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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
(TRENTON DIVISION)

_____x

AMRIT MULA,

Plaintiff,

v.

ELI LILLY AND CO.,

Defendant.

_____x

COMPLAINT

No.
Jury Trial Demanded: Yes

Plaintiff, **AMRIT MULA**, by and through her undersigned counsel, by way of Complaint against Defendant **ELI LILLY AND CO.**, seeks relief for violations of laws protecting an employee acting as a whistleblower from unlawful retaliation under the New Jersey Conscientious Employee Protection Act, N.J.S.A. § 34:19-1 *et seq*. In support of her Complaint, Plaintiff states as follows:

INTRODUCTION

1. Plaintiff Amrit Mula ("Ms. Mula" or "Plaintiff") was a productive and well-regarded employee of the Defendant Eli Lilly and Co. ("Lilly" or "Defendant") as an Associate Director of Employee Relations working in Branchburg, New Jersey. However, beginning in August 2018 and continuing until her termination, Ms. Mula began to investigate employee complaints of serious violations of U.S. Food and Drug Administration ("FDA") regulations in the manufacturing of Lilly pharmaceutical drugs. Among other things, Ms. Mula witnessed and reported Lilly employees failing to adhere to current Good Manufacturing Practices ("cGMPs"); failing to comply with FDA-mandated standard operating procedures ("SOPs"); failing to report batch contaminations; improperly disposing of caustic substances into waterways; and falsifying quality assurance testing. In particular, the failures of production Plaintiff observed and reported were primarily related to the sale of blockbuster Type 2 diabetes medication, Trulicity. Throughout the course of her investigations, Lilly officials continually told Ms. Mula to stop her investigations or

underplay the severity of the violations she uncovered. After Ms. Mula repeatedly pressured site leadership to remedy these serious legal and compliance violations, Lilly executives responded by marginalizing, harassing, and eventually terminating her position under false pretenses on or about March 28, 2019.

2. As a result of Lilly's unlawful termination of Ms. Mula disguised as a job elimination, she has suffered loss of pay, benefits, emotional distress, and serious damage to her career. Plaintiff brings her claims as a whistleblower subjected to unlawful retaliation in violation of the New Jersey Conscientious Employee Protection Act, N.J.S.A. § 34:19-1 to -14 ("CEPA").

JURISDICTION AND VENUE

3. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity between the parties in this civil action and damages in this case exceed $75,000.00, exclusive of interest and costs.

4. Venue is proper in this district pursuant to 29 U.S.C. § 1132(e)(2) as some or all wrongful acts occurred in this District and Defendant operated its Branchburg Site within this District.

PARTIES

5. Ms. Mula is a citizen of the State of Pennsylvania.

6. Defendant Lilly is an Indiana corporation, with its principal place of business located at 893 S Delaware St Indianapolis, Indiana 46225. At all times

relevant herein, Defendant Lilly operated a Branchburg, New Jersey location where Plaintiff was employed.

7. Defendant Lilly is a pharmaceutical company subject to regulation by, inter alia, the United States Government (the "Government"), including the FDA and the Occupational Safety and Health Administration ("OSHA"). Additionally, Defendant Lilly is an employer with thousands of employees worldwide.

FACTUAL ALLEGATIONS

8. At all times relevant herein, Plaintiff Mula has been a competent human resources professional in the pharmaceutical industry, with nearly fifteen years of experience. Plaintiff began working for ImClone Systems on July 21, 2004, and became a Lilly employee when it acquired ImClone Systems in or around November 2008.

9. At all times relevant herein, Plaintiff worked in Lilly's Branchburg, New Jersey location which includes a 250,000 square foot, state-of-the-art multi-product manufacturing facility, the largest of its kind in the biotech industry ("Branchburg Site").

10. Throughout Ms. Mula's employment with ImClone and Lilly, she demonstrated that she was a competent employee, receiving four promotions and four achievement awards for achieving high priority initiatives. Prior to her

termination, Ms. Mula never received any proposed or actual disciplinary action, official reprimands, or unsatisfactory performance evaluations.

11. In or around 2011, Ms. Mula was promoted to Associate Director of Employee Relations. It was from this position she was terminated. Her duties in this role included conducting investigations in response to employee concerns, such as violations of rules and regulations. She thus frequently worked with Lilly's Ethics and Compliance, Security, and Legal and Global Investigations Departments.

12. Beginning in or around 2016, Ms. Mula reported to Richard Ruth ("Mr. Ruth"), Director of Employee Relations, who was based in Lilly's headquarters in Indianapolis, Indiana.

13. In or about January 2017, Victor Cruz ("Mr. Cruz") became the Vice President of Biopharmaceutical and Operations at the Branchburg Site. He brought with him a longtime confidante and friend Efraim Ortiz ("Mr. Ortiz"), Associate Vice President for Human Resources, who also reported to Mr. Cruz.

August 2018 cGMP and Falsification Investigations

14. Beginning in 2018, Ms. Mula began investigating a series of allegations related to violations of the FDA's cGMP occurring at the Branchburg Site as part of its production of Cetuximab ("Erbitux"); Ramucirumab ("Cyramza"); Olaratumab ("Lartruvo"); and Dulaglutide ("Trulicity"). These alleged violations seemed to stem from the policies implemented by, and a culture created under, the leadership

of Mr. Cruz and Mr. Ortiz. Although Ms. Mula's insistence on thorough investigations and documenting noncompliance frequently created tension with Mr. Cruz and Mr. Ortiz throughout 2018, these tensions started to grow increasingly untenable beginning in August 2018.

15. In or around August 2018, Ms. Mula conducted a data integrity investigation pursuant to an instruction from Vice President of Quality Lydia Wible ("Ms. Wible"). This investigation revealed that at least seven employees falsified records and that the Manufacturing Department was consistently overdue on cGMP trainings.

16. As for the falsified records, Ms. Mula uncovered that several Branchburg Site employees repeatedly recorded that SOPs were performed while knowing that a required step had been intentionally omitted and then misrepresented data was being recorded in cGMP documents. The omitted requirement was part of the FDA-approved SOPs in the storage of flammable materials used to manufacture Lilly drugs.

17. As for the trainings, Ms. Mula discovered that not only had employees failed to complete these mandatory cGMP trainings, but that the Learning and Development Department, overseen by Mr. Ortiz, failed to capture the missed trainings in Lilly's cGMP training tracking system. Some of these employees had missed over a year's worth of mandatory trainings. Despite this, Lilly told regulators

during this period that its employees were up to date and compliant with training requirements.

18. Ms. Mula alerted Ms. Wible and Mr. Cruz to the falsification and training issues. They asked Ms. Mula to designate these incidents as "performance issues" in Lilly's Human Resources and Quality Tracking Databases, as opposed to recording them as cGMP violations. If the issues had been recorded as cGMP violations, they could be identified by regulatory agencies during site inspections.

19. Ms. Mula refused to comply with Ms. Wible's and Mr. Cruz's directive as she believed it violated Lilly's regulatory reporting obligations. Mr. Ortiz subsequently told Ms. Mula that he and the Vice President of Manufacturing Elizabeth Gosen ("Ms. Gosen") agreed with classifying the issues as "performance issues," and asked her to reconsider.

20. On August 7, 2018, during a meeting with Ms. Gosen, Ms. Wible, Warehouse Manager Sally Christensen, and Associate Director of Quality and Compliance Michael Cox, Ms. Gosen asked that Ms. Mula refrain from referring to the incidents as "falsifications" moving forward, both verbally and in writing. Ms. Gosen then stated she would discuss the matter with Mr. Ortiz and Mr. Cruz and asked Ms. Mula to close her investigation as soon as possible.

21. On the morning of August 8, 2018, Ms. Mula met with Ms. Wible. Ms. Wible stated that Mr. Cruz and Mr. Ortiz informed her that they wanted language on

any written warnings or quality deviation investigations to omit words like "falsification," "dishonesty," and "noncompliance."

22. Later on August 8, 2018, Ms. Mula met with Mr. Ortiz who insisted that she close her investigation within the next three days. Ms. Mula responded that she was investigating serious allegations of falsification of records and would not have her investigation subjected to an arbitrarily short deadline.

23. Following Ms. Mula's meeting with Mr. Ortiz, she complained to Mr. Ruth that she felt the Branchburg Site leadership was attempting to improperly influence the outcome of her investigation. Mr. Ruth agreed with Ms. Mula and permitted her to record the cases as cGMP violations and to issue written warning to the employees in question.

September 2018 Wage and Staffing Complaint

24. On September 4, 2018, Mr. Ortiz and Ms. Mula learned of an anonymous Ethics and Compliance hotline complaint relating to a possible wage law violation at the Branchburg Site. During a meeting with Ms. Mula, Mr. Ortiz declared an investigation into the incident was unwarranted because he suspected the complaint had been filed by a Branchburg Site leader who frequently raised similar concerns. Mr. Ortiz asked Ms. Mula to follow up with Mr. Ruth and "make this go away." Ms. Mula conferred with Mr. Ruth, to whom the case had been

assigned, and he informed her that he would seek guidance from Lilly's Legal Department and did not require further information from her.

25. Mr. Ruth then proceeded to close out this complaint without investigation.

26. On September 24, 2018, Mr. Ruth followed up about a related issue after receiving an email from a compliance officer notifying him that the anonymous complainant had raised additional concerns. Specifically, they noted that the "GMP requirement that the site has [an] adequate and qualified number of employees to complete the work" was "not being fulfilled." The complainant went on to state that "P6 and P4 level work is being completed by P2 and P3 who were unqualified." Ms. Mula told Mr. Ruth that if this were true, Lilly would not be complying with FDA cGMP staffing requirements.

27. Later that day and with Mr. Ruth's approval, Ms. Mula informed Ms. Wible of these issues by telephone. After this call, Mr. Ortiz informed Ms. Mula that she should not have informed Ms. Wible of the complaints and accused Ms. Mula of "overreacting." Mr. Ortiz then told Ms. Mula to inform Mr. Ruth that the case should be closed without investigation. Ms. Mula refused and encouraged Mr. Ortiz to discuss the matter with Mr. Ruth directly.

October 2018 Staffing Investigation

28. On October 1, 2018, Ms. Mula received a hard copy of an anonymous complaint from a Lilly employee citing various concerns, but primarily stressing that Lilly failed to hire a sufficient number of employees to complete the required work.

29. After receiving this complaint, Ms. Mula informed Mr. Ruth that she intended to open a new case and include the cGMP headcount requirement comments from the September 2018 closed case. Mr. Ruth responded that he "[d]efinitely supported opening up a separate case."

30. When Ms. Mula later raised the complaint with Mr. Ortiz, he asserted that he had already discussed it with Mr. Ruth and that Mr. Ruth had assured him that an investigation was unwarranted. Mr. Ortiz reiterated his suspicions that activist Branchburg Site leaders, Victor Goetz, Babita Parekh, and William Parson, had filed the complaints and thus they were unfounded and the concerns had already been addressed during confidential SLT meetings. Mr. Ortiz asked Ms. Mula to drop the investigation. Ms. Mula recapped the history and importance of the issue and explained to Mr. Ortiz that examination of the complaint was required.

31. Ms. Mula then asked Mr. Ortiz why he was unsupportive of opening an investigation into the complaint. Mr. Ortiz shared that the next day it would be announced that Mr. Cruz was being promoted to lead the manufacturing operations in Puerto Rico and Brazil and the then-Senior Director of Engineering and

Technology Nellie Clark ("Ms. Clark") would be filling Mr. Cruz's role as the Branchburg Site Head. Ms. Mula understood that Mr. Ortiz was attempting to prevent Mr. Cruz from being tarnished by an investigation while on the cusp of promotion.

32. On October 3, 2018, Ms. Mula asked Mr. Ortiz if the Branchburg Site Leadership Team ("SLT") was on notice of the staffing concerns and related cGMP investigation. Mr. Ortiz pushed back on Ms. Mula's desire to inform the SLT of the issue, asserting that she should "follow the established process you normally use to complete an investigation." Ms. Mula responded by noting that the complaints she was investigating "are not related to wage concerns. They are allegations that the site may not be in compliance with fundamental GMP requirement regarding personnel qualification . . . Respectfully, I don't think these facets of the initial complaint have been adequately addressed by us at the site and further analysis is required."

33. Later in the afternoon of October 3, 2018, Ms. Mula emailed the Human Resources Leadership Team ("HRLT") to outline her concerns related to the complaints about insufficient staffing. Ms. Mula specifically stated that the complaints involved allegations of "noncompliance with the GMP requirements regarding Personnel Qualification ([21 C.F.R. § 211.25])" and noted that a "surge in personnel related observations and deviations, resulting in significant media and

product losses, is being attributed to job vacancies and incumbents who do not have the elevated requirements to navigate an intensely regulated environment." The HRLT is a team comprised of the SLT, Associate Vice President of Organizational Learning and Development Kristen Zemanek and Quality Assurance Change Management Senior Specialist Gaius Mount.

34. Mr. Cruz admonished Ms. Mula's for sending her concerns to the larger HRLT group. Mr. Ortiz also separately contacted her to inform her that Mr. Cruz was "not happy" with her persistence in pursuing an investigation on this regulatory issue. Mr. Ortiz argued that because of Mr. Cruz's contributions to the Branchburg Site over his two years there, he deserved "a clean going away."

35. On October 4, 2018, Ms. Mula and Mr. Ruth met and she raised several concerns related to the staffing deficit at the Branchburg Site which posed regulatory problems. Among other things, Ms. Mula shared details of Lilly's violations of federal regulations with Mr. Ruth, which demonstrated that: (1) the Manufacturing and Quality Departments did not employ the required number of workers; (2) some teams were operating without adequate supervision; (3) there were an inadequate number of qualified and trained manufacturing operators to manage the Branchburg Site's two-suite operations[1]; (4) the Manufacturing Department was relying on an

[1] "Two-suite operations" refers to the number of drugs being manufactured at the Branchburg Site. Due to constraints arising from adhering to SOPs and related contamination issues, only one drug may be manufactured in a "suite" of facilities

exorbitant amount of permanent overtime as a long-term solution; and (5) at least three operators had worked over thirty-two (32) consecutive days, putting the health and safety of the workers and customers at risk.

36. Also on October 4, 2018, Ms. Mula met with Ms. Gosen to review these same findings. Ms. Gosen did not dispute that Ms. Mula's findings were accurate.

37. In the afternoon of October 4, 2018, Ms. Mula met with Mr. Cruz and Mr. Ortiz and shared her investigation's findings with them. In response, Mr. Cruz and Mr. Ortiz held an extended conversation in Spanish to ensure Ms. Mula would not understand what was being said. Mr. Cruz concluded the meeting by disputing the data Ms. Mula presented and stating that he would ask Ms. Gosen to conduct her own examination into the issues.

38. On October 5, 2018, Ms. Mula learned from Ms. Gosen and another executive that Mr. Ortiz had instructed them to refrain from cooperating with Ms. Mula's investigations into cGMP issues. Both Ms. Gosen and the other executive were SLT members. Several Manufacturing and Quality Department supervisors also told Ms. Mula that Ms. Gosen and Ms. Wible had told them that they should alert the SLT and/or Mr. Ortiz before having any investigation-related discussions with Ms. Mula and provide generic responses to any questions she asked.

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at one time. Due to the size of the Branchburg Site, it maintains two suites in a single location, which requires additional operators to staff each suite.

39. After learning this information and receiving pressure from Branchburg Site leadership, Ms. Mula emailed and met with Mr. Cruz and Mr. Ortiz to establish strict parameters around confidentiality, including informing them that she would not be sharing the details of her investigation with them.

40. Ms. Mula later learned that details of her investigations were in fact being shared with members of the SLT by Mr. Ruth.

41. In the days following these exchanges, another supervisor in the Manufacturing Department shared with Ms. Mula that insufficient staffing was leading to the falsification of records, with employees falsely attesting in compliance forms that a manufacturing process had been second-person verified, when only one person had been present.

42. On October 11, 2018, Ms. Mula received a complaint regarding Lilly's Annual Product Reviews ("APRs") which are required pursuant to 21 C.F.R. § 211.180.

43. Ms. Mula's investigation made it clear that Lilly lacked the resources necessary to competently complete the FDA-required APRs while attending to other required tasks. It also raised further concerns related to staffing shortages causing falsification of records as well as delays in testing and submissions. Ms. Mula discovered that these staffing shortages were leading to rushed work, which could lead to errors resulting in product deviations.

44. Ms. Mula reported these findings to Mr. Ruth who instructed her to weave the complaint into the previous cGMP violations investigation, which Ms. Mula believed was designed to dampen the impact of the allegations.

45. Weeks later, Mr. Ruth conceded that a separate case was warranted for these allegations. He then stated he would initiate the case and update it with Ms. Mula's documentation.

46. Ms. Mula also discussed the APR complaint and related staffing concerns with Mr. Cruz during their monthly one-on-one meeting. She also raised concerns related to reports circulating about undocumented material dumping.

47. Specifically, reports were circulating that Lilly employees had improperly disposed of a large amount of buffer solution intended for use in Trulicity without proper neutralization. These incidents were documented as observations to avoid detection by regulatory agencies.

48. During this meeting, Mr. Cruz once again dismissed Ms. Mula's concerns related to staffing by asserting that he obtained data on the issue from the Finance and Quality Departments and insisting that the material disposal had been properly documented.

49. The FDA later investigated and determined that these incidents should have been recorded as deviations not observations.

50. On October 12, 2018, Ms. Mula informed Mr. Ruth that she continued to experience a lack of cooperation from the Branchburg SLT, highlighting the fact that the Branchburg leaders were expressly instructing Branchburg Site employees not to communicate with her.

51. During this meeting, Ms. Mula also shared her preliminary findings about the staff shortage issue and related overtime concerns.

52. Finally, Ms. Mula requested that Mr. Ruth permit her to partner with Lilly's Global Quality Assurance Auditing and Compliance team ("GQAAC") ahead of its planned audit of the Branchburg Site on November 11, 2018. Mr. Ruth declined to approve her request, noting that he did not know the appropriate internal contact at the GQAAC and was concerned by the idea of sharing Ms. Mula's investigation findings with GQAAC. When the audit occurred, Ms. Mula was completely excluded.

53. On October 17, 2018, Ms. Mula copied Mr. Cruz on a tense email exchange with Ms. Gosen which Ms. Mula sent in the course of her investigation. In the email, Ms. Mula started by noting certain "generic" information Ms. Gosen had provided "does not help ascertain if we are currently adhering to regulations." Ms. Mula then pointedly asked Ms. Gosen, "Can you with conviction confirm that [the Manufacturing Department] is currently compliant with Sec. 211.25 Personnel

Qualifications?" She added a series of related questions concerning the serious staffing shortages she was investigating at the Branchburg Site.

54. After an exchange with Mr. Cruz, Ms. Mula asked Ms. Gosen to answer her questions. Ms. Gosen asked to meet in person to discuss.

55. During this meeting, Ms. Gosen acknowledged that certain minimum requirements and regulatory standards with respect to staffing were not being met and that her requests for additional headcount had been denied. Ms. Gosen then stated that she would not relay these viewpoints "on the record." She explained that she had drafted answers to Ms. Mula's questions but was not comfortable sending the drafted response. She stated she would sooner resign than disclose the severity of the noncompliance at the Branchburg Site since Mr. Cruz and Mr. Ortiz began leading it in 2017. When Ms. Gosen did respond in writing, her responses were contrary to the facts she disclosed to Ms. Mula in person and constituted a "whitewash" of the ongoing staffing shortfalls and chronic noncompliance. In fact, when Ms. Gosen learned Ms. Mula planned to report Lilly's violations to the FDA, she resigned on May 3, 2019.

56. Ms. Mula continued to investigate these ongoing issues, and on October 23, 2018, she met with Ms. Wible to discuss the concerns related to material dumping, insufficient staffing, and other cGMP issues. Ms. Mula also raised concerns based on reports she had received from other Manufacturing Department

employees who informed her they had been cautioned not to discuss, document, or report irregularities or noncompliance.

57. In late October 2018, Mr. Cruz and Mr. Ortiz informed Mr. Ruth that Ms. Mula would not be involved in GMP-related investigations and all of her investigations were deemed "on hold."

Trulicity Validation Protocols Investigation

58. On October 22, 2018, Associate Director of Validation Technical Services Henry Hoehn informed Ms. Mula of missing binders of validation protocols his team discovered during an initial protocol report review. A validation protocol is a key FDA-approved document that details the manufacturing process meant to ensure a consistent product with the claimed specifications and quality. Ms. Mula opened an investigation into the issue.

59. During the course of the investigation, hundreds of original pages were found missing, some of the documents were discovered dumpsters. Ultimately, all but roughly fifty-two (52) pages of the original validation protocols for the manufacture of Trulicity were recovered.

60. When Mr. Cruz learned that Ms. Mula was investigating the Trulicity protocols, he sternly instructed her to "cease and desist from investigations risking Dula.[2]" He noted that Lilly could face significant regulatory problems if "red

[2] "Dula" is the Lilly shorthand for Dulaglutide, the generic name for Trulicity.

flags" related to Trulicity were documented in Lilly's Human Resources or Quality databases.

61. Following this conversation, Ms. Wible advised Ms. Mula via email and during an in-person meeting that she did not intend to create a deviation to document the event, falsely asserting that only one document was missing and it had since been located.

62. After Ms. Mula presented Ms. Wible with evidence of multiple missing binders, Ms. Wible falsely told Ms. Mula that a Quality investigation had been opened and provided her with a fabricated deviation number. Other employees in Ms. Wible's department subsequently informed Ms. Mula that no deviation had been opened.

63. Ms. Mula escalated the issue by informing Vice President of Global Quality Leanne Hickman ("Ms. Hickman"), Ms. Wible's supervisor, that Ms. Wible appeared to be misrepresenting information to her in an apparent effort to conceal factual data from regulatory agencies. During her meeting with Ms. Hickman, Ms. Mula also shared her concerns regarding several of the issues related to insufficient staffing and resulting compliance issues.

64. Ms. Mula also informed Mr. Ruth that Mr. Cruz was attempting to influence her investigation.

65. Following her meeting with Ms. Mula, Ms. Hickman discussed the identified issues with Senior Director of Human Resources, Raymond Muller ("Mr. Muller"), Mr. Ruth's supervisor. Ms. Hickman requested that the Quality Department conduct an investigation into the issue without an accompanying Human Resources investigation and further requested that Ms. Mula abandon her push to initiate a deviation regarding the matter, noting that doing so would bring "unwanted attention during regulatory inspections." Mr. Muller acceded to these requests and called Ms. Mula to inform her of the same.

66. During this call, Mr. Muller noted that her persistence regarding the deviation was warranted and assured her that, despite Ms. Hickman's complaints, she had done nothing wrong.

67. Despite Ms. Wible's earlier request that Ms. Mula not find a deviation, Ms. Wible informed Ms. Mula that the Quality Department had decided to initiate a deviation for the missing validation protocols. Ms. Wible stated that she, Mr. Cruz, and Mr. Ortiz were "disappointed" that the matter was not handed "locally without escalation to corporate."

68. The FDA later investigated the missing validation protocols and other violations reported by Ms. Mula to Lilly.

69. The FDA ultimately issued an Official Action Indicated ("OAI") notice in 2020 to Lilly, indicating that the serious problems disclosed by Ms. Mula

were significant enough to pose an imminent health hazard.

Retaliatory Complaints against Ms. Mula

70. On October 24, 2018, Mr. Ruth informed Ms. Mula that Mr. Cruz contacted him and stated that he and Mr. Ortiz could no longer work with Ms. Mula. Mr. Ruth believed that the situation likely arose at least in part from the heightened stress related to Ms. Mula's investigations. Mr. Ruth told Ms. Mula to stop working on all investigations involving alleged cGMP violations and asked her to work from home over the next few weeks as Mr. Cruz and Mr. Ortiz did not "want Ms. Mula at the site." Ms. Mula did not comply with this request and continued to work from the Branchburg Site.

71. During this call, Mr. Ruth shared that Ms. Wible and Mr. Ortiz had made a series of "ridiculous" complaints against Ms. Mula, though he did not disclose the substance of these complaints.

72. Ms. Mula later learned that Mr. Ortiz claimed Ms. Mula had implied that he and Mr. Cruz were having an affair while Ms. Wible alleged that Ms. Mula had attributed a negative slogan[3] to Mr. Cruz which had spread throughout the site. Neither allegation was true or credible.

73. On November 7, 2018, Mr. Ruth informed Ms. Mula that Mr. Ortiz and Ms. Wible had formalized their complaints against her and, as a result, Mr.

[3] The slogan was "EEOC= Eventual End of Caucasians."

Cruz requested that Ms. Mula be terminated. Mr. Ruth stated that no one other than Mr. Cruz, Mr. Ortiz, and Ms. Wible believed these accusations were true and that he believed that these individuals were embarking on a pretextual expedition for misconduct to justify Ms. Mula's termination.

74. During this conversation, Mr. Ruth asked Ms. Mula to close all of her open cGMP-related investigations with determinations of "no violations," as doing so would help quell the conflict. Ms. Mula refused to do so.

75. On a call during the week of November 11, 2018, Mr. Ruth reiterated his request that Ms. Mula close her open cGMP-related investigations with determinations of "no violations," and that doing so would help ease tensions with Mr. Cruz and Mr. Ortiz. Ms. Mula again refused this directive, which she believed to represent an effort to suppress evidence of Lilly's noncompliance with FDA regulations.

76. On November 15, 2018, Ms. Mula submitted a response to the complaints by Mr. Ortiz and Ms. Wible. Mr. Ruth then notified her that Lilly leadership, including Mr. Ruth, Mr. Muller, VP Manufacturing HR Sabrina Martin ("Ms. Martin"), Senior Director, Ethics and Compliance Damon Strickland, and Senior Vice President, Human Resources Stephen Fry ("Mr. Fry"), who were involved in the investigation of these complaints, had closed the investigation earlier that week with a "no violation" outcome. Mr. Muller later told Ms. Mula

that leaders had also reviewed Ms. Mula's claims of chronic noncompliance and found them "far-fetched."

77. Following Lilly's closure of the investigation into Ms. Mula's reported violations, Mr. Ruth conveyed to Ms. Mula's colleagues during two separate visits to the Branchburg Site that Mr. Cruz was still pushing for her to be terminated.

78. Four individuals, including two on the SLT, informed Ms. Mula that while Mr. Ruth refused to terminate her, he was agreeable to eliminating her job position. For example, Ms. Wible expressly informed Ms. Mula that Mr. Cruz was "gunning for [her]," and that Mr. Ruth could not hold him off.

79. Further, members of the SLT also informed Ms. Mula that Mr. Cruz had announced that Mr. Ruth agreed during his November 4, 2018, visit to close out all of Ms. Mula's pending regulatory investigations as "no violations."

80. In mid-November 2018, the GQAAC came to the Branchburg Site as scheduled. Ms. Mula was not included in their review or deliberations and was removed from the Skype investigation chat and end-of-business updates that took place during the audit. As the Branchburg Site's Human Resources subject-matter expert, this was the first time in twelve (12) years Ms. Mula had not been included on these communications.

81. During the week of December 2, 2018, Mr. Ruth traveled to the Branchburg Site. During this visit, Mr. Ruth acknowledged that Mr. Cruz had continued to press for her termination. He stated he proposed making her a remote employee, but that Mr. Cruz and Mr. Ortiz insisted she be terminated.

82. During this visit, Ms. Mula also reminded Mr. Ruth that she had uncovered serious compliance deficiencies and cGMP violations, despite attempts of Mr. Cruz and others to thwart her investigations.

83. On February 15, 2019, Mr. Ruth emailed Ms. Mula to inquire about the status of Ms. Mula's investigation into material dumping that took place at the Branchburg Site over a three- to four- month period in 2018. Ms. Mula responded by providing Mr. Ruth with a detailed recounting of the progression of the investigation in October 2018 and the retaliation she had experienced as a result, including Mr. Muller's decision to remove the investigation from her oversight. She reminded Mr. Ruth of the severity of the underlying wrongdoing which appeared linked to the lack of adequate staffing at the Branchburg Site.

Ms. Mula's Retaliation Complaint

84. On December 5, 2018, Ms. Mula filed a complaint with Mr. Ruth against Mr. Cruz, Mr. Ortiz, and Ms. Wible for their retaliatory actions. She alleged Mr. Ortiz and Ms. Wible retaliated against her through their reports of

baseless accusations against her as well as their efforts to prevent her from performing her job duties and completing investigations.

85. Mr. Ruth forwarded Ms. Mula's retaliation complaint to Mr. Muller. On December 10, 2018, Mr. Muller and Ms. Mula had a meeting in which Mr. Muller angrily expressed his displeasure with the situation. He asked Ms. Mula to offer a resolution for the "dysfunctional environment you've gotten yourself into." He also demanded that she rescind her retaliation complaint without investigation. When Ms. Mula refused to do so, Mr. Muller became agitated and eventually hung up on Ms. Mula.

86. Following their conversation, Ms. Mula emailed Mr. Muller and lamented his lack of professionalism in the face of her serious retaliation concerns.

87. On December 11, 2018, Mr. Ruth called Ms. Mula to discuss her conversation with Mr. Muller. After discussing the call, Mr. Ruth stated that Lilly intended to investigate her retaliation complaint and that an attorney would contact her soon to obtain more information from her. Neither Lilly nor its attorneys contacted Ms. Mula about this matter for the next two months.

88. On February 5, 2019, Ms. Mula informed Mr. Ruth that she had not heard from a Lilly investigator or attorney regarding her complaint.

89. On February 8, 2019, Ms. Mula participated in an interview with Susan Kline, an attorney from Fager Baker Daniels investigating Ms. Mula's

complaint on behalf of Lilly. During the interview, Ms. Mula provided information relating to Lilly's efforts to derail her investigations into regulatory investigations, the baseless allegations against her, and other materials set forth in the retaliation complaint. Ms. Mula also later provided Ms. Kline documentation evidencing her concerns.

90. On March 25, 2019, Ms. Mula met with Monique Hunt McWilliams, a member of Lilly's Legal Department, and Ms. Kline to discuss their investigation into the retaliation complaint. They informed Ms. Mula that they discovered no wrongdoing on Lilly's part, either with respect to the underlying wrongdoing or subsequent retaliation.

Ms. Mula's Refusal to Sign Off on the Ethics and Compliance Declaration

91. During late-2018 and early-2019, high-level complaints were circulating at Lilly suggesting that allegations of violations by Lilly in production were not being properly investigated at manufacturing sites and that Lilly was engaged in legal violations as a result. Due to these rumors, Lilly's Ethics and Compliance Department asked Senior Vice President, Manufacturing Darin Moody ("Mr. Moody") to sign off on an "Ethics and Compliance Declaration" which he subsequently sent to Ms. Clark, who became the Branchburg Site Head in January 2019. Mr. Moody wanted Ms. Mula to sign off on the Declaration as well.

92. On February 4, 2019, Ms. Clark asked Ms. Mula to confirm that she had no open cases and that Lilly had investigated all reports made to her and escalated when necessary. Mr. Ruth and Ms. Mula both found this request, a first during their tenues with Lilly, odd.

93. Mr. Ruth responded to Ms. Clark, affirming that there were open cases involving potential violations and asked to schedule a call.

94. Ms. Mula also informed Mr. Ruth that she could not agree to such a statement because of her several open investigations related to cGMP violations and potential ongoing violations.

95. When Ms. Mula failed to reply to Ms. Clark's email, Ms. Clark called her and insisted she submit a written response. In an effort to avoid getting off on the wrong foot with Ms. Clark, Ms. Mula did not mention the many cGMP investigations she had not been permitted to conclude and listed one example of an open case. This example related to a January 16, 2019, "lockout/tagout[4]" ("LOTO") incident that could have resulted in a fatality from electrocution but was not investigated or escalated. In a separate email to Mr. Ruth, Ms. Mula noted that

[4] A LOTO procedure refers to specific practices and procedures designed to safeguard employees from the unexpected energization or startup of machinery and equipment, or the release of hazardous energy during service or maintenance activities.

while this was "one reckless example of SLT failure to report" she "cannot confirm that it is the only one."

96. In a meeting after Ms. Mula's response, Ms. Clark explained that because Ms. Mula had informed Mr. Ruth of the LOTO violation, Ms. Clark had no choice but to inform her manager, Mr. Moody, who asked that Ms. Mula proceed with an investigation. Ms. Clark asked Ms. Mula to speak with her in person, rather than in writing, on topics related to potential violations and investigations, particularly where those allegations related to Trulicity.

LOTO Violations

97. Following this meeting, Ms. Mula continued to investigate the LOTO noncompliance. On February 26, 2019, Ms. Mula received an email from members of the Maintenance and Engineering Departments informing her that the LOTO incident arose from a persistent failure to follow LOTO-related SOPs. Ms. Mula informed Mr. Ruth of this and noted that the Branchburg Site "historically has not been performing the activities described in compliance with SOP requirements."

98. Subsequently, Ms. Mula, Ms. Clark, and Mr. Ruth held a meeting where Ms. Clark informed Ms. Mula that she was displeased with Ms. Mula's findings of violations and recommendation for discipline. After Mr. Ruth dropped off the call, Ms. Clark stated that she intended to meet with Mr. Ruth and ask that

all documentation evidencing noncompliance with SOPs be "stricken" from Ms. Mula's investigation case notes and that Mr. Ruth reject Ms. Mula's recommendation for disciplinary action.

99. On March 11, 2019, Ms. Mula provided the LOTO investigation findings to SLT members.

100. In a meeting with Ms. Gosen and Ms. Clark, they asked Ms. Mula to record the LOTO issue as performance-based rather than serious safety violation ("SSV").

101. Ms. Mula escalated these issues to Mr. Moody who eventually relented and agreed that an SSV and written warning were appropriate.

102. In a subsequent meeting with Ms. Mula, Ms. Clark remarked that she was unhappy with the level of detail Ms. Mula included in her written communications with senior leaders. Ms. Clark stated that this did not allow her "flexibility" with the outcome of the investigation. Ms. Mula understood this to mean that Ms. Clark did not want evidence documented in writing so that she could act in opposition to the evidence if she decided.

Trulicity Batch Release Investigation

103. In or around March 2019, three PhD scientists working in Lilly's Quality Control Department informed Ms. Mula that Lilly was relying on compromised data in making batch release decisions for Trulicity. They informed

her that the data was being falsified and manipulated in a number of ways, including: (1) improperly repeating tests in order to generate favorable results; (2) relabeling and recycling samples from lots that had already passed; and (3) in some cases, deleting unfavorable data altogether. The scientists noted that Lilly finally detected this manipulation of data and the resulting substandard batch in one of the last tests prior to release, meaning that the discarded batch resulted in losses between $8 to $10 million.

104. Specifically, with respect to the deletion of unfavorable data, testers were declining to report impurity test results that showed an "out of specification" result, used unvalidated calculations to generate acceptable results, which enabled them to release batches based upon manipulated "passing" data. Significant integrity and procedural violations were obscured by Lilly due to multiple issues and vulnerabilities related to quality systems operations.

105. These issues were raised on the heels of the resignations of six trained quality control analysts over an eight-month period, which had resulted in Lilly being forced to rely on unqualified and under trained technicians to conduct tests. Some of these analysts resigned due to the falsifications they were observing.

106. Ms. Mula informed Mr. Ruth of this report by the Lilly scientists. Ms. Mula noted to Mr. Ruth that: (1) the Vice President of Quality Control position had been vacant for 10 months, which had potentially created opportunities for

noncompliant activities in the absence of meaningful oversight; (2) a compliant program would have detected the contamination much earlier, which would have greatly reduced the financial impact to Lilly; (3) the allegations were consistent with related issues Ms. Mula had identified, investigated, and notified Mr. Ruth of in the fall of 2018; and (4) if the allegations were accurate, Lilly needed to initiate a major nonconformance event ("NCE") and inform regulatory agencies of the issue.

107. Within the next week, Mr. Ruth informed Ms. Mula that he had spoken to one of the complainants, had many discussions with Ms. Clark and Ms. Gosen, and had determined that the situation was less troubling than it looked when it was presented to Ms. Mula. Mr. Ruth also declined to raise the matter with Lilly's Vice President of Quality Control Luis Alves.

108. Around the same time, Ms. Gosen met with Ms. Mula to express concerns about the allegations that Lilly was not accurately determining pharmaceutical stability of its products and asked what details Ms. Mula could provide. Ms. Mula relayed the details relating to Trulicity and reminded Ms. Gosen of the multiple issues in the Manufacturing Department dating back to 2018 that had never been explained, examined, or addressed. Ms. Gosen acknowledged that there had been an increase in "cutting corners" in the Manufacturing and Quality Departments due to staffing issues and Trulicity supply demands.

109. During the week of March 18, 2019, Ms. Mula met with Ms. Clark who accused Ms. Mula of being responsible for the $8-$10 million Trulicity product loss. Ms. Clark stated that given Trulicity's tremendous revenue generation and sales growth for Lilly, "we don't want to mess with Trulicity." Ms. Mula responded that if Lilly was knowingly manipulating quality control results for Trulicity, then the quantity and strength of the product that Lilly was distributing was substandard and Lilly could be subjected to serious lawsuits, such as a False Claims Act lawsuit, or regulatory penalties by the Government.

110. Ms. Clark then told Ms. Mula that she now understood why Mr. Cruz wanted to have Ms. Mula removed from the Branchburg Site. She also said that it was not Ms. Mula's job to evaluate risk; instead that was the job of leadership and they had made the decision to protect Trulicity against such allegations. She then told Ms. Mula that because Mr. Ruth had refused to comply with the requests of the Branchburg leadership to remove Ms. Mula from the Site, she would "resurrect" the request and escalate it to Ms. Martin.

111. Later that day, Ms. Mula spoke with Mr. Ruth and informed him of Ms. Clark's threats to remove her for her opposition to legal violations relating to Trulicity. Mr. Ruth confirmed that Ms. Clark was upset by Ms. Mula's comment that batches of Trulicity may be "substandard," to which Ms. Mula repeated her

concerns that the quality, purity, and safety of many batches of the drug were uncertain.

Lilly's Retaliatory Elimination of Ms. Mula's Position

112. On February 28, 2019, Mr. Ruth emailed Ms. Mula to inform her that he had rated her as "sufficiently met expectations" in 2018. Despite this, Mr. Ruth informed Ms. Mula that Lilly had not awarded her a merit increase. With the exception of two years during which time Lilly had frozen salary increases for all US-based employees, this was the first time in Ms. Mula's fifteen years of employment with ImClone and Lilly that she did not receive a merit increase.

113. On March 26, 2019, the day after Lilly's attorneys concluded their alleged investigation of her retaliation complaint, Mr. Ruth sent her an invitation to a Skype call for March 28, 2019.

114. On March 28, 2019, Ms. Mula arrived at her office and noticed that a locked drawer in her desk had been emptied. Among the missing items was her Trulicity investigation file, which included information related to the out-of-specification testing results; the shortage of qualified analysts to conduct required testing; documentation irregularities; and other procedural violations.

115. During her meeting with Mr. Ruth, he informed her that Lilly had eliminated her position. He explained that Lilly had decided to centralize its Employee Relations services to Indianapolis. He informed Ms. Mula that he was

not part of the "decisional unit," and could no longer push off the decision due to "pressure from the business."

116. Mr. Ruth repeatedly made it clear that Lilly's decision was not performance related, a position reiterated in a letter Lilly sent to Ms. Mula months later. Mr. Ruth stressed that he had been "very impressed" by her during his time as her supervisor, noting that he had never received negative feedback about her before October 2018, i.e., when the backlash arose to Ms. Mula's opposition to systematic, regulatory non-compliance at the Branchburg Site.

117. Mr. Ruth later informed Ms. Mula that those in the "decisional unit" included: Ms. Martin, the individual to whom Ms. Clark escalated her "resurrected" request to remove Ms. Mula from the Branchburg Site after she pressed Ms. Clark about Trulicity-related compliance issues; Mr. Fry, Ms. Mula's third-level supervisor; and Mr. Moody, Ms. Martin's, Ms. Clark's and Mr. Cruz's supervisor.

118. On the date of Ms. Mula's conversation with Mr. Ruth, external security contractors monitored Ms. Mula's movements throughout the Branchburg Site at the request of Mr. Ortiz, Ms. Clark and Mr. Cruz. One such contractor almost followed Ms. Mula into the women's restroom, and another followed Ms. Mula by car during part of her commute home.

119. Ms. Mula's position was eliminated, effective April 1, 2019. She was given a reallocation period beginning April 5, 2019, and continuing until June 28, 2019.

120. In mid-April 2019, Ms. Mula's employee badge was disengaged and she was placed on a security "look-out list" thereby interfering with her ability to meet with Lilly employees during the reallocation period. This occurred ahead of Mr. Fry's planned visit to the Branchburg Site in May 2019 where he committed to meeting with Ms. Mula to address concerns she had regarding her job elimination and accusations of non-investigations. Ms. Mula was also unable to recover certain personal items left in her office.

121. A few weeks after Ms. Mula's position was eliminated, during her reallocation period, Ms. Wible hosted an off-site gathering with several current and former Lilly Quality Department employees who could be in a position to influence Ms. Mula's ability to obtain employment during the reallocation period. She informed these individuals that Ms. Mula's departure from Lilly had been a "termination disguised as a job elimination," due to Ms. Mula's inability to "get along" with leadership at the Branchburg Site. Ms. Wible expressed relief that Ms. Mula was gone.

122. All conditions precedent to the filing of this lawsuit have been met, have been satisfied or have been waived.

123. This action is timely filed as it is brought after the termination of a tolling agreement between Plaintiff and Defendant entered into on September 19, 2019 (the "tolling agreement") by proper notice on May 24, 2022. The tolling agreement suspended the limitation period on Plaintiff's claim herein from September 19, 2019 through June 3, 2022.

COUNT I
(Retaliation in Violation of the New Jersey Conscientious Employee Protection Act, N.J.S.A. § 34:19-1 *et seq*)

124. Plaintiff incorporates by reference and realleges each and every allegation contained in paragraphs 1-123 of this Complaint with the same force and vigor as if set out here in full.

125. The CEPA provides, in relevant part, that an employer may not take retaliatory personnel action against an employee who objects to, or refuses to participate in any activity, policy, or practice which the employee reasonably believes is in violation of a law, or a rule or regulation promulgated pursuant to law, or is fraudulent or criminal, including any activity, policy or practice of deception or misrepresentation which the employee reasonably believes may defraud others; or is incompatible with a clear mandate of public policy concerning the public health, safety or welfare.

126. Additionally, the CEPA provides, in pertinent part, protection of an employee that discloses, or threatens to disclose to a supervisor or to a public body

an activity, policy, or practice of the employer that the employee reasonably believes is in violation of a law, or a rule or regulation promulgated pursuant to law, including any violation involving deception of, or misrepresentation to, any shareholder, investor, client, patient, customer, employee, former employee, retiree or pensioner of the employer, or any governmental entity, or, in the case of an employee who is a licensed or certified health care professional, reasonably believes constitutes improper quality of patient care; or is fraudulent or criminal, including any activity, policy, or practice of deception or misrepresentation which the employee reasonably believes may defraud any shareholder, investor, client, patient, customer, employee, former employee, retiree or pensioner of the employer or any governmental entity.

127. Plaintiff Mula is an "employee" as defined under the CEPA.

128. Defendant Lilly is an "employer" of Plaintiff as defined under the CEPA.

129. As described above, Plaintiff objected to, and reported to her supervisors, Defendant's serious violations of law, rule or regulation, including but not limited to the issues surrounding the manufacture of drugs at Defendant's Branchburg Site that Plaintiff reasonably believed were occurring.

130. As described above, Plaintiff's objections included violations involving deception of, or misrepresentation to, any shareholder or investor of Defendant Lilly, a public company with stockholders.

131. The laws, rules, or regulations violated by Defendant as well as deception and misrepresentation, as set forth herein, are within the meaning of the CEPA.

132. At all times relevant herein, Plaintiff reasonably believed that Defendant's acts and omissions were violations of laws, rules or regulations and she objected to, and refused to participate in, Defendant's activities, policies and practices alleged herein.

133. Defendant took intentional retaliatory action against Plaintiff, including but not limited to termination of her employment, because Plaintiff objected to, and refused to participate in, Defendant's activities, policies and practices alleged herein that are in violation of the CEPA.

134. The acts and omissions committed by Defendant Lilly directed against Plaintiff Mula were willful, wanton, intentional, conscious and malicious, and in deliberate disregard of Plaintiff's rights.

135. Furthermore, the retaliatory acts by Defendant Lilly against Plaintiff Mula were based upon Plaintiff Mula's protected activity under CEPA and were especially egregious. At all times relevant herein, Defendant Lilly's upper

management employees, including those in the SLT, actually participated in, or were willfully indifferent to, the wrongful conduct perpetrated against Plaintiff Mula.

136. As a direct and proximate result of the unlawful retaliatory actions of Defendant, Plaintiff Mula has suffered and will continue to suffer damages, including lost wages, benefits and entitlements, damage to her career and reputation, personal humiliation, mental anguish, and embarrassment, and other compensatory and punitive damages.

WHEREFORE, Plaintiff Amrit Mula respectfully requests that this Honorable Court grant the following relief:

(A) Enter judgment on behalf of Plaintiff against Defendant on all counts herein;

(B) Award Plaintiff reinstatement and other injunctive relief due to Defendant's wrongful termination of her employment plus pre- and post-judgment interest;

(C) Award compensatory damages to Plaintiff making her whole, including for mental and emotional distress, mental pain and suffering, humiliation, loss of dignity, loss of enjoyment of life, expenses, damage to her career and reputation;

(D) Award Plaintiff punitive damages for Defendant's willful violations;

(E) Award to Plaintiff reasonable attorneys' fees, costs of suit, all litigation costs allowable, and pre-judgment and post-judgment interest; and

(F) Grant such other relief to Plaintiff as this Court may deem fair and just.

REQUEST FOR JURY TRIAL

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

Dated: June 6, 2022

Respectfully submitted,

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