

POLYZEN, INC., a North Carolina  
Company,  
  
Plaintiff,  
  
v.  
RADIADYNE, L.L.C., a Texas  
limited liability corporation,  
Defendant.

1. This is an action for patent infringement brought for Patent Infringement under 35 USC § 271 and for breach of contract and misappropriation of trade secrets under North Carolina law by Plaintiff Polyzen, Inc. (“Polyzen”) against Radiadyne, L.L.C. (“Radiadyne”).

2. This Court has subject matter jurisdiction over issues of patent infringement brought under 35 USC § 271, pursuant to 28 U.S.C. §§ 1331 and 1338(a). This Court pendent and independent subject matter jurisdiction over Polyzen’s claims for breach of contract and missappropriation of trade secrets under North Carolina law, pursuant to 28 U.S.C. § 1332, due to the parties diversity of citizenship, and an amount in controversy exceeding \$75,000.00.

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Defendant having inflicted a tortious injury against Plaintiff here.

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

### **INTRADISTRICT ASSIGNMENT**

5. The Western Division is the appropriate division pursuant to Local Civil Rule 40.1(c)(2) because the acts complained of herein have occurred in this judicial District and Polyzen's principal office is in Wake County.

### **THE PARTIES**

6. Polyzen is a company organized under the laws of North Carolina, with a place of business at 1041 Classic Road, Apex, North Carolina 27539. Polyzen is in the business of developing and manufacturing disposable medical products and devices, including medical balloons, for medical industry original equipment manufacturers. Polyzen developed and patented a Multi-Layer Film Welded Articulated Balloon.

7. Upon information and belief, Defendant is a Texas limited liability corporation with a place of business at 3801 Kirby Drive, Suite 710, Houston, Texas 77098. Defendant sells and offers for sale in the United States, Immobilizer Treatment Devices, which are multi-layer film welded articulated balloons that infringe one or more claims of the '497 patent.

### **GENERAL ALLEGATIONS**

#### **Patent Infringement:**

8. On July 12, 2011, the United States Patent and Trademark Office ("USPTO") duly and properly issued United States Patent No. 7,976,497 ("497 patent"), entitled Multi-Layer Film Welded Articulated Balloon, a copy of which is attached hereto as Exhibit C.

9. Polyzen is the sole assignee of the '497 patent pursuant to an assignment recorded

September 25, 2008 at Reel 021591, Frame 0070 of the USPTO assignment records, and has put Defendant on notice of the '497 patent.

10. The '497 patent grants protection to Polyzen's claimed Multi-Layer Film Welded Articulated Balloon and includes independent claim 1, which describes the protected invention:

1. A medical balloon device, comprising:
  - a first thermoplastic film layer comprising a first material, wherein the first layer includes a first edge;
  - a second thermoplastic film layer comprising a second material, wherein the second layer includes a second edge joined to the first edge to form a bottom inflatable compartment between the first and second layer;
  - a third thermoplastic film layer including proximal and distal portions and comprising a third material different from the first and second materials wherein the third layer includes a third edge joined to the second edge to form a top inflatable compartment between the second and third layer; and
  - an opening in said bottom inflatable compartment to receive a lumen, wherein the bottom inflatable compartment is in fluid communication with the top inflatable compartment.

11. Defendant manufactures and/or causes others to manufacture, uses, offers for sale and sells a multi-layer film welded articulated balloon, identified as an Immobilizer Treatment Device rectal balloon, including a product identified as REF RB-100 ("Radiadyne Device") as well as other like products. Upon information and belief, the Radiadyne Device is manufactured for Defendant by Dielectrics, Inc. of Chicopee, Massachusetts.

12. The Radiadyne Device includes product literature which describes the device and includes instructions for use.

13. The Radiadyne Device is: a medical balloon device, with (i) a first thermoplastic film layer with a first edge; (ii) a second thermoplastic film layer with a second edge joined to the first edge to form a bottom inflatable compartment; (iii) a third thermoplastic film layer, including a third edge joined to the second edge to form a top inflatable compartment between the second and third layer; and (iv) an opening in said bottom inflatable compartment to receive

a lumen, wherein the bottom inflatable compartment is in fluid communication with the top inflatable compartment.

**Breach of Contract and Misappropriation of Trade Secrets:**

14. In early 2007, John Isham, the Chief Executive Officer of Defendant, RadiaDyne, contacted Plaintiff Polyzen to seek their assistance with the development and manufacture of a prostate immobilization balloon. Mr. Isham executed a first Confidential Disclosure Agreement (“CDA”), with Polyzen on RadiaDyne’s behalf on February 9, 2007.

15. The confidential disclosure agreement that Mr. Isham signed contemplated that each party may disclose to the other party certain know how, trade secrets and confidential information relating to specific design specification, processes, use and fabrication of a “Minimally Invasive Rectal Balloon Apparatus (2) Prostate rectal balloon” that the parties were developing. Confidential information protected by the agreement included all processes of manufacture, tooling and equipment, materials, compositions of matter, products and components of products, patent and trade secrets, proprietary know how and manufacturing processes, research and development samples, product designs, product development strategy that becomes known to a recipient party as a result of access granted by the producing party.

16. Under the CDA, the disclosure of information must be in tangible, documentary or graphic form, and/or orally and clearly identified as confidential information of the producing party. The recipient of the confidential information agreed for a period of ten (10) years that it will maintain such information in confidence and will not disclose or use the information during that time period, other than for evaluation purposes.

17. Thereafter, on June 22, 2007, Polyzen and RadiaDyne entered into a second

Confidential Disclosure Agreement (“CDA2”), which consisted of the same essential terms as the February 9, 2007 agreement, but which extended its scope beyond the single rectal balloon design contemplated by the earlier agreement, to the broader category of “various medical devices.”

18. On February 8, 2008, Plaintiff Polyzen and RadiaDyne entered into a Development and Commercialization Agreement (“DCA”). The DCA specifically acknowledged the CDA's entered into between the parties and recited that the obligations of the CDA's remained in effect and would survive termination of the DCA. In addition, the DCA confirmed which party owned which categories of confidential information. In particular, the DCA defined “Polyzen Technology” to mean “all knowledge, know-how, trade secrets, patents, patent applications and other intellectual properties relating to production of various components and/or finished devices out of various polymetric materials, barrier film, various device fabrication processes, various coatings for surface modification, its formulation and fabrication process, and functional coating technology and know-how, owned by or controlled by Polyzen...”

19. In addition, the February 8, 2008 DCA defined Polyzen’s “Device Process Technology” to mean “the Device design, development, fabrication process, material specifications, testing procedures and documentation developed by Polyzen to manufacture specific product for RadiaDyne...” The DCA also defined Polyzen’s “Balloon Process Technology” to mean “Polyzen’s PU film welded balloon technology, including film formulation, thickness and multi-layered film welded, designed to articulate desired shape and profile of balloons for various applications.”

20. In reliance on the two CDA's and the DCA, and RadiaDyne’s perceived good faith in carrying out the terms of those agreements, Polyzen disclosed its most sensitive and

valuable confidential and proprietary information constituting “Polyzen Technology,” “Device Process Technology” and “Balloon Process Technology” to RadiaDyne in the form of numerous documents, photographs, samples and graphical depictions of the prostate immobilization balloon device that Polyzen was developing for RadiaDyne. Those documents and graphical depictions took the form of, without limitation, blueprint drawings, material specifications, manufacturing specifications, and design specifications. Those documents and graphical depictions included Polyzen’s claim of proprietary ownership and confidentiality conspicuously and prominently displayed on them. RadiaDyne never questioned nor objected to the proprietary markings placed on Polyzen's materials by Polyzen.

21. Thereafter, Polyzen proceeded to manufacture prostate immobilization balloon device for RadiaDyne. On information and belief, including the sworn testimony of RadiaDyne's President Mr. John Isham, and unknown to Polyzen at the time, approximately a year later, in early 2008, RadiaDyne decided to investigate the purchase of prostate immobilization balloon devices from a second supplier, Dielectrics, Inc. To assist Dielectrics in making prostate immobilization balloon devices for RadiaDyne at a lower price, RadiaDyne provided to Dielectrics copies of Polyzen’s confidential and proprietary blueprint drawings, material specifications, manufacturing specifications, prototypes, samples, photographs and/or design specifications. Dielectrics knowingly accepted the materials which were clearly and conspicuously marked as the confidential and proprietary property of Polyzen.

22. On information and belief, Dielectrics specifically requested that RadiaDyne provide it with Polyzen’s blueprint drawings, material specifications, manufacturing specifications and/or design specifications to assist Dielectrics in the copying of Polyzen's product. Dielectrics proceeded to use Polyzen’s confidential, proprietary and trade secret

information to manufacture prostate immobilization balloon devices that are virtually identical to, and which competed directly with, the prostate immobilization balloon devices manufactured by Polyzen for RadiaDyne.

23. Dielectrics and RadiaDyne actively worked to conceal the relationship and the manufacture of competitive balloons from Polyzen and actively sought to conceal the improper transfer of Polyzen's confidential materials.

24. Clause 7(a) of the DCA provides that the agreement can only be terminated by RadiaDyne on 90-day written notice if a) Polyzen is in breach, or b) Polyzen is not capable or willing to abide by the manufacturing agreement that the parties intended to enter into. At the time that RadiaDyne terminated the DCA agreement, in November 2009, Polyzen was neither in breach, nor was it incapable or unwilling to abide by any manufacturing agreement that the parties would enter into.

25. Clause 6(d) of the DCA provides that in the event that RadiaDyne decides to use another manufacturer for the "RadiaDyne Product", using Polyzen's IP, Polyzen agrees to grant a non-exclusive license to make and have made the Rectal Balloon catheter, subject to the payment by RadiaDyne to Polyzen of a royalty rate for such manufacturing rights equal to the greater of \$1.00 per unit, or ten percent (10%) of the transfer price per unit to RadiaDyne from the new manufacturer, payable quarterly, based upon an annual open book review between the parties. RadiaDyne has never paid to Polyzen any of the royalties required by Clause 6(d) of the DCA, in spite of the fact that it has been purchasing rectal balloon catheters from Dielectrics which utilize Polyzen's IP since at least as early as mid-2008.

26. Clause 9 of the CDA's states that: Both parties agree that due to the unique nature of the INFORMATION there can be no adequate remedy at law for any breach of Recipient's

obligations under these agreements, thereby resulting in irreparable harm to the Producing Party. Therefore, upon any such breach the Producing Party shall be entitled to appropriate mandatory or negative injunctive relief in addition to whatever remedies it might have at law.

## **COUNT I**

### **PATENT INFRINGEMENT OF U.S. PATENT 7,976,497**

27. Polyzen realleges each and every allegation set forth above and incorporates the same by reference herein.

**28.** Upon information and belief, Defendant has infringed and continues to infringe claims 1 through 5 of the '497 patent.

29. Upon information and belief, Defendant has infringed and continues to infringe the claims of the '497 patent by manufacturing or causing to be manufactured, distributing, using, offering to sell, and/or selling, immobilizer treatment device products within the United States, including causing infringing immobilizer treatment device products to be manufactured by Dielectrics, Inc., 300 Burnett Road, Chicopee, Massachusetts 01020.

30. The Radiadyne Device and Defendant's immobilizer treatment device products are constructed as taught and claimed in the '497 patent in suit and include all of the elements recited in Claims 1 through 5 of the '497 patent.

31. Defendant's infringement is a literal infringement and/or infringement under the doctrine of equivalents, and is direct, contributory, and inducing.

32. Polyzen is entitled to recover from the Defendant the damages sustained, including a reasonable royalty and/or lost profits of Polyzen and/or profits of Defendant as a result of Defendant's infringing acts.

33. Defendant has had knowledge of Polyzen's rights in the '497 patent and has



continued infringement with full knowledge of and in disregard for those rights, wherein such actions constitute willful infringement.

34. Defendant will continue to infringe the claims of Polyzen's '497 patent unless enjoined by this Court.

35. Defendant's infringement of the '497 patent has damaged Polyzen and will continue to cause Polyzen substantial irreparable harm unless enjoined by this Court.

**COUNT II**  
**BREACH OF CONTRACT**

36. Polyzen realleges each and every allegation set forth above and incorporates the same by reference herein.

37. The CDAs and DCA between Polyzen and RadiaDyne represent a lawfully binding and enforceable contracts, supported by adequate consideration.

38. Under the CDAs, the recipient of any confidential information agrees that it will maintain the confidence of the INFORMATION disclosed for a period of ten years, and will not use it for any purpose other than to evaluate Polyzen's development and manufacture of a minimally invasive rectal balloon and other medical devices .

39. The CDAs state that any breach of Recipient will result in irreparable harm to the Producing Party, entitling the Producing Party to injunctive relief.

40. Polyzen performed all conditions, covenants, and promises required to be performed on its part in accordance with the terms and conditions of the CDA.

41. The DCA assigns to Polyzen ownership of the Polyzen Technology, Device Process Technology and Balloon Process Technology, as defined therein.

42. RadiaDyne breached the CDAs and DCA agreements by disclosing to Dielectrics,

Inc. Polyzen's confidential and proprietary blueprint drawings, material specifications, manufacturing specifications and/or design specifications to assist Dielectrics in the copying of Polyzen's products and manufacturing them at a lower price.

43. RadiaDyne breached the DCA by terminating the DCA without cause in violation of Clause 7(a) because at the time of termination Polyzen was neither in breach, nor unwilling or unable to perform the terms of any manufacturing agreement that the parties would enter into.

44. RadiaDyne breached the DCA by failing to pay to Polyzen the royalty set forth in Clause 6(d) for each unit of rectal immobilization balloon and vaginal packing balloon that it purchased from Dielectrics, Inc.

45. Polyzen performed all conditions, covenants, and promises required to be performed on its part in accordance with the terms and conditions of the CDAs and the DCA.

46. As a direct and proximate result of RadiaDyne's breach of contract, Polyzen has suffered damages and is entitled to injunctive relief and compensatory damages in an amount in excess of Seventy Five Thousand Dollars (\$75,000.00)

**COUNT III**  
**MISAPPROPRIATION OF TRADE SECRETS**

47. Polyzen realleges each and every allegation set forth above and incorporates the same by reference herein.

48. The Polyzen blueprint drawings, material specifications, manufacturing specifications, prototypes, samples, photographs and design specifications transferred by RadiaDyne to Defendant Dielectrics, Inc. constitute "Trade Secrets" for purposes of the North Carolina Trade Secrets Act, because they contain technical information relating to the formula, pattern, program, device, compilation of information, method, technique or process for

manufacturing prostate immobilization balloon devices.

49. The Polyzen trade secret information improperly transferred by RadiaDyne to Dielectrics provides detailed technical information concerning the components, materials, material properties, configuration, dimensions, shape, weld placement and manufacturing tolerances, necessary to make the prostate immobilization balloon device with a distal bulge and mid-line groove that is specified. This enabled Dielectrics to manufacture an entire line of nearly identical prostate immobilization balloons for RadiaDyne as a significantly lower price than Polyzen was able to make them for.

50. These materials, techniques, specifications and methods used by Polyzen to make the prostate immobilization balloon are not generally known to the public, and are not readily ascertainable through independent development or reverse engineering, and thus derive substantial commercial value from being maintained as confidential trade secrets. The Polyzen trade secret information misappropriated by RadiaDyne was marked conspicuously with the wording such as: "CONFIDENTIAL" and "THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF POLYZEN, INC. ANY REPRODUCTION IN PART OR WHOLE WITHOUT THE WRITTEN PERMISSION OF POLYZEN, INC., IS PROHIBITED."

51. The Polyzen trade secret information contained within the Polyzen materials transferred by RadiaDyne to Dielectrics constitutes confidential information covered by the CDAs, and it constitutes the "Polyzen Technology," "Device Process Technology" and "Balloon Process Technology" owned by to Polyzen, as explicitly recognized by the DCA. Polyzen made substantial efforts to protect the confidential and proprietary nature of its trade secrets by executing two CDAs and the DCA with RadiaDyne prior to disclosing its trade secrets only to

RadiaDyne and no one else, and by prominently printing a legend on its trade secret documents which gave notice of its proprietary ownership of the information contained therein.

52. RadiaDyne misappropriated Polyzen's trade secrets by acquiring and using those trade secrets contrary to the terms of the CDAs and the DCA without the express or implied authority or consent of Polyzen, and in particular, RadiaDyne did not have the right to disclose those trade secrets to Dielectrics under the terms of the CDAs and DCA.

53. RadiaDyne knew or should have known that the Polyzen information transferred to it by Polyzen was trade secret because of Polyzen's claim of proprietary ownership that was prominently printed on it, and because of RadiaDyne's knowledge of the terms of the CDAs and DCA, as well as its continuous interactions with Polyzen regarding the development of its prostate immobilization balloon catheter.

54. RadiaDyne's misappropriation of trade secrets was unknown to Polyzen until February 2013, when Dielectrics, Inc. produced to Polyzen documents clearly marked as Polyzen proprietary materials in response to a subpoena *duces tecum* in the instant litigation between Polyzen and RadiaDyne. The misappropriation was further confirmed during the March 2013 deposition of RadiaDyne's John Isham. Prior to this information being discovered, Dielectrics and RadiaDyne had acted to conceal from Polyzen the nature of their business activities and the transfer of Polyzen trade secrets.

55. Plaintiff Polyzen is entitled to a return of all misappropriated materials and entitled to recover from Defendant RadiaDyne all of the damages sustained as a result of Defendant's misappropriation of Polyzen's trade secrets, as measured by the economic loss to Polyzen or the unjust enrichment to RadiaDyne caused by the misappropriation of Polyzen's trade secrets, whichever is greater. Polyzen is also entitled to a preliminary and permanent

injunction.

56. Because Polyzen's claim of proprietary ownership of the information contained in its trade secret materials was prominently displayed on the Polyzen materials transferred by Polyzen to RadiaDyne and from RadiaDyne to Dielectrics, Defendant's misappropriation of Polyzen's trade secrets has been willful and malicious, and consequently the trier of fact should also award Polyzen punitive damages, costs and attorneys' fees against RadiaDyne.

57. Defendant RadiaDyne will continue to benefit from the misappropriation of Polyzen's trade secrets by having rectal balloons derived from Polyzen's trade secrets manufactured for it by Dielectrics, unless preliminarily and permanently enjoined from doing so by this Court.

#### **PRAYER FOR RELIEF**

WHEREFORE, Polyzen prays that this Court enter judgment that:

- A. The asserted claims of the '497 patent are infringed by Defendant;
- B. Defendant's infringement of the '497 patent has been willful;
- C. Defendant, and its customers, licensees, directors, officers, agents, servants, employees and all other persons in active concert or privity or in participation with it, be preliminarily and permanently enjoined from manufacturing, using, selling, offering to sell, and importing the Accused Product, and any other infringing products, in and into the United States, directly or indirectly, prior to expiration of the '497 patent;
- D. Defendant be enjoined to deliver upon oath, to be impounded during the pendency of this action, and delivered to Polyzen pursuant to judgment herein, all originals, copies, facsimiles, or duplicates of any device shown to infringe Polyzen's '497 patent.

- E. Judgment be awarded to Polyzen under 35 U.S.C. §§ 271, 281, 284 and/or 285.
- F. Judgment be entered for Polyzen against Defendant, for Polyzen's actual damages, for reasonable royalties or for any profits attributable to infringements of Polyzen's '497 patent.
- G. Defendant be required to account for all gains, profits, and advantages derived from its acts of infringement and for its other violations of law.
- H. Polyzen be awarded damages adequate to compensate for Defendant's infringement of the '497 patent, and that such damages be trebled pursuant to 35 U.S.C. § 284;
- I. This case is exceptional within the meaning of 35 U.S.C. § 285, and that all costs and expenses of this action, including reasonable attorneys' fees, be awarded to Polyzen; and
- J. Judgment be awarded to Polyzen for RadiaDyne's breach of contract under North Carolina law;
- K. Polyzen be awarded all direct, incidental and consequential damages as a result of RadiaDyne's breach of contract;
- L. Judgment be awarded to Polyzen for RadiaDyne misappropriation of trade secrets under the North Carolina Trade Secrets Protection Act, and that the Court find that such misappropriation has been knowing and willful .
- M. Polyzen be awarded the economic damages that it has suffered as a result of RadiaDyne's misappropriation of Polyzen's trade secrets, or the amount by which RadiaDyne had been unjustly enriched as a result of Defendant's misappropriation of Polyzen's trade secrets, if such unjust enrichment is greater than the economic damage suffered by Polyzen as a result of such misappropriation;
- N. Defendant RadiaDyne be ordered to pay to Plaintiff Polyzen punitive damages for its

knowing and willful misappropriation of Polyzen's trade secrets.

O. Defendant RadiaDyne be ordered to pay Plaintiff Polyzen's costs and attorneys' fees incurred in bringing this action as a result of RadiaDyne's knowing and willful misappropriation of Polyzen's trade secrets.

P. Defendant RadiaDyne be preliminarily and permanently enjoined from continuing to use and/or benefit from the misappropriated Polyzen's trade secrets.

Q. Polyzen be awarded such further relief as this Court deems necessary, just and/or proper.

**DEMAND FOR JURY TRIAL**

Polyzen demands a trial by jury on all issues so triable, as provided by Federal Rule of Civil Procedure 38.

Dated: April 12, 2013

Respectfully submitted,

/s/ Joseph J. Zito  
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**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that a copy of the **OPPOSITION TO NOTICE TO DISMISS** was served on April 12, 2013, by electronically filing the same with the Court's CM/ECF system, which caused a Notice of Electronic Filing to be mailed to all counsel of record.

Respectfully submitted,

/s/ Joseph J. Zito  
Joseph J. Zito  
Local Civil Rule 83.1 Counsel  
Attorney for Polyzen