1 is divided.
>
> RX 39, Col. 4 lines 63-70
> (emphasis added)

Conti is designed to have each of the independent chambers reach the same

preset pressure value. RX 39, Col. 4, lines 70-72. There is nothing in the figure 8 embodiment disclosing or suggesting that a gradient is to be maintained throughout the compression cycle.

d. U.S. Letters Patent No. 3,391,692

The Spielberg patent was described in full in the section of this initial determination addressing the alleged invalidity of the '087 patent for anticipation. It claims a single-chambered device, inflated from a source of pressurized gas, which achieves a pressure gradient through the use of a series of straps which are wrapped around the limb undergoing treatment. The Spielberg patent illustrates the use of a timer to regulate the compression/decompression cycle. RX 44, Col. 3 lines 8-21.

e. U.S. Letters Patent No. 2,781,041

The Weinberg patent was described in full in the section of this initial determination addressing the alleged invalidity of the '087 patent for anticipation. It claims a multi-chambered device, inflated from a source of pressurized gas. The chambers are independently inflated and deflated and are not in communication with each other. The patent does not disclose or suggest the use of a pressure gradient to assist in the movement of fluids. The compression/decompression cycle is regulated by a timer.

f. U.S. Letters Patent No. 3,536,063

U.S. Letters Patent No. 3,536,063 ("Werding patent") was issued on October 27, 1970 and claims a device intended to apply a pressure gradient against a patient's leg to improve venous blood flow. RX 38, Col. 1 lines 14-16. The device comprises a boot with an inflatable inner wall creating a single chamber. Because the inner wall is thicker at the thigh than the ankle, when the boot is inflated it imparts greater pressure at the ankle than

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at the thigh. RX 38, Col. 1 lines 27-30. The patent discloses a control box with which the user, by pressing buttons, can initiate the inflation and subsequent deflation of the device. RX 38, Col. 2 lines 15-28. The patent does not teach, however, controlling the compression/decompression cycle to maintain a pressure gradient throughout the compression cycle.

3. Differences Between The Prior Art And Claim 1 Of The '087 Patent

The prior art references set forth almost all of the limitations of Claim 1 of the '087 patent. All of the references disclose an elongated pressure sleeve for enclosing a portion of the patient's limb, a means for filling the sleeve with a fluid (usually air), and a means for emptying the sleeve during the decompression period. The Flowtron Aire, Weinberg, Höflinger and Conti references all depict devices with a plurality of chambers arranged longitudinally along the sleeve. The pressure applied against the patient's limb by the devices depicted in the Flowtron Aire, Spielberg, Höflinger, Conti and Werding references is greatest at one end of the sleeve and decreases progressively towards the opposite end. Finally, the Flowtron Aire, Höflinger and Conti devices are each constructed so the fluid which is pumped into the first chamber is distributed to subsequent chambers at decreasing pressures.

The only limitation of Claim 1 missing from the prior art is the maintenance of a pressure gradient throughout the compression cycle. While several of the prior art patents (e.g. Flowtron Aire, Spielberg, Weinberg, and Conti) disclose the use of a timer or other means to regulate the duration of the compression cycle, none of them disclose using the timer to shut off the compression cycle before the chambers reach equal pressure so as to maintain a pressure gradient throughout the compression cycle.

4. Level Of Ordinary Skill In The Art

At the time of the '087 invention, Mr. Dye had a bachelor's degree in industrial engineering and Mr. Memhardt had a bachelor's degree in physics. Dye, Tr. 56-57, RPX 3 at 4. Dr. Melrose testified that in the early 1970's work in the field of biomedical devices such as dynamic sequential gradient compression devices was being done by engineers such as Mr. Cotton, as well as some medical doctors such as Dr. Pflug (who was also an engineer) and Dr. Melrose. Melrose, Tr. 580. Accordingly, the level of ordinary skill in the art appears to be a person with at least a bachelor's degree in physics or engineering, and/or several years of experience in the field of designing pneumatic medical devices.

5. Objective Indicia Of Nonobviousness

Objective indicia of nonobviousness such as satisfaction of a long felt need, commercial success, failure of others, copying, and unexpected results must always be considered before reaching a conclusion on whether a patent would have been obvious. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986), cert. denied, 107 S.Ct. 1606 (1987). However, there is little objective evidence supporting a conclusion of nonobviousness at this temporary relief phase of the investigation.

Complainant has not established that there was a long felt need for the '087 devices. Indeed, devices designed to stimulate fluid flow in the body such as those devised by Höflinger and Werding had been in existence for many years before Messrs. Dye and Memhardt conceived of their invention. Further, Complainant has not put forward any evidence that others had tried but failed to invent a device that maintained a pressure gradient throughout the compression cycle.

Complainant asserts that the commercial success enjoyed by its SCD and HomeRx devices over the years constitutes objective evidence that the '087 patent would not have been obvious. However, Complainant's SCD and HomeRx devices are not covered by the '087 patent. See Domestic Industry discussion at 46-55. Only the commercial success of products covered by the claims of the patent at issue can be considered in analyzing whether the patent is invalid under § 103. Accordingly, Complainant's sales of its SCD and HomeRx devices do not constitute objective evidence that the '087 patent would not have been obvious.

6. Complainant Has Not Established A Reasonable Likelihood Of Prevailing On The Issue Of Whether Claim 1 Of The '087 Patent Would Have Been Obvious To One Of Ordinary Skill In The Art At The Time Of The Invention

Respondents have come forward with numerous prior art references, all of which are directed to devices intended to address the exact problem faced by the inventors of the '087 patent, i.e., stimulating the movement of fluid in the body.[18] Certain of the prior art references in this crowded field of technology (e.g., Spielberg, Flowtron Aire) teach that it is beneficial to apply a compressive pressure gradient against the limb of a patient in order to facilitate the movement of bodily fluids in a particular direction. The only difference between the prior art and Claim 1 is that Claim 1 requires the maintenance of a pressure gradient throughout the compression cycle. In the case of the Figure 6 embodiment, this can only be achieved through the use of

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[18] Some of the references were known to the examiner during the prosecution of the '087 patent's application (e.g., Conti, Weinberg, Werding). Respondents, however, have also come forward with prior art which was not before the examiner during the prosecution (e.g., Hoflinger, Flowtron Aire). Indeed, the Hoflinger and Flowtron Aire references appear to be closer to the invention claimed in the '087 patent, because they disclose the utilization of flow restrictors to create a pressure gradient. This feature is not in the prior art which was before the examiner.

a timer or equivalent means to stop the compression cycle before the chambers reach equal pressure.

The prior art includes references that disclose regulation of the duration of the compression cycle with a device such as a timer (Conti, Flowtron Aire). One of ordinary skill would know that when air begins to inflate the closed multi-chambered devices disclosed in the prior art (Conti, Flowtron Aire, Höflinger), the chambers will initially be at different pressures, providing a pressure gradient as they fill in sequence. Melrose, Tr. 678. This person, a college-educated engineer with knowledge of devices which stimulate fluid flow in the body through the utilization of a pressure gradient, would have known that the chambers in a closed device will eventually reach equilibrium. Indeed, Conti and other references expressly teach that their devices will achieve an equilibrium state.

This person would also have had knowledge of various devices such as a timer to control the duration of the compression and decompression cycles. Indeed, use of such devices for this purpose is common in the prior art. Dr. Melrose testified that people working with compression devices in the early 1970's frequently adjusted the timing cycles in the devices. Melrose, Tr. 606. Therefore, such a person would have found it obvious to stop the pump before equilibrium, if he wanted to maintain the pressure gradient throughout the compression cycle, and to use a timer (or an equivalent control device) to do so, as is the case with the Figure 6 embodiment of the '087 patent.[19]

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[19] Complainant argues that the prior art references contain no teaching or suggestion that they be combined. However, the Administrative Law Judge's conclusion regarding obviousness is not premised on the person of ordinary skill in the art combining the references. Rather, it is premised on the fact that such a person, viewing the prior art as a whole, would know that one could maintain a pressure gradient by shutting off the timer before

(continued...)

Accordingly, in light of the prior art, the differences between the prior art and the invention set forth in Claim 1, the level of ordinary skill in the art, and the absence of objective evidence of nonobviousness, Complainant has not established that it is likely to prevail on the issue of whether Claim 1 would have been obvious to one of ordinary skill in the art at the time it was invented.

V. DOMESTIC INDUSTRY

A. Introduction

In a patent-based investigation under section 337, the complainant must establish that an industry in the United States, relating to the articles protected by the patent, exists or is in the process of being established. 19 U.S.C. § 1337(a)(2)[20]. Section 337 provides that a domestic industry exists if there is in the United States, with respect to the articles protected by the patent at issue:

(a) significant investment in plant and equipment;

(b) significant employment of labor or capital; or

(c) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3)

A threshold issue in determining whether a domestic industry exists is whether the complainant is exploiting the claimed invention. Certain

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[19](...continued)
equalization of pressure. See, Panduit Corp. v. Dennison Manufacturing Co., 1 U.S.P.Q.2d at (Fed. Cir. 1987) (obviousness determined in light of the prior art, evaluated as a whole).

[20] Complainant does not claim that a domestic industry is in the process of being established. Its motion for temporary relief is based on the allegation that a domestic industry exists. Complainant's Response To Respondents' Motion In Limine (Motion Docket No. 335-4).

Doxorubicin and Preparations Thereof (Inv. No. 337-TA-300), 20 U.S.P.Q.2d 1602, 1610 (U.S.I.T.C. 1991). Activity of the type described in one of the parts of 19 U.S.C. § 1337(a)(3) will not constitute a domestic industry if it is not directed to the exploitation of the patent at issue. Id.

Complainant here must establish a reasonable likelihood that it will prove the existence of a domestic industry, i.e. that it is exploiting the '087 patent. In the complaint, Complainant initially admitted that the devices it manufactures are not literally within the '087 suit patent, and contended they are within the scope of the patent only under the doctrine of equivalents. In its prehearing statement, Complainant amended its position and alleged that its devices are within the scope of the patent both literally and under the doctrine of equivalents. Consequently, in the temporary relief hearing Complainants have the burden of showing their manufactured products are within the scope of the '087 patent either literally or under the doctrine of equivalents as part of its proof of reasonable likelihood of success on the merits.

B. Application Of The Doctrine Of Equivalents To A Means-Plus-Function Claim

Under the doctrine of equivalents, infringement may be found if the accused device performs substantially the same function in substantially the same way to achieve substantially the same result as the claimed invention. Graver Tank & Manufacturing Co. v. Linde Air Products, 380 U.S. 605 (1950). Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 4 U.S.P.Q.2d 1737 (Fed. Cir. 1987). The doctrine of equivalents is an equitable doctrine, designed to prevent a party from practicing a fraud on the patent by making insubstantial changes to the invention disclosed therein. Graver Tank. Application of the doctrine provides the inventor the full scope of his statutory right to

exclude others from making, using or selling his invention by expanding that right to equivalents of what is claimed. Wilson Sporting Goods Co. v. David Geoffrey & Associates, 904 F.2d 677, 14 U.S.P.Q.2d 1942 (Fed. Cir. 1990).

A claim's range of equivalents must be determined in light of the prior art and the prosecution history. A claim cannot be given a range of equivalents so wide that it encompasses the teachings of the prior art. Wilson Sporting Goods Co. v. David Geoffrey & Associates, 904 F.2d 677, 14 U.S.P.Q.2d 1942 (Fed. Cir. 1990). Accordingly, the range of equivalents to which the claim is entitled depends upon the extent and nature of the invention. Texas Instruments v. U.S. International Trade Commission, 805 F.2d 1558, 231 U.S.P.Q. 833 (Fed. Cir. 1986). "Pioneer" inventions are entitled to a broad range of equivalents. Perkin-Elmer Corp. v. Westinghouse Electric Corp., 822 F.2d 1529, 3 U.S.P.Q.2d 1321 (Fed. Cir. 1987). By contrast, inventions that represent a narrow improvement in a crowded field are entitled to little or no range of equivalents. Hughes Aircraft Co. v. United States, 717 F.2d 1351, 219 U.S.P.Q. 473 (Fed. Cir. 1983). Further, under the doctrine of prosecution history estoppel, a patentee cannot recapture through equivalents what was surrendered during prosecution of the patent application. Loctite Corp. v. Ultraseal Ltd., 781 F.2d 861, 221 U.S.P.Q. 669 (Fed. Cir. 1985).

A means-plus-function claim may be infringed under the doctrine of equivalents if the accused device does not literally perform one or more of the claimed functions, but performs a function which is the legal equivalent of each claimed function. Pennwalt Corp. v. Durand-Wayland, Inc. 4 U.S.P.Q.2d at 1742-1743. If the accused device does not perform the legal equivalent of each claimed function, it does not satisfy the "substantially

the same way" part of the Graver Tank test. In Pennwalt, the Federal Circuit characterized the issue as "whether the accused devices performed each of the functional limitation of the claim or its equivalent and, thus, operated in substantially the same way." 4 U.S.P.Q.2d at 1741 (original emphasis). Accordingly, to find infringement under the doctrine of equivalents, each and every claimed function must find an identical or equivalent counterpart in the accused device. Pennwalt Corp. v. Durand-Wayland, Inc. See, Perkin-Elmer Corp. v. Westinghouse Electric Corp., 822 F.2d at 1532, 3 U.S.P.Q.2d at 1324 (A court applying the doctrine of equivalents "may not erase a plethora of meaningful structural and functional limitations of the claim on which the public is entitled to rely in avoiding infringement..."). A finder of fact conducting a doctrine of equivalents analysis under the test set forth in Pennwalt must therefore conduct an element-by-element comparison of the accused product and the claim.

C. Complainant Has Not Established That It Is Likely Its HomeRx And SCD Devices Will Be Found To Be Within The Scope Of Equivalents Of Claim 1

Claim 1 of the patent contains several means-plus-function clauses. Respondents contend that the equivalents of the functions claimed in two of these clauses are not found in Kendall's SCD and HomeRx devices. Particularly, Respondents assert that the Kendall devices do not have 1) a "filling means including means for connecting the source to a lower first chamber in [the] sleeve [and] means for distributing fluid from [the] first chamber to progressively located upper chambers at progressively decreasing pressures..." and 2) a means for filling the chambers "to apply a compressive pressure gradient ... throughout the compression cycles". Under the analysis set forth in Pennwalt, Complainant's devices would fall within the scope of

claim 1 only if they perform the equivalent of each of these functions. Accordingly, the first step in the doctrine of equivalents analysis is to determine the range of equivalents of these two functions.

1. **"Connecting The [Filling] Source To A Lower First Chamber In [The] Sleeve [And] Distributing Fluid From [The] First Chamber To Progressively Located Upper Chambers At Progressively Decreasing Pressures"**

In the '087 patent the embodiments each disclose a source of fluid which is connected to the lowermost, or most distal chamber. This connection is depicted as conduit 34 in Figures 1 and 5. CX 9 Col. 2 line 65. The Figure 6 embodiment is of the sleeve only, but shows a "large port 78" in the lowermost chamber through which the fluid enters the first chamber. CX 9 Col. 6 line 4-5. The embodiments also disclose means for distributing the fluid from the first chamber to progressively located upper chambers at progressively decreasing pressures. These means are shown as valves, tubes or orifices between the various chambers. CX 9, Figs. 1, 3, 6, 7, 8, 11. The fluid (usually air) is inserted first in the lowermost or most distal chamber, then passes progressively to the adjacent upper chambers through the valves, tubes or orifices, filling the chambers sequentially until they all are properly inflated.[21] All of the fluid that fills the upper chambers is supplied from the first chamber. Id. Indeed, the drawings in the '087 patent show that the upper chambers have no source of fluid other than the first chamber. Id. Because the chambers fill sequentially, during the period of inflation, the most distal chamber applies the greatest pressure and the pressure applied decreases as one progresses towards the patient's heart.

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[21] Mr. Dye testified that the invention in the '087 patent encompasses only a single inflation tube leading to the lower most chamber. Dye, Tr. 192; RPX 1, Dye Dep. Tr. 61. The HomeRx and SCD devices utilize multiple inflation tubes, one leading to each chamber. SX 1, Stip. 19.

The prior art Höflinger reference describes an essentially identical feature. In the Höflinger reference, the "pressure medium" is pumped into the first chamber, b^1 and passed into subsequent chambers b^2 and b^3 through flow restrictors. RX 40. The fluid is distributed to the subsequent chambers which fill sequentially. RX 40 Col. 2 lines 89-106. Because the chambers fill sequentially, the pressure applied by the first chamber is greater than that applied by the second before the chambers reach a state of equal pressure. Accordingly, Höflinger discloses a means for filling the first chamber and distributing the fluid from this chamber to progressively located upper chambers at progressively decreasing pressures. In light of the identity between the function claimed in the above-quoted clause of Claim 1 and that performed by the Höflinger device, the clause is entitled to a very limited range of equivalents.

In the devices manufactured by Complainant, the fluid is distributed differently than is claimed in Claim 1. Unlike the embodiments in the specification of the '087 patent, the Complainant's devices do not have short tubes or orifices for distributing fluid between the chambers. CPX 1, CPX 2. None is necessary because each of the separate chambers in the sleeve are connected by a fifteen foot long tube either to a manifold in the controller (SCD device) or to the valve bank in the accumulator (HomeRx device). CPX 1, CPX 2. The source is not connected solely to the lowermost chamber which then supplies fluid progressively to the upper chambers. Instead, the source supplies fluid to each chamber independently. CPX 1, CPX 2. Accordingly, the fluid that enters the upper chambers is not supplied by the first chamber.

Complainant asserts that when the second chamber is opened, some of the air which was pumped into the first chamber exits the first chamber, travels

down the fifteen foot long tube to the controller or accumulator, and is then pumped into the second chamber. Complainant provides no objective evidence that supports this conclusion. The only evidence it presented is a pressure graph which illustrates that when the second chamber opens, the pressure in the first chamber drops to a certain extent, and for a limited period of time (about one to one and one-half seconds). CX 49. Complainant's expert, Dr. Hasty, and the co-inventor of the '087 patent, Mr. Dye, testified that this pressure drop occurs because the air in the first chamber moves towards a region of low pressure, i.e., the second chamber. Dye, Tr. 230; Hasty, Tr. 292. Mr. Dye believes that at least some of the air which moves out of the first chamber is distributed into the second (and upper) chambers. Dye, Tr. 222.[22] However, while the air apparently moves towards the second chamber, Complainant did not adduce any objective evidence that the air from the first chamber moves into the second chamber. Neither Mr. Dye nor Dr. Hasty conducted any tests in this connection. Dye, Tr. 246; Hasty, Tr. 292. Indeed, Mr. Dye testified on cross-examination that he did not "know" whether any air actually moves from the first chamber to the second chamber. Dye, Tr. 246-247. Further, Dr. Hasty admitted that he had "no evidence that substantiates" his theory of airflow. Hasty, Tr. 339. The beliefs of these witnesses, unsubstantiated by any reliable and objective evidence, as to whether air in the first chamber reaches the second and third chambers amount to speculation, and is therefore given no weight by the Administrative Law Judge.

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[22] In his testimony, Dr. Hasty carefully refrained from asserting that the air from the first chamber entered the second chamber, stating only that the air from the first chamber moved toward a "low pressure void". Hasty, Tr. 337.

Indeed, the Kendall devices were not designed to distribute fluid from the first chamber to the subsequent chambers. In both devices each chamber is independent of the others and is separately filled and exhausted by the central source. CPX 1, CPX 2. Complainant's argument that the HomeRx and SCD devices perform an equivalent of the function of distributing fluid from the first chamber to subsequent chambers amounts to an attempt to force devices which are essentially different in the way they work into the very limited range of equivalents allowed this clause.[23] The complainant's devices have no equivalent function.

2. Applying A Pressure Gradient Throughout The Compression Cycle

Claim 1 also requires that the claimed device include means to maintain a compressive pressure gradient against the patient's limb "throughout the compression cycles." CX 9, Col. 7 line 66.

Claim 1, as originally filed, did not require the maintenance of a pressure gradient throughout the compression cycles. RX 155. The specification provides that gradience is maintained "during" the compression cycles. CX 9, Col. 4 lines 24-25, Col. 6 lines 16-19. Because "during" can be alternatively defined as "throughout the course or duration of" or "at some time in" (American Heritage Dictionary, 2d Coll. ed. 430), the claim appears to cover devices which maintain a gradient for only a portion of the compression cycle. The prosecution history shows, however, that the claim covers only devices which maintain a gradient throughout the compression

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[23] Complainant marks its commercial products with a number of its patents, which it deems to cover the devices. Mr. Dye testified that he was involved in the decisions concerning what patent numbers to place on the SCD and HomeRx devices. Dye, Tr. 185. The SCD and HomeRx devices are not marked, and never have been marked, as covered by the '087 patent. Dye, Tr. 185-186; RX 152; RX 153.

cycle.

The application was rejected twice in light of prior art which showed, inter alia, devices which maintained a pressure gradient. See, RX 39 (Conti patent, Col. 4 lines 63-68). On November 30, 1976, Claim 1 was amended to clarify that the '087 claim is for a device which applies a pressure gradient throughout the compression cycles and not just for a portion thereof. RX 155. Therefore, during the prosecution, Complainant narrowed Claim 1 so that it covers only devices which apply a pressure gradient throughout the compression cycles. After this amendment, the Patent and Trademark Office issued the '087 patent. RX 155.

The narrowing of the claim occurred after the Patent and Trademark Office had rejected a more broadly worded claim in light of the prior art references which taught the use of a compressive pressure gradient. Affording the function a range which includes applying a gradient for a period less than the complete compression cycle would impermissibly expand Claim 1 so that it covers what was surrendered during the prosecution of the application. Accordingly, the range of equivalents of this claimed function is extremely limited, and does not include devices that achieve a pressure gradient for part of the compression cycle.[24]

Tests performed on the devices manufactured by the complainant show quite clearly that they do not maintain a pressure gradient throughout the compression cycle. Both Complainant and Respondents submitted pressure graphs illustrating the results of tests performed on Complainant's devices. CX 49,

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[24] Complainant argues that its amendments were of a nature that do not create an estoppel. If that were the case, the function would nonetheless have very limited equivalents since expanding the claim to include devices which apply a gradient for less than the complete compression cycle would cause the claim to cover the prior art.

RX 36. Complainant's Exhibit 49 sets forth the data for a test conducted on Complainant's SCD device (CX 49) and Respondents' Exhibit 36 sets forth the data for a test conducted on Complainant's HomeRx device (Schild, Tr. 723). Both devices have a compression cycle approximately eleven seconds long. Hasty, Tr. 282; Schild, Tr. 813. Dr. Hasty testified that the two devices work in generally the same manner. Hasty, Tr. 295.

The two graphs each show that when the second chamber opens (approximately 2 1/2 seconds into the compression cycle), the pressure in the first chamber initially drops, and then begins to rise again after about one to one and one-half seconds elapse. CX 49, RX 36. The pressure in the second chamber, meanwhile, rises until it reaches a level essentially equal to the pressure in the first chamber. CX 49, RX 36. At this point (approximately halfway through the compression cycle) the third chamber opens and the pressure in the first two chambers falls. CX 49, RX 36. After approximately one second elapses, the pressure in the two chambers begins to rise again. CX 49, RX 36. The pressure in the two chambers remains essentially equal from the point where the third chamber opens until the end of the compression cycle, apparently deviating from each other by less than one millimeter of mercury on Respondents' chart (RX 36) and no more than two millimeters on Complainant's chart (CX 49). Indeed, the lines on Respondents' chart touch each other at several points before the conclusion of the compression cycle, indicating that the chambers have reached equal pressure.

Respondents' expert, Mr. Schild, also conducted tests on a HomeRx device by hooking it to three manometers and photographing the manometers at set

intervals.[25] Schild, Tr. 729; RPX 8A, RPX 8B, RPX 8C. The photographs illustrate that at the beginning of the compression cycle, the pressure at the ankle is higher than the pressure at the calf and thigh. Schild, Tr. 730, 734-735, 737; RPX 8A, RPX 8B, RPX 8C. As the cycle progresses, the calf pressure rises, eventually becoming just about equal with the ankle pressure approximately halfway through the compression cycle. Schild, Tr. 732, 735, 738; RPX 8A, RPX 8B, RPX 8C. At this point, the thigh chamber begins to fill, and the first two chambers maintain approximately equal pressure while the thigh chamber is filling. Schild, Tr. 732, 735, 738; RPX 8A, RPX 8B, RPX 8C. By the conclusion of the compression cycle, all three chambers are at equal pressure. Schild, Tr. 732, 736, 738; RPX 8A, RPX 8B, RPX 8C.

The Administrative Law Judge finds the test results offered by Respondents more reliable than those offered by Complainant. Mr. Schild, the sponsoring witness for RX 36, RPX 8A, RPX 8B and RPX 8C, testified regarding the circumstances under which the Respondents' tests were conducted and was cross-examined regarding those circumstances. Schild, Tr. 721-739, 801-839. In contrast, Mr. Dye, the co-inventor of the '087 patent and the sponsoring witness for CX 49, testified that he did not make the chart and was not present when the test was conducted. Dye, Tr. 239-240. Indeed, it was impossible for Respondents to effectively cross-examine Mr. Dye regarding the circumstances under which the test was run and thus to determine whether the test was performed properly. Dye, Tr. 239-240. The reliability of

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[25] Mr. Schild testified that the photographs in rolls 8A and 8B were taken 1 second apart "nominally" and the photographs in roll 8C were taken one-half second apart "nominally". Mr. Schild testified that it is possible that the photographs were not taken the exact nominal time apart. Schild, Tr. 826. Regardless, the Administrative Law Judge is satisfied that the photographs illustrate the relative pressures in the chambers at different points throughout the compression cycle.

Complainant's test results is further reduced in light of the fact the test was apparently conducted without providing opposing counsel an opportunity to be present.[26] McCormick, Evidence § 202 (3d ed. 1984).

Complainant asserts that the '087 patent does not require a specific degree of gradience, and that any gradience therefore places the devices within the scope of Claim 1. Thus, Complainant's argument continues, the pressure differences on the order of one millimeter illustrated by Respondents' test data constitute the gradient required by Claim 1.

Complainant's argument requires that Claim 1 and the term "gradience" be read in a vacuum. A patent claim and the proper definition of a term within the claim is determined by reference to the specification and to how one of ordinary skill in the art would interpret it. Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 230 U.S.P.Q. 416 (Fed. Cir. 1986). In Bausch & Lomb, the claim at issue was for a contact lens with a "smooth surface of unsublimated polymer material." The district court concluded that because scanning electron microscope photographs showed the defendant's product was not "smooth", the claim was not infringed. 230 U.S.P.Q. at 418. The Federal Circuit ruled that in light of the specification and testimony regarding how one of ordinary skill would interpret the term, "smooth" simply meant that the lens would not scratch the eye or eyelid and that the wearer would feel it as smooth. 230 U.S.P.Q. at 421. Further, the trial testimony demonstrated that one of ordinary skill in the art would not utilize a scanning electron microscope to determine whether a contact lens was "smooth".

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[26] While it is also true that counsel for Complainant and the Staff were not present at the Respondents' tests, Respondents made Mr. Schild available for cross-examination at the hearing regarding how the tests were conducted, thus obviating any prejudice that may have arisen by conducting the tests ex parte.

Id. Accordingly, the Federal Circuit vacated the district court's ruling of noninfringement. Id.

The circumstances regarding "gradience" are analogous to those before the court in Bausch & Lomb. The specification of the '087 patent states that the purpose of the invention is to apply compressive pressure to the limb to prevent the pooling of blood and other fluids. CX 9, Col. 1 lines 5-20. The purpose of the pressure gradience is to enhance the flow of blood from the patient's extremity toward the heart. CX 9, Col. 1 lines 45-48, Col. 4, lines 24-35. Dr. Hasty testified that the professional literature teaches that a "target" gradient for a device that performs this function is a difference of ten millimeters of mercury. Hasty, Tr. 309. Thus it appears that one of ordinary skill in the art, reading Claim 1 in light of the specification, would interpret the term "gradient" as calling for a pressure differential on the order of ten millimeters of mercury.

Respondents' test evidence shows the first two chambers in the HomeRx device reaching almost exactly equal pressures approximately halfway through the compression cycle. RX 36, RPX 8A, RPX 8B, RPX 8C. The chambers maintain this equilibrium throughout the remainder of the compression cycle. What slight variation appears between the first two chambers during the second half of the compression cycle is so slight as to be "physiologically insignificant" (Schild, Tr. 804) and would not constitute a "gradient" as that term is used in the '087 patent. Because of the similarity between the HomeRx and SCD devices and the similar shapes of the pressure graphs for the two devices (CX 36 and RX 49)[27], it appears that the SCD's chambers perform in an

[27] The Administrative Law Judge's acknowledgment that the curves in CX 36 and RX 49 are similar should not be construed as acceptance of the pressure (continued...)

identical manner. Accordingly, Complainant's devices do not maintain a pressure gradient throughout the compression cycle as required by Claim 1.

3. Conclusion

The opinion of the Federal Circuit in Pennwalt addressed the issue of the application of the doctrine of equivalents when a means-plus-function claim is at issue. Indeed, the Pennwalt opinion is directly on point with this case. In Pennwalt, the suit patent was for a sorter claimed in means-plus-function fashion. 4 U.S.P.Q. 2d at 1738. The Federal Circuit noted that the patentee had secured claims only by including very specific functional limitations, having been unable to obtain a patent with claims in which the functions were described more broadly. 4 U.S.P.Q. 2d at 1742-1743. The accused products were also sorters, but they did not perform the equivalents of certain of the functions set forth in the claim at issue. 4 U.S.P.Q. at 1740. The Federal Circuit held that in light of the absence of these functions, the accused sorters did not perform in substantially the same way as the claimed invention, and thus did not fall within the scope of the claim under the doctrine of equivalents. 4 U.S.P.Q. at 1743.

Like the accused sorters in Pennwalt, Complainant's SCD and HomeRx products also do not perform the legal equivalents of all of the claimed functions. Because these devices do not perform the legal equivalents of distributing fluid from the first chamber to the upper chambers, and the application of a compressive pressure gradient throughout the compression cycle, application of the doctrine of equivalents to Claim 1 does not bring

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[27](...continued)
readings in CX 36. The Administrative Law Judge is utilizing CX 36 only as evidence that the pressures in the SCD device's chambers follow the same pattern as those in the HomeRx device and reach equilibrium midway through the compression cycle.

the devices within the scope of the claim. Complainant has not established that it is likely to demonstrate that its devices perform the equivalent of these two limitations of Claim 1. Accordingly, Complainant has not established that it is likely to prevail on the question of whether it is exploiting Claim 1 of the '087 patent under the doctrine of equivalents through the manufacture and sale of its SCD and HomeRx devices.[28]

D. Complainant Has Not Established That It Is Likely Its HomeRx And SCD Devices Will Be Found To Be Within The Literal Scope Of Claim 1

Complainant has alleged that its devices fall within the literal scope of Claim 1. A device falls within the literal scope of Claim 1 only if it performs each of the claimed functions and each claimed function is performed by a means described in the specification or an equivalent of such means. General Instrument Corp. v. U.S. International Trade Commission, 20 U.S.P.Q.2d 1161 (Fed. Cir. 1991).

The embodiments depicted in Figure 6 and the other drawings of the '087 patent require that all of the fluid distributed into the upper chambers is supplied by the first chamber. See discussion supra. at 46-47. Complainant has not demonstrated that all of the fluid that fills the upper chambers of its devices is supplied by the first chamber. Indeed, Complainant has not demonstrated that its SCD and HomeRx devices distribute any fluid whatsoever from the first chamber into the upper chambers, Accordingly, the SCD and HomeRx devices do not perform the claimed function of distributing fluid from the first chamber into upper chambers. Further, Complainant has not

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[28] Complainant has also alleged infringement of Claims 2, 5, 8, 9, 11-13, or 17-20, each of which is dependent upon Claim 1. Because the SCD and HomeRx devices do not incorporate all the elements of Claim 1, they do not incorporate all the elements of any claims dependent on Claim 1. Accordingly, the SCD and HomeRx devices do not constitute an exploitation of Claims 2, 5, 8, 9, 11-13, or 17-20.

demonstrated that its SCD and HomeRx devices maintain a pressure gradient throughout the compression cycle. The absence of these two functions from the SCD and HomeRx devices takes them outside the literal scope of Claim 1. See, Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 4 U.S.P.Q.2d 1737 (Fed. Cir. 1987) (A finding that the accused device does not perform one of the functions specified in the claim negates the possibility of finding literal infringement.) Accordingly, Complainant has not established that there is a reasonable likelihood its manufactured products will be found to fall within the literal scope of Claim 1.

E. Complainant Has Not Established A Likelihood That The SCD And HomeRx Devices Will Be Found To Be Within The Scope Of Claim 25

Complainant has also alleged infringement of Claim 25 of the '087 patent. Complainant adduced no evidence regarding the interpretation of this claim and whether the SCD or HomeRx devices fall within its scope either literally or under the doctrine of equivalents. Indeed, Complainant limited its argument that a domestic industry exists to its assertion that the SCD and HomeRx devices constitute an exploitation of Claim 1, stating in a conclusory footnote that the devices "contain each of the elements of certain other claims of the '087 patent." Complainant's Posthearing Brief at 19. In the absence of any evidence in support of the argument that the SCD or HomeRx devices falls within the scope of Claim 25, Complainant has not carried its burden of establishing a likelihood that it will prove a domestic industry exists in the exploitation of this claim.

F. Domestic Industry Under 19 U.S.C. § 1337(a)(3)(C)

Complainant asserts that a domestic industry exists pursuant to 19 U.S.C. § 1337(a)(3)(C) because of its investment in the exploitation of the '087 patent, including engineering and research and development projects.

1. The Scope Of A Domestic Industry Under 19 U.S.C. § 1337(a)(3)(C)

The assessment of whether a domestic industry exists under this provision requires a careful reading of the statute. The provision expressly refers to the previous paragraph of the statute, and the two must therefore be read together. They provide:

> (2) Subparagraphs (B), (C), and (D) of paragraph 1[29] apply only if an industry in the United States, relating to the articles protected by the patent, copyright, trademark, or mask work concerned, exists or is in the process of being established.
>
> (3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, or mask work concerned -
>
> (A) significant investment in plant and equipment;
>
> (B) significant employment of labor or capital; or
>
> (C) substantial investment in its exploitation, including engineering, research and development, or licensing.
>
> 19 U.S.C. § 1337(a)

When Congress amended Section 337 in 1988, it expanded the scope of activities which could constitute a domestic industry. Subsections (A) and (B) of paragraph 3 codified the existing Commission practice regarding a domestic industry as defined by investment in plant and equipment, or employment of labor or capital. Subsection (C) represents Congress' intent to define certain appropriate non-manufacturing activities as a domestic industry. As provided in the report of the House Ways and Means Committee:

> The first two factors in this definition have been relied on in prior Commission decisions finding that an industry

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[29] Subparagraphs (B), (C), and (D) of paragraph 1 provide that the importation of an article that infringes a copyright, patent, registered trademark, or mask work constitutes a violation of § 337.

> exists in the United States. The third factor, however, goes beyond the ITC's recent decisions in this area. This definition does not require actual production of the article in the United States if it can be demonstrated that substantial investment and activities of the type enumerated are taking place in the United States. Marketing and sales in the United States alone would not, however, be sufficient to meet this test. The definition could, however, encompass universities and other intellectual property owners who engage in extensive licensing of their rights to manufacture.
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> H.R. Rep. No. 40, 100 Cong., 1st Sess., pt. 1 at 157 (1987)

Thus, non-manufacturing activities such as research and development and engineering (as well as licensing)[30] can be sufficient to constitute a domestic industry. Accordingly, a complainant in a Section 337 investigation need not manufacture the product covered by the claims of the patent in order to establish that a domestic industry exists.

Congress did not intend, however, that activities of a complainant which generally relate to the subject area of the patent fall within the statutory definition of a domestic industry. Indeed, the plain language of the statute provides that the domestic industry comprises only those activities (either manufacturing or non-manufacturing) which exploit the intellectual property rights at issue. Paragraph 3 (C) refers to investment in the patent's "exploitation." Paragraph 3 also specifically refers to paragraph 2, which provides that relief under Section 337 is contingent upon the existence of a domestic industry "relating to the articles protected by the patent, ..." (emphasis added). The Commission has therefore consistently held that relief in a patent-based action under Section 337 is dependent upon whether the complainant "is exploiting or practicing the patent in controversy". Certain Plastic Encapsulated Integrated Circuits, Inv. No. 337-TA-315 (U.S.I.T.C.

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[30] The complainant has not engaged in licensing under the '087 patent.

1992), Comm. Opn. at 16; Certain Doxorubicin And Preparations Containing Same, 20 U.S.P.Q.2d 1602 (U.S.I.T.C. 1991), vacated as moot, Erbamont, Inc. v. United States International Trade Commission (Appeal No. 91-1072, Orders of March 26 and April 9, 1991) (Fed. Cir. 1991). Therefore, the activities set forth in paragraph 3 may constitute a domestic industry only if they are sufficiently related to articles protected by the patent as to constitute an exploitation thereof.

Accordingly, a domestic industry exists in this investigation under 19 U.S.C. § 1337(a)(3)(C) only if Complainant's investments in engineering and research and development projects are devoted to the exploitation of the '087 patent. See, Certain Microcomputer Memory Controllers, Components Thereof And Products Containing Same Order No. 6 (January 8, 1992) (summary judgement granted in part and denied in part; complainant's non-manufacturing activities were found to constitute a "substantial investment" for purposes of 19 U.S.C. § 1337(a)(3)(C), but a genuine issue of fact remained as to whether complainant was practicing the patent).

2. Complainant's Activities Do Not Constitute A Domestic Industry

Complainant's investments in research and development, engineering, educational programs, etc. may be divided into three general categories. The first category consists of investments in these areas that have been dedicated to Complainant's SCD and HomeRx devices.[31] Complainant asserts that it has invested millions of dollars over the years in engineering and research and development related to the exploitation of these devices. For purposes of the motion for temporary relief, Respondents do not deny that Complainant has made

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[31] See Complainant's Proposed Findings of Fact Nos. E 14, 19-21, 23-34, 40-44, 47, 51-55, 57-62, 64, 67, 71-99, 101-104, 106-112, 116-118, 120, and 122-132.

these expenditures (Respondents Objections to Complainant's Proposed Findings of Fact at 73). However, Complainant has not established that it is likely to show at the hearing on permanent relief that these devices are within the scope of the '087 patent's claims either literally or under the doctrine of equivalents. See discussion at 46-57. Accordingly, its investments in the exploitation of these devices would not constitute an industry "relating to the articles protected by the ['087] patent" as required by 19 U.S.C. § 1337(a)(2).

The second category comprises investments in the area of dynamic sequential gradient compression technology in general.[32] Complainant asserts that it has made investments in research and development, educational programs, etc. in connection with dynamic sequential compression technology, which also constitute a domestic industry for purposes of 19 U.S.C. § 1337(a)(3)(C). Examples of the investments in this category are C

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C C Gilman, Tr. at 454-455.

Complainant's argument regarding this second category of investments would effectively expand the scope of the domestic industry to all investments that are devoted to the patent's general field of technology. However, the language of 19 U.S.C. § 1337(a)(2) prohibits such an expansive reading of 19 U.S.C. § 1337(a)(3)(C). In enacting the 1988 amendments to Section 337,

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[32] See Complainant's Proposed Findings of Fact Nos. E 5, 7, 10-13, 22, 34, 37-40, 45-50, 52, 54, 56, 62-66, 68-72, 74, 83-84, 87-88, 92, 94, 96, 98-99, 105, and 121.

Congress expressly set forth the scope of the domestic industry. Congress expanded the type of activity which could constitute a domestic industry, but required that the industry comprise only those activities which exploit the patent. To include activities which are in the same field of technology but which do not have the requisite nexus to the patent would be contrary to the statute. The statutory requirement of an industry "relating to the articles protected by the patent" cannot be ignored.[33] Accordingly, Complainant's investments in the area of gradient compression technology in general are not part of the relevant domestic industry pursuant to 19 U.S.C. § 1337(a)(3)(C).

The third category of investment is generally referred to as C

C [34] C

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[33] The Administrative Law Judge does not interpret "articles related to the patent" to require the production of an article from the research and development in order to constitute a domestic industry. The research and development must, however, be devoted to the exploitation of the patent.

[34] See Complainant's Proposed Findings of Fact Nos. E 144-162.

C [35] C

C

C

It is not clear at this time whether the product (if any) that will result C will be an exploitation of the '087 patent.[36]

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C

C

C

C

C

C

C [37]

C

C While it is not necessary that a particular research and development project result in a completed product to be considered part of the relevant domestic industry, it must be clear that the project is devoted to the exploitation of the patent. Absent some evidence C is directed towards a product which would fall within the claims of the '087 patent, it is not possible to

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[35] C
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[36] C
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[37] C
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determine whether C constitutes an exploitation of the patent.[38]

3. Conclusion

Because Complainant has failed to establish that it is likely to prove its SCD and HomeRx devices fall within the scope of the claims of the '087 patent, it has also failed to establish that its engineering and research and development activities in connection with these devices are part of the relevant domestic industry.[39] Further, Complainant's activities in the general field of gradient compression technology which lack the required nexus to the '087 patent cannot be considered part of the relevant domestic industry. Finally, Complainant has failed to establish that it is likely to prove C sufficiently related to the '087 patent to constitute an exploitation thereof. Accordingly, Complainant has failed to establish that it is likely to prove that a domestic industry under 19 U.S.C. § 1337(a)(3)(C) exists with respect to the '087 patent.

VI. INEQUITABLE CONDUCT

Respondents allege that the '087 patent is unenforceable because

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[39] It is undisputed that Complainant's SCD and HomeRx devices are manufactured in the United States and that Complainant has invested C C dollars in the manufacture and sale of these devices. FF E 1 - E 19. If these devices were covered by the claims of the '087 patent, Complainant's investment would constitute a domestic industry for purposes of § 337.

Complainant engaged in inequitable conduct in its prosecution by failing to reveal the Spielberg invention and related patent to the examiner. A decision on the issue of inequitable conduct requires an inquiry into whether the applicant intended to deceive the Patent and Trademark Office. Kingsdown Medical Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 9 U.S.P.Q.2d 1384 (Fed. Cir. 1988). Insufficient evidence was adduced regarding whether the inventors intended to deceive the Patent and Trademark Office. Accordingly, the Administrative Law Judge is reserving ruling on this issue at this time.

VII. IRREPARABLE INJURY

A. Allegations Of Delay

Respondents allege that Complainant has delayed in bringing its motion for temporary relief, rebutting any presumption of irreparable harm. A party's delay in seeking preliminary relief is a factor in considering whether the party will suffer irreparable harm. Hybritech, Inc. v. Abbott Laboratories, 7 U.S.P.Q.2d 1191 (Fed. Cir. 1988). A delay can be evidence that the movant will not suffer irreparable harm in the absence of temporary relief. Certain Pressure Transmitters, Inv. No. 337-TA-304 (USITC 1990). However, delay alone does not preclude, as a matter of law, a determination of irreparable harm. Hybritech, 7 U.S.P.Q.2d at 1200.

In late May, 1991, Complainant learned of Respondents' intention to commence selling in June, 1991 the accused device in the United States. Kendall's Reply to Response to Motion for Temporary Relief, Exhibit 8. Complainant acquired a sample of the accused device, and performed laboratory tests on it in late July, 1991. Id., Exhibit 9. Counsel for the parties exchanged letters regarding the alleged infringement of the '087 patent in September, 1991. Huntleigh's Response to Motion for Temporary Relief,

Exhibits 28 and 29. On January 9, 1992, Complainant filed its complaint and motion for temporary relief in this investigation.

Complainant's delay of slightly over three months is not undue in the circumstances of this investigation. Unlike infringement actions in district court which require only notice pleading, a complaint filed with the International Trade Commission must set forth specific facts regarding all the elements necessary for relief under § 337 (i.e., infringement, importation and sale, existence of a domestic industry, etc.). Commission Interim Rule 210.20(a). It appears that three months is a reasonable period in which to prepare the complaint in this investigation. Accordingly, Complainant's delay does not militate against the awarding of temporary relief.

In its allegation of irreparable injury, complainant has emphasized alleged lost sales, the large volume of respondent's sales, and the respondent's low selling price. It also contends that the short remaining time on the '087 patent will in particular affect its sales of compression devices for home use.

B. Lost Sales

Complainant sells its sequential gradient compression devices to hospitals and to durable medical equipment dealers.[40] Its sales to hospitals of its SCD device are about C (FF F 9) and its sales to the equipment dealers of the HomeRx device were C in 1991.[41] FF F 12. Respondent sells only to the equipment dealers, and in analyzing the significance of the respondents' sales, complainant erroneously excludes its sales of the SCD hospital device and attempts to focus only on its sales to

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[40] The device Complainant sells to these dealers is the HomeRx.

[41] Complainant's total annual sales of all products is C FF F 9.

dealers of the HomeRx device. See Complainant's Post-hearing Brief at 37. However, this investigation concerns all dynamic sequential gradient compression devices allegedly covered by the '087 patent. Notice of Investigation, February 13, 1992, 57 Fed. Reg. 6126 (February 20, 1992). The Commission's rules regarding motions for temporary relief require that a movant set forth facts bearing on "immediate and substantial harm, if any, to the domestic industry in the absence of the requested temporary relief." Commission Interim Rule 210.24(e)(1). The statute defines "domestic industry" as an industry "relating to the articles protected by the patent." 19 U.S.C. § 1337(a)(2). Indeed, complainant contends that both devices represent exploitations of the '087 patent, and while they are not identical, the devices are similar, and work in the same way. Hasty, Tr. 295. Accordingly, the question of irreparable injury is evaluated in terms of complainant's total business in such devices.

The total market in the sale of intermittent compression devices is $70 - 80 million per year, of which complainant's sales constitute 80%. Crosby, Tr. 398. Ninety percent of complainant's sales are to hospitals, which is an expanding segment of the market and has great potential for growth. Crosby, Tr. 399; FF F 57. In its hospital sales Complainant enjoys gross profits of C and net profits of C FF F 24. Respondents do not sell the accused device to hospitals. FF F 73.

Complainant only recently began selling to durable medical equipment dealers for home use. Its sales of the HomeRx device has C C (FF F 12-13) and it projects C C of sales for its home use device for 1992 and 1993 (FF F 16) C

C [42] and substantial sales by the respondent.[43]

Complainant's educational efforts have resulted in the development of "brand loyalty" and have increased the demand for its products. FF F 27, 33.[44]

Complainant and Respondents between them account for about 20% of the sales of these devices for home use. FF F 5. Other competitors account for the remaining home use sales. Id. Complainant contends that Respondents have sold a massive amount of the accused product since its introduction into the market in mid-1991, and that such sales represent Complainant's lost sales. However, the evidence does not show with any degree of reasonable certainty, what portion of Respondent's sales are Complainant's lost sales. The evidence suggests that many of Respondents' Flowplus sales may not represent lost sales to Complainant, but may be sales lost by other competitors, or by the Respondent's other low-end devices. See FF F 67.

Respondents' sales of the accused product have resulted in diminished sales of its low-end products.[45] FF F 67. Respondents' accused device is approved by the FDA for various edemas, including venous edema and lymphedema, as well as for chronic venous insufficiency (CVI). FF F 72. Respondent

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[42] C C C

[43] Respondent has sold C of the accused device since May, 1991. FF F 68.

[44] Complainant plans to continue its research and development activities relating to sequential compression devices, and expenditures for these activities are expected to C every year. FF F 25.

[45] Respondents sold non-gradient compression devices for home use for several years before complainant entered the market. Crosby, Tr. 412; Gilman, Tr. 498.

advertises its Flowplus product as treatment for lymphedema and venous insufficiency. FF F 64. In contrast, Complainant's devices are approved only for chronic venous insufficiency, and were not designed for the treatment of lymphedema. FF F 19. The accused device has a fifty second compression cycle, whereas the Complainant's device has an eleven second compression cycle. FF F 29. Further, the accused device allows for a significantly higher compression pressure, which is necessary for the treatment of lymphedema. FF F 19, 29. It appears that in many instances the devices may be used for different purposes.

C customers on Respondents' customer list of C are also customers of Complainant. FF F 69. However, the record does not reflect how many C were customers of the Respondents, perhaps even before Complainant began selling devices for home use, who began purchasing from the Complainant when it entered the market, and either continued purchasing from both, or resumed purchasing from Respondents when they began selling a multi-chamber, sequential gradient device. The parties do not have exclusive contracts with their customers.[46] FF F 29.

The Medicare reimbursement program has played a significant role in the marketing and sale of these devices, and Complainant considers the reimbursement code program as a key to its success. Gilman, Tr. 528-530; RX 146. The devices are mostly used by aged persons and are reimbursed by Medicare. RX 75 describes the various HCFA codes,[47] E0650, E0651, E0652,

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[46] C C states where Complainant's HomeRx devices have been denied automatic reimbursement under the E0652 category. (See discussion below). Any sales in these states would have to be reimbursed on a case-by-case basis. In such, circumstances, it would not be appropriate to find that these Respondents' sales constitute lost sales of Complainant.

[47] HCFA is an abbreviation for the Health Care Financing Agency which administers the Medicare program.

pursuant to which the end users are reimbursed. FF F 42. The amount of reimbursement (referred to as a fee screen) in code category E0652 ($4000 to $4500) is greater than the amount of reimbursement in either of the other categories. Id. Code category E0652 was created specifically for the Wright Linear Pump which is an expensive system containing complicated controls to regulate the pressure in each chamber. Gilman, Tr. 457; Witko, Tr. 900. However, eventually Medicare allowed the higher fee screen for less complicated, less expensive to manufacture dynamic sequential gradient devices, including the Lymphapress, Biocompression and Complainant's product. Witko, Tr. 906. When this occurred it created an opportunity for the Complainant to greatly expand its sales by pricing its HomeRx device at a level lower than the prices of competitors,[48] thereby giving durable medical equipment dealers an incentive to sell Complainant's product and to greatly increase the revenue the dealers receive in each transaction. Id. Basically, Respondents are utilizing the same strategy.

Medicare has determined that the diagnosis acceptable for reimbursement in each of these categories is intractable lymphedema of the extremity, (FF F 45) although some few states will approve the E0652 fee screen for a CVI diagnosis. FF F 50, 53. Complainant's home use device is not approved by the FDA for treatment of lymphedema. Crosby, Tr. 419-420. It is approved only for treatment of chronic venous insufficiency (CVI). Id. In about forty states Medicare and Medicaid have not approved patients using the

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[48] The durable medical equipment dealers sell the devices to the end user. The sale is made at the amount of the Medicare fee screen. The manufacturers such as Complainant and Respondents, sell to the equipment dealers. If the products are eligible for the E0652 category, the dealers will maximize their revenue by purchasing the product with the lowest price, because the dealer charges the end-user the Medicare reimbursement fee no matter which product is used, and no matter how low the price to the dealer. Gilman, Tr. 506-507.

Complainant's home use device for the E0652 fee screen, except on a case by case basis. FF F 50. A vast majority of Complainant's sales are made in five states in which state reimbursement codes allow the E0652 fee screen for treatment of CVI. FF F 53. Complainant's home use device has been denied reimbursement in C C (FF F 49, 51), whereas Respondents' device is approved for the E0652 fee screen in all fifty states. Consequently, it appears there may be a large territory in which the two companies do not compete for sales.

For these reasons Respondents' sales cannot automatically be considered lost sales to Complainant, and the reasonable likelihood is that many of these sales do not constitute Complainant's lost sales.

C. Complainant's Sales Of Its SCD Hospital Device Must Be Included In Deciding Irreparable Injury

Complainant has chosen to make the HomeRx device a separate profit and loss center (Crosby, Tr. 386-87) because it wishes to C C Gilman, Tr. 453-455. This does not mean that its SCD sales can be ignored in deciding whether Complainant will suffer irreparable injury in the absence of temporary relief. The SCD device is part of the domestic industry and sales of this product C Respondents' sales of these devices. Complainant has C C in its SCD sales[49], and enjoys C profit margins in such

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[49] C C C Schild, Tr. 869-870.

sales.[50] Having this segment of the business to itself to a large extent insulates Complainant from the competitive pressures it is experiencing in the home use segment. Moreover, despite the fact C

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C Complainant has not chosen to lower its HomeRx price, although Respondents are underselling complainant by about $300 to $400.[51] Instead Complainant has decided to compete by C Such non-price competition shows Complainant's financial and market strength. Further, it appears that Complainant's sales of the HomeRx device are C Crosby, Tr. 411. These facts tend to show that during the pendency of this litigation Complainant is well able to withstand the competition of Respondents, without serious or irreparable injury.

D. **Short Time Before Expiration Of Patent**

Complainant attributes unwarranted significance to the fact that its patent is scheduled to expire in about two years. As was stated in Fluidized Supporting Apparatus and Components Thereof, Inv. No. 337-TA-182/188, 225 U.S.P.Q. 1211 (USITC 1984) the Commission will be able to award permanent

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[50] The complainant contends that its HomeRx business C C However, this appears to be a result of segregating these sales from its SCD sales. Undoubtedly HomeRx sales of approximately C C which enjoy a C gross and C net profit margin, would be C

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[51] Complainant's price to a dealer is $1300 to $1400 while Respondents charge $995 for comparable pump and sleeves. FF F 11, 66.

relief, at the conclusion of this investigation. If the Complainant prevails it can seek damages in its companion U.S. District Court action. While the availability of damages does not in itself obviate a finding of irreparable injury, in this case where the Complainant enjoys such a large share of the sales of compression gradient devices, is realizing substantial profits from such sales, and has chosen C the availability of damages, should Complainant prevail on the merits, is an adequate remedy.

This case is unlike Cellular Radiotelephones, in which rapidly developing technology resulting in short product lifespans, and the crucial race for development and maintenance of market share, critical to future participation in the market, justified temporary relief despite the existence of a damage remedy. Certain Cellular Radiotelephones, Inv. No. 337-TA-297, Initial Determination at 142-147. Further, in that case, the evidence showed that the Respondents engaged in a price war which was putting a squeeze on profits, and the investment capacity of the Complainant. None of these important factors exist in this investigation. Complainant has not C

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C No evidence has been produced tending to show short product lifespan, or other similar facts, which might justify the issuance of temporary relief despite the availability of a damage remedy.

E. There Is No Irreparable Injury To Any Market Which Consists Of Complainant's Engineering And Research And Development Activities

The Administrative Law Judge has found that there is no domestic industry for purposes of § 337 in Complainant's engineering and research and development activities. If these activities did constitute a domestic industry, the evidence shows that it would not be irreparably injured.

Complainant plans to continue and indeed C

C FF F 25. C

C

C Consequently, any such domestic industry is not threatened with irreparable injury.

VIII. HARM TO RESPONDENT

The Administrative Law Judge has found that Complainant has not shown a reasonable likelihood that it will prevail on the merits, or will suffer irreparable injury in the absence of temporary relief. Consequently, temporary relief should not be granted. However, this discussion of harm to the Respondent is offered should these findings be reversed by the Commission.

It is likely that Respondents will not be able to sell their other products, if their Flowplus product were excluded from the United States market. Witko Tr. 925-926. This is because Respondents' other products are not eligible for the E0652 fee screen, and therefore the medical equipment dealers would not find it as profitable to sell these products as they would those entitled to the higher medicare fee screen. Consequently, granting temporary relief would in practical effect totally exclude Respondents from the U.S. market, during the pendency of this litigation. To do so might seriously injure its relationships with its medical equipment dealer customers, as well as with physicians and the patient end-users. If the supply of Respondents Flowplus product were interrupted, dealers might be reluctant to resume purchasing from Respondents for fear that future interruptions in supply might occur.

IX. PUBLIC INTEREST CONSIDERATIONS

The Commission may order that imported articles be excluded from entry into the United States if it has reason to believe that the importations are in violation of § 337, unless public interest considerations indicate that the imported articles should not be excluded. 19 U.S.C. § 1337 (e)(1). The public interest includes the effect of exclusion upon the public health and welfare, competitive conditions in the United States, the production of like or directly competitive articles in the United States, and United States consumers. Id.

There is clearly a public interest in enforcing valid patent rights, and where the patent owner has chosen not to license others, in excluding infringing products from the United States, during the pendency of litigation. The Federal Circuit has held, however, that the focus of the public interest analysis is whether there exists some critical public interest that would be injured by the grant of temporary relief. Hybritech, Inc. v. Abbott Laboratories, 849 F.2d 1446, 1458 (Fed. Cir. 1988). This is in harmony with the legislative history of the 1974 Trade Act (the enumerated public interest factors are "paramount in the administration of section 337")[52] and this view was not modified in the 1988 amendments to § 337. Pressure Transmitters at 16-18.

There is an important public interest consideration in this investigation represented by the interests of users of Respondents' devices. If temporary relief were granted and the Respondents' products were excluded from the United States during the pendency of this investigation such users could not simply purchase replacement sleeves for their existing machines. Those

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[52] S. Rep. 1298, 93d Cong., 2d Sess. 193 (1974).

needing replacement sleeves would be required to purchase a new pump from Complainant or another competitor. FF G 1. This would mean a second reimbursement from Medicare for the same product for the same patient, or, if a second reimbursement were denied, such end users would not have access to treatment. Creation of such circumstances through temporary exclusion of the accused product would adversely affect the public health and welfare and would be contrary to the public interest.

X. BALANCING THE INTERESTS

The Complainant has a market share of about C in sales of the subject devices to hospitals, amounting to sales of over C million dollars. These sales which admittedly are made at C to Complainant, plus its HomeRx sales, are about C as Respondents sales of the accused device. Further, Complainant has not found it C C in response to Respondents competition in the home use segment, but instead in January, 1992 has C Also, Complainant's sales in the home use segment, which C from C in 1989 to C in 1991, are likely to continue to C FF F 16. Clearly, Complainant has the financial strength to combat and withstand Respondent's competition during the pendency of the litigation.

On the other hand, Respondents' position as a competitor in the United States in these devices could be seriously compromised if it could not sell its Flowplus product during the pendency of this investigation. The balance of harm, therefore, tips in favor of the Respondents.

Further, public interest considerations further tip the balance against the granting of temporary relief. Users of Respondents' Flowplus device will not be able to purchase replacement sleeves if temporary relief were granted.

Since under the governing statute public interest considerations are "paramount" and since the balance of harm militates against granting temporary relief, even if the Commission were to find that Complainant would likely prevail on the merits, and that the injury to Complainant would be irreparable, a balancing of the various interests indicates that temporary relief should not be granted.

XI. BONDING

The Commission is authorized to require that Complainant post a bond if its motion for temporary relief is granted. The purpose of a bond is to deter frivolous requests for temporary relief and to discourage complainants from seeking such relief for improper purposes or to harass Respondents. Certain Crystalline Cefadroxil Monohydrate, 337-TA-293, Commission Opinion, p. 9. In this investigation the Complainant's case is deficient in many respects. It seeks to utilize a patent which does not cover its commercial products to prove the existence of a domestic industry. It seeks also to interpret this patent to incorporate a later generation technology, which is not disclosed in the patent, to prove infringement. Further, there are serious questions regarding the patent's validity based on prior art references not considered by the PTO.

Therefore, if the Commission were to grant temporary relief in this investigation, it should require a bond of from 15% to 20% of Complainant's total 1991 annual sales of sequential gradient compression devices, i.e., a bond in the range of approximately C

FINDINGS OF FACT

I. BACKGROUND

A. Jurisdiction

FF A 1. The U. S. International Trade Commission has jurisdiction over the subject matter of this investigation and personal jurisdiction over Respondent, Huntleigh Technology Inc. Staff Stip. 12.

B. The Parties

FF A 2. Kendall manufactures or contracts to manufacture its SCD devices through a division known as Kendall Healthcare Products Company. In the United States, Kendall sells its SCD system directly to hospitals or authorized rental dealers, while its HomeRx system is sold indirectly to patients through durable medical equipment dealers. Staff Stip. 1

FF A 3. Huntleigh Technology plc is incorporated under the laws of the United Kingdom and has its principal place of business at 310-312 Dallow Road, Luton, Bedfordshire, England. Staff Stip. 2.

FF A 4. Huntleigh Technology, Inc., a subsidiary of Huntleigh Technology plc, is a Delaware corporation having its principal place of business at 227 Route 33 East, Manalapna, New Jersey 07726. Staff Stip. 3.

FF A 5. Huntleigh Technology, Inc. imports into and sells in the United States the accused systems under the trade name "Flowplus." Staff Stip. 4.

FF A 6. Huntleigh plc owns Huntleigh Luton Ltd. which in turn owns Huntleigh Medical Ltd. which is involved in manufacturing the accused systems in Bedfordshire, England. Staff Stip. 16.

C. U.S. Patent No. 4,029,087 (the "'087 patent")

FF A 7. The '087 patent is entitled "Extremity Compression Device" and

issued on June 14, 1977, based on Application Serial No. 625,967 filed October 28, 1975. The '087 patent expires on June 14, 1994. Staff Stip. 14.

FF A 8. John F. Dye ("Dye") and Charles R. Memhardt ("Memhardt") are the inventors of the invention claimed in the '087 patent. Dye, Tr. 24; CX 9.

FF A 9. The Kendall Company ("Kendall") is the owner of the '087 patent by assignment from Dye and Memhardt. CX 9; CX 26.

FF A 10. Kendall has not licensed its dynamic sequential gradient compression technology under the '087 patent. Staff Stip. 8.

FF A 11. Foreign patents related to the '087 patent have issued in Canada as Canadian Patent No.s 1,085,251, 1,113,330, and 1,114,704. Staff Stip. 9.

D. The Devices In Issue

FF A 12. Huntleigh Medical Limited manufactures the calibrated sequential gradient devices sold by Huntleigh Technology, Inc. under the trademark Flowplus. Staff Stip. 10.

FF A 13. Huntleigh Technology, Inc. first imported a Flowplus device on or about C and first sold a Flowplus device on or about June 19, 1991. Staff Stip. 11.

FF A 14. The Respondents' device, the Flowplus system is marketed for home use and also comprises a pneumatic compression controller, a pair of compression sleeves, and connecting tubing. Staff Stip. 7.

FF A 15. Kendall manufactures and sells in the United States two versions of a dynamic sequential compression device. The first version was introduced in the early 1980's; it is designed primarily for hospital use and is known as the "SCD compression system" or the "SCD system." The second version is designed for home use and is known as the "HomeRx system." Staff

Stip. 13.

FF A 16. In both the hospital SCD device and the HomeRx device, each sleeve consists of multiple separate fluid pressure chambers progressively arranged longitudinally along the sleeve from the distal end (near the foot) to a proximal end closer to the heart. Staff Stip. 6.

FF A 17. As demonstrated in Physical Exhibit B to the Complaint, Kendall's hospital SCD and HomeRx systems each comprise a pair of compression sleeves, a pneumatic compression controller, and multiple connecting tubes between the controller and each sleeve. The sleeves are multi-chambered and may be drawn over, or wrapped around the patient's legs. Staff Stip. 19.

E. The Venous System, DVT And CVI

FF A 18. The venous system is a low pressure part of the circulatory system. Hasty, Tr. 43, l. 8-18.

FF A 19. The venous system transfers blood from the tissues back to the heart for oxygenation in the lung. Hasty, Tr. 43, l. 8-18.

FF A 20. Deep vein thrombosis ("DVT") is the formation of blood clots in the deep veins of the legs. Hasty, Tr. 43-44, l. 23-25, 4-7.

FF A 21. DVT is a common problem in hospitals; surgical and medical patients are at risk for developing DVT. Hasty, Tr. 44, l. 8-16.

FF A 22. Any patient confined to a bed for an extended period of time is at risk for DVT. Hasty, Tr. 44, l. 8-16.

FF A 23. Chronic venous insufficiency ("CVI") is a chronic venous disease effecting the veins of the legs. Hasty, Tr. 44, l. 17-18, 21-25.

FF A 24. As an individual walks the muscles of the leg work in conjunction with the one-way valves in the veins to move blood from the legs and return it back to the heart. Hasty, Tr. 49, l. 9-12.

FF A 25. The valves of the leg veins close to prevent blood from moving back through the veins of the legs toward the foot. Hasty, Tr. 49, l. 17-20.

FF A 26. When a person is confined to bed, as when being treated in a hospital, blood in the leg veins stagnates. Hasty, Tr. 49, l. 21-22.

FF A 27. There are three key factors which indicate a predisposition toward blood clotting. Hasty, Tr. 50-51, l. 14-5.

FF A 28. The three factors are: abnormal changes in blood chemistry, injury to blood vessel wall, and blood stagnation. Hasty, Tr. 50-51.

FF A 29. These three factors are known as Virchow's Triad and were identified in the 19th century. Hasty, Tr. 51, l. 6-9.

FF A 30. Blood clots forming in the legs can lead to pulmonary embolisms. Hasty, Tr. 51-52, l. 11-2.

FF A 31. A pulmonary embolism is a blood clot that travels from the legs back through the heart into the pulmonary artery leading to the lungs. Hasty, Tr. 52, l. 3-7.

FF A 32. Pulmonary embolisms are sometimes fatal to patients. Hasty, Tr. 51-52, l. 23-2, 7-9.

FF A 33. Blood clots in the legs can cause destruction of the one-way valves in the veins of the legs. Hasty, Tr. 52, l. 13-18.

FF A 34. When the valves of the veins are injured to the point where they become dysfunctional the individuals ability to move blood in the veins toward the heart is impaired. Hasty. Tr. 52-53, l. 13-25, 1.

FF A 35. In instances where the valves in the veins of the legs have been severely damaged, blood pools in the legs and the patient experiences chronic elevated venous pressures. Hasty, Tr. 53, l. 5-7.

FF A 36. In severe cases of chronic high venous pressures ulcers may

form on the legs. Hasty, Tr. 53, l. 9-11.

FF A 37. Compression of the legs serves to compress the leg veins and expel blood from the legs. Hasty, Tr. 53, l. 12-19.

FF A 38. Compression acts to increase venous blood velocity thereby reducing venous stagnation. Hasty, Tr. 53-54, l. 25, 1-2.

FF A 39. There is a fundamental difference between the prevention of DVT and edema. Melrose, Tr. 660-661, l. 15-25, 1.

FF A 40. DVT and edema are different medical problems. Melrose, Tr. 661, l. 2-4.

FF A 41. DVT and edema should be treated differently. Melrose, Tr. 661.

FF A 42. Treatment of DVT employs the use of a shorter time cycle and a lower pressure as compared to edema which would require higher pressure at longer cycle times. Melrose, Tr. 661, l. 11-15.

II. INFRINGEMENT

A. Claim Construction

1. The '087 Patent Generally

FF B 1. The invention of the '087 Patent is an intermittent pneumatic compression device that exerts sequential gradient compression. Dye, Tr. 59

FF B 2. Patent drawings are not drawn to scale. Melrose, Tr. 691.

FF B 3. When interpreting a patent drawing mere reference to the drawing is not sufficient. Schild, Tr. 768-772, l. 21-13.

FF B 4. To understand a patent drawing, one must look to the specification for an understanding of the drawing. Schild, Tr. 772.

FF B 5. Huntleigh became aware of the '087 patent in May of 1991. Schild, Tr. 721, l. 6-12.

2. The Meaning Of "During The Compression Cycles As Used In The '087 Patent

FF B 6. The term "during" can mean a portion of the period or it can mean the whole period. Melrose, Tr. 645, l. 22-24.

FF B 7. With respect to the embodiments illustrated as Figures 6-8 in the '087 patent, the '087 patent provides as follows:

> Although the various chambers in the sleeves in FIGS. 6-8 are simultaneously inflated. The sleeve applies a pressure gradient against patient's limb which decreases from the lower chamber 24a to the upper chamber 24d during the compression cycles. This follows since the lower most chamber 24a freely inflates, while the tube section 26a limits passage of air somewhat from the chamber 24a to the chamber 24b, such that a higher pressure is maintained in the chamber 24a than in the chamber 24b during the compression cycle. Similarly, the thinner tube 76b restricts passage of gas from chamber 24b into 24c to a greater extent than through tube section 76a, and thus maintains a higher pressure in the chamber 24b than in chamber 24c during the compression cycle. Finally, the smallest tube section 76c further limits passage of air into the upper most chamber 24d, and maintains a higher pressure in chamber 24c than in chamber 24d during the compression cycles. In this manner, during the compression cycles the pressure in the chamber 24a will be greater than the pressure in chamber 24b, the pressure in chamber in 24b will be greater than the pressure in chamber 24c, and the pressure in chamber 24c will be greater than in chamber 24d. CX 9, col. 6, lines 15-39.

FF B 8. As used in the '087 patent "during the compression cycle" is used to mean that the gradient is maintained throughout the compression cycle. Dye, Tr. 81, l. 5-13.

FF B 9. The '087 patent teaches those who read it to maintain a sequential gradient compression throughout the compression cycle followed by a decompression. Dye, Tr. 60, l. 6-11.

FF B 10. "Throughout the compression cycle" means the entire time taken to compress the garment. Melrose, Tr. 594-595, l. 22-1.

3. The Figure 1 Embodiment Of The '087 Patent

FF B 11. Figure 1 embodiment of the '087 patent is a series of discrete

chambers connected by flow control valves 38. Dye, Tr. 61, l. 3-10; CX 9.

FF B 12. In the Figure 1 embodiment, flow control valve mechanism 38 is a spring valve which opens at some predetermined amount of pressure. Dye, Tr. 61, l. 11-15; CX 9.

FF B 13. In the Figure 1 embodiment, flow control valves 38 are essentially check valves that are spring loaded so the air cannot flow from the more proximal chamber to the more distal chamber but which allow air to flow from the more distal chamber to the more proximal chamber once a certain threshold of pressure has been reached. Dye, Tr. 62, l. 14-21; CX 9.

FF B 14. In the Figure 1 embodiment, flow control valves 38 maintain predetermined pressure relationships between the chambers of the Figure 1 embodiment. Dye, Tr. 63-64, l. 22-2; CX 9.

FF B 15. In the Figure 1 embodiment an air source 28 continually applies air to a timing mechanism 30. Dye, Tr. 61, l. 21-1; CX 9.

FF B 16. In the Figure 1 embodiment, when the timing mechanism opens it allows air to pass through filling tube 34 and begin the inflation of the most distal chamber 24a. Dye, Tr. 61-62, l. 21-1; CX 9.

FF B 17. In the Figure 1 embodiment, tubes 40 connect the flow control valves 38 to the chambers to form airflow pathways between the chambers. Dye, Tr. 62, l. 6-21; CX 9.

FF B 18. In the Figure 1 embodiment, at the end of the compression cycle, the timing device 30 shuts off the air source to the sleeve and allows the sleeve to vent through tube 34 and out exhaust port 36. Dye, Tr. 64, l. 3-10; CX 9.

FF B 19. When the Figure 1 embodiment exhausts; tubes 56 are essentially one-way valves that allow flow from the more proximal portion of the sleeve to

the more distal portion with minimal resistance so that the air from all of the chambers can exhaust from the system. Dye, Tr. 64, l. 10-15; CX 9.

FF B 20. The device depicted in Figure 1 of the '087 patent will create a pressure gradient and maintain the pressure gradient indefinitely even if the inlet tube 34 is clamped off. Melrose, Tr. 590-592, l. 13-15; CX 9.

4. Exhaust Tube 80 In The Figure 6 Embodiment

FF B 21. Figures 6, 9, 10, and 12 of the '087 patent all show exhaust tube 80 connected to the upper chamber 24d. CX 9.

FF B 22. Tube 80 is depicted in the drawings as a tube. Melrose, Tr. 648, l. 4-7; Schild, Tr. 786-787, l. 25-8.

FF B 23. Exhaust tube 80 is separated from inlet port 78 by three flow restrictors. Melrose, Tr. 611, l. 8-9.

FF B 24. The language in the patent that says "the sleeve 22 may be deflated through an exhaust tube 80 connected to the upper most chamber 24 or in a manner as previously described" means that the sleeve could be exhausted through tube 80, or through multiple tubes as in Figure 5. CX 9, Dye, Tr. 85.

5. Poiseuille's Law

FF B 25. Poiseuille's Law governs the laminar flow of fluid through devices such as the device shown in Figure 6 of the '087 patent. RX 112; Melrose, Tr. 650, l. 13-16.

FF B 26. Poiseuille's Law relates to pressure drops across orifices or restrictors. Melrose, Tr. 650, l. 17-20.

FF B 27. The magnitude of the pressure drop is a function of the velocity with which the fluid flows through the restrictors. Melrose, Tr. 650, l. 21-25.

FF B 28. Poiseuille's Law has been known for over a hundred years. Dye,

Tr. 71, 1. 8-10.

FF B 29. Persons who are familiar with the technology or who would be ordinarily skilled in the art relating to the '087 patent would know Poiseuille's Law. Dye, Tr. 71, 1. 11-15.

6. The Figure 6 Embodiment Of The '087 Patent

FF B 30. The flow control tubes 76a, 76b, and 76c between the chambers in the Figure 6 embodiment of the '87 patent have different diameters. Dye, Tr. 68, 1. 13-18, CX 9.

FF B 31. Air enters the Figure 6 embodiment of the '087 patent through tube 78. Dye, Tr. 69, 1. 3-6; CX 9.

FF B 32. When air enters the first chamber it begins to inflate to fill the first chamber 24a with air. Dye, Tr. 69, 1. 7-12.

FF B 33. When there is a pressure rise in the first chamber 24a of the Figure 6 embodiment, then air begins to flow through the restrictor 76a into chamber 24b. Dye, Tr. 69, 1. 7-22, CX 9.

FF B 34. Tube 76a slightly impedes or limits the passage of air between chamber 24a and chamber 24b. Hasty, Tr. 262, 1. 15-22.

FF B 35. The flow control tube 76b impedes the flow of fluid from chamber 24b to chamber 24c. Hasty, Tr. 263, 1. 4-9.

FF B 36. Flow control tube 76c impedes the flow of air between chamber 24c and chamber 24d. Hasty, Tr. 263, 1. 4-9.

FF B 37. So long as there is airflow through the flow control tubes 76 between the chambers, there will be a pressure drop across chambers 24a, 24b, 24c and 24d. Dye, Tr. 70-71, 1. 23-3.

FF B 38. During the inflation of the embodiment shown in Figure 6, there is a pressure gradient against the patient's limb, decreasing from the lower

most chamber to the upper most chamber. Hasty, Tr. 264, 1. 23-7.

FF B 39. The device depicted in Figure 6 of the '087 patent fills at a gradient pressure so long as airflow continues. Melrose, Tr. 593, 1. 3-13.

FF B 40. The '087 patent does not describe the volumes that are being employed in the chambers. Melrose, Tr. 690, 1. 6-9.

B. **Nature Of Huntleigh's Flowplus Device**

FF B 41. Huntleigh's Flowplus device is a multi-chambered sleeve with flow restrictors between the chambers in the form of small diameter tubes. Dye, Tr. 113, 1. 17-22.

FF B 42. The Flowplus device is intended for the treatment of vascular disorders including edemas, DVT and CVI. Schild, Tr. 767-768, 1. 20-11.

FF B 43. The Flowplus device works by initially inflating at an inflation point located at the lower first chamber (foot chamber). Hasty, Tr. 267, 1. 22-25, Dye, Tr. 116, 1. 2-6.

FF B 44. The pump used to inflate the Flowplus device is the same as that presently made for nongradient devices. Schild, Tr. 718-719, 1. 23-17.

FF B 45. The Flowplus device functions by permitting pressurized fluid into an inlet tube, the first chamber being inflated and then the second and then the third being inflated by interconnecting tubes between the chambers. As each chamber reaches its predetermined pressure then a leak will maintain the pressure through the bleed valve. Schild, Tr. 713-714, 1. 18-4, Dye, Tr. 116, 1. 2-12.

FF B 46. There is a mechanism in the Flowplus controller for connecting a source of air to the first chamber (foot portion of the Flowplus device). Hasty, Tr. 268, 1. 10-13.

FF B 47. There is a small metal valve leading from the third chamber of

the Flowplus device that allows air to vent or bleed from the sleeve, making gradience possible in the Flowplus device. Hasty, Tr. 268, l. 7-9; CX 55; CPX 17.

FF B 48. The size and length of the tubing between the chambers is not critical. Schild, Tr. 715, l. 6-9.

FF B 49. Pressure graph CX 48 shows that there is a pressure gradient between the ankle, calf, and thigh chambers of the Flowplus device throughout the compression cycle. Dye, Tr. 115, l. 16-22.

FF B 50. The pressure is higher in the ankle chamber than in the calf chamber, and higher in the calf chamber than in the thigh chamber in the Flowplus device throughout the compression cycle. CX 48, RX 9A.

FF B 51. Because air can continue to flow through the device and out the bleed valve exiting the third chamber, a gradient is maintained between each of the chambers in the Flowplus device. Dye, Tr. 116, l. 2-15; Hasty, Tr. 278.

FF B 52. The Flowplus device has means for deflation. Dye, Tr. 116.

FF B 53. The pressure is higher in the ankle chamber than in the calf chamber, and higher in the calf chamber than the thigh chamber in the Flowplus device throughout the compression cycle. CX 48, RX 9A.

C. Huntleigh's PCT Patent Application On The Flowplus

FF B 54. The device described in Huntleigh's PCT patent application (CX 55) and the device shown in Figure 7 of that application correspond to Huntleigh's Flowplus device. Hasty, Tr. 269-270, l. 20-6; Schild, Tr. 761-762, l. 18-8; 762 l. 9-14.

FF B 55. As shown in Figure 7, the Flowplus device includes a garment or sleeve portion. Schild, Tr. 762, l. 18-23, CX 55.

FF B 56. As shown in Figure 7, the Flowplus device has a lower chamber (foot portion) and a tube is connected into the lower chamber which represents the inlet of the pressure. Schild, Tr. 762-763, 1. 24-4; 768 1. 12-17; CX 55.

FF B 57. As shown in Figure 7, the Flowplus device also has a secondary chamber in the middle, the secondary chamber is separated from the first chamber by a bleed orifice No. 3. Schild, Tr. 763, 1. 5-10, CX 55.

FF B 58. As shown in Figure 7, bleed orifice No. 3 is just a tube. Schild, Tr. 763, 1. 11-13; CX 55.

FF B 59. As shown in Figure 7, the Flowplus device also has an upper or third chamber and like the other chamber is separated by a plastic wall. Schild, Tr. 763, 1. 14-18; CX 55.

FF B 60. As shown in Figure 7, the Flowplus device also includes a bleed orifice no. 4 between the third and second chamber which permits communication between a third and second chamber. Schild, Tr. 763-764, 1. 20-1.

FF B 61. As shown in Figure 7, bleed orifice No. 4 is a tube. Schild, Tr. 764, 1. 2-4; CX 55.

FF B 62. While shown to be longer in Figure 7 of Complainant's Exhibit 55, bleed orifice No. 3 does not have to be longer than bleed orifice No. 4, but can be the same size and still work essentially the same way. Schild, Tr. 764, 1. 5-13; CX 55.

FF B 63. The Flowplus device illustrated in Figure 7 of Complainant's Exhibit 55 shows a bleed No. 6. Schild, Tr. 765, 1. 2-5; CX 55.

FF B 64. The Flowplus device operates as follows: (A) air comes from the compressor into the first chamber; (b) the air flows from the first chamber through the bleed no. 3 into the second chamber; (c) because of the way in which it is constructed there is a pressure drop between the first

chamber and the second chamber; (d) similarly, air flows from the second chamber through bleed no. 4 into the third chamber; and (e) the air that is in the third chamber is permitted to exhaust from the sleeve through the bleed no. 6. Schild, Tr. 765-766, l. 15-9.

FF B 65. The Flowplus device operates in accordance with Poiseuille's Law, but with some modification. Schild, Tr. 766, l. 7-9.

FF B 66. Respondent's description of its commercial Flowplus device in its PCT patent application states that bleed 6 is an adjustable needle valve. CX 55.

FF B 67. The bleed valve in the Huntleigh Flowplus device controls the amount of air which passes through the restrictor tubes. Schild, Tr. 716.

D. The Flowplus Device Performs The Claimed Functions Of The '087 Patent

FF B 68. The Flowplus has "means for filling said chambers from said source during periodic compression cycles while applying a greater pressure in each inflated lower chamber than the pressure in any upper inflated chamber to apply a compressive pressure gradient against the patient's limb by the sleeve, which progressively decreases from said lower to upper portions throughout the compression cycle." Hasty, Tr. 276-277, l. 24-12; CX 3, Claim 1.

FF B 69. The Flowplus has "said filling means including means for connecting the source of a lower first chamber in said sleeve." Hasty, Tr. 278, l. 8-12; CX 3, Claim 1.

FF B 70. The Flowplus device has "means for distributing fluid from said first chamber to progressively located upper chambers at progressively decreasing pressures." Hasty, Tr. 278, l. 16-22; CX 3, Claim 1.

FF B 71. The Flowplus device has "means for emptying said chambers

during periodic compression cycles between said compression cycles." Hasty. Tr. 278-279, 1. 23-4; CX 3, Claim 1.

E. **Timing Cycle Of The Huntleigh Devices**

FF B 72. The tolerance of the patient is important in determining the time cycle for the Flowplus device. Schild, Tr. 840, 1. 5-7.

FF B 73. The Flowplus controller is also sold in Europe. Schild, Tr. 840, 1. 13-15.

FF B 74. The Flowplus device sold in Europe has a 3 minute time cycle. Schild, Tr. 840, 1. 16-18.

FF B 75. The pressure applied by the Flowplus controller delivered in Europe is 90-100 millimeters which is high compared to the pressure delivered in the units sold in America which have 60 millimeter pressure delivery. Schild, Tr. 840-841, 1. 19-6.

FF B 76. All studies used by Huntleigh to determine compression time cycles are directed to only single chamber devices. Schild, Tr. 843.

FF B 77. Huntleigh's current market product called the Flowpress device is primarily used for treating edema. It has a 3 minute time cycle and provides uniform compression. Schild, Tr. 844, 1. 14-21.

FF B 78. Huntleigh's Flowplus device can be used in place of Huntleigh's Flowpress device. Schild, Tr. 845, 1. 1-3.

FF B 79. When one employs a lower pressure, as a rule, faster cycling is needed because patients want to have the device on for a certain period of time and experience so many cycles. Schild, Tr. 849-850, 1. 24-6.

FF B 80. Clinical studies that report effective findings related to animal, human, volunteer and patient studies are important to the medical profession. Melrose, Tr. 659, 1. 6-9.

III. VALIDITY

A. Prior Art

1. Conti (CX 170)

FF C 1. United States Patent No. 3,548,809 issued to Conti, December 22, 1970 ("the Conti patent") discloses a multi-chamber compression sleeve. Melrose, Tr. 663-664, 1. 22-3; Schild, Tr. 780, 1. 5-14; CX 170.

FF C 2. The embodiment of Figure 8 of the Conti patent shows a separate tube providing pressure to each chamber. Melrose, Tr. 664, 1. 4-6.

FF C 3. The chambers of one embodiment of the Conti patent are intended to be filled from the bottom to the top. Schild, Tr. 780, 1. 15-18.

FF C 4. The '809 device fills sequentially from the bottom to the top, and comes to a uniform pressure in the chambers. Schild, Tr. 780; 782.

FF C 5. In another embodiment of the Conti patent, the multiple chambers are filled from the side. Schild, Tr. 780, 1. 19-21.

FF C 6. The Conti patent does not teach gradient compression over the entire period of compression. Hasty, Tr. 298, 1. 22-25.

FF C 7. The Conti patent does not have a bleed valve at the top for the purpose of maintaining gradience throughout the compression cycle. Schild, Tr. 780-781, 1. 22-1.

FF C 8. The Conti patent teaches the application of the sequential compression for the treatment of human limbs. Melrose, Tr. 557, 1. 6-12.

FF C 9. The Conti patent was cited in the prosecution history of the '087 patent and the '087 patent issued over the Conti patent. CX 9.

2. Werding (CX 175)

FF C 10. United States Patent NO. 3,536,063 issued to Werding, October 27, 1990 ("the Werding patent") discloses a single chamber gradient device.

CX 175.

FF C 11. The Werding patent was cited in the prosecution history of the '087 patent and the '087 patent issued over the Werding patent. CX 9; CX 175.

3. **Weinberg (CX 172)**

FF C 12. United States Patent No. 2,781,041 issued to Weinberg, February 12, 1957 ("the Weinberg patent) discloses a multi-chamber pneumatic compression. CX 172.

FF C 13. The Weinberg patent was cited in the prosecution history of the '087 patent and the '087 patent issued over the Weinberg patent. CX 9, CX 175.

4. **Flowtron Aire (CX 167)**

FF C 14. British Patent No. 1,310,492 issued to Flowtron Aire Ltd. ("the Flowtron Aire patent") was published March 21, 1973.

FF C 15. The device shown in the Flowtron Aire patent is a sleeve formed of a series of annular rings extending from the lower portion of the foot through the thigh region with the knee being devoid of rings. Hasty, Tr. 297.

FF C 16. The Flowtron Aire patent shows a multiple-chamber device. Schild, Tr. 774-775, 1. 21-9.

FF C 17. Each of the chambers of the Flowtron Aire patent device are interconnected by a smaller tube which acts as a restrictor. Schild, Tr. 775, 1. 10-16, Hasty, Tr. 297; CX 167.

FF C 18. The device shown in the Flowtron Aire patent inflates through the lowermost chamber. Schild, Tr. 775, 1. 17-19; CX 167.

FF C 19. The Flowtron Aire patent fills sequentially and the construction of this particular device is that when all the chambers are filled, it comes to equilibrium. Schild, Tr. 775-776, 1. 20-13.

FF C 20. The device depicted in the Flowtron Aire patent creates gradience while filling sequentially and comes to rest at a common pressure through the system. Melrose, Tr. 676, l. 8-12.

FF C 21. The Flowtron Aire patent does not disclose a bleed in the top chamber. Schild, Tr. 776, l. 14-16.

FF C 22. If the compression cycle is permitted to continue and in the absence of the bleed at the top of the device, the device shown in the Flowtron Aire Patent would come to equal pressure. Schild, Tr. 776.

FF C 23. Early Flowtron Aire devices such as those depicted in the Flowtron Aire patent were not tested to determine whether such devices produced a pressure gradient during the compression cycle. Melrose, Tr. 576-577, l. 25-6.

FF C 24. The Flowtron Aire patent does not mention whether such devices produce a gradient pressure during the compression cycle. Melrose, Tr. 576-577, l. 1-6.

5. **Höflinger (CX 169)**

FF C 25. British Patent No. 403,859 issued to Höflinger ("the Höflinger patent") was accepted on January 4, 1934. CX 169.

FF C 26. The Höflinger patent describes a three-chamber device wherein the chambers are connected by flow restrictors. Schild, Tr. 778-779.

FF C 27. The Höflinger patent device is an exsanguinator. Melrose, Tr. 632, l. 21-22.

FF C 28. The Höflinger patent shows a multi-chamber device for accumulating blood at a desired point in the human body. Hasty, Tr. 299, l. 15-25.

FF C 29. The device described in the Höflinger patent accumulates blood

at some location of the body. CX 169; Hasty, Tr. 299, l. 15-19.

FF C 30. The Höflinger patent is employed to stop all blood flow, including arterial flow. Melrose, Tr. 674-675, l. 20-11.

FF C 31. The Höflinger patent illustrates a closed system that does not have a vent at the top. Melrose, Tr. 674, l. 20-25, Hasty, Tr. 300, l. 3-7.

FF C 32. The Höflinger patent illustrates a device whose multiple chambers come to equal pressure in the course of its use. Melrose, Tr. 675.

FF C 33. The Höflinger patent illustrates a device used to concentrate blood in the limbs. Schild, Tr. 778, l. 8-17.

FF C 34. Concentration of blood in the limbs is a different purpose than the purpose for using the Flowplus device. Schild, Tr. 778, l. 15-20.

6. **Spielberg (CX 171)**

FF C 35. United States Patent No. 3,391,692 issued to Spielberg, July 9, 1968 ("the Spielberg patent" is a single-chamber device). Melrose, Tr. 665.

FF C 36. The Spielberg patent shows a one-cell device with multiple straps attached to it for wrapping the device around the leg, with the idea being to produce different levels of compression characterized by the tightness with which one wraps the straps. Hasty, Tr. 302, l. 16-24; Melrose, Tr. 665-666, l. 20-3.

FF C 37. The use of the straps in the Spielberg patent could create a set of annular constrictors or restrictors, through which or underneath which air would flow through the device. Melrose, Tr. 670, l. 16-25.

FF C 38. Air naturally flows from high pressure to low pressure. Melrose, Tr. 671, l. 7-9.

FF C 39. There are no vents, bleeds or exhaust valves in the Spielberg patent. Melrose, Tr. 672, l. 3-6.

FF C 40. The Spielberg patent is a closed chambered device. Melrose, Tr. 671-672, 1. 25-2.

FF C 41. There is no teaching in the Spielberg patent that the device would create pressure losses up the length of the sleeve. Melrose, Tr. 672.

FF C 42. The straps wrapped about the single chamber in the Spielberg patent do not constitute valves with predetermined pressure settings. Melrose, Tr. 673, 1. 10-13.

FF C 43. After filling, the pressure along the length of the limb in the device illustrated in the Spielberg patent would come to a point of equilibrium. Melrose, Tr. 674, 1. 1-3.

FF C 44. When pressure along the length of the leg comes to a point of equilibrium, the Spielberg patent has not maintained a pressure gradient. Melrose, Tr. 674, 1. 8-12.

FF C 45. The Spielberg patent is like the Conti patent in that when the device is filled the pressure in the chambers come to a point of equal pressure. Melrose, Tr. 674, 1. 1-18.

FF C 46. In reference to the Spielberg patent, it is not possible to know exactly how tight the straps need to be after it is inflated to have the proper adjustment of the leg. Melrose, Tr. 681-682, 1. 23-1.

FF C 47. In the Spielberg patent device, air is supplied intermittently to the device to inflate the one chamber compartment lying under the straps. Hasty, Tr. 302, 1. 23-24.

FF C 48. There is no teaching in the Spielberg patent that would suggest that the straps actually form independent chambers in the single chamber device. Hasty, Tr. 302, 1. 25-3.

B. **Level Of Ordinary Skill In The Art**

FF C 49. The experience and educational level of a person of ordinary skill in the art in the period of 1972 through 1973 is an undergraduate technical degree, and some experience in the area of measurements, of instrumentation, and laboratory work. Hasty, Tr. 296, l. 11-18.

C. **Miscellaneous**

FF C 50. A reasonable inflation time for a device directed to DVT prevention would be 12 - 15 seconds. Melrose, Tr. 655-656, l. 23-9.

IV. THE SCD DEVICE

FF D 1. The SCD device is a multi-chamber device extending from the ankle through the thigh region of the leg. Hasty, Tr. 282, l. 9-12.

FF D 2. The SCD device has a control unit, with multiple tubes going from the control unit to attachment points on the SCD sleeve. Hasty, Tr. 282

FF D 3. The SCD device has a filling means from the control box to the sleeve chambers. Hasty, Tr. 282, l. 13-16.

FF D 4. The SCD cycle has approximately 11 seconds of compression followed by 60 seconds of noncompression. Hasty, Tr. 282, l. 21-23.

FF D 5. The flow control mechanisms for the SCD device are located in the controller. Hasty, Tr. 282, l. 23-24, 333, l. 6-8.

FF D 6. The SCD device is a closed system. Hasty, Tr. 293, l. 9-15.

FF D 7. Where pressure graph CX 49 shows a drop in pressure in the chambers, the drop in pressure represents a loss of air from the chamber. Hasty, Tr. 293.

FF D 8. Air in the first chamber of the SCD device moves toward the region of low pressure which is towards the direction of the second chamber. Hasty, Tr. 293-294, l. 22-1.

FF D 9. In the SCD device, when the flow control valve to the calf chamber opens there is a pressure drop in the ankle chamber. Dye, Tr. 230.

FF D 10. In the SCD device, when the flow control valve to the thigh chamber opens there is a pressure drop in the ankle and calf chambers. Dye, Tr. 230, l. 5-7.

FF D 11. In the SCD device, when the flow control valve to the calf chamber opens, the calf is a low pressure area while the ankle is a high pressure area. Dye, Tr. 230, l. 9-13.

FF D 12. The air naturally moves from the high pressure towards the low pressure area. Dye, Tr. 230, l. 9-13.

FF D 13. Flow chart CX 51 is a schematic diagram illustrating the valving process by which air is provided to the SCD sleeve using a pressure source and the timing mechanism. Hasty, Tr. 283, l. 12-14.

FF D 14. Flow chart CX 51 represents the mechanism for filling the chambers in the SCD device. Hasty Tr. 283, l. 15-17.

FF D 15. In flow chart CX 51 the pressure source is providing pressure to the sleeve when the initial compression phase begins. Hasty, Tr. 283.

FF D 16. In flow chart CX 51, when valve 1 is activated by the timer it opens and provides air to the first chamber of the SCD sleeve. Hasty, Tr. 283, l. 22-25.

FF D 17. In flow chart CX 51, at a later time the valve which controls the pressure into the second chamber of the SCD device is activated by a timer and opens and begins airflow into the second chamber P-2. Hasty, Tr. 284.

FF D 18. In flow chart CX 51, at still a later point in time the valve controlling the flow into the third chamber P-3 is activated by the timer and opens to allow air to move into the SCD sleeve. Hasty, Tr. 284, l. 9-11.

FF D 19. After a total of about 11 seconds, the timer stops inflation and activates the exhaust to deflate the sleeve. Hasty, Tr. 284, 1. 14-17.

V. THE HOMERX DEVICE

FF D 20. The HomeRx device works generally the same as the SCD device. Hasty, Tr. 295, 1. 9-13.

FF D 21. One of the fundamental differences between the HomeRx device and the SCD device relates to the HomeRx controller unit which utilizes an accumulator tank to build pressure. Hasty, Tr. 294-295, 1. 24-2.

FF D 22. In addition the HomeRx has a baseline pressure associated with the compression chambers of the sleeve which does not exist in the SCD device. Hasty, Tr. 295, 1. 2-4.

FF D 23. Huntleigh tested the HomeRx device and recorded measurements. Schild, Tr. 722, 1. 16-21.

FF D 24. Some of the test results are set forth in Exhibit RX 36. Schild, Tr. 722-723, 1. 24-7.

FF D 25. On the pressure graph RX 36, one second is indicated by the 5 mm divisions. Schild, Tr. 723, 1. 9-24.

FF D 26. The measurement of the pressures in the chambers of the HomeRx device are the measurements shown in graph RX 36. Schild, Tr. 808.

FF D 27. Graph RX 36 is as accurate a representation of pressure measurements as one can get with electronic measurement. Schild, Tr. 808.

FF D 28. Graph RX 36 accurately represents the measurement of the pressures in the ankle, calf and thigh chambers. Schild, Tr. 808-809.

FF D 29. The compression cycle represented by graph RX 36 is about 11 seconds from the beginning of the compression cycle to the beginning of the deflation cycle. Schild, Tr. 813, 1. 19-25.

FF D 30. Huntleigh performed other types of tests on the HomeRx device illustrated in a series of photographs labeled as Respondent's Physical Exhibits 8a, 8b and 8c. Schild, Tr. 729, l. 4-9.

FF D 31. In order to create Respondents' Physical Exhibits 8a, 8b and 8c Huntleigh severed the tubing connected to the HomeRx sleeve. Schild, Tr. 817.

FF D 32. Huntleigh's setup of the HomeRx device including adding a T-junction into the severed tube of the HomeRx sleeve resulting in the addition of two additional lumen fittings because the severed tube must now slip over the T-junction on both ends. Schild, Tr. 818, l. 21-24, Schild, Tr. 833, l. 13-16, Schild, Tr. 834, l. 2.

FF D 33. Another length of tube was connected to the T-junction and traversed to the mercury manometers. Schild, Tr. 817-818, l. 25-14.

FF D 34. The lengths of tubing connecting the T-junctions corresponding to each chamber of the HomeRx device and which traverse through the manometers were all the same length. Schild, Tr. 819, l. 15-17.

FF D 35. Two different cameras were used in creating Respondents' physical exhibits 8a, 8b and 8c. Schild, Tr. 815-816, l. 25-4.

FF D 36. The cameras used by Huntleigh in creating Respondents' physical exhibits 8a, 8b and 8c had different automatic shutter speed capabilities. Schild, Tr. 815-816, l. 25-13.

FF D 37. The time sequence of the frames set forth in Exhibit 8a are all nominally one second. Schild, Tr. 732, l. 14-16.

FF D 38. The cameras used to create Respondents' physical exhibits 8a, 8b and 8c can be off by 50 to 100% in practice. Schild, Tr. 826, l. 3-6.

FF D 39. The test set up for Respondent's Physical Exhibit 8b is the same as the test set up for Exhibit 8a. Schild, Tr. 734, l. 11-13.

FF D 40. Upon review of RPX 8a, Schild testified that in frame 6 the ankle pressure and calf pressure were "approximately the same." Schild, Tr. 732, l. 1-6.

FF D 41. Schild testified that in frame 8 the calf and thigh pressures were "about" equal. Schild, Tr. 732, l. 7-10.

FF D 42. Schild testified that in frame 9 the thigh pressure was shown as being higher than the calf pressure, but that this was during the deflation cycle. Schild, Tr. 733, l. 7-11.

FF D 43. The second frame of RPX 8a represented as being at time 0.0 seconds does not represent the beginning of the inflation cycle. Schild, Tr. 820-821, l. 8-6.

FF D 44. In RPX 8a, the frame labeled 2.0 seconds represents the approximate peak of the compression cycle for the ankle chamber. Schild, Tr. 821-822, l. 21-1.

FF D 45. In RPX 8a, the frame entitled 4.0 seconds represents the approximate peak of the inflation cycle for the calf chamber. Schild, Tr. 822, l. 2-5.

FF D 46. In graph RX 36, the duration of time between the peak of the compression of the ankle chamber and the peak of the compression of the calf chamber is approximately 3 seconds. Schild, Tr. 822-823, l. 21-2.

FF D 47. In RPX 8a, the frame labeled 6.0 seconds represents the approximate peak of the inflation cycle of the thigh chamber. Schild, Tr. 822, l. 6-9.

FF D 48. In graph RX 36, the duration between the peak of the calf compression and the peak of the thigh compression is approximately 5 1/2 seconds. RX 36.

FF D 49. The pressure of air that is found within the chamber is related to the volume of the chamber. Schild, Tr. 819, 1. 18-23.

FF D 50. If the volume gets larger given the same amount of air then the pressure decreases. Schild, Tr. 819-820, 1. 24-1.

FF D 51. Anything that would affect the volume of the chambers could affect the value of the pressures within the chambers. Schild, Tr. 830.

FF D 52. If you put the HomeRx sleeve on in a different way, then you can get a difference in the value of the pressure. Schild, Tr. 831.

FF D 53. If something is done to affect the volume of air in the chambers in the HomeRx sleeve, then that could also affect the pressure that is measured or read. Schild, Tr. 832, 1. 20-23.

FF D 54. If the HomeRx sleeve is wrapped loosely around the limb, there will be a greater volume in the sleeve. Schild, Tr. 874, 1. 22-24.

FF D 55. The pressure within chambers can be affected by how tight the HomeRx sleeve is placed on the limb. Schild, Tr. 829, 1. 10-12.

FF D 56. Improper positioning of the HomeRx sleeve can affect pressure in the chambers. Schild, Tr. 829, 1. 19-24

FF D 57. Mr. Schild did not personally place the HomeRx device upon the person in the test setup shown in RPX 8a. Schild, Tr. 829, 1. 13-15.

FF D 58. In testing the HomeRx device, Huntleigh put a tube in open communication with each of the chambers of the HomeRx device. Schild, Tr. 832-833, 1. 24-4.

FF D 59. Connecting a piece of tube to the T-connector which is in turn in fluid communication with the chambers of the HomeRx device changed the volume of the chambers "a little." Schild, Tr. 834, 1. 6-17.

FF D 60. Each of the chambers of Kendall's HomeRx device has a different

dimension, that is, it has a different air capacity. The volume in the ankle is smaller than the volume at the calf area and the volume of the calf area is smaller than the volume at the thigh area. Schild, Tr. 814-815, 1. 21-4.

FF D 61. Adding a volume of the tubing to each chamber doesn't change the volume equally in proportion to the volume that is in the chambers because the chambers are of different size. Schild, Tr. 834, 1. 18-22.

FF D 62. Mr. Schild did not measure the volume of each chamber in the HomeRx device with the tubes attached, but based his testimony that the volume change was "comparatively little" on his experience with testing such devices. Schild, Tr. 835, 1. 9-19.

FF D 63. At the commencement of the compression cycle of the HomeRx device, the first chamber inflates first opening the valve which communicates with the accumulator which is filled with air to the inlet tube and then travels up to the first chamber. Schild, Tr. 725, 1. 15-18. The valves in the HomeRx are operated by a cam. Schild, Tr. 794, 1. 14-22, CPX 2.

FF D 64. When inflating the HomeRx device the first chamber partially deflates into the tube. It goes from a high pressure point to a low pressure point. Schild, Tr. 740, 1. 16-23.

FF D 65. During the compression cycle of the HomeRx device, after the first chamber has been pressurized, the valve leading to chamber 2 opens. When it opens, there is a low pressure side up the tube leading to chamber 2. Schild, Tr. 795, 1. 6-15.

FF D 66. Because there is a low pressure in the tube leading to chamber 2, when the valve is opened air in communication with the orifice leading to chamber 2 air will move towards the tube leading to chamber 2. Schild, Tr. 795, 1. 16-23.

FF D 67. The SCD device operates in a similar manner. Schild, Tr. 727-728, l. 25-3.

FF D 68. When Kendall does pressure tests on the HomeRx device, those pressure tests are usually done on wooden test legs. Dye, Tr. 218, l. 5-8.

FF D 69. Kendall uses wooden test legs for its pressure tests because it gives more repeatable results. Dye, Tr. 218, l. 9-11.

FF D 70. Kendall performs pressure tests on its pneumatic compression devices for comparisons between various modifications being made to such products. Dye, Tr. 218, l. 17-20.

FF D 71. The pressure test shown in U.S. Patent No. 5,007,411 (RX 159), at Figure 6, was done on a wooden leg form. Dye, Tr. 220.

VI. DOMESTIC INDUSTRY

FF E 1. Kendall has spent C dollars on research and development from the mid-1970s to the present. The monies were dedicated to the development of the product as well as the funding of clinical studies to demonstrate the efficacy of sequential gradient compression for treatment of or prevention of deep vein thrombosis, as well as the treatment of chronic venous insufficiency. Crosby Dep., RPX 4 at 49-50.

FF E 2. From 1981 to the present, Kendall has expended C in research and development with respect to its SCD products. C

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C CX 104; Crosby, Tr. 372.

FF E 3. Kendall has budgeted C in 1992 to spend on outside research, grants, and contracts to prove the efficacy and improve the awareness of other applications of the HomeRx and SCD devices. CX 78 at Hunt 37611.

FF E 4. In the last decade, Kendall has expended C on disseminating the educational materials and information to health care providers to demonstrate the efficacy of its dynamic sequential gradient devices. Crosby, Tr. at 375-76; CX 104.

FF E 5. Kendall has a C continuing engineering projects related to its SCD system. CX 107 at Hunt 29617-20. CX 107 contains an engineering project plan reviewing 30 to 40 projects ranked in terms of potential costs savings, related both to HomeRx and the SCD device. Crosby, Tr. 377.

FF E 6. These projects include C

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FF E 7. Kendall has also invested C in engineering expenses since 1990 dedicated to the HomeRx and SCD devices. Kendall's 1990 promotional budget and 1990 R&D Budget include C

C CX 78 at Hunt 37598. Kendall also has a breakout for C that includes C

C

C

C

C Kendall looks at the probability of success in completing the projects, and these are related to both the HomeRx and the SCD product. Crosby Tr. at 376.

FF E 8. In 1991, Kendall budgeted C for the marketing of its SCD and HomeRx products. CX 87 at Hunt 9777.

FF E 9. Kendall sells its SCD for hospital care and HomeRx for home care. Gilman Dep., RPX 5 at 7; CX-89; CX-90; Witko, Tr. 915.

FF E 10. Kendall sells approximately C pairs of SCD sleeves a month. Crosby Dep., RPX 4 at 99.

FF E 11. Kendall manufactures SCD sleeves in its Seneca, South Carolina manufacturing plant. The SCD sleeve manufacturing operation takes up C square feet and employs 150 people. Crosby, Tr. 378.

FF E 12. The SCD product really has two components. One is the sleeve, which is the disposable component, and the other is the piece of hardware, or the controller. The sleeves are manufactured at Kendall's Seneca facility in Seneca, South Carolina. At Seneca, Kendall has approximately C square feet dedicated to the production of the product. Kendall spends C C for labor at the Seneca facility for the people performing direct labor, on the line as well as the supervisory people, from a wage perspective as well as the benefits that are covered. Crosby, Tr. 378-79.

FF E 13. Kendall spends C per year for direct labor costs on manufacturing and supervisory personnel involved in the SCD sleeve manufacturing process. Crosby, Tr. 378.

FF E 14. Kendall manufactures its hospital version of the SCD in its Seneca facility. Crosby Dep., RPX 4 at 98-99. Kendall is manufacturing C

C

C

C

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FF E 15. The HomeRx sleeve is manufactured C

C

C Crosby, Tr. 381-82.

FF E 16. Projected for 1993, Kendall C

C Gilman, Tr. 543; Crosby Dep., RPX 4 at 99.

FF E 17. Kendall employs C at its Seneca plant dedicated to the manufacturing and a packaging and shipping of Kendall's SCD system. Crosby Tr. 378. In addition, C employees at Seneca perform supervisory and administrative duties relating to the manufacture of the device. Id.

FF E 18. Kendall's capacity to manufacture the HomeRx sleeves is

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C

C

C

C

C Crosby,

Tr. 383-84.

FF E 19. C

C

C

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C

C

C Crosby, Tr. 383-84.

FF E 20. On October 16, 1991, C

C

CX 114 at Hunt 37767.

FF E 21. For 1992, Kendall has budgeted C for C

C CX 78 at Hunt 37611.

FF E 22. On February 24, 1992, C

C

C CX 115.

FF E 23. C

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C

C Gilman, Tr. 474-75.

FF E 24. C

C

C

C Gilman, Tr. 476-77.

VII. IRREPARABLE HARM

FF F 1. In 1986 and 1987, when Kendall studied the home care market, it considered its main competitors to be Jobst and Huntleigh, who were selling intermittent compression devices for CVI treatment. Gilman, Tr. 498; RX 136, RX 75. Jobst, Chattanooga, Camp, Huntleigh, Wright Linear and Biocompression all offered compression devices to treat chronic venous insufficiency and lymphedema in 1987.

FF F 2. The total market for intermittent compression devices in 1991 was approximately $70-80 million, of which Kendall's share was 80%. Crosby, Tr. 398.

FF F 3. 90% of Kendall's business is in the hospital segment. Crosby Tr. p. 398, 11. 24-25; Tr. p. 399, 11. 6-9.

FF F 4. Kendall competes with Wright Linear Pump, Biocompression, Lymphopress, and Huntleigh in the home care market. Crosby, Tr. 397, 399, 411, 424; RX 125, 427, 444, 459 (CX 19).

FF F 5. Kendall and Huntleigh each account for approximately 10% of the homecare market; the remaining 80% is served by competing companies. Witko, Tr. 916.

FF F 6. Officials of HML were aware of Complainant's hospital DVT device since the late 1980's as a pneumatic device on the market and a competitor of HTI. Response to HTplc Interrogatory No. 30.

FF F 7. In November 1990, Audrey Witko was advised by HTI sales representatives that Kendall was selling an SCD device for home care of edema. HTI Response to Interrogatory No. 30, Witko Tr. 906-07.

FF F 8. Rolf Schild first became aware of the '087 patent, on May 3, 1991, as a result of a patentability search reported by HML's British Patent

agent on or about May 5, 1991. Schild Tr. 721.

FF F 9. Of Kendall's total annual sales of C less than C i.e. about C is represented by its SCD business. RX 147; Crosby Tr. 397.

FF F 10. Kendall's products at issue are devices for both home and hospital care. Gilman, Tr. 492.

FF F 11. The price of Kendall's HomeRx pumps to dealers is approximately $1,300, with sleeves priced at $192.50 per pair. CX 142 at I146.

FF F 12. Kendall's sales of the HomeRx C since it was introduced in 1989. Sales in 1989 were C in 1990, C C and in 1991, C Crosby, Tr. 386; CX 102, 104.

FF F 13. C

C

C Crosby Tr. p. 411, 11. 16-23.

FF F 14. Kendall has approximately C percent of the entire vascular compression market, approximately C of which involves sales and service to hospitals. Crosby, Tr. 399.

FF F 15. C

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C Crosby Tr. p. 406; RX 126.

FF F 16. C

C Gilman, Tr. 493.

FF F 17. Kendall's HomeRx project began in C Crosby, Tr. 383.

FF F 18. Kendall is C

C

C Crosby, Tr. 384.

FF F 19. Kendall's HomeRx device was specifically designed to treat chronic venous insufficiency. It is not designed for the treatment of lymphedema. Lymphedema treatment requires "a broader pressure range and longer compression cycle." Kendall's HomeRx product is not approved by HCFA for the treatment of lymphedema. Gilman, Tr. 520, 536-37.

FF F 20. The cycle time for lymphedema pumps is longer than the time required to treat chronic venous insufficiency and is usually two to three minutes. Gilman, Tr. 447.

FF F 21. The FDA approved the HomeRx on the basis of its 510K application as a device to treat chronic venous insufficiency. Crosby, Tr. 419.

FF F 22. Kendall has C

C

Gilman, Tr. 452-53; Crosby, Tr. 435.

FF F 23. C

C

C Crosby, Tr. 375; CPX 5-11.

FF F 24. In the hospital market Kendall has been generating gross profits of C and net profits of C Gilman Tr. p. 494, 11. 11-22.

FF F 25. C

C

C Crosby, Tr. 380, 384, 437-38.

FF F 26. C

C Gilman, Tr. 545.

FF F 27. Kendall's educational and promotional efforts have increased the demand for its devices and have instilled brand loyalty. Crosby, Tr. 375;

Gilman, Tr. 436; CPX 5-11.

FF F 28. Medical equipment dealers do not have exclusive contracts to sell Kendall's products. Gilman, Tr. 536.

FF F 29. Kendall's HomeRx differs from the Huntleigh Flowplus device in inflation time and compression pressures. The Kendall SCD Therapeutic system, now the HomeRx, has an inflation cycle of 11 seconds, and a distal pressure range beginning at either 40 or 50mm of pressure. The Flowplus system has an inflation cycle of 50 seconds, and a pressure range of 30 to 70mm of pressure, based on Huntleigh's Salesman Desk Reference. CX 142. Crosby, Tr. 412-13, 444-447; Witko, Tr. 904; CX 19 at 12; RX 74.

FF F 30. Kendall has invested a great deal to train and educate its dealers to become an extension of Kendall. Gilman, Tr. 540.

FF F 31. Dealers are concerned with volume of sales as well as profits. Gilman, Tr. 540.

FF F 32. C

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C Crosby, Tr. 434-35; Gilman, Tr. 452-53.

FF F 33. C

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C

C Crosby, Tr. 439, 440.

FF F 34. C

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C Gilman, Tr. 454.

FF F 35. Ms. Gilman splits her time equally between marketing the HomeRx

and the hospital SCD device for Kendall. Gilman, Tr. 448-51.

FF F 36. C

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C Gilman, Tr. 453-55.

FF F 37. C

C Gilman, Tr. 546-47; Crosby, Tr. 381-82.

FF F 38. Home care compression devices require a doctor's prescription. If doctors are educated by a sales representative and convinced of the merits of one device, then they would usually recommend that specific brand. Gilman, Tr. 538.

FF F 39. Kendall urges doctors to prescribe the HomeRx by brand and to become educated on the particular benefits of the HomeRx system. Gilman, Tr. 538.

FF F 40. Kendall is not aware that any of its competitors are undertaking major education of health care providers to the same extent as Kendall. Gilman, Tr. 538.

A. Medicare Considerations

FF F 41. "HCFA" stands for Health Care Financing Administration which administers the Medicare program. Gilman, Tr. 535.

FF F 42. RX 75 describes the various HCFA codes. E0650, E0651 and E0652 are all for products intended to treat lymphedema.

FF F 43. Single chamber compression devices are reimbursed under E0650, and multi-chambered uniform devices under E0651. These two codes have reimbursement code screen fees lower than that under E0652, which is for a calibrated gradient pressure device. Gilman, Tr. 499, 502; RX 75.

FF F 44. Calibrated gradient compression means that the system provides segmented gradient compression that would apply a greater pressure distally than proximally. Gilman, Tr. 503.

FF F 45. Medicare has deemed that for these three reimbursement code numbers the acceptable diagnosis, nationwide, in order to obtain reimbursement is intractable lymphedema of the extremity. Witko, Tr. 901, 902.

FF F 46. Kendall's HomeRx is reimbursed by Medicare under the reimbursement code E0652. Other companies providing compression treatment devices that are reimbursed under the same code include Wright Linear Pump, Biocompression, Lymphopress, and Huntleigh. Crosby, Tr. 415, 457, 401; Gilman, Tr. 457, 499-501; Witko, Tr. 895; RX 90; RX 76; RX 78.

FF F 47. Kendall's HomeRx device is not approved for treatment of lymphedema. Gilman Tr. p. 520, 11. 18-20.

FF F 48. It is approved for treatment of chronic venous insufficiency. Gilman Tr. p. 520, 11. 21-23.

FF F 49. C

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FF F 50. In approximately 40 states, Medicare and Medicaid have not approved gradient sequential compression devices as therapy for CVI. These states will not reimburse patients using the HomeRx as therapy for CVI except on a case by case basis. Gilman, Tr. 520-21; Witko, Tr. 927; RX 125.

FF F 51. Many states have denied reimbursement of pumps proscribed to treat CVI under code E0652. Gilman, Tr. 522.

FF F 52. Within the E0652 reimbursement code category, HTI estimates

that Lymphopress holds about 40% of the market, Wright Linear about 20%, Biocompression about 20%, and Kendall and Huntleigh each about 10%. Thus, the original competitors, Wright Linear, Lymphopress and Biocompression, hold about 80% of the home market. Witko Tr. p. 916, 11. 7-15.

FF F 53. The vast majority of Kendall's sales are made in five states in which state reimbursement codes allow for approval of Kendall's pumps for treatment of CVI. Gilman, Tr. 526.

FF F 54. Medical equipment dealers make more money selling systems qualifying for reimbursement in the E0652 product code category than they do if they sell products in the lower reimbursement code categories. Gilman, Tr. 506.

B. **Expanding Market And Increased Demand**

FF F 55. The typical home care user is an older person. Gilman at 451. As the U.S. population ages, use of home care gradient compression devices will continue to grow. Hasty, Tr. 55.

FF F 56. C

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Crosby, Tr. 409, 411.

FF F 57. C

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C

C

C

Crosby, Tr. 404-405; Gilman, Tr. 494; Crosby, Tr. at 398-99, 403; CX 113; RX 126, 407, 409, 411.

FF F 58. C

C

C

Gilman, Dep. Tr. 33.

FF F 59. Home use of sequential gradient compression devices is expanding because dealers are promoting the product to physicians and nurses. Witko, Tr. 929.

FF F 60. Approximately 1.5 million persons in the United States experience chronic venous insufficiency. C

C Crosby, Tr. 409-10.

FF F 61. Kendall does not compete in the lymphedema market. Crosby Tr. p. 412, 11. 12-18. Its product is not intended for treatment of lymphedema. Crosby Tr. p. 414, 11. 13-15.

C. Huntleigh's Sales And Products

FF F 62. Kendall first became aware of Huntleigh's Flowplus product being offered for sale in May, 1991. Gilman, Dep. Tr. 14; RPX 5.

FF F 63. Huntleigh has sold the Flowtron device since 1986 and the Flowpress devices since 1988 in the home care market. Witko, Tr. 892-93.

FF F 64. Huntleigh advertised the Flowplus product as treatment for chronic intractable lymphedema and venous insufficiency problems. Witko, Tr. 896.

FF F 65. The Flowtron, Flowpress, and Flowplus are approved by the FDA for treatment of chronic venous insufficiency and for treatment of chronic lymphedema. Witko, Tr. 900.

FF F 66. Huntleigh's Flowplus device, including the controller and a pair of leg sleeves, sells in the United States for about $995.00, depending

on the components included. Response to Complaint, ¶ 8.8; CX 139 at I608.

FF F 67. Flowplus sales are taking away sales of its lower-end models because of the HCFA reimbursement structure. Witko, Tr. 916-17.

FF F 68. For the period May 1991 through February 19, 1992, Huntleigh imported and sold over C for the home care market. CX 240.

FF F 69. C customers on Huntleigh's customer list of C customers also appear on a list of Kendall's customers. CX 112, CX 240.

FF F 70. Between Jan. 1, 1992 and Feb. 19, 1992, Respondents have sold over C Flowplus pumps in the United States. CX 240.

FF F 71. Dr. Melrose testified that single chamber devices treat edema and chronic venous insufficiency equally well. Melrose, Dept. Tr. at 49; CPX 35.

FF F 72. Huntleigh's 510K application to the FDA stated that its products are for edema, lymphedema and venous edema. CX 159 at I322.

FF F 73. Huntleigh does not currently sell or market a multi-chambered SCD device for the hospital market. Schild, Tr.t 857-59; Witko, Tr. 880-889.

FF F 74. C

C Schild, Tr. 858-61, 867-68.

FF F 75. Complainants' Exhibit 241 describes C

C

C Schild, Tr. 859-60.

FF F 76. C

C Witko, Tr. 883.

FF F 77. C

C

C Witko, Tr. 889.

FF F 78. C

C Schild, Tr. 864.

FF F 79. C

C

C Witko, Tr. 885-86.

FF F 80. C

C

C

C Witko, Tr. 883.

FF F 81. C

C Schild, Tr. 861.

VIII. PUBLIC INTEREST AND HARM TO RESPONDENTS

FF G 1. If Huntleigh were prohibited from selling its Flowplus product in this country, not only would patients needing intermittent compression therapy not have access to the benefits of the Huntleigh system, but existing patients who have already purchased Flowplus products since June, 1991 would not be able to obtain replacement garments for use with their pumps. They would have to purchase an entirely new intermittent compression system from someone else, which amounts would then have to be reimbursed by Medicare. Witko Tr. p. 926, 11. 3-13.

CONCLUSIONS OF LAW

1. The U.S. International Trade Commission has jurisdiction over the subject matter of this investigation. 19 U.S.C. § 1337.

2. Complainant is not likely to prove that the accused device infringes the '087 patent. Opn. at 6-25.

3. Complainant is reasonably likely to prevail on the issue of whether the '087 patent is anticipated. Opn. at 25-31.

4. Complainant is not likely to prevail on the issue of whether the '087 patent is invalid for obviousness. Opn. at 31-43.

5. Complainant is not likely to prevail on the issue of whether a domestic industry exists with respect to the '087 patent. Opn. at 43-65.

6. Complainant will not suffer irreparable harm in the absence of temporary relief. Opn. at 66-75.

7. The balance of harm tips in Respondents' favor if temporary relief were ordered. Opn. at 75.

8. Temporary relief would be contrary to the public interest. Opn. at 76-77.

9. A balancing of the interests does not favor the issuance of temporary relief. Opn. at 77-78.

10. There is no reason to believe that a violation of section 337 of the Tariff Act of 1930, as amended, has occurred in the importation of certain dynamic sequential gradient compression devices and component parts thereof by reason of infringement of U.S. Letters Patent No. 4,029,087 and that a temporary relief is warranted. Conclusions of Law 2-9.

INITIAL DETERMINATION AND ORDER

Based on the foregoing opinion, findings of fact, conclusions of law, the evidence, and the record as a whole, and having considered all pleadings and arguments as well as proposed findings of fact and conclusions of law, it is the Administrative Law Judge's INITIAL DETERMINATION (ID) that there is no reason to believe that Respondents have violated § 337 in the importation of certain dynamic sequential gradient compression devices and component parts thereof by reason of infringement of claims 1, 2, 5, 8, 9, 11-13, 17-20, or 25 of U.S. Letters Patent 4,029,087, and that temporary relief is not warranted.

The Administrative Law Judge hereby CERTIFIES to the Commission this Initial Determination, together with the record of the hearing in this investigation consisting of the following:

1. The transcript of the hearing, with appropriate corrections as may hereafter be ordered by the Administrative Law Judge; and further

2. The exhibits accepted into evidence in this investigation as listed in the attached exhibit lists.

In accordance with Commission Interim Rule 210.44(b), all material found to be confidential by the Administrative Law Judge under Rule 210.6 is to be given in camera treatment.

The Secretary is instructed to serve a public version of this ID upon all parties of record and the confidential version upon counsel who are signatories to the protective order issued by the Administrative Law Judge in this investigation, and the Commission Investigative Attorney. To expedite service of the public version, counsel are hereby ordered to serve on the Administrative Law Judge by no later than May 25, 1992 a copy of this ID with those sections considered by the party to be confidential bracketed in red.

This ID shall become the determination of the Commission 30 days after its date of service unless the Commission within those 30 days modifies or vacates this ID on the basis of errors of law or for policy reasons articulated by the Commission. Commission Interim Rule 210.24(e)(17)(ii).

Sidney Harris
Administrative Law Judge

Issued: May 15, 1992