UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

AMERIDOSE, LLC)	
A Massachusetts Limited Liability Company	·,)	
Plaintiff,)	
)	
v.)	CASE NO.
)	
NOVATION, LLC,)	
A Delaware Limited Liability Company;)	
Defendant.)	
	_)	

PLAINTIFF'S COMPLAINT AND JURY DEMAND

INTRODUCTION

This Complaint is brought by Ameridose, LLC ("Ameridose"), a Massachusetts Limited Liability Company, to compensate it for the substantial damage caused by the willful scheme to substantially injure Ameridose by Novation, LLC ("Novation"), a Delaware LLC, with a principal place of business in Irving, Texas.

As more fully set forth below, Novation committed and orchestrated a series of purposeful and calculated acts with specific intent to permanently and irreparably damage Ameridose's business reputation and to interfere with Ameridose's contractual relationships with medical care providers across the nation, all for the purpose of increasing its own profits, and for the purpose of directing these business relationships to a major competitor of Ameridose.

Ameridose's complaint sounds in claims for Defamation by Slander, Defamation by Libel, Breach of Contract, Intentional Interference With Advantageous and Contractual Relations and Massachusetts General Laws Chapter 93A § 11.

Because Novation's conduct far surpasses the requisite "level of rascality that would raise an eyebrow of someone inured to the rough and tumble of the world of commerce" Ameridose seeks, among other things, treble damages and reimbursement of reasonable attorney's fees, as allowed under M.G.L. Ch. 93A §11.

Parties, Jurisdiction and Venue

- 1. Plaintiff Ameridose LLC ("Ameridose") is a Massachusetts Limited Liability Company, with a principal place of business in Westborough, Massachusetts.
- 2. Novation LLC ("Novation") is a Delaware Limited Liability Company and upon information and belief its principal place of business is located in Irving, Texas.
- 3. This Court has jurisdiction over this matter pursuant to 28. U.S.C. § 1332 (a) (1) since the amount in controversy is in excess of \$75,000 and is this matter is between citizens of two different states.
- 4. Venue is proper in this court, because the Plaintiff is a resident of Massachusetts, the Defendant traveled into Massachusetts, signed a non-disclosure agreement dictating Massachusetts as the proper venue for all disputes, the Defendant regularly conducts business in Massachusetts and the injury to Ameridose occurred in Massachusetts.

Background

- 5. Novation is a Group Purchasing Organization (GPO), in the heath care supply field, which leverages purchasing power of a group of businesses to obtain discounts from vendors based on the collective buying power of the GPO members.
- 6. When Novation negotiates and executes a contract with a particular vendor such as Ameridose, Novation's members then have the option of purchasing products and/or services under that contract. Members may also contract directly with vendors, such as Ameridose, without participating in a contract with Novation.
- 7. Upon information and belief, it is Novation's usual and customary practice to involve its Pharmacy Executive Council when contemplating entering into a new contract, or revising an existing contract, or terminating a contract.
- 8. Ameridose is in the business of producing and delivering pharmacy products and services to hospital pharmacies nationwide.
- 9. In the area of producing and delivering pharmacy products and services to hospital pharmacies, Ameridose is the market leader in quality, service and number of hospitals served.

- 10. Ameridose employs hundreds of employees including hundreds of licensed, registered and certified technicians and pharmacists.
- 11. As the market leader, Ameridose currently provides sterile admixing and oral dose repackaging services to over 3000 hospitals nationwide including hundreds of Novation affiliated facilities. Ameridose works closely with each hospital's Director of Pharmacy to provide only the highest quality medications to insure outstanding patient care and safety.
- 12. To date, Ameridose has expertly produced and dispensed millions of doses to the complete satisfaction of its customers and their patients.
- 13. Ameridose holds the most registrations and licenses in their industry in the nation (over 250 licenses and registrations). Ameridose is permitted to ship medications into all fifty (50) states.
- 14. Many of the licenses and registrations held by Ameridose require a pre-licensure inspection by the licensing agency. All of Ameridose's licenses and registrations require annual or biannual renewal. As such Ameridose is continually being reevaluated and re-examined by the applicable regulatory agencies.
- 15. Ameridose has an outstanding registration and licensure record in all fifty states.
- 16. Ameridose is licensed and/or registered with the United States Food and Drug Administration (FDA), the United States Drug Enforcement Agency (DEA), the Massachusetts Department of Public Health ("MA DPH") and Massachusetts Board of Registration in Pharmacy ("MA BOP").
- 17. During the last three years, Ameridose has been inspected twice by the FDA, three times by the DEA, once by the MA DPH and three times by the MA BOP. All of the aforementioned inspections have resulted in "No Findings" by the respective regulatory agencies.
- 18. In the last several years, many of Ameridose's customers, vendors, representatives of Integrated Delivery Networks ("IDN") and Group Purchasing Organizations ("GPOs") have visited Ameridose's facilities. In each and every case, Ameridose received excellent audit results. These other customers include many of Novation's own member hospitals and hospital groups. For example, just eight (8) months prior to Novation's visit, a team of auditors from one of Ameridose's customers and a Novation member, visited Ameridose's facilities and gave Ameridose outstanding audit results. Representatives from at least four (4) world renowned hospitals and many others have visited during the last eighteen (18) months. In fact, just three days after Novation's visit to Ameridose, representatives from another major GPO, visited all of Ameridose's facilities. All of these audit teams determined that Ameridose's Quality Systems and facilities meets or exceeds their high quality standards.

19. Essentially, Ameridose has only one primary competitor in the industry (the "Competitor").

The Purchasing Supply Agreement

- 20. For many years, with respect to the products and services offered by both Ameridose and its Competitor, Novation contracted solely with the Competitor.
- 21. Without any involvement from Novation, Ameridose has directly contracted with, and continues to contract with, hospitals around the country, who are members of the Novation GPO network. In many cases, by dealing directly with Ameridose (and not Novation, nor its primary vendor the Competitor) the hospital/customers were able to procure high quality medications from Ameridose and achieve better results for their pharmacy department and their patients in the areas of medication availability, timeliness of deliveries and price.
- 22. Upon information and belief, for many years, with respect to the products and services offered by both Ameridose and the Competitor, Novation attempted to have its member hospitals only procure those products and services through Novation (using the Competitor as its primary vendor) while at the same time refusing to permit Ameridose to provide its products and services through a Novation contract.
- 23. For several years, Ameridose directly contracted with the University of Virginia Medical Center and Virginia Commonwealth University Medical Center, both of whom are members of the Novation GPO network.
- 24. After several years of discussions, on or about January 1 2009, Ameridose and Novation, on Behalf of Members: University of Virginia Medical Center and Virginia Commonwealth University Medical Center, entered into that certain Product Supplier Agreement # RX 91040 (the "Virginia Hospital Agreement").
- 25. Ameridose continued to expand its direct relationships with Novation member hospitals while simultaneously becoming the pharmacy outsourcing/admixing industry leader.
- 26. Ameridose now provides its products and services to approximately six hundred (600) Novation member hospitals.

- 27. On or about January of 2011, Ameridose and Novation entered into a written "Pharmacy Supply Agreement" ("the Novation Agreement") wherein Novation agreed to allow Ameridose to provide a very limited number of products and services to its member hospitals. The term of the Novation Agreement was from January 1, 2011 until January 1, 2014. Ameridose attempted at the time of contract execution to expand the number of products and services that could be offered to Novation's member hospitals, however for no apparent reason, Novation flatly refused to do so.
- 28. On or about June 1, 2012 Ameridose and Novation entered into an Addendum Aggregation IDN Agreement, amending the terms of the Virginia Hospital Agreement.
- 29. Pursuant to the terms of the Novation Agreement and the amended Virginia Hospital Agreement, the termination of the Novation Agreement would also act to terminate the Virginia Hospital Agreement.
- 30. Pursuant to section 4 (B) of the Novation Agreement, either party could terminate the Novation Agreement without cause, by giving ninety (90) days written notice (a "Termination Without Cause").
- 31. Additionally, pursuant to section 4 (B) (1) (b) of the Novation Agreement, either party could terminate the Novation Agreement by notifying the other party of a breach and giving the breaching party thirty (30) days to cure the alleged breach (a "Cure").

The Facility Tour

- 32. On or about, April 13, 2012, Ms. Camille Ricci, Portfolio Executive of Novation contacted Mr. William Douglas, National Vice President of Sales of Ameridose to inquire about sending a Novation auditor, Ms. Pam Anderson, Director of Quality Assurance and Regulatory Affairs, to Ameridose for a visit. This request was made by Ms. Ricci under the guise of expanding the relationship between the parties to include additional products and services provided by Ameridose at Novation's request. Ms. Ricci also pointed out that Ms. Anderson was new to Novation. On or about June 15, 2012, two of Novation's employees traveled to Massachusetts for the purpose of auditing Ameridose's facilities.
- 33. Both of Novation's employees, Camille Ricci ("Ricci") and Pam Anderson ("Anderson") (collectively the "Novation Employees"), signed Facility Tour Confidentiality and Non Disclosure Agreements prior to their arrival at Ameridose.
- 34. According to the Novation Employees, the reasons they wished to tour the Ameridose facilities were to perform a routine "audit" of the conditions at the Ameridose facilities.

- 35. The Novation employees arrived at Ameridose's facilities in Westborough, Massachusetts. However, as the tour occurred, Ameridose learned, from statements made by the Novation Employees that neither were registered Pharmacists and that neither of them had any prior experience auditing a facility such as Ameridose. Specifically, Anderson stated she had only been employed by Novation for several months since March of 2012.
- 36. Additionally, during the visit, it became apparent that the Novation Employees had, at best, a woefully inadequate level of knowledge of the business in which Ameridose is involved or the products and services Ameridose provides to its hospital clients, or the pharmacy outsourcing/admixing industry generally. For example, at one point during the visit, Ricci shockingly and absurdly asked whether Ameridose actually refilled used medical devices, returned to Ameridose by its hospital clients.
- 37. The fact that Ricci was completely unaware that such a "recycling program" for single-use medical devices would violate numerous rules, regulations and laws—which were the same rules and regulations the Novation Employees were purportedly there to evaluate Ameridose on--was astounding and quite disturbing.
- 38. By way of further example, Anderson lacked any understanding as to the difference between re-packaging oral dose medications in a non-sterile environment and admixing sterile medications in a clean room environment. By definition, oral dose medications are non-sterile. Oral medications are administered orally and as such are not required to be made from sterile ingredients, nor produced in a sterile admixing clean room. These distinctions were repeatedly explained to Ms. Anderson, to no avail.
- 39. Moreover, virtually no time was spent by the Novation Employees examining what every other similar auditor has examined—the method Ameridose uses to admix medications and the condition of Ameridose's "production clean rooms."
- 40. Ameridose has numerous state of the art production clean rooms and processes which were not viewed, examined nor inspected, in any meaningful or typical way.
- 41. Thus, Novation arranged for a purported tour or audit of Ameridose's facilities under the guise of expanding Ameridose's business with Novation hospital members, but the audit was unprofessional, superficial and not designed for anything but to manufacture issues to be used in Novation's plan to damage Ameridose.

The "Audit Report" and Termination Without Cause

42. Upon information and belief, on or about July 30, 2012, before Ameridose was even notified of the Novation audit findings, Ameridose was called by a representative of

- a Novation member hospital and questioned because they had been advised by Novation that Ameridose had "failed" their audit and that soon Novation would be cancelling the Novation Agreement and recommending the transferring of all of that hospital's business to the Competitor.
- On or about July 31, 2012 Novation's Employees and the Ameridose team members 43. who had participated in the Novation Audit on June 15, 2012 arranged a conference call. Participating in the call from Novation were Mr. David Jameson RPh, Vice President, Pharmacy; Ms. Camille Ricci, Portfolio Executive and Ms. Pam Anderson, Director of Quality Assurance and Regulatory Affairs and from Ameridose were Mr. Gregory Conigliaro, Executive Vice President and General Manager; Ms. Sophia Pasedis, Vice President of Regulatory Affairs and Compliance; Ms. Melanie Cerullo, Vice President of Quality; Mr. William Douglas, National Vice President of Sales and Mr. Sean Fadden, National Accounts Manager. It was only, then, during the call that Ameridose was first advised of Novation's alleged findings during the audit and Ms. Ricci stated that a letter had already been generated terminating the Novation Agreement, and in kind the Virginia Hospital Agreement without cause effective in ninety (90) days pursuant to the terms of the Novation Agreement. It was made clear by the Novation representatives on the call, that the contract was not being canceled under the cure provisions of the contract and as such Ameridose would not be afforded any ability to respond to the alleged findings and that the contract was terminated effective October 30, 2012. Even though the two auditors, and their supervisor, were on the call, in response to Ameridose's incredulous questions about the audit's false and misleading results and their rush to judgment based upon those false and misleading results, Ameridose representatives were told by Mr. Jameson that there was no recourse and Ameridose should "take it up" with Novation's legal department.
- 44. On or about August 1, 2012, a day after the Novation Agreement was terminated orally on the conference call, for the first time, Novation provided Ameridose with a copy of a document entitled "Novation Audit Report" dated June 15th, 2012 (the "Audit Report").
- 45. At the same time Ameridose was first shown the "Audit Report" on or about August 1, 2012, Novation provided Ameridose with a letter entitled "TERMINATION WITHOUT CAUSE" (the "Termination Letter") dated July 31, 2012 that notified Ameridose that pursuant to the Novation Agreement, in 90 days, Novation would terminate the Novation Agreement.
- 46. The Audit Report provided by Novation was grossly inadequate, improper, negligently prepared and upon information and belief, intentionally misleading.
- 47. Specifically, the Audit Report did not provide sufficient detail about each alleged finding to adequately describe the alleged non-conformity nor the proper foundation to support the conclusions stated. This lack of information prevented Ameridose

from responding to each finding, or determining whether any potential corrective actions should be taken. Additionally, the standardized process or definitions used to classify the findings (i.e. "Critical" or "Major") was not and has not been provided. Moreover, Novation made it impossible for Ameridose to comment on the report, since Novation delivered the report simultaneously with the termination letter, which did not allow Ameridose to cure any alleged issues.

- 48. In absence of a standardized classification process, the audit findings are on their face arbitrary and capricious and contain many malicious and intentional misrepresentations solely and exclusively designed to damage Ameridose.
- 49. In issuing the Audit Report, Novation completely ignored the accepted practice of utilizing industry guidelines such as those published by the American Society of Hospital Pharmacists ("ASHP"), the American Society of Quality (ASQ) or the International Organization for Standardization (ISO)when conducting their audit. These guidelines are meant to ensure that quality audits are conducted properly and provide objective, unbiased evaluations of an auditee that are supported by well documented evidence. Upon information and belief, both Ms. Ricci and Ms. Pam Anderson are not, and never have been, Registered Pharmacists or Certified Quality Auditors, nor do they have any prior experience working in a hospital pharmacy or at any regulatory agency with auditing responsibilities in the pharmacy outsourcing/admixing industry.
- 50. Specifically, the Audit Report is insufficient in that it does not document the specific facilities visited, the areas that were toured (warehouse, shipping, laboratories, offices, etc.), the documents reviewed, nor the process the audit followed.

Finding 1

- 51. Specifically, in Finding 1 the Novation Employees stated "There is no separation between sterile and non-sterile products in the warehouse." This statement is false, and completely ignores what the Novation Employees observed and were told repeatedly during the tour.
- 52. During the tour, one of the Novation Employees verbally noted that "non-sterile tubing" was located in the same general area as "sterile tubing" in the warehouse area, an area that is geographically separated from all production areas. (In fact, the sterile and non-sterile tubing were stored separately, in an orderly fashion, were separately boxed, separately labeled and independently bar coded and were clearly marked). The Novation Employees were told that the non-sterile tubing was actually standard pharmacy fluid transfer tubing, used for repackaging oral syringes in the oral dose repackaging area, which is by definition, non-sterile.
- 53. The Novation Employees were also informed that because each type of tubing is different in size and shape and because of their unique design and fittings, the tubing

sets at issue would be unable to be used interchangeably. Had either of the auditors been registered pharmacists or technicians with even basic knowledge of how tubing is utilized to admix or repackage medications, this inability for the two types of tubing to be used interchangeably would have been immediately understood.

- 54. The statement that "there was no separation" between these materials is completely false, since there was separation between both materials. And in fact, the regulatory reference cited in Finding 1 (21 CFR 211.42(b)) does not define the amount of separation, the process for separation, or even use the term separation. It merely states that "Any such building shall have adequate space for orderly placement...to prevent mix-ups between different components..."
- 55. In fact, Ameridose satisfactorily meets the industry's Good Manufacturing Practice ("GMP") requirements in that the materials were placed in an orderly fashion and separated such to prevent a mix-up. And yet, Finding 1 provided no facts or evidence to indicate what was allegedly observed or how what was observed represented a nonconformity with respect to 21 CFR 211.42(b).
- 56. Additionally, the Novation Employees were informed on multiple occasions during the audit that the use of the phrase "non-sterile products" when describing repackaged oral dose medications and/or tubing was misleading and that the Novation Employees should use the exact description for what was observed. Although during the tour the Novation Employees acknowledged this point and stated that they would make a note of that information in the audit report, the Novation Employees, in fact, completely ignored that point.
- 57. Finding 1 was classified by the Novation Employees as "Critical" despite a lack of explanation as to what criteria was used to label something "Critical." The fact that Novation Employees falsely deemed an extremely minor issue such as the method of storage of tubing sets in the warehouse, an area of Ameridose's facility that is geographically separate from all production areas, as a "Critical" finding is not logical or substantiated and makes it evidently clear that Novation's true motives were simply to trump up any excuse to create an issue to use as criticism towards Ameridose and damage its reputation in the industry.

Finding 2

- 58. Specifically, in Finding 2 the Novation Employees stated "there is no standardized procedure in place to ensure new compounded sterile preparations ("CSP") or different dilutions of the same (CSP) are tested through the end of stability to establish BUD prior to releasing for commercialization."
- 59. This statement is an outright fabrication. In fact, not only is there is a standardized process in place ensuring the stability of Ameridose products (SOP 9.050 version 4.0 "Stability Program"), that policy was shown to the Novation Employees and read by the Novation Employees.

- 60. SOP 9.050 version 4.0 "Stability Program" specifically outlines the procedure used to ensure the stability of Ameridose products, clearly defining the SOP's purpose and scope.
- 61. While reviewing this SOP, one of the Novation Employees commented that the SOP did not contain a clear statement stating that stability should be assessed prior to issuing a product. However, that comment was false, since Section 10.1 of the SOP clearly states that "stability shall be evaluated prior to an assignment of an expiry date", a prerequisite for issuing a product.
- 62. One of the Novation Employees asked to see specific information documenting that stability was assessed prior to issuing a new product-line and Ameridose immediately provided the Novation Employees documents for a new product called "Propofol" which was the most recent product-line issued. That documentation clearly showed that all required testing and evaluation was completed in mid-2011, well prior to the issuance of the product line in April 2012.
- 63. The Novation Employees acknowledged that this testing was completed prior to the issuance of the product line, yet all of this (the policy and the past practice of following the policy) was completely ignored by the Novation Employees.
- 64. Therefore, Finding 2 is not only completely false, it is at odds with the verbal statements made by the Novation Employees during the audit and therefore shows that Novation's Audit Report does not simply suffer from gross incompetence, rather it is a product of malicious intentional misrepresentation designed to damage Ameridose. Nevertheless, Novation Employees not only cited this in their Audit, they classified this issue as "Major" which is an outright fabrication.

Finding 3

- 65. Specifically, in making Finding 3 ("There is no system in place to review and confirm whether the organization's internal specification meet or exceed USP/NF specifications"), the Novation Employees blatantly ignored information they were given and intentionally failed to specify in a specific, meaningful way the alleged nonconformity.
- 66. During the audit one of the Novation Employees commented that Ameridose did not have a specific statement in an SOP that stated that personnel should review "current USP requirements in order to ensure that annual changes to the compendia are captured in internal documentation". (The United States Pharmacopeia Convention ("USP") is a scientific, nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements

- manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the Food and Drug Administration.)
- 67. Ameridose explained that Ameridose's management is aware of, and routinely reviews changes to the USP and routinely makes updates to relevant documents whenever necessary. In addition, the Novation Employees were told that Ameridose's Vice President of Regulatory affairs, Ms. Sophia Pasedis, is a nationally recognized expert on "Pharmaceutical Compounding Sterile Preparations," (also known as "USP <797>"). USP <797> is the first set of enforceable sterile compounding standards issued by USP. It describes the guidelines, procedures and compliance requirements for compounding sterile preparations and sets the standards that apply to all settings in which sterile preparations are compounded. Not only do Ameridose's Quality Systems exceed USP, they also comply with current Good Manufacturing Practices, "cGMPs".
- 68. During this portion of the audit the, Novation Employees simply stated they thought Ameridose should have a requirement in their SOP that states that current USP requirements should be assessed against internal procedures to ensure alignment. Once again, Ameridose responded by telling the Novation Employees all SOPs were routinely updated to reflect current applicable parameters of USP.
- 69. Based on that limited exchange, the Novation Employee falsely and maliciously misrepresented in their Audit report that there was no system in place to update the SOPs. That statement is false for a number of reasons, including the fact that in reality there is no requirement whatsoever for "reconstituted in-process" solutions and even if applied, Ameridose's practice was well within the permitted range.
- 70. Nevertheless, Novation Employees not only cited this in their Audit, they classified this issue as "Major" which is an outright fabrication.
- 71. Thus, Novation did not terminate the existing contract between the parties "for cause" (which would have been the usual and customary practice for terminating a contract based on quality issues). Rather, Novation terminated the agreement for convenience, thereby providing Ameridose with ninety (90) days notice of termination, allowing the relationship to continue during that time.
- 72. Clearly, Novation terminated the contract in this manner so as to deny Ameridose the opportunity to respond to the manufactured findings of the audit, and/or prevent Ameridose from being able to remedy any alleged issues.
- 73. In addition, at no time either during their visit, or in their Audit Report did the Novation Employees identify or report any specific product quality or patient safety issue, concern or finding.

The Dissemination of False and Damaging Statements

74. On or about August 2, 2012, the day after Ameridose received the Termination Letter Novation's Pharmacy Department sent an e-mail to Novation's Pharmacy Council Members stating:

Dear Council Members,

We committed to perform a quality audit of the pharmacy compounders we have national agreements with, Ameridose Pharmaceuticals, LLC and PharMEDium Services.

Our Director of Quality performed quality audits of both company's facilities.

Novation determined that Ameridose has material quality systems issues and does not meet the requirements needed to maintain a Novation agreement. Therefore, Novation is terminating its agreement with Ameridose Pharmaceuticals, LLC (RX11010), effective October 30, 2012. (Emphasis supplied).

Thank you,

Pharmacy Department Novation, LLC. 972.581.5129 Novation Customer Service (888) 7/NOVATE

75. Also on August 2, 2012, Novation (through one of its owners, VHA) sent a newsletter to members of Novation that contained the following language:

Contract Termination: AmeriDose Pharmaceuticals (RX11010)

Classes of Trade: Acute, Ambulatory, Home Health, Long Term Care, Physician Clinics/Offices

Novation is terminating its agreement with AmeriDose Pharmaceuticals LLC (RX11010), effective in 90 days, on Oct. 29, 2012. Novation has determined that AmeriDose does not meet the quality systems requirements needed to maintain a Novation agreement.

AmeriDose currently offers pharmaceutical compounding. The pharmacy compounding national agreement is a dual-source award. Following the termination of the AmeriDose agreement, Novation will still offer pharmacy compounding to members through PharMedium Services(RX88270).

For information, contact Camille Ricci, portfolio executive, at (972) 581-5199 or cricci@novationco.com.

(The "Newsletter Communication" Emphasis Supplied)

While at this time it is unknown how many people and/or entities to whom the Newsletter Communication was transmitted, upon information and belief, Novation has over 1500 hospital members, including 1350 members who are affiliated with one of its owners, VHA, and 300 of which are members of United Health Care, which has some of the largest hospitals in the country as members.

- 76. The obvious import of this written communication which contained material, damaging, misleading and erroneous statements was that the Novation Agreement was terminated by Novation for cause, due to quality issues which is contrary to the express statements made in Novation's own written Termination Letter.
- 77. Upon information and belief, on or about August 3, 2012 another customer of Ameridose, who is also a member of Novation, spoke to Novation to inquire about the information Novation had transmitted regarding the termination of the Novation Agreement. During that phone call, representatives from Novation told this customer that:
 - a) During the audit done by the Novation, it was determined that Ameridose did not meet standards for P &P, testing, and dating and that those deficiencies in those areas <u>rose to a level of concern for patient safety</u>, sufficient to terminate the agreement; and
 - b) Due to the fact that Novation signed a non-disclosure agreement, Novation could not provide specifics, only general statements.
- 78. The oral communication made by Novation Employees containing false and defamatory statements concerning alleged quality deficiencies that rose to the level of creating patient safety risks, greatly damaged Ameridose.
- 79. Novation made such statements purposefully and yet refused to release the full report to its members despite request to do so, thereby preventing hospitals from being able

to make their own determination, all under the pretext that Novation was required to comply with the terms of a non-disclosure agreement it had signed.

- 80. In addition, another customer, a member of Novation's Pharmacy Executive Council, who received the August 2, 2012 communication containing false and damaging statements about Ameridose, left a message for Novation employee, Ricci to call that customer. This customer, even though a member of Novation's own Pharmacy Executive Council, (a council which is customarily involved in major decisions regarding Novation and pharmacy outsourcing/admixing contracts) was never informed of the audit results or the decision to terminate the contract prior to receiving notice via the VHA newsletter.
- 81. In response to that voicemail, this customer received a phone call from David Berry, who identified himself as legal counsel to Novation, and Ms. Pam Anderson.
- 82. Among other things, during that phone call this customer was told that during an audit of Ameridose's competitor, Pharmedium, Novation employees had found an issue with PharMedium and PharMedium responded immediately to correct the situation.
- 83. In response to this customer asking how Ameridose had responded to their findings, Novation stated that they did not share their detailed findings with Ameridose, before issuing the report or the Termination Letter (in fact they did not share any findings prior to issuing the termination letter).
- 84. The customer asked Novation whether they thought that was unusual, since even the FDA shares their findings with the entity under audit, so that the entity can correct the situation. Novation admitted that it was unusual, but claimed it was not unprecedented and Novation was within their rights to terminate the contract as they did.
- 85. When the customer asked whether Novation would share their findings with that customer, the customer was told that Novation could not do that, since Novation had signed a non-disclosure agreement with Ameridose before the survey.
- 86. Thus, on the one hand Novation has sent numerous written communications via emails and a newsletter and orally stated that Ameridose did not meet the quality systems requirements needed to maintain a Novation agreement and that alleged deficiencies rose to a level of concern for patient safety, yet at the same time they have stated they could not share specific findings with its members because Novation was bound by a non-disclosure agreement.
- 87. As has been described, upon information and belief, even before Ameridose was called and notified of the Novation findings, Novation told at least some of its members that Ameridose had "failed" their audit and that soon Novation would be

- canceling the Novation Agreement and transferring all of that business to Ameridose's primary competitor.
- 88. By failing to involve its own Pharmacy Executive Council in its process as is the norm and by refusing to release the audit report under the guise of complying with the non disclosure agreement, Novation intentionally and purposefully has allowed the doubt and innuendo of quality and patient safety to spread throughout the industry, with no ability for the Ameridose customers to review the unfounded, erroneous and unprofessional audit results and findings to examine their true content that the audit results are unfounded, false and solely designed to damage Ameridose.
- 89. Novation's conduct and actions in terminating the Novation Agreement for a "without cause" basis, and purposely not invoking the contract's "cure" provisions, shows that Novation did not want to provide Ameridose with any opportunity to respond, or to cure, or to remedy the situation and was a calculated move specifically designed to deny Ameridose the ability to defend itself in the industry.
- 90. By releasing the overall conclusion of the audit, without the specific findings, Novation has intentionally placed the member customers in a position where they cannot judge for themselves the lack of veracity and objectiveness of the audit, forcing Ameridose to either now release a document that it finds to be ludicrous and untrue, or allow third parties to continue to believe the more damaging blanket conclusions published by Novation.
- 91. Novation's breach of the non-disclosure agreement, the purported audit itself, the refusal to share the full audit report and, Novation's false misleading and damaging statements, all taken together, formed an intentionally misleading message, disseminated by Novation for the sole purpose of creating innuendo and suspicion as to the quality of Ameridose's products and damaging Ameridose's pristine record of product quality and patient safety.
- 92. Despite the fact that the Audit Report claimed to have found one "Critical" and two "Major" findings, Novation terminated the Novation Agreement by giving 90 days notice i.e. "without cause" thereby allowing purchases from Ameridose for the next 90 days.
- 93. Clearly, the Novation Agreement was terminated in this manner so as to intentionally deny Ameridose the ability to cure any alleged findings, as Novation had allowed the Competitor to do.
- 94. Moreover, allowing a provider, who has allegedly such abysmal quality standards, to continue to provide its members product and services for ninety (90) more days shows one of two things: either Novation has such a lack of regard for its member hospitals and the safety of their patients, or that the audit findings, the termination of

the Novation Agreement and the dissemination of false and damaging statements were intentional, wrongful acts intended and calculated to damage Ameridose for the purpose of allowing Novation to use the Competitor exclusively (i.e. to assure that Novation and that primary competitor could take away Ameridose's customers and secure them for themselves).

- 95. Given the fact that Novation gave the Competitor the chance to respond to issues that arose during their audit, while not giving Ameridose the same chance and given the fact that Novation terminated the Novation Agreement without cause (giving 90 days notice) yet immediately began to disseminate false and damaging information that the Novation Agreement had been terminated for cause, it is clear that the actions of Novation were motivated by a conscious disregard for the truth and a malicious intent to damage the business reputation and contractual relationships of Ameridose.
- 96. Novation's refusal to terminate the Novation Agreement for cause, thereby allowing Ameridose to respond and defend itself and challenge the absurdity of the Novation audit report clearly and unequivocally shows the true purposes for this calculated and damaging attack on Ameridose.
- 97. Thus, the pretext of Novation's audit, termination and dissemination of these false misleading and damaging statements was, on information and belief, for at least two specific purposes:
 - a) To free Novation to award the Competitor a sole source contract with potentially greater rebates than those paid by Ameridose; and
 - b) To damage Ameridose's reputation with statements purposefully and directly casting doubt on the quality and safety of Ameridose's products and services so as to cause Ameridose's Novation and potentially non-Novation member customers to refuse to purchase products and services from Ameridose and only work with Novation and/or the Competitor.

COUNT I DEFAMATION BY LIBEL OF AMERIDOSE BY NOVATION

- 98. Ameridose re-states and re-alleges each and every allegation set forth in paragraphs 1-97 above.
- 99. Novation is liable for the acts of both of its employees (Ms. Ricci and Ms. Anderson) because the intentional tort of Defamation by Libel was committed within the course of their employment; in furtherance of Novation's work; the false written statements set forth above are conduct that these employees were hired to perform; upon information and belief, the conduct occurred within authorized time and space limits

- of their employer, and the purpose for the conduct was, at least in part, to serve Novation.
- 100. Novation's false written statements as more fully set forth above were communicated in writing to a third party.
- 101. Novation's false written statements were communications tending to harm the business reputation of Ameridose as to lower it in the estimation of the community or to deter third persons or entities from associating or dealing with it.
- 102. Novation's false written statements were false and untrue, and defamed Ameridose.
- 103. Novation's false written statements were communicated to a wide range of potential or actual customers of Ameridose.
- 104. Novation's Employees negligently communicated the false written statements about Ameridose causing it to suffer damages, including but not limited to damaging Ameridose's business reputation.
- 105. Novation's false written statements are actionable, even without proof of economic loss as the statement constitutes Libel per se and also because the statement may prejudice Ameridose's profession or business.
- 106. Novation's Employees communicated the false written statements with the knowledge that the statements were false, or with reckless disregard as to the falsity of the statements.

COUNT II DEFAMATION BY SLANDER OF AMERIDOSE BY NOVATION

- 107. Ameridose re-states and re-alleges each and every allegation set forth in paragraphs 1-106 above.
- 108. Novation is liable for the acts of both of its employees (Ms. Ricci and Ms. Anderson) because the intentional tort of Defamation by Slander was committed within the course of their employment; in furtherance of Novation's work; the false oral statements set forth above are conduct that these employees were hired to perform; upon information and belief, the conduct occurred within authorized time and space limits of their employer, and the purpose for the conduct was, at least in part, to serve Novation.
- 109. Novation's false oral statements as more fully set forth above were communicated orally to a third party.

- 110. Novation's false oral statements were communications tending to harm the business reputation of Ameridose as to lower it in the estimation of the community or to deter third persons or entities from associating or dealing with it.
- 111. Novation's false oral statements were false and untrue, and defamed Ameridose.
- 112. Novation's false oral statements were communicated to a wide range of potential or actual customers of Ameridose.
- 113. Novation's Employees negligently communicated the false oral statements about Ameridose causing it to suffer damages, including but not limited to damaging Ameridose's business reputation.
- 114. Novation's false oral statements are actionable, even without proof of economic loss as the statement constitutes Defamation by Slander per se and also because the statement may prejudice Ameridose's profession or business.
- 115. Novation's Employees communicated the false oral statements with the knowledge that the oral statements were false, or with reckless disregard as to the falsity of the oral statements.

COUNT III INTERFERENCE WITH ADVANTAGEOUS BUSINESS RELATIONS BY NOVATION

- 116. Ameridose re-states and re-alleges each and every allegation set forth in paragraphs 1-115 above.
- 117. Ameridose has business relationships for economic benefit with various third parties who, upon information and belief, were sent the written communications described above in paragraphs 74-75 by Novation, and/or who received oral communications from Novation as described above in Paragraphs 77-85.
- 118. Novation knew of those relationships.
- 119. Novation interfered with that relationship through improper motive or means; to wit: sending false, defamatory and libelous statements for a spiteful and malignant purpose.
- 120. Ameridose's loss of advantage, or other damage, resulted directly from Novation's conduct, in an amount to be proven at trial.

COUNT IV BREACH OF CONTRACT

- 121. Ameridose re-states and re-alleges each and every allegation set forth in paragraphs 1-118 above.
- 122. By executing the Non-Disclosure Facility Tour Confidentiality and Non Disclosure Agreements Novation and Ameridose and the Novation Employees each entered into valid and binding contracts, supported by consideration.
- 123. The Audit conclusions finding deficiencies in Ameridose product and process quality (which was communicated and published), and not just the specific findings contained in the audit, was information that was learned by Novation during the tour.
- 124. Novation materially breached a material term of the non-disclosure agreement by violating the express provisions of Section 6 therein by disclosing "information learned during the tour " to any other person and organization without the prior approval of Ameridose.
- 125. As a direct and proximate cause of Novation's breach, Ameridose was damaged, in an amount to be proven at trial.

COUNT V MASSACHUSETTS GENERAL LAWS CHAPTER 93A § 11

- 126. Ameridose re-states and re-alleges each and every allegation set forth in paragraphs 1-125 above.
- 127. Ameridose is a "person" engaged in "trade or commerce" within the meaning of M.G.L. Ch. 93A § 1.
- 128. Novation is a "person" engaged in "trade or commerce" within the meaning of M.G.L. Ch. 93A § 1.
- 129. Novation engaged in unfair and deceptive conduct by transmitting false, defamatory and libelous statements to third parties.
- 130. Novation is liable for the unfair and deceptive acts of both of the Novation Employees (Ricci and Anderson) and upon information and belief others because the intentional torts or defamation, libel, slander and interference with business relations were committed within the course of their employment; in furtherance of Novation's work; the false statements and interference with advantageous business relations set forth above are the conduct that these employees were hired to perform; upon information and belief, the conduct occurred within authorized time and space

limits of their employer, and the purpose of conducting at least in part, to serve Novation.

- 131. Novation's conduct constitutes an unfair and deceptive business practice in knowing and willful violation of M.G.L. Ch. 93A, § 2 and § 11.
- 132. Ameridose has been damaged in an amount to be proven at trial.

PLAINTIFF DEMANDS A TRIAL BY JURY ON ALL CLAIMS SO TRIABLE.

WHEREFORE, Ameridose prays that this Honorable Court:

- 1. Enter appropriate Injunctive Relief prohibiting Novation from disseminating false and damaging information about Ameridose and from interfering with Ameridose's contractual business relationships;
- 2. Enter judgment for Ameridose and against Novation, on all counts.
- 3. Award Ameridose treble damages and reasonable attorney's fees provided for in M.G.L. Ch. 93A, § 11.
- 4. Award Ameridose and other relief this court deems just and fair.

Respectfully submitted,

PLAINTIFF, AMERIDOSE, LLC

By its Attorneys,

/s/ Daniel M. Rabinovitz

Daniel M. Rabinovitz, BBO # 558419 Nicki Samson BBO # 665730 Michaels, Ward & Rabinovitz, LLP 12 Post Office Square, 4th Floor Boston, MA 02109

Phone: (617) 350-4040

Fax: (617) 350-4050

Dated: August 8, 2012