

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

<hr/>		)	
POLYZEN, INC.,		)	
1041 Classic Road		)	
Apex, North Carolina 27539		)	
		)	
	Plaintiff,	)	
		)	
v.		)	Civil Action No. 3:15-cv-13200 MGM
		)	
DIELECTRICS, INC.		)	
300 Burnett Road		)	
Chicopee, Massachusetts 01020		)	
		)	
	Defendant.	)	
<hr/>		)	

**FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

This is an action for patent infringement claims under 35 USC 271, against Defendant Dielectrics for infringement of United States Patent No. 7,976,497 and United States Patent No. 8,740,845 by Plaintiff Polyzen, Inc. (“Polyzen”) against Defendant Dielectrics, Inc. (“Dielectrics”).

**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 prostate immobilization balloons at issue in this case, which are sold throughout the United States. Jurisdiction and Venue are proper in this District because Defendant is located in this District. This Court has personal jurisdiction over Defendant.

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

### **PARTIES**

4. 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 patented the prostate immobilization balloon device at issue in this case.

5. 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**

6. In early 2007, RadiaDyne, LLC contacted Plaintiff Polyzen to ask Polyzen to develop and manufacture a prostate immobilization balloon. Polyzen and RadiaDyne entered in to a series of agreements, leading to a February 8, 2008, Development and Commercialization Agreement (“DCA”). Under the terms of the DCA, Polyzen owns the patents to the balloon developed by Polyzen and retains the exclusive right to manufacture medical balloons which practice the claims of the '497 and '845 patents. RadiaDyne was granted only the right to use and

sell Medical Balloons manufactured by Polyzen which practice the claims of the '497 and '845 patents.

7. Polyzen manufacture prostate immobilization balloon device for RadiaDyne in 2007 and 2008 under the terms of the DCA.

8. In 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, RadiaDyne provided to Dielectrics copies of Polyzen's confidential and proprietary drawings, material specifications, manufacturing specifications, prototypes, samples, photographs and/or design specifications, which were clearly and conspicuously marked as the confidential and proprietary property of Polyzen.

9. Dielectrics, in 2008, began 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. The Dielectric balloons infringe numerous claims of the '497 and '845 patents.

10. The '497 patent issued on July 12, 2011 and Polyzen sued RadiaDyne for patent infringement shortly thereafter on November 21, 2011. Polyzen file suit for patent infringement against Dielectrics in The District of North Carolina, on March 27, 2013. The Dielectrics suit was dismissed on October 13, 2013 for lack of personal jurisdiction. The '845 patent issued on June 3, 2014 and Polyzen filed suit against RadiaDyne that same day.

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

11. 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.

12. 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.

13. 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.

14. Defendant manufactures, uses, offers for sale and sells a multi-layer film welded medical balloon, identified as an Immobilizer Treatment Device rectal balloon and/or Immobilizer and/or ImmobiLoc, and/or IPSI and/or Alatus Balloon as well as other like products (“Dielectrics Products”).

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

16. 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.

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

18. 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.

19. 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.

20. Defendant’s infringement is a literal infringement and/or infringement under the doctrine of equivalents, and is direct, indirect, contributory, and inducing.

21. 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.

22. 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.

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

24. 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**  
**PATENT INFRINGEMENT OF US PATENT NO. 8,740,845**

25. On June 3, 2014, the United States Patent and Trademark Office ("USPTO") duly and properly issued United States Patent No. 8,740,845 ("845 patent"), entitled Multi-Layer Film Welded Articulated Balloon.

26. Polyzen is the sole assignee of the '845 patent pursuant to an assignment recorded September 25, 2008 at Reel 021591, Frame 0070 of the USPTO assignment records.

27. The '845 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 multiplicity of layers of thermoplastic film including layers sealed at peripheral edges thereof to form an inflatable interior volume enclosed by the sealed edges, wherein the inflatable interior volume enclosed by the sealed edges is sealed by a single seal, and layers at least

one of which is sealed directly to another at one or more locations in the interior volume to enable the device to articulate to a predetermined shape upon inflation of the interior volume with an inflation fluid, to accommodate a predetermined medical application, wherein the inflatable interior volume is adapted to receive an inflation fluid.

28. Defendant manufactures uses, offers for sale and sells a multi-layer film welded medical balloon, identified as an Immobilizer Treatment Device rectal balloon and/or Immobilizer and/or ImmobiLoc, and/or IPSI and/or Alatus Balloon as well as other like products (“Dielectrics Products”).

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

30. The Dielectrics Products are medical balloon devices, with a multiplicity of layers of thermoplastic film including layers sealed at peripheral edges thereof to form an inflatable interior volume enclosed by the sealed edges, and layers sealed at one or more locations in the interior volume to enable the device to articulate to a predetermined shape upon inflation of the interior volume with an inflation fluid, to accommodate a predetermined medical application, wherein the inflatable interior volume is adapted to receive an inflation fluid.

31. Upon information and belief, Defendant has infringed and continues to infringe claims 1 through 21 of the ‘845 patent.

32. Upon information and belief, Defendant has infringed and continues to infringe the claims of the ‘845 patent by manufacturing or causing to be manufactured, distributing, using, offering to sell, and/or selling, the Dielectrics Products within the United States.

33. The Dielectrics Products are constructed as taught and claimed in the '845 patent in suit and include all of the elements recited in Claims 1 through 21 of the '845 patent.

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

35. 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.

36. Defendant has had knowledge of Polyzen's rights in the '845 patent and has continued infringement with full knowledge of and in disregard for those rights, wherein such actions constitute willful infringement.

37. Defendant will continue to infringe the claims of Polyzen's '845 patent unless enjoined by this Court.

38. Defendant's infringement of the '845 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:

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

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

41. 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;

42. 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;

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

44. 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.

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

46. 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;

47. The asserted claims of the '845 patent are infringed by Defendant;

48. Defendant's infringement of the '845 patent has been willful;

49. 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 '845 patent;

50. 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 '845 patent;

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

52. 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 '845 patent.

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

54. Polyzen be awarded damages adequate to compensate for Defendant's infringement of the '845 patent, and that such damages be trebled pursuant to 35 U.S.C. § 284;

55. 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

56. 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.

//////////

Respectfully submitted, this 16th day of November 2015.

/s/ Warren E. Agin

Warren E. Agin, Esq.  
BBO No. 554,242  
Swiggart & Agin, LLC  
197 Portland Street, 4<sup>th</sup> Fl.  
Boston, MA 02114  
Main No.: 617-742-0110  
Direct Dial: 617-517-3203  
[wea@swiggartagin.com](mailto:wea@swiggartagin.com)  
*Counsel for Plaintiff, POLYZEN, INC.*

/s/ Joseph J. Zito

Joseph J. Zito (Pro Hac Vice)  
DNL ZITO  
1250 Connecticut Avenue, NW  
Washington, D.C. 20036  
Tel: (202) 466-3500  
[jzito@dnlzito.com](mailto:jzito@dnlzito.com)  
*Counsel for Plaintiff, POLYZEN, INC.*

### **Certificate of Service**

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the NEF (NEF) and paper copies will be sent to those indicated as non-registered participants on November 16, 2015.

/s/ Joseph J. Zito

Joseph J. Zito