

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

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ADA DAMLA DEMIR,

Plaintiff,

Index No.: 150954/2015

-against-

**SECOND AMENDED
VERIFIED COMPLAINT**

SANDOZ INC. and FOUGERA
PHARMACEUTICALS INC.,

Defendants.

Jury Trial Demanded

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Plaintiff Ada Damla Demir, by and for her second amended verified complaint against the above-referenced defendants, alleges as follows:

PRELIMINARY STATEMENT

1. This is a breach of contract, retaliatory discharge and employment discrimination case against the above-named defendants pursuant to New York State Labor Law §740, the Federal, New York State and New York City False Claims Acts and New York Executive Law, Section 296.

THE PARTIES

2. Plaintiff resides in New York at 10 Park Avenue, Unit 20G, New York, New York 10016, where she has resided since 2013.

3. Plaintiff immigrated to the United States from Turkey, where she was born and raised as a practicing Muslim.

4. Defendant Sandoz Inc. (sometimes referred to herein as “Sandoz”) is a pharmaceutical company with U.S. offices located at 506 Carnegie Center, Princeton, New Jersey 08540. Sandoz Inc. is part of the Sandoz generic pharmaceutical division of Novartis, a worldwide biotechnology and pharmaceutical company. Defendant Sandoz Inc. is a Colorado chartered company doing business in New York as a foreign business corporation since July 2003.

5. Novartis is the second-largest generic company in the world, employing more than 26,500 people worldwide and with sales in over 160 countries.

6. Defendant Fougera Pharmaceuticals Inc. (“Fougera”), a New York corporation with offices located at 60 Baylis Road, Melville, New York 11747, has been a wholly-owned subsidiary of Sandoz Inc. since approximately July 2012.

Jurisdiction

7. Jurisdiction is proper in that plaintiff resides within New York County.

8. This Court also has jurisdiction over this matter in that the causes of action arose, in significant part, within New York County, and many of the relevant events occurred within this County.

Venue

9. Venue in this Court is also proper in that plaintiff resided within New York County as of the filing of the original Complaint in this action, and where she continues to reside as of the date of this Second Amended Verified Complaint.

Relevant Facts

10. Plaintiff hereby realleges and incorporates each of the allegations contained in her original Complaint and her First Amended Complaint.

11. Plaintiff was first employed by Fougera on January 13, 2012 as Director of Procurement.

12. As an incentive for her employment, Fougera gave plaintiff a 2012 “relocation package” pursuant to which Fougera promised to make monthly payments to her for a three (3) year period in order to defray her moving expenses and as a contribution to the payment of her new mortgage (the “Relocation Package”).

13. In or about the spring 2012, Plaintiff and other Fougera personnel were first informed that Fougera was going to be acquired by and/or merged with Sandoz (hereinafter the “Fougera/Sandoz Merger”).

14. In or about the spring 2012, Plaintiff was asked by Fougera/Sandoz management to continue her employment as Director of Procurement and to also to lead the Procurement Division’s Merger Group (the “Merger Group”) during the Fougera/Sandoz Merger pursuant to a three (3) year employment agreement.

Plaintiff’s Duties Included Identifying and Curing Defendants’ FDA Violations

15. Plaintiff’s duties and responsibilities with the Merger Group included identifying and curing some of the Fougera/Sandoz violations of FDA regulations and requirements, including cGMP (current Good Manufacturing Practices) in particular those found during FDA Observations of Fougera.

16. The FDA has promulgated cGMP and other mandatory regulatory requirements for drug products and medical devices and is authorized to perform inspections of pharmaceutical companies to ensure compliance.

17. Compliance with cGMP and other mandatory FDA regulatory requirements is critical and non-compliance may provide the basis for adverse determinations and/or actions by the FDA, including civil and/or criminal enforcement actions.

18. Form “FDA 483” is used by the FDA to document and inform pharmaceutical companies of potential violations of FDA regulatory requirements, including but not limited to cGMPs, discovered during FDA observations sometimes known as “483 Observations”.

19. A recipient of a Form FDA 483 should respond to the FDA, addressing each item and providing a time-line for correction or requesting clarification of what the FDA requires in

order to avoid further adverse determinations and/or actions from the FDA, including civil and/or criminal enforcement actions.

20. Plaintiff's experience and expertise with cGMP and other mandatory FDA regulatory requirements regarding procurement and manufacturing issues was critical to the commercial success of the Fougera/Sandoz Merger because Fougera had received numerous Form FDA 483 violations as a result of a recent FDA 483 Observation that needed to be identified, addressed and cured as efficiently as possible.

21. Upon the closing of the Fougera/Sandoz Merger, in or about July of 2012, Sandoz asked plaintiff to continue her employment with Sandoz (which Plaintiff accepted) and assumed Fougera's obligation to plaintiff under her Employment Agreement and Relocation Package.

22. As further inducement for her agreement to continue her employment with Sandoz, plaintiff was given a retention bonus award (the "Retention Bonus") of 1570 stock units in Sandoz.

23. Plaintiff's Retention Bonus was confirmed by a letter dated July 23, 2012, signed by Jesus Corchero, Head of Technical Operations for Sandoz Americas, granting her the 1570 stock units in the form of restricted stock units under the Novartis Corporation 2012 Stock Incentive Plan for North American Employees.

24. Plaintiff agreed to continue her employment with Sandoz, in large part, based upon the grant of this Retention Bonus, which was scheduled to vest on her third anniversary with Fougera/Sandoz (i.e., January 2015), which, upon information and belief, is now worth approximately \$148,000.

25. Throughout her employment with Fougera/Sandoz, plaintiff's work was exemplary, as evidenced by the fact that numerous managers at Fougera/Sandoz, including Wilfredo Mateo, Sandoz's Director of Manufacturing, Science and Technology, Alan Rankin,

Sandoz's Chief Procurement Officer, and Thomas Dunleavy, Global Transportation Manager at Sandoz, endorsed plaintiff for the LinkedIn "Supply Chain Management" group.

26. Plaintiff's work was also recognized as exemplary due to her handling of the numerous FDA violations that had been identified during the Fougera 483 Observations, which as of October 2012, plaintiff had efficiently identified, addressed and cured in a timely, efficient and cost effective manner.

**Plaintiff Informed Sandoz About Non-Compliance With FDA Regulations
Regarding Solaraze, Defendants' Highest Grossing Product**

27. Beginning in or about October 2012, plaintiff informed Sandoz management about certain practices relating to Sandoz's manufacture and procurement of chemical supplies for Solaraze, an actinic keratoses product, that were non-compliant with of FDA regulatory requirements, including but not limited to cGMPs governing the drug's safety and efficacy.

28. Solaraze was Sandoz' proprietary and highest grossing product that was in transition to a generic drug, Sodium Hyaluronate, which is known as an Active Pharmaceutical Ingredient ("API") due to the nature of the drug's "acting" formula and manufacturing process.

29. Every API must have a Type 2 DMF clearance to ensure that the manufacturing facility and methods are consistent with cGMP. However, the Sandoz' Japanese manufacturer of Sodium Hyaluronate told plaintiff that its sole source (i.e. only) manufacturing facility was not Type 2 DMF compliant.

30. Plaintiff informed Sandoz management that failure to properly source Solaraze' API from a Type 2 DMF compliant manufacturer substantially increased the health and safety risk that a "non-compliant" Solaraze would have on a large number of consumers.

31. Plaintiff also informed Sandoz management that failure to properly source Solaraze' API from a Type 2 DMF compliant manufacturer undermined Solaraze' "efficacy"

which was substantially predicated upon Sandoz's obligation to ensure that the manufacturing facility and methods for the Solaraze API were compliant with cGMP.

32. Plaintiff also informed Sandoz management that failure to adhere to these compliance obligations could potentially result in fraud upon the government because Sandoz received a large portion of Solaraze revenues through Federal, New York State and City administered medicaid and medicare reimbursement claims which were also premised upon Sandoz compliance with of FDA regulatory requirements, including but not limited to cGMPs governing the drug's safety and efficacy.

33. Plaintiff also informed Sandoz management that curing the Solareze non-compliance issues were not as simple as "switching" to a manufacturer Sodium Hyaluronate that was Type 2 DMF compliant as there were a limited number of manufacturer's globally.

34. In fact, even if Sodium Hyaluronate could be procured from a Type 2 DMF compliant manufacturer, Sandoz would have to undertake a series of validation tests to validate that the resulting Solaraze and or its generic equivalent would comply with FDA regulatory requirements.

35. Upon information and belief, Sandoz management knew or should have known that the process of switching to a Type 2 DMF compliant manufacturer and conducting the additional tests necessary to validate compliance with other FDA regulatory requirements, including but not limited to cGMPs, would have taken a minimum of eighteen (18) months to two (2) years during which time Solaraze would have to be taken off the market. Thus, Sandoz management knew or should have known the entire process could not be completed before the transition of Solaraze to a generic product.

36. Upon information and belief, as of October 2012, annual sales of Solaraze were approximately \$200 Million per annum. Accordingly, Sandoz management knew or should have

known that taking Solaraze off the market to ensure compliance with all applicable FDA regulatory requirements would have cost Sandoz approximately \$300-\$400 Million in revenue. Moreover, by the time Solareze could be put back on the market, a competing, cheaper generic form of Solaraze would be available for the first time, costing Sandoz even more in revenues from the sale of Solaraze. In addition, the protective patents for this drug (Solaraze) were about to expire.

37. Predictably, when plaintiff complained about the use of this non-compliant supplier and the related health and safety and potential efficacy/false claims concerns at various Fougera/Sandoz management meetings, which were attended by George Schwab, Fougera's Vice President of Quality, and other managers, plaintiff's concerns were totally ignored.

38. When Plaintiff persisted in voicing these concerns at subsequent management meetings, plaintiff was transferred from her normal procurement "Supply Train" duties to SAP, an IT position completely outside her primary field of expertise (Procurement and Supply) and effectively a demotion.

39. This transfer was clearly designed to force plaintiff to resign from Sandoz/Fougera, but, instead, she persevered through this difficult time period, even though she had to work nights and weekends to meet the tight and near-impossible schedules and deadlines that were imposed on her.

40. Despite her assignment to SAP, plaintiff continued to voice her concerns about the non-compliance issues concerning Solareze and its generic equivalent to Sandoz management at weekly meetings, which Sandoz management continued to ignore.

41. In or about May of 2013, Plaintiff was again formerly "demoted" in title after persisting in her complaints to Sandoz management at weekly meetings.

42. On or about February 3, 2014, after plaintiff's health and safety and false claims concerns about Solaraze and its generic equivalent had been repeatedly ignored by Sandoz management, plaintiff filed a complaint with Sandoz's Business Practices Office.

Defendants Discharged Plaintiff In Retaliation For Her Complaints About Their Non-Compliance With FDA Regulations

43. The following day, February 4, 2014, plaintiff was summarily and improperly terminated without cause, in retaliation for the complaint that she had filed the previous day.

Defendants' Bad Faith Denial of Performance Bonus of \$20,000

44. As stated above, Plaintiff was assigned to work on the SAP implementation team that successfully transitioned Sandoz's acquisition of Fourgera. All the members of the transition team were promised a performance bonus in the event that the transition was successfully implemented, which it was. Nevertheless, plaintiff never received her performance bonus of \$20,000, despite her significant contribution to the transition team's efforts, which was confirmed in writing by her project sponsor/responsible manager. In fact, upon information and belief, plaintiff was the only member of the transition team who did not receive this performance bonus.

Defendants' Bad Faith Denial of Plaintiff's 2013 Bonus (\$29,000)

45. Defendants also used their arbitrary and retaliatory termination of plaintiff as a pretext to deny her the 2013 bonus to which she was entitled to. The denial of this 2013 bonus was based solely on the fact that, because of her discharge, she was no longer working for defendants as of March 15, 2014, the date that the 2013 bonuses were distributed. Plaintiff had worked the entire calendar year for 2013, which entitled her to a 2013 bonus totaling \$29,000 (15% of her base salary), based upon her excellent performance and superior skill set demonstrated during that year, as confirmed and acknowledged in writing by Sandoz's Chief Procurement Officer.

Defendants' Bad Faith Denial of Plaintiff's Retention Bonus

46. Defendants also used their arbitrary and retaliatory termination of plaintiff as a bad faith pretext to deny her rights in her Retention Bonus less than a year before it was scheduled to vest.

Defendants' Bad Faith Denial of Plaintiff's Merit Award (\$2000)

47. Defendants also failed to pay plaintiff for two months of the merit award payments to which she was entitled, totaling \$2000.

48. In addition to the foregoing retaliatory conduct, plaintiff and other employees were repeatedly exposed to discriminatory treatment based upon their gender, national origin and/or religion, while employed by defendants.

Defendants' Discriminatory Treatment of Plaintiff and Others

49. The male-dominated management at Sandoz/Fougera acted as if they were in a "boy's club" where, in addition to the "locker room" jokes designed to demean women in general, and plaintiff in particular, it was considered improper for woman to speak up during meetings or to assert themselves in any meaningful way.

50. Indeed, the Sandoz/Fougera managers made it clear that they felt threatened by plaintiff's assertive approach to the management and professional issues that inevitably arise in this complex industry. In doing so, the male defendant managers applied a double standard, since they asserted themselves on a daily basis, which was considered "normal" and acceptable when done by a male manager. This double standard, based on gender discrimination, was ingrained in defendants' "corporate culture."

51. As a Muslim woman of Turkish origin, plaintiff was exposed to constant discrimination while employed at Sandoz/Fougera. For example, when she first met with Sandoz managers from the Sandoz New Jersey offices, one of the manufacturing vice presidents, Michael Altman, told plaintiff that "we're going to need a translator for you." He was obviously referring

to the fact that plaintiff speaks English with a fairly strong Turkish accent. Plaintiff was also frequently subjected to sarcastic and inappropriate comments about her religion, often under the pretext that such comments were being made “out of curiosity.”

52. Plaintiff was subjected to such discriminatory comments on a fairly regular basis, in particular once she began raising the FDA non-compliance issues detailed above.

53. Sandoz/Fougera managers continued to make off-color and grossly inappropriate jokes about “Indian women” with foreign accents, plainly designed to ridicule foreign woman such as plaintiff of the Islamic faith, particularly because they did not fit in with “boy’s club.”

54. Another example of discriminatory conduct at Sandoz/Fougera was the fact that one of the woman employees who reported to plaintiff, Rahima Chawaudry, a Muslim woman from Bangladesh, was fired for praying four times per day during the work day, despite the fact that she was an excellent employee. When plaintiff complained to management that the firing of Ms. Chawaudry was grossly unfair, she was ignored.

55. Another example of discriminatory conduct at Sandoz/Fougera was the fact that female “contract” workers were terminated on the basis that company policy did not permit them to exceed twelve (12) months without being employed as a permanent employee while male “contract” workers were allowed to exceed this twelve (12) limitation with impunity.

56. Another example of such discriminatory treatment occurred during the annual convention of the industry trade association at the Waldorf Astoria in March 2013. This association, of which both defendants were members, is called the Drug, Chemical & Associated Technologies (“DCAT”) Association.

57. Plaintiff had regularly attended these annual DCAT conventions at the Waldorf Astoria for years before she started working for defendants. The DCAT annual conventions presented an opportunity for plaintiff and other Supply Chain professionals who work in the

pharmaceutical industry to meet with representatives of worldwide suppliers and others in the industry. Over the years, plaintiff had developed a wide circle of professional friends and acquaintances in the industry, and both she and her colleagues looked forward to meeting together during the annual DCAT convention week each March.

58. Accordingly, plaintiff attended the March 2013 DCAT convention at the Waldorf Astoria. However, when she arrived, she was confronted by Jack Loghery, a Sandoz manager and member of the Sandoz procurement team based at the Sandoz offices in Princeton, New Jersey. Mr. Loghery shouted at plaintiff in the presence of other members of the Sandoz procurement team and other DCAT members from other companies, sharply asking her: “What are you doing here?” Plaintiff was so shocked that she was speechless. Mr. Loghery went on to say: “We don’t need you here. We can handle it.” Mr. Loghery’s treatment of plaintiff was clearly calculated to undermine her authority in the eyes of her peers.

59. Still in a state of shock, plaintiff walked out of the room in the presence of representatives of some major suppliers that she had worked with over the years, including Dow Chemical Co. and Biocon. She was totally embarrassed and could not stop crying for an extended period of time.

60. This episode at the Waldorf was typical of how the executives and management at Sandoz/Fougera mistreated plaintiff, who was one of only a handful of female management-level personnel working for the defendants. The male-dominated management at Sandoz/Fougera acted as if they were in a “boy’s club” where, in addition to the “locker room” jokes designed to demean women in general, and plaintiff in particular, it was considered improper for women to speak up during meetings or to assert themselves in any meaningful way.

61. Defendants also prohibited Plaintiff from attending CPHI Pharma annual convention, another major convention in Barcelona and Paris which plaintiff and other Supply

Chain professionals in the industry typically attend to keep abreast of developments in the industry without any cause or reason to do so.

62. Indeed, the Sandoz/Fourgera managers made it clear that they felt threatened by plaintiff's assertive approach to the management and professional issues that inevitably arise in this complex industry. In doing so, the male defendant managers applied a double standard, since they asserted themselves on a daily basis, which was considered "normal" and acceptable when done by a male manager. This double standard, based on gender discrimination, was ingrained in defendants' "corporate culture."

63. However, this entire ordeal took its toll on her, and she developed a severe anxiety disorder that required psychiatric counseling and medication, which she is still taking today. She had at least two visits to the emergency room for severe anxiety attacks, which her supervisors and HR personnel at Sandoz/Fougera were well aware of.

64. During the period of time that Sandoz/Fougera was trying to force her to resign for her "whistleblowing" activities regarding health/safety issues regarding the chemicals that Sandoz/Fougera were purchasing for their products, another woman employed by defendants was forced to resign under similar circumstances. This woman, Lucy Alexander, who had been the senior Director of Procurement & Planning at Sandoz/Fougera, was forced to resign after being similarly subjected to harassment and discrimination for speaking her mind at management meetings and otherwise acting as an assertive female manager, which was repugnant to the corporate culture at Sandoz/Fougera.

65. Moreover, although Plaintiff was next in line for promotion to the position of senior Director of Procurement & Planning upon Ms. Alexander's resignation, plaintiff was passed over for such promotion and the position was filled from outside the organization by a male.

66. In another example of the “targeting” of assertive female employees, plaintiff was approached by Micheal Esquilin to provide negative feedback about Jennifer Asara. Defendants’ in-house legal counsel who had been complaining to Novartis HR about unprofessional conduct of the male-dominated management and abuse of signatory authority at Sandoz/Fougera. Mr. Esquilin, newly employed at that time, did not realize that it was a mistake to come to plaintiff, the victim of discriminatory treatment herself, to gather negative ammunition with which to wrongfully target Ms. Asara.

67. In another example of discriminatory treatment, Melody Gulcan, a female engineer of Turkish descent and a practicing Muslim, was never promoted or given a raise despite exemplary performance. Because Ms. Gulcan was also perceived as being overly assertive with respect to compliance issues, she was wrongfully demoted to the position of associate engineer.

68. On the other hand, women who carried themselves in a sexualized, flirtatious manner were rewarded with perks and bonuses despite their lack of qualifications. For example, Diane Hulser was not a manager, but because she carried herself in a flirtatious manner with the “boys club” she was given a manager’s office, given managerial responsibilities over certain office functions, and on numerous occasions spent time with members of the “boys club” on dinners.

69. Accordingly, plaintiff was one of a handful of assertive, professional, foreign and religiously devout women, who were wrongfully targeted and discriminated against because they did not comply with the “boys club” mentality that pervaded the Defendant Companies.

**AS AND FOR A FIRST CAUSE OF ACTION
(Retaliatory Discharge Pursuant to New York Labor Law §740)**

70. Plaintiff repeats and re-alleges each of the foregoing paragraphs of this Complaint as though fully set forth herein.

71. Upon learning of defendants' non-compliance with FDA rules and/or regulations relating to the safety and efficacy of manufacturing facilities for chemicals used in the manufacture of pharmaceutical products, plaintiff promptly advised other Sandoz/Fougera managers about such non-compliance.

72. Plaintiff's complaints about these non-compliance issues were ignored by defendants. Instead, Fougera/Sandoz management demoted plaintiff from her position as a "Supply Chain" manager and reassigned her to perform other duties which were not within her core areas of expertise. Specifically, defendants assigned her to perform duties within the "SAP" area, *i.e.*, an IT position which was outside her primary area of expertise.

73. However, plaintiff persisted in continuing to raise these non-compliance issues and ultimately lodged a formal complaint with the Sandoz Business Practices Office. This complaint to the Sandoz Business Practices Office, as well as plaintiff's prior complaints to various Sandoz/Fougera managers regarding these health and safety issues, was the kind of complaint that is specifically protected by New York Labor Law §740.

74. Within 24 hours of filing her complaint with the Sandoz Business Practices Office, plaintiff was summarily fired by defendants, without cause or explanation, and was escorted off the premises.

75. Plaintiff's retaliatory discharge was in violation of Labor Law §740 and, as a result, she is entitled to compensation as set forth in the statute and/or as determined by a jury at trial.

76. As a result, plaintiff was damaged in an amount to be determined at trial, but in no event less than \$2 million.

**AS AND FOR A SECOND CAUSE OF ACTION
(Retaliatory Discharge Under the Federal False Claims Act)**

77. Plaintiff repeats and re-alleges each of the foregoing paragraphs of this Complaint as though fully set forth herein.

78. Upon learning that defendant was not in compliance with FDA rules and/or regulations relating to the safety and efficacy of manufacturing facilities for chemicals used in the manufacture of pharmaceutical products, plaintiff promptly complained to and advised other Sandoz/Fougera managers about this important issue and the fact that such non-compliance could potentially constitute fraud upon the government and a violation of the Federal False Claims Act.

79. Plaintiff's complaints were ignored by defendants. Instead, Fougera/Sandoz management demoted plaintiff from her position as a "Supply Chain" manager and reassigned her to perform other duties which were not within her core areas of expertise. Specifically, defendants assigned her to perform duties within the "SAP" area, *i.e.*, an IT position which was outside her primary area of expertise.

80. However, plaintiff persisted in continuing to raise these non-compliance issues and ultimately lodged a formal complaint with the Sandoz Business Practices Office. This complaint to the Sandoz Business Practices Office, as well as plaintiff's prior complaints to various Sandoz/Fougera managers regarding these health and safety issues, was the kind of complaint that is specifically protected by the anti-retaliation provisions of the Federal False Claims Act.

81. Within 24 hours of filing her complaint with the Sandoz Business Practices Office, plaintiff was summarily fired by defendants, without cause or explanation, and was escorted off the premises.

82. Plaintiff's retaliatory discharge was in violation of the Federal False Claims Act and, as a result, she is entitled to compensation as set forth in the statute and/or as determined by a jury at trial.

83. As a result, plaintiff was damaged in an amount to be determined at trial, but in no event less than \$2 million.

**AS AND FOR A THIRD CAUSE OF ACTION
(Retaliatory Discharge Under the New York State False Claims Act)**

84. Plaintiff repeats and realleges each of the foregoing paragraphs of this Complaint as though fully set forth herein.

85. Upon learning that defendant was not in compliance with FDA rules and/or regulations relating to the safety and efficacy of manufacturing facilities for chemicals used in the manufacture of pharmaceutical products, plaintiff promptly complained to and advised other Sandoz/Fougera managers about this important issue and the fact that such non-compliance could potentially constitute fraud upon the government and a violation of the New York State False Claims Act.

86. Plaintiff's complaints were ignored by defendants. Instead, Fougera/Sandoz management demoted plaintiff from her position as a "Supply Chain" manager and reassigned her to perform other duties which were not within her core areas of expertise. Specifically, defendants assigned her to perform duties within the "SAP" area, *i.e.*, an IT position which was outside her primary area of expertise.

87. However, plaintiff persisted in continuing to raise these non-compliance issues and ultimately lodged a formal complaint with the Sandoz Business Practices Office. This complaint to the Sandoz Business Practices Office, as well as plaintiff's prior complaints to various Sandoz/Fougera managers regarding these health and safety issues, was the kind of complaint that is specifically protected by the by the anti-retaliation provisions of the New York State False Claims Act.

88. Within 24 hours of filing her complaint with the Sandoz Business Practices Office, plaintiff was summarily fired by defendants, without cause or explanation, and was escorted off the premises.

89. Plaintiff's retaliatory discharge was in violation of the ant-retaliation provisions of the New York State False Claims Act and, as a result, she is entitled to compensation as set forth in the statute and/or as determined by a jury at trial.

90. As a result, plaintiff was damaged in an amount to be determined at trial, but in no event less than \$2 million.

**AS AND FOR A FOURTH CAUSE OF ACTION
(Retaliatory Discharge Under the New York City False Claims Act)**

91. Plaintiff repeats and realleges each of the foregoing paragraphs of this Complaint as though fully set forth herein.

92. Upon learning that defendant was not in compliance with FDA rules and/or regulations relating to the safety and efficacy of manufacturing facilities for chemicals used in the manufacture of pharmaceutical products, plaintiff promptly complained to and advised other Sandoz/Fougera managers about this important issue and the fact that such non-compliance could potentially constitute fraud upon the government and a violation of the New York City False Claims Act.

93. Plaintiff's complaints were ignored by defendants. Instead, Fougera/Sandoz management demoted plaintiff from her position as a "Supply Chain" manager and reassigned her to perform other duties which were not within her core areas of expertise. Specifically, defendants assigned her to perform duties within the "SAP" area, *i.e.*, an IT position which was outside her primary area of expertise.

94. However, plaintiff persisted in continuing to raise these non-compliance issues and ultimately lodged a formal complaint with the Sandoz Business Practices Office. This complaint to the Sandoz Business Practices Office, as well as plaintiff's prior complaints to various Sandoz/Fougera managers regarding these health and safety issues, was the kind of complaint that

is specifically protected by the by the anti-retaliation provisions of the New York City False Claims Act.

95. Within 24 hours of filing her complaint with the Sandoz Business Practices Office, plaintiff was summarily fired by defendants, without cause or explanation, and was escorted off the premises.

96. Plaintiff's retaliatory discharge was in violation of the ant-retaliation provisions of the New York City False Claims Act and, as a result, she is entitled to compensation as set forth in the statute and/or as determined by a jury at trial.

97. As a result, plaintiff was damaged in an amount to be determined at trial, but in no event less than \$2 million.

**AS AND FOR A FIFTH CAUSE OF ACTION
(Breach of Contract/Implied Covenant of Good Faith and Fair Dealing)**

98. Plaintiff repeats and re-alleges each of the foregoing paragraphs of this Complaint as though fully set forth herein.

99. Plaintiff was hired by Defendants as Director of Procurement under the Employment Agreement and assigned to the Merger Team because of her experience and expertise with cGMP and other mandatory FDA regulatory requirements regarding drug procurement and manufacturing issues. Plaintiff's duties and responsibilities with the Merger Group included identifying and curing Fougera/Sandoz violations of FDA regulations and requirements, including cGMP (current Good Manufacturing Practices) in particular those found during FDA Observations of Fougera.

100. Defendants recognized plaintiff's work as exemplary as long as she identified violations that could addressed and cured in a timely, efficient and cost effective manner.

101. However, once Plaintiff identified their failure to procure Sodium Hyaluronate from a Type 2 DMF compliant manufacturer, a violation that would likely cost Defendants \$200-

\$400 Million in revenues from Solaraze to cure, plaintiffs concerns were ignored, and she was expected to not press her concerns further.

102. When Plaintiff persisted in her complaints, she was first demoted, in an effort to isolate her and induce her to resign. When Plaintiff made a formal complaint, she was terminated.

103. Defendants' actions were thus clearly calculated in bad faith to prevent Plaintiff from performing her duties under her Employment Agreement and to also withhold her benefits due under her Employment Agreement. Defendants thus breached their covenant of good faith and fair dealing under their Employment Agreement, Relocation Package and Retention Bonus by, among other things, failing to pay her the \$29,000 due her for the 2013 bonus to which she was entitled; failing to pay her the \$20,000 project bonus to which she was entitled as part of the transition team; failing to pay her all of the Relocation Package Payments that had been promised to her; failing to pay her all of the Merit Award Payments to which she was entitled; and failing to pay her the Retention Bonus Award to which she would have been entitled after three years of service, but for the bad faith wrongful termination of her by defendants.

104. As a result, plaintiff was damaged in an amount to be determined at trial, but in no event less than \$2 million.

**AS AND FOR A SIXTH CAUSE OF ACTION
(Employment Discrimination pursuant to
N.Y. Executive Law, Article 15, Section 296)**

105. Plaintiff repeats and re-alleges each of the foregoing paragraphs of this Complaint as though fully set forth herein.

106. Defendants violated the New York State Human Rights Laws, N.Y. Executive Law, Article 15, Section 296, by engaging in unlawful discrimination of plaintiff based upon her gender (female), her religion (Muslim), and her national origin (Turkish).

107. As a result, plaintiff was damaged in an amount to be determined at trial, but in no event less than \$2 million.

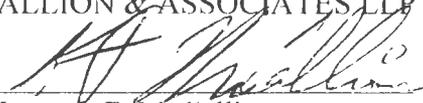
JURY TRIAL DEMANDED

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

WHEREFORE, plaintiff demands judgment against the defendants on the first through sixth causes of action in an amount to be determined at trial, but in no event less than \$12 million, plus attorneys' fees and costs, and for such other and further relief as this Court deems just and proper.

Dated: October 17, 2015

McCALLION & ASSOCIATES LLP

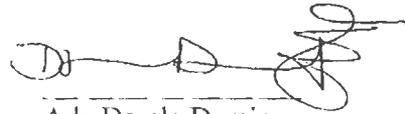


By: Kenneth F. McCallion
100 Park Avenue -- 16th floor
New York, New York 10017
(646) 366-0884
Attorneys for Plaintiff

VERIFICATION

ADA DAMLA DEMIR, being duly sworn, states that she has read the foregoing Second Amended Complaint and finds that its contents are true and correct, except as to matters based upon information and belief, and as to those matters, she believes them to be true and correct.

Dated: October 17, 2015



Ada Damla Demir