

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MARILYN RAPPAPORT,)	
)	
Plaintiff,)	
)	
v.)	
)	
ADVANCED BIONICS, LLC d/b/a)	
ADVANCED BIONICS CORPORATION)	
and ADVANCED BIONICS HOLDING)	Civil Action No. 08-10502-DPW
CORPORATION d/b/a ADVANCED)	
BIONICS CORPORATION)	
)	
and)	
)	
ASTRO SEAL, INC.)	
)	
Defendants.)	

FIRST AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff Marilyn Rappaport (“**Plaintiff**” or “**Mrs. Rappaport**”), by and through her undersigned counsel, sues Defendants Advanced Bionics, LLC d/b/a/ Advanced Bionics Corporation and Advanced Bionics Holding Corporation d/b/a Advanced Bionics Corporation (“**Advanced Bionics**”) and Astro Seal, Inc. (“**Astro Seal**”) (collectively, “**Defendants**”) and says for her Complaint as follows:

SUMMARY OF THE ACTION

1. Mrs. Rappaport suffered permanent hearing loss and underwent a 7 ½ hour surgery as a result of the failure of a medical device recalled by its manufacturer, Advanced Bionics, because it contained a manufacturing defect in a component supplied by Astro Seal and

was, therefore, not in compliance with applicable federal law, including federal device manufacturing requirements.

2. Advanced Bionics and Astro Seal violated the basic principal of biomedical engineering that moisture is to be avoided in electronic devices implanted in the human body. Advanced Bionics sold cochlear implants, medical devices used to provide a sense of sound to persons with profound hearing loss, that leak water. Advanced Bionics' specification for moisture content was 0.5%, yet Mrs. Rappaport's failed implant contained 44.6% water. Water entered Advanced Bionics' implants through a leak in an Astro Seal manufactured component, causing device failure and requiring revision surgery. As a result, Advanced Bionics recalled all of its implants containing the Astro Seal component.

3. The Advanced Bionics implant placed in Mrs. Rappaport's head was designed, manufactured, and sold in violation of federal law and in violation of Advanced Bionics' federally-approved device specifications. It contained a latent defect not disclosed to the Food and Drug Administration ("**FDA**"), was adulterated, breached Advanced Bionics' express and implied warranties, and was unsafe and unreasonably dangerous for its intended use. Both Advanced Bionics and Astro Seal were negligent in the design, manufacture and labeling of the implant and the Astro Seal component meant to provide a hermetic¹ seal. Advanced Bionics knew that its implants were failing at an alarming and unacceptable rate as a result of water intrusion, had been cited by the FDA for violating federal manufacturing regulations, and yet the company continued to produce defective implants knowing full well that it had not solved the moisture problem with its implants.

¹ In lay usage a hermetic seal is an airtight seal. In the context of medical device manufacturing the term is also used to refer to water proof seal.

4. The FDA has filed an administrative enforcement action against Advanced Bionics for selling implants of the exact same type given to Mrs. Rappaport because they were not FDA approved for sale in the United States and manufactured in violation of federal law.

5. Advanced Bionics is liable to Mrs. Rappaport for damages including pain, suffering, temporary and permanent hearing loss, a 7½ hour revision surgery, punitive damages, interest, attorneys' fees, and costs. Plaintiff demands trial by jury.

JURISDICTION, VENUE AND THE PARTIES

6. The Court has subject matter jurisdiction over this case pursuant to 28 U.S.C. § 1332. This is an action for damages in excess of \$75,000.00 between citizens of different states.

7. The Court has personal jurisdiction over Advanced Bionics and Astro Seal pursuant to the due process clause of the Fifth Amendment to the U.S. Constitution and the Massachusetts long arm statute, MASS. GEN. LAWS ch. 223A, § 3(a)-(g), because Defendants, *inter alia*, caused tortious injury to Plaintiff in this District, sold a product in this District to a resident of this District, regularly conducted business in this District, and regularly do or solicit business, or engage in other persistent course of conduct, or derive substantial revenue from goods or services rendered, in this District.

8. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a) insofar as a substantial part of the events or omissions giving rise to the claim occurred in this District.

9. Marilyn Rappaport is a resident of Randolph, Massachusetts.

10. Defendant Advanced Bionics, LLC is a Delaware limited liability company with a principal place of business in Valencia, California. Advanced Bionics, LLC has done and continues to do business as Advanced Bionics Corporation and is a corporate successor to prior entities using the name "Advanced Bionics" for all purposes relevant to this complaint and

subject to all liabilities relevant to the complaint attributable to a prior entity know as Advanced Bionics Corporation, a Delaware Corporation that was at one time a wholly owned subsidiary of Boston Scientific Scimed, Inc.

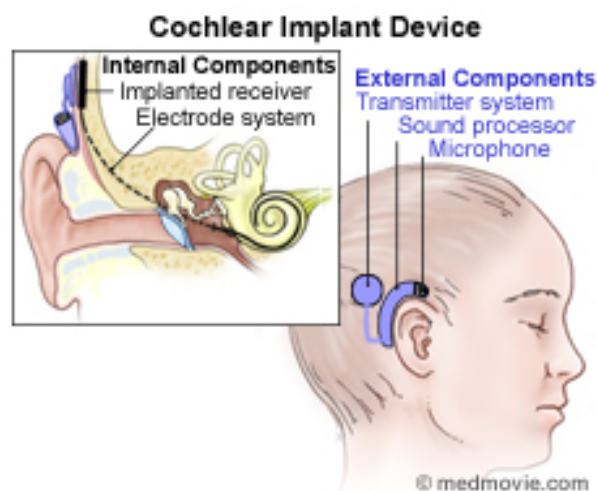
11. Defendant Advanced Bionics Holding Corporation is a California corporation with a principal place of business in Valencia, California. Advanced Bionics Holding Corporation has done and continues to do business as Advanced Bionics Corporation and is a corporate successor to prior entities using the name “Advanced Bionics” for all purposes relevant to this complaint and subject to all liabilities relevant to the complaint attributable to a prior entity know as Advanced Bionics Corporation, a Delaware Corporation that was at one time a wholly owned subsidiary of Boston Scientific Scimed, Inc.

12. Defendant Astro Seal, Inc. is a California corporation with a principal place of business in Riverside, California.

GENERAL ALLEGATIONS

I. Cochlear implants are prosthetic hearing devices.

13. A cochlear implant is a surgically implanted electronic device that can help provide a sense of sound to a person who is profoundly deaf or severely hard of hearing.



14. A cochlear implant does not amplify sounds as does a typical hearing aid, but instead functions by electrical stimulation of the auditory nerve through a part of the inner ear called the cochlea.

15. Sound enters the cochlear implant system by a microphone. The microphone is connected to a processor. The processor, worn behind the ear, converts sound into digital code that has been programmed or “mapped” to maximize sound and speech understanding. The processor transmits the code through the skin to the implant. The processor may contain a microphone and battery, or the microphone and battery may be worn separately.

16. Modern cochlear implants allow the typical user with profound hearing loss to have substantial hearing improvement, including the ability to conduct a conversation on the telephone.

II. Moisture is death to cochlear implants.

17. Moisture is a well-known cause of failure of electronic circuits.

18. Moisture causes corrosion, dendrite growth, and other processes that damage electronic circuits and cause them to fail.

19. Implantable medical devices, such as cochlear implants, are exposed to more moisture than most electronic devices because the human body is a very wet and salty (saline) environment.

20. To function reliably electronic circuits inside cochlear implants should be clean, dry, and free of moisture.

21. It is critical that a cochlear implant not allow moisture in, or any toxic compound out.

22. The failure of a cochlear implant requires surgery to remove and replace the failed implant. Revision surgery risks damage to the cochlea, permanent loss of hearing, and other complications.

23. Moisture inside a cochlear implant may have been sealed in during the manufacturing process, leaked in at some point afterwards (including after the device was implanted in a patient), or both.

24. A variety of techniques exist to determine the effectiveness of the seal (whether the seal is water proof or hermetic) of microelectronic devices with designed internal cavities. A designed internal cavity is the void space inside the device.

25. A variety of techniques exist to determine the moisture content (for example, the percentage of water vapor) within sealed microelectronic devices with designed internal cavities.

26. Residual gas analysis (“**RGA**”) is an analytical technique used primarily for hermeticity quality assurance and failure analysis purposes. In RGA, the test device is placed in a sealed chamber and punctured. The interior gases are sucked out and analyzed. The RGA can reveal, for example, the percentage of water vapor within a sealed medical device.

27. The RGA and other techniques to evaluate the hermeticity of a device may provide data to determine if, and why, a device leaked. Such techniques can also be used to determine if a device was properly assembled in the first place.

28. To adequately validate a device for moisture content and hermeticity requires testing of production lots under actual or simulated use conditions.

29. At all relevant times Advanced Bionics knew that its medical devices had to be water proof, hermetically sealed, and without excessive moisture content.

30. At all relevant times Astro Seal knew that the component parts it supplied to Advanced Bionics had to be capable of providing a water proof and hermetic seal to prevent excessive moisture entry into Advanced Bionics' medical devices.

III. Advanced Bionics' HiResolution Cochlear Implant.

31. Advanced Bionics manufactured and sold a cochlear implant system referred to as the "HiResolution Bionic Ear System." The HiResolution system was an improved version of Advanced Bionics' former "CLARION Multi-Strategy Cochlear Implant."

32. The implant component of the system was the implantable cochlear stimulator (the "**Device**").

33. The Device consisted of a "can," a sealed titanium metal housing containing an electronic circuit, an electrode (an insulated wire) that goes into and stimulates the cochlea, and an antenna to receive signals from the external processor.

34. The Device included a feed-through assembly. The feed-through kept moisture from entering the implant and connected the electronic circuit inside the implant to the electrode through a water proof fitting.

35. Advanced Bionics has used two different feed-through suppliers, Pacific Aerospace & Electronics, Inc. ("**PA&E**") and Astro Seal.

36. Both suppliers are supposed to provide interchangeable feed-through assemblies meeting the same high standard of functionality and Advanced Bionics' specifications, including that the feed through provide a water proof and hermetic seal during the implant's anticipated 10-year life span.

37. Advanced Bionics changed its primary feed-through supplier to Astro Seal sometime in 2005.

IV. Federal Regulations

38. The removal of Devices from the market and other corrective actions taken by Advanced Bionics are product recalls under federal regulations.

39. Under federal regulations, a “[r]ecall means a firm’s removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure.” 21 C.F.R. § 7.3(g).

40. A device is deemed to be “adulterated” if, among other things, it fails to meet established performance standards, or if the methods, facilities, or controls used for its manufacture, packing, storage, or installation are not in conformity with federal regulations pursuant to 21 U.S.C. § 351 and 21 C.F.R. § 820.1(c).

41. A device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular way, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

42. Advanced Bionics is required to comply with applicable FDA regulations, including FDA regulations relating to records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of its medical devices.

43. Adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be

obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. *See* 21 C.F.R. § 803.50.

44. Manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to the FDA as a removal or correction of the device. *See* 21 C.F.R. § 803.52.

45. Manufacturers must report to the FDA in five business days after becoming aware that a medical device reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. Medical device reportable events require the manufacturer to conduct a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to public health. *See* 21 C.F.R. § 803.53

46. Device manufacturers must report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of federal law caused by the device that may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which

are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. *See* 21 C.F.R. § 806.10.

47. Manufacturers must comply with current Good Manufacturing Practice (“**CGMP**”) requirements set forth in the FDA’s quality system regulations. Manufacturers must meet design-control requirements, including but not limited to conducting design verification and validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must establish purchasing controls to ensure that all purchased products, parts and components conform to specified requirements. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions. Manufacturers must investigate the cause of nonconforming product and take corrective action to prevent recurrence. Manufacturers are required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. *See generally* 21 C.F.R. Part 820.

48. A device is deemed adulterated if the methods used in, and the facilities and controls used for, its manufacture, packing, storage, and installation are not in conformity with CGMP requirements. Each introduction of an adulterated device into interstate commerce is a violation of federal law. 21 U.S.C. § 331(a).

49. FDA regulations require manufacturers to submit Pre-Market Approval Application (“**PMA**”) supplements for changes that affect the safety or effectiveness of a device, including “[t]he use of a different facility or establishment to manufacture” the device, and “[c]hanges in the performance or design specifications, circuits, components, ingredients,

principle of operation, or physical layout of the device.” 21 C.F.R. § 814.39(a)(3) and (6). Such supplements are referred to as “180-day PMA supplements.”

50. Any change in specifications of the materials used in manufacture requires a 180-day PMA supplement.

51. A manufacturer may make a change to a device without filing a PMA supplement *only* if the change does not affect the device’s safety or effectiveness and the change is reported to FDA in post-approval periodic reports. 21 C.F.R. § 814.39(b).

52. A device lacking necessary PMA approval (including approval of supplements) is deemed adulterated. 21 U.S.C. § 351(f)(1)(B).

53. Federal regulations require that a PMA supplement be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification. *See* 21 C.F.R. § 814.39.

54. Advanced Bionics must submit an “Adverse Reaction Report” or “Device Defect Report” pursuant to 21 C.F.R. § 814.82(a)(9) within 10 days after Advanced Bionic receives or has knowledge of information concerning any “adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device” and (a) has not been addressed by the device’s labeling or (b) has been addressed by the device’s labeling, but is occurring with unexpected severity or frequency.

55. Advanced Bionics’ failure to meet the above-referenced federal requirements applicable to medical devices and Advanced Bionics’ other acts and omissions as described herein directly and proximately caused the Device to be in violation of federal law, adulterated, unfit for sale, and proximately caused harm and injury to Plaintiff.

56. Plaintiff's state law claims against Advanced Bionics are premised on Advanced Bionics' violation of federal regulations, and are parallel state law requirements that do not conflict with and are not in addition to or different from federal requirements.

57. Astro Seal, as a manufacturer of components or parts of finished devices, was not subject to federal CGMP requirements set forth in the quality system regulation, 21 C.F.R. Part 820, although they were "encouraged to use appropriate provisions of the CGMP requirements as guidance," pursuant to 21 C.F.R. § 820.1(a).

58. To the extent Astro Seal may be subject to federal regulations, Plaintiff's state law claims against Astro Seal are premised on Astro Seal's violation of federal regulations, and are parallel state law requirements that do not conflict with and are not in addition to or different from federal requirements.

V. The FDA required that the Device be hermetically sealed and free of moisture.

59. Advanced Bionics' federally approved manufacturing specification required that the Device be "hermetically sealed" to prevent water intrusion.

60. Advanced Bionics federally approved manufacturing specification required that the Device have a leak rate of less than 1×10^{-9} cc-atm/s of helium.

61. Advanced Bionics' federally approved manufacturing specification required that the Device be 100% tested at the time of manufacture for hermeticity.

62. Advanced Bionics' federally approved manufacturing specification required that the Device contain no more than 0.500% (5,000 ppm) moisture.

63. Advanced Bionics' federally approved manufacturing specification required that the Device be sealed with an inert gas mixture, 25% helium and 75% argon.

64. The expected functional life span of the Device was at least 10 years.

65. Advanced Bionics expressly warranted the Device for 10 years.

66. To have any reasonable chance of operating over the anticipated 10-year life span, the Device must remain hermetically sealed and free of excessive moisture.

67. Advanced Bionics was required to comply with the CGMP, 21 C.F.R. Part 820, and other applicable FDA regulations.

68. The CGMP required that Advanced Bionics sufficiently evaluate and select Astro Seal as a supplier of feed-through assemblies on the basis of its ability to meet specified device requirements, as required by 21 C.F.R. § 820.50(a).

69. The CGMP required that Advanced Bionics adequately validate Devices containing the Astro Seal feed-through assemblies by testing production lots under actual or simulated use conditions, as required by 21 C.F.R. § 820.30(g).

VI. Advanced Bionics has known that the Device leaks since 2004.

70. In approximately July of 2003, Advanced Bionics commercially released the HiResolution cochlear implant.

71. Advanced Bionics periodically received returned implants.

72. Implants were removed and returned for medical reasons (for example, infection or other medical complications) or because of device failure.

73. Advanced Bionics performed hermeticity and moisture content testing on returned implants.

74. Advanced Bionics' reasons for testing returned implants included to understand the reason for device failure, to improve device reliability, and to comply with the CGMP and other applicable federal regulations applicable to medical devices.

75. On February 12, 2004, Advanced Bionics performed an RGA on an explanted device. The RGA showed that the device had moisture in excess of 0.500%.

76. On April 14, 2004, Advanced Bionics performed an RGA on an explanted device. The RGA showed that the device had moisture in excess of 0.500%.

77. Advanced Bionics opened an investigation to understand the reason(s) for excessive moisture inside the Device.

78. By June 25, 2004, a total of fourteen (14) Devices were tested, eight (8) of which (57%) contained moisture in excess of 0.500%. In one instance the moisture content in the Device was 30%.

79. Advanced Bionics knew that its Devices contained water above specifications at an alarming and unacceptable rate and that patients were, as a result, experiencing Device failure at an excessive rate and suffering hearing loss and surgery to remove the failed Devices.

80. As of the Summer of 2004, Advanced Bionics attributed the root cause of moisture in most explanted Devices to leaks after manufacture – the failure of the implant to maintain an effective hermetic seal.

VII. Advanced Bionics flunks FDA inspections.

81. In 2001, FDA conducted an inspection of Advanced Bionics manufacturing facility. The primary manufacturing issue assessed by FDA at that inspection was hermeticity failure of the cochlear implant model marketed by Advanced Bionics at that time. The FDA issued a List of Inspectional Observations (“**FDA-483**”) listing six objectionable conditions, including the firm’s failure to file PMA supplements for four separate testing, manufacturing process, and design changes to its cochlear implants.

82. From August 25 to September 15, 2004, the FDA inspected Advanced Bionics' manufacturing facility in Sylmar, California.

83. On September 15, 2004, the FDA issued FDA-483 observations identifying serious non-conformities and weaknesses in Advanced Bionics' quality system that required improvement.

84. The FDA identified twenty-three (23) objectionable practices by Advanced Bionics in connection with the company's cochlear implants.

VIII. Advanced Bionics issued its first Device recall in September of 2004.

85. On September 27, 2004, as a result of the FDA inspection, Advanced Bionics initiated a Class II Recall of all of its un-implanted CLARION and HiResolution Devices, Recall Number Z-0046-05, due to the "potential presence of moisture in the internal circuitry, which can cause the device to stop functioning."

86. Advanced Bionics suspended shipment of new Devices until November 8, 2004.

IX. The FDA found that Advanced Bionics' Devices were adulterated.

87. On February 1, 2005, the FDA took further action against Advanced Bionics' cochlear implant business, issuing it a "Warning Letter" identifying eighteen (18) "significant deviations" from federal regulations in the "manufacturing, packaging, storage or installation" of medical devices. A true and accurate copy of the FDA letter is attached hereto as Exhibit A.

88. The FDA reported to Advanced Bionics that its inspection "disclosed that your devices are adulterated" within the meaning of Section 501(h) of the Federal Food, Drug and Cosmetic Act.

89. The FDA reported that Advanced Bionics was in violation of the CGMP regulations for medical devices set forth in the quality system regulation, specified in 21 C.F.R. Part 820.

90. The FDA reported that it had found “significant deviations” from GMP requirements including, but “not limited to,” eighteen (18) such “significant deviations” listed in the Warning Letter. The FDA findings included:

- a. that Advanced Bionics’ quality system failed “to control moisture limits within the hermetically sealed cochlear implants;”
- b. that “[t]here is inadequate knowledge regarding how [RGA] results can be used to determine if the device was hermetically sealed with water within the device at the time of manufacture or if the water entered the device as a result of a loss of hermeticity;”
- c. that Advanced Bionics failed to document the 0.500% (5,000 ppm) “water content limit for the [Device]” in a design document;
- d. that Advanced Bionics failed to implement a verification and validated process for the Device to ensure it met the water content limit of 0.500% (5,000 ppm);
- e. that Advanced Bionics failed to perform a complete risk analysis in connection with Device failures that may result form a loss of hermeticity (i.e., a leak) or moisture trapped in the device during manufacturing;
- f. that Advanced Bionics failed to validate manufacture processes to ensure that Devices identified with moisture were hermetically sealed and that non-hermetically sealed devices were identified as unacceptable for distribution and implantation;

- g. that Advanced Bionics failed to sample and test products to ensure that they were hermetically sealed in compliance with the moisture specification; and
- h. that Advanced Bionics failed to identify appropriate corrective action to prevent recurrence of non-conforming product.

91. The FDA reported to Advanced Bionics that “[u]ntil you have adequately demonstrated that you have corrected the violations . . . we continue to believe that the violations still pose a significant risk to public health.”

92. The FDA directed that Advanced Bionics take “prompt action to correct these deviations” and that failure to do so may result in “seizure, injunction, and/or civil penalties.”

93. The Warning Letter remained in place until early 2006.

X. Internal audits found serious ongoing quality problems at Advanced Bionics.

94. Shortly after the FDA Warning Letter, Boston Scientific, the corporate parent of Advanced Bionics at the time with a principal place of business in Natick, Massachusetts, performed an internal investigation and audit of quality control at Advanced Bionics.

95. The audit discovered seven (7) major non-conformities and many uncorrected issues remaining from the original Form 483 observations issued by the FDA.

96. On January 25, 2006, the FDA issued Boston Scientific a corporate-wide Warning Letter.

97. This letter, only the third ever issued in the history of the FDA, placed a heavy burden on Boston Scientific. All subsidiaries and divisions of the company were subject to the Warning Letter, including Advanced Bionics at that time.

98. In February of 2006, Boston Scientific contracted with an independent quality auditor, Quality Hub, to do an onsite audit of Advanced Bionics to verify the adequacy and

completeness of Advanced Bionics corrective actions related to the Form 483 and the Warning Letter observations.

99. The Quality Hub audit uncovered numerous deficiencies at Advanced Bionics.

100. On May 5, 2006, Advanced Bionics issued a formal response to the audit report, noting that “[Bionics’ management] agrees that its organizational structure does not sufficiently demonstrate that quality is the company’s first priority.”

101. As a result of the audit, Advanced Bionics undertook a corporate reorganization meant to improve quality control.

102. Advanced Bionics failed to timely correct deviations noted by the FDA and by its internal auditors.

103. At all relevant times, Advanced Bionics remained out of compliance with federal requirements.

104. Advanced Bionics knew that Device failures continued to occur in 2005 and 2006 at an alarming rate as a result of moisture inside the Devices.

105. Advanced Bionics knew that the manufacturing process and quality changes it had implemented in 2004 and 2005 had not solved its moisture problem.

106. Advanced Bionics recklessly, maliciously, and outrageously continued to market and sell cochlear implants in 2005 and early 2006 despite knowing that the Devices had a moisture problem, having repeatedly been cited by the FDA for violations of federal regulations, including the CGMP, and yet Advanced Bionics failed to identify the root cause of the moisture problem and solve it in time to prevent Mrs. Rappaport from receiving a leaky Device that failed because of water intrusion.

XI. Advanced Bionics issued its second and third Device recalls in March 2006.

107. On March 8, 2006, Advanced Bionics initiated two Class II recalls of all unimplanted HiResolution cochlear implants containing feed-through assemblies manufactured by Astro Seal, Recall Number Z-0759-06 for Model number CI-1400-2H and Recall Number Z-0758-06 for Model Number CI-1400-01.

108. Advanced Bionics initiated the recall because it belatedly acknowledged that Devices containing the Astro Seal feed-through were causing premature device failure and temporary and permanent hearing loss, pain, and suffering to patients and requiring surgery to remove and replace defective implants.

109. Advanced Bionics also initiated the recall because the Devices containing the Astro Seal feed-through were out of compliance with federal requirements and the CGMP.

110. Devices containing the Astro Seal feed-through were adulterated, misbranded, and non-compliant with the company's own standards and FDA-approved specifications.

111. Advanced Bionics determined that moisture was not entering its implants during its manufacturing process, but instead, that moisture was leaking into the device through a defective feed-through assembly manufactured by Astro-Seal after the Devices had been shipped and implanted in patients.

112. Advanced Bionics determined that the feed-through manufactured by Astro Seal failed to reliably maintain a hermetic seal resulting in moisture content inside the Devices above the company's 0.500% specification.

113. The defective Astro-Seal feed-through, according to Advanced Bionics, came to light after the product reached market and was not included or referenced in any manner in connection with the company's filings with the FDA.

114. Advanced Bionics failed to include any warning or labeling to the effect that its Devices were not hermetically sealed and contained excessive moisture.

115. Instead of the inert argon and helium gas that was supposed to be present inside the Devices, they contained water.

116. The Astro Seal feed-through, according to Advanced Bionics, “was not designed and built to effectively keep moisture out.”

117. The Astro Seal feed-through, according to Advanced Bionics “did not meet our standards.”

118. According to Advanced Bionics’ Summer 2007 Auditory Reliability Report, 79.8% of Devices containing the Astro-Seal feed-through were functional after 3 years.

119. For a device warranted to last 10 years, failure of 20% of the Devices containing the Astro Seal feed-through after 3 years as a result of moisture intrusion is an outrageous and catastrophic failure rate not approved by FDA and unacceptable by any standard of reliability, including Advanced Bionics’ own standard.

120. By contrast, according to Advanced Bionics, its Devices manufactured with a PA&E seal have a failure rate of 1.5% after 3 years.

121. Advanced Bionics had information on the problem with the Astro Seal feed-through assembly prior to March of 2006, but failed to timely notify the FDA and the medical community and patients and failed to take appropriate action to prevent harm to patients receiving the implant.

122. The Devices containing Astro Seal feed-through assemblies were defective, negligent, unreasonably dangerous, and not in compliance with any applicable standard or

regulation, including FDA-approved Device manufacturing specifications and CGMP regulations promulgated by the FDA.

XII. FDA files an enforcement action against Advanced Bionics for violating federal law.

123. The FDA filed a complaint against Advanced Bionics in November 2006 seeking penalties against Advanced Bionics and its President and Co-CEO Jeffrey H. Greiner.

124. The FDA amended its complaint on March 17, 2007.

125. The amended complaint seeks a \$2.2 million penalty against Advanced Bionics for violating federal law, including the CGMP standards and failure to notify the FDA of a change in an outside supplier of the feed-through component to Astro-Seal, thereby exposing recipients of the Device to unnecessary health risks.

126. The FDA announced that the Device poses a “public health risk due to excessive moisture, exposing patients to the risk of device failure, possible surgery, and the potential for additional hearing loss.” A true and accurate copy of the FDA’s March 28, 2008 press release is attached as Exhibit B.

127. According to the FDA, Advanced Bionics CGMP violations include “the failure to sufficiently evaluate and select a new vendor as the supplier of a critical device component and the failure to adequately validate the continued safety and effectiveness of the hearing aid by testing lots under actual or simulated use when the unapproved vendor’s component was used.”

128. According to the FDA, “Advanced Bionics shipped hearing aids in violation of the law between January 2005 and July 2006.”

XIII. Mrs. Rappaport received a defective Device containing an Astro Seal component.

129. An audiologist evaluated Mrs. Rappaport on June 23, 2005 to determine whether she would be a good candidate for a cochlear implant.

130. The audiologist confirmed that Mrs. Rappaport had profound hearing loss.

131. The audiologist determined that Mrs. Rappaport was an excellent implant candidate.

132. Mrs. Rappaport underwent successful surgery to place an Advanced Bionics Hi-Resolution implant in her right ear on October 27, 2005 at Massachusetts Eye and Ear Infirmary (“**MEEI**”) in Boston, MA.

133. Mrs. Rappaport received Advanced Bionics HiResolution implant Model number CI-1400-01, SN 301584, manufactured on July 12, 2005.

134. Advanced Bionics failed to warn Mrs. Rappaport, her surgeon, or MEEI that it had failed an FDA inspection, that it was still under a Warning Letter issued by the FDA, that it had an unresolved moisture problem with its implants, that it had changed feed-through suppliers to Astro Seal, or that she was receiving an untested implant with an Astro Seal feed-through.

135. Mrs. Rappaport’s implant was activated on December 2, 2005.

136. Within about 3 months, Mrs. Rappaport achieved excellent results with the implant.

137. Mrs. Rappaport experienced the greater independence, improved communication and interaction with family and friends she hoped for. She found it easier to understand her grandchildren. She could, literally, hear the birds chirping. The life changing impact she hoped for with the implant had come true.

138. In March of 2006, Mrs. Rappaport's audiologist noted two shorted electrodes in Mrs. Rappaport's implant. The audiologist disabled channels 10 and 15.

139. In the Summer of 2006, Mrs. Rappaport participated in a clinical trial of Advanced Bionics' new Harmony speech processor in California. Her results with the Harmony were excellent. She looked forward to using the Harmony processor once it reached the market.

140. During the second half of October, 2006, Mrs. Rappaport started having problems with her implant.

141. Her first symptoms were sound fading in and out, then constant clicking sounds.

142. Starting in November of 2006 Mrs. Rappaport experienced piercing loud sounds and painful shocks in her head and on the right side of her face.

143. After a very painful shock, she ripped the processor off her head, but the sound persisted – like she had been zapped very painfully in the head. Her face was quivering for several days. She was also experiencing intermittency and a humming noise.

144. In December of 2006, Mrs. Rappaport was informed for the first time her implant was a "Vendor B" Device, meaning a Device containing a feed-through manufactured by Astro Seal.

145. Mrs. Rappaport received a letter from MEEI dated December 14, 2006 informing her that unimplanted HiRes implants of the type she received had been recalled because of an elevated level of Device failure. The letter provided a recommendation that the implant be replaced if it failed and described symptoms of failure as follows:

The common symptoms suggesting failure include inability for the internal implant device to accept communication from the external head piece resulting in no sound perception. This may be preceded by a period of intermittency in which the sound goes on and off or the perception of an overly loud sound.

146. Other known symptoms of failure of “Supplier B” HiResolution cochlear implants include loud noises or popping sounds, sudden discomfort or pain.

147. Mrs. Rappaport had the tell-tale symptoms of internal Device failure.

148. Amy Stein, Clinical Specialist with Advanced Bionics, evaluated Mrs. Rappaport’s implant to check the function of the Device and look for possible programming solutions.

149. Attempts to solve the problems with Mrs. Rappaport’s implant by exchange of her processor and headpiece and various programming adjustments were unsuccessful.

150. Mrs. Rappaport’s audiologist and surgeon recommended that Mrs. Rappaport undergo a revision surgery to remove the failed implant and place a new implant.

151. Advanced Bionics concurred with the recommendation to remove and replace Mrs. Rappaport’s implant.

XIV. Mrs. Rappaport underwent revision surgery on January 22, 2007.

152. Mrs. Rappaport underwent a revision surgery at MEEI to remove the defective cochlear implant and to place a new implant on January 22, 2007. Mrs. Rappaport received Model CI-1400-01, SN 312886 (manufactured in July of 2006).

153. There were complications inserting the electrodes and removing scar tissue, which resulted in a 7½ hour surgery. According to the Operative Report,

In summary, the patient had a very difficult replacement of the cochlear implant electrode array. Secondary to scar tissue, it seemed to fold in on itself and could not be extracted easily. It required multiple hours of surgical time to try to overcome this and eventually get the canal opened again.

154. Mrs. Rappaport’s new implant was activated on March 8, 2007.

XV. Advanced Bionics concluded that Mrs. Rappaport's Device leaked as a result of a defective Astro Seal component.

155. MEEI returned Mrs. Rappaport's Device to Advanced Bionics for evaluation.

156. Advanced Bionics sent Mrs. Rappaport's returned Device to a subcontractor, Pernicka Corp. ("**Pernicka**") in Fort Collins, Colorado, for testing.

157. Pernicka performed a RGA on Mrs. Rappaport's Device to test the amount of moisture inside the Device.

158. The Failure Analysis Report (Report # 20130294; 03/07) prepared by Advanced Bionics indicates that Mrs. Rappaport's Device failed the RGA Test. "RGA result was 44.6396% water/vapor. This was above the 0.5% limit."

159. Instead of the inert gases that were to be present inside the implant, nearly 44.6% of the interior void space was filled with water.

160. Advanced Bionics' Failure Analysis Report concluded:

[T]his device had moisture that exceeded the RGA test limit of 0.5%. The source of the moisture was a leak in the feedthru assembly. Feedthru assemblies from this vendor are no longer used. A corrective action has been implemented in the CAPA system (CAR 247) to determine the root cause of the problem and to implement the appropriate changes.

161. Advanced Bionics failed to design and manufacture a Device meeting the federally approved design requirements that the Device contain only inert gases, no more than 0.500% moisture and provide a hermetic seal to prevent moisture from leaking into the device.

XVI. Mrs. Rappaport's replacement Device has not worked well.

162. Mrs. Rappaport has had much less success with her replacement Device as compared with what she had with the first Device, before it failed.

163. Mrs. Rappaport's speech discrimination score for her right ear is significantly lower than with her previous Device.

164. Mrs. Rappaport has particular difficulty using the telephone, hearing the television, and communicating as compared with the success she had with the first Device.

165. Mrs. Rappaport has had intermittent difficulty with facial nerve stimulation with the replacement Device.

166. Most adult cochlear implant patients have adjusted to the Device and obtained whatever improvement can be expected within 6 months to a year after surgery.

167. Mrs. Rappaport's difficulties with the replacement Device may be the result of permanent neurological damage to the cochlea and/or damage to nerve endings caused by the electric shocks she experienced with the first implant.

168. Other contributing factors may be scar tissue in the ear as a result of the revision surgery, that the electrodes are not sitting in precisely the same location, different programs, or other idiopathic factors.

169. Revision surgeries are generally understood to result in the same or worse outcomes as compared to the initial surgery.

170. In this instance, unfortunately, Mrs. Rappaport has experienced a much worse outcome.

COUNT I
NEGLIGENCE
(Advanced Bionics and Astro Seal)

171. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

172. At all relevant times, Defendants had a duty and continue to owe a duty to Plaintiff to provide a safe Device in design and manufacture, to notify the FDA of design flaws, to manufacture the Device properly in compliance with applicable regulations and FDA-approved specifications, and to warn the FDA and Plaintiff of the defective nature of the Device and that the Device is not hermetically sealed and/or is not free of excessive moisture. Defendants breached their duty of reasonable care to Plaintiff by incorporating a defect into the design of the Device, by failing to manufacture the device within the standard of care, and by failing to warn Plaintiff of the risk that the Device would not be hermetically sealed and free of excessive moisture, thereby causing Plaintiff's injuries.

173. Defendants breached their duty of reasonable care to Plaintiff by manufacturing and assembling the Device in such a manner that they were not hermetically sealed, contained moisture, allowed moisture to leak in after the Device has been implanted, and would, therefore, short circuit, corrode, or otherwise malfunction and expose patients, including Mrs. Rappaport, to loss of hearing, unnecessary surgery, to life-threatening physical trauma, and pain and suffering.

174. Defendants breached their duty of reasonable care to Plaintiff by failing to notify and warn the FDA, Plaintiff's treating physicians, Plaintiff and the public at the earliest possible date of known design or manufacturing defects in the Device.

175. Defendants breached their duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances.

176. As a direct and proximate result of Defendants' wrongful conduct, including failure to comply with applicable FDA requirements and FDA-approved Device specifications, Plaintiff has sustained and will continue to sustain severe physical injuries, hearing loss,

unnecessary surgery, severe emotional distress, economic losses and other damages for which she is entitled to compensatory damages in an amount to be proven at trial. Defendants are liable to Plaintiff jointly and/or severally for all general, special and equitable relief to which Plaintiff is entitled by law.

COUNT II

**STRICT LIABILITY – DESIGN AND/OR MANUFACTURING DEFECT
(Advanced Bionics and Astro Seal)**

177. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

178. The Device is defectively designed and/or manufactured because the foreseeable risks of mechanical malfunction and failure using a Device that leaks water outweighs the benefits associated with the Device, particularly given that correct manufacturing technology allows medical device manufacturers to produce devices that do not leak to an excessive degree

179. The Devices were designed and/or manufactured in a manner violative of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 321 *et seq.* (hereinafter "FDCA") and applicable FDA regulations. The facilities or controls used by Defendants in the manufacture, packing, storage, or installation of the Devices were not in conformity with applicable regulations and FDA-approved specifications for the Device or the CGMP requirements set forth in FDA's quality system regulations, 21 C.F.R. Part 820.

180. The Device was expected to and did reach the Plaintiff without substantial change or adjustment to its mechanical function before implantation.

181. Defendants knew or should have known of the design and manufacturing defect and the risk of serious bodily injury that exceeded the benefits associated with the design of the Device.

182. Furthermore, the Device and its defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

183. The Device is inherently dangerous for its intended use due to design and/or manufacturing defect and improper functioning. Defendants are, therefore, strictly liable.

184. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has sustained and will continue to sustain severe physical injuries and/or death, hearing loss, unnecessary surgery, severe emotional distress, economic losses, and other damages for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Plaintiff jointly and/or severally for all general, special, and equitable relief to which Plaintiff is entitled by law.

COUNT III
STRICT LIABILITY – FAILURE TO WARN
(Advanced Bionics)

185. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

186. At all relevant times hereto, Advanced Bionics was engaged in the development, testing, manufacturing, marketing and sales of the Device. Advanced Bionics designed, manufactured, assembled and sold the Device to medical professionals and their patients, knowing that they would then be implanted in patients with severe or profound hearing loss.

187. Advanced Bionics distributed and sold the Device in the condition in which it left their place of manufacture, in their original form of manufacture, which included the defects described herein. The Device was expected to and did reach Plaintiff without substantial change in its condition as manufactured and sold by Defendant. At no time did Plaintiff have reason to

believe that the Device was in a condition not suitable for the Device's proper and intended use among the patients in whom the Devices were to be implanted.

188. The Device designed, developed, tested, manufactured, marketed, and sold or otherwise placed into the stream of commerce by Advanced Bionics was in a dangerous and defective condition and posed a threat to any user or consumer of the Devices. Plaintiff was and is in a class of persons that Advanced Bionics should have considered to be subject to the harm caused by the defective nature of the Device.

189. The Device was implanted and used in the manner for which it was intended, that is, to provide hearing through surgical implantation. This use has resulted in injury to Plaintiff.

190. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable care, the defective nature of the Device. Further, in no way could Plaintiff have known that Advanced Bionics had designed, developed, and manufactured the Device in such a way as to increase the risk of harm, injury or death to the recipients of the Device.

191. The Device was defective due to inadequate warnings or instruction because Defendants knew or should have known that the Device created a high risk of bodily injury and serious harm, that the Device was not hermetically sealed, that the Device was suffering a failure rate (sometimes referred to as a cumulative survival rate or "CSR") in excess of what had been represented to the medical profession and the public, and that the Device was far less reliable than cochlear implants manufactured by its competitors. Defendants failed to adequately and timely warn consumers of this risk.

192. As a direct and proximate result of Advanced Bionics' wrongful conduct, Plaintiff has sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses and other damages for which she is entitled to compensatory and

equitable damages and declaratory relief in an amount to be proven at trial. Advanced Bionics is liable to Plaintiff jointly and/or severally for all general, special, and equitable relief to which Plaintiff is entitled by law.

COUNT IV
NEGLIGENCE PER SE
(Advanced Bionics and Astro Seal)

193. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

194. Defendants have an obligation not to violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, distribution, advertising, preparing for use, warning of the risks and dangers of the Device.

195. Defendants' acts constitute an adulteration, misbranding, or both, as defined by the Federal FDCA, 21 U.S.C. §§ 331(a) and 333(a)(2) and applicable FDA regulations, and constitute a breach of duty subjecting Defendants to civil liability for all damages arising therefrom and from parallel state law requirements, under the theory of negligence per se.

196. Plaintiff, as purchaser of the Defendants' Device, is within the class of persons the statutes and regulations described above are designed to protect and Plaintiff's injuries are the type of harm these statutes and regulations are designed to prevent.

197. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses and other damages for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendants are liable to Plaintiff jointly and/or severally for all general, special, and equitable relief to which Plaintiff is entitled by law.

COUNT V
(BREACH OF EXPRESS WARRANTY)
(Advanced Bionics)

198. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

199. Advanced Bionics by its acts and those of their agents expressly warranted to Plaintiff that it was safe to use the Device.

200. Advanced Bionics offers a "10-year warranty on all Advanced Bionics cochlear implants."

201. As a direct and proximate result of Advanced Bionics' breach of such express warranty, Plaintiff suffered injuries and damages.

202. WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally, for damages in an appropriate amount to be determined at trial, plus interest and costs.

COUNT VI
BREACH OF IMPLIED WARRANTY
(Advanced Bionics)

203. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

204. Advanced Bionics impliedly warranted that its Device, which Advanced Bionics designed, manufactured, assembled, promoted and sold to Plaintiff, was merchantable and fit and safe for ordinary use. Advanced Bionics further impliedly warranted that their Device, which Advanced Bionics designed, manufactured, assembled, promoted and sold to Plaintiff, was fit for their particular purposes.

205. As a result of a manufacturing defect and violations of applicable CGMP requirements, Advanced Bionics' Device was defective, unmerchantable, and unfit for ordinary

use when sold, and unfit for the particular purpose for which they were sold, and subjected Plaintiff to severe and permanent injuries and death.

206. Advanced Bionics breached the implied warranties of merchantability and fitness for a particular purpose when their Device was sold to Plaintiff, in that the Device is defective and has suffered water leaks and, therefore, failed to function.

207. Any disclaimers of implied warranties are ineffectual as they were not provided to Plaintiff or otherwise made known to Plaintiff. In addition, any such disclaimers are unconscionable.

208. Any purported written warranty fails of its essential purpose.

209. As a direct and proximate result of Advanced Bionics' breach of implied warranties, Plaintiff has sustained economic losses and other damages for which she is entitled to compensatory and equitable damages in an amount to be proven at trial. Any disclaimer of consequential damages is invalid as the limited remedy provided fails in its essential purpose to redress the harm and personal injury to Plaintiff in that it, in effect, provides no remedy at all for the defect necessary to be redressed. In addition, any such disclaimer of consequential damages is unconscionable. Advanced Bionics is liable to Plaintiff jointly and/or severally for all damages to which Plaintiff is entitled by law.

COUNT VII
DECEPTIVE, UNFAIR, FRAUDULENT, AND/OR TORTIOUS
BUSINESS PRACTICES
(Advanced Bionics)

210. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

211. Advanced Bionics willfully and knowingly engaged in false advertising and other acts or practices that were deceptive, unfair, fraudulent, and/or tortious in the conduct of its

business, trade, or commerce or in the furnishing of its services in contravention of MASS. GEN. LAWS ch. 93A, § 1, *et seq.*

212. As a result of Defendant's aforementioned violative conduct, Plaintiff was deceived and lured under false pretenses into undergoing the implantation of the Device.

213. As a result of Defendant's aforementioned violative conduct, Plaintiff has suffered – and will continue to suffer – personal injuries and physical pain, as well as severe emotional and mental harm. In addition, Plaintiff has sustained – and will continue to sustain – expenses for medical and/or surgical care that would have been unnecessary but for Defendant's aforementioned violative conduct.

214. Plaintiff satisfied the prerequisite to this cause of action prescribed by MASS. GEN. LAWS ch. 93A, § 9(3) by submitting a demand letter to Advanced Bionics at least thirty days prior to filing this lawsuit.

215. Defendants had a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of the Devices.

216. Had Defendant not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Devices, and would not have incurred related medical costs.

217. Defendant's deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed below.

218. Defendant engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff for the Device for which she would not have paid had Defendant not engaged in unfair and deceptive conduct.

219. Defendant's actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of MASS. GEN. LAWS ch. 93A § 1, *et seq.*

220. The cumulative effect of Defendant's conduct directed at patients, physicians and consumers was to create demand for and sell the Devices. Each aspect of Defendant's conduct combined to artificially create sales of the Devices.

221. The medical community relied upon Defendant's misrepresentations and omissions in determining which cochlear implant to utilize.

222. By reason of the unlawful acts engaged in by Defendant, Plaintiff has suffered ascertainable loss and damages.

223. As a direct and proximate result of Defendant's wrongful conduct, Plaintiff was damaged by paying for the Device.

224. As a direct and proximate result of Defendant's violations of the consumer protection statute, Plaintiff has sustained economic losses and other damages for which she is entitled to statutory, compensatory damages and declaratory relief in an amount to be proven at trial. Defendant is liable to Plaintiff jointly and/or severally for all general, special and injunctive relief to which Plaintiff is entitled by law, and attorneys' fees, costs and interest.

COUNT VIII

**NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS
(Advanced Bionics and Astro Seal)**

225. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

226. Defendants carelessly and negligently designed, manufactured, marketed, and sold the Device to Plaintiff, carelessly and negligently concealed the defects in the Device from Plaintiff, and carelessly and negligently misrepresented the quality, safety, and usefulness of the Device. Defendants should have realized that such conduct involved an unreasonable risk of causing emotional distress to reasonable persons, that might, in turn, result in illness or bodily harm.

227. Defendants owed a duty to treating physicians and users of the Device, including Plaintiff, to accurately and truthfully represent the risks of the Device. Defendants breached that duty by misrepresenting and/or failing to adequately warn of the risks of the Device – effects of which Defendants knew or in the exercise of diligence should have known – to the treating physicians and Plaintiff.

228. As a direct and proximate result of Defendants' wrongful conduct and breach of duty, Plaintiff has sustained and will continue to sustain severe emotional distress either due to physical injury or a rational fear of physical injury or death and is entitled to recovery of damages in an amount to be proven at trial. Defendants are liable to Plaintiff jointly and/or severally for all general, special and equitable relief to which Plaintiff is entitled by law.

COUNT IX

**INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS
(Advanced Bionics and Astro Seal)**

229. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

230. Defendants' conduct directed toward Plaintiff, was, by act and omission, intentional, knowing, and/or reckless, and evidenced a willful intention to inflict injury upon Plaintiff, or a reckless disregard for the rights and interests of Plaintiff equivalent to an intentional violation of them. This conduct exceeded all bounds usually tolerated by decent and civilized society and was directed toward an inherently vulnerable population of persons with profound hearing loss.

231. As a direct, proximate, intended, known, natural, and foreseeable result of Defendants' conduct, Plaintiff was and is suffering injury in the form of serious, severe, extreme and/or disabling emotional distress that no reasonable person could or should be expected to endure.

232. Defendants are liable and accountable at law to compensate Plaintiff for such emotional distress, and for all such damages and injuries resulting therefrom and related thereto.

233. Defendants' conduct was intentional, knowing, oppressive, fraudulent, malicious, extreme and outrageous, and done in conscious and reckless disregard of Plaintiff's rights, thereby entitling Plaintiff to seek to assert claims for exemplary and punitive damages, at the appropriate time under governing law, in an amount sufficient, necessary and appropriate to punish Defendants for their reprehensible conduct and to deter them and others from such conduct in the future. Defendants are liable to Plaintiff jointly and/or severally for all general, special and equitable relief to which Plaintiff is entitled by law.

COUNT X

**PUNITIVE DAMAGES
(Advanced Bionics and Astro Seal)**

234. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

235. The wrongs done by Defendants were aggravated by malice, fraud, and reckless disregard for the rights of others, the public, and Plaintiff.

236. Defendants were actually, subjectively aware of the risk involved in continuing to market the Device in 2005 despite having failed to ensure that the Device was hermetically sealed and free of excessive moisture, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of patients, including Mrs. Rappaport.

237. Plaintiff asserts claims for exemplary and punitive damages in an amount allowed by Constitution in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

COUNT XI

**UNJUST ENRICHMENT
(Advanced Bionics and Astro Seal)**

238. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

239. As the intended and expected result of their conscious wrongdoing, Defendants have profited and derived substantial benefit from the purchase and implementation of the Device into Mrs. Rappaport.

240. Defendants have voluntarily accepted and retained these profits and benefits, derived from Plaintiff, with full knowledge and awareness that, as a result of Defendants' and other conscious and intentional wrongdoing, Plaintiff was not receiving a product of the quality,

nature or fitness that had been represented by Defendants, or that Plaintiff, as a reasonable consumer, expected to receive.

241. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of Plaintiff, who is entitled to in equity, and hereby seeks, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court, and such other relief as the Court deems just and proper to remedy Defendants' unjust enrichment.

COUNT XII

**(STATE AND FEDERAL LAW DECLARATORY JUDGMENT AS TO
INVALIDITY OF CERTAIN WARRANTY PROVISIONS)
(Advanced Bionics)**

242. Plaintiff hereby incorporates by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

243. This is an action for declaratory judgment under state law and pursuant to 28 U.S.C. § 2201, *et seq.*

244. Plaintiff is interested under Advanced Bionics' purported limited warranty and certain Massachusetts statutes which govern the sale of goods and wishes to have determined certain questions of construction and validity arising thereunder and obtain a declaration of rights, status or other legal relations thereunder. There is an actual controversy as to this matter within this Court's jurisdiction.

245. Plaintiff is uncertain and in doubt as to her rights under the law, including Advanced Bionics' purported limited warranty which appears to be irreconcilable with Massachusetts law.

246. Pursuant to MASS. GEN. LAWS ch. 106, § 2-316A(4), "Any language, oral or written, used by a seller or manufacturer of goods and services, which attempts to exclude or

modify any implied warranties of merchantability and fitness for a particular purpose or to exclude or modify remedies for breach of those warranties, shall be unenforceable with respect to injury to the person. This subsection does not affect the validity under other law of an agreement between a seller or manufacturer of goods and services and a buyer that is an organization (see Section 1-201(28)), allocating, as between them, the risk of damages from or providing indemnity for breaches of those warranties with respect to injury to the person.”

247. Pursuant to MASS. GEN. LAWS ch. 106, § 2-302(1), “If the court as a matter of law finds the contract or any clause of the contract to have been unconscionable at the time it was made the court may refuse to enforce the contract, or it may enforce the remainder of the contract without the unconscionable clause, or it may so limit the application of any unconscionable clause as to avoid any unconscionable result.”

WHEREFORE, Plaintiff demands judgment declaring that Advanced Bionics’ purported limited warranty is unenforceable and unconscionable under Massachusetts law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

- A. For compensatory damages according to proof;
- B. For punitive damages against Defendants consistent with the degree of Defendants’ reprehensibility and the resulting harm or potential harm to Plaintiff and in an amount sufficient to punish Defendants and deter others from similar wrongdoing;
- C. For all applicable statutory damages under consumer protection legislation;
- D. For declaratory judgment with regard to the warranty claims;
- E. For a disgorgement of profits and restitution of all costs related to the Device;
- F. For an award of attorneys’ fees and costs;

- G. For prejudgment interest and the costs and expenses of suit; and
- H. For such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiff hereby demands a jury trial on all issues so triable.

DATED at Portland, Maine and Boston, Massachusetts this 11th day of April, 2008.

Respectfully submitted,

/s/ Sigmund D. Schutz

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(admitted pro hac vice)

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