

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss

DEPARTMENT OF THE TRIAL COURT
DOCKET NO.

**HAYRULLAH CETIR, Individually and as §
Anticipated Co-Personal Representative and §
PERRY GANZ, as Anticipated Co-Personal §
Representative and of the Estate of YESIM §
CETIR §**

Plaintiffs,

vs.

**HARVARD BIO SCIENCE, INC. §
84 October Hill Road §
Holliston, MA 01746 §
and §
HARVARD APPARATUS §
REGENERATIVE TECHNOLOGY, INC. §
84 October Hill Road §
Holliston, MA 01746 §
and §
BIOSTAGE, INC. §
f/k/a HARVARD APPARATUS §
84 October Hill Road, Suite 11 §
Holliston, MA 01746 §
and §
NANOFIBER SOLUTIONS LLC §
1275 Kinnear Road §
Columbus, OH 43212 §
and §
NANOFIBER SOLUTIONS, INC. §
1275 Kinnear Road §
Columbus, OH 43212 §**

Defendants

**WRONGFUL DEATH COMPLAINT
and DEMAND FOR JURY TRIAL**

Plaintiffs, Hayrullah Cetir, Individually and as anticipated Co-Personal Representative and Perry Ganz, as anticipated Co-Personal Representative and of the Estate of Yesim Cetir, deceased, by and through her undersigned attorneys, hereby brings this wrongful death action against the above named Defendants and for Plaintiff's Complaint alleges, upon information and

belief and based on the investigation to date of counsel, as follows:

SUMMARY OF THE ALLEGATIONS

Yesim Cetir sustained terminal injuries caused by Defendants' negligent misleading and fraudulent use of their synthetic trachea and bio reactor. This synthetic tracheas and the bio reactor technology utilized therewith were defective and unreasonably dangerous and should not have been used in the medical treatment of Yesim Cetir. The synthetic trachea and bio reactor technology was defective, unreasonably dangerous and negligently and fraudulently misrepresented to Yesim Cetir to her detriment.

PARTIES

1. Plaintiff, Hayrullah Cetir, anticipated Co-Personal Representative of the Estate of Yesim Cetir and Attorney-in-Fact for his daughter, Yesim Cetir, is an individual who resides at 3345 Park Avenue, Apartment 1R, Philadelphia, PA 19140.

2. Plaintiff, Perry Ganz, as anticipated Co-Personal Representative of the Estate of Yesim Cetir, is an individual whose address is 160 Gould Street, Suite 320, Needham, Massachusetts 02494.

3. Decedent, Yesim Cetir resided in Philadelphia, Philadelphia County prior to her death. She died in Philadelphia in Philadelphia County, Pennsylvania.

4. Defendant, Harvard Bio Science, Inc. (HBS) is a corporation organized under the laws of the State of Delaware, with its principal place of business located at 84 October Hill Road, Suite 10, Holliston, Massachusetts 01746.

5. Defendant, Harvard Apparatus Regenerative Technology, (HART) originally a subsidiary of HBS, and now a spin-off corporation is organized under the laws of the State of

Delaware, with its principal place of business located at 84 October Hill Road, Holliston, MA 01746.

6. Defendant, Biostage, Inc., f/k/a Harvard Apparatus Regenerative Technology (Biostage) is a corporation organized under the laws of the State of Delaware, with its principal place of business located at 84 October Hill Road, Holliston, MA 01746.

7. Defendant, Nanofiber Solutions LLC, (Nanofiber) is a corporation organized under the laws of the State of Delaware with its principal place of business located at 1275 Kinnear Road, Columbus, Ohio 43212.

8. Defendant, Nanofiber Solutions Inc., is a corporation organized under the laws of the State of Delaware with its principal place of business located at 1275 Kinnear Road, Columbus, Ohio 43212.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to G.L. c. 212, § 4. This Court has personal jurisdiction over the Defendants pursuant to G.L. c. 223A, §§ 2 and 3.

10. Venue is proper in Middlesex County pursuant to G.L. c. 223, §8(4).

FACTS RELEVANT TO ALL COUNTS

11. Plaintiffs incorporate herein by reference therefore all assertions set forth in the preceding paragraphs specifically including but not limited to all assertions regarding agents, servants, workmen, employees and co-conspirators.

12. David Green is a Director of both HBS and Biostage (f/k/a HART).

13. At all times relevant and upon information and belief, Mr. Green was President of HBS and CEO of HART.

14. Upon information and belief, Dr. Paolo Macchiarini is a thoracic surgeon who together with David Green and the Defendants developed a synthetic trachea transplant using synthetic scaffolds and bio reactor technology.

15. Defendant, Nanofiber, either individually and/or by and through its agents, servants, workmen and/or employees and/or co-conspirators including but not limited to the other Defendants named herein and David Green and Dr. Paolo Macchiarini who were acting at all times within the course and scope of their employment and/or respective authority, designed, developed, manufactured, marketed, sold and/or distributed one or both of the Scaffolds utilized in the trachea transplant surgeries performed on decedent, Yesim Cetir.

16. Defendant, Nanofiber by and through its agents, servants, workmen and/or employees and/or co-conspirators including but not limited to the other named Defendants herein, David Green and Dr. Paolo Macchiarini, who were acting at all times within the course and scope of their employment and/or respective authority, designed, consulted, observed and/or participated in the medical treatment of decedent, Yesim Cetir, related to her trachea transplant surgeries.

17. Defendant, HBS, either individually and/or by and through its agents, servants, workmen and/or employees and/or co-conspirators and/or by and through other agents, servants, workmen and/or employees and/or co-conspirators including but not limited to the other named Defendants herein and David Green and Dr. Paolo Macchiarini who were acting at all times within the course and scope of their employment and/or respective authority, designed, developed, manufactured, marketed, sold and/or distributed one or both of the scaffolds and the bio reactor technology utilized in the trachea transplant surgeries performed on decedent, Yesim Cetir.

18. Defendant, HBS by and through its agents, servants, workmen and/or employees, and/or co-conspirators including but not limited to the other named Defendants herein and David Green and Dr. Paolo Macchiarini, who were acting at all times within the course and scope of their employment and/or respective authority, consulted, observed and/or participated in the medical treatment of decedent, Yesim Cetir, related to her trachea transplant surgeries.

19. Defendant, HART, either individually and/or by and through its agents, servants, workmen and/or employees, and/or co-conspirators including but not limited to the other Defendants named herein and David Green and Dr. Paolo Macchiarini who were acting at all times within the course and scope of their employment and/or respective authority, designed, developed, manufactured, marketed, sold and/or distributed one or both of the scaffold and the bio reactor technology utilized in the trachea transplant surgeries performed on decedent, Yesim Cetir.

20. Defendant, HART, by and through its agents, servants, workmen and/or employees, and/or co-conspirators including but not limited to the other Defendants named herein and David Green and Dr. Paolo Macchiarini, who were acting at all times within the course and scope of their employment and/or respective authority, consulted, observed and/or participated in the medical treatment of decedent, Yesim Cetir, related to her trachea transplant surgeries.

21. Plaintiffs believe and therefore avers that Defendant, HART, may have assumed the assets and/or liabilities of Defendant, HBS.

22. Plaintiffs believe and therefore aver that Defendant, BIOSTAGE has assumed the assets and/or liabilities of Defendants, HART and HBS.

23. All Defendants herein acted both individually and through the acts of their agents, servants, workmen and/or employees and/or co-conspirators, including but not limited to Dr. Macchiarini and David Green, are liable herein under agency, respondent superior, vicarious liability, master-servant, and right of control.

24. When this complaint refers to Defendants it is referring to all Defendants both individually and through the acts of their agents, servants, workmen and/or employees and/or co-conspirators including but not limited to Dr. Macchiarini and David Green, are liable herein under agency, respondent superior, vicarious liability, master-servant, and right of control and/or as co-conspirators.

25. Decedent and her father relied on the medical knowledge, skill, advice, evaluations, diagnoses and treatment provided by the Defendants who consulted with and/or provided information to the Plaintiff, her father and her doctors who were not aware of the true risks of the Defendants' synthetic tracheas and scaffolds and the associated bio reactor technology, regarding the advisability of receiving a transplant of an artificial trachea as described in detail herein.

26. In 2011, Yesim Cetir, then underwent an operation to control the sweat in the palms of her hands in Turkey. During the course of her surgery, her trachea was damaged. The doctors providing care for Yesim Cetir were unable to repair the damages to her trachea and therefor, undertook a search for medical treatment for Yesim Cetir.

27. As a result of the search, on or about July 24, 2012 Yesim Cetir came under the care and treatment of Dr. Paolo Macchiarini for treatment of her damaged trachea. At this time in 2012, Yesim Cetir was capable of making medical decisions for herself.

28. At this time in 2012 and upon information and belief, Dr. Paolo Macchiarini had only performed four other synthetic trachea transplants.

29. At this time in 2012 and upon information and belief, at least one of the four patients had died. At this time in 2012 and upon information and belief, the synthetic trachea and scaffolds had not been approved safe and effective by any regulatory agency, including the United States Food and Drug Agency, in the world.

30. The Defendants actively participated in providing information to prospective transplant patients including Yesim Cetir regarding the alleged benefits of synthetic trachea implant to encourage them to undergo the surgery.

31. At no time relevant hereto, did the Defendants provide adequate and sufficient explanation to Yesim Cetir regarding the experimental nature of proposed artificial trachea transplant, that the implantation of the synthetic trachea was clinical research, that there was not adequate scientific foundation for a human transplant of the synthetic trachea, that the concept of the synthetic trachea seeded with bone marrow cells conflicted with scientific and proven experience, that the material being used to construct the trachea was flawed, the known risks of the procedure, and the fact that not all the risks of the surgery were known. Nor was she provided the opportunity or suggestion to discuss the procedure with an independent expert.

32. At no time relevant hereto, did the Defendants offer or inform plaintiff of the alternatives to the trachea transplant including the option of a trachea transplant from a cadaver which did not have had all of the risks associated with the artificial trachea and bio reactor technology utilized and would have had greater benefit.

33. On or about August 7, 2012, the Defendants and Dr. Paolo Macchiarini were responsible for the decision to perform and for the performance of the implantation of a synthetic

trachea which had utilized bio reactor technology into Yesim Cetir.

34. Following her surgery, Yesim Cetir suffered many complications including failure of the synthetic trachea.

35. At all times relevant hereto, Yesim Cetir was informed by Defendants and her medical treaters that the complications she was suffering were normal complications of her surgery and at no time was she informed that the complications were as a result of the fact that the synthetic trachea was defective, dangerous, unproven and experimental which was the reason for the failure.

36. At this time in 2013, Yesim Cetir was capable of making medical decisions for herself and/or in concert with her father, Hayrullah Cetir.

37. The Defendants actively participated in providing information to Yesim Cetir and her father and her medical treaters who were not associated with or co-conspirators of the Defendants, regarding the alleged benefits of second synthetic trachea implant to encourage them to agree that she should undergo the second surgery.

38. At no time relevant hereto, did the Defendants provide adequate and sufficient explanation to Yesim Cetir or her medical treaters who were not associated with or co-conspirators of the Defendants, of the experimental nature of the proposed artificial trachea transplant, that the implantation of the synthetic trachea was clinical research, that there was not adequate scientific foundation for a human transplant of the synthetic trachea, that the concept of the synthetic trachea seeded with bone marrow cells conflicted with scientific and proven experience, that different material was being used to construct the trachea because of flaws in the prior material, the known risks of the procedure, and the fact that not all the risks of the surgery

were known. Nor was she provided the opportunity or suggestion to discuss the procedure with an independent expert.

39. At no time relevant hereto, did the Defendants offer Yesim Cetir alternatives to the trachea transplant including the option of a trachea transplant from a cadaver.

40. At no time relevant hereto, did the Defendants provide Yesim Cetir full information on the risks and benefits of the synthetic trachea which utilized bio reactor technology, thus at no time hereto was Yesim Cetir able to make an informed decision about her care and treatment with respect to her damaged trachea.

41. On or about July 9, 2013, the Defendants were responsible for the decision to perform and for the performance of a second implantation of a synthetic trachea which utilized bio reactor technology into Yesim Cetir.

42. At this time and upon information and belief, at least two patients out of five had died following this same procedure.

43. Following this surgery, Yesim Cetir suffered many complications including but not limited to failure of the synthetic trachea, lung failure, and damages to her esophagus requiring tube feeding. At all times relevant hereto, Yesim Cetir was informed by Defendants that the complications she was suffering from were normal complications of her surgery and at no time was she informed that the synthetic trachea transplant was defective, dangerous, unproven and experimental which was the reason for the failure. At all times relevant hereto Yesim Cetir and her father relied upon the Defendants' misrepresentations.

44. At no time prior to the publication of various articles beginning in the latter part of 2014 documenting issues surrounding the use of Defendants' artificial trachea and bio reactor

technology did Yesim Cetir know nor should she have known that the Defendants conduct and product caused her harm.

45. In September 2015, Yesim Cetir was transferred to Temple Hospital in Philadelphia Pennsylvania for further care and treatment related to the failure of Defendants' synthetic trachea, scaffold and bio reactor technology.

46. On or about May 25, 2016, Yesim Cetir, underwent a tracheal and lung transplant utilizing human cadaver organs and a gastric conduit.

47. Yesim Cetir continued to incur health complications and damages as a result of Defendants conduct and dangerous artificial tracheas and associated bio reactor technology, including but not limited to, a stroke, visual loss, foot drop.

48. Yesim Cetir died March 19, 2017.

49. Yesim Cetir's death was caused by the Defendants' conduct and products as referenced in this complaint.

50. At no time prior to the implantations into Yesim Cetir of the synthetic tracheal grafts was approval obtained under any compassionate use exemption, or any other exemption from any regulatory governmental authority for these procedures.

51. At all times relevant hereto the implantations into Yesim Cetir of the synthetic tracheal grafts were off label uses pursuant to the rules and regulations of the pertinent regulatory authorities.

52. At all times relevant hereto, Defendants knew or should have known the rules and guidelines of the various regulatory agencies which were required to be followed in order to obtain approval to transplant a synthetic trachea, yet Defendants negligently and intentionally failed to follow them.

53. At all times relevant hereto, Defendants failed to assure that the synthetic trachea was suitable for its intended purposes.

54. At no time prior to the implantations of the synthetic tracheal grafts into Yesim Cetir were the synthetic tracheal grafts appropriately studied in animals, clinical trials nor were they approved by any of pertinent regulatory agency in either the United States or Europe for the use for which they were used in Yesim Cetir.

55. Upon information and belief, almost all patients receiving this synthetic thrachea using the bio reactor technology have died.

COUNT I
Wrongful Death G.L. c. 229 §2
Negligence
(Against All Defendants)

56. Plaintiffs incorporate herein by reference therefore all assertions set forth in the preceding paragraphs specifically including but not limited to all assertions regarding agents, servants, workmen, employees and conspirators.

57. Defendants directly or indirectly negligently manufactured, designed, tested, researched and developed, labeled, packaged, distributed, promoted, marketed, advertised, and sold synthetic tracheas and the associated bio reactor technology in the State of Massachusetts, in the United States, and Internationally.

58. At all times material hereto, Defendants had a duty to Yesim Cetir to exercise reasonable care in the design, manufacture, research and development, testing, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of synthetic tracheas and the associated bio reactor technology.

59. Defendants breached their duty and were negligent in their actions, misrepresentations, and omissions toward Yesim Cetir in the following ways:

- a) Failing to study, test and/or research synthetic tracheas in a reasonable manner in order to ascertain whether or not it was safe and proper for the purpose for which it was designed, manufactured, labeled, promoted and sold;
- b) Failing to utilize and implement a reasonably safe design in the manufacture of synthetic tracheas;
- c) Failing to manufacture synthetic tracheas in a reasonably safe condition;
- d) Failing to warn the Decedent or Decedent's health care providers of the dangers of adverse medical conditions from the use of synthetic tracheas when used as instructed;
- e) Failing to remove synthetic tracheas from the market for certain classes of patients or for all patients when Defendants knew the risks outweighed the benefits;
- f) Failing to label synthetic tracheas reasonably so as to warn the Decedent and Decedent's health care providers of the accurate risks and limited and/or nonexistent benefits of synthetic tracheas; and
- g) Manufacturing and/or distributing and/or selling synthetic tracheas and the associated bio reactor technology which were unreasonably dangerous and defective when used as instructed.
- h) Promoting and/or marketing and/or advertising synthetic tracheas and the associated bio reactor technology in false, misleading and dangerous manner.

60. Defendants knew or should have known that synthetic tracheas had unreasonably dangerous risks of which Decedent and Decedent's health care providers who were not associated with or co-conspirators of the Defendants would not be aware. As a direct and proximate result of the negligent actions and inactions of the Defendants as set forth above, Yesim Cetir sustained injuries including, but not limited to those listed herein including but not limited to failure of the synthetic tracheas, physical harm, pain and suffering, mental anguish, loss of capacity for the enjoyment of life, medical expenses, expenses of funeral, and death.

WHEREFORE, Plaintiff demands judgment of the Defendants for damages as described herein in an amount determined by the jury and such other and further relief as allowed in equity or law.

COUNT II
Wrongful Death G.L. c. 229 §2
Breach of Warranty
Failure to Warn
(Against All Defendants)

61. Plaintiffs incorporate herein by reference therefore all assertions set forth in the preceding paragraphs specifically including but not limited to all assertions regarding agents, servants, workmen, employees and conspirators.

62. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce synthetic tracheas and associated bio reactor technology and in the course of same, directly promoted or marketed the products to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of synthetic tracheas and associated bio reactor technology.

63. Decedent's and her physician's use of synthetic tracheas and associated bio reactor technology was entirely foreseeable to Defendants. Defendants expected and intended patients like and including Yesim Cetir to use their products all the while knowing their products were experimental, dangerous, defective and would cause serious lethal harm.

64. The synthetic tracheas which incorporated the bio reaction technology were defective and unreasonably dangerous when they left the possession of Defendants in that the products contained warnings and directions which were misleading and were inadequate and insufficient to alert the physicians and consumers, such as Decedent's physicians who were not associated with co-conspirators of the Defendants and Decedent, to the dangerous risks and reactions associated with the products, including but not limited to the life-threatening effects suffered by Decedent resulting in Decedent's death.

65. Defendants, as global leaders in the development, manufacturing and marketing of specialized pharmaceutical and/or medical products are held to the level of knowledge of an expert in the field, and further, Defendants had knowledge of the dangerous risks and side effects of synthetic tracheas and the associated bio reactor technology of which they failed to warn Decedent, and/or protect Decedent by informing Decedent or Decedent's health care providers who did not have this information.

66. Decedent and Decedent's health care providers who did not have the information withheld by Defendants, regarding the dangers of the synthetic tracheas and the associated bio reactor technology, did not have the same knowledge as Defendants and no adequate warning was communicated to Decedent and/or Decedent's health care providers who did not have this information.

67. Defendants had a continuing duty to warn consumers, including Decedent and Decedent's health care providers who did not have this information, of their products, and the risks and dangers associated with them, and negligently and/or wantonly breached their duty as follows:

- a. Failed to include adequate warnings and labels with their synthetic tracheas that employed the bio reactor technology which would alert consumers and consumer's health care providers who did not have this information to the dangerous risks and of the product.
- b. Failed to provide adequate post-marketing warnings and instructions after the Defendants knew or should have known of the significant risks of injury and death associated from the use of synthetic tracheas and the associated bio reactor technology.
- c. Failed to inform that synthetic tracheas and the associated bio reactor technology had not been adequately and thoroughly tested, studied or proven for safety in certain classes of patients or in all patients.

68. Defendants deliberately concealed and/or intentionally withheld knowledge of the risks and dangers and defective nature of the synthetic tracheas and the associated bio reactor

technology from Decedent, Decedent's health care providers who were associated with nor were co-conspirators of the defendants, and the medical community. By so acting, Defendants acted with conscious and deliberate disregard of the foreseeable harm caused by synthetic tracheas and the associated bio reactor technology.

69. Although Defendants knew, or were reckless in not knowing, of the dangerous defective nature of synthetic tracheas and the associated bio reactor technology, they continued to promote the same aggressively without providing adequate warnings and instructions concerning its use so as to maximize sales and profits at the expense of the public health and safety, and of the health and safety of Yesim Cetir specifically in knowing, conscious, and deliberate disregard of the foreseeable harm caused by these products.

70. As a direct and proximate result of the actions and inactions of the Defendants as set forth above, Decedent sustained injuries including, but not limited to failure of the synthetic tracheas, physical harm, pain and suffering, mental anguish, loss of capacity for the enjoyment of life, medical expenses, expense of funeral, and death.

WHEREFORE, Plaintiff demands judgment of the Defendants for damages as described herein in an amount determined by the jury and such other and further relief as allowed in equity or law.

COUNT III
Wrongful Death G.L. c. 229 §2
Breach of Warranty
Defective Design
(Against All Defendants)

71. Plaintiffs incorporate herein by reference therefore all assertions set forth in the preceding paragraphs specifically including but not limited to all assertions regarding agents, servants, workmen, employees and conspirators.

72. At all times material hereto, Defendants engaged in the business of selling, distributing, manufacturing, marketing, labeling, and/or promoting synthetic tracheas and the associated bio reactor technology, which was unreasonably dangerous, and therefore defective as designed, labeled and sold.

73. At all times material hereto, synthetic tracheas which incorporated the bio reactor technology reached Decedent without substantial change in the condition in which it left the possession of the Defendants and was used in the manner for which it had been contemplated and labeled.

74. These synthetic tracheas and incorporated bio reactor technology were defective and unreasonably dangerous when it entered the stream of commerce and were received by implanted into Decedent because:

- a. When placed in the stream of commerce the synthetic tracheas and associated bio reactor technology contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting users and consumers like Decedent to risks which exceeded the benefits of the products;
- b. When placed in the stream of commerce, the synthetic tracheas and the associated bio reactor technology were defective in design and formulation, making the use of the products more dangerous than an ordinary consumer would expect and more dangerous than other risks associated with trachea transplants from a cadaver;
- c. Synthetic tracheas and the associated bio reactor technology were insufficiently and inadequately tested, studied, and researched ;
- d. Synthetic tracheas and the associated bio reactor technology were unreasonably defective when used as intended especially in light of the fact that there existed safer alternatives;
- e. The intended use of the products caused predictable harm and death which outweighed any potential utility; and
- f. Synthetic tracheas and the associated bio reactor technology was marketed and promoted for use as safe products, when they were not safe for the intended use.
- g. The past use of the product prior to its use in Decedent evidenced the dangers referenced herein.

75. As a direct and proximate result of the actions and inactions of the Defendants as

set forth above, Decedent sustained injuries, significant pain and suffering and died. Plaintiff is entitled to damages as enumerated herein.

76. Defendants' actions and inactions as set forth above were intentional and deliberate, and resulted in injuries to the Decedent including, but not limited to physical harm, pain and suffering, mental anguish, loss of capacity for the enjoyment of life, medical expenses, expense of funeral, and death.

WHEREFORE, Plaintiff demands judgment of the Defendants for damages as described herein in an amount determined by the jury and such other and further relief as allowed in equity or law.

COUNT IV
Wrongful Death M.G.L. c.229, § 6
Wrongful Death, Fraudulent Concealment
(Against All Defendants)

77. Plaintiffs incorporate herein by reference therefore all assertions set forth in the preceding paragraphs specifically including but not limited to all assertions regarding agents, servants, workmen, employees and conspirators.

78. At all material times relevant hereto, the Defendants had actual subjective knowledge that their conduct including their misrepresentations were illegal and in direct violation of the pertinent regulatory authorities' guidelines and was tortious and that their conduct would be the direct and proximate cause of harm and probable death to Yesim Cetir.

79. The Defendants knew that their false representations that the synthetic tracheas with the associated bio reactor technology were not safe before and when they were implanted in Yesim Cetir.

80. Defendants knew that the synthetic tracheas with the associated bio reactor technology were not appropriately researched, studied or tested and that there were not

appropriate clinical trials regarding them before and when they were implanted in Yesim Cetir.

81. Defendants knew that Yesim Cetir did not know that the synthetic tracheas with the associated bio reactor technology were not safe, had not been appropriately, researched, studied or tested and that there was not appropriate clinical trials regarding them before she agreed to their use.

82. Despite the knowledge referenced herein Defendants omitted and failed to share this information with Yesim Cetir and her treating physicians who were not associated with or co-conspirators of Defendants.

83. Defendants affirmatively represented to Yesim Cetir and her who were not associated with or co-conspirators of Defendants referenced herein that that synthetic tracheas with the associated bio reactor technology were safe.

84. Defendants affirmatively represented to Yesim Cetir and her physicians who were not associated with or co-conspirators of Defendants referenced herein that that synthetic tracheas with the associated bio reactor technology were an appropriate product for use in Yesim Cetir's transplant surgery.

85. Defendants never disclosed to Yesim Cetir and her physicians who were not associated with or co-conspirators of Defendants, that a tracheal transplant utilizing a trachea from a cadaver would be a safer product with less risks.

86. Defendants never disclosed the record of the problems with their synthetic tracheas with the associated bio reactor technology which they knew about from use in patients prior to implantation of synthetic tracheas in Yesim Cetir to Yesim Cetir or her physicians who were not associated with or co-conspirators of the Defendants.

87. Defendants instead promoted their synthetic tracheas with the associated bio

reactor technology as safe and successful, despite the evidence to the contrary, in various forums including directly to Yesim Cetir, directly to Yesim Cetir's father, directly to her physicians who were not associated with or co-conspirators of the Defendants, on their website, in their publications, and in publications over which they either had influence and/or contributions, and in their communications with the medical community.

88. Yesim Cetir and her physicians who were not associated with or co-conspirators of Defendants reasonably relied on Defendants' fraudulent deception and concealment.

89. Yesim Cetir in the exercise of reasonable care and diligence did not discover nor should she have discovered the Defendants illegal, tortious and fraudulent conduct until the same became public knowledge.

90. Defendants had a duty not to make fraudulent intentional misrepresentations regarding the benefits and risks of the synthetic tracheas with the associated bio reactor technology designed, manufactured, distributed, sold, promoted, marketed and advertised by them to Yesim Cetir and to her physicians who were not associated with or co-conspirators of Defendants.

91. As a direct and proximate result of the fraudulent concealment of the Defendants as set forth above, Yesim Cetir sustained injuries including, but not limited to those listed herein including but not limited to failure of the synthetic tracheas, physical harm, pain and suffering, mental anguish, loss of capacity for the enjoyment of life, medical expenses, expenses of funeral, and death.

COUNT VI
CIVIL CONSPIRACY
(Against The Defendants)

92. Plaintiffs incorporate herein by reference therefore all assertions set forth in the

preceding paragraphs specifically including but not limited to all assertions regarding agents, servants, workmen, employees and conspirators.

93. The Defendants, each acted in concert and joined together in an unlawful and unfair manner, pursuant to a common design to conceal or omit information regarding the health consequences of artificial trachea utilizing the bio reactor technology and their defective and unsafe nature with the intention that consumers, including Yesim Cetir, would rely on this information.

94. Each co-conspirator knew, or in the exercise of reasonable care should have known, about the conduct of the others and about the common tortious scheme.

95. The Defendants each engaged in a myriad of overt acts in furtherance of the conspiracy. Such acts included, but are not limited to:

- a. Defendants had meetings, discussions, and communications regarding the promotion and dissemination of false and misleading information regarding the dangers and risk and benefits of their synthetic tracheas and associated bio reactor technology. Defendants conspired during these meetings, discussions and communications to intentionally falsely and misleadingly understate or omit the true dangers and risks associated with the synthetic tracheas and associated bio reactor technology and to overstate the alleged and probably non-existent benefits of the same;
- b. Defendants had meetings, discussions and communications regarding promoting, marketing, and publishing the false information referenced above and throughout this complaint jointly as co-conspirators to intentionally, fraudulently and illegally mislead the public including patients, including Yesim Cetir, her medical treaters who were not associated with or co-conspirators of the Defendants and the medical community at large.

96. As a result of the conspiracy the Defendants are responsible for the tortious and wrongful acts of the other co-conspirators.

97. As a direct and proximate result of the Defendants roles in the conspiracy Yesim Cetir, along with her physicians who were not associated with or co-conspirators of the Defendants, agreed to implantation of Defendants dangerous and defective synthetic tracheas

which utilized the bio reactor technology causing her death.

98. As a direct and proximate result of the conspiracy of the Defendants as set forth above, Yesim Cetir sustained injuries including, but not limited to those listed herein including but not limited to failure of the synthetic tracheas, physical harm, pain and suffering, mental anguish, loss of capacity for the enjoyment of life, medical expenses, expenses of funeral, and death.

COUNT VI
Wrongful Death M.G.L. c.229, § 6
Conscious Pain and Suffering
(Against All Defendants)

99. Plaintiffs incorporate herein by reference therefore all assertions set forth in the preceding paragraphs specifically including but not limited to all assertions regarding agents, servants, workmen, employees and conspirators.

100. As a consequence of the events set forth in this Complaint, and as a direct and proximate cause of the negligence of the Defendants, Yesim Cetir was caused to sustain great conscious pain and suffering prior to her death, which injuries to her are compensable under G.L. c. 229, § 6.

101. Yesim Cetir was consciously, painfully and seriously injured as a result of the negligence of the Defendants, for which a claim is hereby made by her estate for full and complete compensation for her conscious pain and suffering.

COUNT VII
Wrongful Death M.G.L. c.229, § 2
Punitive Damages
(Against All Defendants)

102. Plaintiffs incorporate herein by reference therefore all assertions set forth in the preceding paragraphs specifically including but not limited to all assertions regarding agents,

servants, workmen, employees and conspirators.

103. The acts and/or omissions of Defendants set forth herein were grossly negligent and/or reckless conduct within the meaning of G.L. c. 229, § 2. Said acts and/or omissions proximately caused or contributed to Yesim Cetir's untimely death and as such give rise to, and warrant, the imposition by a jury of significant punitive damages against all defendants.

COUNT VIII
Loss of Consortium
(Against All Defendants)

104. Plaintiffs incorporate herein by reference therefore all assertions set forth in the preceding paragraphs specifically including but not limited to all assertions regarding agents, servants, workmen, employees and conspirators.

105. As a consequence of the events set forth in this Complaint, the family of Yesim Cetir was caused to sustain loss of the reasonably expected care, assistance, society, companionship, comfort, guidance, counsel and advice of Yesim Cetir's injuries which are compensable under M.G.L. c. 229, § 2(1).

WHEREFORE, Plaintiff demands judgment against the Defendants for damages, including actual and punitive damages, as well as reasonable attorney's fees and costs incurred in connection with this action, and any other relief this Court deems proper.

PRAYER FOR RELIEF

WHEREFORE: Plaintiffs, requests judgment against all Defendants for damages for all injuries and losses recoverable, but not limited to:

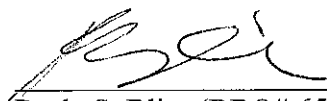
- A) pain and suffering of Yesmin Cetir;
- B) Ms. Cetir's past medical and funeral expenses;
- C) all recoverable costs of this action, including attorney fees, and all legally recoverable interest;

- D) all available damages permitted under Massachusetts' Wrongful Death Statute, including punitive damages; and
- E) any other relief which the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury of all claims so triable.

Respectfully submitted,



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