

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

ALEXANDER AREFOLOV,)	
)	
Plaintiff,)	ECF CASE
)	
v.)	
)	Case No.
PRESIDENTS AND FELLOWS OF)	
HARVARD COLLEGE)	
and)	
MATTHEW SHAIR)	
)	JURY TRIAL DEMANDED
Defendants.)	

COMPLAINT

Plaintiff Dr. Alexander Arefolov files this Complaint against Defendants and alleges the following:

NATURE OF ACTION

1. Dr. Arefolov alleges breach of contract, declaratory judgment of no contract, breach of fiduciary duty, unjust enrichment, quantum meruit and violations of M.G.L. c. 93A §11.

PARTIES

2. Plaintiff Dr. Alexander Arefolov is a resident of 260 Hunting Road, Needham, MA 02494.

3. Defendant Presidents and Fellows of Harvard College (“Harvard University” or “Harvard”) is a not-for-profit corporation organized under the laws of the Commonwealth of Massachusetts, having a principal place of business in Cambridge, Massachusetts.

4. Defendant Dr. Matthew Shair is a professor of chemistry at Harvard University and works and resides in Massachusetts.

JURISDICTION AND VENUE

5. This Court has jurisdiction to hear this action pursuant to 28 U.S.C. § 1331 because it requires interpretation of federal law, namely the Bayh-Dole Act, 35 U.S.C. § 200 and patent inventorship, 35 U.S.C. § 116.

6. This Court has authority to order declaratory relief under 28 U.S.C. §§ 2201 and 2202 because there is a live controversy between Plaintiff and Defendants that includes a dispute over whether there is a valid contract between Dr. Arefolov and Harvard to assign certain patent rights.

7. Venue in this district is proper pursuant to 28 U.S.C. § 1391 because a substantial part of the events on which this action is based occurred in the District of Massachusetts and all of the parties reside in the district.

BACKGROUND

I. HARVARD’S IP POLICY

a. Harvard’s IP Policy is a contract between Dr. Arefolov and Harvard.

8. When Dr. Arefolov joined Harvard, he signed a participation agreement, agreeing to assign any inventions he made to Harvard and also agreeing to the terms of the Statement of

Policy in Regard to Intellectual Property (the “IP Policy”). (Ex. A, Harvard University’s Statement of Policy in Regard to Intellectual Property.)

9. The IP Policy dictates Harvard University’s responsibilities with respect to assignment of patents, including procedural safeguards and the terms of any royalty payments.

10. Harvard University agrees that its IP Policy is a binding contract between the University and student or employee. In *Charest v. Presidents and Fellows of Harvard College*, Civ. No. 13-11556 (D. Mass), Harvard accepted the Court’s determination that its IP Policy forms a binding contract.

b. Harvard’s IP Policy requires Harvard to adhere to specific procedures when determining patent inventorship and awarding patent royalties.

11. The IP Policy states that inventorship for purposes of distributing royalties is determined according to United States patent laws and regulations. (Exhibit A, IP Policy, Section I(A).)

12. When Harvard identifies an invention made at the university, the IP Policy requires its Office of Technology and Development (“OTD”), in conjunction with its patent counsel, determine the inventors of the invention in accordance with United States patent law. (*Id.*, Section I(C).)

13. Harvard’s IP Policy requires that OTD develop “documentation and procedures as necessary to implement[]” the IP Policy. The IP Policy also requires that the “Committee on Intellectual Property” approve any procedures proposed by OTD. (*Id.*, Section VII(A).)

14. The Committee on Intellectual Property consists of members appointed by the president of the university. The Committee on Intellectual Property is responsible for interpreting the IP Policy and resolving related disputes. (*Id.*, Section VI(A).)

15. Under the IP Policy, all inventors on a patented invention share royalties equally unless they agree otherwise. That means in order for professors to receive an outsized royalty shares, any student or post-doctorial inventors must agree to receive less. (*Id.*, Section V(E)(1).)

16. After a 15% administrative fee is deducted, inventors receive 35% of patent royalties, or about 30% of all patent royalties. (*Id.*, Section V(C)(ii).)

c. Harvard breached its obligations under the IP Policy.

17. Harvard has violated its IP Policy by failing to create the Committee on Intellectual Property and have the Committee oversee the inventorship determination process created by OTD.

18. Harvard updated its IP Policy on February 4, 2008. In that update, Harvard identified the Committee on Intellectual Property and required that it oversee OTD as well as interpret and resolve disputes related to the IP Policy.

19. Yet for the last decade, Harvard has intentionally avoided creating the oversight body called for in the IP Policy. In *Charest v. Presidents and Fellows of Harvard College*, Harvard's counsel agreed that Harvard's process under the IP Policy was subpar. Yet even in the years since that admission, Harvard has failed to create the IP Committee. (Ex. B, Harvard Magazine, C. Ramsey Fahs, October 20, 2016, Patent Pending, pg. 13.)

20. As recently as October 2016, Harvard admitted it still had not created the Committee on Intellectual Property. When asked about creating the committee tasked with overseeing OTD for the last decade, Mr. Isaac Kohlberg, the head of OTD, stated "it is something we are considering." (*Id.*)

21. Harvard violated the IP Policy by failing to disclose certain patenting decisions to Dr. Arefolov, failing to conduct a proper inventorship analysis, and failing to name him as an inventor on certain patents in which he made inventive contributions.

22. In addition to breaching its IP Policy by not paying him royalties, Defendants knowingly engaged in unfair acts. In June 2016, Harvard applied for a patent on Dr. Arefolov's work without listing him as an inventor. If any related patents issue, and Dr. Arefolov challenges inventorship, he faces significant challenges to prove his case. For example, in an inventorship challenge, he must prove his contributions by clear and convincing evidence and overcome other evidentiary hurdles.

II. DR. AREFOLOV'S WORK ON THE CORTISTATIN A PROJECT

a. The Cortistatin A Project was an attempt to commercialize a drug product and was funded by the government.

23. In the early 2000's, a group of researchers at Harvard investigated a compound named Cortistatin A for the treatment of cancer. Although Cortistatin A showed some promise, the group realized that it would need to create newer and better analogs if the project was going to result in a successful drug treatment. (Analogous are chemical molecules that are similar to one another but have differing substituents or alignments.)

24. Then, one of the chemistry professors at Harvard, Dr. Matthew Shair, began the search for new and better analogs of Cortistatin A (the "Cortistatin A Project").

25. The Cortistatin A Project was different than most research endeavors at Harvard. The Cortistatin A Project was funded in part by the Harvard's Blavatnik Biomedical Accelerator (the "Accelerator"). The Accelerator is intended to act as a substitute for early stage investors so that Harvard can commercialize its research.

26. The Cortistatin A Project was undertaken in a direct attempt to monetize research efforts at the University.

27. Nevertheless, much of the funding for the Cortistatin A Project came from government grants, subjecting the intellectual property generated from the Cortistatin A Project to the Bayh-Dole Act, 35 U.S.C. § 200.

28. As part of the agreement to accept federal funds under the Bayh-Dole Act, Harvard agreed that it would share all royalties received from the licensing of intellectual property with all of the inventors.

b. Dr. Shair recruited Dr. Arefolov to work on the Cortistatin A Project.

29. Between 2006 and 2011, Dr. Arefolov and Dr. Shair worked together at Makoto Life Sciences, a biotechnology startup. Dr. Arefolov was a research scientist and Dr. Shair was a Scientific Advisory Board member at the company. During that time, Dr. Arefolov and Dr. Shair worked closely together.

30. In July 2011, Professor Shair invited Dr. Arefolov to accept a visiting scientist position at Harvard.

31. Over the next three months, Dr. Arefolov worked on the Cortistatin A Project. During that time, he made an important breakthrough that had beguiled previous lab members.

32. Seeing Dr. Arefolov's contribution to the Cortistatin A Project, in October 2011, Dr. Shair offered Dr. Arefolov a position as a post-doctorial scientist to continue his work on the project.

33. Dr. Arefolov accepted the position and continued to work on the project until April 2015.

c. Dr. Arefolov relied on Dr. Shair to protect his patent interests related to Cortistatin A Project.

34. The pay for post-doctorial scientist was substantially less than many industry positions. Part of the allure of taking a position as a post-doctorial scientist in Dr. Shair's laboratory was the hope that he would receive patent royalties from his work.

35. Dr. Shair repeatedly assured Dr. Arefolov that his work on the Cortistatin A Project was valuable and that he would ensure that Harvard would recognize Dr. Arefolov's contributions if they were successful in securing a patent and any patent royalties.

36. And as Dr. Shair was Dr. Arefolov's post-doctorial advisor, Dr. Arefolov believed that Dr. Shair would look out for Dr. Arefolov's best interest and ensure his contributions were recognized in any future patent.

37. And Dr. Shair affirmatively represented that he would ensure that Harvard properly recognized Dr. Arefolov's contributions. On several occasions, in response to questions about patent rights and royalties, Dr. Shair made statements such as: "don't worry, you will all be recognized;" "I will take care of you in the future;" "Alex, you are building your future with this project."

38. Dr. Arefolov understood that Dr. Shair was representing that Dr. Shair would oversee the patenting of Cortistatin A inventions and ensure that Dr. Arefolov was properly recognized and compensated.

d. Dr. Arefolov made significant contributions to the successful completion of the Cortistatin A Project.

39. During the four years Dr. Arefolov worked in Dr. Shair's lab he worked long hours and dedicated his work exclusively to the Cortistatin A Project. Central to the Cortistatin

A Project was the effort to investigate, create, and test new Cortistatin A analogs. Dr. Arefolov's worked extensively on the investigation and creation of Cortistatin analogs.

40. When Dr. Arefolov started in Dr. Shair's lab, he was the only chemist working on the Cortistatin A Project other than Dr. Shair, and he was the only chemist devoting 100% of his time to the project.

41. During his time on the project, Dr. Arefolov was involved in almost all aspects of the project. He participated in frequent group "brainstorming" sessions to tackle the then current problems the group was facing accomplishing the Cortistatin A Project. He had frequent conversations with Dr. Shair and other team members to mull over problems and potential solutions the group was facing with respect to the Cortistatin A Project. He worked daily in the lab carrying out experiments to further investigate ways to find novel compounds to treat cancer. And he continually worked on his own, both in the lab and outside of it, to try to come up with unique solutions and compounds to advance the project.

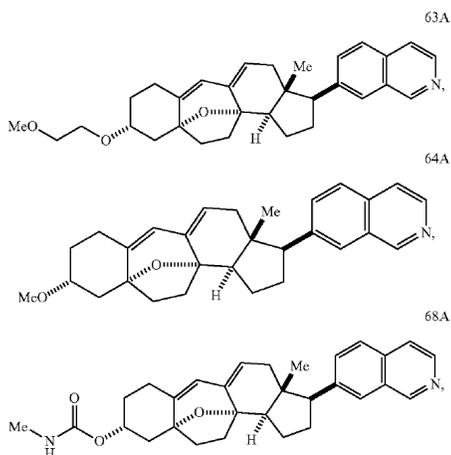
42. From the conception of a broad category of Cortistatin A analogs, to the creation of numerous specific analogs, Dr. Arefolov was part of the creative team that created theoretical as well as actual Cortistatin A analogs.

43. While many of Dr. Arefolov contributions to the Cortistatin A Project were done orally in the formal and informal day-to-day exchange that is common in a chemistry lab, many of his contributions were recorded. Dr. Arefolov kept a lab notebook detailing many of his experiments related to the Cortistatin A Project. He also kept a personal notebook where he contemporaneously recorded many of his ideas related to the Cortistatin A Project. And he sometimes emailed team members about his ideas related to the project from both his Harvard email and his personal Gmail account.

44. An example of Dr. Arefolov's contribution to the Cortistatin A Project is seen in Claim 32 of United States Patent Application Serial No. 15/192,629 (the "629 Application"). (Ex. C, pg. 137.)

45. Claim 32 of the '629 Application reads:

32. The compound of claim 31, wherein the compound is selected from the group consisting of:



46. Dr. Arefolov contributed to the invention of each compound listed in Claim 32 in different ways.

47. During a discussion with Dr. Shair, Dr. Arefolov suggested analog 63A, the first compound depicted in Claim 32. Dr. Arefolov suggested this compound because he had previously worked with the 2-methoxyethoxy substituent group while he was employed at Makoto and thought that the addition of this group could help with solubility and other desirable chemical properties. Dr. Shair agreed that testing this substituent group made sense.

48. Dr. Arefolov suggested the 68A compound (the third compound depicted in Claim 32) to Dr. Shair by email. (Ex. D, email A. Arefolov to M. Shair dated 6/27/2014.) In an

email, Dr. Arefolov proposed several compounds that he believed—based on his chemistry expertise—had the possibility of improved activity and solubility. One of the analogs he suggested was analog 68A. (*Id.*, compound on lower left of email attachment.)

49. Dr. Arefolov also devised the method for creating, and in fact created, analog 64A, the second compound depicted in Claim 32. On June 26, 2014, Dr. Arefolov started work on creating analog 64A and began contemporaneously recording his work in his lab notebook. On June 30, 2014, Dr. Arefolov completed his related entry in his lab notebook, and signed the bottom of the page, ensuring there is no question as to its accuracy and timeliness. (Ex. E, A. Arefolov Lab Notebook, June 26, 2014, pg. 139.)

50. While Claim 32 is a clear example of Dr. Arefolov's contributions to the Cortistatin A Project and the resultant patent(s), it is by no means exhaustive. As an integral team member of the Cortistatin A Project for four years, Dr. Arefolov was involved in almost all aspects of the project, from the broad conceptions of classes of analogs to the conception and creation of numerous other specific analogs. Four years of lab notebooks, personal journals, email correspondence, and the testimony of the scientists working on the Cortistatin A Project will bear that out.

III. THE EXCLUSION OF DR. AREFOLOV FROM THE CORTISTATIN A PATENTS

a. **Despite Dr. Arefolov's inventive contributions to the Cortistatin A Project, Dr. Shair made the decision to exclude Dr. Arefolov as an inventor.**

51. Harvard's patent attorneys often fail to interview or review the lab notebooks of students and post-doctoral research scientists when determining patent inventorship. Instead, the attorneys rely on professors to accurately describe the contributions of students and post-docs

in making inventorship decisions. Thus, as a practical matter, professors can determine inventorship of Harvard's patents.

52. Here, on information and belief, Dr. Shair made the decisions to exclude Dr. Arefolov as an inventor on the Cortistatin A patents.

53. Harvard's patent lawyers did not interview Dr. Arefolov to determine his contributions to the Cortistatin A inventions.

54. On information and belief, Harvard's patent lawyers did not review Dr. Arefolov's lab notebooks to assess his contributions to the Cortistatin A inventions.

55. On information and belief, Harvard's patent lawyers did not interview or review the lab notebooks of the other lab members.

56. Instead, on information and belief, Harvard's patent lawyers relied on the representations of Dr. Shair to identify the inventors for the Cortistatin A patent(s).

57. On information and belief, Dr. Shair was the only person with knowledge of Dr. Arefolov's contribution to the Cortistatin A inventions involved in the decision to exclude him as an inventor.

58. Yet despite his years of work on the Cortistan A Project, Dr. Arefolov's direct contributions to the invention and his discovery of certain claimed analogs, upon information and belief, Dr. Shair did not suggest that Harvard's patent attorneys investigate to determine if Dr. Arefolov was an inventor.

b. Dr. Shair excluded Dr. Arefolov as an inventor to increase his monetary return.

59. Under Harvard's IP Policy, Dr. Shair is required to share the inventor royalties equally among all inventors. The addition of inventors to the Cortistatin A patent directly reduces the share of royalties to Dr. Shair.

60. At Harvard, professors sometimes take an unequal share of patent royalties under the IP Policy—to the detriment of their students and post-doctorial scientists. Professors can only do so, however, upon unanimous consent of all the inventors. (Ex. B, pg. 12.)

61. As Dr. Shair knew that Dr. Arefolov viewed his royalty share as a form of payment, payment he used to keep Dr. Arefolov working on the Cortistatin A Project, he also understood that Dr. Arefolov would not have agreed to accept a reduced share of royalties. Thus Dr. Shair also had an incentive to remove Dr. Arefolov as an inventor to increase his ability to seek an increased share of the patent royalties.

62. In multiple conversations with Dr. Shair, Dr. Arefolov inquired about possible patent royalties he could receive from his work on the Cortistatin A Project. Dr. Shair reassured Dr. Arefolov that Harvard would recognize his work. Dr. Shair understood that it was unlikely Dr. Arefolov would agree to a reduced share of the royalties in order to increase Dr. Shair's share of the royalties.

63. In fact, it was that very reliance on future royalties that Dr. Shair used to convince Dr. Arefolov to stay on as post-doctorial scientist. On multiple occasions, Dr. Shair made statements such as “Alex, the inventors at Harvard University receive 35% of any license fee, if the project is successful – you will receive your fair share.”

64. Upon information and belief, the reduction in royalties to Dr. Shair would receive through the dilutive force of adding Dr. Arefolov as an inventor and the understanding that Dr. Arefolov would not agree to a reduced share of any patent royalties, thereby preventing Dr. Shair from forming an agreement with the other inventors to receive an outsized share of the royalties, led Dr. Shair to exclude him as an inventor on the Cortistatin A patent application.

c. Dr. Shair and the other listed inventors of the Cortistatin A Patents received at least \$5,950,000.00 in patent royalties from the license of those patents.

65. Harvard licensed intellectual property from the Cortistatin A Project to Merck in early 2016. As part of this license, Harvard received an upfront payment of \$20,000,000.00. In addition, the license calls for Harvard to receive numerous other undisclosed milestone payments if certain criteria are met. (Ex. F, Boston Globe, Robert Weisman, March 21, 2016, Harvard to work with Merck on Leukemia Therapy, pg. 1.)

66. Although Harvard would not disclose the value of the milestone payments, Mr. Kolhberg described them as potentially the “most significant” to date for his technology transfer office. (*Id.*)

67. Under the terms of Harvard’s IP Policy, the inventors of the Cortistatin A invention are collectively entitled to about 30% of royalties received. Here that means the inventors will or have received \$5,950,000.00 to date. In addition, the inventors will or have received about 30% of all undisclosed milestone payments—payments that are potentially the most significant Harvard has ever received.

CLAIMS FOR RELIEF

**First Claim for Relief
(Breach of Contract)**

68. The allegations in paragraphs 1- 66 are incorporated into this claim for relief.

69. Harvard and Dr. Arefolov entered into a contract whereby Dr. Arefolov agreed to assign his patent rights in inventions he created at Harvard in return for a share of any royalties apportioned according to Harvard’s IP Policy for any invention on which he was an inventor.

70. Dr. Arefolov invented a substantial portion of the patented drug product and process licensed to Merck.

71. Harvard knowingly excluded Dr. Arefolov as inventor on the patent licensed to Merck.

72. For almost a decade, in violation of its IP Policy, Harvard also failed to create the Committee on Intellectual Property that oversees OTD and its processes related to inventorship determinations.

73. Harvard did not make a good faith inventorship determination related to Dr. Arefolov's contribution to the Cortistatin A Project because at a minimum they did not interview him or review his lab notebooks or other personal records related to his contributions.

74. Harvard's efforts to withhold royalties from Dr. Arefolov were a bad faith material breach of its contract with him.

**Second Claim for Relief
(Declaratory Judgment of No Contract)**

75. The allegations in paragraphs 1- 71 are incorporated into this claim for relief.

76. Harvard has previously taken the position that its IP Policy is not a contract.

77. Dr. Arefolov argues that the IP Policy is a binding contract.

78. To the extent Harvard is correct, and the IP Policy is not a contract, Dr. Arefolov does not have to assign any of his rights in Cortistatin A intellectual property to Harvard.

**Third Claim for Relief
(Quantum Meruit)**

79. The allegations in paragraphs 1- 75 are incorporated into this claim for relief.

80. To the extent the IP Policy is not a contract, and Dr. Arefolov is required to assign his patent rights to Harvard, he is entitled to royalties under the theory of Quantum Meruit.

81. The federal government provided much of the funding used to complete the research that lead to the Cortistatin A intellectual property.

82. Under the Bayh-Dole Act, not-for profit institutes like Harvard are allowed to keep royalties from licensing inventions created with government funding if they comply with certain obligations.

83. One of those obligations is to share the royalties with the inventors, here Dr. Arefolov.

84. “Law and Justice” require Harvard to pay the royalties the federal government mandates it pays.

**Fourth Claim for Relief
(Breach of Fiduciary Duty)**

85. The allegations in paragraphs 1- 81 are incorporated into this claim for relief.

86. Dr. Shair was Dr. Arefolov’s post-doctorial research advisor. Dr. Shair advised Dr. Arefolov and headed the lab in which he worked on the research that led to Cortistatin A patent.

87. Dr. Shair represented to Dr. Arefolov that he would ensure that Harvard would properly recognize his contributions to the Cortistatin A Project and resultant patents and that he would receive a portion of any resulting royalties.

88. Dr. Shair was responsible for determining and did determine which members of the Cortistatin A Project were listed as inventors on the Cortistatin A Patents.

89. Dr. Shair had a fiduciary duty to Dr. Arefolov.

90. Dr. Shair breached his fiduciary duty to Dr. Arefolov by using his position as a fiduciary to secure more royalties for himself to the detriment of Dr. Arefolov.

**Fifth Claim for Relief
(Unjust Enrichment)**

91. The allegations in paragraphs 1- 87 are incorporated into this claim for relief.

92. Dr. Shair received an increase in patent royalties as a result of excluding Dr. Arefolov from Cortistatin A patent.

93. Dr. Shair knew that excluding Dr. Arefolov from the Cortistatin A patent would increase his share of patent royalties.

94. Dr. Shair's increase in patent royalties is inequitable because he secured those royalties by breaching his fiduciary duty to Dr. Arefolov, misleading Harvard's lawyers as to the proper inventorship of the Cortistatin A patent, and by misleading Dr. Arefolov as to the patenting process of the Cortistatin A patent.

95. Defendants were unjustly enriched at the detriment of Dr. Arefolov.

**Sixth Claim for Relief
(93A § 11)**

96. The allegations in paragraphs 1- 92 are incorporated into this claim for relief.

97. After Dr. Arefolov left Harvard, Defendants knowingly hid the fact that they excluded Dr. Arefolov from the Cortistatin A intellectual property and licensed the intellectual property to Merck for at least \$20,000,000.

98. By hiding these facts from Dr. Arefolov, Defendants denied Dr. Arefolov his opportunity to challenge these decisions.

99. By excluding Dr. Arefolov from the Cortistatin A patent, Defendants have seriously impaired his ability to challenge patent inventorship in the future. Because of

Defendants' actions, in any future patent inventorship dispute, Dr. Arefolov must prove his contributions by clear and convincing evidence and overcome other evidentiary hurdles.

100. Defendants used unfair and deceptive acts, or practices in the conduct of trade and commerce—beyond the breach of Harvard's contractual obligations—in order to deny Dr. Arefolov patent royalties and to increase Dr. Shairs's patent royalties.

101. Defendants violated M.G.L. c. 93A § 11.

PRAYER FOR RELIEF

Wherefore, Plaintiff respectfully requests the following relief:

- A. Rescission of the Harvard-Arefolov Contract;
- B. Declaratory judgment that Dr. Arefolov is not obligated to assign patent rights in patents or patent applications licensed to Merck to Harvard;
- C. Awarding a share of all future royalties received from licensing of the Cortistatin A intellectual property at least proportional to the number of inventors;
- D. Monetary damages at least equal to a share of all royalties received from the licensing of the Cortistatin A intellectual property proportional to the number of inventors;
- E. Restitution of benefit received by Dr. Shair, including but not limited to the difference in the amount of patent royalties Dr. Shair would have received if Dr. Arefolov was named as an inventor on the Cortistatin A patent and the patent royalties he received from the Cortistatin A intellectual property.
- F. Disgorgement of any benefits Dr. Shair received from the above actions, including but not limited to the difference in the amount of patent royalties Dr. Shair would have received if Dr. Arefolov was named as an inventor on the Cortistatin A patent and the patent

royalties he received from the Cortistatin A intellectual property;

- G. Treble damages;
- H. Punitive damages;
- I. Attorney's fees; and
- J. Any relief deemed just by the Court.

Respectfully submitted,

/s/ Brian D. O'Reilly

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