

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
WESTERN DIVISION

POLYZEN, INC.,  
1041 Classic Road  
Apex, North Carolina 27539  
A North Carolina Company

Plaintiff,

v.

DIELECTRICS, INC.  
300 Burnett Road  
Chicopee, Massachusetts 01020  
a Massachusetts Company,

Defendant.

Civil Action No. 5:13-cv-226

**COMPLAINT AND DEMAND FOR JURY TRIAL**

This is an action for misappropriation of trade secrets, tortious interference with contract, and unfair and deceptive trade practices under the laws of the State of North Carolina by Plaintiff Polyzen, Inc. (“Polyzen”) against Defendant Dielectrics, Inc. (“Dielectrics”). This Complaint also asserts patent infringement claims under 35 USC 271, against Defendant Dielectrics for infringement of United States Patent 7,976,497.

**JURISDICTION AND VENUE**

1. This Court has subject matter jurisdiction over Polyzen’s claims, pursuant to 28 U.S.C. 1332 due to the diversity of citizenship between the parties. This Court also has subject matter jurisdiction over the issues of patent infringement under 28 USC 1331 and 1338.

2. Defendant Dielectrics is engaged in manufacturing medical devices, including the prostate immobilization balloons at issue in this case, which are sold throughout the United States and within the Eastern District of North Carolina. Jurisdiction and Venue are proper in this District

as to Defendant, under 28 U.S.C. 1391 and 1400(b). This Court has personal jurisdiction over Defendant by virtue of, at a minimum, Defendant Dielectrics' ongoing and continuous profits from sales within this Judicial District, and the fact that it has committed a tortuous injury against Polyzen in this Judicial District where the Trade Secrets were developed and maintained and used by Polyzen to manufacture product in this Judicial District. Dielectrics' actions reached into this Judicial District and caused economic harm.

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

### **INTRADISTRICT ASSIGNMENT**

4. 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.

### **PARTIES**

5. 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 invested significant resources in the development of confidential engineering specifications and drawings, process techniques and material specifications used in the development of a unique and proprietary prostrate immobilization balloon. Polyzen also patented the prostate immobilization balloon device at issue in this case.

6. On information and belief, Defendant Dielectrics is a corporation organized and existing under the laws of the State of Massachusetts, with a principal place of business located at 300 Burnett Road, Chicopee, Massachusetts 01020. Defendant Dielectrics manufactures, sells,

and offers for sale various medical devices in the United States, including the prostate immobilization balloon device at issue in this case.

### **GENERAL ALLEGATIONS**

7. In early 2007, John Isham, the Chief Executive Officer of RadiaDyne, LLC contacted Plaintiff Polyzen to seek their assistance with the development and manufacture of a prostate immobilization balloon. A call from Mr. Isham to Polyzen led to a February 6, 2007 email from Polyzen's Inside Sales Coordinator, Brenda Owen, forwarding a draft confidential disclosure agreement ("CDA"), which Mr. Isham executed on RadiaDyne's behalf three days later, on February 9, 2007.

8. 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.

9. 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.

10. 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.”

11. On February 8, 2008, Plaintiff Polyzen and RadiaDyne entered into a development and commercialization agreement (“DCA”). The DCA specifically acknowledged the CDA entered into between the parties and recited that the obligations of the CDA 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 polymeric 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...”

12. 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.”

13. In reliance on the two CDAs 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.

14. Thereafter, Polyzen proceeded to manufacture prostate immobilization balloon device for RadiaDyne. On information and belief, 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, Defendant Dielectrics. To assist Dielectrics in making prostate immobilization balloon devices for RadiaDyne at a lower price, on information and belief, including the sworn testimony of RadiaDyne's President Mr. John Isham, 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.

15. 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. On information and belief, Dielectrics knew that this information constituted confidential, proprietary and trade secret information that was protected by the CDAs and the DCA, as a result

of Polyzen's conspicuous and prominent claim of ownership that was printed on the relevant documents. 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.

16. Dielectrics and RadiDyne 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.

**COUNT I**  
**MISSAPPROPRIATION OF TRADE SECRETS**

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

18. The Polyzen blueprint drawings, material specifications, manufacturing specifications, prototypes, samples, photographs and design specifications transferred by RadiaDyne to Defendant Dielectrics 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.

19. The Polyzen trade secret information 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. The 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 Dielectrics 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."

20. 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.

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

22. Dielectrics knew or should have known that the Polyzen information transferred to it by RadiaDyne was trade secret because of Polyzen's claim of proprietary ownership that was prominently printed on it, and on information and belief, because of Dielectrics' interactions with John Isham and others at RadiaDyne and because of Dielectrics prior knowledge of Polyzen.

23. Dielectrics' misappropriation of trade secrets was unknown to Polyzen until

February 2013, when Dielectrics produced Polyzen documents clearly marked as Polyzen proprietary materials, relating to the misappropriation in connection with third party discovery in a related 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 the nature of their business activities and the transfer of Polyzen trade secrets, from Polyzen.

24. Plaintiff Polyzen is entitled to a return of all misappropriated materials and entitled to recover from Defendant Dielectrics 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 unjust enrichment to Dielectrics caused by the misappropriation of Polyzen's trade secrets, whichever is greater.

25. 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 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 Dielectrics.

26. Defendant Dielectrics will continue to benefit from the misappropriation of Polyzen's trade secrets by manufacturing and selling prostate immobilization balloons to RadiaDyne that are virtually identical to Polyzen's balloon device unless preliminarily and permanently enjoined from doing so by this Court.

**COUNT II**  
**TORTIOUS INTERFERENCE WITH CONTRACT**

27. Plaintiff realleges each and every allegation set forth above and incorporates them by reference herein.



28. Defendant Dielectrics knew that RadiaDyne maintained contractual agreements with Polyzen which protected Polyzen's confidential, proprietary and trade secret information that relates to Polyzen's design, development and manufacture of a prostate immobilization balloon for RadiaDyne.

29. On information and belief, Dielectrics requested that RadiaDyne transfer Polyzen's, confidential, proprietary and trade secret information to it, so that it could manufacture Polyzen's minimally invasive, rectal catheter balloon for RadiaDyne at a lower cost. In doing so, Dielectrics actively induced RadiaDyne to breach its CDAs and DCA with Polyzen. Dielectrics had no justification for doing so, because it knew from its own business operations that the Polyzen's detailed manufacturing, material and design specifications that it was requesting from RadiaDyne would have been among the most confidential and proprietary items of information maintained by an original equipment manufacturer like Polyzen. Dielectrics also knew the commercial value and commercial advantage to Dielectrics in obtaining these materials which represented a considerable investment by Polyzen and thus specifically requested this material. As a result, its actions to induce RadiaDyne to breach its contractual agreement with Polyzen were not justified.

30. Plaintiff Polyzen is entitled to recover from Defendant Dielectrics all of the economic damages it has sustained as a result of Defendant's tortious interference with its contractual relationships with RadiaDyne, including at a minimum the lost sales of minimally invasive, rectal catheter balloons and related items that it would have made to RadiaDyne, but for Dielectric's tortious actions. There are no other sources of the minimally invasive, rectal catheter balloons purchased by RadiaDyne.

31. Dielectrics tortious interference with Polyzen's contractual agreements with

RadiaDyne was done willfully or under circumstances which evidence a reckless and wanton disregard for Polyzen's rights. This is particularly true, given the fact that Dielectrics was aware of the contractual relationship between RadiaDyne and Polyzen and because Polyzen's claim of proprietary ownership of its confidential, trade secret information was prominently and conspicuously displayed on the materials that Dielectrics obtained from RadiaDyne. As a result, Polyzen respectfully requests that the Court award it its costs and attorneys fees in bringing this action.

**COUNT III**  
**UNFAIR AND DECEPTIVE TRADE PRACTICES**

32. Plaintiff realleges each and every allegation set forth above and incorporates them by reference herein.

33. Defendant Dielectrics engaged in an unfair and deceptive method of competition with respect to Plaintiff Polyzen in the marketplace for prostate immobilization balloons by obtaining, without Polyzen's knowledge or consent, highly confidential, valuable and detailed Polyzen technical information regarding the materials, specifications and manufacturing tolerances used to make the Polyzen balloon, and then using that information to manufacture a virtually identical prostate immobilization balloon, and to sell that balloon to RadiaDyne (Polyzen's only customer for its balloon) at a lower price.

34. Defendant Dielectrics' unfair and deceptive methods of competition directly and dramatically affected commerce in the marketplace for prostate immobilization balloons because through its actions, Dielectrics was able to replace Polyzen as RadiaDyne's sole supplier of such balloon devices when RadiaDyne cancelled its contract with Polyzen in November 2009.

35. Defendant's unfair and deceptive acts of competition have proximately caused Polyzen to lose sales of minimally invasive, rectal catheter balloons and related items to

RadiaDyne. Polyzen is entitled to recover, at a minimum, the economic value of those lost sales, and any other damages that it can prove to have suffered as a proximate result of Dielectrics' unfair and deceptive business practices.

**COUNT IV**  
**PATENT INFRINGEMENT OF US PATENT NO. 7,976,497**

36. 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.

37. 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.

38. 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.

39. Defendant manufactures uses, offers for sale and sells a multi-layer film welded articulated balloon, identified as an Immobilizer Treatment Device rectal balloon and/or ImmobiLoc, including products manufactured for sale to RadiaDyne and identified as GRB-60F; GRB-90F; GRB-100F; ILG-60F; ILG-90F; ILG-100F; RB-100LS; RB-100F; RB-100; RB-60; and the Alatus Balloon ("Dielectrics Products") as well as other like products.

40. The Dielectric Products re packaged with product literature which describes the device and includes instructions for use.

41. The Dielectrics Products are medical balloon devices, 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.

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

43. 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, the Dielectrics Products within the United States.

44. The Dielectrics 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.

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

46. 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.

47. 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.

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

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

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff Polyzen prays that this Court enter judgment that:

**A.** Dielectrics has misappropriated Polyzen's trade secrets, and that such misappropriation has been knowing and willful;

**B.** Dielectrics has tortuously interfered with Polyzen's contractual relationships with RadiaDyne, and that such tortuous interference was willful;

**C.** Dielectrics has committed acts of unfair and deceptive business practices with respect to its design, development and manufacture of a prostate immobilization balloon for RadiaDyne;

**D.** Plaintiff Polyzen be awarded the economic damages that it has suffered as a result of Defendant Dielectrics' misappropriation of Polyzen's trade secrets, its tortuous interference with Polyzen's contractual relationships with RadiaDyne, and its acts of unfair and deceptive business practices;

**E.** Plaintiff Polyzen be awarded the amount by which Defendant Dielectrics has 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 Dielectrics' misappropriation.

**F.** Defendant Dielectrics be ordered to pay to Plaintiff Polyzen punitive damages for

its knowing and willful misappropriation of Polyzen's trade secrets;

**G.** Defendant Dielectrics be ordered to pay Plaintiff Polyzen's costs and attorneys' fees incurred in bringing this action as a result of Defendants' knowing and willful misappropriation of Polyzen's trade secrets and its willfully tortuous interference with Polyzen's contractual relationships with RadiaDyne;

**H.** Defendant Dielectrics be preliminarily and permanently enjoined from continuing to misappropriate Polyzen's trade secrets by manufacturing and selling a prostate immobilization balloon derived therefrom;

**I.** The asserted claims of the '497 patent are infringed by Defendant;

**J.** Defendant's infringement of the '497 patent has been willful;

**K.** 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;

**L.** 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;

**M.** Judgment be awarded to Polyzen under 35 U.S.C. §§ 271, 281, 284 and/or 285;

**N.** 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.

**O.** Defendant be required to account for all gains, profits, and advantages derived from its acts of infringement and for its other violations of law;

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

#### **DEMAND FOR JURY TRIAL**

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

#### **VERIFICATION**

I have read the foregoing Complaint and declare under penalty of perjury under the laws of the united states that the foregoing facts are correct and true to the best of my knowledge and understanding.

Dated: this 27<sup>th</sup> Day of March, 2013

  
\_\_\_\_\_  
Tilak Shah  
CEO, Polyzen, Inc.  
1041 Classic Road  
Apex, NC 27539

Respectfully submitted, this 27th day of March 2013.

/s/ Steven J. Hultquist  
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