In the Matter of

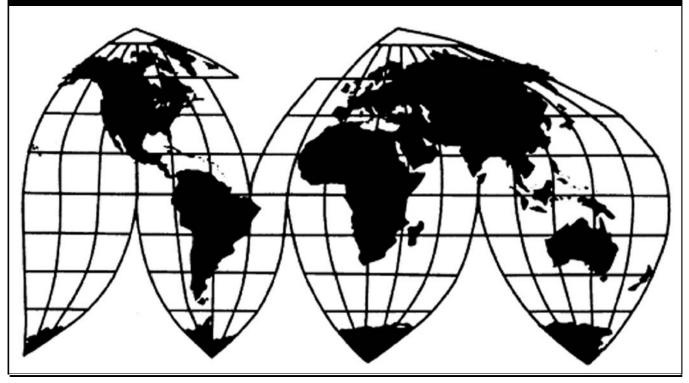
Certain Endoscopic Probes For Use In Argon Plasma Coagulation Systems

Investigation No. 337-TA-569

Publication 4111

November 2009

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

COMMISSIONERS

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U.S. International Trade Commission

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Certain Endoscopic Probes For Use In Argon Plasma Coagulation Systems

Investigation No. 337-TA-569



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

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In the Matter of

CERTAIN ENDOSCOPIC PROBES FOR USE IN ARGON PLASMA COAGULATION SYSTEMS

Inv. No. 337-TA-569

NOTICE OF COMMISSION DECISION TO REVIEW IN PART AN INITIAL DETERMINATION AND ON REVIEW TO AFFIRM THE ADMINISTRATIVE LAW JUDGE'S DETERMINATION THAT THERE IS NO VIOLATION OF SECTION 337

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part an initial determination ("ID") issued by the presiding administrative law judge ("ALJ") determining that there is no violation of section 337 of the Tariff Act of 1930. Specifically, the Commission has determined to review the portions of the ALJ's determination relating to construction of the claim term "predetermined minimum safety distance" and associated findings on infringement and domestic industry. On review, the Commission has determined to take no position with respect to these issues, and to affirm the ALJ's determination of no violation of section 337.

FOR FURTHER INFORMATION CONTACT: Jonathan J. Engler, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone 202-205-3112. Copies of the public version of the ID and all 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 202-205-1810. General information concerning the Commission may also be obtained by accessing its Internet server (<u>http://www.usitc.gov</u>). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <u>http://edis.usitc.gov</u>.

SUPPLEMENTARY INFORMATION: This investigation was instituted by the Commission based on a complaint filed by ERBE Elektromedizin GmbH and ERBE USA, Inc. (collectively, "ERBE"). 71 Fed. Reg. 29386 (May 16, 2006). The complaint alleged violations of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain endoscopic probes for use in argon plasma coagulation systems by reason of infringement of 10 claims of U.S. Patent No. 5,720,745 ("the '745 patent") and infringement of U.S. Supplemental Trademark Registration No. 2,637,630 ("the '630 registration"). The complaint also alleged that a domestic industry exists and/or is in the process of being established, with regard to the '745 patent and the '630 registration under subsection (a)(2). The notice of investigation named Canady Technology, LLC of Hampton, Virginia ("Canady USA"); Canady Technology Germany GmbH of Germany ("Canady Gmbh"); and KLS Martin as the respondents. The complaint requested that the Commission institute an investigation pursuant to Section 337 and, after the investigation, issue a permanent exclusion order and a permanent cease and desist order. The investigation has been terminated as to KLS Martin on the basis of a settlement agreement.

On January 16, 2008 the administrative law judge issued a final ID finding no violation of section 337 in this investigation. The ALJ found no violation of section 337 through the importation or sale for importation of argon plasma probes sold by the Canady in the United States. In particular, the ID found that the Canady probes do not directly infringe the '745 patent; that even if there were direct infringement there is no contributory infringement or inducement to infringe the '745 patent by Canady; that ERBE has not shown that there is a domestic industry with respect to the '745 patent because the ERBE products are not used to practice its claims; and that the '745 patent is not invalid.

On January 28, 2008, ERBE filed its petition for review of the ID, challenging the ALJ's findings with respect to no infringement of the '745 patent and the absence of a domestic industry. Canady filed its Contingent Petition for review of the ID on January 29, 2008.

Having examined the record of this investigation, including the ALJ's final ID and the submissions of the parties, the Commission has determined to review the portions of the ALJ's determination relating to the construction of the phrase "predetermined minimum safety distance" the associated findings on infringement and domestic industry. On review, the Commission has determined to take no position with respect to these issues, and to affirm the ALJ's determination of no violation of section 337.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, and Commission rule 210.42, 19 C.F.R. § 210.42.

By order of the Commission.

June

Marilyn R. Abbett Secretary to the Commission

Issued: March 17, 2008

CERTAIN ENDSCOPIC PROBES FOR USE IN, COMPONENTS ARGON PLASMA COAGULATION SYSTEMS

PUBLIC CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached NOTICE OF COMMISSION DECISION TO REVIEW IN PART AN INITIAL DETERMINATION AND ON REVIEW TO AFFIRM THE ADMINISTRATIVE LAW JUDGE'S DETERMINATION THAT THERE IS NO VIOLATION OF SECTION 337 has been served by hand upon the Commission Investigative Attorney, Jeffrey Hsu, Esq., and the following parties as indicated, on <u>March 18, 2008</u>.

Marilyn R. Abbott, Secretary

U.S. International Trade Commission 500 E Street, SW Washington, DC 20436

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PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

CERTAIN ENDOSCOPIC PROBES FOR USE IN ARGON PLASMA COAGULATION SYSTEMS Inv. No. 337-TA-569

INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

Administrative Law Judge Charles E. Bullock

(January 16, 2008)

Appearances:

For the Complainants ERBE Elektromedizin GmbH and ERBE USA, Inc.:

Philip G. Hampton, II, Esq.; Steven War, Esq.; Lawrence Fisher, Esq.; Charles J. Monterio, Jr., Esq.; Amanda S. Pitcher, Esq.; and Hye Joo Min, Esq. of Dickstein Shapiro LLP of Washington, D.C.

For the Respondents Canady Technology, LLC and Canady Technology German GmbH: Charles Schill, Esq. and Timothy C. Bickham, Esq., of Steptoe & Johnson LLP of Washington, D.C.

Timothy R. DeWitt, Esq. of 24 IP Law Group USA, PLLC of Washington, D.C.

For the Commission Investigative Staff:

Lynn I. Levine, Esq., Director; Thomas Fusco, Esq., Supervising Attorney; Karin Norton, Esq., Investigative Attorney; Jeffrey Hsu, Esq., Investigative Attorney; of the Office of Unfair Import Investigations, U.S. International Trade Commission, of Washington, D.C.

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LIST OF ABBREVIATION

CDX	Complainants' demonstrative exhibit		
CFF	Complainants' proposed findings of fact		
CIB	Complainants' initial post-hearing brief		
CORFF	Complainants' objections to Respondents' proposed findings of fact		
COSFF	Complainants' objections to Staff's proposed findings of fact		
СРХ	Complainants' physical exhibit		
CRB	Complainants' reply post-hearing brief		
СХ	Complainants' exhibit		
Dep.	Deposition		
JSUF	Joint Statement of Undisputed Facts		
JX	Joint Exhibit		
RDX	Respondents' demonstrative exhibit		
RFF	Respondents' proposed findings of fact		
RIB	Respondents' initial post-hearing brief		
ROCFF	Respondents' objections to Complainants' proposed findings of fact		
ROSFF	Respondents' objections to Staff's proposed findings of fact		
RPX	Respondents' physical exhibit		
RRB	Respondents' reply post-hearing brief		
RRX	Respondents' rebuttal exhibit		
RX	Respondents' exhibit		
SFF	Staff's proposed findings of fact		
SIB	Staff's initial post-hearing brief		
SOCFF	Staff's objections to Complainants' proposed findings of fact		
SORFF	Staff's objections to Respondents' proposed findings of fact		
SRB	Staff's reply post-hearing brief		
Tr.	Transcript		

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

CERTAIN ENDOSCOPIC PROBES FOR USE IN ARGON PLASMA COAGULATION SYSTEMS Inv. No. 337-TA-569

INITIAL DETERMINATION ON VIOLATION OF SECTION 337 AND RECOMMENDED DETERMINATION ON REMEDY AND BOND

Administrative Law Judge Charles E. Bullock (January 16, 2008)

Pursuant to the Notice of Investigation¹ and Rule 210.42(a) of the Rules of Practice and Procedure of the United States International Trade Commission, this is the Administrative Law Judge's Initial Determination in the matter of Certain Endoscopic Probes for Use in Argon Plasma Coagulation Systems, Investigation No. 337-TA-569.

The Administrative Law Judge hereby determines that a violation of Section 337 of the Tariff Act of 1930, as amended has not been found in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain endoscopic probes for use in argon plasma coagulation systems in connection with claims 1, 3, 4, 11, 13, 35, 37, 38, 39 and 41 of U.S. Patent No. 5,720,745. Furthermore, the Administrative Law Judge hereby determines that a domestic industry in the United States does not exist that practices U.S. Patent No. 5,720,745.

¹ 71 Fed. Reg. 28,386 (May 16, 2006).

I. INTRODUCTION

A. Procedural History

1. In General

On April 10, 2006, Complainants ERBE Elektromedizin GmbH and ERBE USA, Inc. (collectively "ERBE") filed a complaint with the Commission pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337. The complaint asserts unfair methods of competition and unfair acts in violation of Section 337 by Respondents Canady Technology, LLC and Canady Technology Germany GmbH (collectively "Canady"), and KLS Martin GmbH & Co. KG ("KLS Martin") in connection with the importation, sale for importation, and sale within the United States after importation of certain endoscopic probes for use in argon plasma coagulation systems.

The complaint accuses Canady and KLS Martin's products of infringing claims 1, 3, 4, 11, 13, 35, 37, 38, 39, and 41 of U.S. Patent No. 5,720,745 ("the '745 patent") owned by ERBE. The complaint also accuses Canady and KLS Martin's products of infringing U.S. Supplemental Trademark Registration No. 2,637,630 ("the '630 mark"). The complaint further alleges that there exists a domestic industry with respect to the '745 patent and the '630 mark. ERBE seeks, among other things, a limited exclusion order of the infringing endoscopic probes for use in argon plasma coagulation systems. On May 11, 2006, the Commission issued a notice of investigation that was subsequently published in the Federal Register on May 16, 2006.² The notice of investigation named ERBE as complainant and Canady and KLS Martin as respondents.³ The notice of investigation also

² 71 Fed. Reg. 28,386 (May 16, 2006). ³ *Id.*

named the Commission Investigative Staff ("Staff") as a party.⁴

On June 28, 2006, Administrative Law Judge Harris issued Order No. 2, setting the target date for completion of this investigation to July 18, 2007.

On September 1, 2006, Judge Harris issued Order No. 4, an unreviewed initial determination terminating the investigation as to Respondent KLS Martin on the basis of a settlement agreement.⁵

On November 6, 2006, Judge Harris issued Order No. 5, setting a procedural schedule and modifying the target date for completion of this investigation from July 18, 2007, to August 16, 2007.

On December 29, 2006, the Commission reassigned this investigation from Judge Harris to Administrative Law Judge Barton.⁶

On April 26, 2007, Judge Barton issued Order No. 17, an unreviewed initial determination setting a new procedural schedule and extending the target date for completion of this investigation from October 18, 2007, to April 3, 2008.⁷

On July 5, 2007, the Commission reassigned this investigation from Judge Barton to Administrative Law Judge Bullock.⁸

On November 9, 2007, Order No. 47 issued as an initial determination extending the target date in this investigation to May 16, 2008. The initial determination was unreviewed by the Commission.⁹

⁴ *Id.*

⁵ See Notice of a Comm'n Determination Not to Review (October 3, 2006).

⁶ See Notice of a Comm'n Determination to Reassign (December 29, 2006).

⁷ See Notice of a Comm'n Determination Not to Review (June 11, 2007).

⁸ See Notice of a Comm'n Determination to Reassign (July 5, 2007).

⁹ See Notice of a Comm'n Determination Not to Review (December 3, 2007).

The parties have stipulated as to certain material facts.¹⁰ Particular stipulated facts that are relevant to this Initial Determination are cited accordingly.

An evidentiary hearing was conducted before the undersigned from August 24-31, 2007. During the hearing, ERBE withdrew its claims that Canady infringed the '630 mark. In addition, ERBE further narrowed its claims of infringement of the '745 patent and the accused products imported and sold in the United States by Canady.¹¹ In support of its case-in-chief and rebuttal case, ERBE called the following witnesses:

- Dr. Jerome Waye (Chief of the Gastrointestinal Endoscopy Unit at Mt. Sinai Medical Center);¹²
- Rickie L. Steward (National Service Manager for ERBE USA);¹³
- Sara Eisenbacher (Manager of the Digestive Health Center Endoscopy Suite at North Carolina Baptist Hospital);
- John Day (Vice President of Marketing at ERBE USA);¹⁴
- Steven Wereley (ERBE's expert witness);¹⁵
- Harold Walbrink (ERBE's expert witness);¹⁶ and
- Creighton White (President and CEO of ERBE USA).¹⁷

In support of its case-in-chief and rebuttal case, Canady called the following witnesses:

¹⁰ See Joint Statement of Undisputed Facts ("JSUF"), filed on July 19, 2007.

¹¹ See, Tr. at 231-33 (8/27/07); Tr. at 267-68 (8/28/07).

¹² CX-3 (Waye Direct).

¹³ CX-6C (Steward Direct).

¹⁴ CX-5C (Day Direct).

¹⁵ CX-1 (Wereley Direct); CX-258 (Wereley Rebuttal).

¹⁶ CX-2C (Walbrink Direct); CX-267C (Walbrink Rebuttal).

¹⁷ CX-4C (White Direct).

- Nathaniel Fisch, Ph.D. (Canady's expert witness);¹⁸
- James Michael Shifflette (Canady's expert witness);¹⁹
- Brian G. Gore (Canady's expert witness);²⁰ and
- Dr. Jerome Canady (employee of Canady Technology LLC).²¹

After the hearing, post-hearing briefs and reply briefs, together with proposed findings of fact, conclusions of law and rebuttals to the same, were filed on September 18, 2007 and October 9, 2007, respectively.

On September 18, 2007, the Staff filed an uncontested motion for admission of SX-3 into evidence, which is hereby granted.

On September 20, 2007, ERBE filed a motion to strike new arguments in Canady's posthearing brief which were not previously disclosed during discovery or in Canady's pre-hearing brief. On October 1, 2007, the undersigned issued Order No. 45, granting ERBE's motion. Specifically, the undersigned ruled that the only obviousness combinations that will be considered are U.S. Patent No. 5,207,675 ("the '675 patent") in combination with the 1994 article by Gunter Farin and Karl Grund, the 1994 article by K. Grund, D. Storek and G. Farin, and/or the '138 Marwaring patent.

On December 21, 2007, the Staff informed the undersigned via letter that on December 18, 2007, the United States District Court for the Western District of Pennsylvania, issued an order granting Canady's motion for partial summary judgment of noninfringement of the '745 patent.²²

¹⁸ RX-95 (Fisch Direct); RRX-28 (Fisch Rebuttal).

¹⁹ RX-88 (Shifflette Direct); RRX-6 (Shifflette Rebuttal).

²⁰ RRX-27 (Gore Rebuttal).

²¹ RX-1C (Canady Direct).

²² See ERBE Electromedizin GmbH v. Canady Technology LLC, Civ. Action No. 05-1674 (W.D. Pa.)

Specifically, the Court found that Canady does not indirectly infringe claims 1, 3, 4, 11, 13, 35, 37, 38, 39, and 41 of the '745 patent through its sale of KLS Martin 1.5 mm, KLS Martin 2.3 mm, and KLS Martin 3.2 mm probes. As in the district court case, ERBE accuses Canady in this investigation of indirectly infringing claims 1, 3, 4, 11, 13, 35, 37, 38, 39, and 41 of the '745 patent through its sale, offer for sale and/or importation of KLS Martin 1.5 mm probes and KLS Martin 2.3 mm probes.²³

In light of the relevance of the district court's order to this investigation, on December 21, 2007, the undersigned issued Order No. 47, ordering the parties to comment by December 27, 2007, on how the district court opinion impacts this investigation. Based on the parties' responses to Order No. 47, it does not appear that the district court's order is currently appealable as it only granted partial summary judgment and neither party has moved to have it certified as final under Federal Rule of Civil Procedure 54(b). Additionally, as of the time of this writing, the parties could still file motions for reconsideration of the district court's order granting partial summary judgment of noninfringement. Thus, the undersigned does not believe at this point in time that the district court's order is a final judgment that would have a preclusive effect on this investigation.²⁴ Because

²³ The Soring 2.3 mm probes accused in this investigation were not at issue before the district court.

²⁴ For claim preclusion to apply, the party asserting the bar must prove that: (1) the parties are identical or in privity; (2) the first suit proceeded to a final judgment on the merits; and (3) the second claim is based on the same set of transactional facts as the first. *See Ammex v. U.S.*, 334 F.3d 1052, 1055 (Fed. Cir. 2003); *see also Federated Dep't Stores, Inc. v. Moitie*, 452 U.S. 394, 398 (1981); *Young Eng'rs, Inc. v. United States Int'l Trade Comm'n*, 721 F.2d 1305, 1314 (Fed. Cir. 1983)(stating that this court would adopt the transactional approach advocated by the Restatement (Second) of Judgments). For issue preclusion to apply: (1) the issue must be identical to the one decided in the first action; (2) the issue must actually have been litigated in the first action; and (4) the party against whom preclusion is asserted must have had a full and fair opportunity to litigate the

circumstances may change in the interim period between the issuance of this initial determination and the Commission's final determination, the undersigned has attached to this initial determination as Appendix B a copy of the order and opinion of the U.S. District Court for the Western District of Pennsylvania as part of the record in this investigation.²⁵

2. Motion for Sanctions

On September 10, 2007, ERBE filed a motion (Motion Docket No. 569-56) for issuance of an order sanctioning Canady for failure to make or cooperate in discovery and failure to comply with Order No. 22. ERBE asks the undersigned to sanction Canady for its alleged behavior by issuing the following adverse inferences: 1) the 2.3 mm Soring probes include an electrode offset from the opening at the distal end of the tube a predetermined minimum safety distance; and 2) the gas exiting the distal end of the 2.3 mm Soring probes is a not-directed, non laminar stream that forms an inert gas atmosphere between the distal end of the tube and the region of the tissue to be coagulated.²⁶ On September 24, 2007, Canady filed an opposition to ERBE's motion for sanctions. The Staff did not file a response.

On May 30, 2007, Administrative Law Judge Barton issued Order No. 22, granting in part ERBE's motion to compel discovery but denying inspection of Canady's facility.²⁷ Among other

issue in the first action. See Certain NOR and NAND Flash Memory Devices and Products Containing Same, 337-TA-560, 2006 ITC LEXIS 749, at *7, Order No. 5 (May 2006); see also Morgan v. Dep't of Energy, 424 F.3d 1271, 1274-75 (Fed. Cir 2005).

²⁵ The district court's order encompasses more than Canady's motion for summary judgment of noninfringement. The portions of the District Court's order that are relevant to this investigation are addressed under Section E of the court's order titled, "Defendant's Motion for Summary Judgement." See District Court Order at 33-38, 46-47; Appendix B

²⁶ ERBE Mot. at 1-2.

²⁷ See Order No. 22 (May 30, 2007).

things, Order No. 22 required Canady to produce "those probes which reside in its inventory in significant quantities, or which may be obtained by other means, and produce for inspection those probes which are available in more limited quantities or explain why they cannot be produced."²⁸ On June 13, 2007, Canady made available to ERBE a CT-3500 electrosurgical generator and produced four Soring probes S-422535, S-422537, S-422538, and S-422541. On August 20, 2007, while inspecting ERBE's direct exhibits, counsel for Canady noted for the first time that he believed one of the Soring probes may have been tampered with. At the hearing in this investigation, Dr. Canady testified that he was "1000% sure" that Soring probes S-422535 and S-422537 had been altered.

ERBE argues that because they have a video demonstration showing them opening the packages of probes and photos showing the condition of the probes once removed from the packaging that any tampering had to have been by Canady before their production on June 13, 2007.²⁹ According to ERBE, because the tampering took place before the June 13, 2007 production of the probes, Canady's actions violate both Order No. 22 and Canady's obligation to cooperate in discovery.³⁰ Canady on the other hand argues that they shipped the probes sealed to ERBE from their inventory and thus it must be ERBE who altered the probes.³¹

ERBE relies on its video demonstration, close-up photos, and accompanying declarations in support of its assertion that Canady must have altered the probes. The video demonstration, photos and many of the declarations submitted therewith were offered as evidence at the hearing in this

²⁸ *Id.* at 7.

²⁹ ERBE Mem. at 2.

³⁰ *Id*.

³¹ Canady Mem. at 4.

investigation and were the subject of much contention. Ultimately, the undersigned ruled that the video and declarations were inadmissible.³² Because the video and declarations have already been ruled inadmissible, it would be inconsistent with that ruling to consider such evidence in support of ERBE's post-hearing motion for sanctions. Regardless, the evidence submitted does not prove that Canady tampered with the probes. Thus, the undersigned finds ERBE has failed to prove that Canady's production of the Soring probes on June 13, 2007, violated Order No. 22. Accordingly, ERBE's motion for sanctions (Motion Docket No. 569-56) is denied.

B. The Parties

1. Complainants

Complainant ERBE Elektromedizin GmbH is a German corporation with a principal place of business in Tubingen, Germany.³³ Complainant ERBE USA, Inc. is a wholly-owned subsidiary of ERBE Elektromedizin GmbH and is a Georgia corporation with its corporate headquarters and principal place of business in Marietta, Georgia.³⁴

2. Respondents

Respondent Canady Technology, LLC is a Delaware corporation with its principal place of business in Hampton, Virginia and sales and distribution offices in McKeesport, Pennsylvania.³⁵ Respondent Canady Technology Germany GmbH is a German corporation with its principal place of business in Berlin, Germany.³⁶

³² See Tr. at 79:1-80:24 (Aug. 24, 2007); Tr. at 1328:7-14, 1329:14-19 (Aug. 31, 2007).

³³ JSUF ¶ 10 (July 19, 2007).

³⁴ *Id.* at \P 11.

³⁵ *Id.* at ¶ 12.

³⁶ *Id.* at ¶ 13.

KLS Martin GmbH & Co. KG is a German corporation with is principal place of business in Tuttlingen, Germany.³⁷

C. Overview of the Technology

At issue in this investigation are certain endoscopic probes for use in argon plasma coagulation systems. The flexible argon probes at issue in this investigation are used as part of an electrosurgical system that includes an argon unit, a radio frequency (RF) generator, a flexible argon probe, and a connecting cable which attaches the flexible argon probes to the argon unit/RF generator combination.³⁸ The electrosurgical systems are used for, among other things, gas assisted coagulation in the gastrointestinal and tracheobronchial systems. The flexible argon probes at issue in this investigation are single use disposable items that must be replaced after each endoscopy procedure.³⁹ The argon units, RF generators and connecting cables may be used in multiple procedures.⁴⁰

D. The Patent at Issue - The '745 Patent

The '745 patent is entitled "Electrosurgical Unit and Method for Achieving Coagulation of Biological Tissue" and was issued to inventors Günther Farin, Karl Ernst Grund, and Klaus Fischer on February 24, 1998.⁴¹ The patent is assigned to ERBE Electromedizin GmbH.⁴² The '745 patent application, App. No. 579,879, was filed on December 28, 1995, and is a continuation-in-part of Ser.

⁴² JSUF at ¶¶ 55, 56 (July 19, 2007).

³⁷ *Id.* at ¶ 14.

³⁸ *Id.* at \P 21.

³⁹ *Id.* at \P 22.

⁴⁰ *Id.* at \P 23.

⁴¹ Id. at ¶ 53-54; JX-1 (the '745 patent); JX-2 (the '745 patent prosecution history).

No. 981,009, which was filed on November 24, 1992, and subsequently abandoned.⁴³ Generally, the '745 patent concerns a high-frequency electrosurgery unit for coagulating biological tissue.⁴⁴ The '745 patent has 48 claims.⁴⁵ Of the 48 claims, two independent claims, claims 1 and 35 are at issue in this investigation.⁴⁶ Dependent claims 3, 4, 11, 13, which depend from claim 1, are also at issue.⁴⁷ Dependent claims 37, 38, and 39, which depend either directly or indirectly from claim 35, are also at issue.⁴⁸

The notice of investigation also lists dependent claim 41 as at issue in this investigation and each of the parties have addressed this claim in their briefs. According to the '745 patent, however, claim 41 depends from claim 32, which depends from independent claim 29.⁴⁹ Neither dependent claim 32 nor independent claim 29 is at issue in this investigation and no party has addressed either claim. From a footnote in ERBE's opening post-hearing brief it appears that ERBE (and by extension the other parties through their own briefing) believe dependent claim 41 depends either directly or indirectly on independent claim 35. However, there is nothing in the certificate of correction attached to the patent in JX-1, nor anything that could be found in the prosecution history in JX-2 to support ERBE's assertion that claim 41 depends from claim 35. Because the two claims on which claim 41 depends, independent claim 29 and dependent claim 32, have not been asserted or addressed by the parties in this investigation, the undersigned will not consider dependant claim

⁴⁷ Id.

⁴³ *Id.* at \P 57.

⁴⁴ *Id.* at ¶ 59.

⁴⁵ See JX-1 at 11:10-18:6.

⁴⁶ CIB at 1 n.3.

⁴⁸ Id.

⁴⁹ See JX-1 at 16:29-30.

41 in this initial determination.

E. The Products at Issue

1. ERBE's Products

ERBE sells the following electrosurgical generators in combination with argon supply units in the United States: ICC 350 RF generator and APC 300 argon supply unit; ICC 200EA RF generator and APC 300 argon supply unit; and VIO300D RF generator and APC 2 argon supply unit.⁵⁰ In addition, ERBE sells various sizes of "single use only" ERBE APC straight-fire probes.⁵¹ ERBE asserts that the above products satisfy the technical prong of the domestic industry requirement for the '745 patent.

2. Canady's Products

Canady sells, in the United States, various sizes of imported "single use only" argon probes, manufactured by KLS Martin, for use in ERBE APC system.⁵² ERBE accuses the 1.5 mm diameter and 2.3 mm diameter KLS Martin Probes of infringing the asserted claims of the '745 patent when used in combination with an ERBE electrosurgical unit, argon supply unit, connecting cables, and commercial endoscopes. ERBE accuses the following KLS Martin probes of indirect infringement: 1322535 (1.5 mm), 1322537 (2.3 mm), and 1322538 (2.3 mm).

Canady also sells, in the United States, various sizes of imported "single use only" argon probes manufactured by Soring GmbH.⁵³ ERBE accuses the Soring 2.3 mm probes of infringing the asserted claims of the '745 patent when used in combination with the Canady CT 3500

⁵⁰ CFF ¶¶ 27, 29-35; JSUF ¶¶ 37, 38 (July 19, 2007).

⁵¹ JSUF ¶ 50 (July 19, 2007).

⁵² *Id.* at ¶¶ 39, 40, 67.

⁵³ Id. at ¶¶ 45, 46, 74.

electrosurgical unit, also manufactured by Soring, Soring argon supply unit, connecting cables, and commercial endoscopes. ERBE accuses the following Soring probes of indirect infringement: \$422537 and \$422538.

II. JURISDICTION AND IMPORTATION

Section 337 confers subject matter jurisdiction on the International Trade Commission to investigate, and if appropriate, to provide a remedy for, unfair acts and unfair methods of competition in the importation of articles into the United States. In order to have the power to decide a case, a court or agency must have both subject matter jurisdiction, and jurisdiction over either the parties or the property involved.⁵⁴

A. Subject Matter Jurisdiction

ERBE alleges that Canady has violated Subsection 337(a)(1)(A) and (B) in the importation and sale of products that infringe the '745 patent. The parties have stipulated that Canady has imported into the United States, has sold to third parties who later imported into the United States, and/or has sold within the United States after importation the accused products.⁵⁵ Accordingly, the Commission has subject matter jurisdiction over Canady in this investigation.⁵⁶

B. Personal Jurisdiction

Canady has responded to the complaint and notice of investigation, participated in the investigation, including participating in discovery, made an appearance at the hearing, and submitted

⁵⁴ 19 U.S.C. § 1337; also see Certain Steel Rod Treating Apparatus and Components Thereof, Inv. No. 337-TA-97, Commission Memorandum Opinion, 215 U.S.P.Q. 229, 231 (1981) ("Steel Rod").

⁵⁵ JSUF at ¶¶ 67, 74 (July 19, 2007).

⁵⁶ See Amgen, Inc. v. U.S. Int'l Trade Comm'n, 902 F.2d 1532, 1536 (Fed. Cir. 1990) ("Amgen").

post-hearing briefs, thereby submitting to the personal jurisdiction of the Commission.⁵⁷

III. STANDARDS OF LAW

A. Claim Construction

Analyzing whether a patent is infringed "entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device or process accused of infringing."⁵⁸ The first step is a question of law, whereas the second step is a factual determination.⁵⁹ Concerning the first step of claim construction, "[i]t is well-settled that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language."⁶⁰

"In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point [] out and distinctly claim [] the subject matter which the patentee regards as his invention."⁶¹

"Quite apart from the written description and the prosecution history, the claims themselves

⁵⁷ See Certain Miniature Hacksaws, Inv. No. 337-TA-237, U.S.I.T.C. Pub. No. 1948, Initial Determination (unreviewed by Commission in relevant part) at 4, 1986 WL 379287 (U.S.I.T.C., October 15, 1986) ("Miniature Hacksaws").

⁵⁸ Dow Chem. Co. v. United States, 226 F.3d 1334, 1338 (Fed. Cir. 2000) ("Dow Chemical"), citing Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996) ("Markman").

⁵⁹ Markman, supra.

⁶⁰ Bell Atlantic Network Serv., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1267 (Fed. Cir. 2001) ("Bell Atlantic"). See also Phillips v. AWH Corp., 415 F.3d 1303, 1312-17 (Fed. Cir. 2005) ("Phillips"), cert. denied, 126 S.Ct. 1332.

⁶¹ Interactive Gift Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001) ("Interactive Gift Express") (citing 35 U.S.C. § 112, \P 2).

provide substantial guidance as to the meaning of particular claim terms."⁶² Usage of a term in both the asserted and unasserted claims is "highly instructive" in determining the meaning of the same term in other claims.⁶³ "Furthermore, a claim term should be construed consistently with its appearance in other places in the same claim or in other claims of the same patent."⁶⁴

"While not an absolute rule, all claim terms are presumed to have meaning in a claim."⁶⁵ If the claim language is not clear on its face, "[t]hen we look to the rest of the intrinsic evidence, beginning with the specification and concluding with the prosecution history, if in evidence" for the purpose of "resolving, if possible, the lack of clarity."⁶⁶

There is a "heavy presumption" that claim terms are to be given "their ordinary and accustomed meaning as understood by one of ordinary skill in the art," and in aid of this interpretation, "[d]ictionaries and technical treatises, which are extrinsic evidence, hold a 'special place' and may sometimes be considered along with the intrinsic evidence when determining the ordinary meaning of claim terms."⁶⁷ Caution must be used, however, when referring to non-scientific dictionaries "lest dictionary definitions . . . be converted into technical terms of art having legal, not linguistic significance."⁶⁸

⁶² Phillips, 415 F.3d at 1314 (citing Vitronics Corp. v. Conceptronic Inc., 90 F.3d 1576, 1582 (Fed. Cir. 2003) ("Vitronics")).

⁶³ Id.

⁶⁴ Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342 (Fed. Cir. 2001) ("Rexnord") (citing Phonometrics Inc. v. Northern Telecom Inc., 133 F.3d 1459, 1465 (Fed. Cir. 1998) ("Phonometrics")).

⁶⁵ Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1119 (Fed. Cir. 2004) ("Innova")).

⁶⁶ Id.

⁶⁷ Bell Atlantic, 262 F.3d at 1267-68.

⁶⁸ *Id.* at 1267 (internal quotation marks omitted).

The presumption in favor of according a claim term its ordinary meaning is overcome "(1) where the patentee has chosen to be his own lexicographer, or (2) where a claim term deprives the claim of clarity such that there is 'no means by which the scope of the claim may be ascertained from the language used."⁶⁹ In this regard, "[t]he specification acts as a dictionary 'when it expressly defines terms used in the claims or when it defines terms by implication."⁷⁰

The specification is considered "always highly relevant" to claim construction and "[u]sually, it is dispositive; it is the single best guide to the meaning of a disputed term."⁷¹ The prosecution history is also examined for a claim's scope and meaning "to determine whether the patentee has relinquished a potential claim construction in an amendment to the claim or in an argument to overcome or distinguish a reference."⁷²

"[I]f the meaning of the claim limitation is apparent from the intrinsic evidence alone, it is improper to rely on extrinsic evidence other than that used to ascertain the ordinary meaning of the claim limitation. [citation omitted] However, in the rare circumstance that the court is unable to determine the meaning of the asserted claims after assessing the intrinsic evidence, it may look to additional evidence that is extrinsic to the complete document record to help resolve any lack of clarity."⁷³

"Extrinsic evidence consists of all evidence external to the patent and prosecution history

⁶⁹ *Id.* at 1268.

⁷⁰ *Id. See also Phillips*, 415 F.3d at 1316.

⁷¹ Id.

⁷² Id.

⁷³ *Id.* at 1268-69.

....⁷⁷⁴ It includes "such evidence as expert testimony, articles, and inventor testimony."⁷⁵ But, "[i]f the intrinsic evidence resolves any ambiguity in a disputed claim, extrinsic evidence cannot be used to contradict the established meaning of the claim language."⁷⁶ "What is disapproved of is an attempt to use extrinsic evidence to arrive at a claim construction that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent."⁷⁷

In interpreting particular limitations within each claim, "adding limitations to claims not required by the claim terms themselves, or unambiguously required by the specification or prosecution history, is impermissible."⁷⁸ Usually, a patent is not limited to its preferred embodiments in the face of evidence of broader coverage by the claims.⁷⁹ A claim construction that excludes the preferred embodiment in the specification of a patent, however, is "rarely, if ever, correct."⁸⁰

On the other hand, "there is sometimes 'a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification."⁸¹ In order to negotiate

⁷⁴ Markman, 52 F.3d at 980.

⁷⁵ Bell Atlantic, 262 F.3d at 1269.

⁷⁶ DeMarini Sports, Inc. v. Worth, Inc., 239 F.3d 1314, 1322-23 (Fed. Cir. 2001) ("DeMarini").

⁷⁷ Markman, 52 F.3d at 979.

⁷⁸ Dayco Prod., Inc. v. Total Containment, Inc., 258 F.3d 1317, 1327 (Fed. Cir. 2001) ("Dayco Products"), citing Laitram Corp. v. NEC Corp., 163 F.3d 1342, 1347 (Fed. Cir. 1998) ("Laitram") ("a court may not import limitations from the written description into the claims").

⁷⁹ Acromed Corp. v. Sofamor Danek Group, Inc., 253 F.3d 1371, 1382-83 (Fed. Cir. 2001) ("Acromed"); Electro Med. Sys. S.A. v. Cooper Life Sci., Inc., 34 F.3d 1048, 1054 (Fed. Cir. 1994) ("Electro Med") ("particular embodiments appearing in a specification will not be read into the claims when the claim language is broader than such embodiments").

⁸⁰ Vitronics, 90 F.3d at 1583-34.

⁸¹ Bell Atlantic, 262 F.3d at 1270.

this "fine line," one guideline is that features of embodiments in the specification do not restrict patent claims "unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction."⁸² Another guideline is that features of an embodiment in the specification do not restrict claims unless the specification defines the claim terms "by implication" as may be "found in or ascertained by a reading of the patent documents."⁸³ For the specification to limit the claims, there must be "a clear case of the disclaimer of subject matter that, absent the disclaimer, could have been considered to fall within the scope of the claim language."⁸⁴

Claims amenable to more than one construction should, when it is reasonably possible to do so, be construed to preserve their validity.⁸⁵ A claim cannot, however, be construed contrary to its plain language.⁸⁶ Claims cannot be judicially rewritten in order to fulfill the axiom of preserving their validity; "if the only claim construction that is consistent with the claim's language and the

⁸² Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) ("Liebel-Flarsheim").

⁸³ Irdeto Access, Inc. v. Echostar Satellite Corp., 383 F.3d 1295, 1300 (Fed. Cir. 2004) ("Irdeto").

⁸⁴ Liebel-Flarsheim, 358 F.3d at 907. The Federal Circuit "has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." Liebel-Flarsheim, supra, 358 F.3d at 906 (emphasis added); also see, e.g., Golight, Inc. v. Wal-Mart Stores, Inc., 355 F.3d 1327, 1331 (Fed. Cir. 2004) ("Golight"); Bio-Technology General Corp. v. Duramed Pharmaceuticals, Inc., 325 F.3d 1356, 1362 (Fed. Cir. 2003) ("Bio-Technology") (aspects of only embodiment described in specification not read into claims). The Liebel-Flarsheim panel further held that even where a patent describes only a single embodiment, claims will not be "read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction." Id.

⁸⁵ Karsten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376, 1384 (Fed. Cir. 2001) ("Karsten").

⁸⁶ See Rhine v. Casio, Inc., 183 F.3d 1342, 1345 (Fed. Cir. 1999) ("Rhine").

written description renders the claim invalid, then the axiom does not apply and the claim is simply .

Pursuant to 35 U.S.C. § 112, ¶ 6, "[a]n 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." An applicant may therefore "claim an element of a combination functionally, without reciting structures for performing those functions."⁸⁸ To invoke this rule, "a claim limitation that actually uses the word 'means' will invoke a rebuttable presumption that § 112, ¶ 6 applies. By contrast, a claim term that does not use 'means' will trigger the rebuttable presumption that § 112, ¶ 6 does not apply."⁸⁹

B. Infringement

1. Literal Infringement

Literal infringement is a question of fact.⁹⁰ Literal infringement requires the patentee to prove that the accused device contains each limitation of the asserted claim(s). Each element of a claim is considered material and essential, and in order to show literal infringement, every element must be found to be present in the accused device.⁹¹ If any claim limitation is absent from the

⁸⁷ Id.

⁸⁸ Apex Inc. v. Raritan Computer, Inc., 325 F.3d 1364, 1371 (Fed. Cir.), cert. denied, 540 U.S. 1073 (2003) ("Apex").

⁸⁹ Linear Technology Corp. v. Impala Linear Corp., 379 F.3d 1311, 1319 (Fed. Cir. 2004) ("Linear").

⁹⁰ Tegal Corp. v. Tokyo Electron Am., Inc., 257 F.3d 1331, 1350 (Fed. Cir. 2001) ("Tegal "), cert. denied, 535 U.S. 927 (2002).

⁹¹ London v. Carson Pirie Scott & Co., 946 F.2d 1534, 1538 (Fed. Cir. 1991) ("London").

accused device, there is no literal infringement of that claim as a matter of law.⁹²

2. Infringement Under the Doctrine of Equivalents

Under the doctrine of equivalents, infringement may be found if the accused product performs substantially the same function in substantially the same way to obtain substantially thee same result.⁹³

3. Indirect Infringement

To establish a claim for induced infringement, a complainant must show that a respondent has actively induced a person to make, use, or sell a product or use a method that falls within the scope of the claims of the patent at issue.⁹⁴ The required elements of a claim of induced infringement are: "(1) an act of direct infringement; (2) the accused infringer actively induced a third party to infringe the patent; and (3) the accused infringer knew or should have known that his actions would induce infringement."⁹⁵

Under 35 U.S.C. § 271(c), a seller of a component of an infringing product can be held liable for contributory infringement if: "(1) there has been an act of direct infringement by a third party; (2) the accused contributory infringer knows that the combination for which its component was made

⁹² Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1247 (Fed. Cir. 2000) ("Bayer").

⁹³ Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 608 (1950) ("Graver Tank").

⁹⁴ 35 U.S.C. § 271(b).

⁹⁵ Certain Flash Memory Circuits and Products Containing Same, Inv. No. 337-TA-382, U.S.I.T.C. Pub. 3046, Commission Opinion on the Issues Under Review and on Remedy, the Public Interest, and Bonding, at 16, 1997 WL 817778 (U.S.I.T.C., July 1997) ("Flash Memory") citing Manville Sales Corp. v. Paramount Sys. Inc., 917 F.2d 544, 553 (Fed. Cir. 1990) ("Manville"). See also Certain Headboxes and Papermaking Machine Forming Sections for the Continuous Production of Paper, and Components Thereof, Inv. No. 337-TA-82, USITC Pub. No. 1138 at 18-19 (1981) ("Headboxes").

was both patented and infringing; and (3) there are no substantial non-infringing uses for the component part, *i.e.*, the component is not a 'staple article' of commerce."⁹⁶

C. Domestic Industry - Technical Prong

In a patent-based complaint, a violation of Section 337 can be found "only if an industry in the United States, relating to the articles protected by the patent . . . concerned, exists or is in the process of being established."⁹⁷ This "domestic industry requirement" has an "economic" prong and a "technical" prong.

A complainant in a patent-based Section 337 investigation must demonstrate that it is practicing or exploiting the patents at issue.⁹⁸ In order to find the existence of a domestic industry exploiting a patent at issue, it is sufficient to show that the domestic industry practices any claim of that patent, not necessarily an asserted claim of that patent.⁹⁹ Fulfillment of this so-called "technical prong" of the domestic industry requirement is not determined by a rigid formula, but rather by the articles of commerce and the realities of the marketplace.¹⁰⁰

⁹⁹ *Microsphere Adhesives*, Commission Opinion at 7-16.

¹⁰⁰ Certain Diltiazem Hydrochloride and Diltiazem Preparations, Inv. No. 337-TA-349, U.S.I.T.C. Pub. No. 2902, Initial Determination at 138, 1995 WL 945191 (U.S.I.T.C., February 1, 1995) (unreviewed in relevant part) ("Diltiazem"); Certain Double-Sided Floppy Disk Drives and Components Thereof, Inv. No. 337-TA-215, 227 U.S.P.Q. 982, 989 (Commission Opinion 1985) ("Floppy Disk Drives").

⁹⁶ Flash Memory, Commission Opinion at 9-10.

⁹⁷ 19 U.S.C. § 1337(a)(2).

⁹⁸ See 19 U.S.C. § 1337(a)(2) and (3); also see Certain Microsphere Adhesives, Process for Making Same, and Products Containing Same, Including Self-Stick Repositionable Notes, Inv. No. 337-TA-366, Commission Opinion at 8, 1996 WL 1056095 (U.S.I.T.C., January 16, 1996) ("Microsphere Adhesives"), aff'd sub nom. Minnesota Mining & Mfg. Co. v. U.S. Int'l Trade Comm'n, 91 F.3d 171 (Fed. Cir. 1996) (Table) ("3M"); Certain Plastic Encapsulated Integrated Circuits, Inv. No. 337-TA-315, U.S.I.T.C. Pub. No. 2574 (November 1992), Commission Opinion at 16, 1992 WL 813959 ("Encapsulated Circuits").

The test for claim coverage for the purposes of the technical prong of the domestic industry requirement is the same as that for infringement.¹⁰¹ "First, the claims of the patent are construed. Second, the complainant's article or process is examined to determine whether it falls within the scope of the claims."¹⁰² As with infringement, the first step of claim construction is a question of law, whereas the second step of comparing the article to the claims is a factual determination.¹⁰³ To prevail, the patentee must establish by a preponderance of the evidence that the domestic product practices one or more claims of the patent either literally or under the doctrine of equivalents.¹⁰⁴

D. Validity

A patent is presumed valid.¹⁰⁵ The party challenging a patent's validity has the burden of overcoming this presumption by clear and convincing evidence.¹⁰⁶ Since the claims of a patent measure the invention at issue, the claims must be interpreted and given the same meaning for purposes of both validity and infringement analyses. As with an infringement analysis, an analysis of invalidity involves two steps: the claim scope is first determined, and then the properly construed claim is compared with the prior art to determine whether the claimed invention is anticipated and/or rendered obvious.¹⁰⁷

¹⁰¹ Certain Doxorubicin and Preparations Containing Same, Inv. No. 337-TA-300, Initial Determination at 109, 1990 WL 710463 (U.S.I.T.C., May 21, 1990) ("Doxorubicin"), aff'd, Views of the Commission at 22 (October 31, 1990).

 $^{^{102}}$ Id.

¹⁰³ *Markman*, 52 F.3d at 976.

¹⁰⁴ See Bayer, 212 F.3d at 1247.

¹⁰⁵ 35 U.S.C. § 282; *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1480 (Fed. Cir. 1997) ("*Richardson-Vicks*").

¹⁰⁶ Richardson-Vicks Inc., supra; Uniroyal, Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044 (Fed. Cir.) ("Uniroyal"), cert. denied, 488 U.S. 825 (1988).

¹⁰⁷ Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1351 (Fed. Cir. 2001) ("Amazon.com").

1. Anticipation, 35 U.S.C. §§ 102 (a) and (b)

A patent may be found invalid as anticipated under 35 U.S.C. § 102(a) if "the invention was known or used by others in this country, or patented or described in a printed publication in this country, or patented or described in a printed publication in a foreign country, before the invention thereof by the applicant for patent." 35 U.S.C. § 102(a). A patent may be found invalid as anticipated under 35 U.S.C. § 102(b) if "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States."¹⁰⁸ Under 35 U.S.C. § 102(e), a patent is invalid as anticipated if "the invention was described in a patent granted on an application for patent."¹⁰⁹ Anticipation is a question of fact.¹¹⁰

Under the foregoing statutory provision, a claim is anticipated and therefore invalid when "the four corners of a single, prior art document describe[s] every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation."¹¹¹ To be considered anticipatory, the prior art reference must be enabling and describe the applicant's claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention.¹¹² But, the degree of enabling

¹⁰⁸ 35 U.S.C. § 102(b).

¹⁰⁹ 35 U.S.C. § 102(e).

¹¹⁰ Texas Instruments, Inc. v. U.S. Int'l Trade Comm'n, 988 F.2d 1165, 1177 (Fed. Cir. 1993) ("Texas Instruments II").

¹¹¹ Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000), cert. denied, 532 U.S. 904 (2001) ("Advanced Display Systems").

¹¹² Helifix Ltd. v. Blok-Lok, Ltd., 208 F.3d 1339, 1346 (Fed. Cir. 2000) ("Helifix"); In re Paulsen, 30 F.3d 1475, 1478 (Fed. Cir. 1994) ("Paulsen").

detail contained in the reference does not have to exceed that contained in the patent at issue.¹¹³

Further, the disclosure in the prior art reference does not have to be express, but may anticipate by inherency where the inherency would be appreciated by one of ordinary skill in the art.¹¹⁴ To be inherent, the feature must necessarily be present in the prior art.¹¹⁵ Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient. This modest flexibility in the rule that "anticipation" requires that every element of the claims appear in a single reference accommodates situations where the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges.¹¹⁶

2. Obviousness, 35 U.S.C. § 103 (a)

Under 35 U.S.C. § 103(a), a patent is valid unless "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."¹¹⁷ The ultimate question of obviousness is a question of law, but "it is well

¹¹⁷ 35 U.S.C. § 103(a).

¹¹³ Paulsen, 30 F.3d at 1481 n.9.

¹¹⁴ Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1047 (Fed. Cir.), cert. denied, 516 U.S. 988 (1995) ("Glaxo").

¹¹⁵ See Finnigan Corp. v. U.S. Int'l Trade Comm'n, 180 F.3d 1354, 1365-66 (Fed. Cir. 1999) ("Finnigan").

¹¹⁶ See Cont'l Can Co. v. Monsanto Co., 948 F.2d 1264, 1268-69 (Fed. Cir. 1991) ("Continental Can"); Finnigan, 180 F.2d at 1365.

understood that there are factual issues underlying the ultimate obviousness decision."¹¹⁸

Once claims have been properly construed, "[t]he second step in an obviousness inquiry is to determine whether the claimed invention would have been obvious as a legal matter, based on underlying factual inquiries including : (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art ; and (4) secondary considerations of non-obviousness" (also known as "objective evidence").¹¹⁹

Although the Federal Circuit case law also required that, in order to prove obviousness, the patent challenger must demonstrate, by clear and convincing evidence, that there is a "teaching, suggestion, or motivation to combine, the Supreme Court has rejected this "rigid approach" employed by the Federal Circuit in *KSR Int'l Co. v. Teleflex Inc.*:¹²⁰

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. Sakraida and Anderson's-Black Rock are illustrative–a court must ask whether the improvement is more than the predictable use of prior art elements according to their established function.

Following these principles may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement. Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to

¹¹⁸ Richardson-Vicks Inc., 122 F.3d at 1479; Wang Lab., Inc. v. Toshiba Corp., 993 F.2d 858, 863 (Fed. Cir. 1993) ("Wang Laboratories").

 ¹¹⁹ Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1354 (Fed. Cir. 1999)
 ("Smiths Industries"), citing Graham v. John Deere Co., 383 U.S. 1, 17 (1966) ("Graham").
 ¹²⁰ KSR Int'l Co. v. Teleflex Inc., 500 U.S. – (2007), 127 S.Ct. 1727, 1739 ("KSR").

determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicitly. See *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusions of obviousness"). As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

[...]

The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents. The diversity of inventive pursuits and of modern technology counsels against limiting the analysis in this way. In many fields it may be that there is little discussion of obvious techniques or combinations, and it often may be the case that market demand, rather than scientific literature, will drive design trends. Granting patent protection to advance that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility.¹²¹

"Secondary considerations," also referred to as "objective evidence of non-obviousness,"

such as "commercial success, long felt but unsolved needs, failure of others, etc." may be used to

understand the origin of the subject matter at issue, and may be relevant as indicia of obviousness

or non-obviousness.¹²² Secondary considerations may also include copying by others, prior art

teaching away, and professional acclaim.¹²³

¹²¹ KSR, 500 U.S. at -; 127 S.Ct. at 1740-41.

¹²² Graham, 383 U.S. at 17-18.

¹²³ See Perkin-Elmer Corp. v. Computervision Corp., 732 F.2d 888, 894 (Fed. Cir. 1984) ("Perkin-Elmer"), cert. denied, 469 U.S. 857 (1984); Avia Group Int'l, Inc. v. L.A. Gear California, 853 F.2d 1557, 1564 (Fed. Cir. 1988) ("Avia") (copying by others); In re Hedges, 783 F.2d 1038, 1041 (Fed. Cir. 1986) ("Hedges") (prior art teaching away; invention contrary to accepted wisdom); Kloster Speedsteel AB v. Crucible Inc., 793 F.2d 1565 (Fed. ir. 1986) ("Kloster"), cert. denied, 479 U.S. 1034 (1987) (wide acceptance and recognition of the invention).

Evidence of "objective indicia of non-obviousness," also known as "secondary considerations," must be considered in evaluating the obviousness of a claimed invention, but the existence of such evidence does not control the obviousness determination. A court must consider all of the evidence under the *Graham* factors before reaching a decision on obviousness.¹²⁴ In order to accord objective evidence substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention, and a *prima facie* case is generally made out "when the patentee shows both that there is commercial success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent."¹²⁵ Once the patentee has made a *prima facie* case of nexus, the burden shifts to the challenger to show that the commercial success was caused by "extraneous factors other than the patented invention, such as advertising, superior workmanship, etc."¹²⁶

IV. CLAIM CONSTRUCTION

A. Asserted Claims

The asserted claims read as follows (with the first instance of the disputed terms highlighted in *italics*):

1. An electrosurgical unit for achieving coagulation of tissue, comprising:

an endoscope having:

a proximal end and an opposing distal end, and

¹²⁴ *Richardson-Vicks Inc.*, 122 F.3d at 1483-84.

 ¹²⁵ In re GPAC Inc., 57 F.3d 1573, 1580 (Fed. Cir. 1995) ("GPAC"); Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392 (Fed. Cir. 1988), cert. denied, 488 U.S. 956 (1988) ("Demaco"); Certain Crystalline Cefadroxil Monohydrate, Inv. No. 337-TA-293, Commission Opinion (March 15, 1990),15 U.S.P.Q.2d 1263, 1270 ("Certain Crystalline").
 ¹²⁶ Id. at 1393.

a plurality of *working channels* extending between the two ends, each channel having a predetermined diameter and having an opening at each end;

a flexible, hollow tube having a longitudinal axis disposed in one of the working channels of the endoscope, the tube having a diameter which is less than the diameter of the channel through which it is inserted, the tube including:

a distal end and an opposing proximal end, each end of the tube having an opening, the tube having an inside and an outside,

the tube positioned within the endoscope such that a portion of the tube including the opening at the distal end of the tube protrudes beyond the opening at the distal end of the endoscope and such that a *gas stream* exits from the opening at the distal end of the tube in order to establish an *inert gas atmosphere* between the distal end of the tube and the region of the tissue to be coagulated, and

an electrode for ionizing the inert gas positioned inside the tube and offset from the opening at the distal end of the tube a *predetermined minimum safety distance*, such that the electrode can not come in contact with the tissue;

a source of pressurized ionizable, inert gas connected to the opening at the proximal end of the tube and pressurized such that a stream of gas flows from the source, through the tube and exits through the opening at the distal end of the tube at a *low flow rate* of *less than about 1 liter/minute*;

optical means positioned within a second working channel of the endoscope and protruding sufficiently from the opening at the distal end of the second channel of the endoscope to view the distal end of the tube and the tissue to be coagulated; and

the portion of the tube protruding from the distal end of the endoscope positioned such that the longitudinal axis of the tube is arranged *sidewardly* of the area of tissue to be coagulated.

- 3. The electrosurgical unit for achieving coagulation of tissue of claim 1, wherein the opening at the distal end of the tube *positioned longitudinally from the tube*.
- 4. The electrosurgical unit for achieving coagulation of tissue of claim 1, wherein the gas comprising [sic] argon.
- 11. The electrosurgical unit for achieving coagulation of tissue during endoscopic surgery of claim 1, wherein an endpiece made out of a heat resistant material like ceramics is inserted into a distal end portion of the tube.

- 13. The electrosurgical unit for achieving coagulation of tissue during endoscopic surgery of claim 1, whereby the distal end portion of the tube protruding out of the distal end portion of the endoscope is provided with ring shaped markings permitting observation through said optical means how far the distal end of the tube protrudes out of the distal end of the working channel of the endoscope, into which the tube is inserted.
- 35. A method for coagulating tissue during endoscopic surgery comprising the following steps:

providing a surgical endoscope, the endoscope having a proximal end, an opposing distal end, an opening at each end, and a plurality of working channels extending between the openings at each end, each channel having a predetermined diameter, the endoscope having a flexible, hollow tube having a longitudinal axis inserted through one of the working channels of the endoscope, the tube having a diameter which is less than the diameter of the channel through which it is inserted, the tube having a distal end, an opposing proximal end connected to a source of ionizable, inert gas, an opening at each end, a channel extending between the two ends, an inside, an outside; and an electrode, arranged stationarily inside the tube and being offset from the opening at the distal end of the tube a predetermined minimum safety distance in such a manner that the electrode can not come into contact with the tissue; the tube positioned within the working channel of the endoscope such that the opening at the distal end Of the tube protrudes beyond the opening at the distal end of the endoscope, and can be observed through optical means provided at or near the distal end of said endoscope;

supplying the inert gas from the source of said gas through the tube to the distal end opening of said tube with such a low flow rate, that gas exiting through said distal end opening is a *not directed, non laminar stream* but forms an inert gas atmosphere between the distal end of the tube and the region of the tissue to be coagulated, while the distal end opening is maintained at a distance from the tissue to be coagulated in which situation the area of tissue to be coagulated is positioned sidewardly of the extended longitudinal axis of the said protruding end portion of said tube;

ionizing said inert gas atmosphere by activating a high frequency voltage source connected to the electrode by establishing an electric field in the inert gas atmosphere between the electrode and the sidewardly arranged area of tissue to be coagulated; and

supplying an electric current by means of a plasma jet as a function of the direction of said electric field and the electric conductivity of the tissue surface to be coagulated, and coagulating an area of the tissue sidewardly of the extended longitudinal axis of the protruding end of the tube while the distal end opening of the tube is maintained in a substantially stationary position at a predetermined distance from the tissue to be coagulated, and while the ionized gas is being supplied through the distal end opening of the tube as a not directed, non laminar stream with a low flow rate.

- 37. The method as claimed in claim 35, whereby a distal end portion of said tube is a tubular end piece made out of a heat resistant ceramic material.
- 38. The method as claimed in claim 35, whereby the stream of gas exits through said distal end opening with a flow rate of less than about one liter per minute.
- 39. The method as claimed in claim 38, whereby tissue in the gastrointestinal tract is coagulated.

B. Disputed Claim Terms

The parties assert that the following claim terms are in dispute: "working channels," "gas stream," "inert gas atmosphere," "predetermined minimum safety distance," "low flow rate," "less than about 1 liter/minute," "optical means," "sidewardly," "positioned longitudinally from the tube," and "not directed, non laminar stream."¹²⁷ However, only those claim terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy.¹²⁸ To resolve the controversy among the parties, the limitations "predetermined minimum safety distance," "sidewardly," and "working channel" must be construed.¹²⁹

1. "predetermined minimum safety distance" (claims 1 and 35)

The parties couch their claim construction dispute in terms of the limitation "minimum safety distance." However, the post trial briefs indicate that the parties are in general agreement as to the limitation's proper construction. ERBE argues that the limitation "minimum safety distance" should be construed to mean the minimum distance between the electrode and the opening in the distal end

¹²⁷ See CIB at 14-28; RIB at 9-28; SIB at 10-42.

¹²⁸ Vanderlande Indus. Nederland BV v. Int'l Trade Comm., 366 F.3d 1311, 1323 (Fed. Cir. 2004); Vivid Tech., Inc. v. American Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999).

¹²⁹ As discussed in detail, *infra*, at V.A.1., the undersigned finds that ERBE has failed to prove that anyone has performed an APC procedure using the accused products in a manner that satisfies the limitations "predetermined minimum safety distance," "sidewardly," and "working channel" of the asserted claims of the '745 patent. Accordingly, the undersigned need not construe the other allegedly disputed limitations.

of the tube that will not allow the electrode to contact tissue.¹³⁰ Canady argues that the limitation is properly construed as the predetermined minimum distance to prevent an electrode from coming into contact with the tissue.¹³¹ The Staff argues that properly construed the "minimum safety distance" means the minimum distance between the electrode and the distal end of the tube that will not allow the electrode to contact tissue.¹³²

The parties true dispute appears not to be the proper construction of the phrase "predetermined minimum safety distance," but rather the proper construction of the limitation "an electrode . . . positioned inside the tube and offset from the opening at the distal end of the tube a predetermined minimum safety distance" of claim 1 and the limitation "an electrode, arranged . . . inside the tube and being offset from the opening at the distal end of the tube a predetermined minimum safety distance" of claim 3 the distal end of the tube a predetermined minimum safety distance" of claim 35. In this regard, ERBE argues that these limitations are properly construed as requiring the electrode to be recessed from the working face of the probe whether the working face of the probe is the plastic tube or a ceramic tip.¹³³ Canady and the Staff both argue that the electrode must be recessed from the end of the tube, not the working face of the probe as ERBE suggests.¹³⁴

Turning first to the claims of the '745 patent, the language of independent claims 1 and 35 is examined. Claim 1 is drawn to an electrosurgical unit.¹³⁵ Claim 35 is drawn to a method for

¹³⁰ CIB at 17.

¹³¹ RIB at 14.

¹³² SIB at 16.

¹³³ CIB at 18; CRB at 9-12.

¹³⁴ RIB at 15-16; SIB at 19-20; RRB at 4-5; SRB at 12.

¹³⁵ JX-1 at 11:11.

coagulating tissue during endoscopic surgery.¹³⁶ Both claims require, inter alia, an endoscope that has a flexible, hollow tube disposed in one of its working channels.¹³⁷ The tube has a distal end and an opposing proximal end, with an electrode positioned "inside the tube and offset from the opening at the distal end of the tube."¹³⁸ Thus, in accordance with the clear and unambiguous language of claims 1 and 35, the electrode must be positioned so that it is: (1) inside the tube; and (2) offset from the opening at the distal end of the tube.

In addition to claims 1 and 35, it is asserted by the Staff that dependent claims 11 and 37 also inform the proper claim construction.¹³⁹ Claim 11 depends from claim 1 and adds a limitation requiring that "an endpiece made out of a heat resistant material like ceramics is inserted into a distal end portion of the tube."¹⁴⁰ Claim 37 depends from claim 35 and adds a limitation requiring that "a distal end portion of said tube is a tubular endpiece made out of a heat resistant ceramic material."¹⁴¹ Having reviewed the language of dependent claims 11 and 37, the undersigned finds that dependent claims 11 and 37 do not aid in the proper construction of the limitation of claims 1 and 35 requiring the electrode to be offset from the distal end of the tube. There simply is nothing in the dependent claims 11 and 37 aid in determining the correct claim construction, they do so, as discussed in more detail below, only by illuminating the weakness of ERBE's claim construction argument.

In contrast to the clear and unambiguous language of claims 1 and 35 calling for the electrode

¹³⁶ *Id.* at 15:25-26.

¹³⁷ *Id.* at 11:13, 11:17-19, 15:27, 15:31-33.

¹³⁸ *Id.* at 11:22-24, 11:32-35, 15:36-37, 15:41-43.

¹³⁹ See SIB at 19-20.

¹⁴⁰ JX-1 at 12:13-16.

¹⁴¹ *Id.* at 16:18-20.

to be offset from the distal end of the tube, ERBE's proposed claim construction requires the electrode to be offset from what ERBE refers to as "the working face of the probe," whether the working face be the end of the tube or the end of a ceramic insert.¹⁴² ERBE points to several aspects of the claims that it alleges support its claim construction. Specifically, ERBE argues that claim 37, which depends from claim 35, "makes clear that the tube may include a ceramic insert."¹⁴³ Under such conditions, ERBE argues that "the end of the insert is the end of the tube, and is the point from which the electrode is recessed."¹⁴⁴ In further support of its claim construction, ERBE points to the fact that claims 1 and 35 require a gas stream to exit through the opening at the distal end of the tube.¹⁴⁵ According to ERBE, "[g]as can only exit at the very end of the tube, whether or not the tube includes an insert.¹⁴⁶

ERBE's claim construction presupposes that claims 1 and 35 are broad enough to encompass an endoscope having a tube with a ceramic endpiece inserted therein. On this point, however, the Staff argues that it would be improper to construe claims 1 and 35 to cover a probe with a ceramic endpiece inserted into the distal end portion of the flexible tube.¹⁴⁷ Specifically, the Staff argues that because dependent claims 11 and 37 add a ceramic endpiece limitation, the doctrine of claim differentiation bars construing claims 1 and 35 to incorporate ceramic endpieces.¹⁴⁸ In support of its argument, the Staff cites to *Liebel-Flarsheim Co. v. Medrad, Inc.*¹⁴⁹ In *Liebel Flarsheim*, the

 144 *Id*.

 146 *Id*.

¹⁴⁸ SIB at 19.

¹⁴² CIB at 18; CRB at 9-12.

¹⁴³ CIB at 18 n.20.

¹⁴⁵ Id.

¹⁴⁷ SIB at 19.

¹⁴⁹ 358 F.3d 898 (Fed. Cir 2004).

Federal Circuit applied the doctrine of claim differentiation to the facts of that case stating that "the juxtaposition of independent claims lacking any reference to a pressure jacket with dependent claims that add a pressure jacket limitation provides strong support for Liebel's argument that the independent claims were not intended to require the presence of the pressure jacket."¹⁵⁰ While the Staff cites the proper law, the Staff misapplies its teachings.

"Under the doctrine of claim differentiation, dependent claims are presumed to be narrower in scope than the independent claims from which they depend."¹⁵¹ Because of this presumed difference in scope, the doctrine of claim differentiation generally prohibits construing an independent claim as **requiring** that which is contained in the dependent claim, because to do so would make the dependant claim superfluous.¹⁵² Contrary to the Staff's argument, that does not mean that the scope of the independent claim cannot encompass that which is in its dependent claim. In fact, quite the opposite, because a dependent claim is necessarily narrower in scope than the independent claim on which it depends, an independent claim is typically construed broad enough to encompass those limitations in the dependent claim.¹⁵³ The undersigned, therefore, finds the

¹⁵⁰ *Id.* at 909-910.

¹⁵¹ See AK Steel Corp. v. Sollac, 344 F.3d 1234, 1242 (Fed. Cir. 2003); see also 35 U.S.C. § 112 ("[A] claim in dependent form shall contain a further limitation of the subject matter claimed. A claim in dependent form shall be construed so as to incorporate by reference all the limitations of the claim to which it refers.").

¹⁵² See Karlin Tech., Inc. v. Surgical Dynamics, Inc., 177 F.3d 968 (Fed. Cir. 1999)("[The doctrine of claim differentiation,] which is ultimately based on the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope, ... normally means that limitations stated in dependent claims are not to be read into the independent claim from which they depend.").

¹⁵³ See AK Steel Corp., 344 F.3d at 1242 ("Moreover, and most importantly, claims 1 and 5 must also encompass aluminum with up to about 10% silicon, *i.e.*, Type 1 silicon, because claims 3 and 7, which depend from claims 1 and 5, respectively, expressly recite 'up to about 10% silicon."); see also 35 U.S.C. § 112.

Staff's argument on this point unpersuasive. Based on the language of the claims, it is presumed that independent claims 1 and 35 are broad enough to read on an endoscope having a tube with a ceramic endpiece.

Although claims 1 and 35 are broad enough to read on an endoscope having a tube with a ceramic endpiece, that does not mean as ERBE suggests that "the end of the insert is the end of the tube, and is the point from which the electrode is recessed."¹⁵⁴ As previously stated, dependent claim 11 adds a limitation to claim 1 requiring that "an endpiece made out of a heat resistant material like ceramics is inserted into a distal end portion of the tube."¹⁵⁵ Likewise, as previously stated, dependent claim 37 adds a limitation to claim 35 requiring that "a distal end portion of said tube is a tubular endpiece made out of a heat resistant ceramic material."¹⁵⁶ Absent something in the specification or prosecution history that would demand otherwise, "[t]here is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims."¹⁵⁷ Thus, the applicant's introduction of the new term "endpiece" in dependent claims 11 and 37 presumes that the "endpiece" is different from the "tube" introduced in claims 1 and 35. Moreover, dependent claim 11 explicitly requires that the endpiece be "inserted" into a distal end portion of the tube, thereby clearly defining the "endpiece" as a separate element from the "tube." Contrary to ERBE's general argument, dependent claims 11 and 37 do not suggest the limitations of claims 1 and 35 requiring that the electrode be offset from the end of the tube should be construed as

¹⁵⁴ CIB at 18 n.20.

¹⁵⁵ JX-1 at 12:13-16.

¹⁵⁶ *Id.* at 16:18-20.

¹⁵⁷ Tandon Corp. v. United States Int'l Trade Comm'n, 831 F.2d 1017, 1023 (Fed. Cir. 1987).

permitting the offset to be determined from "the working end of the probe."

With regard to ERBE's claim construction argument based on the limitation of claims 1 and 35 requiring a gas stream to exit through the opening at the distal end of the tube, the undersigned is unpersuaded. ERBE's argument is premised on its assertion that, in an endoscope with a tube having a ceramic insert, the gas stream will not exit through the opening at the distal end of the tube, but rather the opening at the end of the ceramic insert.¹⁵⁸ ERBE's premise, however, is incorrect. Even with a ceramic endpiece inserted into the distal end of the tube, the gas will still exit through the opening at the end of the tube. The end of the tube is the end of the tube, and adding a ceramic insert does not change that fact. Once the gas proceeds past the plane at the end of the tube, the gas has exited the distal end of the tube.

Having examined the language of the claims, the specification is consulted. ERBE relies heavily on the specification of the '745 patent to support its argument that claims 1 and 35 should be construed as requiring the electrode to be recessed from the face of the probe whether the working face of the probe is the plastic tube or a ceramic tip.¹⁵⁹ In particular, ERBE notes that in some embodiments of the invention, such as that shown in Figure 14, "the distal end of the APC probe is a plain end of the plastic tube," while in other embodiments, such as that shown in Figure 13, "the distal end of the APC probe is a ceramic insert."¹⁶⁰ Additionally, ERBE points to a sentence in the specification that states that "[t]he electrode 8 is arranged in all embodiments in such a manner, that substantially no direct contact is possible with the tissue to be coagulated or with other tissue, out

¹⁵⁸ See CIB at 18 ("Gas can only exit at the very end of the tube, whether or not the tube includes an insert.").

¹⁵⁹ See CIB at 18-19.

¹⁶⁰ *Id.* at 18.

of which reason the electrode 8 is offset from the face 10 of the tube 2 and the endpiece 12, respectively, for a minium distance A.^{"161} ERBE never explains in its opening brief the legal significance of these observations or why they support its proposed claim construction. While ERBE does state in its reply brief that "[o]ne of ordinary skill in the art would refer to the specification to resolve any doubts as to how to measure the "predetermined minimum safety distance," ERBE does not elaborate as to what "doubts" it is referring.¹⁶² As discussed *supra*, the language of claims 1 and 35 is unambiguous that the electrode must be offset from the opening at the distal end of the tube. Moreover, there is nothing in the passages in the specification to which ERBE cites that indicate a clear intent on the part of the applicant to define the distal end of the tube as "the working end of the probe, whether the working end be that of the tube or of a ceramic insert." In fact, the specification carefully differentiates between the tube and the endpiece thereby supporting the notion that the tube and endpiece are separate and distinct elements.

ERBE also notes in its reply brief that if the Staff's and Canady's interpretation were correct, Figure 13 of the '745 patent would have the safety distance A measured from the end of the tube rather than the opening 9.¹⁶³ According to ERBE, there is no such illustration in the specification and no indication that one of ordinary skill in the art would interpret the predetermined minimum safety distance in a way that is not illustrated in any embodiment of the patent.¹⁶⁴ Again, ERBE fails to explain the legal significance of its argument. Contrary to ERBE's assertion, at a minimum Figures 2-4, 12, 14, and 15 of the '745 patent disclose embodiments of the invention configured

¹⁶¹ *Id.* (quoting JX-1 at 4:41-44).

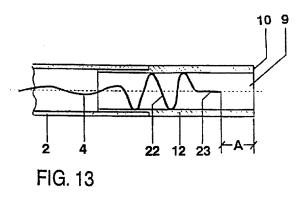
¹⁶² *See* CRB at 10.

 $^{^{163}}$ *Id.*

¹⁶⁴ *Id.* at 11.

with the electrode positioned as properly construed herein to be both inside the tube and offset a predetermined minimum safety distance from the end of the tube. *See* JX-1 at Figs. 2-4, 12, 14, 15. Notably, each of the embodiments includes an endpiece inserted into the distal end of the tube. *Id.*

Figure 13, which is reproduced below, shows a ceramic endpiece 12 inserted into the distal end of the tube 2.¹⁶⁵ The ceramic endpiece 12 has an orifice 9 in which an electrode 23 is disposed.¹⁶⁶ The electrode 23 is offset a minimum safety distance "A" from the distal end 10 of the ceramic endpiece 12.¹⁶⁷



As seen above, Figure 13 shows the electrode 23 disposed outside the tube 2 and offset from the end 10 of the ceramic endpiece 12. In contrast, as discussed *supra*, the clear and unambiguous language of claims 1 and 35 require the electrode to be: (1) "positioned inside the tube" and (2) "offset from the opening at the distal end of the tube." Thus, even assuming *arguendo* that ERBE's proposed claim construction were adopted and the limitation requiring the electrode to be offset from the distal end of the probe,

¹⁶⁵ See JX-1 at 5:37-46, Figure 13.

¹⁶⁶ Id.

¹⁶⁷ Id.

whether the working end of the probe be the end of the tube or the end of the endpiece, claims 1 and 35 would still not read on the embodiment illustrated in Figure 13 of the '745 patent because the electrode is not "positioned inside the tube." Accordingly, to construe claims 1 and 35 to read on the embodiment illustrated in Figure 13, the limitation of claims 1 and 35 requiring the electrode to be positioned inside the tube would have to be ignored. As the Federal Circuit stated in *Harold Schoenhaus v. Genesco, Inc*, "where a patent specification includes a description [of an embodiment] lacking a feature, but the claim recites that feature, the language of the claim controls. In that case, the claim excludes the described embodiment, which is dedicated to the public."¹⁶⁸ Here, Figure 13 describes an embodiment with the electrode positioned outside the tube, while the claim explicitly requires the electrode to be positioned inside the tube.

Having examined the specification, the prosecution history is consulted. In this instance, however, the prosecution history does not aid in the construction of the disputed limitation. No party argues otherwise.

In the end, it is "the claims made in the patent [that] are the sole measure of the grant."¹⁶⁹

¹⁶⁸ Harold Schoenhaus v. Genesco, Inc, 440 F.3d 1354, 1359 (Fed. Cir. 2006) (citing Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1562-63 (Fed. Cir. 1991)); See Unique Concepts, Inc., 939 F.2d at 1563 (Fed. Cir. 1991) ("When the language of a claim is clear, as here, and a different interpretation would render meaningless express claim limitations, we do not resort to speculative interpretation based on claims not granted."); see also Innova/Pure Water, Inc., 381 F.3d at 1119, reaffirmed in Phillips, 415 F.3d 1303 (Fed. Cir. 2005) (en banc) ("we observe that Safari's interpretation largely reads the term 'operatively' out of the phrase 'operatively connected.' While not an absolute rule, all claim terms are presumed to have meaning in a claim."); Texas Instruments Inc. v. United States Int'l Trade Comm'n, 988 F.2d 1165, 1171 (Fed. Cir. 1993) ("To construe the claims in the manner suggested [by the patentee] would read an express limitation out of the claims. This we will not do because courts can neither broaden nor narrow claims to give the patentee something different than what he has set forth." (internal quotations omitted)).

¹⁶⁹ See Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336 (1961); White v. Dunbar, 119 U.S. 47, 52 (1886) ("The claim is a statutory requirement, prescribed for the very

As the Federal Circuit stated in Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.,

the claim requirement presupposes that a patent applicant defines his invention in the claims, not in the specification. After all, the claims, not the specification, provide the measure of the patentee's right to exclude.¹⁷⁰

Here, claims 1 and 35 clearly and unambiguously require that the electrode be positioned "inside the tube" and "offset from the opening at the distal end of the tube."¹⁷¹ As discussed above, nothing in the specification or prosecution history demands a contrary result. Accordingly, the undersigned finds that one of ordinary skill in the art at the time of the invention would construe the limitation "an electrode . . . positioned inside the tube and offset from the opening at the distal end of the tube a predetermined minimum safety distance" of claim 1 and the limitation "an electrode, arranged . . . inside the tube and being offset from the opening at the distal end of the tube a predetermined minimum safety distance" of claim 35 as requiring the electrode to be positioned inside the tube and offset from the opening at the distal end of the tube and offset from the opening at the distal end of the tube and offset from the opening at the distal end of the tube and offset from the opening at the distal end of the tube and offset from the opening at the distal end of the tube and offset from the opening at the distal end of the tube and offset from the opening at the distal end of the tube and offset from the opening at the distal end of the tube and offset from the opening at the distal end of the tube and offset from the opening at the distal end of the tube and offset from the opening at the distal end of the tube and offset from the opening at the distal end of the tube and offset from the opening at the distal end of the tube and offset from the opening at the distal end of the tube a predetermined inside the tube and offset from the opening at the distal end of the tube a predetermined distance that will not allow the electrode to contact tissue.

purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.").

¹⁷⁰ Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co., 285 F.3d 1046, 1052 (Fed. Cir. 2002) (en banc); see also Milcor Steel Co. v. George A. Fuller Co., 316 U.S. 143, 146 (1942) ("Out of all the possible permutations of elements which can be made from the specifications, he reserves for himself only those contained in the claims."); McClain v. Ortmayer, 141 U.S. 419 (1891) ("The claim is the measure of his right to relief, and while the specification may be referred to to limit the claim, it can never be made available to expand it.").

¹⁷¹ "In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to particularly point out and distinctly claim the subject matter which the patentee regards as his invention." *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001).

2. "sidewardly" (claims 1 and 35)

ERBE argues that the limitation "sidewardly" should be construed to mean alongside.¹⁷² Canady argues in its opening post-hearing brief that the limitation "arranged sidewardly of the area of tissue to be coagulated" is properly construed as the longitudinal axis of the tube being tangential to and spaced a distance from the tissue to be coagulated.¹⁷³ However, in its reply post-hearing brief, Canady states that it would agree to a construction of the limitation "arranged sidewardly of the area of tissue to be coagulated" as the area of the tissue to be coagulated is positioned alongside of, or parallel to, the longitudinal axis of the flexible tube and not in the axial direction of the tube.¹⁷⁴ While the Staff argues in its opening brief that "sidewardly" should be construed as at or toward one side, the Staff notes in its reply brief that it would find acceptable ERBE's proposed construction of "sidewardly" as alongside.¹⁷⁵

The term "sidewardly" is used in independent claims 1 and 35 of the '745 patent. In claim 1, the portion of the tube protruding from the distal end of the endoscope is required to be positioned such that the extended longitudinal axis of the tube is arranged sidewardly of the area of tissue to be coagulated. In claim 35, the tissue to be coagulated is again required to be positioned sidewardly of the extended longitudinal axis of the protruding end portion of the tube.¹⁷⁶ It is plain from the claim language cited above that the term "sidewardly" describes the positional relationship between the tissue to be coagulated and the extended longitudinal axis of the protruding axis of the protruding end portion of the tube.

¹⁷² CIB at 22.

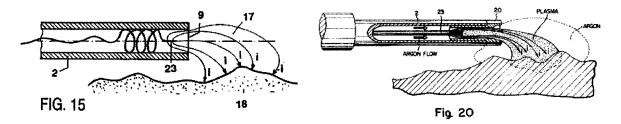
¹⁷³ RIB at 20.

¹⁷⁴ RRB at 7-8.

¹⁷⁵ See SIB at 35-36; SRB at 15.

¹⁷⁶ JX-1 at 15:60-63, 16:1-2, 16:6-8.

Having examined the language of the claims, the specification is consulted. The specification uses the term "sidewardly" only once, stating: "in this case rather large areas of tissue can be coagulated sidewardly from the axis 41 of tube 2 as shown in FIGS. 15 and 20."¹⁷⁷ Figures 15 and 20 are reproduced below.



As seen above, the figures show the tissue to be coagulated (labeled 18 in Fig. 15) oriented alongside, or generally parallel to, the extended longitudinal axis (i.e., the dashed line in Fig. 15) of the protruding end of the tube (labeled 2 in Figs. 15, 20). Thus, the specification supports the parties' proposed claim constructions.

Having examined the specification, the prosecution history is consulted. However, in this instance, the prosecution history does not aid in the proper construction of the limitation "sidewardly." No party argues otherwise.

Accordingly, based on the language of the claims in light of the specification and prosecution history, the undersigned finds one of ordinary skill in the art would construe the limitation "sidewardly" as "alongside."

3. "working channel" (claims 1 and 35)

ERBE argues in its pre-hearing brief that the limitation "working channel" should be

¹⁷⁷ *Id.* at 9:30-34.

construed as a channel of an endoscope through which a device (e.g. flexible endoscopic tubes, optical means and/or surgical instruments) may be inserted.¹⁷⁸ However, in its post-hearing briefs, ERBE now argues that the limitation "working channel" should be construed as a channel of an endoscope through which work is performed.¹⁷⁹ Canady argues that the limitation should be construed as a channel that has an opening at each end through which a device may be inserted.¹⁸⁰ The Staff argues that properly construed "working channel" means a course through which a device (e.g., flexible endoscope tube, optical means, surgical instrument) may be directed or moved.¹⁸¹ It appears from the parties post-hearing briefs that the dispute regarding the limitation "working" modifies or narrows the word "channel."

Turning first to the claims, it is noted that asserted independent claims 1 and 35 each call for a "plurality of working channels." The term "plurality" is construed in accord with its plain and customary meaning to mean at least two. Thus, claims 1 and 35 each require at least two working channels.

Claims 1 and 35 each describe a working channel as a feature of an endoscope.¹⁸² According to the both claims 1 and 35, a working channel must extend between the two ends of the endoscope and have a predetermined diameter.¹⁸³ In claim 1, one of the at least two working channels is also explicitly required to be capable of having a tube of smaller diameter inserted there through, while

¹⁸¹ SIB at 11.

¹⁷⁸ CPHB at 18.

¹⁷⁹ CIB at 14.

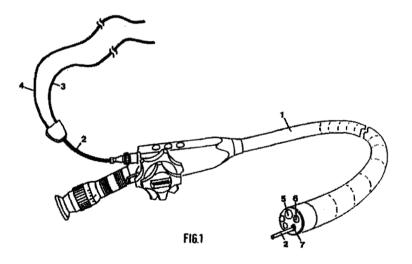
¹⁸⁰ RIB at 6.

¹⁸² JX-1 at 11:12-14,15:27-29.

¹⁸³ Id.

a second working channel is explicitly required to have optical means positioned therein.¹⁸⁴ In claim 35, one of the working channels is explicitly required to have a tube of smaller diameter inserted there through.¹⁸⁵ Unlike claim 1, claim 35 does not add any additional limitations on the second of the at least two working channels. While none of the above limitations placed on a "working channel" are particularly useful in determining the proper meaning of the limitation, they are nevertheless useful from a claim construction standpoint because any construction of the limitation "working channel" must be broad enough to encompass those limitations. Any claim construction that reads out one of the limitations of a working channel explicitly recited in claims 1 and 35 would be impermissible.

Having examined the claims, the specification is consulted. Figure 1, reproduced below, shows an endoscope with two working channels labeled 6 and 7.¹⁸⁶



¹⁸⁴ *Id.* at 11:17-19, 11:44-45.

- ¹⁸⁵ *Id.* at 15:33-35.
- ¹⁸⁶ Id. at Figure 1.

The specification describes the channels in Figure 1 by stating that "[t]he tube 2 protrudes out of the distal end of a working channel 7" and "the distal end of a second working channel 6 can be seen."¹⁸⁷ Unfortunately, this description does not add anything new that would aid in the proper construction of the limitation.

In addition to the description of the endoscope in Figure 1 of the '745 patent, the specification also describes other aspects of a working channel. For example, the specification repeatedly states that the tube used to perform the tissue coagulation is inserted through a working channel of the endoscope. In addition, the specification states that a manipulator, which is used to adjust the direction of the distal end of the tube, may also be inserted through a second working channel of an endoscope.¹⁸⁸ Additionally, the specification states that a working channel may serve as a gas supply conduit.¹⁸⁹ Further, the specification teaches that in a double-channel therapeutic endoscope, a working channel may also be used to supply suction.¹⁹⁰

Having examined the specification the prosecution history is examined. However, in this instance, the prosecution history does not aid in the proper construction of the limitation "working channel." No party argues otherwise.

"While not an absolute rule, all claim terms are presumed to have meaning in a claim."¹⁹¹ Thus, the word "working" in the limitation "working channel" is presumed to be significant.

¹⁸⁷ *Id.* at 3:67-4:1, 4:3-4.

¹⁸⁸ *Id.* at 5:21-30.

¹⁸⁹ *Id.* at 4:51-54.

¹⁹⁰ *Id.* at 10:49-51.

¹⁹¹ See Innova/Pure Water, Inc., 381 F.3d at 1119 ("we observe that Safari's interpretation largely reads the term 'operatively' out of the phrase 'operatively connected.' While not an absolute rule, all claim terms are presumed to have meaning in a claim.").

Accordingly, it would be improper, absent something in the specification or prosecution history, to construe the limitation "working channel" the same as the word "channel." The impropriety of such action is reinforced in this instance by the fact that claim 35 explicitly includes limitations directed to both a "working channel" and a "channel." Specifically, in addition to requiring a plurality of working channels, claim 35 also requires a tube with a distal end, a proximal end, an opening at each end, and a "channel" extending between the two ends.¹⁹² The fact that the claim distinguishes between the "working channel" in which the tube is inserted and the "channel" that runs between the ends of the tube, further supports the notion that the term "working" in the limitation "working channel" is significant.

ERBE argues that only its proposed construction gives meaning to the word "working" and distinguishes a "working channel" from a "channel."¹⁹³ The undersigned disagrees. In fact, the opposite appears true. According to ERBE, the limitation "working channel" must be construed broadly enough to include "channels that allow for the carriage of surgical instruments, endoscopic probes and manipulators, the placement of optical means, and the delivery of gas."¹⁹⁴ ERBE also argues that the limitation must be construed to include channels for air, water and suction.¹⁹⁵ Thus, under ERBE's proposed construction of "working channel" as a channel through which work is performed, it appears that every channel in an endoscope would be a working channel.¹⁹⁶ On that

¹⁹² See JX-1 at 15:37-41.

¹⁹³ CRB at 7.

¹⁹⁴ *See* CIB at 15.

¹⁹⁵ *Id.*; CRB at 6.

¹⁹⁶ See CORFF 176 (noting that a biopsy channel, air/water channel, lens channel, water jet channel, and light guide channel are all "working channels."); CORFF 102 ("A working channel is a channel used to perform work such as to house devices for irrigation or suction, to introduce light, to house a lens and/or lens system for visualization purposes, or other means for making the system

point, the undersigned notes that conspicuously absent from ERBE's post-hearing briefs is any indication of what type of a channel an endoscope would have that is not a working channel under ERBE's proposed construction.

Regardless, the language of asserted claim 35 contradicts ERBE's proposed construction. Claim 35, which is a method for coagulating tissue, includes the step of "supplying the inert gas from the source of said gas through the tube to the distal end opening of said tube."¹⁹⁷ As previously discussed, the tube has a "channel" extending between its two ends.¹⁹⁸ Therefore, according to the language of claim 35, the inert gas travels through the channel of the tube. Because the channel acts as a gas conduit, under ERBE's proposed construction it would be a working channel, and one would expect that if ERBE's construction were correct the applicant would refer to it as such. However, claim 35 does not refer to it in such a manner. Rather claim 35 specifically refers to it simply as a "channel." This further undermines the propriety of ERBE's proposed construction.

ERBE also argues that because the specification teaches that a working channel can be used to supply suction or serve as a gas conduit, the limitation "working channel" must be broader than just a channel through which a device may be inserted.¹⁹⁹ The undersigned, however, is unpersuaded. The fact that the specification teaches that a working channel can be used to supply suction or serve as a gas conduit does not run afoul of a construction of "working channel" as a channel through which a device may be inserted. Under the Staff's and Canady's proposed constructions, as long as a working channel is capable of having a device inserted there through,

work within the human body.").

¹⁹⁷ JX-1 at 15:53-54.

¹⁹⁸ See JX-1 at 15:37-41.

¹⁹⁹ CRB at 6.

there is nothing preventing the working channel from being used to supply gas or suction.

Having examined the language of the claims and specification of the '745 patent, the undersigned finds Canady's and the Staff's claim construction arguments generally persuasive. However, the undersigned takes issue in some respects with both parties' constructions. Specifically, the undersigned finds fault in the fact that neither proposed construction seemingly gives any significance to the word "working" in the limitation "working channel." Additionally, the undersigned finds that the Staff's proposed construction requiring a working channel to be a channel through which a device may be directed or moved impermissibly reads limitations from the specification into the claims. Although the specification does discuss directing and/or moving devices through a working channel, none of the statements in the specification amount to an explicit disavowal of claim scope and there is nothing in the claim language to suggest the applicant intended to define "working channel" in such terms.

Accordingly, based on the language of the claims in light of the specification, the undersigned finds that one of ordinary skill in the art would construe the limitation "working channel" as a channel through which a device that performs work may be inserted.

V. INFRINGEMENT

The following table summarizes ERBE's allegations of infringement against Canady.²⁰⁰

²⁰⁰ See SFF ¶ 10; see also Tr. at 231, 267, 268, 233 (Aug. 27, 2007). For each accused product alleged to infringe independent claim 1, ERBE also alleges that the product infringes dependent claims 3, 4, 11, and 13, of the '745 patent. For each accused product alleged to infringe independent claim 35, ERBE also alleges that the product infringes dependent claims 37, 38, and 39, of the '745 patent.

	Part Number	Dimensions	Contributory Infringement, Claim 1	Induced Infringement, Claim 1	Contributory Infringement, Claim 35	Induced Infringement, Claim 35
KLS Martin Argon Probes	1322535	1.5 mm x 1.6 m	~	~	~	۲
	1322537	2.3 mm x 2.3 m	Withdrawn	v	v	*
	1322538	2.3 mm x 3.4 m	Withdrawn	v	v	~
Soring Argon Probes	S-422537 was S1322537	2.3 mm x 2.3 m	Withdrawn	r	~	~
	S-422538 was S1322538	2.3 mm x 3.4 m	Withdrawn	v	2	v

A. Direct Infringement

As seen in the table above, ERBE alleges that Canady's accused products indirectly infringe the asserted claims of the '745 patent through contributory infringement and inducement. To prevail on its allegations of indirect infringement, ERBE must first prove that the asserted claims of the '745 patent have been directly infringed.²⁰¹ To prove direct infringement, "a patentee must either point to specific instances of direct infringement or show that the accused device necessarily infringes the patent in suit."²⁰² ERBE does not argue that the accused products necessarily infringe the '745 patent and thus pursuant to Ground Rule 8.2, ERBE has waived any such argument.²⁰³ Accordingly, to

²⁰¹ Dynacore Holdings Corp. v. U.S. Philips Corp., 363 F.3d 1263, 1272 (Fed Cir. 2004) ("Indirect infringement, whether inducement to infringe or contributory infringement, can only arise in the presence of direct infringement."); *Linear Tech. Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1326 (Fed. Cir. 2004) ("There can be no inducement or contributory infringement without an underlying act of direct infringement.").

²⁰² ACCO Crands, Inc. v. ABA Locks Manufactureer Co., Ltd., 501 F.3d 1307, 1313 (Fed Cir. 2007)

²⁰³ See infra, at V.B.1.a., c. (discussing noninfringing uses of accused products).

prove direct infringement, ERBE must point to specific instances of direct infringement.

1. Claims 1 and 35

a. KLS Martin Probes

(1) KLS Martin 1.5 mm probes (part no. 1322535)

ERBE alleges that the North Carolina Baptist Hospital (NCBH) uses KLS Martin 1.5 mm probes to directly infringe claims 1 and 35 of the '745 patent.²⁰⁴ In support, ERBE relies entirely on the testimony of Ms. Sara Eisenbacher, manager of the digestive health center endoscopy suite at NCBH. At the hearing, Ms. Eisenbacher testified as to the following pertinent facts: (1) NCBH performs Argon Plasma Coagulation ("APC") procedures in bronchoscopy;²⁰⁵ (2) in the last fiscal year, NCBH has performed approximately twelve APC bronchoscopy procedures;²⁰⁶ (3) NCBH uses APC units with generator systems made by ERBE;²⁰⁷ (4) the APC units have a default setting of 0.3 liters/min;²⁰⁸ (5) the APC bronchoscopy procedures are performed using 1.5 mm probes;²⁰⁹ (6) over the last fiscal year NCBH has utilized both Canady and ERBE probes;²¹⁰ (7) at the time NCBH started ordering Canady probes, it is not known the number of ERBE probes in inventory;²¹¹ (8) NCBH purchased twenty Canady 1.5 mm probes of which nine probes remain in inventory;²¹² and (9) there are many ways that a probe can be pulled from inventory without having been used on a

- ²⁰⁸ *Id.* at 456:12-23.
- ²⁰⁹ *Id.* at 457:4-7.
- ²¹⁰ *Id.* at 454:2-5.
- ²¹¹ Id. at 458:5-16, 465:5-10.
- ²¹² *Id.* at 454:19-455:2.

²⁰⁴ *See* CIB at 31, 42.

²⁰⁵ See Tr. at 452:6-9 (Aug. 27, 2007).

²⁰⁶ *Id.* at 452:10–19.

²⁰⁷ *Id.* at 452:20-25.

patient, including being misplaced in inventory, used for management, or used for review in the institution.²¹³

ERBE argues that "it is more likely than not that eleven KLS Martin probes have been used in APC procedures in bronchoscopy at NCBH during its previous fiscal year."²¹⁴ However, the evidence of record does not support such a conclusion. The evidence of record merely establishes that NCBH purchased 20 Canady 1.5 mm probes, performed approximately 12 APC bronchoscopy procedures in the last fiscal year, and that 11 Canady 1.5 mm probes are no longer in inventory. Contrary to ERBE's argument, the absense of 11 Canady probes from inventory does not establish their use in bronchoscopy procedures.

As stated above, Ms. Eisenbacher testified that there are many ways that a probe can be pulled from inventory without having been used on a patient, including being misplaced in inventory, used for management, or used for review in the institution.²¹⁵ Additionally, when explicitly asked whether she had "any reason to believe that no Canady probes have been used on patients," Ms. Eisenbacher answered that "[u]ntil I were to go through medical records, I cannot - I cannot presume any information on what was used and what was not used."²¹⁶ Further, Ms. Eisenbacher testified that she did not know how many ERBE 1.5mm probes were in inventory at the time NCBH began purchasing KLS Martin 1.5 mm probes from Canady.²¹⁷ Thus, while approximately twelve APC procedures were performed at NCBH over the last fiscal year, there is no evidence of record

²¹³ *Id.* at 455:21-456:5.

²¹⁴ CRB at 21 n.15.

²¹⁵ Tr. at 455:21-456:5.

²¹⁶ *Id.* at 456:9-11.

²¹⁷ Id. at 458:5-16, 465:5-10.

regarding how many of those procedures were performed using ERBE probes and how many, if any, were performed using KLS Martin 1.5 mm probes purchased from Canady. Ms. Eisenbacher's testimony on this point is entirely inconclusive.

Moreover, ERBE has failed to prove that any 1.5 mm KLS Martin probe sold by Canady has an electrode positioned inside the tube and offset from the opening at the distal end of the tube as required by claims 1 and 35 of the '745 patent. As construed herein, the limitation "an electrode . . . positioned inside the tube and offset from the opening at the distal end of the tube a predetermined minimum safety distance" of claim 1 and the limitation "an electrode, arranged . . . inside the tube and being offset from the opening at the distal end of the tube a predetermined minimum safety distance" of claim 35 require the electrode to be positioned inside the tube and offset from the opening at the distal end of the tube a predetermined distance that will not allow the electrode to contact tissue. ERBE admits that for KLS Martin probes, the electrode protrudes from the distal end of the tubing portion of the probe into the ceramic tip or endpiece.²¹⁸ Because the electrode in the KLS Martin probes extends beyond the end of the tube and into the ceramic endpiece, the electrode cannot be said to be positioned inside the tube and offset from the opening at the distal end of the tube a predetermined minimum safety distance as required by independent claims 1 and 35 of the '745 patent.²¹⁹

²¹⁸ See SFF ¶ 104; CX-65; CX-73; CPX-1; CPX-8.

²¹⁹ ERBE argues that even if the claim language of the '745 patent is interpreted to require an electrode offset from the end of the plastic tube and not the end of a ceramic insert, the Canady probes still infringe the '745 patent under the doctrine of equivalents. *See* CIB at 36. According to ERBE, an electrode recessed from the tip of a ceramic insert has the same function and result of protecting tissue from contact with the electrode and works in the same way by offsetting the electrode from the opening of the probe as an electrode offset from the end of the plastic tube. *Id*. ERBE did not include in its pre-hearing brief any doctrine of equivalents arguments with respect to

Additionally, ERBE has failed to prove any specific instance of a KLS Martin 1.5 mm probe

having been used in an APC procedure in a manner such that the longitudinal axis of the tube is arranged "sidewardly" of the area of tissue to be coagulated. As construed herein, the limitation "sidewardly" means alongside. Thus, to satisfy this claim element, ERBE must show that NCBH used a KLS Martin 1.5 mm probe in an APC procedure where the longitudinal axis of the tube was arranged alongside the area of tissue to be coagulated. The only evidence of record on this point comes from Ms. Eisenbacher who testified as follows:

- Q. Have you ever observed any APC procedures in bronchoscopy?
- A. Yes.
- Q. When you are doing an APC procedure in bronchoscopy, is it typical for the physician to aim the probe at the tissue to be coagulated?
- A. Certainly.

Even if it had not been waived, however, the undersigned finds ERBE's argument entirely deficient. ERBE's argument consists of nothing more than one sentence of attorney argument with no citation to any record evidence. Infringement under the doctrine of equivalents is a question of fact that requires evidence. See Hebert v. Lisle Corp., 99 F.3d 1109, 1117 (Fed. Cir. 1996) ("Questions of the technologic equivalency of a claimed invention and an accused device are ... questions of fact, and require determination by the trier of fact, based on evidence."). Moreover, Claims 1 and 35 both expressly require the electrode to be positioned "inside the tube." However, under ERBE's DOE argument, the electrode would be disposed outside the tube. Thus, ERBE's argument completely vitiates the "inside the tube" limitation of claims 1 and 35, in violation of the all-elements rule. See K-2 Corp. v. Salomon S.A., 191 F.3d 1356, 1367 (Fed. Cir. 1999) ("It is also fundamental that the text of the claim must be closely followed: each element contained in a patent claim is deemed material to defining the scope of the patented invention, and thus the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole. Therefore, the doctrine of equivalents cannot be used to vitiate an element from the claim in its entirety.")(internal quotations and citations omitted); see also Tronzo v. Biomet, Inc., 156 F.3d 1154, 1160 (Fed. Cir. 1998) ("If a theory of equivalence would vitiate a claim limitation, however, then there can be no infringement under the doctrine of equivalents as a matter of law."). Accordingly, for the reasons discussed above, even if ERBE had not waived its DOE argument, the undersigned would still find no equivalency.

the limitations of claims 1 and 35 requiring an electrode positioned "inside the tube" and "offset from the opening at the distal end of the tube." *See* CPHB at 36-62. Accordingly, pursuant to Ground Rule 8.2, ERBE has waived any such arguments.

- Q. What percentage of the time are they able to aim directly at tissue, if they are in a bronchi?
- A. Depends on the lesion location. . . . However, if the lesion is completely lateral to your view, you must angulate the endoscope to have the lesion in view to be able to apply the therapy.²²⁰

ERBE argues that Ms. Eisenbacher testified that in some procedures the physician must angulate the endoscope to be able to coagulate the tissue and that this testimony satisfies the claim limitation of claims 1 and 35 requiring the longitudinal axis of the tube arranged alongside the area of tissue to be coagulated. The undersigned disagrees.

As Ms. Eisenbacher plainly testified, when the "lesion is completely lateral to your view" (i.e., the probe is arranged alongside the lesion), "you must angulate the endoscope to have the lesion in view" (i.e., the endoscope must be moved from its position alongside the lesion to a position where the endoscope is at an angle to the tissue to be coagulated). In light of Ms. Eisenbacher's testimony that when a lesion is alongside the probe, the physician must move the endoscope from its sidewardly position to one that is at an angle to the tissue to be coagulated, the undesigned finds ERBE has failed to prove that a KLS Martin 1.5 mm probe was used in an APC procedure where the longitudinal axis of the tube is arranged sidewardly of the area of tissue to be coagulated as required by claims 1 and 35 of the '745 patent.

Further, ERBE has failed to prove a specific instance where NCBH used a KLS Martin 1.5 mm probe in an APC procedure with an endoscope having a plurality of working channels. ERBE relies entirely on Ms. Eisenbacher's testimony that the Olympus bronchoscope used by NCBH has built-in optics to conclude that the endoscope used by NCBH has a second working channel.²²¹

²²⁰ Tr. 458:20-459:12.

²²¹ *See* CRB at 24.

However, there is no testimony in the record that each of the alleged working channels in the Olympus bronchoscope used by NCBH extend between the two ends of the endoscope or have a predetermined diameter as required by claims 1 and 35 of the '745 patent. Moreover, there is no testimony that the endoscope has at least two working channels that are capable of having a device that performs work inserted there through. In fact the testimony is inopposite. Specifically, Ms. Eisenbacher testified as follows:

Q. Now, with respect to the Olympus bronchoscope that you mentioned, how many channels does that have into which a probe can be inserted?

A. One.

- Q. So there is only one channel that the APC probe can be inserted into?
- A. Into our inventory, correct.²²²

Accordingly, the undersigned finds ERBE has failed to prove that a KLS Martin 1.5 mm probe has been used by anyone at NCBH in an APC procedure with an endoscope having a plurality of working channels as required by claims 1 and 35 of the '745 patent.

To prove direct infringement, ERBE must prove that a KLS Martin 1.5 mm probe was actually used in a way that infringes the asserted claims of the '745 patent. As discussed above, ERBE has failed to establish that NCBH has ever used a KLS Martin 1.5 mm probe in an APC procedure. Additionally, even if the evidence showed that NCBH had actually used a KLS Martin 1.5 mm probe in an APC procedure, ERBE has failed to prove that the probes are used in a manner that infringes claims 1 and 35 of the '745 patent. Specifically, ERBE has failed to at least prove: (1) that a KLS Martin 1.5 mm probe satisfies the limitations of the asserted claims requiring an electrode

²²² Tr. 462:9-16 (Aug. 27, 2007).

positioned "inside the tube" and "offset from the opening at the distal end of the tube a predetermined minimum safety distance;" (2) that a KLS Martin 1.5 mm probe was used with an endoscope having a plurality of working channels; and (3) that a KLS Martin 1.5 mm probe was used in a procedure where the longitudinal axis of the tube was arranged sidewardly of the tissue to be coagulated. Accordingly, the undersigned finds that ERBE has failed to prove that KLS Martin 1.5 mm probes (part no. 1322535) imported and sold by Canady directly infringe either independent claim 35 of the '745 patent.

(2) KLS Martin 2.3 mm probes (part nos. 1322537, 1322538)

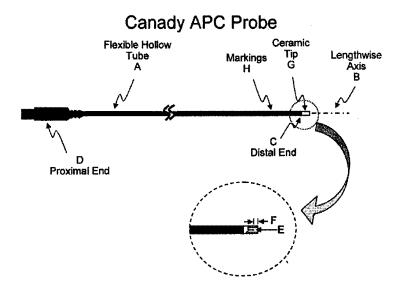
ERBE alleges that the Cleveland Clinic Foundation uses KLS Martin 2.3 mm probes (part no. 1322537) to directly infringe claim 1 of the '745 patent.²²³ Additionally, ERBE alleges that the Cleveland Clinic Foundation, Mayo Clinic, MetroHealth General Hospital, Indiana University Hospital and Georgetown University Hospital use of KLS Martin 2.3 mm probes (part nos. 1322537, 1322538) directly infringes claim 35 of the '745 patent.²²⁴

Exhibit CX-65, reproduced below, is a drawing of an exemplary KLS Martin probe created by ERBE's expert, Dr. Walbrink, based upon his inspection of a sample KLS Martin probe.²²⁵

²²³ CIB at 31.

²²⁴ *Id.* at 42.

²²⁵ See CIB at 34-35; CX-2C at 248-49.



As can be plainly seen in the above drawing, the electrode in a KLS Martin probe extends beyond the end of the tube and into the ceramic insert.²²⁶ In fact, ERBE admits that for KLS Martin probes, the electrode protrudes from the distal end of the tubing portion of the probe into the ceramic tip or endpiece.²²⁷

As construed herein, the limitation "an electrode . . . positioned inside the tube and offset from the opening at the distal end of the tube a predetermined minimum safety distance" of claim 1 and the limitation "an electrode, arranged . . . inside the tube and being offset from the opening at the distal end of the tube a predetermined minimum safety distance" of claim 35 require the electrode to be positioned inside the tube and offset from the opening at the distal end of the tube a predetermined distance that will not allow the electrode to contact tissue. Because the electrode in a KLS Martin probe extends beyond the opening at the distal end of the tube and into the ceramic endpiece, the electrode cannot be said to be positioned inside the tube and offset from the opening

²²⁶ See CX-65; see also CX-73, CPX-1, CPX-8.

²²⁷ See SFF ¶ 104.

at the distal end of the tube a predetermined minimum safety distance as required by claims 1 and 35.²²⁸

Additionally, ERBE has failed to prove a specific instance where a KLS Martin 2.3 mm probe has been used in an APC procedure with an endoscope having a plurality of working channels. In its opening post-hearing brief, ERBE relies entirely on the testimony of its expert, Mr. Walbrink, and illustrations of two exemplary endoscopes to support its argument that a KLS Martin 2.3 mm probe has been used with an endoscope having a plurality of working channels.²²⁹ In its reply posthearing brief, ERBE switches gears and specifically points to the testimony of various KLS Martin 2.3 mm probe users that ERBE's alleges use an endoscope with a plurality of working channels.²³⁰

The exemplary endoscope shown in Exhibit CX-59 has an instrument channel, two light guide lenses, an air/water nozzle, and auxiliary water channel and an objective lens.²³¹ The exemplary endoscope shown in SX-11 has a biopsy channel, air/water nozzle, objective lens, a water jet, and a light guide lens.²³² According to Mr. Walbrink, each of the channels, lenses, water jets, etc. in the exemplary endoscopes are working channels since each is used to perform work such as diagnosis, washing, lighting an area, or manipulating an instrument.²³³ However, the limitation

²²⁸ ERBE again argues that even if the claim language of the '745 patent is interpreted to require an electrode offset from the end of the plastic tube and not the end of a ceramic insert, the Canady probes still infringe the '745 patent under the doctrine of equivalents. *See* CIB at 36. As discussed *supra*, the undersigned finds that ERBE has waived any such argument. Moreover, even if ERBE had not waived its DOE argument, as discussed *supra*, the undersigned would still find no equivalency. *See* supra, at n.213.

²²⁹ See CIB at 32-33, 42.

²³⁰ See CRB at 23-24.

²³¹ See CX-59.

²³² See SX-11.

²³³ See Tr 826:11-830:6 (Aug. 29, 2007).

"working channel" has been construed herein as a channel through which a device that performs work may be inserted. Thus, contrary to Mr. Walbrink's testimony, each of the exemplary endoscopes only has one working channel, labeled instrument channel in CX-59 and biopsy channel in SX-11.

As stated above, the limitation " working channel" has been construed herein as a channel through which a device that performs work may be inserted. Of the various KLS Martin 2.3 mm probe users cited by ERBE in its reply post-hearing brief, only Dr. Ferguson from MetroHealth and Dr. Al-Kawas from Georgetown University Hospital testified that they have used endoscopes with a plurality of working channels.²³⁴ Notably, both doctors indicated that such endoscopes are used only on occasion.²³⁵ Although both Dr. Ferguson and Dr. Al-Kawas testified to having used on occasion endoscopes with a plurality of working channels, the record is devoid of any evidence that on any occasion where such an endoscope was used that a KLS Martin 2.3 mm probe was used therewith. Thus, the undersigned finds ERBE has failed to prove a specific instance where a KLS Martin 2.3 mm probe was used in an APC procedure with an endoscope having a plurality of working channels as required by claims 1 and 35 of the '745 patent.

To prove direct infringement, ERBE must prove that a KLS Martin 2.3 mm probe was actually used in a way that infringes the asserted claims of the '745 patent. As discussed above, ERBE has failed to establish that a KLS Martin 2.3 mm probes has actually been used in an APC procedure in a manner that infringes claims 1 and 35 of the '745 patent. Specifically, ERBE has failed to at least prove: (1) that a KLS Martin 2.3 mm probe satisfies the limitations of the asserted

²³⁴ See JX-27 at 000078:13-17; JX-25 at 000013:7-11.

²³⁵ Id.

claims requiring an electrode positioned "inside the tube" and "offset from the opening at the distal end of the tube a predetermined minimum safety distance;" and (2) that a KLS Martin 2.3 mm probe was used with an endoscope having a plurality of working channels. Accordingly, the undersigned finds that ERBE has failed to prove that KLS Martin 2.3 mm probes (part nos. 1322537, 1322538) imported and sold by Canady directly infringe either independent claim 1 or independent claim 35 of the '745 patent.

b. Soring Probes (part nos. S-422537, S-422538)

ERBE alleges that the Grace/Valdese Hospital uses Soring 2.3mm probes (part no. S-422537) to directly infringe claim 1 of the '745 patent.²³⁶ ERBE also alleges that the Grace/Valdese Hospital and MetroHealth General Hospital use Soring 2.3 mm probes (part no. S-422537) to directly infringe claim 35 of the '745 patent.²³⁷

ERBE does not allege that any institution uses the accused Soring 2.3 mm probes (part no. S-422538) in a manner that directly infringes either claim 1 or claim 35 of the '745 patent.²³⁸ However, in a footnote ERBE argues that if the Soring 2.3 mm probes (part no. S-422537) infringed the asserted claims of the '745 patent, then the Soring 2.3 mm probes (part no. S-422538) also infringe the asserted claims.²³⁹ According to ERBE, Dr. Canady testified that the 2.3 mm Soring probes (part no. S-422538) have the same flow characteristics as the 2.3 mm Soring probes (part no. S-422537), that Canady's counsel represented in its opening statement that the two probes should be treated the same for infringement purposes, and that Canady represented in its 510(k) application

²³⁶ CIB at 31.

²³⁷ *Id.* at 42.

²³⁸ See id. at 30-56.

²³⁹ See id. at 31 n.31.

that the differences in lengths between the predicate ERBE probes and the KLS Martin probes did not cause any difference in flow resistance.²⁴⁰ As previously discussed, to prove direct infringement ERBE must point to specific instances of direct infringement. "Hypothetical instances of direct infringement are insufficient to establish vicarious liability or indirect infringement."²⁴¹ Even assuming *arguendo* that Soring probes with part number S-422538 were to be treated the same as Soring 2.3 mm probes with part number S-422537 for purposes of infringement, that does not relieve ERBE of its obligation to prove a specific instance of direct infringement using a Soring 2.3 mm probe (part no. S-422538). The record in this investigation contains no evidence of anyone having used a Soring 2.3 mm probe (part no. S-422538) in an infringing manner. Accordingly, the undersigned finds that ERBE has failed to prove that Soring 2.3 mm probes (part no. S-422538) directly infringe either independent claim 1 or independent claim 35 of the '745 patent.

With regard to the Soring 2.3 mm probes (part no. S-422537), a dispute exists over the proper structure of the probes. Specifically, the parties dispute the position of the electrode in the probes. ERBE argues that a visual inspection of the Soring 2.3 mm probes shows that each includes a recessed electrode.²⁴² ERBE also argues that Canady's 510(k) application supports a finding that the electrode in a Soring 2.3 mm probe is recessed.²⁴³ In contrast, both Canady and the Staff argue that the record evidence shows the electrode in a Soring 2.3 mm probe is not recessed from the distal end of the tube, but rather the electrode is flush with the end of the tube or slightly protruding from it.²⁴⁴

²⁴⁴ RIB at 42-43; SIB at 54; SRB at 29-30.

²⁴⁰ *Id*.

²⁴¹ See ACCO Brands, 501 F.3d at 1313.

²⁴² CRB at 26.

²⁴³ Id.

In support, Canady and the Staff cite to the testimony of Dr. Canady, a mammogram of a Soring 2.3mm probe, and an assembly drawing of a Soring 2.3 mm probe.²⁴⁵

ERBE argues that by visual inspection of the Soring 2.3 mm probes the undersigned can conclude that the electrode satisfies the limitations of claims 1 and 35.²⁴⁶ The undersigned has visually inspected the Soring probes admitted as Exhibits CPX-10 and CPX-11 and finds it impossible to tell with any certainty where the electrode is located within the scant opening at the end of a 2.3mm Soring probe. The electrode inside the probe appears to be about as thick as a human hair and just being able to tilt the end of the probe under a light in a way that allows one to find the electrode in the opening at the end of the probe is very difficult. Moreover, once the electrode is found it is impossible to determine whether it is flush with the end of the tube or recessed from the opening as ERBE suggests.

ERBE also argues that Canady's 510(k) application²⁴⁷ to the United States Food and Drug Administration ("FDA") establishes that the electrode in a Soring 2.3 mm probe is offset from the end of the tube.²⁴⁸ As submitted, Canady's 510(k) application only applies to KLS Martin probes.²⁴⁹

²⁴⁵ *Id*.

²⁴⁶ See CRB at 26. Notably, ERBE chose not to have any of its experts examine the Soring 2.3 mm probes. ERBE also did not have any of its experts opine or testify about the structure of the Soring 2.3 mm probes.

 $^{^{247}}$ "510(k) notifications are submittals of engineering and clinical information which are provided to the FDA to permit that agency to assess the safety and effectiveness of a new product with regard to a predicate product which is already on the market." *Cardiovention, Inc. v. Medtronic, Inc.*, 483 F. Supp. 2d 830, 840 (D. Minn. 2007) (quoting *Sunrise Med. HHG, Inc. v. AirSep Corp.*, 95 F. Supp. 2d 348, 405 (W.D. Pa. 2000)). In the 510(k) context, "substantial equivalence" means that the proposed device has the same intended use as the predicate device and that it either has the same technological characteristics as the predicate device or is as safe and effective as the predicate device. *See* 21 C.F.R. § 807.100(b).

²⁴⁸ See CIB at 35.

²⁴⁹ See CX-183 at 2, 7, 11.

However, at the hearing in this investigation, Dr. Canady testified that he believed the 510(k) application also covered Soring probes.²⁵⁰ Based on this testimony, ERBE argues that a statement in Canady's 510(k) application describing the placement of the electrode in the KLS Martin probes as recessed 1-2 mm supports a finding that "every Soring [2.3 mm] probe has the electrode set back from the distal opening a predetermined minimum distance for safety purposes."²⁵¹

Although Dr. Canady did testify that he believed the 510(k) application covered the accused Soring probes, he made clear that his testimony should not be taken to mean that he believed the KLS Martin probes were equivalent to the Soring probes in all respects, but only that they were equivalent in their intended use.²⁵² In fact, in contrast to the statement in the 510(k) application, Dr. Canady testified that in the Soring probes the electrode is either flush with the end of the ceramic insert or protrudes slightly therefrom.²⁵³ Furthermore, when asked whether there is a difference in the construction of the Soring probes and the KLS Martin probes, Dr. Canady testified that there was a difference with regard to the placement of the electrode.²⁵⁴ In light of the above testimony of Dr. Canady, the undersigned finds ERBE's 510(k) argument unpersuasive. The record simply does not

²⁵⁰ See Tr. at 1330:10-15 (Aug. 31, 2007)("Q. And do you believe that the Soring probes that fit to the CT-3500 are covered by the same 510(k) for which the Soring probe – for which the KLS Marin probes had been cleared? A. Yes."); see also JX-23C at 108:4-6.

²⁵¹ See CIB at 35; CX-183 at 15 ("[r] eccessed positioned in the ceramic tip (1-2 mm to the outlet) is an electrode made of tungsten.").

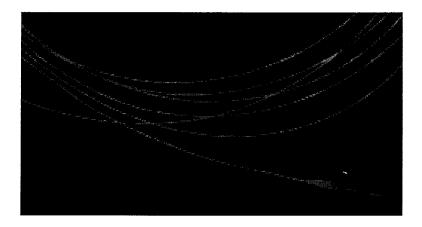
²⁵² See Tr. at 1330:10-20 (Aug. 31, 2007)("Q. So you believe that the KLS Martin probes and the Soring probes are equivalent probes? A. They are equivalent in its intended use, yes.").

²⁵³ *Id.* at 1334:19-1335:3 (Aug. 31, 2007)("This is the third time I will say the Soring probes sit just flush or just outside the ceramic tip. They do not recess back from the ceramic tip."); *see also id.* at 1332:4-11.

²⁵⁴ *Id.* at 1337:1-8 ("Q. Okay. So there is a difference in the construction of the Soring probes from the KLS Martin probes with regards to the electrode's positioning vis-avis the ceramic tip? A. Yeah, there is a difference of the KLS Martin's wire outside of the tubing, but it is set back a little bit from the opening of the ceramic tip versus the Soring probe.").

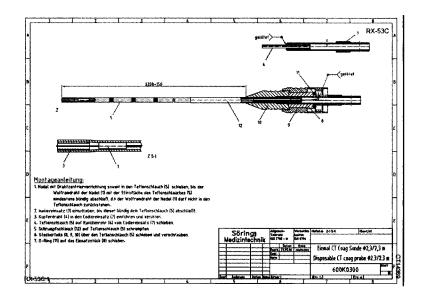
support the conclusion that when Dr. Canady testified that the 510(k) application "covered" the Soring probes that he intended the specific structural details of the KLS Martin probes described in the 510(k) application to also describe the accused Soring 2.3 mm probes.

Moreover, the record evidence relied on by the Staff and Canady further supports Dr. Canady's testimony regarding the placement of the electrode in the Soring probes. As seen below, an image of a Soring 2.3mm probe created by x-ray mamography shows the electrode flush or slightly protruding from the end of the ceramic insert.²⁵⁵



In addition, the assembly drawing below plainly shows and describes the placement of the electrode in a Soring 2.3 mm probe as being at least flush with the end of the ceramic insert.²⁵⁶

 ²⁵⁵ See RX-56; see also Tr. at 1247:3-6, 1250:14:18 (Aug, 31, 2007).
 ²⁵⁶ RX-53C.



As translated, the assembly instructions enumerated in the above assembly drawing state, in pertinent part:

1. Slide the needle with wire-centering device into the Teflon tube (5) until the end of the Tungsten wire of the needle (1) is at least flush with the end face of the Teflon tube (5), i.e. the Tungsten wire of the needle (1) should not be recessed into the Teflon tube.

2. Slide in the insulating insert (3) until it is flush with the Teflon tube (5).²⁵⁷

Accordingly, based on the above evidence of record, the undersigned finds the electrode in a Soring

2.3 mm probe is at least flush with the end of the tube.

As construed herein, the limitation "an electrode . . . positioned inside the tube and offset from the opening at the distal end of the tube a predetermined minimum safety distance" of claim 1 and the limitation "an electrode, arranged . . . inside the tube and being offset from the opening at the distal end of the tube a predetermined minimum safety distance" of claim 35 require the electrode to be positioned inside the tube and offset from the opening at the distal end of the tube a

²⁵⁷ *See* RX-54C.

predetermined distance that will not allow the electrode to contact tissue. Because the electrode in a Soring 2.3 mm probe is at least flush with the distal end of the tube, the electrode cannot be said to be offset from the opening at the distal end of the tube a predetermined minimum safety distance. Thus, contrary to ERBE's argument, the record evidence demonstrates that the accused Soring probes (part no. S-422537) do not satisfy every limitation of either independent claim 1 or independent claim 35 of the '745 patent.²⁵⁸

Additionally, ERBE has failed to prove that either Grace/Valdese Hospital or MetroHealth General Hospital has used a Soring 2.3 mm probe in an APC procedure with an endoscope having a plurality of working channels as required by claims 1 and 35. In its opening post-hearing brief, ERBE cites only to the testimony of its expert, Mr. Walbrink, and the illustrations of two exemplary endoscopes to prove that a Soring 2.3 mm probe has been used with an endoscope having a plurality of working channels.²⁵⁹ In its reply post-hearing brief, ERBE also relies on the testimony of Ms. Marshburn from Grace/Valdese Hospital for support.²⁶⁰

The exemplary endoscope shown in Exhibit CX-59 has an instrument channel, two light guide lenses, an air/water nozzle, and auxiliary water channel and an objective lens.²⁶¹ The exemplary endoscope shown in SX-11 has a biopsy channel, air/water nozzle, objective lens, a water

²⁵⁸ ERBE again argues that even if the claim language of the '745 patent is interpreted to require an electrode offset from the end of the plastic tube and not the end of a ceramic insert, the Canady probes still infringe the '745 patent under the doctrine of equivalents. *See* CIB at 36. As discussed *supra*, the undersigned finds that ERBE has waived any such argument. Moreover, even if ERBE had not waived its DOE argument, as discussed *supra*, the undersigned would still find no equivalency. *See* supra, at n.213.

²⁵⁹ See CIB at 32-33, 42.

²⁶⁰ *See* CRB at 25.

²⁶¹ *See* CX-59.

jet, and a light guide lens.²⁶² According to Mr. Walbrink, each of the channels, lenses, water jets, etc. in the exemplary endoscopes are working channels since each is used to perform work such as diagnosis, washing, lighting an area, or manipulating an instrument.²⁶³ However, the limitation "working channel" has been construed herein as a channel through which a device that performs work may be inserted. Thus, contrary to Mr. Walbrink's testimony, each of the exemplary endoscopes only has one working channel, labeled instrument channel in CX-59 and biopsy channel in SX-11.

With regard to Ms. Marshburn's testimony, the record shows that when Grace/Valdese Hospital performs an APC procedure with a Soring probe, it uses a gastroscope with a lumen for suction, air and biopsy.²⁶⁴ According to Ms. Marshburn, during an APC procedure a Soring 2.3 mm probe is inserted through the biopsy channel of the gastroscope.²⁶⁵ In addition to having a lumen for suction, air and biopsy, the record also shows that the gastroscope has a lens with a cord that runs through the endoscope and connects with a computer monitor for viewing.²⁶⁶ Thus, ERBE argues that the endocope used by Grace/Valdese has two working channels, one in which the probe is inserted and another in which the lens is disposed.²⁶⁷ However, as construed herein, a "working channel" is a channel through which a device that performs work may be inserted. Thus, contrary to ERBE's argument, the endoscope used by Grace/Valdese Hospital has only one working channel, the biospy channel. Accordingly, the undersigned finds that ERBE has failed to prove that a 2.3 mm

²⁶² See SX-11.

²⁶³ See Tr 826:11-830:6 (Aug. 29, 2007).

²⁶⁴ JX-19 at 13:25-14:8.

²⁶⁵ *Id.* at 11:1-7.

²⁶⁶ *Id.* at 22:3-21.

²⁶⁷ CRB at 25.

Soring probe has been used with an endoscope having a plurality of working channels as required by both independent claim 1 and independent claim 35 of the '745 patent.

Further, with regard to both claims 1 and 35 of the '745 patent, ERBE has failed to prove any specific instance of a Soring 2.3 mm probe having been used by Grace/Valdese Hospital in an APC procedure in a manner such that the longitudinal axis of the tube is arranged "sidewardly" of the area of tissue to be coagulated. As construed herein, the limitation "sidewardly" means alongside. Thus, to satisfy this claim element with regard to claims 1 and 35, ERBE must show Grace/Valdese Hospital used a Soring 2.3 mm probe in an APC procedure where the longitudinal axis of the tube was arranged alongside the area of tissue to be coagulated.

The only evidence of record regarding Grace/Valdese Hospital that ERBE relies on to prove that the longitudinal axis of the tube is arranged "sidewardly" of the area of tissue to be coagulated comes from the deposition testimony of Ms. Cynthia H. Marshburn. Ms. Marshburn works at Grace/Valdese Hospital as a nurse for surgical services in the endoscopy lab.²⁶⁸ On this point, Ms. Marshburn testified, in pertinent part, as follows:

Mr. War: I'm going to hand you what's already been marked as Exhibit No. ITC 203. It's a different type of catheter, but I'd like you to take the end of the catheter, and with your hand, show me what the orientation between the catheter and the tissue that's being coagulated is that you typically see on the video screen.

The Witness: It's like you're looking at the TV screen. You're actually looking at the image of what you're – the polyp or whatever you're looking at. It's usually aimed right at it, straight to it.

Mr. War: Is it always aimed right at it?

The Witness: Yes, because the end of the catheter is straight. I mean, you may be

²⁶⁸ JX-19 at 000002:15-17, 000003:10-22.

looking – you may be – it's according to how he has the angle of the scope. It could be – like if you're looking at the lumen, he could be angled a little bit because of the folds, especially in the colon at a side, but you're aiming right at the tissue.²⁶⁹

ERBE argues that Ms. Marshburn's testimony stating that "he could be angled a little bit because of the folds" supports a conclusion that Grace/Valdese Hospital has used a Soring 2.3 mm probe in a manner where the probe is "sidewardly" of the tissue to be coagulated. The undersigned disagrees. Contrary to ERBE's argument, Ms. Marshburn explicitly testified that even if the probe is angled a little bit the probe is still aimed "right at the tissue."²⁷⁰ Additionally, Ms. Marshburn testified that the view on the TV screen of a polyp, or whatever is being looking at, is "right at it, straight to it."²⁷¹ Ms. Marshburn's testimony that the probe is oriented "right at the tissue" indicates that the probe is perpendicular to the tissue to be coagulated and not alongside the tissue as required by claims 1 and 35 of the '745 patent. Accordingly, the undersigned finds ERBE has failed to prove that a Soring 2.3 mm probe sold by Canady has been used by Grace/Valdese Hospital in an APC procedure where the longitudinal axis of the tube is arranged "sidewardly" of the area of tissue to be coagulated as required by both independent claim 1 and independent claim 35 of the '745 patent.

To prove direct infringement, ERBE must prove that a Soring 2.3 mm probe was actually used in a way that infringes the asserted claims of the '745 patent. As discussed above, ERBE has failed to prove that the probes are used in manner that infringes either independent claim 1 or independent claim 35 of the '745 patent. Specifically, ERBE has failed to at least prove: (1) that a Soring 2.3 mm probe satisfies the limitations of the asserted claims requiring an electrode positioned

²⁶⁹ *Id.* at 000024:9-000025:4.

²⁷⁰ *Id.* at 000025:1-4.

²⁷¹ *Id.* at 000024:17-20.

"offset from the opening at the distal end of the tube a predetermined minimum safety distance;" (2) that a Soring 2.3 mm probe has been used in an APC procedure with an endoscope having a plurality of working channels; and (3) that with regard to Grace/Valdese Hospital that anyone has used a Soring 2.3 mm probe in a procedure where the longitudinal axis of the tube was arranged sidewardly of the tissue to be coagulated. Accordingly, the undersigned finds that ERBE has failed to prove that Soring 2.3 mm probes (part no. S-422537) imported and sold by Canady directly infringe either independent claim 1 or independent claim 35 of the '745 patent.²⁷²

2. Claims 3, 4, 11, 13, 38, 39

As discussed, above, the undersigned finds that ERBE has failed to prove that any of the accused KLS Martin and Soring probes directly infringe either independent claim 1 or independent 35 of the '745 patent. Because neither independent claim 1 nor independent claim 35 is directly infringed, dependent claims 3, 4, 11, 13, 38, and 39, cannot be directly infringed. Accordingly, the undersigned finds that ERBE has failed to prove that any of the accused KLS Martin and Soring probes directly infringe claims 3, 4, 11, 13, 38, and 39, of the '745 patent.

B. Indirect Infringement

1. Contributory Infringement

a. KLS Martin 1.5 mm probes (part no. 1322535)

ERBE asserts that Canady contributes to the infringement of the asserted claims of the '745 patent by offering for sale, selling and importing the KLS Martin 1.5 mm probes (part no.

²⁷² The undersigned would find that the Soring 2.3 mm probes (part no. S-422538), do not directly infringe either independent claim 1 or independent claim 35 of the '745 patent for the same reasons relied on for the Soring 2.3 mm probes (part no. S-422537).

1322535).²⁷³ To prevail on its contributory infringement claim, ERBE must show that the KLS Martin 1.5 mm probes sold by Canady directly infringe the asserted claims of the '745 patent.²⁷⁴ As discussed *supra*, the undersigned finds ERBE failed to prove that the KLS Martin 1.5 mm probes were used in a manner that infringes the asserted claims. Accordingly, the undersigned finds Canady is not liable for contributory infringement with regard to the KLS Martin 1.5 mm probes (part no. 1322535).

Notwithstanding the above finding, even if ERBE had proven an act of direct infringement using a KLS Martin 1.5 mm probe, the undersigned would still find no contributory infringement. Under 35 U.S.C. § 271(c), a seller of a component of an infringing product can be held liable for contributory infringement if: "(1) there has been an act of direct infringement by a third party; (2) the accused contributory infringer knows that the combination for which its component was made was both patented and infringing; and (3) there are no substantial non-infringing uses for the component part."²⁷⁵ ERBE has the burden of establishing a *prima facia* case that the accused probes are not "suitable for substantially noninfringing use." Once it does so, the burden shifts to Canady to introduce evidence that end-users actually use the accused products in a noninfringing manner.²⁷⁶ Under 35 U.S.C. § 271(c), the determination of whether there are substantial non-infringing uses

²⁷³ CIB at 55.

²⁷⁴ Dynacore Holdings Corp. v. U.S. Philips Corp., 363 F.3d 1263, 1272 (Fed Cir. 2004) ("Indirect infringement, whether inducement to infringe or contributory infringement, can only arise in the presence of direct infringement."); *Linear Tech. Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1326 (Fed. Cir. 2004) ("There can be no inducement or contributory infringement without an underlying act of direct infringement.").

²⁷⁵ Flash Memory, Commission Opinion at 9-10.

²⁷⁶ Golden Blount, Inc. v. Robert H.Peterson Co., 438 F.3d 1354, 1363-64 (Fed. Cir. 2006); Lucent Techs., Inc. v. Gateway, Inc., 2007 U.S. Dist. LEXIS 19219 (D. Cal. 2007).

focuses on "the thing sold" by the one accused of contributing to infringement.²⁷⁷

ERBE argues that there are no substantial noninfringing uses of the KLS Martin 1.5 mm probes because the probes can only be used with ERBE APC systems and because almost all the flow rates within the default flow rate range of 0.0 to 1.0 liter per minute set by the instrument recognition feature of ERBE APC Systems are covered by the asserted claims of the '745 patent.²⁷⁸ Canady, on the other hand, argues that the KLS Martin 1.5 mm probes have substantial noninfringing uses. Specifically, Canady argues that use of the KLS Martin 1.5 mm probes in a manner that is not "sidewardly" of the tissue to be coagulated constitutes a substantial noninfringing use.²⁷⁹

There can be no dispute that the asserted claims of the '745 patent each require the probe to be positioned sidewardly of the tissue to be coagulated. Thus, use of a KLS Martin 1.5 mm probe in a manner that is not sidewardly of the tissue to be coagulated is a noninfringing use. The only evidence of record regarding the use of a KLS Martin 1.5 mm probe comes from Ms. Eisenbacher of NCBH. At the hearing, Ms. Eisenbacher testified as follows:

- Q. Have you ever observed any APC procedures in bronchoscopy?
- A. Yes.
- Q. When you are doing an APC procedure in bronchoscopy, is it typical for the physician to aim the probe at the tissue to be coagulated?
- A. Certainly.
- Q. What percentage of the time are they able to aim directly at the tissue, if they are in a bronchi?
- A. Depends on the lesion location. If you are looking down a tube, which

²⁷⁷ Hodosh v. Block Drug Co., Inc., 833 F.2d 1575, 1578 (Fed. Cir. 1987); see also Aquatex Industries, Inc. v. Techniche Solutions, 419 F.3d 1374, 1380 n.* * (Fed. Cir. 2005) (noting that the proper question for contributory infringement was whether defendant's product as sold was a staple article, not whether the product contained components that themselves could have other noninfringing uses).

²⁷⁸ See CIB at 55.

²⁷⁹ RIB at 32.

essentially is the bronchus, at the junction it bifurcates into a branch. If the lesion is directly in front of you, it is very easy to apply and direct the probe at a lesion. However, if the lesion is completely lateral to your view, you must angulate the endoscope to have the lesion in view to be able to apply the therapy.²⁸⁰

Ms. Eisenbacher's testimony makes plain that physicians at NCBH do not "typically" use the probes sidewardly of the tissue to be coagulated, but rather aim the probe at the tissue to be coagulated. Moreover, in cases where the lesion is at the junction of where the bronchi branches, Ms. Eisenbacher testified that it was very easy to apply and direct the probe at the lesion. In light of Ms. Eisenbacher's testimony, the undersigned finds that the use of a KLS Martin 1.5 mm probe in a manner that is not sidewardly of the tissue to be coagulated constitutes a substantial noninfringing use. Accordingly, the undersigned finds Canady not liable for contributory infringement under 35 U.S.C. 271(c) for its offer for sale, sale, or importation of KLS Martin 1.5 mm probes (part no. 1322535).

b. KLS Martin 2.3 mm probes (part nos. 1322537, 1322538)

ERBE asserts that Canady contributes to the infringement of claims 35, 37, and 39, of the '745 patent by offering for sale, selling and importing the KLS Martin 2.3 mm probes (part nos. 1322537, 1322538).²⁸¹ To prevail on its contributory infringement claim, ERBE must show that the KLS Martin 2.3 mm probes sold by Canady directly infringe the asserted claims of the '745 patent.²⁸² As discussed *supra*, the undersigned finds ERBE failed to prove that the KLS Martin 2.3 mm probes

²⁸⁰ Tr. 458:17-459:12 (Aug. 27, 2007).

²⁸¹ CIB at 55.

²⁸² Dynacore Holdings Corp. v. U.S. Philips Corp., 363 F.3d 1263, 1272 (Fed Cir. 2004) ("Indirect infringement, whether inducement to infringe or contributory infringement, can only arise in the presence of direct infringement."); *Linear Tech. Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1326 (Fed. Cir. 2004) ("There can be no inducement or contributory infringement without an underlying act of direct infringement.").

were used in a manner that infringes claims 35, 37, and 39 of the '745 patent. Accordingly, the undersigned finds Canady is not liable for contributory infringement with regard to the KLS Martin 2.3 mm probes (part nos. 1322537, 1322538).

c. Soring 2.3 mm probes (part nos. 422537, 422538)

ERBE asserts that Canady contributes to the infringement of claims 35, 37, and 39, of the '745 patent by offering for sale, selling and importing the Soring 2.3 mm probes (part nos. S-422537, S-422538).²⁸³ To prevail on its contributory infringement claim, ERBE must show that the Soring 2.3 mm probes sold by Canady directly infringe the asserted claims of the '745 patent.²⁸⁴ As discussed *supra*, the undersigned finds ERBE failed to prove that the Soring 2.3 mm probes were used in a manner that infringes claims 35, 37, and 39, of the '745 patent. Accordingly, the undersigned finds Canady is not liable for contributory infringement with regard to the Soring 2.3 mm probes (part nos. S-422537, S-422538).

Notwithstanding the above finding, even if ERBE had proven an act of direct infringement using the Soring 2.3 mm probes, the undersigned would still find no contributory infringement. Under 35 U.S.C. § 271(c), a seller of a component of an infringing product can be held liable for contributory infringement if: "(1) there has been an act of direct infringement by a third party; (2) the accused contributory infringer knows that the combination for which its component was made was both patented and infringing; and (3) there are no substantial non-infringing uses for the

²⁸³ CIB at 55-56.

²⁸⁴ Dynacore Holdings Corp. v. U.S. Philips Corp., 363 F.3d 1263, 1272 (Fed Cir. 2004) ("Indirect infringement, whether inducement to infringe or contributory infringement, can only arise in the presence of direct infringement."); *Linear Tech. Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1326 (Fed. Cir. 2004) ("There can be no inducement or contributory infringement without an underlying act of direct infringement.").

component part."²⁸⁵ ERBE has the burden of establishing a *prima facia* case that the accused probes are not "suitable for substantially noninfringing use." Once it does so, the burden shifts to Canady to introduce evidence that end-users actually use the accused products in a noninfringing manner.²⁸⁶ Under 35 U.S.C. § 271(c), the determination of whether there are substantial noninfringing uses focuses on "the thing sold" by the one accused of contributing to infringement.²⁸⁷

ERBE argues that there are no substantial noninfringing uses of the Soring 2.3 mm probes because the CT-3500 is sold with preset flow rate/wattage combinations, both Grace/Valdese and MetroHealth use the probes at 0.5 liters per minute, neither Ms. Marshburn of Grace/Valdese Hospital nor Dr. Ferguson of MetroHealth has identified a substantial noninfringing use, and at the Argon 1 and Argon 2 settings, all the flow rates within the preprogrammed flow rate ranges infringe claims 35, 37, 39 and 41.²⁸⁸ ERBE notes that Grace/Valdese Hospital purchases 82% of the Soring probes purchased (i.e., 900 out of 1,100) and argues that in light of the number of probes purchased by Grace/Valdese Hospital and their infringing use, Canady cannot show a substantial noninfringing use.²⁸⁹ Canady and the Staff argue to the contrary that the Soring 2.3 mm probes have substantial noninfringing uses.²⁹⁰ Specifically, both Canady and the Staff argue that the use of Soring 2.3 mm

²⁸⁵ Flash Memory, Commission Opinion at 9-10.

²⁸⁶ Golden Blount, Inc. v. Robert H.Peterson Co., 438 F.3d 1354, 1363-64 (Fed. Cir. 2006); Lucent Techs., Inc. v. Gateway, Inc., 2007 U.S. Dist. LEXIS 19219 (D. Cal. 2007).

²⁸⁷ Hodosh v. Block Drug Co., Inc., 833 F.2d 1575, 1578 (Fed. Cir. 1987); see also Aquatex Industries, Inc. v. Techniche Solutions, 419 F.3d 1374, 1380 n.* * (Fed. Cir. 2005) (noting that the proper question for contributory infringement was whether defendant's product as sold was a staple article, not whether the product contained components that themselves could have other noninfringing uses).

²⁸⁸ See CIB at 56.

²⁸⁹ Id.

²⁹⁰ See RRB at 27; SIB at 65-66.

probes in a manner where the extended longitudinal axis of the protruding end of the tube is not "sidewardly" of the tissue to be coagulated constitutes a substantial noninfringing use.²⁹¹

There can be no dispute that the asserted claims of the '745 patent each require the probe to be positioned sidewardly of the tissue to be coagulated. Thus, use of a Soring 2.3 mm probe in a manner that is not sidewardly of the tissue to be coagulated is a noninfringing use. As discussed in detail, *supra*, with regard to ERBE's allegations of direct infringement by Grace/Valdese Hospital, the record evidence in this investigation does not show that Grace/Valdese Hospital ever used a Soring 2.3 mm probe in a manner where the extended longitudinal axis of the protruding end of the tube was "sidewardly" of the tissue to be coagulated.²⁹² Moreover, Ms. Marshburn testified that when performing an APC procedure at Grace/Valdese Hospital the probe is always aimed right at the tissue.²⁹³ A probe aimed right at the tissue cannot be said to be alongside the tissue to be coagulated. Thus, using ERBE's own calculations from Exhibit CX-168C, the record evidence shows that 82% of Soring 2.3 mm probes sold by Canady are used in a noninfringing manner by Grace/Valdese Hospital.²⁹⁴

Additionally, the testimony of Dr. Ferguson from MetroHealth supports the conclusion that the Soring 2.3 mm probes have substantial noninfringing uses. Although Dr. Ferguson did testify that he has used a straight-fire probe in a manner where the probe is "tangential" to the tissue to be coagulated, he made clear that such use was only on occasion and only when MetroHealth was out

²⁹¹ Id.

²⁹² See supra, at V.A.1.b.

²⁹³ See JX-19 at 000024:9-000025:4.

²⁹⁴ See CX-168C; see also CIB at 56.

of stock of side-fire probes.²⁹⁵ Moreover, Dr. Ferguson explicitly testified that his typical practice is to point the opening at the end of the tube at the tissue to be coagulated.²⁹⁶ If the tube is pointed at the tissue to be coagulated, the tube cannot be said to be alongside the tissue. Thus, the testimony from Dr. Ferguson indicates that typically the Soring 2.3 mm probes are used in a noninfringing manner.

For the reasons discussed above, the undersigned finds that both Grace/Valdese Hospital and MetroHealth's use of Soring 2.3 mm probes in a manner where the extended longitudinal axis of the protruding portion of the tube is not "sidewardly" of the tissue to be coagulated constitutes a substantial noninfringing use. Accordingly, the undersigned finds Canady not liable for contributory infringement under 35 U.S.C. 271(c) for its offer for sale, sale, or importation of Soring 2.3 mm probes (part nos. S-422537, S-422538).

2. Inducement

a. KLS Martin Probes

ERBE asserts that Canady induces infringement of all the asserted claims of the '745 patent by its offer for sale, sale, and importation of KLS Martin 1.5 mm and 2.3 mm probes.²⁹⁷ To prevail on its claim of inducement, ERBE must show that the KLS Martin 1.5 mm and 2.3 mm probes sold by Canady directly infringe the asserted claims of the '745 patent.²⁹⁸ As discussed supra, the undersigned finds ERBE failed to prove that the KLS Martin 1.5 mm and 2.3 mm probes were used

²⁹⁵ See JX-27 at 000083:13-000084:1.

²⁹⁶ See id. at 000076:20-000077:1.

²⁹⁷ See CIB at 50.

²⁹⁸ Dynacore Holdings Corp., 363 F.3d at 1272 (Fed Cir. 2004); Linear Tech. Corp., 379 F.3d at 1326.

in a manner that directly infringes the asserted claims. Accordingly, the undersigned finds Canady is not liable for inducing infringement of the asserted claims of the '745 patent with regard to the accused KLS Martin 1.5 mm and 2.3 mm probes (part nos. 1322535, 1322537, 1322538).

b. Soring Probes

ERBE asserts that Canady induces infringement of all the asserted claims of the '745 patent by its offer for sale, sale, and importation of Soring 2.3 mm probes.²⁹⁹ To prevail on its claim of inducement, ERBE must show that the Soring 2.3 mm probes sold by Canady directly infringe the asserted claims of the '745 patent.³⁰⁰ As discussed supra, the undersigned finds ERBE failed to prove that the Soring 2.3 mm probes were used in a manner that directly infringes the asserted claims. Accordingly, the undersigned finds Canady is not liable for inducing infringement of the asserted claims of the '745 patent with regard to the accused Soring 2.3 mm probes (part nos. S-422537, S-422538).

Notwithstanding the above finding, even if ERBE had proven an act of direct infringement using the Soring 2.3 mm probes, the undersigned would still find no inducement. Under 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). To sustain its claim for inducement, ERBE must prove that once Canady knew of the patent, Canady actively and knowingly aided and abetted another's direct infringement.³⁰¹ It is not enough, however, for Canady to merely have knowledge of the acts alleged to constitute

²⁹⁹ See CIB at 50, 54-56.

³⁰⁰ Dynacore Holdings Corp., 363 F.3d at 1272 (Fed Cir. 2004); Linear Tech. Corp., 379 F.3d at 1326.

³⁰¹ DSU Medical Corp. v. JMS Co., Ltd., 471 F.3d 1293, 1305 (Fed. Cir. 2006).

infringement.³⁰² "The mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven."³⁰³

ERBE argues that Canady knows that when it sells Soring 2.3 mm probes that the probes will be used at low flow rates because Canady sells the CT-3500 with default flow rates of 0.5 lpm, 1.0 lpm, and 1.5 lpm.³⁰⁴ In addition, ERBE asserts that Dr. Canady demonstrated the CT-3500 to Dr. Ferguson at MetroHealth using a starting flow rate of 0.5 lpm.³⁰⁵ Also, ERBE asserts that Dr. Canady suggested to Grace/Valdese Hospital that they should use the lower flow rates.³⁰⁶ Further, ERBE argues that because Canady asserts its 510(k) clearance applies to the Soring probes that Canady must "intend for the Soring probes to be used in a similar, infringing manner as KLS Martin probes."³⁰⁷ Further, ERBE asserts that Dr. Canady testified in his deposition that there was no

³⁰² *Id*.

³⁰⁴ CIB at 54.

³⁰⁵ *Id*.

 307 Id. The 510(k) application submitted to the FDA is written only for probes manufactured by KLS Martin. See CX-183 at 00002-00007,00011. However, at the hearing in this investigation, Dr. Canady testified that he believed the 510(k) application also applied to its Soring probes. See Tr. at 1330:10-15, 1330:24-1331:15 (Aug. 31, 2007). To the extent that ERBE is relying on any statements in the 510(k) application regarding the equivalence of the KLS Martin probes (and by extension under ERBE's argument the Soring probes) and the ERBE probes that are listed as the predicate devices in the 510(k) application to prove that the Soring probes are equivalent to the ERBE predicate probes for purposes of patent infringement, the undersigned finds error.

"510(k) notifications are submittals of engineering and clinical information which are provided to the FDA to permit that agency to assess the safety and effectiveness of a new product with regard to a predicate product which is already on the market." *Cardiovention, Inc. v. Medtronic, Inc.*, 483 F. Supp. 2d 830, 840 (D. Minn. 2007) (quoting *Sunrise Med. HHG, Inc. v. AirSep Corp.*, 95 F. Supp. 2d 348, 405 (W.D. Pa. 2000)). In the 510(k) context, "substantial equivalence" means that the proposed device has the same intended use as the predicate device and that it either has the same technological characteristics as the predicate device or is as safe and effective as the predicate device. *See* 21 C.F.R. § 807.100(b). Thus, the term "equivalence" as used in a 510(k) application has a meaning different from the way the term is used in the area of patent

³⁰³ *Id.* (internal quotations omitted).

³⁰⁶ *Id*.

difference between the KLS Martin probes and the Soring probes regarding the distance the electrode is recessed from the orifice at the end of the probe.³⁰⁸

It is noted at the outset that ERBE fails to make an actual inducement argument regarding the Soring probes in either its opening brief or reply brief.³⁰⁹ All ERBE includes in the one paragraph in each of its briefs devoted to inducement of the Soring 2.3 mm probes are a series of assertions, as outlined above. Nowhere in the briefs is there an actual argument tying those assertions to the legal standard for proving inducement. On this fact alone, ERBE's inducement allegation fails.

Even ignoring this fact, however, the merits of ERBE's inducement argument are woefully inadequate. The only acts of Canady that ERBE relies on in support of its inducement argument are Canady's sale of the Soring 2.3 mm probes, a possible demonstration to MetroHealth using a 0.5 lpm flow rate, and a suggestion made to Grace/Valdese Hospital to use the lower flow rates. None of these acts either individually or in concert show a specific intent on the part of Canady to have MetroHealth or Grace/Valdese Hospital infringe the asserted claims of the '745 patent.

law. Because statements of equivalence in a 510(k) application need mean nothing more than the proposed device is as safe and effective as the predicate device, it would be error to conclude merely from a statement of equivalence in a 510(k) application that the proposed device and the predicate device are equivalent for purposes of proving infringement under the patent laws. Other courts have similarly concluded. *See Cardiovention, Inc.*, 483 F. Supp. 2d 830; *Univ. of Fla. Research Foundation, Inc. v. Orthovita, Inc.*, 1998 U.S. Dist. LEXIS 22648, *80 n.23 (D. Fla. 1998), *aff'd*, 217 F.3d 854 (Fed. Cir. 1999)(decision without published opinion).

Canady and the Staff argue that as a matter of law, statements in a 510(k) application can not be used to support a finding of infringement. Other than what is stated above, the undersigned expresses no opinion on this point.

³⁰⁸ See CIB at 54. In support, ERBE cites to Dr. Canady's deposition testimony in JX-23C at 000133:13-21. The passage cited by ERBE, however, does not support its assertion.

³⁰⁹ See CIB at 54, CRB at 36.

Conspicuously absent from ERBE's briefs is any assertion whatsoever that Canady took any action to induce Grace/Valdese Hospital or MetroHealth to use the Soring 2.3 mm probes in a manner where the extended longitudinal axis of the protruding portion of the tube is arranged sidewardly of the tissue to be coagulated as required by the asserted claims of the '745 patent.

For the reasons discussed above, the undersigned finds ERBE has failed to prove that Canady has the specific intent necessary to support a finding of inducement. Accordingly, the undersigned finds Canady not liable for inducing infringement under 35 U.S.C. 271(b) for its offer for sale, sale, or importation of Soring 2.3 mm probes (part nos. S-422537, S-422538).

VI. DOMESTIC INDUSTRY

A. Technical Prong

To satisfy the technical prong of the domestic industry requirement of Section 337, the complainant must demonstrate that it practices or exploits the patent at issue.³¹⁰ The complainant need only show that it practices one claim of the asserted patent.³¹¹ The standard for determining whether the complainant practices at least one claim of the asserted patent is the same as that for infringement.³¹² That is, the complainant must show that the domestic industry either directly or indirectly infringes at least one claim of the asserted patent.

To directly infringe the asserted claims of the '745 patent requires at least an RF generator,

³¹⁰ See 19 U.S.C. 1337(a)(2); Certain Microlithographic Machines, Inv. No. 337-TA-468, Initial Determination at 63 (April 3, 2003).

³¹¹ Certain Microsphere Adhesives, Process for Making Same, and Products Containing Same, Including Self-Stick Repositionable Notes, Inv. No. 337-TA-366, Commission Opinion at 16 (1996).

³¹² Certain Microlithographic Machines, Initial Determination at 64.

an argon source, a probe and an endoscope.³¹³ ERBE, however, does not sell endoscopes. Thus, the domestic industry cannot directly infringe the claims of the asserted patent. Accordingly, to satisfy the technical prong requirement ERBE must prove that its domestic industry indirectly infringes at least one claim of the '745 patent.

"Indirect infringement, whether inducement to infringe or contributory infringement, can only arise in the presence of direct infringement."³¹⁴ To prove direct infringement, ERBE must either point to specific instances of direct infringement or show that its APC systems necessarily infringe the '745 patent.³¹⁵ On this point, ERBE argues that its APC systems are used by NCBH, Robert Wood Johnson University Hospital, Dr. Jerome Waye, Cleveland Clinic Foundation, and Indiana University Hospital to directly practice independent claims 1 and 35 of the '745 patent.³¹⁶ ERBE also argues that its APC systems are used by the Mayo Clinic to directly practice claim 35 of the '745 patent.³¹⁷ Canady asserts that ERBE has failed to prove direct infringement by any of these users, arguing that: (1) none of ERBE's users use an ERBE APC system at a "low flow rate" (claim 35); (2) an ERBE APC system does not produce a flow of argon that is "non-directed, non laminar" (claim 35); (3) none of ERBE's users use an ERBE APC system with the probe maintained in a "substantially stationary position" (claim 35); (4) none of ERBE's users use an ERBE APC system with the probe maintained in a plurality of working channels (claims 1 and 35) and optical means protruding from a distal end of a working channel (claim 1); and (5) the probe in an ERBE APC

³¹³ See CIB at 30.

³¹⁴ Dynacore Holdings Corp., 363 F.3d at 1272.

³¹⁵ ACCO Crands, Inc. v. ABA Locks Manufactureer Co., Ltd., 501 F.3d 1307, 1313 (Fed Cir. 2007)

³¹⁶ See CIB at 60, 63-64.

³¹⁷ *Id.* at 63-64.

system does not have an electrode that is offset from the distal opening at the end of the tube by a predetermined minimum safety distance (claims 1 and 35).³¹⁸ The Staff argues that ERBE has shown that Dr. Waye and Dr. Goustout of the Mayo Clinic use ERBE APC systems to practice at least claims 1 and 35 of the '745 patent.³¹⁹

ERBE sets forth claim by claim, element by element, where in the record it finds support for its assertion that a particular limitation is satisfied by each of the users listed above.³²⁰ As discussed above, to satisfy the technical prong requirement, ERBE need only show that one of these users of its APC systems practices one claim of the '745 patent. However, for the reasons discussed below, the undersigned finds ERBE has failed to prove that any user of an ERBE APC system has directly practiced any claim of the '745 patent.

Specifically, the undersigned finds ERBE has failed to prove that any user of its APC system uses an endoscope with a plurality of working channels, required of both independent claim 1 and independent claim 35. Since ERBE only asserts that it satisfies the technical prong vis a vis claims 1 and 35, the undersigned will confine the analysis herein to those claims. Independent claims 1 and 35 of the '745 patent each require an endoscope having a plurality of working channels extending between the ends of the endoscope with each channel having a predetermined diameter.³²¹ In addition, both claims 1 and 35 require one of the working channels to be capable of having a tube of smaller diameter inserted therein. Further, with regard to claim 1, a second working channel is

³¹⁸ RRB at 39.

³¹⁹ SRB at 41.

³²⁰ See CIB at 61-68.

³²¹ See JX-1 at 11:14-16, 15:29-31.

required to have an optical means positioned therein.³²²

Although ERBE asserts that nine different users of its APC Systems directly practice at least one claim of the '745 patent, almost all the record evidence cited to and relied on in ERBE's posthearing briefs regarding the above limitations comes from the testimony of ERBE's expert, Mr. Walbrink.³²³ Mr. Walbrink did not testify about any specific endoscope used by any of the nine ERBE APC System users, but rather testfied only as to what he refered to as a "typical endoscope."³²⁴ With regard to claim 35, ERBE also asserts that Dr. Gostout of the Mayo Clinic uses an endoscope with a plurality of working channels.³²⁵

Exhibits CX-59 and SX-11 illustrate the two exemplary endoscopes relied on by ERBE and Mr. Walbrink to prove that ERBE APC system users actually perform APC procedures with an endoscope having a plurality of working channels.³²⁶ The illustration in CX-59 is of the distal end of an Olympus Innoflex Colonovideoscope (i.e. endoscope). According to the illustration, the Olympus endoscope has an instrument channel, two light guide lenses, an air/water nozzle, and auxiliary water channel and an objective lens.³²⁷ Exhibit SX-11 shows an exemplary video endoscope from a book titled, "Colonoscopy: Principles and Practice."³²⁸ The endoscope in SX-11 has a biopsy channel, air/water nozzle, objective lens, a water jet, and a light guide lens.³²⁹

- ³²⁴ See CX-2C at 107:9-13.
- ³²⁵ *See* CIB at 64.
- ³²⁶ See CX-59; SX-11.
- ³²⁷ See CX-59.
- ³²⁸ See SX-11.

³²² *Id.* at 11:44-45.

³²³ See CIB at 60-61, 64; CRB at 44-45.

³²⁹ See SX-11.

endoscopes are working channels since each is used to perform work such as diagnosis, washing, lighting an area, or manipulating an instrument.³³⁰ However, the limitation "working channel" has been construed herein as a channel through which a device that performs work may be inserted. Thus, contrary to Mr. Walbrink's testimony, each of the exemplary endoscopes has only one working channel, labeled instrument channel in CX-59 and biopsy channel in SX-11.

With regard to the testimony of Dr. Gostout, the record indicates that Dr. Gostout uses an endoscope when performing APC procedures that has optics and "a working channel to place devices through it."³³¹ According to Dr. Gostout, most current endoscopes are video-based.³³² Dr. Gostout's testimony is woefully inadequate to support a finding that an ERBE APC system user has used an endoscope with a plurality of working channels during an APC procedure. Notably, there is no testimony that the alleged working channels run from one end of the endoscope to the other or that each channel has a predetermined diameter as explicitly required by both claims 1 and 35 of the '745 patent. Further, because the optics are video-based, the alleged channel in which the lens and video chip camera are disposed is not a course through which a device that performs work may be inserted. Thus, the alleged optics channel is not a working channel as the limitation has been construed herein. Accordingly, the undersigned finds that ERBE has failed to prove a specific instance of any of its ERBE APC system users actually using an endoscope with a plurality of working channels as required by independent claim 1 and independent claim 35 of the '745 patent.

Additionally, with regard to claim 1, ERBE has failed to prove that any of its APC system

³³⁰ See Tr 826:11-830:6 (Aug. 29, 2007).

³³¹ See JX-24:00009:16-18.

³³² *Id.* at 10:1-3.

users have used an endoscope with optical means positioned in one of the working channels. To prove that its APC system users have used an endoscope with optical means positioned in one of the plurality of working channels, ERBE relies on its expert, Mr. Walbrink. Mr. Walbrink testified that a "typical endoscope" would have multiple working channels with optical means in one of the working channels.³³³ According to Mr. Walbrink, the optical means would consist of either a fiberoptic bundle and a lens or a video chip camera and a lens.³³⁴ Although Mr. Walbrink testified that the examined endoscopes that had an optical means consisting of either a lens and fiberoptic bundle or a lens and video chip camera, there is no evidence that an ERBE APC system user has ever used an endoscope that has a fiberoptic bundle and lens combination in a manner that infringes a claim of the '745 patent. In fact, the record evidence in the investigation is clear that in today's endoscopes use of a video chip camera in conjunction with a lens is the norm.³³⁵ Thus, for Mr. Walbrink's testimony to be at all relevant in trying to prove that an ERBE APC system user actually practices a claim of the '745 patent, it must show that an endoscope with a video chip camera and lens satisfies the limitations of a claim of the '745 patent.

In support of his conclusion that an ERBE APC system used in a surgical procedure would satisfy the limitation of claim 1 requiring an endoscope with optical means positioned in one of the

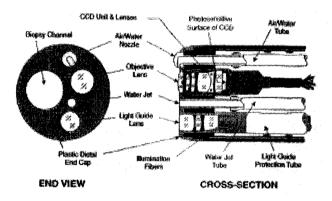
³³³ See CX-2C at 107:9-13.

³³⁴ *Id.* at 186:12-187:7. While the undersigned has not construed the limitation "optical means" herein, it is assumed for purposes of deciding whether ERBE satisfies the technical prong requirement, that a video chip camera and lens satisfies the optical means limitation of the asserted claims of the '745 patent.

³³⁵ See e.g., RFF No. 105 ("Viewing optics is built into the single-channel and doublechannel endoscopes that are on the market today."); RFF No. 177 ("Modern endoscopes have a video chip located at the distal end of the endoscope."); RFF No. 186 ("Video chips are the predominant method in the industry of sending optical signals from a probe to a monitor in the operating room.").

working channels, Mr. Walbrink points to Exhibit CX-34, which as previously discussed is a brochure for an Olympus Innoflex Colonovideoscope (i.e., endoscope) and Exhibit CX-59, which is an enlarged schematic from the brochure showing the distal end of the Olympus Innoflex endoscope.³³⁶ According to Mr. Walbrink, the Olympus Innoflex endoscope would be "typical of an endoscope."³³⁷ Exhibits CX-34 and CX-59 only show the distal end of a video endoscope and thus it is impossible to confirm in such an endoscope whether the alleged working channel that contains the optical means extends between the two ends of the endoscope or whether the working channel has a predetermined diameter as required by claims 1 and 35.³³⁸

Exhibit SX-11, which also has previously been discussed, includes a schematic, reproduced below, of an exemplary video endoscope showing both an end view and cross sectional view of the endoscope.



The cross section view shows an optical means consisting of the lens and video chip camera

³³⁶ See CX-2C at 108:21-109:2; see also CX-34; CX-59. Exhibit CX-59 has annotaions made by Mr. Walbrink (seen as A, B, $C_1 - C_6$, D) and as such would be more appropriately classified as a demonstrative exhibit. See CX-2C at 111:2-10.

³³⁷ See CX-2C at 109:3, 117:2-7.

³³⁸ See CX-34; CX-59.

combination dicussed by Mr. Walbrink.³³⁹ As previously stated, claim 1 requires a plurality of working channels with optical means positioned in one of the working channels. Additionally, claim 1 explicitly requires that each working channel extend between the two ends of the endoscope and have a predetermined diameter. As is plainly seen in the cross sectional view above, the course in which the lens and video chip camera combination are positioned has one diameter in which the CCD signal wires are positioned and a larger diameter to accomodate the lens and CCD camera.³⁴⁰ Because the course in which the lens and video chip camera are positioned has more than one diameter it cannot be said to have a singular predetermined diameter. Thus, the undersigned finds that ERBE has failed to prove a specific instance of an ERBE APC system user using an endoscope during an APC procedure that has optical means positioned in one of the plurality of working channels as required by claim 1.

To prove that one of its products practices at least one of the claims of the '745 patent, ERBE must prove that a user of its APC system actually performs an APC procedure in a way that infringes the asserted claims of the '745 patent. As discussed above, ERBE has failed to prove that any of its ERBE APC system users have performed an APC procedure in manner that practices either independent claim 1 or independent claim 35 of the '745 patent. Specifically, ERBE has failed to at least prove: (1) with regard to claims 1 and 35, that its users use an endoscope with a plurality of working channels; and (2) with regard to claim 1, that its users use an endoscope with optical means positioned in one of the working channels. Accordingly, the undersigned finds that ERBE has failed

³³⁹ Id.

³⁴⁰ See SX-11 at 241; see also SX-11 at Fig. 22.2 (showing the smaller diameter sheathing that encapsulates the wires coming from the video chip camera).

to prove that any of its ERBE APC system users practice a claim of the '745 patent. Because ERBE has failed to prove that any of its APC system users practice a claim of the '745 patent, the undersigned finds that ERBE has failed to satisfy the technical prong of the domestic industry requirement.

B. Economic Prong

Section 337(a)(3) sets forth the criteria for determining whether a domestic industry exists stating that:

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 . . . 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.³⁴¹

As the statute uses the disjunctive term "or," ERBE can satisfy the economic prong of the domestic industry rquirement under any one of the three criteria set forth in Section 337(a)(3). Thus, while ERBE argues that it satisfies the economic prong under each of the criteria listed above, it is sufficient that the undersigned finds, as discussed in detail below, that ERBE has satisfied the economic prong under Section 337(a)(3)(C) through its investments in the exploitation of the '745 patent.

Before getting into the merits of ERBE's assertion that it satisfies the economic prong of the domestic industry requirement through its exploitation of the '745 patent, Canady raises an issue which must first be addressed. Specifically, Canady argues that because ERBE never pled in its complaint a domestic industry under 19 U.S.C. § 1337 (a)(3)(C) that it is now precluded from so

³⁴¹ 19 U.S.C. § 1337(a)(3)

doing.³⁴² Canady cites to the Initial Determination in *EPROM*, *EEPROM*, *Flash Memory*, *and Flash Microcontroller Semiconductor Devices and Products Containing Same* ("*EPROM*") in support of its argument that ERBE has waived its right to pursue a domestic industry under section 337(a)(3)(C) because it is was not pled in the complaint.³⁴³ *EPROM*, however, does not support that conclusion.³⁴⁴

Ground Rule 8.2 states in pertinent part that "[a]ny contentions not set forth in detail as required herein shall be deemed abandoned or withdrawn, except for contentions of which a party is not aware and could not be aware in the exercise of reasonable diligence at the time of filing the pre-trial brief."³⁴⁵ ERBE raised the argument that it satisfied the domestic industry requirement of section 337 through the exploitation of the '745 patent at least as early as the filing on July 26, 2007, of its motion for summary determination on the economic prong.³⁴⁶ Notably, in its opposition to ERBE's motion for summary determination, Canady never argues that ERBE waived its right to argue a domestic industry under 337(a)(3)(C). Based on the summary determination motion filed, Canady should have been well aware that ERBE was alleging a domestic industry through its substantial investment in the exploitation of the '745 patent. However, Canady did not include in its pre-hearing brief an argument that ERBE had waived its right to assert a domestic industry under section 337(a)(3)(C).³⁴⁷ Furthermore, even after pre-hearing briefs were filed,³⁴⁸ Canady never filed

³⁴⁵ See Order No. (July 5, 2007).

³⁴⁷ *See* RPHB at 86-92.

³⁴² See RIB at 67-68.

³⁴³ *Id.* at 67.

³⁴⁴ See EPROM, Inv. No. 337-TA-395, Initial Determination, 1998 ITC Lexis 85 at *175 (March 19, 1998).

³⁴⁶ See ERBE Mot. For Sum. Det. On Economic Prong at 17 (July 26, 2007)("(iii) substantial investment in exploitation").

 $^{^{348}}$ There can be no argument that after pre-hearing briefs were filed, Canady was on notice that ERBE was going to argue domestic industry under 337(a)(3)(C). See CPHB at 63-84.

a motion in limine to preclude ERBE's section 337(a)(3)(C) domestic industry argument or exclude the related evidence, nor did Canady raise its waiver argument at the pre-hearing conference or during the hearing in this investigation. Accordingly, the undersigned finds Canady has waived its right to argue that ERBE is precluded from asserting a domestic industry under 337(a)(3)(C).

Although the APC systems and probes sold by ERBE in the United States are all manufactured in Germany and then imported into the United States,³⁴⁹ the Commission has found that a domestic industry may exist for purposes of Section 337 based on a complainant's investments in domestic nonmanufacturing activities. For example, in Certain Variable Speed Wind Turbines and Components Thereof, Inv. No. 337-TA-376 ("Wind Turbines"), the Commission noted that while the complainant had ceased to manufacture the article covered by the patent at issue, it continued to exploit the patent "albeit in a more limited fashion" through its operation and maintenance of wind turbines already in place.³⁵⁰ Similarly, activities such as quality control, repair and packaging of imported products, domestic repair and installation activities and domestic product servicing have served as the basis for a domestic industry.³⁵¹

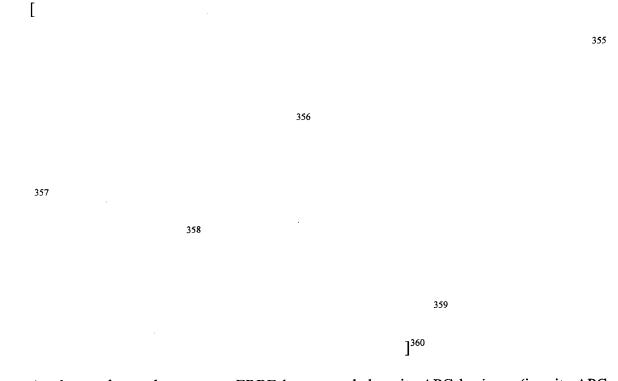
The record shows that ERBE performs extensive service and repair for APC systems in the United States. In fact, ERBE has approximately [] worth of equipment devoted to APC products and testing at its facility in Georgia.³⁵² Additionally, ERBE recently added space

³⁴⁹ See Complaint at ¶56.

³⁵⁰ Wind Turbines, U.S.I.T.C. Pub. 3003, Comm. Opn. at 17-18 (August 30, 1996).

³⁵¹ See Certain Home Vacuum Packaging Machines, Inv. No. 337-TA-496, Initial Determination on Temporary Relief (unreviewed in relevant part) at 143: Certain Diltiazem Hydrochloride and Diltiazem Preparations, Inv. No. 337-TA-349, USITC Pub. No. 2902, Initial Determination (unreviewed in relevant part) at 138-39, 1995 WL 945191 (U.S.I.T.C., February 1, 1995) ("Diltiazem"). ³⁵² See CX-4C:000014.

to its Georgia facility and added equipment worth approximately []³⁵³ The record shows that the majority of the recent expansion of the Georgia facility was needed to accommodate ERBE's APC systems business and to facilitate the software upgrades for VIO APC systems.³⁵⁴



As shown above, the amounts ERBE has expended on its APC business (i.e., its APC systems and probes) in the United States are substantial. Accordingly, the undersigned finds ERBE has establish the existence of a domestic industry in APC systems and probes.

- ³⁵⁴ CX:4C:0000012.
- ³⁵⁵ CX-6C:000008 10 (Q.46-53.).
- ³⁵⁶ CX-6C:000020 (Q.111, 112); CIB at 69-70.
- ³⁵⁷ CX-6C:000016-17 (Q.91-96).
- ³⁵⁸ CX-6C:000017; Trial Tr. 8/27/2007 at 408-09.
- ³⁵⁹ CX-6C:000018-19 (Q.101, 102).
- ³⁶⁰ CX-6C:000019 (Q. 103).

³⁵³ CX-4C:000014.

VII. VALIDITY

A. Anticipation

1. **Prior Use of Dr. Canady's Prototype**

Canady argues that Dr. Canady's design, development, and use of prototype APC probes constitutes prior art to the '745 patent under 35 U.S.C. § 102(a) and anticipates the asserted claims of the '745 patent.³⁶¹ To prove anticipation, Canady must show that every limitation in the asserted claims of the '745 patent are disclosed expressly, or inherently, by the use of Dr. Canady's prototype. Among the many limitations in the '745 patent that Canady has the burden of showing are disclosed by the use of Dr. Canady's prototype is the limitation in independent claims 1 and 35 requiring that the extended longitudinal axis of the protruding portion of the tube be arranged "sidewardly" of the tissue to be coagulated.³⁶²

Canady argues that Dr. Canady's prototype was used sidewardly of the tissue to be coagulated and thus satisfies this claim limitation.³⁶³ In support, Canady cites to its finding of fact 701 and states that "it plainly can be seen in the videos of Dr. Canady's procedures that in many instances the prototype probe was not perpendicular to the tissue when coagulation was performed."³⁶⁴ Moreover, Canady argues that the videos show examples in which the longitudinal axis of the prototype probe was substantially parallel to the tissue to be coagulated.³⁶⁵

³⁶¹ See RIB at 80, 83.

³⁶² JX-1 at 11:49-52, 15:59-64.

³⁶³ *See* RIB at 90.

³⁶⁴ *Id*.

³⁶⁵ Id.

Canady's finding of fact 701 states:

In a video (Respondents' Exhibit RPX-3) of an endoscopic coagulation procedure performed by Dr. Canady on December 29, 1991 using one of the prototype probes, you can see that the snare was used in a normal manner to remove the polyp. The snare was then withdrawn into the probe and APC was performed using the probe while the same was withdrawn inside the tube. RX-1C (Canady, p.3); RPX-3; Canady, Tr. 1361:1-17.³⁶⁶

This finding does not even mention, much less support the assertion that Dr. Canady's prototype was used in a manner where the longitudinal axis of the protruding portion of the tube was sidewardly of the tissue to be coagulated. Additionally, the cited testimony in the finding of fact does not support Canady's assertion. With regard to the video, produced as Exhibit RPX-3, Canady does not cite to any specific time segment(s) in the video that would show the alleged use of the probe sidewardly of the tissue to be coagulated. Apparently Canady relies on its statement in its brief that it can be "plainly" seen from the video.³⁶⁷ However, such is not the case. To the contrary, the video is not of very good quality.³⁶⁸ Absent testimony describing the procedure(s) taking place on the video, the video is of little value. With regard to the portion of the video shown and discussed at the hearing, in response to a question from ERBE asking whether the tissue that was shown to be coagulated was directly in front of the probe, Dr. Canady responded "[t]hat's what I see there."³⁶⁹

As properly construed herein, the limitation "sidewardly" in the asserted claims of the '745 patent means alongside.³⁷⁰ If the tissue to be coagulated is directly in front of the probe it cannot be said to be alongside the probe as required by the asserted claims of the '745 patent. Thus, the

³⁶⁶ RFF ¶ 701.

³⁶⁷ See RIB at 90.

³⁶⁸ *See* RPX-3.

³⁶⁹ Tr. 1363 at 12-16.

³⁷⁰ See supra, at IV.B.2.

undersigned finds that Canady has failed to prove by clear and convincing evidence that Dr. Canady's prototype was ever used in a manner where the longitudinal axis of the protruding portion of the tube was arranged "sidewardly" of the tissue to be coagulated as required by the asserted claims of the '745 patent. Accordingly, for at least the reasons discussed above, the undersigned finds that the use of Dr. Canady's prototype does not anticipate the asserted claims of the '745 patent.

2. The '675 Patent

Canady argues that the asserted claims of the '745 patent are anticipated under 35 U.S.C. § 102(b) by United States Patent No. 5,207,675 ("the '675 patent"). Notably, the '675 patent was considered by the examiner during the prosecution of the '745 patent at issue in this investigation and is cited on the front page of the '745 patent. Because the '675 patent was considered by the patent examiner, Canady's burden of showing anticipation is made more difficult.³⁷¹

To prove anticipation, Canady must show that every limitation in the asserted claims of the '745 patent are disclosed expressly, or inherently, in the '675 patent. Among the many limitations in the '745 patent that Canady has the burden of showing are disclosed by the '675 patent is the limitation in independent claims 1 and 35 requiring that the extended longitudinal axis of the protruding portion of the tube be arranged "sidewardly" of the tissue to be coagulated.³⁷² On this point, Canady argues that although the '675 patent does not explicitly disclose this limitation, it

³⁷¹ See Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1348 (Fed. Cir. 2004)("Apotex has the burden of showing invalidity by clear and convincing evidence. This burden is "especially difficult" when, as is the present case, the infringer attempts to rely on prior art that was before the patent examiner during prosecution.")(internal citations omitted).

³⁷² JX-1 at 11:49-52,15:59-64.

would nevertheless be inherent.³⁷³ Specifically, Canady argues that it is a property of physics that current will follow the path of least resistance and thus the probes disclosed in the '675 patent inherently would arc to the side when positioned sidewardly of the tissue.³⁷⁴ To prove inherency, Candy must show that the limitation of the asserted claims requiring the extended longitudinal axis of the protruding portion of the tube be arranged sidewardly of the tissue to be coagulated is necessary present in the '675 patent.³⁷⁵ Even assuming *arguendo* that Canady's assertion that current will follow the path of least resistance is inherently disclosed, Canady has still failed to set forth any evidence that would show that the '675 patent necessarly discloses the positioning of the protruding end of the probe such that it is arranged alongside the tissue to be coagulated. Thus, the undersigned finds that Canady has failed to prove by clear and convincing evidence that the '675 patent discloses the extended longitudinal axis of the protruding portion of the tube arranged "sidewardly" of the tissue to be coagulated as required by the asserted claims of the '745 patent.

The '675 patent also fails to disclose the limitation of the asserted claims of the '745 patent requiring an electrode positioned inside the tube and offset from the opening at the distal end of the tube a predetermined minimum safety distance.³⁷⁶ While the '675 patent does disclose that "[a] flexible wire is provided within the tube for conducting radio frequency (RF) current," the '675 patent makes clear that "[t]he wire has a distal end for placement adjacent the distal end of the

³⁷³ *See* CIB at 90.

³⁷⁴ *Id.* at 90-91.

³⁷⁵ Abbott Labs. v. Baxter Pharm. Prods., 471 F.3d 1363, 1368 (Fed. Cir. 2006)("[A] prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference.").

³⁷⁶ See JX-1 at 11:33-37, 15:40-46.

tube.³³⁷⁷ If the distal end of the wire is positioned adjacent the distal end of the tube the wire cannot be said to be offset form the opening at the distal end of the tube as required by the asserted claims. Canady's only other citation to the '675 patent states that "[i]n the embodiment shown, polypectomy snare 64 is moveable with wire 28 from inside the tube 10 to outside the tube 10 . . .³⁷⁸ Canady provides no explanation as to why or how this passage satisfies the limitation in the asserted claims and one is not readily apparent.³⁷⁹ The undersigned finds that this passage does not disclose an electrode inside the tube and offset from the opening at the end of the tube a predetermined minimum safety distance. Thus, the undersigned finds that Canady has failed to prove by clear and convincing evidence that the '675 patent discloses an electrode positioned inside the tube and offset from the opening at the distal end of the tube a predetermined minimum safety distance as required by the asserted claims of the '745 patent.

Accordingly, for at least the reasons discussed above, the undersigned finds that the '675 patent does not anticipate the asserted claims of the '745 patent.

B. Obviousness

Canady argues that asserted claims of the '745 patent are obvious under 35 U.S.C. §103 in light of the '675 patent in combination with the 1994 article by Gunter Farin and Karl Grund, the 1994 article by K. Grund, D. Storek and G. Farin, and/or the '138 Marwaring patent.³⁸⁰ Both ERBE and the Staff argue that Canady has failed to prove by clear and convincing evidence that the asserted

³⁷⁷ See RX-3 at 3:17-18,1:61-65; see also RIB at 88.

³⁷⁸ RIB at 88.

³⁷⁹ Id.

³⁸⁰ See Order No. 45 (October 1, 2007)(granting ERBE's Motion to Strike New Arguments in Respondents' Post-hearing Brief).

claims of the '745 patent are obvious in light of the above combinations of references.³⁸¹

Section 103 forbids issuance of a patent when "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."³⁸² The Supreme Court in *Graham v. John Deere Co of Kansas City* set forth the framework for determining obviousness under section 103.

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. Against this background the obviousness or nonobviousness of the subject mater is determined. 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.³⁸³

Canady's obviousness argument merely consists of stringing together elements of the invention that are allegedly present in the cited prior art.³⁸⁴ Canady offers absolutely no analysis, no explanation and no evidence addressing any of the *John Deere* factors.³⁸⁵ Moreover, Canady has failed to articulate any reason or basis that would have prompted a person of ordinary skill in the relevant art to combine the elements from the prior art references in the manner reflected in the

³⁸¹ CRB at 48-49; SRB at 45. The parties dispute the priority date of the '745 patent at issue and thus whether the Farin and Grund articles are prior art. *See* CIB at 45; RIB at 76; SRB at 45. However, even assuming *arguendo* that the Farin and Grund references are prior art to the '745 patent, as discussed infra, the undersigned still finds Canady has failed to prove by clear and convincing evidence that the asserted claims of the '745 patent are invalid under Section 103.

³⁸² 35 U.SC. §103(a).

³⁸³ 383 U.S. 1, 17-18 (1966); KSR International Co. v. Teleflex Inc., 2007 U.S. LEXIS 4745 (2007).

³⁸⁴ See RIB at 83-94.

³⁸⁵ See Id.

asserted claims of the '745 patent.³⁸⁶ In its reply brief, Canady asserts that the motivation to combine the references can be found in the references themselves.³⁸⁷ However, Canady provides no further explanation or citation pointing to where such motivation can be found.³⁸⁸ In essence, it appears that Canady is asking the undersigned to take the references on which it relies and then figure out on its behalf whether one of ordinary skill in the art would have a motivation to combine them.

Based on the evidence presented by Canady in its post-hearing briefs, or rather lack thereof, the undersigned finds that Candy has failed to prove by clear and convincing evidence that any of the asserted claims of the '745 patent are obvious in light of the '675 patent in combination with the 1994 article by Gunter Farin and Karl Grund, the 1994 article by K. Grund, D. Storek and G. Farin, and/or the '138 Marwaring patent.

VIII. UNENFORCEABILITY - PATENT EXHAUSTION

The undersigned notes at the outset that a finding of patent exhaustion does not result in a finding of unenforceability as suggested from the heading under which Canady makes its argument. Patent exhaustion, otherwise known as the first sale doctrine, is an affirmative defense to infringement.³⁸⁹

³⁸⁶ *Id.*

³⁸⁷ RRB at 42.

³⁸⁸ *Id.*

³⁸⁹ See Jazz Photo Corp. v. United States, 439 F.3d 1344, 1350 (Fed. Cir. 2006)("We articulated the affirmative defense of first sale and permissible repair in Jazz I, holding that the "unrestricted sale of a patented article, by or with the authority of the patentee, 'exhausts' the patentee's right to control further sale and use of that article by enforcing the patent under which it was first sold."); see also Monsanto Co. v. Scruggs, 459 F.3d 1328, 1332-36 (Fed. Cir. 2006)(referring to patent exhaustion doctrine as an affirmative defense and discussing whether patent exhaustion doctrine barred patent infringement claims); Anton/Bauer, Inc. v. PAG, Ltd., 329 F.3d 1343, 1349-50 (Fed. Cir. 2003)(discussing patent infringement analysis and presenting patent exhaustion doctrine as a defense).

Canady argues that because ERBE placed no conditions on purchasers of its argon units and electrosurgical generators at the time of sale that ERBE has exhausted any patent rights under the '745 patent.³⁹⁰ As the Federal Circuit Court has held, "when a patented product has been sold the purchaser acquires 'the right to use and sell it, and ... the authorized sale of an article which is capable of use only in practicing the patent is a relinquishment of the patent monopoly with respect to the article sold."³⁹¹ However, it is not any sale that invokes this "first sale" or "patent exhaustion" doctrine. Rather,

The unrestricted sale of a patented article, by or with the authority of the patentee, "exhausts" the patentee's right to control further sale and use of that article by enforcing the patent under which it was first sold. In *United States v. Masonite Corp.*, 316 U.S. 265, 278, 62 S. Ct. 1070, 86 L. Ed. 1461, 1942 Dec. Comm'r Pat. 777 (1942), the Court explained that exhaustion of the patent right depends on "whether or not there has been such a disposition of the article that it may fairly be said that the patentee has received his reward for the use of the article." *See, e.g., Intel Corp. v. ULSI Sys. Tech., Inc.*, 995 F.2d 1566, 1568, 27 USPQ2d 1136, 1138 (Fed. Cir. 1993) ("The law is well settled that an authorized sale of a patented product places that product beyond the reach of the patent.") Thus when a patented device has been lawfully sold in the United States, subsequent purchasers inherit the same immunity under the doctrine of patent exhaustion.³⁹²

The '745 patent does not protect the individual argon units, generators or probes sold by

ERBE. As has been previously discussed and acknowledged by Canady, to practice the asserted claims of the '745 patent requires at a minimum, a gas source, generator, probe and endoscope. ERBE does not sell endoscopes. Therefore, the sales by ERBE are not of a "patented article" as the law requires. Accordingly, the undersigned finds Canady's argument unpersuasive.

³⁹⁰ See RIB at 94-95.

³⁹¹ Monsanto Co. v. McFarling, 302 F.3d 1291, 1298 (Fed. Cir. 2002) (quoting United States v. Univis Lens Co., 316 U.S. 241, 249 (1942)).

³⁹² Jazz Photo Corp. v. International Trade Comm'n, 264 F.3d 1094, 1105 (Fed. Cir. 2001), cert. denied, 536 U.S. 950, 153 L. Ed. 2d 823, 122 S. Ct. 2644 (2002).

CONCLUSIONS OF LAW

- 1. The Commission has subject matter jurisdiction in this investigation.
- 2. The Commission has personal jurisdiction over Canady.
- Canady's accused products are not used in a manner that directly infringes claims 1, 3, 4, 11, 13, 35, 37, 38, or 39 of U.S. Patent No. 5,720,745 in violation of 35 U.S.C. § 271(a). In addition, Canady's accused products do not indirectly infringe these claims under 35 U.S.C §§ 271(b) or (c).
- An industry in the United States does not exist with respect to ERBE's products that is protected by any claim of U.S. Patent No. 5,720,745, as required by 19 U.S.C. § 1337(a)(2) and (3).
- Claims 1, 3, 4, 11, 13, 35, 37, 38, and 39 of U.S. Patent No. 5,720,745 are not invalid under
 35 U.S.C. § 102 for anticipation.
- Claims 1, 3, 4, 11, 13, 35, 37, 38, and 39 of U.S. Patent No. 5,720,745 are not invalid under 35 U.S.C. § 103 for obviousness.

INITIAL DETERMINATION

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, including the proposed findings of fact and conclusions of law, it is the Administrative Law Judge's Initial Determination that a violation of Section 337 of the Tariff Act of 1930, as amended has not been found in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain endoscopic probes for use in argon plasma coagulation systems in connection with claims 1, 3, 4, 11, 13, 35, 37, 38, 39 and 41 of U.S. Patent No. 5,720,745. Furthermore, the Administrative Law Judge hereby determines that a domestic industry in the United States does not exist that practices U.S. Patent No. 5,720,745.

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: the transcript of the evidentiary hearing, with appropriate corrections as may hereafter be ordered by the Administrative Law Judge; and further the exhibits accepted into evidence in this investigation as listed in the attached exhibit lists.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall become the determination of the Commission unless a party files a petition for review pursuant to 19 C.F.R. § 210.43(a) or the Commission, pursuant to 19 C.F.R. § 210.44, orders on its own motion a review of the Initial Determination or certain issues therein.

RECOMMENDED DETERMINATION ON REMEDY AND BOND

I. Remedy and Bonding

A. Limited Exclusion Order

Under Section 337(d), the Commission may issue either a limited or a general exclusion order. A limited exclusion order instructs the U.S. Customs Service to exclude from entry all articles that are covered by the patent at issue and that originate from a named respondent in the investigation. A general exclusion order instructs the U.S. Customs Service to exclude from entry all articles that are covered by the patent at issue, without regard to source.

ERBE requests that a limited exclusion order be issued that prohibits the importation of all infringing endoscopic probes for use in argon plasma coagulation systems.³⁹³ Canady asserts that no exclusion order should be issued, as it would adversely affect the public interest.³⁹⁴ While Staff does not believe that the evidence supports a violation of Section 337, Staff asserts that, should a violation be found, that a limited exclusion order as to the infringing probes imported by or on behalf of Canady would be appropriate.³⁹⁵

The undersigned agrees that the evidence shows that if a violation is found, a limited exclusion order would be proper.

B. Cease and Desist

Under Section 337(f)(1), the Commission may issue a cease and desist order in addition to, or instead of, an exclusion order. Cease and desist orders are warranted primarily when the

³⁹³ CIB 98.

³⁹⁴ RIB 95-96.

³⁹⁵ SIB 87-88; SRB 49.

respondent maintains a commercially significant inventory of the accused products in the United States.³⁹⁶

Staff asserts that the evidence shows that Canady has no commercially significant inventory of the KLS Martin probes, but that the evidence shows that Canady has a commercially significant inventory of Soring probes in the United States. Therefore, Staff asserts that if a violation is found, a cease and desist order would be appropriate.³⁹⁷

The undersigned agrees that the evidence shows that Canady maintains significant inventories of Soring probes in the United States and that if a violation is found, a cease and desist order is warranted.

C. Bond During Presidential Review Period

If the Commission enters an exclusion order or cease and desist order, parties may continue to import and sell their products during the pendency of the Presidential review under a bond in an amount determined by the Commission to be "sufficient to protect the Complainants from any injury."³⁹⁸

ERBE requests a bond in the amount of 100% of the entered value of accused products.³⁹⁹ Canady requests that no bond be set. In the alternative, Canady requests that the bond be set at \$3,860.10, which is the royalty amount that Canady asserts that ERBE received from ConMed Corporation in a prior district court litigation.⁴⁰⁰ Staff requests a bond in the amount of \$15-\$50 per

³⁹⁶ Certain Crystalline, 15 U.S.P.Q.2d at 1277-79.

³⁹⁷ SIB 88; SRB 49.

³⁹⁸ 19 U.S.C. § 1337(e); 19 C.F.R. § 210.50(a)(3).

³⁹⁹ CIB 98.

⁴⁰⁰ RIB 96-97; RRB 43-44.

probe, which represents the price differential between ERBE and Canady's probes.⁴⁰¹

The Commission frequently sets the bond by attempting to eliminate the difference in sales prices between the patented domestic product and the infringing product.⁴⁰² In this case, the parties have introduced evidence that the price differential between ERBE and Canady's probes is \$15-\$50 per probe. Accordingly, the undersigned recommends a bond in the amount of \$50 per probe.

Within seven days of the date of this document, each party shall submit to the office of the Administrative Law Judge a statement as to whether or not it seeks to have any portion of this document deleted from the public version. The parties' submissions must be made by hard copy by the aforementioned date.

Any party seeking to have any portion of this document deleted from the public version thereof must submit to this office a copy of this document with red brackets indicating any portion asserted to contain confidential business information. The parties' submission concerning the public version of this document need not be filed with the Commission Secretary.

SO ORDERED.

Charles E. Bullock Administrative Law Judge

⁴⁰¹ SIB 88; SRB 50. See SFF 154.

⁴⁰² See Certain Microsphere Adhesives, Commission Opinion at 24.

APPENDIX A

FINAL EXHIBIT LISTS

		Adminiation Direct LAMINIS LIST			
Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
CX-1		Witness Statement of Dr. Steven T. Wereley	Patent Infringement; Technical Background	Dr. Steven T. Wereley Admitted 8/28	Admitted 8/28
CX-2C		Witness Statement of Harold J. Walbrink	Patent Infringement; Claim Interpretation; Technical Background; Harold J. Walbrink FDA Regulatory Aspects	Harold J. Walbrink	Admitted 8/31
CX-3		Witness Statement of Dr. Jerome D. Waye	c Industry; al Background	Jerome Waye	Admitted 8/27
CX-4C		. White	Domestic Industry	Creighton A. White	Admitted 8/29
-Y-20		Witness Statement of John L. Day	Domestic Industry	John L. Day	Admitted 8/28
CX-6C		Witness Statement of Rickie L. Steward	Domestic Industry; Patent Infringement	Rickie L. Steward	Admitted 8/27
-Y-1					Withdrawn
CX-8	CT 10156- CT 10159	Complainant's Exhibit No. 7- Brochure- Canady Plasma Beam- The Fourth State of Matter (Reichle)	Patent Infringement	Jens Reichle/Dr. Jerome Canady	Admitted 8/31
CX-9C	CT 12520- CT 12540	Complainant's Exhibit No. 22- Canady Technology Delivery Notes and Packing Lists (Reichle) TRANSLATION	Patent Infringement	Jens Reichle	Admitted 8/31
CX-10C	CT 10011- CT 10055	Complainant's Exhibit No. 3 - CT 3500 User Manual (Korinko)	Patent Infringement	Kate Korinko/Dr. Jerome Canady/Troy Baker	Admitted 8/31
CX-11	EITC 014696- EITC 014704	Resume of Dr. Steven T. Wereley	Expert Qualifications	even T. Wereley	Admitted 8/28
CX-12	EITC 014705	Picture of test set up (Ex. A- first picture)	Patent Infringement	Dr. Steven T. Wereley Admitted 8/28	Admitted 8/28
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Complainants' Direct Exhibits List

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Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
CX-13	EITC 014706	Picture of test set up (Ex. A- second picture)	Patent Infringement	Dr. Steven T. Wereley	Admitted 8/28
CX-14		CD of Test Photos	Patent Infringement	Dr. Steven T. Wereley Admitted 8/28	Admitted 8/28
CX-15		CD of Test Video Clips	Patent Infringement	Dr. Steven T. Wereley Admitted 8/28	Admitted 8/28
CX-16		Unenhanced video - Test X	Patent Infringement	Dr. Steven T. Wereley Admitted 8/28	Admitted 8/28
CX-17		Still Photo of Unenhanced video - Test X	Patent Infringement; Domestic Industry	Dr. Steven T. Wereley Admitted 8/28	Admitted 8/28
CX-18		Unenhanced video - Test JJ	Patent Infringement	Dr. Steven T. Wereley Admitted 8/28	Admitted 8/28
CX-19		Still Photo of unenhanced video - Test JJ	Patent Infringement	Dr. Steven T. Wereley Admitted 8/28	Admitted 8/28
CX-20		Unenhanced video - Test RRR	Patent Infringement	Dr. Steven T. Wereley Admitted 8/28	Admitted 8/28
CX-21		Still Photo of unenhanced video - Test RRR	Patent Infringement	Dr. Steven T. Wereley	Admitted 8/28
CX-22	EITC 005700- EITC 005812	ERBE ICC 350 User Manual 03.06	Patent Infringement; Domestic Industry	Harold J. Walbrink; Rickie L. Steward	Admitted 8/27
CX-23	EITC 005549- EITC 005611	ERBE APC 2 User Manual V1.4x	Patent Infringement; Domestic Industry	Harold J. Walbrink; Rickie L. Steward	Admitted 8/27
CX-24	CT 10435	ERBE VIO literature	Patent Infringement; Domestic Industry	Harold J. Walbrink; Rickie L. Steward; John Day	Admitted 8/27
CX-25	CT 12056	ERBE ICC 200/ICC200EA Common settings	Patent Infringement; Domestic Industry	Harold J. Walbrink; Rickie L. Steward	Admitted 8/27

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Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
CX-26	EITC 003120- EITC 003131	ERBE "Principles of Electroscopy"	Patent Infringement; Domestic Industry; Technical Background	Harold J. Walbrink; Rickie L. Steward	Admitted 8/27
CX-27	EITC 005612- EITC 005699	ERBE APC300 Service Manual V2.xx	Patent Infringement; Domestic Industry	Harold J. Walbrink; Rickie L. Steward	Admitted 8/27
CX-28	EITC 005813- EITC 005914	ERBE ICC 200 User Manual V2.x	Patent Infringement; Domestic Industry	Harold J. Walbrink; Rickie L. Steward	Admitted 8/27
CX-29	EITC 005396- EITC 005548	ERBE VIO 300D User Manual V1.4x	Patent Infringement; Domestic Industry	Harold J. Walbrink; Rickie L. Steward	Admitted 8/27
CX-30	EITC 003185- EITC 003215	Using Argon Plasma Coagulation In Flexible Endoscopy Nurse Self Study Activity	Patent Infringement; Domestic Industry; Technical Background	Harold J. Walbrink; Rickie L. Steward	Admitted 8/27
CX-31	EITC 003295- EITC 003328	VIO 300D/APC Self Study and Competency Testing	Patent Infringement; Domestic Industry; Technical Background	Harold J. Walbrink; Rickie L. Steward	Admitted 8/27
CX-32	EITC 003149- EITC 003159	VIO APC2: The Full Range of Argon Plasma Coagulation (APC)	Patent Infringement; Domestic Industry; Technical Background	Harold J. Walbrink; Rickie L. Steward	Admitted 8/27
CX-33	EITC 003250- EITC 003256	ERBE Practical Tips for the Use of High- frequency Surgical Units	Patent Infringement; Domestic Industry; Technical Background	Harold J. Walbrink; Rickie L. Steward	Admitted 8/27

Complainants' Direct Exhibits List

Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
CX-34	EITC 116734	Patent Infringemen Olympus Literature -Olympus CF Type Q160AL/I Domestic Industry; Technical Backgro	Patent Infringement; Domestic Industry; Technical Background	Harold J. Walbrink	Admitted 8/29
CX-35	EITC 004152- EITC 004159	ERBE APC Probes for flexible endoscopes Instructions	Domestic Industry; Technical Background	Harold J. Walbrink; Rickie L. Steward	Admitted 8/27
CX-36	EITC 003415- EITC 003416	ERBE APC probes for flexible endoscopes- Notes on use	Domestic Industry; Technical Background	Harold J. Walbrink; Rickie L. Steward; John Day	Admitted 8/27
CX-37	EITC 005920- EITC 005925	APC in Tracheobronchial System	Domestic Industry; Technical Background	Harold J. Walbrink; Rickie L. Steward; John Day	Admitted 8/27
CX-38C	EITC 004297	20132-048/3 1.5 mm ERBE APC Probe Drawing	Patent Infringement; Domestic Industry	Harold J. Walbrink; Rickie L. Steward;Creighton White	Admitted 8/27
CX-39C	EITC 004299	20132-049/3 2.3 mm ERBE APC Probe Drawing	Patent Infringement; Domestic Industry	Harold J. Walbrink; Creighton White	Admitted 8/29
CX-40C	EITC 004300	20132-050/3 3.2 mm ERBE APC Probe Drawing	Patent Infringement, Domestic Industry	Harold J. Walbrink; Creighton White	Admitted 8/29
CX-41C	EITC 004389	20132-135/3 2.3 mm ERBE APC Probe Drawing	Patent Infringement; Domestic Industry	Harold J. Walbrink; Creighton White	Admitted 8/29
CX-42C	EITC 004404	20131-135/3 1.5 mm ERBE APC Probe Drawing	Patent Infringement, Domestic Industry	Harold J. Walbrink; Creighton White	Admitted 8/29
CX-43C	EITC 004408	20132-156/3 2.3 mm ERBE APC Probe Drawing	Patent Infringement; Domestic Industry	Harold J. Walbrink; Creighton White	Admitted 8/29

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			EXIIIDILS LISI		
Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
CX-44	CT 10150- CT 10154	APC - Argon Plasma Coagulation for Open & Endoscopic Applications	Domestic Industry; Technical Background	Harold J. Walbrink; Rickie L. Steward	Admitted 8/27
CX-45	EITC 001915- EITC 001921	ERBE APC 300 Argon Plasma Coagulation Unit Domestic Industry; for Endoscopic Literature	pur	Harold J. Walbrink; Rickie L. Steward	Admitted 8/27
CX-46C					Withdrawn
CX-47	EITC 005962- EITC 005968	ERBE Package and notes 20132-166 - 2.3 mm APC	Domestic Industry; Technical Background	Harold J. Walbrink; Rickie L. Steward	Admitted 8/27
CX-48	EITC 005915- EITC 005919	ERBE Package and notes 20132-155 - 1.5 mm APC	Domestic Industry; Technical Background	Harold J. Walbrink; Rickie L. Steward	Admitted 8/27
CX-49	EITC 014645- EITC 014695	CV of Jerome D. Waye	Qualifications	Jerome D. Waye	Admitted 8/27
CX-50C	EITC 013617- EITC 013699	ERBE- Functional Test for Argon Plasma Coagulator Model APC 300	Domestic Industry; Technical Background	Rickie L. Steward	Rejected
CX-51C	EITC 013700- EITC 013833	ERBE- Functional Test for Electrosurgical Generators Models ICC 80, ICC 200, ICC 300, and ICC 350 Series	Domestic Industry; Technical Background	Rickie L. Steward	Rejected
CX-52C	EITC 013834- EITC 013933	ERBE- Electrical Safety Check for Electrosurgical Generator Model ICC 350	Domestic Industry; Technicał Background	Rickie L. Steward	Rejected
CX-53C	EITC 011031- EITC 011036	Product Information Flexible APC Probes, Single Domestic Industry; Use Technical Backgrou	Domestic Industry; Harold J. Technical Background John Day	Harold J. Walbrink; John Day	Admitted 8/28

Complainants' Direct Exhibits List

Exhibit Number	Bates Number	Description	Purpose For Exhibit Being	Sponsoring Witness	Date Received
CX-54	EITC 003234- EITC 003237	VIO System, Your System Literature	Domestic Industry;	Harold J. Walbrink;	Admitted 8/27
CX-55C			i continuatio acception of	Kickle L. Steward	
	EITC 003444				Withdrawn
CX-56	EITC 003141-	Portion of Canady Technology's Canady Plasma Beam - The Fourth State of Matter brochure	Patent Infringement	Harold J. Walbrink	Admitted 8/31
CX-57C	EITC 014638-	Summary of Electrosurgery & Gas Plasma			
	ELLC 014640	Expertise for Harold J. Walbrink	Expert Qualifications	Harold J. Walbrink	Rejected
CX-58	EITC 014643	Hal Walbrink's CV	Expert Qualifications	Harold J. Walbrink	Admitted 8/29
CX-59	EITC 014644	Endoscope drawing including profile view of tube Patent Infringement;	Patent Infringement; Technical Background:	Horold 1 Malburg	
			Domestic Industry		Admitted 8/29
CX-60	EITC 011692- EITC 011693	VIO 300D/APC 2 Quickstart Guide	Domestic Industry; Technical Backoround	Harold J. Walbrink; Rickia I. Staward	Admitted 8/27
		Single page from Exhibit 7 of complaint - Canadi			
CX-61	EITC 003138	Pricing Schedule September 2005 - December 2005	Patent Infringement	Harold J. Walbrink	Admitted 8/31
CX-62	СТ 02099- СТ 02177	510(k) for Canady Technology plasma probes	Patent Infringement	Harold J. Walbrink; Bernard Hurr Jaroma	Admittad 0/21
				Canady	
	EILC 004416	20132-166/3 2.3 L -ERBE Technical Drawing	Patent Infringement; Domestic Industry	Harold J. Walbrink	Admitted 8/29
CX-64	EITC 000603- EITC 000649	U.S. Patent No. 4,781,175	Technical Background: Claim Interpretation		Admitted 8/29

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Exhibit Number	Bates Number	Description	Purpose For Exhibit Being	Sponsoring	Date Received
CV CF			Offered	Aviuless	
CV-02	EIIC 014/09	Drawing of Canady Probes- Walbrink file	Patent Infringement	Harold J. Walbrink	Admitted 8/29
CV 67					Withdrawn
10-22					Withdrawn
02-20 22-00					Withdrawn
CV-03					Withdrawn
CX-71					Withdrawn
CX-70					Withdrawn
71-22					Withdrawn
CX-73	EITC 003144	Price List September 2005-December 2005 Canady Plasma Probes for Flexible Endoscopy & Patent Infringement Bronchoscopy	Patent Infringement	/albrink; romell;	Admitted 8/31
CX-74				I TOY DAKET	1 1 1
					Withdrawn
CX-75	EITC 003139	Catalogue Numbers with cross refereces	Patent Infringement	Harold J. Walbrink; Jarmaine Bromell; Trov Boker	Admitted 8/31
				ויטן שמהכו	
CX-76	EITC 003140	Canady Technology Price List, January 2006 - December 2006	Patent Infringement	Harold J. Walbrink; Jarmaine Bromell; Troy Baker	Admitted 8/31
CX-77C	EITC 013934- EITC 014026	ERBE- Functional Test for Electrosurgical Generator Model VIO 300D	Technical Background; Domestic Industry	Rickie L. Steward	Rejected
CX-78C	EITC 014027- EITC 014078	ERBE- Functional Test for Argon Plasma Coagulator Model APC 2	Technical Background; Domestic Industry	Rickie L. Steward	Rejected
CX-79C	EITC 014079- EITC 014469	ERBE- Equipment Manual Revision	Technical Background; Rickie L. Steward Domestic Industry	Rickie L. Steward	Rejected

Complainants' Direct Exhibits List

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Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
CX-80C	EITC 014470- EITC 014526	Customer VIO Initial Program Settings	Technical Background; Rickie L. Steward Domestic Industry	Rickie L. Steward	Rejected
CX-81C	EITC 005132- EITC 005135	APC 2 Technical Safety Check Data Form	Technical Background; Rickie L. Steward Domestic Industry	Rickie L. Steward	Admitted 8/27
CX-82C	EITC 005120- EITC 005131	ERBE Service and Repair Report	Technical Background; Rickie L. Steward Domestic Industry	Rickie L. Steward	Admitted 8/27
CX-83					Withdrawn
CX-85	FITC 014715				Withdrawn
CX-86	01110011		Patent Infringement	Steven M. War	Rejected
					Withdrawn
CX-87	EITC 003729- EITC 003738	ERBE- Sales Support Materials- Electrosurgery	Technical Background; Domestic Industry		Admitted 8/28
CX-88	EITC 010929	New Techniques in ENT: Specialty Instruments for APC and Electrosurgery	Technical Background; Domestic Industry		Admitted 8/28
CX-89	EITC 011029	The Principle- ERBE Argon Plasma Coagulator sample of trademark advertisement	Technical Background; John L. Day Domestic Industry		Admitted 8/28
CX-90	EITC 011851	Video- APC Clinical Applications Presented by Dr. Kenneth Binmoeller	Technical Background; Domestic Industry		Admitted 8/28
CX-91					
CX-92					Withdrawn
	EITC 014722	Photo CD- Dax Parise	Τ		Withdrawn
CX-94				Dax Parise	Rejected
				_	Withdrawn

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Exhibit Number	Bates Number	Description	Purpose For Exhibit Being	Sponsoring Witness	Date Received
CX-95C			Ollered		
CX-96C					Withdrawn
CX-97C					Withdrawn
CX-98C					Withdrawn
					Withdrawn
CX-99		Complainant's Exhibit No. 4- Canady Technology Patent Infringement Pricing Schedule (Korinko)	Patent Infringement	Kate Korinko/Troy Baker/Jarmaine Bromwall	Admitted 8/31
CX-100C	CT 01557- CT 01560	Complainant's Exhibit No. 9- Canady Technology Patent Infringement Income by Customer Detail (Korinko)	Patent Infringement	Kate Korinko	Admitted 8/31
		Complainant's Exhibit No. 188- 7/31/06 Conceli			
	MEI 0135		Patent Infringement; Canady Information	Kate Korinko	Admitted 8/31
CX-102					
CX-103					Withdrawn
		Comulainant's Denosition Evikit No. 244 A-11			Withdrawn
CX-104		o deposition Extual No. 244- Article- complications of argon plasma or hematochezia related to radiation	Patent Infringement, Technical Background	Dr. Douglas Rex	Admitted 8/31
CX-105		6			
		Complainant's Denosition Evhibit No. 191			Withdrawn
CX-106	MET 0120- MET 0125	Dr. d price	Patent Infringement	Dr. Roy Ferguson	Admitted 8/31
		Complainant's Deposition Exhibit No 184-			
CX-107	MET 0132	for	Patent Infringement	Dr. Roy Ferguson	Admitted 8/31

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Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
CX-108	MET 056- MET 059	Complainant's Deposition Exhibit No. 185- 1856/30/06 Fax from Dr. Canady to S. Williams enclosing Letter re price quote for generators and probes (Ferguson)	Patent Infringement	Dr. Roy Ferguson	Admitted 8/31
CX-109	MET 0221- MET 0111	Complainant's Deposition Exhibit No. 193- Canady Technology Service Manual- CT-3500 (Ferguson)	Patent Infringement	Dr. Roy Ferguson	Admitted 8/31
CX-110	MET 0099- MET 0111	Complainant's Deposition Exhibit No. 195- Brochure for CT-3500 Electrosurgical Generator (Ferguson)	Patent Infringement	Dr. Roy Ferguson	Admitted 8/31
CX-111	MET 0112- MET 0115	Complainant's Deposition Exhibit No. 196- Brochure- CT-3500: A Quantum Leap Into the Future (Ferguson)	Patent Infringement, Information on CT- 3500	Dr. Roy Ferguson	Admitted 8/31
CX-112					VA/ithedron
CX-113		Complainant's Deposition Exhibit No. 248- Canady CT-3500 User Instructions	Patent Infringement	Cynthia Marshburn, B S N	Admitted 8/31
CX-114					Withdrawn
CX-115		Complainant's Deposition Exhibit No. 195- (Gostout) 10/03 Article: Endoscopic treatment of Technical Background chronic radiation proctopathy	Technical Background	Dr. Christopher Gostout	Admitted 8/31
CX-116		Complainant's Deposition Exhibit No. 196- (Gostout)- Set-up Instructions, APC 300 Argon Plasma Coagulator- ERBE (2-sided document)	Technical Background, Dr. Christopher Patent Infringement Gostout	Dr. Christopher Gostout	Admitted 8/31
CX-117	EITC 004517- EITC 004532	Complainant's Exhibit No. 197- Practice of Therapeutic Endoscopy Second Edition- 2000	Technical Background, Dr. Christopher Patent Infringement Gostout		Admitted 8/31

Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
CX-118C	MAYO 0086	Complainant's Exhibit No. 198- 2/5/06 E-mail from C. Gostout to A. Bailey & C. Frie Re APC	Patent Infringement	Dr. Christopher Gostout	Admitted 8/31
CX-119C	MAYO 0145- MAYO 0148	Complainant's Exhibit No. 200- 4/25/06 E-mail from M. Morris to C. Frie Re Follow up	Technical Background	Dr. Christopher Gostout	Admitted 8/31
CX-120C	MAYO 0098	Complainant's Exhibit No. 201- 5/16/06 E-mail from C. Gostout to C. Frie Re ERBE proposal	Technical Background	Dr. Christopher Gostout	Admitted 8/31
CX-121C	MAYO 0081	Complainant's Exhibit No. 202- 6/4/06 E-mail from C. Gostout to C. Frie and 6/02/06 e-mail from Drjcanady to Dr. Gostout, C. Frie and Troy Baker.	Patent Infringement	stopher	Admitted 8/31
CX-122	EITC 005107	Complainant's Exhibit No. 209- Faculty Financial Relationships Report	Canady Background	Dr. Christopher Gostout	Admitted 8/31
CX-123C	MAYO 0087- MAYO 0088	Complainant's Exhibit No. 210- 10/31/06 E-mail from C. Gostout to B. Peterson et al. Re APC probes and related chain of e-mails	Patent Infringement	Dr. Christopher Gostout	Admitted 8/31
CX- 124C	MAYO 0073- MAYO 0078	Complainant's Exhibit No. 212- 8/31/06 Letter from M. Melkerson, FDA, to S. Preiss Re K052035	Patent Infringement	Dr. Christopher Gostout	Admitted 8/31
CX-125					Withdrawn
CX-126		Complainant's Deposition Ex. 169 (Baker)- http://www.erbe-med.com/hf_e/apc_probes.html- Patent Infringement 9/19/05	Patent Infringement	Troy Baker	Admitted 8/31
CX-127					Withdrawn
CX-128					Withdrawn
CX-129C		Complainant's Deposition Exhibit No. 174 (Baker) - Faxed List of Hospitals	Patent Infringement	Troy Baker	Admitted 8/31
CX-130					Withdrawn
LA-131					Withdrawn

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CX-132			ollered		
		Deposition Exhibit No 246-510/k) Latter from			Withdrawn
CX-133		Dr. Canady to Tim Ingram of Blue Ridge Health Care	Patent Infringement	Phillip Webb	Admitted 8/31
CX-134					
CX-135	EITC 013773-	Complainant's Deposition Exhibit No. 250-CV of Bookarous - Book	Doolversing and and		Withdrawn
CX-136	EITC 013616	Dr John Vargo	background on Ur. Vargo	Dr. John Vargo	Admitted 8/31
		Complainant's Denceition Exclinit No. 200			Withdrawn
CX-137	EITC 003672- EITC 003679	al applications of the argon plasma	Patent Infringement, Technical Background	Dr. John Vargo	Admitted 8/31
CX-138C					
					Withdrawn
CX-139C	CT 01750- CT 01751	Complainant's Deposition Exhibit No. 27- KLS Martin's 9/28/04 Letter of offer	Patent Infringement	Dr. Jerome Canady/Michael Martin Admitted 8/31	Admitted 8/31
CX-140	KLS 0116- KLS 0117	Complainant's Deposition Exhibit No. 28- KLS Martin's 9/28/04 Letter of offer	Patent Infringement	Dr. Jerome Canadv/Michael Martin Admitted 8/31	Admitted 8/31
CX-141C	KLS 0123- KLS 0127	Complainant's Deposition Exhibit No. 45- APC- probe Tracheobronchial and Gastrointestinal – Drawings	jement;	Dr. Jerome Canady/ Michael Martin/Troy	Admitted 8/31
			Τ	Baker	
CX-142	KLS 0002- KLS 0003	Complainant's Deposition Exhibit No. 47- 9/22/04 Patent Infringement E-mail from Michael Martin to Susanne Stachel Canady Technology re WG: Offer flexible APC probes Background		Dr. Jerome Canady/Michael Martin	Admitted 8/31
	KI S 0110 KI S	Complainant's Deposition Exhibit No 49- 9/28/04			
CX-143C	0122		Patent Infringement	Dr. Jerome Canady/Michael Martin	Admitted 8/31

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Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offorod	Sponsoring Witness	Date Received
CX-144C	CT 01742- CT 01750	Complainant's Deposition Exhibit No. 50- 9/28/04 Patent Infringement; KLS Martin Specification Sheet flexible Argon- Plasma-Coagulation-Probe single use Infringement	Patent Infringement; Trademark Infringement	Dr. Jerome Canady/Michael Martin	Admitted 8/31
CX-145C	СТ 01778- СТ 01780	Complainant's Deposition Exhibit No. 51- 11/24/04 E-mail from Canady ('Drcanady03@cs.com') to Michael Martin re FWD: KLS Martin/Canady Purchase Order	Patent Infringement	Dr. Jerome Canady	Admitted 8/31
CX-146	0078 KLS 0075- KLS	Complainant's Deposition Exhibit No. 30- KLS Martin's 2/28/05 Letter re "offer AM 2620 'Flexible APC Probes Single Use"	Patent Infringement	Dr. Jerome Canady/Michael Martin Admitted 8/31	Admitted 8/31
CX-147	CT 01974- CT 01975	Complainant's Deposition Exhibit No. 60- 6/23/05 E-mail from Bernhard Hug to Canady "Drcanady03@cs.com" re User Manual	Patent Infringement	Dr. Jerome Canady/Michael Martin Admitted 8/31	Admitted 8/31
CX-148C	CT 02184- CT 02187	e e ints	Patent Infringement	Dr. Jerome Canady	Admitted 8/31
CX- 149C	CT 01850- CT 01855	90	Patent Infringement	Dr. Jerome Canady	Admitted 8/31
CX- 150C	CT 01856 - CT01857; CT 01953 - CT 01958; CT 01858 - CT 01858 - CT	ę	Patent Infringement, Background on Canady Technology	Dr. Jerome Canady	Admitted 8/31
CX-151C	CT 01786- CT 01814	Complainant's Deposition Exhibit No. 125- 1/26/06 E-mail to Canady enclosing final supply agreement	Patent Infringement, Background on Canady Technology	Dr. Jerome Canady	Admitted 8/31

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		Complainants' Direct Exhibits List	Exhibits List		
Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
CX-152	CT 10411- CT 10414	t's Deposition Exhibit No. 131- CT- antum Leap into the Future	Patent Infringement, Background on Canady Technology	Dr. Jerome Canady	Admitted 8/31
CX-153	CT 05968- CT 05969	· · · · · · · · · · · · · · · · · · ·	Background on Canady Technology	Dr. Jerome Canady	Admitted 8/31
CX-154		Complainant's Deposition Exhibit No. 133- FOIA Response Database	Background on Canady Technology	Dr. Jerome Canady	Admitted 8/31
CX-155	CT 04079- CT 04083	tion Exhibit No. 134- List of	-	Dr. Jerome Canady	Admitted 8/31
CX-156C	CT 12484	Complainant's Deposition Exhibit No. 138- 2/17/06 E-mail from Wilkinson re Canady probe equivalent to ERBE	Patent Infringement, Background on Canady Technology	Dr. Jerome Canady	Admitted 8/31
CX-157	CT 01964- CT 01968	Complainant's Deposition Exhibit No. 140- 8/26/05 E-mail to Canady re Brochure	Patent Infringement, Background on Canady Technology	Dr. Jerome Canady	Admitted 8/31
CX-158	EITC 003144	s Deposition Exhibit No. 142- Price 06	Patent Infringement, Background on Canady Technology	Dr. Jerome Canady	Admitted 8/31
CX-159	EITC 003139	Complainant's Deposition Exhibit No. 143- http://www.erbe-med.com/hf_e/apc_probes.html E 9/19/05	Patent Infringement, Background on Canady Technology	Dr. Jerome Canady	Admitted 8/31
CX-160	СТ 02292	Complainant's Deposition Exhibit No. 144- E-mail Background on to Beth Israel Hosp. re FOIA request 10/05/06 Canady Techno	Background on Canady Technology	Dr. Jerome Canady	Admitted 8/31
CX-161	KLS 0146- KLS 0148	Complainant's Deposition Exhibit No. 66- 9/17/92 Patent Infringement, Itr to Canady re Patent info on probes Canady Technology	Patent Infringement, Background on Canady Technology	Dr. Jerome Canady/Michael Martin	Admitted 8/31

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Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offorod	Sponsoring Witness	Date Received
CX-162	KLS 0056	Complainant's Deposition Exhibit No. 74- Canady Patent Infringer Technology Germany GMBH (TRANSLATION)	Patent Infringement, Background on	Dr. Jerome Canadv/Michael Martin Admitted 8/31	Admitted 8/31
CX-163	GUHO 00011 - GUHO 00015	Complainant's Deposition Exhibit No. 216- 510(K) Summary for Soring GmbH Medizintechnik	Canady recrinology Patent Infringement	Dr. Jerome Canady	Admitted 8/31
CX-164	GUHO 00030	Deposition Exhibit No. 220- Safety anady Plasma Probes		Dr. Jerome Canady	Admitted 8/31
CX-165C	CT 13714	Complainant's Deposition Exhibit No. 222- Inventory of KLS Martin Probes	Background on	Dr. Jerome Canady	Admitted 8/31
CX-166C	CT 13716- CT 13727	's Deposition Exhibit No. 223- ce Tracking Log Order- KLS Martin	Patent Infringement, Background on	Dr. Jerome Canady	Admitted 8/31
CX-167C	CT 13715	nant's Deposition Exhibit No. 224- Inventory on Soring Probes	Background on Canady Technology	Dr. Jerome Canady	Admitted 8/31
CX-168C	CT 13728- CT 13731	s Deposition Exhibit No. 225- ce Tracking Log for Soring Probes	Patent Infringement	Dr. Jerome Canady	Admitted 8/31
	GUHO 00038- GUHO 00098	Complainant's Deposition Exhibit No. 227- User Manual CT-3500	Patent Infringement, Background on Canady Technology	Dr. Jerome Canady	Admitted 8/31
CX-170			(Rololling) (paring		Mithdrawn
CX-177					Withdrawn
					Withdrawn
CX-173	CT 10056 - CT 10057	Technology Ad. ~ The Fourth State of Matter. First to Invent Argon Plasma Coagulator via Flexible Catheters.	Patent Infringement, Background on Canady Technology	Dr. Jerome Canady	Admitted 8/31

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Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
CX-174C		Complainant's Deposition Exhibit No. 233- Medical Device Tracking Log for sample distribution of KLS Martin Probes	Patent Infringement	Dr. Jerome Canady	Admitted 8/31
CX-175C		Complainant's Deposition Exhibit No. 234- Medical Device Tracking Log for sample distribution of Soring Probes	Patent Infringement	Dr. Jerome Canady	Admitted 8/31
CX-176	GUHO 00023- GUHO 00027	Complainant's Deposition Exhibit No. 236- Canady Technology's 510(K) Notification for the Canady Technology Probes	Patent Infringement, Background on Canady Technology	Dr. Jerome Canady	Admitted 8/31
CX-177C					Withdrawn
CX-178C	CT 01752- CT 01753	Complainant's Deposition Exhibit No. 32- 1/3/05 Letter of Intent between Canady Technology Inc. and KLS Martin GmbH + Co. KG	Patent Infringement, Background on Canady Technology	Michael Martin	Admitted 8/31
CX-179					Withdrawn
CX-180C	CT 02203 - CT 02210	Complainant's Deposition Exhibit No. 43- 11/6/99 Patent License Agreement between Dr. Jerome Canady/Alfonso Canady and HUTTINGER Medizintechnik GmbH + Co. KG	Patent Infringement, Background on Canady Technology	Michael Martin	Admitted 8/31
CX-181C	CT 11472 - CT 11473	Complainant's Deposition Exhibit No. 44- 10/16/01 E-mail from Scott Dillenback to Bernhard Hug et al. re Introduction of Technical Experts in Probe and Adapter Development	Patent Infringement, Background on Canady Technology	Michael Martin	Admitted 8/31
CX-182C	KLS 0084- KLS 0087	Complainant's Deposition Exhibit No. 48- APC- probe Tracheobronchial and Gastrointestinal – Drawings	Patent Infringement, Background on Canady Technology; Trademark Infringement	Michael Martin	Admitted 8/31

Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
CX-183	KLS 0287 - KLS 0294; KLS 0299 - KLS 0307; KLS 0295; KLS 0298; KLS 0255 - KLS 0268; KLS 0180 - KLS 0223	Complainant's Deposition Exhibit No. 53- 7/1/05 Canady Plasma Probe / 510(k) Premarket Notification		Michael Martin	Admitted 8/31
CX-184		5	Patent Infringement	Michael Martin	Admitted 8/31
CX-185	NLS 0149- KLS 0152	Letter	Patent Infringement, Importation	Michael Martin	Admitted 8/31
CX-186	KLS 161	Complainant's Deposition Exhibit No. 75- 12/05/05 E-mail re Chargen-Nummem (TRANSLATION)	Patent Infringement, Importation	Michael Martin	Admitted 8/31
CX-187	KLS 0005	Complainant's Deposition Exhibit No. 76- 1/16/06 Patent Infringement, Ltr to Reiche from Martin (TRANSLATION) Importation	Patent Infringement, Importation	Michael Martin	Admitted 8/31
CX-188	KLS 0058	<u> </u>	Patent Infringement, Importation	Michael Martin	Admitted 8/31
CX-189	KLS 0051		Patent Infringement, Importation	Michael Martin	Admitted 8/31
CX-190	KLS 0052	Complainant's Deposition Exhibit No. 79- Chart- F Canady Technology Germany GmbH (TRANSLATION)	Patent Infringement, Importation	Michael Martin	Admitted 8/31

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Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
CX-191	KLS 0053	Complainant's Deposition Exhibit No. 80- Chart- Canady Technology Germany GmbH (TRANSLATION)	Patent Infringement, Importation	Michael Martin	Admitted 8/31
CX-192C	KLS 0020- KLS 0027	Complainant's Deposition Exhibit No. 81- Tech Drawing - Stecker (TRANSLATION)	Patent Infringement, Importation	Michael Martin/Bernard Admitted 8/31 Hug	Admitted 8/31
CX-193C					Withdrawn
CX-194	EITC 005964- EITC 005965	Complainant's Deposition Exhibit No. 84- APC probes for flexible endoscopes – notes on use 10/04	Patent Infringement, Importation	Bernard Hug	Admitted 8/31
CX-195	CT 10519- CT 10522	Complainant's Deposition Exhibit No. 85- Technical Specs – ERBE VIO APC 2 (8/03)	Patent Infringement, Importation	Bernard Hug	Admitted 8/31
CX-196	KLS 0360	Complainant's Deposition Exhibit No. 86- Invoice ERBE to Trumpf Medizin 5/15/03 (TRANSLATION)		Bernard Hug	Admitted 8/31
CX-197	KLS 0349- KLS 0350		Patent Infringement, Importation	Bernard Hug	Admitted 8/31
CX-198	KLS 0353- KLS 0354	Complainant's Deposition Exhibit No. 88- 9/23/03 Trumpf to ERBE for APC Probe and connecting cable 9/25/03 (TRANSLATION)	Patent Infringement, Importation	Bernard Hug	Admitted 8/31
CX-199	KLS 0355	Complainant's Deposition Exhibit No. 89- Invoice ERBE to Trumpf Medizin 9/25/03 (TRANSLATION)	Patent Infringement, Importation	Bernard Hug	Admitted 8/31
CX-200	KLS 0339- KLS 0340	Complainant's Deposition Exhibit No. 91- Invoice ERBE to Trumpf Medizin 3/24/04 (TRANSLATION)	Patent Infringement, Importation	Bernard Hug	Admitted 8/31
CX-201C	CT 01741	Complainant's Deposition Exhibit No. 92- 2/02/05 E-mail from Martin to Canady re confirming payment transfer	Patent Infringement, Importation	Bernard Hug	Admitted 8/31

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Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
CX-202C	0083 KLS 0079- KLS	Complainant's Exhibit No. 93- Spec sheet for argon plasma coagulation probes 2/24/05	Patent Infringement, Importation	Bernard Hug	Admitted 8/31
CX-203	KLS 0357	Complainant's Exhibit No. 90- Invoice ERBE to Trumpf Medizin 9/25/03 with handwriting	Patent Infringement, Importation	Bernard Hug	Admitted 8/31
CX-204C					Withdrawn
CX-205		Complainant's Deposition Exhibit No. 6- Canady Plasma Probe / 510(k) Pre-Market Notification	Patent Infringement, Background on Canady Technology	Troy Baker/Jarmaine Bromwell	Admitted 8/31
CX-206		Complainant's Deposition Exhibit No. 172- (Baker) - Canady 510(k) Pre-Market Notification 7/01/05	Patent Infringement, Background on Canady Technology	Troy Baker	Admitted 8/31
CX-207			(Balance (and		Withdrawn
CX-208C		Complainant's Deposition Exhibit No. 176- Pro Forma Forecast Statement of Profit and Loss	Patent Infringement, Background on Canady Technology	Troy Baker	Admitted 8/31
CX-209		Complainant's Deposition Exhibit No. 178- Safety Patent Infringement instruction sheet	Patent Infringement	Troy Baker	Admitted 8/31
CX-210C		s Deposition Exhibit No. 173- Faxed als	Patent Infringement	Troy Baker	Admitted 8/31
CX-211C	CT 01945- CT 01952	Complainant's Deposition Exhibit No. 18- Faxed Brochure from Jerome Canady to Joel Nied - "Canady Plasma Beam – The Fourth State of Matter	Patent Infringement	Troy Baker	Admitted 8/31
CX-212C					Withdrawn
CX-213C					Withdrawn
CX-214		Complainant's Deposition Exhibit No. 1- ERBE's 9/27/06 Notice of Deposition of Jarmaine Bromell	Patent Infringement	Jarmaine Bromwell	Admitted 8/31

Complainants' Direct Exhibits List

Exhibit Number	Bates Number	Description	Purpose For Exhibit Being	Sponsoring Witness	Date Received
CX-215	CT 02089- CT 02098	Complainant's Deposition Exhibit No. 2- Letter from Mark N. Melkerson (FDA) to Preiss (Canady Technology, LLC) re: K052035 Canady	-	Jarmaine Bromwell	Admitted 8/31
CX-216		Complainant's Exhibit No. 5- "Canady Plasma Beam – The Fourth State of Matter" (Brochure, Price List, and KLS Martin Marketing Material –	Patent Infringement	Jarmaine Bromwell	Admitted 8/31
CX-217		German Document)			
CX-218					Withdrawn
CX-219					Withdrawn
CX-220					Withdrawn
CX-221					Withdrawn
CX-222					Withdrawn
CX-223					Withdrawn
CX-224					Withdrawn
CX-225					Withdrawn
CX-226					Withdrawn
CX-227					Withdrawn
CX-228					Withdrawn
CX-229					Withdrawn
CX-230					Withdrawn
CX-231					Withdrawn
CX-232					Withdrawn
CX-233					Withdrawn
CX-234					Withdrawn
CX-235					Withdrawn
CX-236C	1 12222	An Email of W. Wilkinson dated Sentember 6			Withdrawn
		l exhibit)	Patent Infringement	William Wilkinson	Admitted 8/31

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Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
CX-237C	CT 12452	An Email of W. Wilkinson, dated June 1, 2006 (Rebuttal exhibit)	Patent Infringement	William Wilkinson	Admitted 8/31
CX-238C	CT 12453	An Email of W. Wilkinson, dated June 5, 2006 (Rebuttal exihibit)	Patent Infringement	William Wilkinson	Admitted 8/31
CX-239C	CT 12488- CT 12489	An Email of W. Wilkinson, dated February 17, 2006 (Rebuttal exhibit)	Patent Infringement	William Wilkinson	Admitted 8/31
CX-240C	CT 12498	An Email of W. Wilkinson, dated February 16, 2006 (Rebuttal exhibit)	Patent Infringement	William Wilkinson	Admitted 8/31
CX-241					Mitholican
CX-242					Withdrawn
CX-243					Withdrawn
CV-244					Withdrawn
CX-245C	EITC 005117- EITC 005188	Terms and Conditions from ERBE Purchase Agreement (Rebuttal exhibit)	Patent Infringement, Enforceability	Creighton White, John Admitted 8/29	Admitted 8/29
U	EITC 013563- EITC 013564	Terms and Conditions from ERBE Purchase Agreement (Rebuttal exhibit)	Patent Infringement, Enforceability	ihton White, John	Admitted 8/29
CX-247					Withdrawn
CX-248C					Withdrawn
CX-249C					Withdrawn
CX 250C					Withdrawn
CV 262					Withdrawn
707-00					Withdrawn
CX-253		Redacted email from Bromell re Canady Technology (A new APC competitor) - (Complainants' Deposition Exhibit no. 16)	Patent Infringement, Validity	Jarmaine Bromwell	Admitted 8/31
CX-254					Withdrawn
CX-255					Withdrawn
CX-256					Withdrawn
CX-257					Withdrawn

United States International Trade Commission In the Matter of Certain Endoscopic Probes For Use in Argon Plasma Coagulation Systems Investigation No. 337-TA-569 **Complainants' Direct Exhibits List**

		COMPRESSION SUBSILIES COMPRESSION SUBSILIES			
Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
CX-258		Rebuttal Witness Statement of Steven Wereley	Patent Infringement, Validity, Technical Background	Steven Wereley	Admitted 8/28
CX-259					Withdrawn
CX-260					Withdrawn
CX-261					Withdrawn
CX-262					Withdrawn
CX-263					Withdrawn
CX-264					Withdrawn
. CX-265					Withdrawn
CX-266					Withdrawn
CX-267C		Rebuttal Witness Statement of Hal Walbrink	Patent Infringement, Validity, Claim Intepretation, Technical Background	Hal Walbrink	Admitted 8/29
CX-268		Summary of Opinion- formerly CDX-7	Patent Infringement	Steven T. Wereley	Rejected
CX-269			Patent Infringement	Steven T. Wereley	Rejected
CX-270		Chart summarizing tests- formerly CDX-10	Patent Infringement	Steven T. Wereley	Rejected
CX-271		Summary of Conclusions from test- formerly CDX-13	Patent Infringement	Steven T. Wereley	Rejected
CX-272		Bircher ABC Demonstrative- formerly CDX-26	Claim Interpretation, Technical Background	Harold J. Walbrink	Rejected
CX-273		ERBE Combinations- formerly CDX-31	Domestic Industry	Harold J. Walbrink	Rejected
CX-274		Canady Combinations- formerly CDX-32	Patent Infringement	Harold J. Walbrink	Rejected
CX-275		Claim Interpretation Chart- formerly CDX-33	Claim Interpretation	Harold J. Walbrink	Rejected
CX-276		ERBE Coverage Chart- formerly CDX-34	Domestic Industry	Harold J. Walbrink	Rejected
CX-277		Canady Infringement Chart- formerly CDX-35	Patent Infringement	Harold J. Walbrink	Rejected

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Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
CX-278		Combined Claim Chart- formerly CDX-36	Patent Infringement, Domestic Industry	Harold J. Walbrink	Rejected
CX-279C	EITC 004408	Annoted ERBE Probe Drawing- formerly CDX- 37C	Domestic Industry	Harold J. Walbrink	Rejected
CX-280		Power Point Presentation- formerly CDX-38	APC History	Harold J. Walbrink	Rejected

Complainants' Demonstrative Exhibits List

Exhibit	Bates	Description	Purpose For Evhihit Boing	Sponsoring	Date
Number	Number		Offered	Witness	Received
CDX-1		Picture of laminar flow (still from animation)	Technical Background	Steven T. Werelev	Admitted 8/30
CDX-2		Animation of laminar flow	Technical Background		Admitted 8/30
CDX-3		Picture of turbulent flow (still from animation)	Technical Background	T	Admitted 8/30
CDX-4		Animation of turbulent flow	Technical Background	Steven T. Wereley	Admitted 8/30
CDX-5		Picture of low flow non-laminar flow (still from animation	Technical Background		Admitted 8/30
CDX-6		Animation of low flow non-laminar flow	Technical Background	Steven T. Werelev Admitted 8/30	Admitted 8/30
CDX-7		Summary of Opinion	Patent Infringement	Steven T. Wereley	Admitted 8/30
CDX-8		ERBE electrosurgical units tested	Patent Infringement	1	Admitted 8/30
CDX-9		Drawing of test set up	Patent Infringement	Steven T. Wereley Admitted 8/30	Admitted 8/30
CDX-10		Chart summarizing tests	Patent Infringement	Steven T. Wereley	Admitted 8/30
CDX-11		Enhanced video of X	Patent Infringement		Admitted 8/30
CDX-12		Enhanced video of JJ	Patent Infringement	Steven T. Wereley Admitted 8/30	Admitted 8/30
CDX-13		Summary of Conclusions from test	Patent Infringement	Steven T. Wereley	Admitted 8/30
CDX-14	-				Withdrawn
CDX-15		Bipolar Demonstrative	Technical Background	Harold J. Walbrink Admitted 8/29	Admitted 8/29
CDX-16		Monopolar Demonstrative	Technical Background	Harold J. Walbrink Admitted 8/29	Admitted 8/29
CDX-17		Current/Heat Density Demonstrative	Technical Background	Harold J. Walbrink	Admitted 8/29
CDX-18		Frequency/Electrocution Demonstrative	Technical Background	Harold J. Walbrink	Admitted 8/29
CDX-19		Open Surgery Demonstrative	Technical Background	Harold J. Walbrink	
CDX-20		Minimally Invasive Demonstrative	Technical Background	Harold J. Walbrink	Admitted 8/29
CDX-21			Technical Background	Harold J. Walbrink	Admitted 8/29
CDX-22		Upper GI Endoscopy Demonstrative	Technical Background	Harold J. Walbrink	Admitted 8/29
CDX-23		Photo of Upper GI Endoscopy	Technical Background	Harold J. Walbrink Admitted 8/29	Admitted 8/29
CDX-24			Technical Background	Harold J. Walbrink	Admitted 8/29
CDX-25		Animation of Lower GI Endoscopy	Technical Background	Harold J. Walbrink	Admitted 8/29
CDX-26		Birtcher ABC Demonstrative	Claim Interpretation, Technical Background	Harold J. Walbrink Admitted 8/29	Admitted 8/29

United States International Trade Commission In the Matter of Certain Endoscopic Probes For Use in Argon Plasma Coagulation Systems Investigation No. 337-TA-569 Commissionante' Demonstrative Exhibite 1 int

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Exhibit Number	Bates Number	Description	Purpose For Exhibit Being	Sponsoring Witness	Date
			Uttered		necelved
17-21		ABC Animation	Claim Interpretation, Technical Background	Harold J. Walbrink Admitted 8/29	Admitted 8/29
CDX-28		"No Elbow Room" Animation	Claim Interpretation, Technical Background	Harold J. Walbrink Admitted 8/29	Admitted 8/29
CDX-29		Figs. 15 and 20	Claim Interpretation, Technical Background	Harold J. Walbrink	Admitted 8/29
CDX-30		APC Animation	Claim Interpretation,	Harold J Walhrink	Admitted 0/20
CDX-31		ERBF Combinations	lechnical Background		עמווווובת מלק
CDX-32		Canady Combinations	Domestic Industry	Harold J. Walbrink Admitted 8/29	Admitted 8/29
CDX-33			Patent Intringement	Harold J. Walbrink Admitted 8/29	Admitted 8/29
CDX-34		ERBE Coverane Chart	Claim Interpretation		Admitted 8/29
CDX-35		Canady Infrincement Chart	Lomestic Industry		Admitted 8/29
			Patent Infringement	Harold J. Walbrink	Admitted 8/29
0C-V-30		Combined Claim Chart	Patent Infringement,	Harold J. Walbrink	Admitted 8/29
CDX-37C		Annoted ERBE Probe Drawing			
CDX-38				Harold J. Walbrink	Admitted 8/29
		Coagulation	APC History	Jerome D. Waye	Admitted 8/27
CDX-39		"Backfilling" Animation- Rebuttal Demonstrative Exhibit	Claim Interpretation, Technical Background,	Harold J. Walbrink Admitted 8/31	Admitted 8/31
CDX-40		Bankshot" Animation- Rebuttal Demonstrative Exhibit	Claim Interpretation, Technical Background, Molidia:	Harold J. Walbrink Admitted 8/31	Admitted 8/31
CDX-41			valiulty		
					Withdrawn

Complainants' Physical Exhibits List

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Exhibit Number	Bates Number	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
CPX-1		Canady APC Probe- 2.3 mm x 2.3 m	Patent Infringement	Harold J. Walbrink Admitted 8/29	Admitted 8/29
CPX-2		ERBE APC Probe- 1.5 mm- 20312-155	Domestic Industry	Steward	Admitted 8/27
CPX-3		ERBE APC Probe- 2.3 mm x 7'.2"- 20132-156	Domestic Industry	Steward	Admitted 8/27
CPX-4		ERBE APC Probe- 2.3 mm x 9'.8"- 20132-166	Domestic Industry	Steward	Admitted 8/27
CPX-5		ERBE APC Probe- 3.2 mm x 7'.2."- 20132-157	Domestic Industry	Steward	Admitted 8/27
		ERBE APC Probe- 1.5mm x 150 cm- 20132-070	Domestic Industry	Steward	Admitted 8/27
0LA-1					Withdrawn
CPX-8		Complainant's Exhibit No. 42- Canady Plasma GIT Probe- 2.3 mm x 2.3 m- 1322537 (Reichle)	Patent Infringement Jens Reichle		Admitted 8/31
CPX-9	-				VARth almoster
CPX-10		Soring Single Use Probe-S-422537	Patent Infrincement	Ctoven Mer	VVILITULAWI
		Complainant's Exhibit No. 214- Soring Single Use			Aumilieu o/31
UFA-11		Probe- S-422538	Patent Infringement	Steven War	Admitted 8/31
CPX-12	EITC 011694	Canady Plasma GIT Probe 2.3 mm (Probe tested by Steven Wereley)	Patent Infringement	Dr. Steven T. Werelev	Admitted 8/28
CPX-13		Canady Plasma GIT Probe- 2.3 mm x 3.4 m- 1322538	Patent Infringement	Var	Admitted 8/31
CPX-14		Complainant's Exhibit No. 243- 2.3 mm x 3.4 m- 1322538	Patent Infringement	Dr. Douglas Rex	Admitted 8/31
CPX-15		Complainant's Exhibit No. 203- Probe shown to Marshburn and Gostout	Patent Infringement	Cynthia Marshburn, B.S.N.	Admitted 8/31
CPX-16		Complainant's Exhibit No. 213- Probe shown to Al- Kawas- Rebuttal Exhibit	Patent Infringement	Firas Al-Kawas	Admitted 8/31
			-	-	-

		United States International Trade Commission In the Matter of Certain Endoscopic Probes For Use in Argon Plasma Coagulation Systems Investigation No. 337-TA-569 Joint Exhibits List	e Commission e in Argon Plasma C 569 ist	oagulation Systems	
Exhibit Number	Bates Number Description	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
JX-1	EITC 000518- EITC 000543	Complainants' Deposition Exhibit No. 14- Certified copy of U.S. Patent No. 5,720,745- Farin et al Electrosurgical Unit and Method for Achieving Coagulation of Biological Tissue	Patent Infringement	Creighton White	Admitted 8/29
JX-2	EITC 000001- EITC 000387	Prosecution History of U.S. Patent No. 5,720,745- Farin et al Electrosurgical Unit and Method for Achieving Coagulation of Biological Tissue	Patent Infringement	Creighton White	Admitted 8/29
JX-3					Withdrawn
JX-4					Withdrawn
JX-5	EITC 000713- EITC 000975	Prosecution History of U.S. Patent Application No. 07/981,009- Farin et al Electrosurgical Unit and Method for Achieving Coagulation	Patent Infringement	Creighton White	Admitted 8/29
JX-6	EITC 000603- EITC 000649	chnique ion	Patent Infringement	Harold Walbrink	Admitted 8/31
7-XL	CT 01201- CT 01214	U.S. Patent No. 5,449,356- Walbrink et al Multifunctional Probe for Minimally Invasive Surgery	Expert Qualifications	Harold Walbrink	Admitted 8/31
JX-8					Withdrawn
JX-9C		Combined Deposition Designations for Christian Erbe	Validity, Patent Infringement	Christian Erbe	Admitted 8/31
JX-10					Withdrawn
JX-11C		Combined Deposition Designations for Johnny Boatwright	Patent Infringement	Johnny Boatwright	Admitted 8/31

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	Admitted 8/31	Rejected	Admitted 8/31	Rejected	Admitted 8/31	Admitted 8/31	Withdrawn	Admitted 8/31	Admitted 8/31	Admitted 8/31	Admitted 8/31
Coagulation Systems	Johannes Bohnenberger	Johannes Bohnenberger	Gunther Farin	Gunther Farin	Bernard Hug	Michael Martin	Harold Walbrink	Cynthia Marshburn	Dr. John Vargo, II	Kate Korinko	Phillip Webb
de Commission se in Argon Plasma (-569 iSt	Patent Infringement, Validity	Patent Infringement, Validity	Patent Infringement, Validity	Patent Infringement, Validitv	Patent Infringement, Importation, Validitv	Patent Infringement, Background on Canady Technology, Validity	Patent Infringement	Patent Infringement	Patent Infringement	Patent Infringement	Patent Infringement
United States International Trade Commission In the Matter of Certain Endoscopic Probes For Use in Argon Plasma Coagulation Systems Investigation No. 337-TA-569 Joint Exhibits List	Combined Deposition Designations for Johannes Bohnenberger (ITC transcript)	Combined Depositon Designations for Johannes Bohnenberger (ConMed transcript)	Combined Deposition Designations for Gunther Farin (ITC transcript)	Combined Deposition Designations for Gunther Farin (ConMed transcript)	Combined Deposition Designations for Bernard Hug	Combined Deposition Designations for Michael Martin	Combined Deposition Designations for Harold Walbrink (PAWD transcript)	Combined Deposition Designations for Cynthia Marshburn	Combined Deposition Designations for Dr. John Vargo, II	Combined Deposition Designations for Kate Korinko	Combined Deposition Designations for Phillip Webb
	JX-12C	JX-13	JX-14C	JX-15	JX-16C	JX-17C	JX-18	JX-19	JX-20	JX-21C	JX-22

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	_	United States International Trade Commission In the Matter of Certain Endoscopic Probes For Use in Argon Plasma Coagulation Systems Investigation No. 337-TA-569	de Commission e in Argon Plasma (-569	Coagulation Systems		[
		Joint Exhibits List	ist		,	
JX-23C		compined Deposition Designations for Jerome Canady	Patent Infringement	Jerome Canady	Admitted 8/31	· · · ·
JX-24	00	Combined Deposition Designations for Christopher Gostout		Christopher Gostout Admitted 8/31	Admitted 8/31	
JX-25	0¥	Patent Combined Deposition Designations for Dr. Firas Al- Technical Background,	Patent Infringement, Technical Background,	Dr. Firas Al-Kawas	Admitted 8/31	
JX-26C	0	Combined Deposition Designations for Troy Baker	Validity Patent Infringement, Validity	Troy Baker	Admitted 8/31	
JX-27	О Ľ	Combined Deposition Designations for Dr. Roy Ferguson	Patent Infringement, Technical Background,	Dr. Roy Ferguson	Admitted 8/31	
JX-28C	03	E	valuty Patent Infringement, Validitv	William Wilkinson	Admitted 8/31	
JX-29C	ŬĔ	Combined Deposition Designations for Jens Reichle	Patent Infringement	Jens Reichle	Admitted 8/31	
JX-30C	ŬĂ	Combined Deposition Designations for Jarmaine Bromell	Patent Infringement, Validity	Jarmaine Bromell	Admitted 8/31	
JX-31	Ŭ Ĕ	Combined Deposition Designations for Dr. Douglas	Patent Infringement, Technical Background, Validity	Dr. Douglas Rex	Admitted 8/31	
JX-32C	Ö	Combined Deposition Designations for Mark Mrvos	Patent Infringement	Mark Mrvos	Admitted 8/31	

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		Admitted 8/31
Coagulation Systems		Gardy Gerard
United States International Trade Commission r of Certain Endoscopic Probes For Use in Argon Plasma Coagulation Systems Investigation No. 337-TA-569	ts L	Patent Infringement
United States International Trade Commission rtain Endoscopic Probes For Use in Argon Plasr Investigation No. 337-TA-569	Joint Exhibits List	ceposition Designations for Gardy
Ur In the Matter of Certai	Combined Denocition	Gerard
		00-40

In the Matter of Certain Endoscopic Probes For Use in Argon Plasma Coagulation Systems Investigation # 337-TA-569 United States International Trade Commission

Respondents' Final Exhibit List

Date Received	Admitted 8/30/07	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07
Sponsoring Witness	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady
Purpose For Exhibit Being Offered	Issues relating to invalidity and non- infringement of the '745 patent	Issues relating to invalidity and non- infringement of the '745 patent	Issues relating to invalidity and non- infringement of the '745 patent	Issues relating to invalidity of the '745 patent	Issues relating to invalidity of the '745 patent	Issues relating to invalidity of the '745 patent	Issues relating to invalidity of the '745 patent	Issues relating to invalidity of the '745 patent	Issues relating to invalidity of the '745 patent
Description	Witness Statement of Dr. Jerome Canady	Curriculum Vitae of Dr. Jerome Canady	U.S. Patent No. 5,207,675 to Canady (Resp. Depo. Ex.94)	Reexamination Certificate for U.S. Patent No. 5,207,675	ERBE's Request for Reexamination of U.S. Patent No. 5,207,675	ERBE's Second Request for Reexamination of U.S. Patent No. 5,207,675	ERBE's Third Request for Reexamination of U.S. Patent No. 5,207,675	Notice of Intent to Issue Ex Parte Reexamination Certificate of U.S. Patent No. 5,207,675	U.S. Patent No. 5,122,138 to Manwaring
Bates Number Description		(CT11691 - CT11702)	(CT00001 - 00006)	(CT00193 - CT00194)	(CT00479 - CT00525)	(CT14669 - CT14746)	(CT14747 - CT14862)	(CT00179 - CT00190)	(CT00167 - CT00175)
Exhibit Number	RX-1C	RX-2	RX-3	RX-4	RX-5	RX-6	RX-7	RX-8	RX-9

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Date Received	Admitted 8/31/07	Withdrawn	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07
Sponsoring Witness	J. Canady		J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady
Purpose For Exhibit Being Offered	Issues relating to invalidity of the '745 patent		Issues relating to non-infringement of the '745 patent	Issues relating to non-infringement of the '745 patent	Issues relating to invalidity of the '745 patent	Issues relating to invalidity of the '745 patent	Issues relating to non-infringement of the '745 patent	Issues relating to non-infringement of the '745 patent	Issues relating to non-infringement of the '745 patent	Issues relating to non-infringement of the '745 patent	Issues relating to non-infringement of the '745 patent	lssues relating to non-infringement of the '745 patent
Bates Number Description	U.S. 510(k) K902996		Canady 1994 Article	Canady 2006 Article	Grund et al., "Endoscopic Argon Plasma Flexible Endoscopy," Endoscopic Surgery and Allied Technologies, No. 1, vol. 2, pp. 42-46, Feb. 1994.	Farin et al., "Technology of Argon Plasma Endoscopic Applications" Endoscopic Surgery and Allied Technologies, No. 1, vol. 2, pp. 71-77, Feb. 1994.	Chen et al., "Watermelon colon treated by argon plasma coagulation," Gastrointestinal Endoscopy, No. 4, Vol. 61, 2005.	Morice et al., "EndoBronchial Argon Plasma Coagulation for Treatment of Hemoptysis and Neoplastic Airway Obstruction," CHEST,119.3, pp. 781-787, Mar. 2001.	Iwamoto et al., "Interventional Bronchoscopy in the Management of Airway Stenosis Due to Tracheobronchial Tuberculosis," CHEST, 126, pp 1344-1352, 2004.	Tam et al, "Treatment of Radiation Proctitis with Argon Plasma Coagulation," Endoscopy, 32, 91:667-672, 2000.	Silva et al, "Argon Plasma Coagulation Therapy for Hemorrhagic Radiation Proctosigmoiditis," Gastrointestinal Endoscopy, Vol. 50, No. 2, 1999.	Pereira-Lima et al., "High Power Setting Argon Plasma Coagulation for the Eradication of Barrett's Esophagus," The American Journal of Gastroenterology, Vol. 95, No. 7, 2000
Bates Number	(CT13665 - CT13713)		(CT13135 - CT13137)	(CT10423 - CT10434)	(CT01675 – CT01679)	(CT00115 - CT00121)	(CT14346 - CT14348)	(CT01562 – CT01569)	(CT01570 – CT01581)	(CT01587 – CT01592)	(CT01593 CT01596)	(CT01597 – CT01604)
Exhibit Number	RX-10	RX-11	RX-12	RX-13	RX-14	RX-15	RX-16	RX-17	RX-18	RX-19	RX-20	RX-21

Date	Admitted	Admitted	Admitted	Admitted	Admitted	Admitted	Admitted	Admitted	Admitted	Admitted
Received	8/31/07	8/31/07	8/31/07	8/31/07	8/31/07	8/31/07	8/31/07	8/31/07	8/31/07	8/31/07
Sponsoring Witness	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady
Purpose For	Issues relating to	Issues relating to	Issues relating to	Issues relating to	Issues relating to	Issues relating to	Issues relating to	Issues relating to	Issues relating to	Issues relating to
Exhibit Being	non-infringement of	non-infringement of	non-infringement of	non-infringement of	non-infringement of	non-infringement of	non-infringement of	non-infringement of	non-infringement of	non-infringement of
Offered	the '745 patent	the '745 patent	the '745 patent	the '745 patent	the '745 patent	the '745 patent	the '745 patent	the '745 patent	the '745 patent	the '745 patent
Bates Number Description	Endoscopic Induction of Mucosal Fibrosis by Argon Plasma Coagulation (APC) for Esophageal Varices: A Prospective Randomized Trial of Ligation plus APC vs. Ligation Alone	Heindorff et al., "Endoscopic Palliation of Inoperable Cancer of the Oesophagus or Cardia by Argon Electrocoagulation," Scand J Gastroenterol, 33:21-23, 1998.	Cipolletta et al., "Prospective Comparison of Argon Plasma Coagulator and Heater Probe in the Endoscopic Treatment of Major Peptic Ulcer Bleeding," Gastrointestinal Endoscopy, Vol. 48, No. 2, 1998.	Schulz et al., "Ablation of Barrett's Epithelium by Endoscopic Argon Plasma Coagulation in combination with High-dose Omeprazole," Gastrointestinal Endoscopy, Vol. 51, No. 6, 2000.	Dumoulin et al., "Treatment of Barrett's Esophagus by Endoscopic Argon Plasma Coagulation," Endoscopy, 29, pp 751-753, 1997.	Mitsufuji et al., "Argon Plasma Coagulation: In Vivo Tissue Damage to the Esophagus and Stomach and Clinical Efficacy for Early Esophageal and Gastric Cancer," Digestive Endoscopy, Vol. 17, No. 1, pp 21-27, Jan. 2005.	Pedrazzani et al., "Endoscopic Ablation of Barrett's Esophagus Using High Power Setting Argon Plasma Coagulation: A Prospective Study," World J Gastroenterol, 11(12), pp 1872- 1875, 2005.	J. Lee, "Radiation Proctitis – A Niche for the Argon Plasma Coagulator," Gastrointestinal Endoscopy, Vol. 561, No. 5, 2002.	Murakami et al., "Argon Plasma Coagulation for the Treatment of Early Gastric Cancer," Hepato-Sagtroenterology, 51, pp 1685 1661, 2004.	Isomoto et al., "A Case of Haemorrhagic Radiation Proctitis: Successful Treatment with Argon Plasma Coagulation," European Journal of Gastroenterology & Hepatology, Vol. 14, No. 8, pp 901-904, 2002.
Bates Numbe	(CT01605 -	(CT01611 –	(CT01614 –	(CT01619 –	(CT01624 –	(CT01627 –	(CT01629 –	(CT01633 –	(CT01636 –	(CT01640 –
	CT01610)	CT01613)	CT01617)	CT01623)	CT01626)	CT01628)	CT01632)	CT01635)	CT01639)	CT01643)
Exhibit Number	RX-22	RX-23	RX-24	RX-25	RX-26	RX-27	RX-28	RX-29	RX-30	RX-31

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Date	Admitted	Admitted	Admitted	Admitted	Admitted	Admitted	Admitted	Admitted	Admitted	Admitted
Received	8/31/07	8/31/07	8/31/07	8/31/07	8/31/07	8/31/07	8/31/07	8/31/07	8/31/07	8/31/07
Sponsoring Witness	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady	J. Canady
Purpose For	Issues relating to	Issues relating to	lssues relating to	Issues relating to	Issues relating to	Issues relating to	Issues relating to	Issues relating to	lssues relating to	Issues relating to
Exhibit Being	non-infringement of	non-infringement of	non-infringement of	non-infringement of	non-infringement of	non-infringement of	non-infringement of	non-infringement of	non-infringement of	non-infringement of
Offered	the '745 patent	the '745 patent	the '745 patent	the '745 natent	the '745 patent	the '745 patent	the '745 patent	the '745 patent	the '745 patent	the '745 patent
Description	Dulai et al., "Randomized Trial of Argon Plasma Coagulation vs. Multipolar Electrocoagulation for Ablation of Barrett's Esophagus," Gastrointestinal Endoscopy, Vol. 61, No. 2, 2005.	Robertson et al., "Palliation of Oesophageal Carcinoma Using the Argon Beam Coagulator," British Journal of Sugery, 83, pp 1769-1771, 1996. (Resp. Depo. Ex. 122)	Byrne et al., "Restoration of the Normal Squamous Lining in Barrett's Esophagus by Argon Beam Plasma Coagulation," American Journal of Gastroenterology, Vol. 3, No. 10, pp 1810- 1815, 1998.	 J. Vargo, "Clinical Applications of the Argon Plasma Coagulator," Gastrointestinal Endoscopy, Vol. 59, No. 1, pp 81- 88, 2004. 	Wahab et al., "Argon Plasma Coagulation in Flexible Gastrointestinal Endoscopy: Pilot Experiences," Endoscopy, 29, pp 176-181, 1997. (Resp. Depo. Ex. 123)	Sebastian et al., "Argon Plasma Coagulation as First-line Treatment for Chronic Radiation Proctopathy," Journal of Gastroenterology & Hepatology, 19, pp 1169-1173, 2004.	Villavicencio et al., "Efficacy and Complication of Argon Plasma Coagulation for Hematochezia Related to Radiation Proctopathy," Gastrointestinal Endoscopy, Vol. 55, No. 1, 2002.	Taïeb et al., "Effective Use of Argon Plasma Coagulation in the Treatment of Severe Radiation Proctitis," Dis Colon Rectum, Vol. 44, No. 12, Dec. 2001.	Ackroyd et al., "Prospective Randomized Controlled Trial of Argon Plasma Coagulation Ablation vs. Endoscopic Surveillance of Patients with Barrett's Esophagus after Antireflux Surgery," Gastrointestinal Endoscopy, Vol. 59, No. 1, pp 1-7, 2004.	Ravizza et al., "Frequency and Outcomes of Rectal Ulcers During Argon Plasma Coagulation for Chronic Radiation- induced Proctopathy," Gastrointestinal Endoscopy, Vol. 57, No. 4, 2003. (Resp. Depo. Ex. 124)
Bates Number Description	(CT01645 –	(CT01653 –	(CT01656 –	(CT01662 –	(CT01670 –	(CT01680 –	(CT01685 –	(CT01690 -	(CT01701 –	(CT01708 –
	CT01652)	CT01655)	CT01661)	CT01669)	CT01674)	CT01684)	CT01689)	CT01695)	CT01707)	CT01714)
Exhibit. Number	RX-32	RX-33	RX-34	RX-35	RX-36	RX-37	RX-38	RX-39	RX-40	RX-41

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s NUMDE	Bates Number Description	Exhibit Being Offered	Witness	uate Received
(CT01715 – CT01724)	Sagawa et al., "Argon Plasma Coagulation for Successful Treatment of Early Gastric Cancer with Intramucosal Invasion," Gut, 52, pp 334-339, 2003.	Issues relating to non-infringement of the '745 patent	J. Canady	Admitted 8/31/07
(CT01734 – CT01737)	Bergler et al., "Treatment of Recurrent Respiratory Papillomatosis with Argon Plasma Coagulation," Journal of Laryngology and Otology, Vol. 111, pp. 381-384, Apr. 1997.	Issues relating to non-infringement of the '745 patent	J. Canady	Admitted 8/31/07
(CT01738 – CT01740)	Okada et al., "Endoscopic Surgery with a Flexible Bronchoscope and Argon Plasma Coagulation for Tracheobronchial Tumors," J Thorac Cardiovasc Surg, 121, pp 180-182, 2001. (Resp. Depo. Ex. 125)	Issues relating to non-infringement of the '745 patent	J. Canady	Admitted 8/31/07
(CT014667 - CT014668)	Photo of Canady Technology argon probe manufacturered by KLS Martin GmbH	Issues relating to non-infringement of the '745 patent and '630 trademark	J. Canady	Admitted 8/31/07
(CT10169)	Scan of KLS Martin Probe from Germany (CT10169)	Issues relating to non-infringement of the '745 patent and '630 trademark	J. Canady	Admitted 8/31/07
(CT14167 - CT14178)	KLS Martin Probe Medical Device Tracking Log (CT14167 - CT14178)	Issues relating to non-infringement of the '745 patent and '630 trademark	J. Canady	Admitted 8/31/07
				Withdrawn
				Withdrawn
	Photo of Canady Technology argon probe manufacturered by Soring GmbH	Issues relating to non-infringement of the '745 patent and '630 trademark	J. Canady	Admitted 8/31/07
	Label of Canady Technology argon probe manufacturered by Soring GmbH	Issues relating to non-infringement of the '745 patent and '630 trademark	J. Canady	Admitted 8/31/07
(CT14158 - CT14164)	Soring Probe Medical Device Tracking Log	Issues relating to non-infringement of the '745 patent	J. Canady	Admitted 8/31/07

Exhibit Number	Bates Number Description	Description	Purpose For Exhibit Reinn	Sponsoring	Date
			Offered	Witness	Received
RX-53C	(CT14369)	Soring Manufacturing Drawing	Issues relating to non-infringement of	J. Canady	Admitted 8/31/07
RX-54C		Translation of Soring Manufacturing Drawing	Issues relating to non-infringement of	J. Canadv	Admitted
RX-55			the '745 patent		8/31/07
	(CT14374 -				Withdrawn
KX-56	CT14376)	Mammogram of Soring probe	non-infringement of	J. Canady	Admitted
/с-XX			ule /45 patent		10100
RX-58					Withdrawn
KX-59					Withdrawn
RX-60					Withdrawn
RX-61					Withdrawn
RX-62					Withdrawn
RX-63					Withdrawn
RX-64					Withdrawn
RX-65					Withdrawn
RX-66					Withdrawn
RX-67					Withdrawn
RX-68					Withdrawn
RX-69					Withdrawn
RX-70					Withdrawn
RX-71					Withdrawn
RX-72					Withdrawn
RX-73					Withdrawn
RX-74					Withdrawn
RX-75					Withdrawn
RX-76					Withdrawn
RX-77					Withdrawn
RX-78					Withdrawn
RX-79					Withdrawn
RX-80					Withdrawn
RX-81					Withdrawn
RX-82					Withdrawn
RX-83					Withdrawn
					Withdrawn

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Date Received	Withdrawn	Withdrawn	Withdrawn	Withdrawn	Admitted 8/30/07	Withdrawn	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Withdrawn	Admitted 8/29/07	Withdrawn	Withdrawn	Withdrawn
Sponsoring Witness					Shifflette		Shifflette	Shifflette	Shifflette	Shifflette	Shifflette		Fisch			
Purpose For Exhibit Being Offered					Issues relating to invalidity and non- infringement of the '745 patent		Issues relating to invalidity and non- infringement of the '745 patent	Issues relating to invalidity and non- infringement of the '745 patent	Issues relating to invalidity and non- infringement of the '745 patent	Issues relating to invalidity and non- infringement of the	Issues relating to invalidity and non- infringement of the '745 patent		Issues relating to invalidity and non- infringement of the '745 patent			
Bates Number Description					Witness Statement of J. Michael Shifflette		CV of J. Michael Shifflette	Shifflette Figure 1, Rlow Rates to 12 lpm, larger tubes	Shifflette Figure 2, Flow to 1.2 lpm, small tube	Shiftlette Flow Velocity Graph	G. Farin, K. Grund, ""Principles of Electrosurgery, Laser, and Argon Plasma Coagulation with Particular Regard to Colonoscopy," <u>Colonoscopy Principles and Practice</u> , Ch. 34, pp. 393-398 (2003)(Resp. Depo. Ex. 83)		Witness Statement of Dr. Nathaniel Fisch			
Bates Number											(EITC004495 - EITC004502)					
Exhibit Number	RX-84 RX-85	50-XXI	DV-72	10-221	RX-88	HX-89	RX-89A	RX-90	RX-91	RX-92	RX-93	RX-94	RX-95	HX-96	RX-07C	> > > >

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Date Received	Admitted 8/28/07	012001	Withdrawn	Withdrawn	Withdrawn	Withdrawn Admitted 8/29/07		Withdrawn	Withdrawn	Withdrawn	Withdrawn	Withdrawn	Admitted 8/30/07	V 1711-1	vvitnarawn	Withdrawn	Withdrawn	Withdrawn	Withdrawn	Admitted 8/29/07	Rejected 8/31/07	Rejected 8/31/07
Sponsoring Witness	Boatright					Erbe							Farin							Farin	Farin	Farin
Purpose For Exhibit Being	Issues relating to non-infringement of	the 745 patent				Issues relating to invalidity and non- infringement of the	'745 patent						Issues relating to invalidity and non- infringement of the	140 patent						Issues relating to invalidity and non- infringement of the '745 patent	Issues relating to invalidity and non- infringement of the '745 natent	Issues relating to invalidity and non- infringement of the '745 patent
Description	ERBE Brochure entitled "Argon Plasma Coagulation" (Resp. Depo. Ex. 7)					Letter from ConMed to ERBE re payment for '745 patent license (EITC5969 - EITC5970)							G. Frain, "Argon Plasma Coagulation (APC) in Flexible Endoscopy," Dec. 16-17, 2004 (Resp. Depo. Ex. 84)							1997 Amendment from Prosecution of '745 Patent (Resp. Depo. Ex. 93)	Designations for Gunter Farin deposition dated August 15, 2001 (Resp. Depo. Ex. 92)	Deposition Transcript of Gunter Farin dated August 15, 2001 (Resp. Depo. Ex. 92)
Bates Number Description	(CT10150 - CT10154)					(EITC5969 - EITC5970)							(EITC4488- EITC4494)							(ER601 - ER612)		
Exhibit Number	RX-98	RX-99A	RX-99C	RX-100A	RX-100C	RX-101C	RX-102	RX-103	RX-104A	RX-104C	RX-105		RX-106	RX-107	KX-108	RX-109	RX-110	RX-111		RX-112	RX-113A	RX-113C

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ing Date	12	Withdrawn	Withdrawn	Withdrawn			ger Rejected 8/31/07		Withdrawn																						
Sponsoring Witnose	20				Bohnenberger		Bohnenberger													-											
Purpose For Exhibit Being	Offered				Issues relating to invalidity and non- infringement of the	745 patent	infringement of the	'745 patent																							
Bates Number Description					Designations for Johannes Bohnenberger deposition dated January 31, 2002		Deposition Transcript of Johannes Bohnenberger dated January 31, 2002																								
Bates Numbe																															
Exhibit Number	RX-114A	RX-114C	RX-115		RX-116A		RX-116C	RX-117C	RX-118	RX-119A	RX-119C	RX-120C	RX-121A	RX-121C	RX-122A	RX-122C	RX-123A	RX-123C	RX-124A	RX-124C	RX-125A	RX-125C	RX-126A	RX-126	RX-127A	RX-127	RX-128A	RX-128	RX-129	RX-130C	RX-131C

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For Sponsoring Date Witness Perceivod	J. Canady	ing to d non- of the J. Canady 8/31/07		VVIthdrawn	VVIIIIDITAWN VVIIIHAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAA	Withdrawn	Withdrawn	Withdrawn	J. Canady		Withdrawn	Withdrawn	Withdrawn	White		Withdrawn									
Purpose For Exhibit Being	Onered Issues relating to invalidity and non- infringement of the '745 patent	Issues relating to invalidity and non- infringement of the	745 patent						Issues relating to invalidity and non- infringement of the	'745 patent				Issues relating to invalidity and non- infringement of the	745 patent										
Bates Number Description	Letter from J. Klein to J. Canady	Letter from G. Repper to G. Farin							Complaints' Responses to Respondent Canady Technology LLC's and Canady Technology GmbH's Third Set of Requests for Admissions (Nos. 21-151)					ERBE APC300 Handbook Standard Version, Copyright 1998											
Bates Numbe	(CT10305)	(CT10309)												(ERBFM000724 - ERBFM000827											
Exhibit Number	RX-132	RX-133	RX-134A	RX-135	RX-136A	RX-136	RX-137		RX-138	RX-139C	KX-140	RX-141	RX-142	 RX-143	RX-144	RX-145	RX-146C	RX-147	RX-148	RX-149	RX-150	RX-151	RX-152	RX-153	

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Date Received	Admitted 8/29/07	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Withdrawn	Admitted 8/31/07	Admitted 8/31/07	Admitted 8/31/07	Withdrawn	Withdrawn	Admitted 8/30/07	Withdrawn	Withdrawn	Withdrawn	Admitted 8/30/07	Withdrawn
Sponsoring Witness	White	Martin	Erbe	Erbe	Erbe		Erbe	Erbe	Ш Ц Ш			Gore				Shifflette	
Purpose For Exhibit Being Offered	Issues relating to invalidity of the '745 patent	Issues relating to invalidity of the '745 patent	Issues relating to invalidity of the '745 patent	Issues relating to invalidity of the '745 patent	Remedy and Bonding		Issues relating to non-infringement of the '745 patent	Issues relating to non-infringement of the '745 patent	Issues relating to non-infringement of the '745 patent			Rebut Witness Statement of Steven Werelev				Rebut Witness Statement of Steven Werelev	
Description.	Licence Agreement ERBE to ConMed to '745 Patent	Email of 10/16/2001 to Hug et al. (from PX-44 used in Martin deposition)	Email of 4/4/2006 to White, Day, et al. (from DX-29 used in Erbe deposition)	Decision Revoking European Patent EP-B-957793 (from DX-50 used in Erbe deposition)	Letter from J. Powers to J. D'Attomo regarding ConMed's license payment to ERBE (from DX-52 used in Erbe deposition)		Settlement Agreement (from DX-57 used in Erbe deposition)	Email of 4/27/2006 to White, Day (from DX-59 used in Erbe deposition)	Email of 4/27/2006 to White, Day (from DX-60 used in Erbe deposition)			CV of Brian Gore				Rebuttal Witness Statement of J. Michael Shifflette	
Bates Number Description	(EITC003417 - EITC003423	(CT11472 - CT11473)		(CT10183 - CT10192)	(EITC005969 - EITC005970)		(EITC003424 - EITC003431)	(EITC011291 - EITC011292)	(EITC011528 - EITC011529)								
Exhibit Number	RX-155C	RX-156C	RX-157C	RX-158	RX-159C	RX-160C	RX-161	RX-162C	RX-163C	RX-164	RRX-1	RRX-2	RRX-3	RRX-4	RRX-5	RRX-6	RRX-7

Date Received	Withdrawn	Withdrawn	Withdrawn	Withdrawn	Withdrawn	Admitted	0121101	Withdrawn	Withdrawn	Withdrawn	Withdrawn	Withdrawn	Withdrawn	Withdrawn	Withdrawn	Admitted 8/28/07		Admitted 8/28/07	VA/ith Jan	VVILIUI AWI	Withdrawn	Admitted 8/30/07	Admitted 8/29/07	Admitted 8/31/07
Sponsoring Witness						Waye										Wereley		Wereley				Gore	Fisch	
Purpose For Exhibit Being Offered						Rebut Witness Statement of Jerome	Waye									Rebut Witness Statement of Steven	Rebut Witness	Statement of Steven Werelev	600.000			Rebut Witness Statement of Steven Werelev	Rebut Witness Statement of Steven	Rebut Witness Statement of Steven Wereley
Bates Number Description						Waye article										An Album of Fluid Motion , M. Van Dyke, Parabolic Press	Physical Fluid Dynamics, 2nd Edition, D.J. Tritton, Clarendon	Press				Rebuttal Witness Statement of Brian Gore	Rebuttal Witness Statement of Nathaniel Fisch	Potential Flows of Viscous and Viscoelastic Fluids, Daniel D. Joseph, Toshio Funada, Jing Wang, Fig. 4.2
Bates Numb																DX-127	DX-129							
Exhibit Number RRX-8	RRX-9	RRX-10	RRX-11	RRX-12		RRX-13	RRX-14	RRX-15	RRX-16	RRX-17	RRX-18	RRX-19	RRX-20C	RRX-21		RRX-22	RRX-23			67-VUV	07-2010	RRX-27	RRX-28	RRDX-1

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Exhibit Number	Bates Number Description	Description	Purpose For Exhibit Being Offered	Sponsoring Witness	Date Received
RPX-1		ConMed Flexible Endoscopic Argon Probe	Issues relating to invalidity and non- infringement of the "630 redistration	J. Canady	Admitted 8/31/07
RPX-2		KLS Martin Flexible Endoscopic Argon Probe	Issues relating to invalidity and non- infringement of the "630 registration	J. Canady	Admitted 8/31/07
RPX-3		Video of 1991 Clinical Experience with Flexible Endoscopic Argon Probe	Issues relating to invalidity and non- infringement of the '745 patent	J. Canady	Admitted 8/31/07
RPX-4		Soring Flexible Endoscopic Argon Probe	Issues relating to invalidity and non- infringement of the '745 patent	J. Canady	Admitted 8/31/07

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UNITED STATES INTERNATIONAL TRADE COMMISSION Washington, D.C.

Before Charles E. Bullock Administrative Law Judge

In the Matter of

CERTAIN ENDOSCOPIC PROBES FOR USE IN ARGON PLASMA COAGULATION SYSTEMS

Inv. No. 337-TA-569

COMMISSION INVESTIGATIVE STAFF'S FINAL EXHIBIT LIST

(September 4, 2007)

Exhibit No.	Exhibit Title	Exhibit Purpose	Sponsoring Witness	Exhibit Status
SX-1	Excerpts from McGraw-Hill Dictionary of Scientific and Technical Terms at 127, 147, 777, 780, 1009, 1070, 1104, 1348, 1521, 1705, 1932, 1933, 2083, and 2137 (5th ed., 1994)	Technical Background; Claim Construction	By motion	Admitted 8/31
SX-2				Withdrawn
SX-3	"Tools of the Trade" - ASGE First Year Fellows Endoscopy Course 2006 (previously marked as Complainants' Deposition Exhibit 13)	Technical Background; Patent Infringement/Non- Infringement	Bromell	Admitted 8/31
SX-4C through SX-10				Withdrawn
SX-11	Chapter 22 from "Colonoscopy: Principles and Practice," Jerome D. Waye, Douglas K. Rex, & Christopher B. Williams, eds. (2003) at 238-58 (previously marked as Defendants' Deposition Exhibit 117) (WAYE 000033-57)	Technical Background; Claim Construction	Waye	Admitted 8/27

SX-12 through SX-14C				Withdrawn
SX-15C	E-mail chain from Unspecified Sender to Creighton White dated October 24, 2005 re: APC Warranty Statement (previously marked as Defendants' Deposition Exhibit 12) (EITC 11547-48)	Trademark Infringement	White; Erbe; Day	Admitted 8/28
SX-16C through SX-30C				Withdrawn
SX-31	Chapter entitled "Fluid Mechanics Theory" by Nguyen and Wereley (Wereley 000039-83)	Technical Background; Claim Construction; Infringement/Non- Infringement	Wereley	Admitted 8/28
SX-32	Excerpts from Webster's II New Riverside University Dictionary at (1984) at 248, and 1082.	Claim Construction	By motion	Admitted 8/31
SX-33				Withdrawn

Respectfully submitted,

<u>/s/ Karin J. Norton</u> Lynn I. Levine, Director Thomas S. Fusco, Supervisory Attorney Karin J. Norton, Investigative Attorney Jeffrey T. Hsu, Investigative Attorney OFFICE OF UNFAIR IMPORT INVESTIGATIONS U.S. International Trade Commission 500 E Street, S.W., Suite 401 Washington, D.C. 20436 (202) 205-2606 (202) 205-2579 (202) 205-2158 (Facsimile)

-2-

APPENDIX B

U.S. DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA ORDER AND OPINION GRANTING PARTIALLY SUMMARY JUDGMENT OF NONINFRINGEMENT OF THE '745 PATENT

Office of Unfair Import Investigations



JEFFREY T. HSU

Investigative Attorney Direct Dial: (202) 205-2579 Fax: (202) 205-2158

UNITED STATES INTERNATIONAL TRADE COMMISSION

WASHINGTON, D.C. 20436

December 21, 2007

Re: Certain Endoscopic Probes for Use in Argon Plasma Coagulation Procedures, Inv. No. 337-TA-569

<u>VIA HAND DELIVERY</u> The Honorable Charles E. Bullock Administrative Law Judge U.S. International Trade Commission 500 E Street SW, Rm 317-I Washington, D.C. 20436

Dear Judge Bullock:

Enclosed with this letter is a copy of the December 18, 2007 Order and Opinion of Court in *ERBE Electromedizin GmbH v. Canady Technology LLC*, Civ. Action No. 05-1674, U.S. District Court, W.D. Pa., in which ERBE accuses certain products sold by Canady of infringing claims of U.S. Patent No. 5,720,745 (the "745 Patent"). The Order grants Canady's motion for summary judgment of non-infringement of the '745 patent as to certain endoscopic probes sold by Canady that are manufactured by KLS Martin GmbH & Co. KG ("KLS Martin"). *See* Order at pp. 33-38.

The same claims of the 745 patent asserted by ERBE in the district court (which the Staff understands to be claims 1, 3, 4, 11, 13, 35, 37, 38, 39 and 41), and KLS Martin probes, are also at issue in the above-referenced investigation. However, the Söring GmbH probes sold by Canady that are at issue in the above-referenced investigation were not before the Court. Nonetheless, the Staff thought that it should bring this recently-issued Order to your attention.

Sincerely,

Jeffrey T. Hsu, Esq. Investigative Attorney

Enclosure

9

cc: Timothy R. Dewitt, Esq. Charles E. Schill, Esq. Timothy C. Bickham, Esq. Phillip G. Hampton, II Esq. Steven M. War, Esq. (all cc's w/o enclosure) Case 2:05-cv-01674-DWA Document 222 Filed 12/18/2007 Page 1 of 47

IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF PENNSYLVANIA

ERBE ELECTROMEDIZIN GMBH, et al.,)
)
)
Plaintiffs,)
· · · · · · · · · · · · · · · · · · ·)
-VS-)
	Civil Action No. 05-1674
)
CANADY TECHNOLOGY LLC, et al.,)
)
)
Defendants.	.)

AMBROSE, Chief District Judge.

OPINION and ORDER OF COURT

SYNOPSIS

Plaintiff, ConMed Corporation ("ConMed"), filed a Motion for Partial Summary Judgment. (Docket No. 114). Plaintiff, ERBE Elektromedizin GmbH and ERBE USA, Inc. (collectively "ERBE"), filed a Motion for Partial Summary Judgment (Docket No. 137). Defendants, Dr. Jerome Canady and Canady Technology LLC, also filed a Motion for Summary Judgment. (Docket No. 182). The briefing regarding the same is finally complete. After careful consideration of the submissions of the parties, ConMed's Motion for Partial Summary Judgment (Docket No. 114) is granted in part and denied in part, ERBE's Motion for Partial Summary Judgment (Docket No. 137) is granted in part and denied in part, and Defendants' Motion for Summary Judgment (Docket No. 182) is granted in part and denied in part.

I. BACKGROUND

Plaintiff, Erbe Elektromedizin GmbH, manufactures and sells flexible endoscopic probes for argon plasma coagulation ("APC"). ERBE is the owner, by assignment, of Patent No. 5,720,745 ("Patent '745) issued on February 24, 1998, titled "Electrosurgical Unit and Method for Achieving Coagulation of Biological Tissue." It was filed as a continuation-in-part of ERBE's prior Application Serial No. 981,009 ("the '009 application'),¹ and had a six year prosecution history. Plaintiff, Erbe USA, Inc., is a subsidiary of ERBE Elektromedizin GmbH.

ERBE USA is the owner of U.S. Trademark Reg. No. 2,637,630 ("the '630 Registration), registered on the Supplemental Register by the USPTO on October 15, 2002. The '630 Registration is for the color blue as applied to the tube portion of its flexible endoscopic probes for use in argon plasma coagulation ("the Blue Probe Mark"). According to the Amended Complaint, ERBE asserts the following as their trade dress: "a substantially elongated blue tube having a plurality of graduated black markings at the end of the elongated tube. (Docket No. 18, ¶48).

Plaintiff, ConMed Corporation ("Conmed"), is in the business of manufacturing and selling electrosurgical generators and related devices, including argon gasenhanced electrocoagulation equipment. ConMed is the owner, by assignment, of Patent No. 4,781,175 ("'175 patent"), which was issued on November 1, 1988, titled "Electrosurgical Conductive Gas Stream Technique of Achieving Improved Eschar for

¹The '009 application was filed on November 24, 1992. The '009 application was rejected by the USPTO on August 2, 1993. After losing an appeal of the rejection, ERBE filed the continuation-in-part application on December 28, 1995, that led to the issuance of the '745 patent.

Coagulation." The '175 patent was filed on April 8, 1986, by Francis T. McGreevy, Carol Bertrand, and Karl W. Hahn, and expired on April 8, 2006.

On January 21, 2000, ERBE entered into an agreement with ConMed to license several ConMed patents, including the '175 patent. Under the Agreement, ERBE was licensed to manufacture and sell various argon gas-enhanced electrocoagulation equipment, including electrosurgical generators and flexible probes related to argon gas-enhanced electrocoagulation.

Defendant, Canady Technology, markets and sells single use disposable flexible APC probes that may be connected to an adapter that in turn is connected to an ERBE APC electrosurgical unit. Defendant, Dr. Jerome Canady, is the CEO and partial owner of Canady Technology.

ERBE and ConMed filed an Amended Complaint against Defendants setting forth the following six counts:

Count I: Infringement of the '745 Patent

Count II: Infringement of the '175 Patent

Count III: Federal Trademark Infringement under the Lanham Act

Count IV: Unfair Competition in Violation of 15 U.S.C. §1125

Count V: Common Law Infringement and Unfair Competition

Count VI Passing Off

(Docket No. 18). In response, Defendants answered the Amended Complaint and Defendant, Canady Technologies, filed the following Counterclaims:

First Counterclaim: Declaratory Judgment of Non-Infringement

<u>Second Counterclaim</u>: Declaratory Judgment of Invalidity

Third Counterclaim: Declaratory Judgment of Implied License

<u>Fourth Counterclaim</u>: Declaratory Judgment of Unenforceability Due to Inequitable Conduct

<u>Fifth Counterclaim</u>: Agreement in Restraint of Trade/Conspiracy to Monopolize - Violation of §§1 and 2 of The Sherman Act

<u>Six Counterclaim:</u> Monopolization and Attempted Monopolization Violation of §2 of The Sherman Act

Seventh Counterclaim:	Declaratory Judgment of Unenforceability Due to Patent Misuse									
Eighth Counterclaim:	Tortious Interference with a Contract									
Ninth Counterclaim:	Tortious Interference with a Business Expectancy									

(Docket No. 27).

Pending are the following Motions: 1) ConMed's Motion to Strike Portions of Defendants' Summary Judgment Papers under Rule 56(e) (Docket No. 142); 2) ConMed's Motion for Partial Summary Judgment (Docket No. 114); 3) ERBE's Motion for Partial Summary Judgment (Docket No. 137); and 4) Defendants' Motion for Summary Judgment as to all of Plaintiffs' claims (Docket No. 182). The parties have all responded and replied to the pending Motions. Therefore, the issues are now ripe for review.

II. LEGAL ANALYSIS

A. STANDARD OF REVIEW

Summary judgment may only be granted if the pleadings, depositions,

answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). Rule 56 mandates the entry of summary judgment, after adequate time for discovery and upon motion, against the party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

In considering a motion for summary judgment, this Court must examine the facts in a light most favorable to the party opposing the motion. *International Raw Materials, Ltd. v. Stauffer Chemical Co.*, 898 F.2d 946, 949 (3d Cir. 1990). The burden is on the moving party to demonstrate that the evidence creates no genuine issue of material fact. *Chipollini v. Spencer Gifts, Inc.*, 814 F.2d 893, 896 (3d Cir. 1987). The dispute is genuine if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is material when it might affect the outcome of the suit under the governing law. *Id.* Where the non-moving party will bear the burden of proof at trial, the party moving for summary judgment may meet its burden by showing that the evidentiary materials of record, if reduced to admissible evidence, would be insufficient to carry the non-movant's burden of proof at trial. *Celotex*, 477 U.S. at 322.

Once the moving party satisfies its burden, the burden shifts to the

nonmoving party, who must go beyond its pleadings, and designate specific facts by the use of affidavits, depositions, admissions, or answers to interrogatories showing that there is a genuine issue for trial. *Id*. at 324. Summary judgment must therefore be granted "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *White v. Westinghouse Electric Co.*, 862 F.2d 56, 59 (3d Cir. 1988), *quoting, Celotex*, 477 U.S. at 322. Furthermore, in antitrust litigation, "Itlo survive a motion for summary judgment, an antitrust plaintiff must produce economically plausible evidence supporting the elements of its claim." *Harrison Aire, Inc. v. Aerostar Intern., Inc.,* 423 F.3d 374, 380 (3d Cir. 2005); *citing, Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986). "If the plaintiff's theory is economically senseless, no reasonable jury could find in its favor, and summary judgment should be granted." *Id., quoting, Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 468-69 (1992).

B. CONMED'S MOTION TO STRIKE

ConMed filed a Motion for Summary Judgment. (Docket No. 114). Defendants filed various documents in opposition thereto including, a Memorandum of Law with Exhibit (Docket Nos. 129, 132), a Responsive Statement of Material Facts (Docket No. 131), a declaration of Jerome Canady (Docket No. 133), and a declaration of Lewis Gelbman. (Docket No. 134). ConMed, filed a Motion to Strike Portions of Defendants' Summary Judgment Papers Under Federal Rule of Civil Procedure 56(e). (Docket No. 142). Generally, ConMed is seeking an order striking seventy-seven (77) different

portions of Defendants' opposition papers. Id. Defendants have filed a Brief in

Opposition to the same. (Docket No. 155).

Rule 56(e) of the Federal Rules of Civil Procedure provides as follows:

(e) Form of Affidavits; Further Testimony; Defense Required. Supporting and opposing affidavits shall be made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively that the affiant is competent to testify to the matters stated therein. Sworn or certified copies of all papers or parts thereof referred to in an affidavit shall be attached thereto or served therewith. The court may permit affidavits to be supplemented or opposed by depositions, answers to interrogatories, or further affidavits. When a motion for summary judgment is made and supported as provided in this rule, an adverse party may not rest upon the mere allegations or denials of the adverse party's pleading, but the adverse party's response, by affidavits or as otherwise provided in this rule, must set forth specific facts showing that there is a genuine issue for trial. If the adverse party does not so respond, summary judgment, if appropriate, shall be entered against the adverse party.

F.R.C.P. 56(e). Moreover "Iain affidavit that is 'essentially conclusory' and lacking in specific facts is inadequate..." to defeat a motion for summary judgment. *Mandonado v. Ramirez,* 757 F.2d 48, 51 (3d Cir. 1985), *quoting Drexel Union Prescription Centers, Inc.,* 582 F.2d 781, 789-90 (3d Cir. 1978). *See, Schoch v. First Fidelity Bancorporation,* 912 F.2d 654, 657 (3d Cir. 1990); *Quiroga v. Hasbro, Inc.,* 934 F.2d 497, 500 (3d Cir. 1990), *cert. denied,* 502 U.S. 940 (1991). "Legal memoranda and oral argument are not evidence and cannot by themselves create a factual dispute sufficient to defeat a summary judgment motion." *Jersey Cent. Power & Light Co. v. Township of Lacey,* 772 F.2d 1103, 1109-10 (3d Cir. 1985).

ConMed has broken down the specific statements it wishes to have stricken into seven categories: 1) statements in Defendants' Brief and Statement of Facts that are unsupported by any citation; 2) factual assertions regarding the state of mind of another; 3) factual assertions based on hearsay; 4) factual assertions based on conclusory allegations, speculation, and unsubstantiated assertions; 5) improper expert opinion testimony; 6) loose exhibits attached to the brief with no sponsoring testimony; and 7) sham fact issues. (Docket No. 144, pp. 3-16; see also, Docket No. 142, Ex. A). With regard to the first category, ConMed argues specifically that item numbers 3-5, 7-8, 10-11, 15-16, 18, 20-22, 24-26, 29-34, 36-37, 64, 67, 69, 71 and 75 of Exhibit A (Docket No. 142) should be stricken because they all contain assertions that are unsupported by any citation to admissible proof. (Docket No. 144, pp. 3-4). In response, Defendants assert that the statements set forth in item numbers 1-44 and 64-77 are not evidence, but are attorney argument explaining the evidence and reasonable inferences to be drawn therefrom. (Docket No. 155, p. 3). Because Defendants concede that these statements are argument and not evidence, I need not accept them as true. That does not mean, however, that the statements must be stricken from record. Consequently, ConMed's Motion to Strike is denied in this regard.

With regard to its second argument, ConMed specifically argues that item numbers 15, 19, 20, 22, 43-44, 54-55, and 57-61 of Exhibit A (Docket No. 142) should be stricken because they contain factual assertions regarding the state of mind of another. (Docket No. 144, pp. 5-6). In response, Defendants argue that the items

identified relate to Dr. Canady's and Mr. Gelbman's personal knowledge that KLS Martin has refused to supply generators and dual mode probes to Canady Technology and that the statements are admissible to show KLS Martin's reasons for not supplying the generators and dual mode probes. (Docket No. 155, pp. 5-6). I agree with Defendants that item numbers 58 and 59 are admissible to show the state of mind of why KLM Martin no long supplied generators and dual mode probes to Canady Technology. See, Callahan v. A.E.V., Inc., 182 F.3d 237, 241 (3d Cir. 1999) ("IPllaintiffs themselves can testify that the customers are in fact no longer shopping at their stores. Furthermore, although the reports of the customers' statements are hearsay, they are admissible as evidence of the customers' states of mind, i.e., their reasons for no longer shopping at the plaintiffs' stores."). Moreover, item numbers 57, 60 and 61 may be admissible for other reasons. See, Callahan, 182 F.3d at 253 ("IT]he plaintiffs' own testimony about the actual behavior of their customers is not hearsay. Rather, it is admissible evidence of lost business, although not of the reason therefore. Thus, in the present case, the plaintiffs' testimony that certain customers no longer purchased beer from them, coupled with their testimony concerning the customers' statements of their motive, which is admissible hearsay under Rule 803(3), are together evidence of the fact of damage."). Furthermore, as pointed out earlier, Defendants admit that item numbers 1-44 and 64-77 are attorney argument, and therefore, I need not strike those items. Finally, item number 54 and 55 relate to Dr. Canady's state of mind and should not be stricken. Thus, ConMed's Motion to Strike in this regard is denied and item numbers 15, 19, 20, 22, 43-44, 54-55, 58-59, and

60-61 should not be stricken.

With regard to ConMed's third argument, ConMed summarily submits that item numbers 1, 6, 9, 12-15, 53, and 60-61 should be stricken from the summary judgment papers since they are based on hearsay. (Docket No. 144, p. 7). Again, items 1, 6, 9, and 12-15 will not be stricken because they are simply attorney argument. With regard to item 53, 60 and 61, Defendants argue that they are not being offered for the truth of the matter but rather fall within one of the hearsay exceptions such as an admission against interest. As set forth above, item numbers 60 and 61 are admissible, not for the truth of the matter, but for other purposes. Item number 53 is admissible for that same reason. Consequently, ConMed's Motion to Strike in this regard is denied.

With regard to ConMed's fourth argument, ConMed summarily submits that item numbers 2, 4, 7, 9, 14-16, 18-19, 22, 24, 31, 36, 43-44, 47-48, 51-52, 54-55, and 57-62 should be stricken because they are conclusory, speculation, or unsubstantiated assertions. (Docket No. 144, p. 7-8). Again, items 2, 4, 7, 9, 14-16, 18-19, 22, 24, 31, 36, and 43-44 will not be stricken because they are simply attorney argument. With regard to item numbers 47-48, 51-52, 54-55, and 57-62, the statements made therein are based on Mr. Gelbman's and Dr. Canady's knowledge and go to the weight of the evidence. Therefore, ConMed's Motion to Strike in this regard is denied.

With regard to ConMed's fifth argument, ConMed argues that item numbers 3, 5, 7, 11, 33, 34, 45-48, 52, 63-65, 67, and 75 should be stricken because the statements contain improper expert opinion testimony. (Docket No. 144, pp. 8-12).

First, ConMed argues that Dr. Canady's testimony regarding the definition of the relevant market should be stricken because the antitrust element requiring the definition of the relevant market requires expert testimony and Dr. Canady was not listed as an expert witness in this case. (Docket No. 144, pp. 8-9). As ConMed recognizes in a footnote, however, I have held that "IwIhile it appears as though many parties in antitrust cases utilize expert testimony in order to establish relevant market and market power, we have found no authority which indicates that expert testimony is required, and we do not venture to so hold." *F.B. Leopold Co., Inc. v. Roberts Filter Mfg. Co., Inc.,* 882 F.Supp. 433, 452 (W.D.Pa. 1995). Based on the same, I decline to require expert testimony here.

ConMed further argues that if Dr. Canady is attempting to define the relevant market, said testimony is inadmissable because "it is based entirely on unsubstantiated conclusory statements that neither provide probative evidence nor reach the key question of what the relevant customers have come to define as the relevant market." (Docket No. 144, p. 10). I disagree. Dr. Canady sufficiently sets forth his personal knowledge to discuss the interchangeability aspect of the relevant market. Furthermore, Defendants do not rely solely on Dr. Canady's affidavit to define the relevant market. (Docket No. 155, p. 8-11). Consequently, I will not strike item numbers 3, 5, 7, 11, 33, 34, 64-65, 67, 75 of Defendants' Brief in Opposition / Statement of Facts or item number 63 regarding Dr. Canady's affidavit.

Additionally, ConMed argues that item numbers 45-48 should be stricken because they relate to Mr. Gelbman's expert opinions on how to evaluate

investment in a start-up company, what circumstances are more or less attractive to potential investors, and the causes for the delay in Canady Technology's roll out of new product. (Docket No. 144, p. 12). I disagree that this is expert testimony. To the contrary, Mr. Gelbman was hired by Dr. Canady to assist him in developing a business plan and introducing Dr. Canady to a number of potential investors. (Docket No. 134, ¶2). Consequently, he is permitted to discuss his background and what he did for Canady Technology.

Finally, ConMed argues that item numbers 53-55 should be stricken because they relate to expert opinion of Dr. Canady on what investors in a start-up company view as important. (Docket No. 144, p. 12). I disagree that the statements therein are expert testimony. Furthermore, as I stated previously, these items are admissible for other purposes. Consequently, ConMed's Motion to Strike in this regard is denied.

With regard to ConMed's sixth argument, ConMed argues that the exhibits attached to Defendants' Brief in Opposition should be stricken because the exhibits are not referenced, authenticated, nor explained in either of the declarations filed by Defendants. (Docket No. 144, pp. 13-14). This is not the standard, however. It is well-established in this jurisdiction that the nonmoving party does not have to produce evidence in a form that would be admissible at trial to avoid summary judgment. *J.F. Feeser, Inc. v. Serv-A-Portion, Inc.,* 909 F.2d 1524, 1542 (3d Cir. 1990), *citing Celotex,* 477 U.S. at 324. Instead, the court must be satisfied that the nonmoving party's evidence is capable of being reduced to admissible evidence at

trial. *J.F. Feeser*, *Inc.*, 909 F.2d at 1542. Consequently, ConMed's Motion to Strike is denied in this regard.

With regard to ConMed's seventh argument, ConMed argues that portions of Dr. Canady's affidavit should be stricken because they are a sham. (Docket No. 144, pp. 14-16). The "sham affidavit" doctrine is well established in the Third Circuit. See, Baer v. Chase, 392 F.3d 609, 623-26 (3d Cir. 2004). Under the doctrine, a party may not create a genuine issue of material fact by filing an affidavit contradicting his/her own sworn testimony without offering a plausible explanation for the conflict. Id., citing Hackman v. Valley Fair, 932 F.2d 239, 241 (3d Cir. 1991). In such situation, a trial court may disregard the offsetting affidavit. Id. Nevertheless, just because there is a discrepancy between deposition testimony and the deponent's later affidavit. the trial court is not required to disregard the affidavit. Id. at 624, citing Kennett-Murray Corp. v. Bone, 622 F.2d 887, 894 (5th Cir.1980). The Third Circuit has recognized that "there are situations in which sworn testimony can guite properly be corrected by a subsequent affidavit ... landl lwlhere the witness was confused at the earlier deposition or for some other reason misspoke, the subsequent correcting or clarifying affidavit may be sufficient to create a material dispute of fact." Martin v. Merrell Dow Pharmaceuticals, Inc., 851 F.2d 703, 705 (3d Cir.1988).

Here, the two statements in question by Dr. Canady are not directly in opposition to each other.² To that end, there could be plausible explanations for ConMed's perceived discrepancy. In fact, in opposition, Dr. Canady states that his

²The first statement was made in an affidavit on October 27, 2005, at ¶26. The second statement was made in an affidavit on April 23, 2007, at ¶14. (Docket No. 114, p. 15).

April 23, 2007, affidavit was not referring to the January 26, 2005, meeting, but rather to meetings that occurred on April 19-20, 2005 and May 11, 2005, and thus, there is no conflict. (Docket No. 155, p. 12-13). Consequently, I will not disregard the April 23, 2007, affidavit. Therefore, ConMed's Motion to Strike in this regard is denied.

Accordingly, ConMed's Motion to Strike is denied in its entirety.

C. CONMED'S MOTION FOR PARTIAL SUMMARY JUDGMENT

ConMed is moving for summary judgment as to Canady Technology's antitrust counterclaims (Counterclaims Five and Six), Canady Technology's patent misuse counterclaim (Counterclaim Seven), and Canady Technology's tort counterclaims (Counterclaims Eight and Nine).³ (Docket No. 114). Specifically, ConMed seeks summary judgment as to Counterclaims Five, Six and Seven⁴ under the *Noerr Pennington* doctrine, or alternatively, because Canady Technology allegedly cannot offer admissible evidence creating a jury question as to the essential elements

³ConMed mistakenly states that the Counterclaims were asserted by both Defendants, when in fact, the Counterclaims were asserted only by Canady Technology. *Compare,* Motion for Partial Summary Judgment (Docket No. 114), *with,* Answer to Amended Complaint and Counterclaims, ¶¶103-216 (Docket No. 27).

⁴Canady Technology's patent misuse counterclaim merely incorporates the paragraphs set forth in its Affirmative Defenses and Counterclaims and then simply concludes that ERBE and ConMed misused the '745 and '175 patents. (Docket No. 27, ¶¶204-05). ConMed argues that the patent misuse counterclaim is nothing more than alleging the "wrongful" enforcement of the patents, to which it is entitled to immunity under the *Noerr-Pennington* doctrine. (Docket No. 120, p. 26). Canady Technology does not address Counterclaim Seven in its Brief in Opposition. (Docket No. 132). After a review of the record, I find there is no genuine issue that Counterclaim Seven is based on the wrongful enforcement of the patents. Therefore, in determining whether ConMed is entitled to summary judgment under the *Noerr-Pennington* doctrine, I will address Counterclaim Seven together with Counterclaim Five. *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1373 (Fed. Cir. 1998) ("'[WIrongful' enforcement of patents, is activity protected under *Noerr* and *California Motor*, and is not subject to collateral attack as a new ground of 'misuse.'")

under §§1or 2 of the Sherman Act. *Id.* Additionally, ConMed seeks summary judgment as to Counterclaims Eight and Nine because the fraudulent statement attributed to ConMed allegedly was not made, was not fraudulent, and would not be actionable as a matter of law. *Id.*

1. <u>Counterclaim Six</u>

In response to ConMed's Motion for Partial Summary Judgment, Canady Technology submits that "based upon discovery taken in the case" it is no longer pursuing Counterclaim Six against ConMed. (Docket No. 132, pp. 1-2). Consequently, Counterclaim Six is dismissed against ConMed and its Motion for Partial Summary Judgment as to Counterclaim Six is denied as moot.

2. Counterclaim Five and Seven

In this case, Counterclaims Five and Seven are based on the act of ConMed bringing a patent infringement claim against Defendants as a sham. (Docket No. 27, Counterclaims Five and Seven). ConMed first argues that it is entitled to summary judgment as to Counterclaims Five and Seven based on the *Noerr-Pennington* doctrine⁵ and because Canady Technology cannot satisfy the "sham" litigation exception. (Docket No. 120, pp. 10-19 and Docket No. 154, pp. 3-4). "Under the *Noerr-Pennington* doctrine, 'Ial party who petitions the government for redress generally is immune from antitrust liability.' (Citation omitted). That immunity is so potent that it protects petitioning notwithstanding an improper purpose or motive." *Mariana v. Fisher*, 338 F.3d 189, 198 (3d Cir. 2003), *quoting A.D. Bedell Wholesale Co.*,

⁵See, Eastern R.R. Presidents Conference v. Noerr Motor Freight, 365 U.S. 127 (1961) and United Mine Workers of Am. v. Pennington, 381 U.S. 657 (1965).

Inc. v. Philip Morris Inc., 263 F.3d 239, 250 (3d Cir. 2001), *cert. denied,* 534 U.S. 1081 (2002). "The *Noerr/Pennington* doctrine protects antitrust defendants' rights to 'freely inform the government of their wishes' and 'to seek action on laws in the hope that they may bring about an advantage to themselves and a disadvantage to their competitors.'" *Santana Products Inc. v. Bobrick Washroom Equip., Inc.,* 401 F.3d 123, 131 n. 13 (3d Cir. 2005), *quoting Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.,* 365 U.S. 127 (1961).

The immunity under *Noerr-Pennington* doctrine, however, is not unlimited. There is a "sham" litigation exception to the doctrine. *Armstrong Surgical Center, Inc. v. Armstrong County Memorial Hospital,* 185 F.3d 154, 158 (3d Cir. 1999). "Where the challenged private conduct is only 'sham' petitioning - i.e., where it 'is not genuinely aimed at procuring favorable government action as opposed to a valid effort to influence government action" - *NoerrI-Pennington1* immunity is not available. *Id., quoting, Professional Real Estate Investors, Inc. v. Columbia Pictures, Inc.,* 508 U.S. 49 (1993)("PRE"). "In essence, sham petitioning entails 'the use of the governmental process-as opposed to the *outcome* of that process-as an anticompetitive weapon.'" *Id.* (emphasis in original), *quoting, PRE,* 508 U.S. at 61. *PRE* outlined a two-part test to apply to determine whether a petition is "sham" litigation. *PRE,* 508 U.S. at 60-61.

> First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized under *Noerr*, and an antitrust claim premised on the sham exception

must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals an attempt to interfere *directly* with the business relationships of a competitor, through the use of governmental *process*-as opposed to the *outcome* of that process-as an anticompetitive weapon. This two-tiered process requires the plaintiff to disprove the challenged lawsuit's legal viability before the court will entertain evidence of the suit's economic viability.

Cheminor Drugs, Ltd. v. Ethyl Corp., 168 F.3d 119, 122-23 (3d Cir. 1999), quoting PRE,

508 U.S. at 60-61(citations omitted).

Canady Technology, however, argues that where the defendant has filed "a

whole series of legal proceedings," the test is different. (Docket No. 132, pp. 14-15).

In cases in which "the defendant is accused of bringing a whole series of legal proceedings," the test is not "retrospective" but "prospective": "Were the legal filings made, not out of a genuine interest in redressing grievances, but as part of a pattern or practice of successive filings undertaken essentially for purposes of harassment?" Id. As the Ninth Circuit has noted, it is immaterial that some of the claims might, "as a matter of chance," have merit. The relevant issue is whether the legal challenges "are brought pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival." Id.

Primetime 24 Joint Venture v. National Broadcasting, Co., Inc., 219 F.3d 92, 101 (2d Cir.

2000), *quoting, USS-POSCO Indus. v. Contra Costa County Bldg. & Constr. Trades Council, AFL-CIO*, 31 F.3d 800, 811 (9th Cir.1994). In looking at ConMed solely, and not at ConMed and ERBE jointly as Canady Technology does, I disagree with Canady

Technology that *Primetime* applies to ConMed. To begin with, the Counterclaim

facts only assert one previous litigation which was brought by ConMed against ERBE.

(Docket No. 27, ¶182). After a review of the record, the exhibits supplied by Canady Technology also reveal one arbitration brought by ConMed against Jerome Canady, M.D. (Docket No. 129-5, Ex. 6). I do not find that this amounts to "simultaneous and voluminous," a "series of," or a "pattern of," legal proceedings. *See, Marchon Eyewear, Inc. v. Tura LP*, 2002 WL 31253199, *9 (E.D.N.Y. 2002) (two other lawsuits did not amount to a "pattern" or "a whole series of legal proceedings"); *Livingston Downs Racing Ass'n Inc. v. Jefferson Downs Corp.*, 192 F.Supp.2d 519, 539 (M.D.La.,2001)(presumably four lawsuits not enough, but nine lawsuits were enough); *See Amarel v. Connell*, 102 F.3d 1494, 1519 (9th Cir.1996); *See also Applera Corp. v. MJ Research, Inc.*, 303 F.Supp.2d 130, 133-34 (D.Conn. 2004)(explaining context of Primetime, as involving " 'huge volumes' of legal challenges," referred to as "automatic petitioning")(quoting Primetime, 219 F.3d at 95-96, 101); *In re Fresh Del Monte Pineapple*, 2007 WL 64189, *17 n. 19 (S.D.N.Y. January 4, 2007). Consequently, I find that Canady Technology must meet the two part test set forth in *PRE*.

Thus, I must first determine if the filing against Defendants is "objectively baseless." If it is not objectively baseless, then the filing of the lawsuit was not a sham and ConMed is entitled to immunity under the *Noerr-Pennington* doctrine. *PRE*, 508 U.S. at 60-61. Canady Technology, argues that patent infringement claim by ConMed is objectively baseless because the '175 Patent and the '745 Patents are diametrically opposed and therefore it is impossible to infringe on both Patents at the same time. (Docket No. 132, pp. 16-18). When considering this Motion brought by ConMed, I am only concerned with ConMed's claim of infringement of the '175

Patent. ConMed does not have any claims regarding the '745 Patent. *See,* Amended Complaint (Docket No. 18). Therefore, I find this argument lacks merit.

Canady Technology also argues in one paragraph that the patent infringement claim by ConMed is objectively baseless due to the doctrine of patent exhaustion. (Docket No. 132, pp. 21-22). "The first sale/patent exhaustion doctrine establishes that the unrestricted first sale by a patentee of his patented article exhausts his patent rights in the article." *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1336 (Fed. Cir. 2006), *citing Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 701 (Fed. Cir. 1992); and *LG Elecs., Inc. v. Bizcom Elecs., Inc.*, 453 F.3d 1364 (Fed. Cir. 2006). I find that Canady Technology's one paragraph argument fails to adequately address the issues germane to such a discussion and how the application of the patent exhaustion doctrine would destroy the application of the *Noerr-Pennington* immunity as it applies to ConMed. Consequently, I find no merit to this argument either.

Finally, Canady Technology argues that ConMed's "attempts to characterize its settlement and license agreement with ERBE as a 'successful' enforcement action," as a means to justify its suit filed against it, is irrelevant to the issue of whether ConMed's infringement claim is objectively baseless. (Docket No. 132, p. 19). Even assuming this to be true, it does not mean that there are not other reasons upon which the claim was objectively based. After a review of the evidence, I find there was probable cause to bring the claim. *See*, Jonas Decl. and Exs. (Docket No. 124). Thus, I find that Count II of the Amended Complaint (Docket No. 18) regarding

the '175 Patent, is not objectively baseless.

Therfefore, I find that Canady Technology's sham exception argument fails to defeat the application of the *Noerr-Pennington* doctrine as it relates to ConMed. Consequently, ConMed is entitled to summary judgment as to the antitrust and patent misuse Counterclaims.⁶

3. Counterclaims Eight and Nine

Next, ConMed argues that it is entitled to summary judgment as to Counterclaims Eight and Nine because Canady Technology failed to establish its tortious interference claims. (Docket No. 120, pp. 26-29; Docket No. 154, pp. 4-5). To assert a cause of action for intentional interference with a contractual relation, whether existing or prospective, under Pennsylvania law, the moving part must prove:

(1) the existence of a contractual, or prospective contractual relation between the complainant and a third party;

(2) purposeful action on the part of the defendant, specifically intended to harm the existing relation, or to prevent a prospective relation from occurring;

(3) the absence of privilege or justification on the part of the defendant; and

(4) the occasioning of actual legal damage as a result of the defendant's conduct."

⁶Since I have not found that the challenged litigation is objectively baseless, I may not consider the second prong of the sham litigation exception, the litigant's subjective motive. *Cheminor Drugs, Ltd.,* 168 F.3d at 122-23, *quoting PRE,* 508 U.S. at 60-61("Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation."). Additionally, based on this finding, I need not consider ConMed's alternative arguments regarding Counterclaims Five and Seven. *See,* ConMed's Brief in Support (Docket No. 120, pp. 17-25).

Crivelli v. General Motors Corp., 215 F.3d 386, 394-95 (3d Cir. 2000), *citing, Strickland v. University of Scranton,* 700 A.2d 979, 985 (Pa.Super. 1997). ConMed only argues that Canady Technology cannot prove the first two elements. (Docket No. 120, p. 27).

With regard to the first element, Canady Technology alleges in its Amended Complaint that it had a binding contract with KLS Martin for the supply of APC generators for distribution in the United States and based on a Letter of Intent from KLS Martin, it has a reasonably certain business expectation. (Docket No. 27, ¶¶207, 213). To that end, Canady Technology has only come forward with a Letter of Intent. (Docket No. 132, Ex. 10). Thus, there is no evidence of an existing contract with KLS Martin. Consequently, ConMed is entitled to summary judgment as to Counterclaim Eight.

There is, however, evidence of a prospective contractual relation. (Docket No. 132, Ex. 10). As a result, I will consider whether there is a genuine issue of material fact with regard to the second element for Counterclaim Nine. ConMed argues that there is no evidence of a purposeful action on its part to prevent a prospective relation from occurring. (Docket No. 120, pp. 27-29). After a review of the record, I disagree. The letter authored by Joseph Corasanti, President and CEO of ConMed, dated May 27, 2005, was a letter sent to Dr. Canady regarding "Amendments to License and Supply Agreements." *See*, Jonas Decl. at Ex. O (Docket No. 124, Ex. O). This letter was sent not only to Dr. Canady, but to Michael Martin of KLS Martin. Viewing this letter in the light most favorable to the non-moving party, Canady

Technology, I find there is a genuine issue of material fact as to the second element. As a result, ConMed's Motion for Summary Judgment as to Counterclaim Nine is denied.

D. ERBE'S MOTION FOR PARTIAL SUMMARY JUDGMENT

ERBE is moving for summary judgment as to Canady Technology's inequitable conduct counterclaim (Counterclaim Four), patent misuse counterclaim (Counterclaim Seven), and the antitrust counterclaims (Counterclaims Five and Six). (Docket No. 137).

1. Counterclaim Four - Inequitable Conduct

Counterclaim Four asserts a cause of action for inequitable conduct. (Docket No. 27). ERBE argues that it is entitled to summary judgment as to Counterclaim Four because Canady Technology cannot establish any inequitable conduct. (Docket No. 149, pp. 14-19). Applicants for patents and their representatives are required to prosecute applications in the PTO with candor, good faith, and honesty. *Molins PLC v. Textron*, 48 F.3d 1172, 1178 (Fed. Cir. 1995), *citing Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806, 818 (1945). A breach of this duty constitutes inequitable conduct. *Molins, supra*. As the Federal Circuit Court of Appeals has summarized:

Inequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive. Determination of inequitable conduct requires a two-step analysis. First, the trial court must determine whether the conduct meets a threshold level of materiality. The trial court must then also determine whether the evidence shows a threshold level of intent to mislead the PTO.... Once the threshold levels of materiality and intent have been established, the trial court is required to weigh them. In light of all the circumstances, the court must then determine whether the applicant's conduct is so culpable that the patent should be held unenforceable.

Bd. of Educ. ex rel. Bd. of Tr. of FSU v. Am. Bioscience, Inc., 333 F.3d 1330, 1343 (Fed. Cir. 2003) (internal citations omitted).

Information is material "if there is a 'substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent.' " *Honeywell Intern. Inc. v. Universal Avionics Systems Corp.*, 488 F.3d 982, 1000 (Fed. Cir. 2007), *quoting, Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1440 (Fed. Cir.1991) *quoting*, 37 C.F.R. § 1.56 (1989). Intent means the "design, resolve, or determination with which a person acts; a state of mind in which a person seeks to accomplish a given result through a course of action." *Molins*, 48 F.3d at 1180. That does not mean that the party alleging inequitable conduct must come forward with "smoking gun" evidence. *Merck & Co. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989) ("Intent need not, and rarely can, be proven by direct evidence."). Rather, intent to deceive may be inferred from the facts and circumstances surrounding the applicant's overall conduct. *Id.* (Intent "is most often proven by a showing of acts the natural consequences of which are presumably intended by the actor.")

Inequitable conduct is a question of equity to be decided by the court. *Paragon Podiatry Lab. v. KLM Labs*, 984 F.2d 1182, 1190 (Fed. Cir. 1993). A party alleging inequitable conduct as a defense must prove the threshold elements of materiality

and intent by clear and convincing evidence. *Abbott Labs v. Torpharm, Inc.*, 300 F.3d 1367, 1380 (Fed. Cir. 2002). While generally, "precedent urges caution in the grant of summary judgment respecting a defense of inequitable conduct, summary judgment is not foreclosed." *Paragon Podiatry*, 984 F.2d at 1190. "IAI motion for summary judgment may be granted when, drawing all reasonable factual inferences in favor of the non-movant, the evidence is such that the non-movant can not prevail." *Abbott Labs*, 300 F.3d at 1379, *citing ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 547 (Fed. Cir. 1998).

In this case, ERBE specifically argues that there is no evidence of a misrepresentation or omission, that its conduct was immaterial, and there was no evidence of intent with regard to the alleged misrepresentations cited to by Canady Technology in its Answer to Amended Complaint and Counterclaims. (Docket No. 149, pp. 14-19, *citing* Docket No. 27, ¶¶ 62-76).⁷ In response, Canady Technology does not address these alleged misrepresentations. (Docket No. 165, p. 23). Rather, it appears from its Brief that the inequitable conduct complained about now by Canady Technology is that "the inventors of the '745 patent and the patent attorneys failed to disclose to the USPTO material information relating to laparoscopic use of argon plasma coagulation prior to 1992." (Docket No. 165, p. 23).

As pointed out by Canady Technology, in 1985, ERBE became a distributor for a company called "Beacon." (Docket No. 167, p. 19). The Beacon products dealt with

⁷In addition, Canady Technology asserts other statements were material misrepresentations with the intent to deceive. (Docket No. 27, \P 70-76). These statements have nothing to do with laparoscopy. *Id.*

by ERBE included Beamer One and Beamer Two. *Id.* at 20. These were argon gas sources with controlled elements for the flow rates. *Id.* Additionally, ERBE distributed electrosurgical pencils, laparoscopic probes and one other instrument. *Id.* at 20-21. ERBE's work on its own argon gas-assisted coagulation equipment or apparatus did not begin until 1993. *Id.* at 25. According to Canady Technology, "Itlhe laparoscopic probes distributed by ERBE unquestionably constituted prior art to the '745 patent and its parent '009 application⁸ yet were never disclosed to the USPTO during the prosecution." (Docket No. 165, p. 23).

ERBE's only argument in opposition is that the information was immaterial because it was cumulative. (Docket No. 187, p. 6). Specifically, ERBE argues that "Itlhe use of laparoscopy was disclosed to the Examiner" in the article <u>Technology</u> of Argon Plasma Coagulation with Particular Regard to Endoscopic Applications and in U.S. Patent No. 4,753,223 ("the '223 Patent), which appear on the face of the '745 Patent. (Docket No. 187, p. 6). While I agree that cumulative information is not material, *Honeywell Intern. Inc.*, 488 F.3d. at 1000, I do not find this information to be cumulative.

To begin with, the reference to the '223 Patent on the face of the '745 Patent refers to "Bremer" and not Beamer. I have no evidence regarding the '223 Patent, let alone that it states anything about prior laparoscopic art. Consequently, the reference of the '223 Patent does not support ERBE cumulative argument.

Furthermore, the above referenced article merely references laparoscopy in

⁸The '009 application was filed on November 24, 1992. (Docket No. 179-4, Ex. 3).

one sentence: "Applicators for laparoscopy are designed so as to facilitate their application via trocar sleeves (Figure 9)." (Docket No. 138-38, Ex. 30, p. 34). Based on the same, I do not find the information discussed by Canady Technology to be cumulative of other information already before the Patent Office.

Therefore, after a review of the evidence set forth above, I find that Canady Technology had met its burden of showing a genuine issue regarding inequitable conduct. Consequently, summary judgment as to Counterclaim four is not warranted.

2. Counterclaims Five and Six

Counterclaims Five and Six are based on the act of ERBE bringing a patent infringement claim against Defendants as a sham. (Docket No. 27, Counterclaims Five and Six). ERBE argues that it is entitled to summary judgment as to Counterclaims Five and Six based on the *Noerr-Pennington* doctrine and because Canady Technology cannot satisfy the "sham" litigation exception.⁹ (Docket No. 137 and Docket No. 149, pp. 19-20, 24-28). The standard for the *Noerr-Pennington* doctrine is set forth above.

The exception to the *Noerr-Pennington* doctrine relied upon by Canady Technologies is the "sham litigation" exception. (Docket No. 165, p. 5). As set forth above, *PRE* outlined a two-part test to apply to determine whether a petition is

⁹ERBE also asserts that Canady Technology cannot prove the other exception to *Noerr-Pennington* immunity. (Docket No. 137 and Docket No. 149, pp. 20-24). This exception is called the *Walker Process* fraud exception. *See, Walker Process Equip., Inc. v. Food Mach. & Chem., Corp.,* 382 U.S. 172, (1965). Canady Technology, however, does not base its Counterclaims upon the *Walker Process* fraud exception. (Docket No. 165, p. 5). Therefore, I need not consider this exception.

"sham" litigation. *PRE*, 508 U.S. at 60-61. First, the lawsuit must be objectively baseless. *Id.* If, and only if the lawsuit is objectively baseless, then the court may examine the litigant's subjective motivation. *Id.*

Canady Technology, however, argues that where the defendant has filed "a whole series of legal proceedings," the test is different. (Docket No. 132, pp. 14-15).

> In cases in which "the defendant is accused of bringing a whole series of legal proceedings," the test is not "retrospective" but "prospective": "Were the legal filings made, not out of a genuine interest in redressing grievances, but as part of a pattern or practice of successive filings undertaken essentially for purposes of harassment?" As the Ninth Circuit has noted, it is immaterial that some of the claims might, "as a matter of chance," have merit. The relevant issue is whether the legal challenges "are brought pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival."

Primetime 24 Joint Venture v. National Broadcasting, Co., Inc., 219 F.3d 92, 101 (2d Cir.
2000), quoting, USS-POSCO Indus. v. Contra Costa County Bldg. & Constr. Trades
Council, AFL-CIO, 31 F.3d 800, 811 (9th Cir.1994). In looking at ERBE solely, and not at
ConMed and ERBE jointly as Canady Technology does, I disagree with Canady
Technology that Primetime applies to ERBE. Canady Technology asserts that
ERBE has brought four separate litigations against Defendants.¹⁰ (Docket No. 165, p.
8). ERBE does not dispute that there are four lawsuits. (Docket No. 187, pp. 3-5;
Docket No. 149, pp. 29-33). While I do not attempt to set forth the exact number of

¹⁰Canady Technology specifically asserts that "ConMed and ERBE have brought against Canady Technology and its CEO, Dr. Canady, four separate lawsuits and an arbitration." (Docket No. 165, p. 8). As set forth above, the record reveals that the arbitration was brought only by ConMed against Dr. Canady. (Docket No. 129-5, Ex. 6). As a result, I only consider the four lawsuits.

litigations necessary to fall within the *Primetime* standard, I do not find that four lawsuits amount to "simultaneous and voluminous," a "series of," or a "pattern of," legal proceedings. *See, Marchon Eyewear, Inc. v. Tura LP*, 2002 WL 31253199, *9 (E.D.N.Y. 2002) (two other lawsuits did not amount to a "pattern" or "a whole series of legal proceedings"); *Livingston Downs Racing Ass'n Inc. v. Jefferson Downs Corp.*, 192 F.Supp.2d 519, 539 (M.D.La.,2001)(presumably four lawsuits not enough, but nine lawsuits were enough); *See Amarel v. Connell*, 102 F.3d 1494, 1519 (9th Cir.1996); *See also Applera Corp. v. MJ Research, Inc.*, 303 F.Supp.2d 130, 133-34 (D.Conn. 2004)(explaining context of *Primetime*, as involving " 'huge volumes' of legal challenges," referred to as "automatic petitioning")(*quoting Primetime*, 219 F.3d at 95-96, 101). Consequently, I find that Canady Technology must meet the two part test set forth in PRE.

Thus, I must now determine whether ERBE's lawsuit against Defendants is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *PRE*, 508 U.S. at 60; *Cheminor Drugs, Ltd.*, 168 F.3d at 122. "The existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation." *PRE*, 508 U.S. at 62. "Probable cause to institute civil proceedings requires no more than a reasonable belief that there is a chance that a claim may be held valid upon adjudication...the existence of probable cause is an absolute defense." *Id.* at 62-62.

Canady Technology asserts that ERBE's trademark and trade dress claims are objectively baseless. (Docket No. 165, pp. 8-9). As support for this position, Canady

Technology makes a number of conclusory statements without any references to the record or supportive case law. *Id.* Moreover, the case law cited to by Canady Technology does not suggest that ERBE did not have "probable cause to institute" the case, which is the test to be applied. Consequently, I find that Canady Technology has failed to show, based on the evidence, that ERBE's trademark and trade dress claims are "objectively baseless." *PRE*, 508 U.S. at 60; *Cheminor Drugs*, *Ltd.*, 168 F.3d at 122.

Next, Canady Technology argues that the patent infringement claims were objectively baseless. (Docket No. 165, pp. 9-13). Canady Technology sets forth three arguments as to why ERBE's patent infringement claims were objectively baseless: 1) since there is no direct infringement, there can be no indirect infringement; 2) the '745 Patent and the '175 Patent are diametrically opposed so it cannot be infringing on both; and 3) ERBE litigated the same claims against ConMed in another lawsuit and lost the case on summary judgment. (Docket No. 165, pp. 9-13). I will address each of these arguments.

ERBE's patent claims are for indirect infringement. (Amended Complaint, Docket No. 18, Counts I and II). There can be no indirect infringement without direct infringement. *See*, 35 U.S.C. §271(c);¹¹ *Argo Mfg. Co. v. Convertible Top Replacement*

¹¹35 U.S.C.A. § 271(c) provides as follows:

⁽c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

Co., 365 U.S. 336, 341 (1961) ("[I]It is settled that if there is no direct infringement of a patent there can be no contributory infringement."). Along those lines, Canady Technology's first argument is that ERBE's patent claims are objectively baseless because there is no direct infringement. In support of this conclusion, Canady Technology argues that "ERBE's and ConMed's entire argument is that the accused Canady Technology probes are unpatented components of the larger patented systems (APC units, generators, etc) sold by ERBE." (Docket No. 165, p. 11). It continues that purchasers of an ERBE system have an implied license to use and to repair the system it purchased. (Docket No. 165, p. 11). Because the probes are single use disposable items, or "spent" parts, Canady Technology argues that the probe may permissibly be replaced by the user. *Id*. Therefore, it concludes that there can be no direct act of infringement of either patent. *Id*.

"A patentee grants an implied license Ifor the life of an article1¹² to a purchaser when (1) the patentee sells an article that has no noninfringing uses and (2) the circumstances of the sale plainly indicate that the grant of a license should be inferred." *Anton/Bauer, Inc. v. PAG, LTD.,* 329 F.3d 1343 (Fed. Cir. 2003), *citing, Met-Coil Sys. Corp. v. Korners Unlimited, Inc.,* 803 F.2d 684, 686 (Fed. Cir. 1986). Once a purchaser has an implied license, the purchaser may then repair it with replacement parts from others under the doctrine of repair and continue to use the article in the patented combination without infringing upon the patent. The Kendall Co. v.

⁴² [A]n implied license arising from sale of a component to be used in a patented combination extends only for the life of the component whose sale and purchase created the license." *Carborundum Co. v. Molten Metal Equipment Innovations, Inc.,* 72 F.3d 872, 879 (Fed. Cir. 1995).

Progressive Med. Tech., 85 F.3d 1570, 1573-74 (Fed. Cir. 1996). In such a case, direct

infringement can only occur when there is a complete reconstruction of the device.

Id. at 1574.

IThe terms "repair" and "reconstruction" are used to define the boundary between permitted and prohibited activities with respect to patented items after they have been placed in commerce. Originating in the principle of exhaustion of the patent right after first sale, the general rule is that "while the ownership of a patented article does not include the right to recreate a substantially new article, it does include the right to preserve the useful life of the original article." Precedent has elaborated on the right of the owner to replace unpateneted components, provided that the activity is not such as to make a new article. In *Aro Manuf. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, (1961) the Court stated the controlling inquiry governing the replacement of unpatented parts of a patented article:

reconstruction of a patented entity, comprised of unpatented elements, is limited to such a true reconstruction of the entity as to "in fact make a new article," after the entity, viewed as a whole, has become spent....Mere replacement of individual unpatented parts, one at a time, whether of the same part repeatedly or different parts successively, is no more than the lawful right of the owner to repair his property. *Id.* at 364.

Id. (Citations omitted).

Thus, to begin with, the articles sold must have no noninfringing uses. *Anton/Bauer, Inc. v. PAG, LTD.,* 329 F.3d 1343 (Fed. Cir. 2003). In this case, I find that Canady Technology has failed to demonstrate that the articles sold have no noninfringing uses. (Docket No. 165, pp. 9-11). Consequently, I find that Canady Technology has not met its burden under this argument.

With regard to Canady Technology's second argument, even assuming that both patents are diametrically opposed, there is evidence that some of its probes could potentially function at flow rates as low as 0.1 l/min for the 1.5 mm Canady probe, 0.5 l/min for the 2.3 mm Canady probe, and 0.6 l/min for the Canady 3.2 mm probe. ERBE Ex. 13, Summary (Docket No. 138-18, p. 20). Therefore, I do not find ERBE's claims to be objectively baseless in this regard.

With regard to its third argument, I agree with Canady Technology that ERBE cannot put its head in the sand and play dumb even though the opinion was vacated.¹³ This does not mean, however, that ERBE did not have an objective basis for filing its patent claims against Canady Technology. The claims in this case are not exactly the same. Consequently, I find that Canady Technology has failed to meet its burden of showing that the patent claims are objectively baseless. Consequently, I find that Canady Technology has failed to meet its burden of showing that the patent claims are objectively baseless. Consequently, I find that Canady Technology has failed to meet infringement claims were objectively baseless. Therefore, ERBE is entitled to *Noerr-Pennington* immunity with regard to its patent infringement claims and, thus, entitled to summary judgment as to Counterclaims Five and Six.

3. <u>Counterclaim Seven</u>

Canady Technology's seventh Counterclaim is one of patent misuse. (Docket No. 27). Like the antitrust counterclaims, ERBE argues, *inter alia*, that Canady

¹³ERBE attempts to disown the findings within the vacated summary judgment opinion by the U.S. District Court for the Northern District of New York at 00-CV-0987 as set forth at Docket No. 163-11 (Ex. LL), while in the same brief attempts to use those portions it believes are helpful. *Compare*, Docket No. 149, p. 25 with p. 19. ERBE cannot have it both ways.

Technology's patent misuse counterclaim is based on sham litigation. (Docket No. 149, pp. 37-39). In response, Canady Technology merely states one sentence: "For the reasons stated above with respect to Defendants' antitrust claims, ERBE (sic) frivolous enforcement actions constitute patent misuse and render the '745 patent unenforceable." (Docket No. 165, p. 24). Consequently, Canady Technology has failed to present any argument as to why ERBE is not entitled to *Noerr-Pennington* immunity for its patent misuse counterclaim. As a result, Canady Technology has not met its burden. Therefore, I find that ERBE is entitled to *Noerr-Pennington* immunity with regard to Counterclaim Seven and, thus, summary judgment in favor of ERBE is warranted as to Counterclaim Seven.

E. DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Defendants, both Dr. Canady and Canady Technology, move for summary judgment as to "all of Plaintiffs' claims." (Docket No. 182). As set forth above, there are six (6) counts to Plaintiffs' Amended Complaint. (Docket No. 18). I will begin with the patent infringement claims (Counts I and II).

1. Patent Infringement Claims - Counts I and II

There is a two-part test to be applied in all patent infringement claims. *Dynacore Holdings Corp. v. U.S. Philips Corp.*, 363 F.3d 1263, 1273 (Fed. Cir. 2004). First, a court must engage in a claims construction. *Id., citing, Cybor Corp. v. FAS Techs., Inc.,* 138 F.3d 1448, 1454 (Fed. Cir. 1998)(*en banc*). Then, a court must compare the properly construed claims to the allegedly infringing device. *Id.* I have previously construed the claims. (Docket No. 112). Therefore, I must now engage in the second

part of the two-part test.

Plaintiffs have brought indirect infringement claims as to both the '745 Patent and the '175 Patent . (Docket No. 18 - Counts I and II). The indirect infringement claims are for contributory infringement and inducement to infringe. *Id.* "Indirect infringement, whether inducement to infringe or contributory infringement, can only arise in the presence of direct infringement...." *Dynacore Holdings Corp.*, 363 F.3d at 1272. Title 35 U.S.C.A. § 271 relates to infringement of patents and provides, in pertinent part, as follows:

> a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

> (b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

35 U.S.C.A. § 271. Thus, to prove contributory infringement pursuant to §271(c), a patent holder must demonstrate the following: 1) that the alleged infringer made and sold the alleged infringing product; 2) the alleged infringing product has no substantial non-infringing uses; 3) that the alleged infringer made sales within the

United States that contributed to another's direct infringement; and 4) direct infringement. *DSU Medical Corp. v. JMS Co., Ltd.,* 471 F.3d 1293, 1303 (Fed. Cir. 2006). To prove inducement to infringe under §271(b), "a patent holder must prove that once the defendants knew of the patent, they 'actively and knowingly aidled] and abettled] another's direct infringement.' However, 'knowledge of the acts alleged to constitute infringement' is not enough. The 'mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven.'" *Id.* at 1305 (citations omitted). As with contributory infringement, to prove inducement to infringe a patent holder must also prove direct infringement. *Dynacore Holdings Corp.*, 363 F.3d at 1272.

I will now apply this law to the patents at issue in this case.

a. <u>'745 Patent - Count I</u>

Defendants first argue that there can be neither contributory infringement or induced infringement because there is no direct infringement. (Docket No. 183, pp. 9-14). To begin with, there are three types of accused probes: 1.5 mm, 2.3 mm, and 3.2 mm. A "patentee always has the burden to show direct infringement for each instance of indirect infringement." *DSU Medical Corp. v. JMS Co., Ltd.,* 471 F.3d 1293, 1303 (Fed. Cir. 2006). After a review of the evidence, I agree with Defendants that ERBE has failed to produce or cite to any evidence of anyone ever using an accused 1.5 mm probe or a 3.2 mm probe. *See*, Docket No. 211. Thus, there is no genuine issue of material fact that the accused 1.5 mm probes and its 3.2 mm probes did not directly infringe on the '745 Patent. *DSU Medical Corp.* 471 F.3d at

1305. Accordingly, summary judgment in favor of Defendants is warranted with regard to Count I as it relates to Defendants' 1.5 mm probes and 3.2 mm probes.

The other accused probes at issue are the Canady 2.3 mm probes. To that end. Defendants submit that their 2.3 mm probes do not infringe the '745 Patent because they are used at flow rates greater than 1 l/min and flow velocities greater than 19 km/hr. (Docket No. 183, pp. 9-14). Based in part on the prosecution history, I construed the term "less than about 1 liter/minute" to mean "less than 1 liter/minute" and the term "low flow rate" to mean a rate of flow of less than about 1 liter/minute and producing flow velocities less than 19 km/hour such that the gas exiting through the distal end opening forms a non laminar inert gas atmosphere. (Docket No. 112, p. 18-21). Accordingly, based on the rationale set forth in the claims construction opinion, I find that when any probe is used with an ERBE APC system with a flow rate of 1 l/min or greater or has flow veocities of 19 km/hour or greater, there can be no direct infringement of the '745 Patent. (Docket No. 112). With regard to the flow velocities of less than 19 km/hour, ERBE cites to the rebuttal report of its expert, Steven Wereley. (Docket No. 211, p. 14-15, citing ERBE Ex. 10, pp. 4-5 at Docket No. 207-13). While he suggests the calculations used by Defendants' expert are incorrect, Mr. Wereley does not provide any testimony with regard to what the flow velocities are, let alone, that they are less than 19 km/hour. Id.; see also, ERBE Ex. 30 at Docket No. 207-32. Thus, after a review of the record, I find that ERBE has failed to produce direct evidence that the flow velocities of the accused 2.3 mm probes were less than 19 km/hour. See, Docket No. 211, pp. 14-15. Without

such evidence, ERBE cannot meet its burden of proving that the accused 2.3 mm probes directly infringed on the '745 Patent. Thus, there is no genuine issue of material fact that the accused 2.3 mm probes did not directly infringe on the '745 Patent. *DSU Medical Corp*, 471 F.3d at 1305. Accordingly, summary judgment in favor of Defendants is warranted with regard to Count I as it relates to Defendants' 2.3 mm probes.

Even if I did not find this to be the case, summary judgment would still be warranted as to ERBE's contributory infringement because ERBE has failed to demonstrate a genuine issue of material fact that the accused 2.3 mm probes have no substantial non-infringing uses. Specifically, Defendants argue that ERBE has failed to meet its burden of proving that there are no substantial non-infringing uses on the accused probes. (Docket No. 183, pp. 11-12; Docket No. 217, pp. 2-3). In support of the same, Defendants produced the depositions of Dr. Gostout of the Mayo Clinic and Dr. Al-Kawas of Georgetown University Hospital who testified that they use flow rates higher than 1 l/min when using the accused probes. (Docket No. 179-28, pp. 11-12; Docket No. 196-5, pp. 11-12). In addition, they have produced a chart which indicates all of their sales. (Docket No. 27, pp. 12-24, Ex. A).

In response, ERBE argues that this evidence does not amount to "a substantial non-infringing use" because they are not a "qualitatively significant noninfringing use" since they have produced evidence from Dr. Vargo of the Cleveland Clinic who testified that when he begins all of his APC procedures, he sets the argon flow rate at 0.8 and then adjusts the flow rate up or down to achieve the desired effect.

(Docket No. 211, p. 15, citing Ex. 22 at Docket No. 207-24). I am not persuaded by ERBE's argument. The affidavit of Dr. Vargo merely shows that one doctor has used the probes in a potentially infringing manner.¹⁴ The issue, however, is not whether the accused probes have been used in an infringing manner, but whether the accused probes have a substantial non-infringing use. *DSU Medical Corp*, 471 F.3d at 1303.

According to the evidence submitted, Dr. Gostout and Dr. Al-Kawas have used 650 of the accused probes at flow rates at 1 l/min or higher, while Dr. Vargo has used 160 of the accused probes below 1 l/min. Based on this evidence, the accused probe is used 80% of the time in a non infringing manner. It is unreasonable to consider an 80% noninfrining usage as an occasional aberrant use of the accused probes. To the contrary, I find this evidence to be a qualitatively significant noninfringing use.

Consequently, I find that there is no genuine issue of material fact that the accused 2.3 mm probes have substantial non-infringing uses. Accordingly, the claim of contributory infringement contained in Count I cannot stand for this reason as well.

b. <u>'175 Patent - Count II</u>

Defendants argue that they are entitled to summary judgment as to Count II of the Amended Complaint alleging infringement of the '175 Patent because: 1) their accused probe does not contain a pencil; and 2) their accused probe does not

¹⁴There is no evidence from Dr. Vargo regarding the flow velocity.

have a "plurality of individual passageways."¹⁵ (Docket No. 183, p. 14; Docket No. 217, p. 4-5). In response, ConMed acknowledges that this court construed Claim 1 to require a pencil and "all equivalents of that" pencil. (Docket No. 200, pp. 5-6). ConMed argues, however, that based on Mr. Walbrink's interpretation of the claims the pencil structure should not properly be included in Claim 1. Additionally, ConMed argues, based on Mr. Walbrink's interpretation of the claims, that the "plurality of passageways" structure should not be included in Claim 1. To that end, ConMed requests that I revise my claim construction decision accordingly. (Docket No. 200, p. 6). I decline to do so.

ConMed next argues that there is a genuine issue of material fact that the accused probes contain a structure that satisfies the requirement of a "pencil or its equivalent." (Docket No. 200, pp. 6-10). In support of its position, ConMed supplies the expert declaration of Harold J. Walbrink. (Docket No. 200, pp. 6-10, *citing*, Expert Report of Dr. Walbrink at Docket No. 204, ¶7(e)-(f)). Based on the same and viewing it in the light most favorable to the non-moving party, I find there is a genuine issue of material fact on this issue. Therefore, summary judgment is not warranted on this basis.

ConMed further argues that there is a genuine issue of material fact that the accused probes have a structure that satisfies the requirement of a "flexible cord with a plurality of individual passageways. (Docket No. 200, pp. 11-14). In support of

¹⁵In their Reply Brief, Defendants argue in two sentences that summary judgment is warranted because ConMed fails to satisfy its burden of proving no substantial non-infringing uses. (Docket No. 217, p. 5). I refuse to consider such a fleeting argument not made in their original Motion or Brief and for which ConMed had no opportunity to respond. (Docket Nos. 182 and 183).

its position, ConMed once again relies on the expert declaration of Mr. Walbrink. (Docket No. 200, pp. 11-14, *citing*, Expert Report of Dr. Walbrink at Docket No. 204, (7(c)). Based on the same and viewing it in the light most favorable to the nonmoving party, I find there is a genuine issue of material fact on this issue as well. Therefore, summary judgment is not warranted on this basis.

Consequently, summary judgment as to Count II of Plaintiffs' Complaint is denied

Count III - Federal Trademark Infringement of US. Trademark Reg. No. 2,637,603 ("'630 Registration") under the Lanham Act AND Count IV -Unfair Competition in Violation of 15 U.S.C. §1125 (Trade Dress)¹⁶

Defendants argue that they are entitled to summary judgment as to the '630 trademark (Count III) and trade dress (Count IV) claims because they are invalid and that Defendants do not infringe upon them. (Docket No. 183, pp. 14-2). The '630 trademark is not registered on the Primary Register, but rather is registered on the Supplemental Register. (Docket No. 211, p. 19; Docket No. 179-13 - Ex. 12). Furthermore, the trade dress is unregistered. (Docket No. 211, p. 19). The parties agree that the elements necessary to prove both ERBE's trademark infringement claim and ERBE's trade dress claim are virtually the same. (Docket No. 183, pp. 14-24; Docket No. 211, pp. 8-9, 19-24). Specifically, ERBE must prove that the Blue Probe mark and its trade dress are non-functional, that they are inherently distinctive or

⁴⁶ 'Trade dress' refers to the design or packaging of a product which serves to identify the product's source." *Shire US Inc. v. Barr Laboratories, Inc.*, 329 F.3d 348, 353 (3d Cir. 2003).

have acquired inherent distinctiveness through secondary meaning,¹⁷ and that there is a likelihood of confusion. *See, Qualitex Co. v. Jacobson Prods. Co., Inc.,* 514 U.S. 159 (1995); *Wal-Mart Stores, Inc. v. Samara Bros., Inc.,* 529 U.S. 205, 210-11 (2000); *Shire US Inc. v. Barr Laboratories, Inc.,* 329 F.3d 348, 353 (3d Cir. 2003); *Duraco Prods., Inc. v. Joy Plastic Enterprises, Ltd.,* 40 F.3d 1431, 1439 (3d Cir. 1994); *see also,* Docket No. 183, p. 15. Defendants argue that ERBE cannot prove any of the elements. (Docket No. 183, pp. 15-24).

With regard to the first element, the Supreme Court has explained that "'[i]n general terms, a product feature is functional,' and cannot serve as a trademark, 'if it is essential to the use or purpose of the article or if it affects the cost or quality of the article,' that is, if exclusive use of the feature would put competitors at a significant non-reputation-related disadvantage." *Qualitex Co.*, 514 U.S. at 165, *quoting Inwood Lab oratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844, 850, n. 10 (1982). "The Restatement (Third) of Unfair Competition adds that, if a design's 'aesthetic value' lies in its ability to 'confeirl a significant benefit that cannot practically be duplicated by the use of alternative designs,' then the design is 'functional.' Restatement (Third) of Unfair Competition § 17, Comment c, pp. 175-176 (1993). The 'ultimate test of aesthetic functionality,' it explains, 'is whether the recognition of trademark rights would significantly hinder competition.' Id., at 176." *Qualitex Co.*, 514 U.S. at 170.

¹⁷ERBE does not argue that the blue probe trademark or trade dress is inherently distinctive. See, Docket No. 211. Rather, ERBE relies on the proposition that the Blue Probe mark and trade dress have acquired inherent distinctiveness (secondary meaning).

Defendants argue that the color blue is functional for surgical procedures in that blue enhances endoscopic identification. *See*, CT Ex. 14 at Docket No. 179-15 (stating that "Iblue color enhances positive Endoscopic identification"). Furthermore, Defendants submit that the only other competitor is ConMed and it probes are blue in color. *See*, CT Ex. 21 at Docket No. 179-22. Specifically, with regard to the trade dress, Defendants submit that the black markings are, "by ERBE's own binding admission, functional." (Docket No. 183, p. 24). As support Defendants point to the patent wherein it states:

> As may be seen from FIGS. 22 and 23, the distal end portion of tube 2 protruding from the end of the working channel 7 of the endoscope 1 may be provided with markings 50, 51, 52. An arrangement of such ring shaped markings allows to observe, how far tube 2 protrudes out of the distal end of the working channel 7 of the endoscope.

CT. Ex. 2 (Docket No. 179-3, p. 21).

In opposition, ERBE argues that the blue color of its probes is not essential to their use or propose. (Docket No. 211, p. 19). In support of this position, ERBE only submits the declaration of Christian Erbe who declares that "Ibllue is one of many colors available for APC Probes. Any color, other than beige or red, would be clearly visible during endoscopic procedures." (Docket No. 211, p. 20, *citing*, Ex. 25, ¶24 at Docket No. 207-27). Based on the same, ERBE concludes that the color blue is not "uniquely superior." (Docket No. 211, p. 20). The Third Circuit has held, however, that "merely because there are other shapes and designs ' which defendant could use and still produce a workable' product, the design used is not thereby non-

functional." *Keene Corp. v. Paraflex Indus., Inc.,* 653 F.2d 822, 827 (3d Cir. 1981). ERBE does not submit any argument that the black markings are non-functional. (Docket No. 211, p. 19). Thus, viewing the evidence in the light most favorable to ERBE, I find there is no genuine regarding the issue that the blue color of its APC probes or that the black markings are non-functional. Consequently, summary judgment in favor of Defendants as to ERBE's trademark (Count III) and trade dress claims (Count IV) is warranted on this ground.

Even if there was a genuine issue as to whether the blue color and the black markings were found to be non-functional, summary judgment as to ERBE's trademark (Count III) and trade dress claims (Count IV) would still be warranted because there is no genuine issue of material fact as to whether the trademark and trade dress have acquired secondary meaning. "To establish secondary meaning, a manufacturer must show that, in the minds of the public, the primary significance of a product feature or term is to identify the source of the product rather than the product itself." *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.,* 456 U.S. 844, 851 (1982), *citing, Kellogg Co. v. National Biscuit Co.,* 305 U.S. 111, 118 (1938); *Duraco Prods., Inc.,* 40 F.3d at 1440.

Factors relevant to a finding of secondary meaning in a product configuration include: (1) plaintiff's advertising expenditures, measured primarily with regard to those advertisements which highlight the supposedly distinctive, identifying feature, *see First Brands Corp. v. Fred Meyer, Inc.,* 809 F.2d 1378, 1383 (9th Cir.1987); (2) consumer surveys linking the distinctive product configuration to a particular, single source (although the identity of the source need not be known); and (3) length and exclusivity of use. Consumer surveys and testimony

are probably the only direct evidence of secondary meaning; the other sources are circumstantial, though the plaintiff may rely solely on them.

Duraco Products, Inc., 40 F.3d at 1452.

Defendants argue that ERBE cannot prove that the blue probe trademark and trade dress have acquired secondary meaning. (Docket No. 183, pp. 19-21). Specifically, Defendants submit that: 1) there is no evidence to conclude that the color blue identifies ERBE as the supplier of flexible endoscopic tubing; 2) the probes of the other competitor, ConMed, are blue; 3) there is very little advertising evidence regarding the color blue; 4) there are no surveys; and 5) the length of use of the color blue has been 8 ½ years, which is a short time in the world of trademarks. (Docket No. 183, p. 20-21). Additionally, with regard to the trade dress, Defendants assert that ConMed's probes have a plurality of graduated black markings as well. (Docket No. 183, p. 24; *see*, CT Ex. 21).

In response, ERBE submits that its blue probe mark and trade dress have acquired secondary meaning. (Docket No. 211, pp. 21-22). ERBE argues that it can prove that the blue probe trademark and trade dress have acquired secondary meaning because it has been using the color blue for over 30 years on its medical equipment and its has promoted the Blue Probe mark in various marketing materials including brochures, giveaways and through the use of the tagline "TRUE BLUE PROBE FOR ARGON PLASMA COAGULATION." (Docket No. 211, pp. 21-22). ERBE does not submit any specific evidence with regard to the black markings. *Id*.

After a review of the evidence, however, I find that ERBE has failed to come

forward with sufficient evidence to create a genuine issue of material fact with regard to the issue of whether the blue probe trademark and trade dress have acquired secondary meaning. Specifically, I find that while ERBE may have been using the color blue for over 30 years, there is no evidence that, in the minds of the public, the primary significance of the color blue is to identify ERBE as the source of the product rather than the probes. *Inwood, supra.* Furthermore, while ERBE concludes that it has promoted the Blue Probe mark in various marketing materials, ERBE has failed to provide any evidence of the marketed materials or the related expenditures. Furthermore, ERBE has failed to supply any surveys or customer testimony regarding the same. Finally, as Defendants point out, ConMed, the other competitor, uses blue tubing on its probes. Thus, I find that there is no genuine issue regarding secondary meaning. Consequently, summary judgment in favor of Defendants as to ERBE's trademark (Count III) and trade dress claims (Count IV) is warranted on this ground as well.¹⁸

Counts V and VI are titled Common Law Infringement and Unfair Competition and Common Law Passing Off. (Docket No. 18). "The test for common law trademark infringement and unfair competition is essentially the same as the test for infringement and unfair competition under the Lanham Act." *Tillery v. Leonard & Sciolla, LLP,* 437 F.Supp.2d 312, 328 (E.D.Pa. 2006), *citing, Fisons Horticulture, Inc. v.*

¹⁸Since I have found that summary judgment as to Counts III and IV is warranted based on functionality and secondary meaning, I need not consider the arguments regarding likelihood of confusion. Furthermore, since I have granted summary judgment in favor of Defendants as to ERBE's trademark claim, I need not address Defendants' argument regarding whether Defendants' alleged use of the ERBE trademark in comparing the prices of its products to ERBE's products is lawful. (Docket No. 183, pp. 25-26).

Vigoro Indus., 30 F.3d 466, 472 (3d Cir.1994). Since I have found that summary judgment is warranted as to Counts III and IV, summary judgment is similarly warranted as to Counts V and VI.

ORDER OF COURT

AND NOW, this **18th** day of December, 2007, after careful consideration of the submissions of the parties and for the reasons set forth in the accompanying Opinion it is ordered as follows:

- 1. ConMed's Motion to Strike (Docket No. 142) is denied.
- 2. ConMed's Motion for Partial Summary Judgment (Docket No. 114) is granted in part and denied in part as follows:
 - a. Counterclaim Six is dismissed against ConMed and its Motion for Partial Summary Judgment as to Counterclaim Six is denied as moot;
 - b. ConMed's Motion is granted as to Counterclaims Five, Seven, and Eight, and, as such, summary judgment is entered in favor of ConMed as to the same; and
 - c. ConMed's Motion is denied as to Counterclaim Nine.
- 3. ERBE's Motion for Partial Summary Judgment (Docket No. 137) is granted in part and denied in part as follows:
 - a. ERBE's Motion is denied as to Counterclaim Four; and
 - b. ERBE's Motion is granted as to Counterclaims Five, Six and Seven.
- 4. Defendants' Motion for Summary Judgment (Docket No. 182) is granted in part and denied in part as follows:

a. Defendants' Motion is granted as to Counts I, III-VI of the Amended Complaint; and

b. Defendants' Motion is denied as to Count II of the Amended Complaint.

It is further Ordered that a settlement/pre-trial conference is scheduled for Tuesday, January 8, 2008, at 10:30 A.M. before the undersigned on the Third Floor, Suite 3280 of the U.S. Post Office & Courthouse. Counsel are to have settlement authority and parties are to be either present or available by telephone. Position letters are to be faxed to Chief Judge Ambrose three (3) days prior to the conference.

BY THE COURT:

/S/ Donetta W. Ambrose

Donetta W. Ambrose, Chief U. S. District Judge

INV. NO. 337-TA-569

CERTAIN ENDOSCOPIC PROBES FOR USE IN ARGON PLASMA COAGULATION SYSTEMS AND PRODUCTS CONTAINING SAME

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **ORDER** was served upon **Jeffrey T**. **Hus, Esq.**, Commission Investigative Attorney, and the following parties via first class mail and air mail where necessary on <u>January 28</u>, **2008**.

Marilyn R. Abbott, Secretary U.S. International Trade Commission 500 E Street, SW Washington, D. C. 20436

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INV. NO. 337-TA-569

CERTAIN ENDOSCOPIC PROBES FOR USE IN ARGON PLASMA COAGULATION SYSTEMS AND PRODUCTS CONTAINING SAME

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

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In the Matter of

CERTAIN ENDOSCOPIC PROBES FOR USE IN ARGON PLASMA COAGULATION SYSTEMS

Inv. No. 337-TA-569

NOTICE OF A COMMISSION DETERMINATION NOT TO REVIEW AN INITIAL DETERMINATION TERMINATING THE INVESTIGATION AS TO A RESPONDENT ON THE BASIS OF A SETTLEMENT AGREEMENT

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination ("ID") of the presiding administrative law judge ("ALJ") granting the joint motion of complainants ERBE Elektromedizin GmbH of Germany and ERBE USA, Inc. of Marietta, Georgia (collectively, "ERBE") and respondent KLS Martin GmbH & Co. KG ("KLS Martin") to terminate the above-captioned investigation as to KLS Martin on the basis of a settlement agreement.

FOR FURTHER INFORMATION CONTACT: Jonathan J. Engler, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone 202-205-3112. Copies of the public version of the ID and all 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 202-205-1810. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <u>http://edis.usitc.gov</u>.

SUPPLEMENTARY INFORMATION: This investigation was instituted by the Commission based on a complaint filed by ERBE. 71 Fed. Reg. 29386 (May 16, 2006). The complaint alleged violations of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain endoscopic probes for use in argon plasma coagulation systems by reason of infringement of 10 claims of U.S. Patent No. 5,720,745 ("the '745 patent") and infringement of U.S. Supplemental Trademark Registration No. 2,637,630 ("the '630 registration"). The complaint also alleged that a domestic industry exists and/or is in the process of being established, with regard to the '745 patent and the '630 registration under subsection (a)(2). The notice of investigation named Canady Technology, LLC of Hampton, Virginia ("Canady USA"); Canady Technology Germany GmbH of Germany ("Canady Gmbh"); and KLS Martin as the respondents. The complaint requested that the Commission institute an investigation pursuant to Section 337 and, after the investigation, issue a permanent exclusion order and a permanent cease and desist order.

On June 20, 2006, ERBE and KLS Martin filed a "Joint Motion to Terminate Investigation As to KLS Martin Based on a Settlement Agreement." On July 7, 2006, the Commission Investigative Attorney filed a motion in support of the joint motion to terminate, noting that she was unaware of any information indicating that the settlement agreement would be contrary to the public interest.

On September 1, 2006, the ALJ issued the subject ID (Order No. 4) terminating the investigation as to KLS Martin on the basis of a settlement agreement. The ALJ found no indication that termination of the investigation on the basis of the settlement agreement would adversely affect the public interest, and that the procedural requirements for terminating the investigation had been met. No petitions for review were filed.

The Commission has determined not to review the ID.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, and Commission rule 210.42, 19 C.F.R. § 210.42.

By order of the Commission.

R. Abbott

Secretary to the Commission

Issued: October 3, 2006

CERTAIN ENDSCOPIC PROBES FOR USE IN ARGON PLASMA COAGULATION SYSTEMS

337-TA-569

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached NOTICE OF A COMMISSION DETERMINATION NOT TO REVIEW AN INITIAL DETERMINATION TERMINATING THE INVESTIGATION AS TO A RESPONDENT ON THE BASSIS OF A SETTLEMENT AGREEMENT has been served on upon the Commission Investigative, Attorney Karin J. Norton and all parties via first class mail and air mail where necessary on October 3, 2006.

Marilyn R. Abbott, Secretary U.S. International Trade Commission 500 E Street, SW Washington, DC 20436

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P-202-785-9700 ON BEHALF OF RESPONDENTS CANADY TECHNOLOGY LLC AND

<u>CANADY TECHNOLOGY LLC AND</u> <u>CANADY TECHNOLOGY GERMANY</u> <u>GmbH:</u>

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