

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DR. PIERO ANVERSA and)
DR. ANNAROSA LERI,)

Plaintiffs)

v.)

PARTNERS HEALTHCARE SYSTEM, INC.,)
HARVARD MEDICAL SCHOOL,)
BRIGHAM AND WOMEN’S HOSPITAL,)
DR. ELIZABETH NABEL, and DEAN)
GRETCHEN BRODNICKI,)

Defendants.)

Case No. _____

COMPLAINT AND JURY DEMAND

Defendants Partners HealthCare System, Inc. (“Partners”), Harvard Medical School (“Harvard”), Brigham and Women’s Hospital (“Brigham”), Dr. Elizabeth Nabel, and Dean Gretchen Brodnicki (collectively, “Defendants”) have caused and are causing ongoing harm to Plaintiffs Dr. Piero Anversa and Dr. Annarosa Leri’s (collectively, “Plaintiffs”) reputations and careers by conducting a procedurally and legally flawed investigation into alleged research misconduct at a Brigham laboratory. Despite lacking any evidence that Plaintiffs personally ever fabricated or falsified research data, Defendants have let the investigation drag on for over a year and a half, have publicly disclosed confidential information, have installed a biased and conflicted investigation panel, and have not applied standards mandated by federal law. To bring this investigation to a conclusion and continue with their life-saving research, Plaintiffs are now compelled to bring this action for (1) breach of contract and violation of the covenant of good faith and fair dealing, (2) tortious interference with advantageous business relations or

prospective contractual relations, (3) unfair or deceptive acts or practices in violation of Mass. Gen. Laws ch. 93A, § 11, and (4) tortious invasion of privacy in violation of Mass. Gen. Laws ch. 214, § 1B.

PARTIES

1. Plaintiff Dr. Piero Anversa is a Professor of Anesthesia and Medicine at Harvard, and the Director of the Center for Regenerative Medicine at Brigham. Dr. Anversa resides at 42 Commonwealth Avenue, Unit 2, Boston, Massachusetts 02116.

2. Plaintiff Dr. Annarosa Leri is an Associate Professor of Anesthesia and Medicine at Harvard, and a Staff Scientist in the Department of Anesthesia at Brigham. Dr. Leri resides at 160 Commonwealth Avenue, Apartment 212, Boston, Massachusetts 02116.

3. Defendant Partners HealthCare System, Inc. (“Partners”) is a Massachusetts corporation with a principal place of business located at 800 Boylston Street, 11th Floor, Boston, Massachusetts 02199.

4. Defendant Harvard Medical School (“Harvard”) is located at 25 Shattuck Street, Boston, Massachusetts 02115. Harvard is an affiliate of Partners.

5. Defendant Brigham and Women’s Hospital (“Brigham”) is a Massachusetts hospital with a principal place of business located at 75 Francis Street, Boston, Massachusetts 02115. Brigham is a teaching affiliate of Harvard and a founding member of Partners.

6. Defendant Dr. Elizabeth Nabel is the President of Brigham and a resident of Massachusetts.

7. Defendant Gretchen Brodnicki is the Dean for Faculty and Research Integrity at Harvard and a resident of Massachusetts.

JURISDICTION AND VENUE

8. The individual Defendants are subject to personal jurisdiction in this District because they reside in Massachusetts.

9. Partners, Harvard, and Brigham are subject to personal jurisdiction in this District because their principal places of business are located in Massachusetts.

10. The United States District Court for the District of Massachusetts has jurisdiction in this matter, which arises under the laws and regulations of the United States, pursuant to 28 U.S.C. § 1331.

11. The United States District Court for the District of Massachusetts also has supplemental jurisdiction over all claims that form part of the same case or controversy pursuant to 28 U.S.C. § 1367.

12. Venue is proper in this District pursuant to 28 U.S.C. § 1391.

FACTS

I. Drs. Anversa and Leri

13. Dr. Piero Anversa is a distinguished cardiovascular scientist and world-renowned pioneer in heart stem cell research.

14. Dr. Anversa is currently a Professor of Anesthesia and Medicine at Harvard.

15. Dr. Anversa is also the Director of the Center for Regenerative Medicine at Brigham.

16. Dr. Anversa is the head of a laboratory at Brigham (the “Brigham laboratory”) focused on myocardial regeneration and cardiac stem cells.

17. The Brigham laboratory has worked to demonstrate that the heart is a constantly renewing organ, with the hope of developing stem cell therapies to repair damaged hearts.

18. Dr. Annarosa Leri is a nationally recognized and very highly regarded physician

and researcher whose work focuses on the molecular biology of cardiac stem cells.

19. In 2007, Dr. Leri became a Lecturer at Harvard and Staff Scientist in the Department of Anesthesia at Brigham.

20. Dr. Leri was promoted to Associate Professor of Anesthesia at Harvard in 2010.

21. Dr. Leri also became Associate Professor of Medicine at Harvard in 2013.

22. Dr. Leri is a Principal Investigator in the Brigham laboratory, where she supervises research fellows in the molecular and biochemistry group.

II. The 2012 Circulation Paper

23. The Brigham laboratory collaborated with the Lawrence Livermore National Laboratory (“LLNL”) on the following paper published in the journal Circulation in 2012: Jan Kajstura, Marcello Rota, Donato Cappetta, Barbara Ogórek, Christian Arranto, Yingnan Bai, João Ferreira-Martins, Sergio Signore, Fumihiko Sanada, Alex Matsuda, James Kostyla, Maria-Virginia Caballero, Claudia Fiorini, David A. D’Alessandro, Robert E. Michler, Federica del Monte, Toru Hosoda, Mark A. Perrella, Annarosa Leri, Bruce A. Buchholz, Joseph Loscalzo & Piero Anversa, Cardiomyogenesis in the Aging and Failing Human Heart, 126 *Circulation* 1869 (2012) (the “2012 Circulation paper”).

24. Dr. Jan Kajstura, a senior scientist in the Brigham laboratory, and a then associate professor at Harvard, is the first author and a co-corresponding author of the 2012 Circulation paper.

25. The 2012 Circulation paper reported 108 carbon-14 (C-14) measurements performed at LLNL’s Center for Accelerator Mass Spectrometry by Dr. Bruce Buchholz.

26. Dr. Kajstura was solely responsible for receiving the data from LLNL and converting that data into figures or tables to accompany the 2012 Circulation paper.

27. On December 23, 2011, Dr. Buchholz emailed Dr. Kajstura two geochemistry

reports (Excel spreadsheets titled “Anversa_BB_122211” and “Anversa_BB_121811”) comprising the C-14 data for the paper.

28. At some point prior to April 2013, Dr. Kajstura apparently altered the “Anversa_BB_122211” Excel spreadsheet he had received from Dr. Buchholz by adding data points that were not reported by LLNL.

29. The tables Dr. Kajstura prepared reflected the doctored “Anversa_BB_122211” Excel spreadsheet data, including the fictitious measurements he apparently added to the spreadsheet.

30. Neither Dr. Anversa nor Dr. Leri saw the raw data from LLNL prior to the publication of the 2012 Circulation paper; they only saw the tables prepared by Dr. Kajstura prior to publication.

31. Dr. Anversa, drafted the 2012 Circulation paper based on the data provided to him by Dr. Kajstura.

32. Dr. Leri’s role in the study reported in the 2012 Circulation paper was limited to supervising her fellows in isolating DNA samples.

33. Dr. Leri had nothing to do with receipt of data from LLNL expect for being copied on one early email from Dr. Buchholz, to which she did not respond.

34. On October 16, 2012, after the paper was published, Dr. Buchholz emailed Drs. Kajstura, Anversa, and Leri regarding a discrepancy between the data provided by LLNL and the data reported in the 2012 Circulation paper.

35. Specifically, Dr. Buchholz indicated that he had only provided 88 C-14 measurements to Dr. Kajstura, fewer than the 108 data points reported in the 2012 Circulation paper.

36. Drs. Anversa and Leri were not aware of any problems with the C-14 data prior to Dr. Buchholz's October 16, 2012 email.

37. Over the course of the next several weeks, Dr. Anversa asked Dr. Kajstura several times whether there were any problems with the C-14 data.

38. Each time, Dr. Kajstura assured Dr. Anversa that there was no problem with the C-14 data.

39. Dr. Anversa worked with Dr. Kajstura on a daily basis for over twenty years. Dr. Anversa had no basis to believe that Dr. Kajstura was dishonest or unreliable prior to these events.

40. Throughout October and November 2012, the leadership of the Brigham laboratory relied on Dr. Kajstura's assurances that the copy of "Anversa_BB_122211" in his files accurately reflected the data he received from LLNL.

41. Dr. Kajstura's assurances may have been untrue. Dr. Kajstura may have added fictitious data points to the "Anversa_BB_122211" spreadsheet in such a way that the altered document remained as an attachment to the original email message.

42. Drs. Anversa and Leri did not understand until later, in April 2013, that the copy of the "Anversa_BB_122211" spreadsheet residing on Dr. Kajstura's computer did not match the version on LLNL's email storage system.

43. On November 14, 2012, LLNL notified Dean Brodnicki at Harvard of the data discrepancy.

III. The Inquiry

44. Under the applicable federal rule and institutional guidelines, the first step in response to allegations of research misconduct is an institutional inquiry to determine whether an investigation is warranted. 42 C.F.R. § 93.307.

45. On January 10, 2013, Dean Brodnicki notified Drs. Anversa and Leri that Harvard and Brigham would conduct a joint inquiry into three allegations of research misconduct.

46. The inquiry was to be governed by Harvard's Principles and Procedures for Dealing with Allegations of Faculty Misconduct (the "Harvard bylaws"), Partners' Policy and Procedures for Handling Allegations of Research Misconduct (the "Partners bylaws"), and the Public Health Services Final Rule, 42 C.F.R. Part 93.

A. The Allegations

47. Allegation 1 states that Drs. Anversa and Leri falsified and/or fabricated the C-14 measurements in the 2012 Circulation paper by (1) reporting 108 distinct data points when LLNL provided data for only 88 distinct measurements and (2) reporting 8 data points with values inconsistent with the measurements provided by LLNL.

48. Allegation 2 states that Drs. Anversa and Leri falsified and/or fabricated data in the 2012 Circulation paper by assigning isotope ratios to samples that have not been measured or reported by LLNL.

49. Dr. Kajstura was solely responsible for working with the LLNL data at issue in Allegations 1 and 2.

50. Allegation 3 states that Drs. Anversa and Leri "falsified and/or fabricated data relating to the characterization of stem cells" and notes that "[q]uestions have arisen regarding the reproducibility of the phenotyping of cell populations."

51. Allegation 3 apparently relates to three issues:

- a. Concerns that other scientists or laboratories had been unable to isolate c-kit positive cardiac stem cells ("CSCs") following the Brigham laboratory's published protocols;
- b. Dr. Kajstura's apparent alteration of two figures in a 2011 Lancet paper, entitled

Roberto Bolli, Atul R. Chugh, Domenico D'Amario, John H. Loughran, Marcus F. Stoddard, Sohail Ikram, Garth M. Beache, Stephen G. Wagner, Annarosa Leri, Toru Hosoda, Fumihiro Sanada, Julius B. Elmore, Polina Goichberg, Donato Cappetta, Naresh K. Solankhi, Ibrahim Fahsah, D. Gregg Rokosh, Mark S. Slaughter, Jan Kajstura & Piero Anversa, Effect of Cardiac Stem Cells in Patients with Ischaemic Cardiomyopathy: Initial Results of the SCIPIO Trial, 378 *The Lancet* 1847 (2011) (the "2011 Lancet SCIPIO paper"); and

- c. Discrepancies between the 2011 Lancet SCIPIO paper and the Certificates of Analysis for the SCIPIO study.

52. With respect to the first issue, Drs. Anversa and Leri have never been told which researchers were unable to follow the Brigham laboratory protocols.

53. Dr. Kajstura, along with another scientist in the laboratory supervised by Dr. Kajstura, was responsible for the figures in the 2011 Lancet SCIPIO paper.

54. Neither Dr. Anversa nor Dr. Leri was responsible for preparing the figures that are the subject of Allegation 3.

55. Dr. Kajstura was the quality and safety officer on the 2011 Lancet SCIPIO study, and was solely responsible for the Certificates of Analysis.

56. On March 8, 2013, Dean Brodnicki informed Drs. Anversa and Leri that the inquiry would be expanded to include a fourth allegation relating to Dr. Kajstura's apparent manipulation of confocal microscope images in an unpublished manuscript submitted to The Lancet and Science in 2013.

57. Dr. Kajstura has acknowledged that he was responsible for conducting all of the 2013 Submitted Manuscript research that is the subject of Allegation 4.

58. Drs. Anversa and Leri were not responsible for conducting the research that is the subject of Allegation 4.

B. The Inquiry Panel's Undue Delay

59. Drs. K. Frank Austen, Steven Gygi, and Robert E. Kingston were appointed to serve on the inquiry panel.

60. Federal regulations, as well as the Harvard and Partners bylaws, require that an inquiry into allegations of research misconduct must be completed within 60 days unless circumstances warranting a longer period are document in the inquiry record. 42 C.F.R. § 93.307(g); Harvard bylaws at Addendum ¶ 1; Partners bylaws at 6.

61. The inquiry panel simply ignored the 60 day time limit.

62. Counsel for Drs. Anversa and Leri notified the inquiry panel on at least two occasions (on June 28, 2013 and September 30, 2013) that continued delay was causing unjustified damage to Plaintiffs' professional reputations and careers.

63. Nevertheless, the inquiry proceeded at a very slow pace, meeting only approximately once a month until its final meeting in October 2013.

64. The inquiry panel then took over two months to write draft reports and recommendations, which were provided to Drs. Anversa and Leri on January 8, 2014.

65. Drs. Anversa and Leri submitted comments on the inquiry panel's draft reports on February 6, 2014, including specific comments supported by affidavits and testimony.

66. The final inquiry reports did not address or rebut any of Drs. Anversa and Leri's detailed and substantive comments.

67. Drs. Anversa and Leri did not receive the final inquiry reports until February 28, 2014, more than a year after they were first notified of the allegations against them.

C. The Inquiry Panel's Recommendations Were Contrary to Law

68. The inquiry panel recommended that the authors retract the 2011 Lancet SCIPPIO paper and the 2012 Circulation paper, evaluation of whether the Brigham laboratory is an appropriate environment for trainees, and that the inquiry proceed to investigation.

69. Under federal regulations and the Harvard and Partners bylaws, research misconduct is defined as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.” 42 C.F.R. § 93.103; Harvard bylaws at 6; Partners bylaws at 2.

70. The inquiry panel found substantial evidence that Dr. Kajstura, acting alone, may have committed research misconduct by fabricating or falsifying research data or results.

71. The inquiry panel found no evidence that Drs. Anversa or Leri ever participated in falsifying or fabricating research data or results, or that they even knew of any research misconduct at the time it occurred.

72. Instead, the inquiry panel recommended that the inquiry proceed to investigation against them on the theory that Dr. Anversa should be held responsible for arguably negligent failure to investigate Dr. Kajstura's research misconduct.

73. The inquiry panel's recommendations (based on a negligence theory) are contrary to law, which provides that research misconduct must “be committed intentionally, knowingly, or recklessly.” 42 C.F.R. § 93.104(b); see also Harvard bylaws at 6 (incorporating federal rule on research misconduct).

74. The inquiry panel's recommendations are even more egregious with respect to Dr. Leri, who is not the head of the Brigham laboratory and was not Dr. Kajstura's supervisor.

75. The inquiry panel reports were also riddled with other careless errors. For example:

- a. The inquiry panel criticized Dr. Anversa for not requiring independent replication of Dr. Kajstura's results reported in the 2012 Circulation paper, without asking any of the witnesses whether replication was even possible. In fact, Dr. Kajstura's results could not be replicated because LLNL graphitized the samples provided to them, and therefore destroyed them, during the carbon dating process.
- b. The panel confused telomere length tests (which were conducted by Dr. Kajstura and recorded in one of the altered figures in the 2011 Lancet SCIPPIO paper) with telomerase activity qPCR tests (an entirely different set of tests).
- c. The panel incorrectly implied that Dr. Leri was somehow involved in the issues pertaining to Allegation 3 by referencing two email exchanges. Those email exchanges, which are entirely innocent, were conducted in Italian. The panel admitted to being confused about the content of those emails, and relied only on a virtually unintelligible translation generated by Google Translate.

IV. The Investigation

76. Drs. Anversa and Leri were notified on February 28, 2014 that Harvard and Brigham would proceed with an investigation.

A. The Investigation Panel is Not Impartial and Unbiased

77. Harvard, Brigham, and Partners have not ensured, as they must under federal law, that the investigation is conducted in compliance with the Harvard and Partners bylaws. 42 C.F.R. § 93.301.

78. The composition of the investigation panel is in violation of Harvard's bylaws, which provides that the investigation must be conducted by the Harvard Committee on Faculty Conduct. Harvard bylaws at ¶ 4.

79. None of the investigation panel members are members of the Harvard Committee

on Faculty Conduct.

80. Under federal law, Harvard, Brigham, and Partners are obligated to “[t]ake reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practicable, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved in the inquiry of investigation.” 42 C.F.R. § 93.310(f).

81. Harvard, Brigham, and Partners have not fulfilled their obligation to ensure an impartial and unbiased investigation to the maximum extent practicable.

82. Initially, Harvard and Brigham appointed the inquiry panel members, Drs. Austen, Gygi, and Kingston, as the sole members of the investigation panel.

83. Drs. Austen, Gygi, and Kingston lack substantial expertise in the relevant scientific areas, including cardiac stem cells, AMS carbon dating methodologies, or confocal microscopy imaging and related software.

84. Panel members are obligated to carry out the investigation in good faith, meaning they must “carry[] out the duties assigned impartially for the purpose of helping an institution meet its responsibilities.” Panel members do not act in good faith where their “acts or omissions on the committee are dishonest or influenced by some personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.” 42 C.F.R. § 93.210.

85. Drs. Austen, Gygi, and Kingston cannot in good faith conduct a fair and impartial investigation.

86. Drs. Austen, Gygi, and Kingston authored the inquiry reports, which made faulty recommendations that were unsupported by the evidence, contrary to law, and failed to respond

any of the comments submitted by Drs. Anversa and Leri.

87. On April 3, 2014, Harvard, Brigham, and Partners added Dr. Ulrich von Andrian to the investigation panel.

88. Dr. von Andrian suffers from serious conflicts of interest that impede his ability to participate in the investigation in an impartial manner.

89. Upon information and belief, Dr. von Andrian serves on the Scientific Advisory Board of Moderna Therapeutics, Inc. (“Moderna”) and has a personal financial interest in that company.

90. Upon information and belief, Moderna is pursuing an alternative modality for regenerative treatment of cardiac disease.

91. Moderna therefore competes for clinical trial opportunities, funding, and commercial development with laboratories and entities, such as the Brigham laboratory, that are pursuing autologous cardiac stem cell therapies.

92. Dr. von Andrian serves on the Moderna Scientific Advisory Board with, among others, Dr. Nabel, Dr. Kenneth Chien, and Dr. Douglas Melton.

93. Upon information and belief, Drs. Nabel, Chien, and Melton, as members of the Scientific Advisory Board, also have a personal financial stake in Moderna.

94. Dr. Chien, who is also an academic co-founder of Moderna, is a long-standing critic of the c-kit positive human cardiac stem cell model that is espoused by Drs. Anversa and Leri.

95. Upon information and belief, Dr. Melton, a close friend of Dr. Chien, unduly delayed Dr. Anversa’s appointment to the Harvard faculty for over three years.

96. Harvard, Brigham, and Partners have also failed to ensure an impartial and

unbiased investigation because Dr. Nabel, the president of Brigham, has not recused herself (and in fact has personally intervened in the investigation in at least two instances).

97. Upon information and belief, Dr. Nabel has a personal financial tie to Dr. von Andrian because they both serve on the Moderna Scientific Advisory Board.

98. Dr. Nabel's personal financial interest in Moderna presents a serious conflict of interest with Drs. Anversa and Leri, who are in competition with Moderna.

99. Dr. Nabel also has close ties to Dr. Chien (a critic of the model espoused by Drs. Anversa and Leri) and Partners.

100. Upon information and belief, as the former Director of the National Heart, Lung, and Blood Institute ("NHLBI"), Dr. Nabel used her discretionary authority to award a grant in excess of \$20 million to Dr. Chien at MGH, after the proposal for the grant did not make even the initial cut for funding by three reviewers assigned by NHLBI, let alone the Council of NHLBI.

101. Upon information and belief, just two weeks after the grant to Dr. Chien was awarded, Dr. Nabel was appointed President of Brigham, a co-founder of Partners.

102. MGH is a teaching hospital of Harvard and a founding member of Partners.

103. Dr. Gygi resigned from the investigation panel on September 15, 2014, after concerns were raised by Drs. Anversa and Leri about conversations he had with scientific collaborators regarding the investigation. In his resignation Dr. Gygi acknowledged the perception of bias caused by his participation on the panel.

B. The Investigation Panel's Undue Delay

104. The investigation, like the inquiry process, has been marred by a pattern of unnecessary delay while adding new piecemeal allegations that only delay the process further.

105. On May 15, 2014, Dean Brodnicki informed Drs. Anversa and Leri that the

investigation panel would review additional papers that were not before the inquiry panel.

106. These papers were published before the investigation began on February 28, 2014.

107. On October 2, 2014, Drs. Anversa and Leri were informed that the investigation would look into additional allegations concerning even more papers.

108. There is no justification for expanding the investigation to encompass these additional papers at this late stage. Most were published before the inquiry process began in January 2013, and all were published before the investigation began in February 2014.

109. Federal law, as well as the Harvard and Partners bylaws, require that the investigation must be completed within 120 days unless Harvard and Brigham request and obtain in writing an extension of that deadline from the Office of Research Integrity (“ORI”) at the US Department of Health and Human Services. 42 C.F.R. § 93.311(a)-(b); Harvard bylaws at Addendum ¶ 4; Partners bylaws at 7.

110. Because the investigation began on February 28, 2014, the investigation panel was required to complete the investigation by June 28, 2014.

111. The investigation panel did not obtain an extension of the 120 day deadline from ORI prior to June 28, 2014.

112. As of the date of this complaint, over nine months after the investigation began on February 28, 2014, the investigation continues to drag on with no signs of concluding.

V. Breaches of Confidentiality

113. Defendants have disclosed confidential information regarding the inquiry and investigation to numerous third parties, in violation of federal law and the Harvard and Partners bylaws. 42 C.F.R. § 93.108; Harvard bylaws at ¶ 6(d); Partners bylaws at 3.

114. Drs. Anversa and Leri have a reasonable expectation of privacy in confidential

information protected by federal law and the Harvard and Partners bylaws.

115. Drs. Anversa and Leri have suffered ongoing harm, including reputational and economic harm, due to Defendants' breaches of confidentiality.

A. Disclosures to the Scientific Community

116. Prominent individuals in the medical community have asked Drs. Anversa and Leri about the inquiry, including, but not limited to, Dr. Steven Houser (Temple University), Dr. Joshua Hare (University of Miami), Dr. Mark Sussman (San Diego State University), Dr. Peipei Ping (University of California Los Angeles), and Dr. Eduardo Marban (Cedars-Sinai Hospital).

117. Drs. Anversa and Leri did not disclose the existence of the inquiry to Drs. Houser, Hare, Sussman, Ping, and Marban. Those individuals learned of the inquiry from Defendants or as a result of Defendants' disclosures to third parties.

118. A senior member of NLHBI was already aware of the inquiry before the panel issued its recommendations.

119. Drs. Houser, Hare, Sussman, Ping, Marban, and others had no need to know of the inquiry.

B. Retraction Requests and Media Coverage

120. In letters dated March 25, 2014, Dean Brodnicki (on behalf of Harvard and Brigham) notified both Circulation and The Lancet of the existence of the investigation and recommended that the journals retract the 2012 Circulation paper and the 2011 Lancet SCIPIO paper, before the investigation was even completed.

121. Dean Brodnicki's letter (on behalf of Harvard and Brigham) did not acknowledge that there is no evidence any individual other than Dr. Kajstura ever fabricated or falsified data or images reported in the 2012 Circulation paper and the 2011 Lancet SCIPIO paper.

122. Dean Brodnicki's retraction request was contrary to established practices; papers

are rarely or never retracted without first exploring the possibility of issuing a less serious correction and without the consent of the authors.

123. Dean Brodnicki did not obtain the consent of Drs. Anversa and Leri prior to issuing her retraction request.

124. There was no need to disclose the investigation to Circulation or The Lancet before the panel completed its work.

125. Circulation retracted the 2012 Circulation paper shortly after Dean Brodnicki's March 25, 2014 letter.

126. The Lancet issued an expression of concern regarding the 2011 Lancet SCIPIO paper shortly after Dean Brodnicki's letter, but did not retract it.

127. Drs. Anversa and Leri are willing to correct the 2011 Lancet SCIPIO paper, but because that paper relates to a clinical study, Plaintiffs cannot do so without the approval of the Partners Institutional Review Board ("IRB").

128. The IRB has not approved to date any corrections to the 2011 Lancet SCIPIO paper.

129. The Circulation and Lancet actions were widely reported in the media.

130. Dr. Anversa was specifically identified as a co-author of the papers and the laboratory head in many of these media reports, falsely implying that he was responsible for the falsified or fabricated data. For example:

- a. "There's more trouble for Piero Anversa, the prominent and controversial stem cell researcher." Larry Husten, Lancet Editors Raise More Questions About Prominent Harvard Stem Cell Researcher, Forbes.com, April 11, 2014
- b. "In an 'expression of concern' posted online Thursday night, editors of the British

medical journal The Lancet said Harvard Medical School had notified them of an ongoing investigation examining the ‘integrity of certain data’ used in two sets of images of cells in a 2011 paper overseen by Dr. Piero Anversa at the Brigham.”

Carolyn Y. Johnson, Brigham Researcher Facing New Questions After Retraction, Boston Globe, April 11, 2014.

- c. One report on a recent study published in Nature noted that the study “will further roil a deeply divided field that owes many of its foundational ideas to Dr. Piero Anversa, a Brigham and Women’s Hospital researcher whose laboratory is in the midst of a Harvard Medical School investigation that has found problems with data integrity in two of its papers. Anversa was already controversial because his results were often in conflict with those of other researchers in the field.” That same report referred to “data integrity problems with images in the paper created by Anversa’s laboratory.” Carolyn Y. Johnson, Study Questions Use of Stem Cells to Repair Heart, Boston Globe, May 7, 2014.
- d. A recent article in Science identified Dr. Anversa as the head of a lab at Harvard and Brigham that is the subject of “an ongoing [Brigham] investigation” that has his colleagues “transfixed.” The article also quotes a colleague as saying that “[p]eople are talking about [the investigation] all the time – at every scientific meeting I go to.” A photograph of Dr. Anversa appears in the center of the article. Kelly Servick, Top Heart Lab Comes Under Fire, 345 Science 254 (2014).

131. In contrast to Dr. Anversa’s treatment, the reports take pains to note that other named co-authors are not suspected of any research misconduct: For example,

- a. With respect to Dr. Joseph Loscalzo, Chairman of the Department of Medicine at Brigham, “Robertson said that based on the information provided by Harvard, the Heart Association did not have concerns about the role Loscalzo played in the paper.” Carolyn Y. Johnson, Data Faulted, Brigham Study on Heart Cells is Withdrawn, Boston Globe, April 9, 2014.
- b. Dr. Roberto Bolli, a collaborator on the SCIPIO trial from the University of Louisville, is quoted as saying that “[t]he data in question were generated by Dr. Anversa’s lab independently of us in Louisville; we in Louisville have nothing to do with the issues cited in the Expression of Concern.” Carolyn Y. Johnson, Brigham Researcher Facing New Questions After Retraction, Boston Globe, April 11, 2014.

132. Dr. Kajstura was not identified in any of these media reports as the individual who was responsible for the data and images at issue, or as the individual who is accused of falsifying or fabricating research data.

133. Dr. Kajstura was not even named in any of the Boston Globe stories, and was only identified as a co-author in the blog Retraction Watch.

134. The Boston Globe has reported that Dean Brodnicki’s partial disclosures have left Dr. Anversa’s colleagues uncertain about the status of the rest of his work. For example,

- a. “We need to know which parts of [Dr. Anversa’s] work are really true for the field.” Carolyn Y. Johnson, Data Faulted, Brigham Study on Heart Cells is Withdrawn, Boston Globe, April 9, 2014.
- b. The disclosures “left other scientists unsure of how serious or widespread the issues might be – and what to make of Anversa’s other work.” Carolyn Y.

Johnson, Retracted Stem Cell Papers Get Public, Private Scrutiny, Boston Globe, April 24, 2014.

135. Because stem cell research is a matter of public interest, Defendants' public disclosures of the investigation will have a long-term effect on Drs. Anversa and Leri.

136. The general public had no need to know of the existence of the investigation.

C. Dr. Nabel's Disclosures

137. Dr. Nabel has disclosed information regarding the investigation, and intervened in the investigation, on at least two occasions.

138. Dr. Nabel personally intervened to encourage Dr. Loscalzo, who is also a co-author of the 2012 Circulation paper and that journal's Editor-in-Chief, to retract the paper.

139. Upon information and belief, Dr. Nabel informed Dr. Loscalzo that the paper included "fraud."

140. Upon information and belief, Dr. Nabel stated or implied to Dr. Loscalzo that Drs. Anversa and/or Leri had personally committed research misconduct.

141. Dr. Nabel made that statement to Dr. Loscalzo before the investigation concluded, and with no evidence that Drs. Anversa and/or Leri ever personally committed research misconduct.

142. Dr. Nabel did not need to disclose the investigation to Dr. Loscalzo before it was completed.

143. In a May 2014 letter, Dr. Nabel also disclosed partial information regarding the investigation to Dr. Simon Gelman and all of the individuals working in the Brigham laboratory.

144. Dr. Nabel asked Dr. Gelman, an anesthesiologist, to "mentor" staff, students, trainees, and junior faculty performing research in the Brigham laboratory, including with respect to "appropriate research policies and procedures."

145. The Brigham laboratory researches cardiac related diseases, which have absolutely nothing to do with Dr. Gelman's work in anesthesiology.

146. Dr. Nabel then caused the substance of her letter to be sent to all individuals working in the Brigham laboratory, without including or copying Drs. Anversa and Leri.

147. Dr. Nabel's disclosure caused concern among the members of the Brigham laboratory, and falsely implied that there was some problem or difficulty with the mentorship provided by Drs. Anversa and Leri.

148. Dr. Gelman and other individuals working in the Brigham laboratory did not need to know of the investigation before it was concluded.

D. Dr. Gygi's Disclosure and Resignation

149. Upon information and belief, Dr. Gygi, who served on both the inquiry and investigation panels, discussed the investigation with Dr. Robert Lefkowitz of Duke University.

150. Dr. Gygi told Dr. Lefkowitz that the panel was going to retract more papers authored by Drs. Anversa and Leri and is "going after all their work."

151. After this conversation, Harvard and Brigham added allegations relating to fifteen additional papers to the investigation. One of the papers does not even list Dr. Anversa as an author; another of the papers does not list Dr. Leri as an author. Nonetheless, they have both been told that they are being investigated for all of the papers, including the one they did not author.

152. Dr. Gygi recently resigned his position on the investigation panel, on September 15, 2014.

153. In his resignation letter, Dr. Gygi acknowledged that he had disclosed to scientific collaborators that he was serving on a research misconduct review panel.

154. Dr. Lefkowitz had no need to know of the investigation.

VI. Drs. Anversa and Leri Are Suffering Ongoing Damages

155. Drs. Anversa and Leri had stellar reputations in the scientific community before these allegations were brought against them.

156. Drs. Anversa and Leri's professional reputations and careers have been shattered by an inquiry and investigation process that has been conducted contrary to federal regulation and institutional policies, and has been publicly disclosed by Defendants.

157. Drs. Anversa and Leri had a multimillion dollar offer to purchase their company, Autologous/Progenital, which was withdrawn when the investigation was publicly disclosed.

158. Mt. Sinai was actively pursuing Drs. Anversa and Leri for prestigious and lucrative positions, but has put them on hold during the pendency of the investigation.

159. The University of Miami was also pursuing Drs. Anversa and Leri prior to the investigation, and put that offer on hold when the investigation was publicly disclosed.

160. Harvard had promised Dr. Leri an appointment as full professor, a position that is consistent with her achievements and receives a higher salary, but that appointment has been delayed.

161. Most distressingly, Defendants have interfered with Plaintiffs' ability to focus on their potentially life-saving work.

VII. Demand

162. On September 30, 2014, Plaintiffs served Defendants with a demand letter in an attempt to resolve these issues without the need for litigation.

163. In a letter dated November 17, 2014, Harvard, Brigham, and Partners refused to take any further steps to comply with federal regulations or the applicable bylaws.

164. The individual Defendants have not responded to Plaintiffs' demand.

CLAIMS

COUNT 1

**(Breach of Contract, Violation of Covenant of Good Faith and Fair Dealing,
Against Harvard, Brigham, and Partners)**

165. Plaintiffs repeat and re-allege the allegations contained in paragraphs 1 through 164 above as if set forth fully herein.

166. Dr. Anversa is in a contractual relationship with Harvard, Brigham, and Partners comprising (1) his employment agreements with Harvard, Brigham, and Partners; (2) the Harvard and Partners bylaws; and (3) the provisions of the Public Health Service Final Rule, 42 C.F.R. Part 93, which is incorporated by reference into the Harvard and Partners bylaws.

167. Dr. Leri is in a contractual relationship with Harvard, Brigham, and Partners comprising (1) her employment agreements with Harvard, Brigham, and Partners; (2) the Harvard and Partners bylaws; and (3) the provisions of the Public Health Service Final Rule, 42 C.F.R. Part 93, which is incorporated by reference into the Harvard and Partners bylaws.

168. A covenant of good faith and fair dealing is implied in every employment relationship and contract in the Commonwealth of Massachusetts, including those between Plaintiffs and Harvard, Brigham, and Partners.

169. As more fully alleged above, Harvard, Brigham, and Partners breached their contracts with Drs. Anversa and Leri by failing to follow the procedures and protections guaranteed under federal law and the Harvard and Partners bylaws.

170. Harvard, Brigham, and Partners have breached the covenant of good faith and fair dealing by, among other things:

- a. Failing to complete the inquiry and investigation by the deadlines imposed by federal law and the Harvard and Partners bylaws;

- b. Disclosing confidential information concerning the inquiry and investigation in violation of federal law and the Harvard and Partners bylaws;
- c. Failing to ensure that the inquiry and investigations are carried out in a fair and impartial manner, by a panel of experts in the relevant scientific area who are free from personal, professional, and financial conflicts of interest; and
- d. Failing to ensure that the inquiry panel implemented the correct legal standard, and accepting recommendations and proceeding to investigation based on the inquiry panel's incorrect legal standard.

171. As a direct result of Harvard, Brigham, and Partners' breaches, Drs. Anversa and Leri have suffered damages including the following:

- a. Long-term injury to their professional reputations and careers;
- b. Loss of a multimillion dollar offer to purchase Autologous/Progenital;
- c. Delay of prospective employment, and loss of future salary, at Mt. Sinai, NY Medical College, and the University of Miami;
- d. Loss of income from speaking and consulting engagements; and
- e. Delay of Dr. Leri's appointment as full professor at Harvard, including delay of the accompanying salary.

COUNT II
**(Tortious Interference with Advantageous Business Relations or
Prospective Contractual Relations, Against all Defendants)**

172. Plaintiffs repeat and re-allege the allegations contained in paragraphs 1 through 164 above as if set forth fully herein.

173. Drs. Anversa and Leri had an advantageous business relationship or prospective contractual relation with Autologous/Progenital and the prospective purchaser of that company.

174. Drs. Anversa and Leri had an advantageous business relationship or prospective contractual relationship with Mt. Sinai, NY Medical College, and the University of Miami.

175. Dr. Leri has an advantageous business relationship or a prospective contractual relation with Harvard.

176. Defendants knew of these relationships and wrongfully, intentionally, and with actual malice interfered with those relationships by:

- a. Conducting the inquiry and investigation in an unfair and biased manner, including by appointing panel members who are subject to serious personal, professional, and financial conflicts of interest, and by relying on an incorrect legal standard;
- b. Disclosing confidential information regarding the inquiry and investigation in violation of federal law and the Harvard and Partners bylaws;
- c. Unreasonably delaying the conclusion of the inquiry and investigation; and
- d. Delaying Dr. Leri's promised appointment to the position of professor at Harvard.

177. Defendants' interference was improper in motive and means because Defendants acted contrary to federal law and the Harvard and Partners bylaws, and because Defendants acted in bad faith.

178. Defendants' interference has significantly impaired Plaintiffs' advantageous business relationships and prospective contractual relations.

179. Drs. Anversa and Leri have been damaged by Defendants' interference, including:

- a. Long-term injury to their professional reputations and careers;
- b. Loss of a multimillion dollar offer to purchase Autologous/Progenital;
- c. Delay of prospective employment, and loss of future salary, at Mt. Sinai, NY

Medical College, and the University of Miami;

- d. Loss of income as speakers and consultants; and
- e. Delay of Dr. Leri's appointment as full professor at Harvard, including delay of the accompanying salary.

COUNT III

**(Unfair or Deceptive Acts or Practices, Mass. Gen. Laws ch. 93A, § 11,
Against all Defendants)**

180. Plaintiffs repeat and re-allege the allegations contained in paragraphs 1 through 164 above as if set forth fully herein.

181. Defendants have willfully and knowingly engaged in unfair and deceptive acts or practices, including:

- a. Conducting the inquiry and investigation in an unfair and biased manner, including by appointing panel members who are not experts in the relevant scientific area and are subject to serious personal, professional, and financial conflicts of interest;
- b. Disclosing confidential information regarding the inquiry and investigation in violation of federal law and the Harvard and Partners bylaws;
- c. Relying on an incorrect legal standard and accepting recommendations based on an incorrect legal standard;
- d. Failing to complete the inquiry and investigation by the deadlines imposed by federal law and the Harvard and Partners bylaws; and
- e. Delaying Dr. Leri's appointment as professor at Harvard.

182. Drs. Anversa and Leri have suffered losses as a result of Defendants' unfair and deceptive acts and practices, including:

- a. Long-term injury to their professional reputations and careers;
- b. Loss of a multimillion dollar offer to purchase Autologous/Progenital;
- c. Delay of prospective employment, and loss of future salary, at Mt. Sinai, NY Medical College, and the University of Miami; and
- d. Delay of Dr. Leri's appointment as full professor at Harvard, including delay of the accompanying salary.

183. Harvard, Brigham, and Partners are engaged in the conduct of trade or commerce, and engaged in unfair and deceptive acts and practices in a business context. For example, Harvard, Brigham, and Partners compete in the marketplace for grant funding, including against Plaintiffs in their capacity as owners of Autologous/Progenital. In seven years, Drs. Anversa and Leri have brought in over \$30 million in grants at Harvard and Brigham. Harvard, Brigham, and Partners aim to chase Drs. Anversa and Leri out of their lab while at the same time continue to receive their grant overhead funding and income.

184. The individual defendants are engaged in the conduct of trade or commerce as agents of Harvard, Brigham, and Partners; competitors for grant funding; and as members of the Scientific Advisory Board of Moderna.

185. Plaintiffs are engaged in the conduct of trade or commerce as competitors for grant funding, as individual speakers and consultants, and as owners of Autologous/Progenital.

186. The relationship between the parties is commercial in nature, including as competitors for grant funding and as owners or advisors of competing companies (Moderna and Autologous/Progenital).

187. Defendants' unfair and deceptive acts or practices occurred primarily in Massachusetts.

COUNT IV

(Tortious Invasion of Privacy, Mass. Gen. Laws ch. 214, § 1B, Against all Defendants)

188. Plaintiffs repeat and re-allege the allegations contained in paragraphs 1 through 164 above as if set forth fully herein.

189. As described herein, Defendants improperly released confidential information concerning the inquiry and investigation, to Plaintiffs' professional colleagues and the public.

190. The confidentiality of information concerning the inquiry and investigation is protected by federal law (42 C.F.R. § 93.108) and the Harvard and Partners bylaws.

191. This conduct was in bad faith, unreasonable, and constituted an unreasonable, substantial, and series invasion of Drs. Anversa and Leri's privacy.

192. Defendants actions injured Drs. Anversa and Leri, including:

- a. Long-term injury to their professional reputations and careers;
- b. Loss of a multimillion dollar offer to purchase Autologous/Progenital;
- c. Delay of prospective employment, and loss of future salary, at Mt. Sinai, NY Medical College, and the University of Miami;
- d. Loss of paid engagements as speakers and consultants; and
- e. Delay of Dr. Leri's appointment as full professor at Harvard, including delay of the accompanying salary.

WHEREFORE, Plaintiffs respectfully request that this Court:

- (a) Enter judgment in their favor;
- (b) Award Plaintiffs damages against each Defendant, including treble damages;
- (c) Award Plaintiffs declaratory relief;
- (d) Award Plaintiffs' reasonable attorneys fees and costs; and
- (e) Award Plaintiffs any other relief as may be appropriate.

JURY DEMAND

Plaintiffs Dr. Piero Anversa and Dr. Annarosa Leri hereby demand a trial by jury on all issues so triable.

Respectfully submitted,

DR. PIERO ANVERSA and
DR. ANNAROSA LERI

By their attorney,

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