

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of

**CERTAIN BALLOON DISSECTION
DEVICES AND PRODUCTS CONTAINING
SAME**

Investigation No. 337-TA-____

**COMPLAINT OF COVIDIEN
UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED**

COMPLAINANT

Covidien LP
15 Hampshire Street
Mansfield, MA 02048 USA
Tel: (508) 261-8000

COUNSEL FOR COMPLAINANT

J. Michael Jakes
Christine E. Lehman
Kathleen A. Daley
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001
Tel. (202) 408-4000

Tina E. Hulse
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
3300 Hillview Avenue
Palo Alto, CA 94304
Tel. (650) 849-6600

PROPOSED RESPONDENTS

Pajunk Medizintechnik GmbH
Karl-Hall-Str. 1
D-78187 Geisingen
Germany

Pajunk Medizintechnologie GmbH
Karl-Hall-Str. 1
D-78187 Geisingen
Germany

Pajunk Medical Systems L.P.
6611 Bay Circle
Norcross, GA 30071
(770) 493-6832

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I. INTRODUCTION

1. This complaint is filed by Complainant Covidien LP (“Covidien”) pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337. Covidien is a global healthcare leader dedicated to innovation. Covidien manufactures and sells the leading dissection balloon products in the United States, which are used in laparoscopic surgical procedures.

2. Covidien brings this action seeking relief under Section 337 to prevent the unlawful importation into the United States, the sale for importation, and the sale within the United States after importation by owners, importers, or consignees of certain dissection balloons and products containing the same that infringe United States Patent No. 6,312,442 (“the ’442 patent” or “the Asserted Patent”). Independent claims 3, 6, 8 and 10 are being asserted in this investigation.

3. The proposed respondents are Pajunk Medizintechnik GmbH (“Pajunk Parent”), Pajunk Medizintechnologie GmbH (“Pajunk Germany”) and Pajunk Medical Systems LP (“Pajunk USA”), collectively, “Respondents.”

4. A certified copy of the ’442 patent is attached to this complaint as Exhibit 1. As shown in the copy of the recorded assignments for the ’442 patent, (Exhibit 2), Covidien owns all right, title, and interest in the Asserted Patent. Copies of the ’442 patent prosecution history and technical references cited therein are also being submitted with this complaint.

5. A domestic industry as required by 19 U.S.C. § 1337(a)(2) and (3) exists in the United States relating to the technology protected by the Asserted Patent, through Covidien’s investments in plant and equipment, as well as labor and capital, related to Covidien’s dissection balloon products covered by the ’442 patent.

6. Covidien seeks, as relief, an exclusion order barring from entry into the United States dissection balloon products that infringe the '442 patent that are imported by or on behalf of Respondents. Covidien also seeks a cease and desist order against Respondents, directing each Respondent to cease and desist from importing, marketing, advertising, demonstrating, warehousing inventory for distribution, offering for sale, selling, distributing, licensing, or using dissection balloons and products containing the dissection balloons that infringe one or more claims of the Asserted Patent.

II. COMPLAINANT

7. Complainant Covidien LP is a Delaware Limited Partnership, headquartered at 15 Hampshire Street, Mansfield, Massachusetts.

8. With 2011 sales of \$11.6 billion, the Covidien family of companies create innovative medical solutions for better patient outcomes and deliver value through clinical leadership and excellence. Ex. 3. The family of companies manufactures, distributes, and services a diverse range of industry-leading product lines in three segments: medical devices, pharmaceuticals, and medical supplies. Covidien and its affiliates have 41,000 employees worldwide in more than 65 countries, have products sold in over 140 countries, and have 48 manufacturing sites located throughout the world. Ex. 3.

9. Covidien is the leading manufacturer of dissection balloon products in the United States. The dissection balloon products are used throughout the world for endoscopic and laparoscopic hernia repair.

III. RESPONDENTS

10. Upon information and belief, and as discussed in greater detail below, respondent Pajunk Germany designs, manufactures, markets, and sells for importation into the United States dissection balloon products and products containing the same. Respondent Pajunk USA markets,

imports and sells these products in the United States. Respondent Pajunk Parent controls the subsidiaries Pajunk Germany, Pajunk USA, as well as a third subsidiary, Pajunk Medical Produkte GmbH, including control of the manufacture and sale for importation of these products. See Ex. 4.

11. Pajunk Parent and Pajunk Germany are located at Karl-Hall-Str. 1, D-78187 Geisingen, Germany. Pajunk Parent states that it “is one of the leading manufacturers of medical systems for the most varied application methods in regional anesthesia, laparoscopy, organ biopsy and dentistry.” Ex. 5.

12. Respondent Pajunk USA maintains its principal place of business at 6611 Bay Circle, Suite 100, Norcross, Georgia 30071. According to the website www.pajunk.com, the American subsidiary company was founded in 2001.

13. On its website, Pajunk describes its balloon systems as “ideally suited” for hernioplasty:

The PAJUNK[®] balloon systems are ideally suited to the endoscopic totally extraperitoneal hernioplasty (TEP). With this gentle method, the preperitoneal space is dilated pneumatically by inserting and inflating a balloon and the abdominal wall is reinforced with a plastic mesh. Not only the risk of infection, but also the size of the incision is significantly reduced, and at the same time the necessary recovery time after the operation is minimised. The balloon systems together with the trocar systems offer you a modular kit of PAJUNK[®] instruments with all you need for extraperitoneal surgery.

Ex. 6. Pajunk also advertises its balloon systems to surgeons in the United States specifically for hernioplasty:

Hernia surgeons will be able to create and maintain the space they need for total extraperitoneal hernia surgery easily, quickly and confidently with disposable and reusable balloon systems from Pajunk. To dissect the peritoneum from the abdominal wall, use a blunt obturator to introduce a dilatation balloon, then inflate. The balloon will separate the layers and tamponade any bleeding. If

you use insufflation gas to maintain the space, you can use a ring anchor balloon to seal in the gas; the ring anchor balloon includes a working channel for your laparoscopic instruments. The systems come in disposable and reusable models in all shapes and sizes; all are made in Germany.

Ex. 7.

IV. THE TECHNOLOGY AND PRODUCTS IN ISSUE

14. The products at issue are dissection balloon products and products containing the same for use in laparoscopic surgery methods covered by one or more of the claims of the patent being asserted.

15. Laparoscopic surgery is a modern surgical technique in which surgical operations in the abdomen are performed with instruments introduced into the body through small incisions.

16. A number of methods have been used to develop cavities within a body to perform laparoscopic operations. One basic method involves developing a cavity using a blunt instrument.

17. Dissection balloons are used to develop cavities between tissue layers for laparoscopic surgery. Figure 1 illustrates the operation of a dissection balloon to create a cavity for laparoscopic surgery. First, a deflated dissection balloon is inserted into an abdominal incision between tissue layers. Figure 1(a). The balloon is then inflated, causing force to be exerted perpendicular to the tissue planes. Figure 1(b). The force of the balloon causes separation of the tissue layers, forming a discrete cavity.

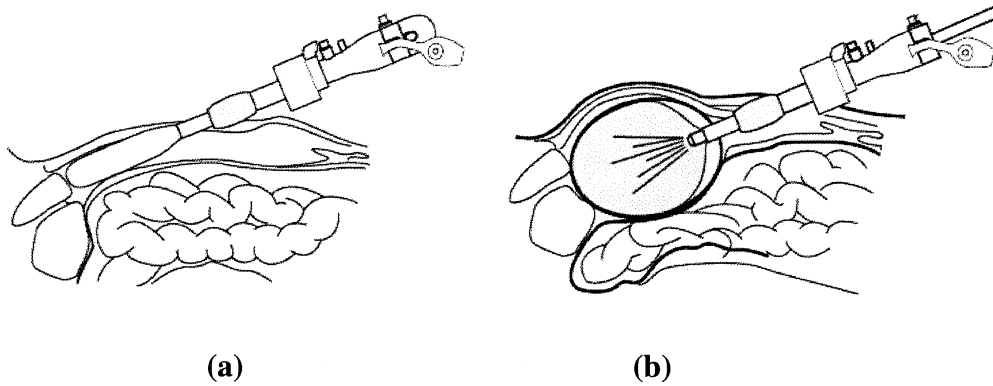


Figure 1. Images illustrating the operation of a Covidien dissection balloon.

18. Dissection balloons are able to create more natural, less traumatic, and relatively bloodless cavities compared with other methods.

19. Among other benefits, laparoscopic surgery allows for accelerated post-operative recovery times and less pain than with conventional open surgery techniques.

V. THE PATENT-IN-SUIT AND NON-TECHNICAL DESCRIPTION OF THE INVENTION

A. Identification of the Patent and Ownership by Covidien

20. Complainant asserts U.S. Patent No. 6,312,442 in this investigation. The '442 patent, entitled "Method for Developing an Anatomic Space for Laparoscopic Hernia Repair," issued on November 6, 2001. The '442 patent is based on U.S. Patent Application No. 07/893,988, filed June 2, 1992. Covidien owns by assignment the entire right, title, and interest in the '442 patent. *See Ex. 2.*

21. The '442 patent has eight independent claims and two dependent claims. Independent claims 3, 6, 8, and 10 are being asserted against Respondents in this investigation. This complaint is accompanied by a prosecution history of the '442 patent, three additional copies of the prosecution history, and four copies of each reference cited on the face of the '442 patent or mentioned in the prosecution history. *See Appendices A and B.* Complainant has requested, but has not received, a certified copy of the prosecution history of the '442 patent.

This certified copy and additional copies will be submitted as soon as it is received from the U.S. Patent and Trademark Office.

B. Non-Technical Description of the Patent

22. The '442 patent generally relates to a method for performing laparoscopic hernia repair by developing a cavity within a body with a dissection balloon. Under the method of the '442 patent, a deflated balloon is introduced, by incision, between two layers of tissue in the patient's abdomen. The balloon is then inflated, causing separation of the tissue layers and forming a discrete cavity. The balloon is then deflated and removed from the incision.

23. After removal of the balloon, the resulting cavity is inflated with gas. Surgical operations, such as a laparoscopic hernia repair, are performed in the inflated cavity with instruments introduced into the cavity. After surgical operations are complete, the cavity is deflated, allowing the tissue layers to collapse toward their pre-dissection positions.

C. Foreign Counterparts to the Patent

24. The '442 patent has a number of foreign counterparts. Those foreign patents and applications are set forth, including their current status, in Exhibit 7. There are no other foreign counterpart patents or applications, abandoned, rejected, or pending anywhere in the world.

D. Related Litigation

25. The '442 patent has not been asserted in any litigation in court. The '442 patent was the subject of an interference proceeding before the U.S. Patent and Trademark Office, entitled *Chin v. Kieturakis*, Interference No. 103,343.

26. On March 10, 1994, the Board of Patent Appeals and Interferences ("Board") at the U.S. Patent and Trademark Office declared Interference No. 103,343 between U.S. Application No. 07/911,714 to Albert K. Chin and John P. Lunsford (collectively "Chin") and U.S. Application No. 07/893,988 to Maciej J. Kieturakis, Kenneth H. Mollenauer, and Michelle

Y. Monfort (collectively “Kieturakis”). The Board declared Kieturakis to be the Senior Party (i.e., the party with the earliest effective filing date) and Chin to be the Junior Party. The real parties-in-interest were Origin Medsystems, Inc. for Chin and General Surgical Innovations, Inc. for Kieturakis. Count 1, which defined the interfering subject matter in dispute, was identical to Chin claim 66 and Kieturakis claim 80 (i.e., claim 10 of the '442 patent).

27. Interferences are typically divided into two phases: a preliminary motions phase and a priority phase. In the preliminary motions phase, the parties may assert various nonpriority issues, such as unpatentability of the opponent’s claims, claims for benefit of earlier-filed applications, and whether claims should correspond to the count (and therefore rise or fall together). In the *Chin* interference, the parties filed numerous preliminary motions, but agreed to binding arbitration for the priority phase.

28. During the preliminary motions phase, the administrative patent judge (“APJ”) granted Kieturakis’s unopposed motion to correct inventorship by deleting Michelle Monfort as a coinventor on the ground that Monfort’s contribution related to other claims that were canceled before declaration of the interference. The APJ also denied Chin’s motion for unpatentability. After the APJ’s initial decision on the motions, the Board reviewed several aspects of the APJ’s decision. Among other things, the Board affirmed the denial of Chin’s motion for unpatentability of Kieturakis’s claims, finding that the claims were not anticipated or made obvious by U.S. Patent No. 5,163,949.

29. Regarding priority, the arbitrator held a hearing on April 17, 1998, and found that Chin had not satisfied its burden, as the junior party, to show priority by a preponderance of the evidence. The arbitrator concluded that Chin failed to establish conception or reduction to practice in 1991. In particular, Chin did not prove that its 1991 pig trials included all the steps of

the count. On the other hand, the arbitrator found that Kieturakis provided sufficient evidence to show that it reduced to practice the invention of the count on September 30, 1991. Thus, the arbitrator awarded priority to Kieturakis.

30. Because the parties agreed that the arbitrator's priority decision in favor of Kieturakis was binding, and because the Board denied Chin's motion attacking the patentability of Kieturakis's claims, the Board entered judgment in favor of Kieturakis and held that Kieturakis was entitled to a patent including the involved claims. Although Chin filed an appeal to the Federal Circuit, the appeal was later voluntarily dismissed.

31. There have been no other court or agency litigations involving the '442 patent or its foreign counterparts anywhere in the world.

E. Licenses

32. The '442 patent is being licensed from Covidien LP to Covidien Sales LLC, which is a subsidiary of Covidien LP. Pursuant to Commission Rule 210.12(a)(9)(iii), there are no other entities with a license to the '442 patent.

VI. UNLAWFUL AND UNFAIR ACTS OF RESPONDENTS—PATENT INFRINGEMENT

33. The accused products are dissection balloon products and products containing the same that infringe the '442 patent. Upon information and belief, infringing products are designed and manufactured in Germany by Pajunk Germany and/or Pajunk Parent, and then shipped and/or sold for importation to Pajunk USA.

34. Pajunk received regulatory approval to sell dissection balloons from the U.S. Food and Drug Administration in 2009. Ex. 9. In order to receive approval, Pajunk relied on Covidien's Spacemaker Dissection Balloon products as predicate devices to which Pajunk stated are substantially equivalent to Pajunk's dissection balloon products.

35. Pajunk's accused products include dissection balloons, which it calls dilatation balloons, and products containing the same. As Pajunk says, its balloons "are ideally suited to the endoscopic totally extraperitoneal hernioplasty (TEP)." Ex. 10 at 9; Ex. 11 at 9. Pajunk's accused products include at least the Unilateral Dilatation Balloon, Unilateral Dilatation Balloon extra-large, and Bilateral Dilatation Balloon.

36. Pajunk's accused products also include at least double balloon sets. Along with its dilatation balloons, Pajunk has a ring anchor balloon system and a URO ring-anchor balloon system for hernia surgery. Pajunk's accused products include at least double balloon sets made up of a dilatation balloon and a ring-anchor balloon. Specifically, Pajunk's accused products include at least a double balloon set of unilateral dilatation balloon and ring anchor balloon system, a double balloon set of unilateral dilatation balloon and URO ring anchor balloon system, a double balloon set of unilateral dilatation balloon extra-large and ring anchor balloon system, a double balloon set of unilateral dilatation balloon extra-large and URO ring anchor balloon system, a double balloon set of bilateral dilatation balloon and ring anchor balloon system, and a double balloon set of bilateral dilatation balloon and URO ring anchor balloon system.

37. Pajunk's dilatation balloons are designed to be used as part of a method of separating a first layer of tissue from a second layer of tissue creating an operating space for the performance of laparoscopic hernia repair. *See* Exs. 10-14. Pajunk markets the accused products to surgeons in the United States "to create and maintain the space they need for total extraperitoneal hernia surgery." Ex. 7. Pajunk instructs its customers on how to use its dilatation balloons in these procedures. Pajunk instructs that its balloon systems "are ideally suited to the endoscopic totally extraperitoneal hernioplasty (TEP). With this gentle method, the preperitoneal space is dilated pneumatically by inserting and inflating a balloon and the

abdominal wall is reinforced with a plastic mesh.” Ex. 10 at 9; Ex. 11 at 9. To perform “reinforcement of the abdominal wall by means of a plastic mesh” and to prepare the surgical space, Pajunk instructs that the “dilatation balloon is introduced by means of a blunt obturator,” that the “layers are separated by the pneumatic dilatation,” that the “laparoscope and deflated balloon are then removed,” and that “carbon dioxide is injected,” which “maintains the preperitoneal space during the operation.” *Id.*

38. Upon information and belief and at least upon notice of infringement allegations regarding the '442 patent, Pajunk knows about the '442 patent and has induced and continues to induce acts that Pajunk knows or should have known would induce actual infringement of at least the asserted claims of the '442 patent. Pajunk actively induces infringement of the asserted claims of the '442 patent by designing its products to be capable of infringement and by promoting and encouraging the use of its products in ways that infringe at least the asserted claims of the '442 patent.

39. Respondents have knowledge of the '442 patent and their infringement of the '442 patent, at least by virtue of receiving a letter from Covidien dated December 14, 2012 providing Respondents with actual notice of the patent and allegations of infringement.

40. Upon information and belief, Pajunk's accused products are especially designed to be used in the claimed method. Pajunk's accused products are not a staple article or commodity of commerce suitable for substantial non-infringing use. Also, upon information and belief, Pajunk has sold or offered to sell its accused products to others whose use of those accused products has constituted an act of direct infringement of at least the asserted claims of the '442 patent. Pajunk has thereby contributed to and continues to contribute to the infringement of at least the asserted claims of the '442 patent.

41. A chart that applies claim 3 of the '442 patent to a representative accused product is attached as Exhibit 16.

42. A chart that applies claim 6 of the '442 patent to a representative accused product is attached as Exhibit 17.

43. A chart that applies claim 8 of the '442 patent to a representative accused product is attached as Exhibit 18.

44. A chart that applies claim 10 of the '442 patent to a representative accused product is attached as Exhibit 19.

VII. SPECIFIC INSTANCES OF UNFAIR IMPORTATION AND SALE

45. Exemplary instances of importation, sale, and offers for sale of Pajunk's dissection balloon products that infringe the '442 patent are set forth below.

46. Upon information and belief, Pajunk Germany manufactures the accused dissection balloon products in Germany. According to product packaging, the infringing balloon products are "Made in Germany." *See* Ex. 21. In its product literature, Pajunk describes its balloon products as "high grade products Made in Germany." *See* Exs. 10 and 11. Pajunk's corporate video, available on youtube.com on Pajunk USA's channel at http://www.youtube.com/watch?v=OCST5VxSJ60&list=UUcufelzjZXwP_fGoyIj13xA&index=12, also advertises that its products are 100% made in Germany. *See also* Ex. 7 ("The systems come in disposable and reusable models in all shapes and sizes; all are made in Germany.").

47. Upon information and belief, Pajunk USA advertises its infringing balloon products for sale in the United States. On its website, Pajunk USA markets the balloon systems for sale in the United States. *See* Ex. 22 ("Three different balloon forms are available for unilateral and bilateral hernias."). On its website, Pajunk USA represents its distribution territories as covering the United States and Mexico. Ex. 23. A Pajunk product instruction

manual includes a listing of “Balloon Systems – Sets” with corresponding item numbers in the “English USA” section. Ex. 13 at 29. Pajunk has advertised its balloon products in *Outpatient Surgery Magazine*, a print and digital publication circulated in the United States. See Exs. 7 and 15.

48. Upon information and belief, Pajunk has solicited sales of its infringing balloon systems in the United States. For example, Pajunk advertised its balloon products in a publication of the American College of Surgeons. Ex. 24. According to this advertisement, Pajunk had an exhibitor booth for its balloon products and laparoscopy instruments at the American College of Surgeons 97th Clinical Congress in San Francisco, California between October 23 and 27, 2011.

49. On December 10, 2008, Pajunk Germany filed a 510(k) premarket notification submission with the U.S. Food and Drug Administration covering “Balloons and Balloon Systems.” Ex. 9. The 510(k) FDA submission lists as a USA contact Pajunk USA, with an address in Georgia. *Id.* That submission was approved in April 2009, based on the substantial equivalence of the Pajunk Balloon Systems to certain predicate devices, including Covidien’s Spacemaker Balloon Systems. *Id.*

50. Upon information and belief, Pajunk Germany sells the infringing dissection balloon products for importation into the United States. A company profile brochure prepared by Pajunk states that its surgical products are “being sold and distributed around the globe by company-owned distributors in Germany, the USA and in Great Britain.” Ex. 5.

51. On November 12, 2012, two Pajunk dissection balloon systems were purchased in the United States from a medical supply website, eSutures.com. Ex. 25. The purchased products were sent by eSutures.com via Fedex from Mokena, Illinois to an address in New Haven,

Connecticut. Ex. 26. Product packaging indicates the purchased products were manufactured in Germany. Ex. 21. A photograph of each type of the purchased infringing products is shown in Exhibit 27.

VIII. HARMONIZED TARIFF SCHEDULE ITEM NUMBERS

52. On information and belief, the Harmonized Tariff Schedule of the United States item number under which the infringing dissection balloon products and products containing the same may be imported into the United States may be at least HTSUS 9018.90.8000.

IX. THE DOMESTIC INDUSTRY

53. Covidien has established a domestic industry under at least 19 U.S.C. §§ 1337(a)(3)(A) and (B).

54. Covidien employs significant personnel to manufacture the patented dissection balloon products at a leased plant located in Ponce, Puerto Rico. A portion of the clean room manufacturing area is dedicated to the manufacture of the patented dissection balloon products. As detailed in Confidential Exhibit 30C (and public version Exhibit 30), Covidien has made and is making substantial investments in a domestic industry under 19 U.S.C. §§ 1337(a)(3)(A) and (B).

55. Covidien manufactures two families of dissection balloon products: the Spacemaker™ Dissection Balloon family of products, and the Spacemaker™ Plus Dissector System.

56. The Spacemaker™ Dissection Balloons (including the Extra View™) use a dissection balloon (either oval or round) to separate tissue planes, forming a discrete cavity for inguinal hernia repair.

57. The Spacemaker™ Plus Dissector System is a combination of two dissectors and two access devices integrated into a single, modular device. The dissection balloons are

available in two shapes (round or oval) depending upon surgeon preference and patient anatomy. Following initial dissection, the dissection balloon is inserted between the desired tissue planes and inflated to separate tissue layers along naturally occurring planes, thus forming a discrete cavity. After withdrawal of the deflated balloon, the cavity is insufflated. In this newly created discrete cavity, surgeons are able to perform laparoscopic inguinal hernia repair.

58. Covidien's two families of dissection balloon products, the Spacemaker™ and the Spacemaker™ Plus, practice at least claim 10 of the '442 patent. A claim chart is set forth in Exhibit 31 comparing claim 10 to the Covidien Spacemaker™ Plus Dissector System as an exemplary product.

X. SAMPLE ARTICLES

59. An exemplary sample infringing product from Pajunk and an exemplary sample domestic industry dissection balloon product from Covidien are being provided with this Complaint as Exhibits 32 and 33.

XI. RELIEF REQUESTED

60. WHEREFORE, by reason of the foregoing, Complainant Covidien respectfully requests that the United States International Trade Commission:

(a) Institute an immediate investigation, pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(a)(1)(B)(i) and (b)(1), with respect to violations of Section 337 based upon the importation, sale for importation, and sale after importation into the United States of dissection balloons and products containing the same that infringe one or more of the asserted claims of Covidien's U.S. Patent No. 6,312,442;

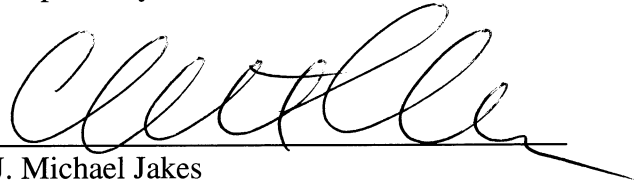
(b) Schedule and conduct a hearing on said unlawful acts and, following said hearing;

(c) Issue a permanent exclusion order pursuant to 19 U.S.C. § 1337(d)(1) barring from entry into the United States all dissection balloons and products containing the same imported by or on behalf of any of the Respondents;

(d) Issue permanent cease and desist orders, pursuant to 19 U.S.C. § 1337(f), directing each respondent to cease and desist from importing, marketing, advertising, demonstrating, warehousing inventory for distribution, offering for sale, selling, distributing, licensing, or using dissection balloons and products containing the same that infringe one or more claims of the Asserted Patent; and

(e) Grant such other and further relief as the Commission deems just and proper based on the facts determined by the investigation and the authority of the Commission.

Respectfully Submitted,



J. Michael Jakes
Christine E. Lehman
Kathleen Daley
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
901 New York Avenue, N.W.
Washington, D.C. 20001
Tel. (202) 408-4000

Tina E. Hulse
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
3300 Hillview Avenue
Palo Alto, CA 94304
Tel. (650) 849-6600