IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PROGRESSIVE STERLIZATION, LLC, a Florida Limited Liability Company, Plaintiff, v. TURBETT SURGICAL LLC, a Delaware Limited Liability Company, TURBETT SURGICAL, INC., a Delaware Corporation, and ROBERT TURBETT, individually Defendants.	Civil Action No: 1:19-cv-00627-CFC **JURY TRIAL DEMANDED**

SECOND AMENDED COMPLAINT

Plaintiff Progressive Sterilization, LLC, by and through its undersigned counsel, hereby files the following First Amended Complaint against Defendants Turbett Surgical LLC and Turbett Surgical, Inc. (collectively referred to as "Turbett Surgical" or Turbett Surgical LLC"), and Robert Turbett and alleges:

INTRODUCTION

1. This lawsuit is based on patent infringement and false advertising by Turbett Surgical LLC, misappropriation of trade secrets by Turbett Surgical LLC and Robert Turbett, breach of fiduciary duty and breach of contract by Robert Turbett, tortious interference with contract by Turbett Surgical LLC, aiding and abetting by Turbett Surgical LLC and Robert Turbett, and conspiracy between Turbett Surgical LLC and Robert Turbett.

2. At its heart, the lawsuit is about how three people developed medical device businesses around a ground-breaking technology for sterilizing surgical instruments. Two of them, Maryellen Keenan and Michele Mauzerall (and their company Progressive Sterilization, LLC), competed and innovated fairly. The third person, Robert Turbett (and his company Turbett Surgical LLC), did not.

3. The underlying technology was invented by Clarence and Barry Snyder and was originally called SCORES (short for Self-Contained Operating Room Equipment Sterilization). Multiple trays containing surgical instruments for one specific surgery are loaded, sterilized and stored and delivered to the operating room ("OR") in a SCORES mobile cabinet. SCORES units (the mobile cabinet and its transfer cart) greatly reduce the time, expense and health hazards associated with delivering sterile surgical instruments to the OR from the hospital's sterile processing department ("SPD") and back again.

4. The Snyders founded AmMed Surgical in 2009 to produce and sell SCORES units and related filters and accessories.

5. They separately engaged Robert,[1] Keenan and Mauzerall in the 2011-2012 time frame to promote AmMed and its products with the goal of developing AmMed into a commercially successful medical device business.

6. Robert, Keenan and Mauzerall received direct access to, and instruction on, all of AmMed's trade secrets, patented inventions and other confidential and proprietary business information. They participated directly in the process of applying for FDA clearance of SCORES units, sourcing the units for commercial manufacture, and the marketing and sales of SCORES units to hospital customers.

[1] As discussed below in the description of the parties, Robert Turbett is identified as "Robert" when referred to individually to avoid confusion with his company.

7. Robert terminated his relationship with AmMed in October, 2013, but Keenan and Mauzerall continued to work on developing the SCORES technology into a successful business. Keenan and Mauzerall invented improvements to the SCORES technology and obtained patents on these improvements. They acquired all of AmMed's intellectual property rights in surgical instrument sterilization technology including the patents originally obtained by the Snyders on this technology. In 2015, they formed their own company, Progressive, to sell an improved multiple tray sterilization system called the CUBE.

8. Robert and Turbett Surgical have recently begun selling a competing system called the POD. Investigation reveals that, instead of developing his own technology, Robert and his company are using trade secrets and confidential information stolen from Progressive, and are infringing patents owned by Progressive that protect the Snyders', Keenan's and Mauzerall's inventions. Turbett Surgical's POD technology is actually Progressive's CUBE technology.

9. Robert and his company must be held accountable for patent infringement, misappropriation of trade secrets and confidential business information, false advertising, breach of contract and tortious interference with contract, and aiding and abetting and conspiring in support of the unlawful conduct of one another. Judicial intervention is necessary to prevent any further misuse of Progressive's proprietary technology, obtain fair compensation for Progressive's damages, restitution and disgorgement of Defendants' unjust enrichment, and punitive damages, and other injunctive relief or remedies in law or equity as are just and proper.

RELEVANT PERSONS, COMPANIES AND PARTIES

10. Brothers Barry Snyder and Clarence Snyder invented the original SCORES units used to sterilize multiple trays of surgical instruments. They may be identified respectively as "Barry" and "Clarence" when referred to individually.

11. The Snyders formed AmMed Surgical Equipment, LLC ("AmMed"), a Florida limited liability company, on March 2, 2009 for purposes of producing SCORES units and related filters and accessories.

12. Plaintiff Progressive Sterilization, LLC ("Progressive"), is a Florida limited liability company formed on February 6, 2015 for purposes of acquiring AmMed's assets, including without limitation all of AmMed's patents, trade secrets, and other confidential and proprietary information and intellectual property relating to SCORES units and surgical instrument sterilization systems. Subsequent to the acquisition, AmMed ceased active operations and ultimately dissolved effective March 4, 2016.

13. As originally formed, Progressive was capitalized and owned by PMBS, LLC ("PMBS"), a New Jersey limited liability company, Phoenix Enterprises of New York, Inc. ("Phoenix"), a New York corporation, Steri SC, LLC ("Steri"), a Florida limited liability company, and Promedica, Inc. ("Promedica"), a Florida corporation, each of which was a member of Progressive as originally formed.

14. Currently, the members and owners of Progressive are PMBS, Phoenix and Steri. Original member Promedica no longer has any equity or ownership in Progressive, is no longer a member of Progressive, but Promedica does continue to have an economic interest.

15. The working members of Progressive are PMBS and Phoenix, and the principal members, owners and managers of each of PMBS and Phoenix are Michele Mauzerall ("Mauzerall") and Maryellen Keenan ("Keenan"), respectively.

16. Progressive owns all patents, trade secrets and confidential information infringed or misappropriated by Defendants.

17. Defendant Turbett Surgical LLC ("Turbett Surgical"), is a Delaware limited

liability company, which, on information and belief, has a business office in Rochester, New York.

18. Defendant Robert Turbett capitalized, founded and formed Turbett Surgical as a Delaware limited liability company in which he is a member and holds the title of CEO/ President. On information and belief, Robert Turbett has at all relevant times served as the manager of Turbett Surgical within the meaning of 6 DEL. CODE ANN. § 18-101(10) and/or participated materially in the management of the company within the meaning of 6 DEL. CODE ANN. § 18-109(a)(ii). On information and belief, he resides in Penfield, New York. Robert Turbett may be identified as "Robert" when referred to individually.

JURISDICTION AND VENUE

19. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §§ 271 and 281, *et seq.*, for misappropriation of trade secrets under the Defend Trade Secrets Act, 18 U.S.C. §§ 1836 *et seq.*, and for false or misleading advertising under the Lanham Act, 15 U.S.C. § 1125 *et seq.* This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a)-(b).

20. This action also asserts state-law claims for trade secret misappropriation and deceptive trade practices under Delaware state law, 6 DEL. CODE ANN. §§ 2001-2009 and 6 DEL. CODE ANN. §§ 2531 *et seq.*, and common law claims for disclosure and use of confidential information in breach of fiduciary duties and contractual obligations, tortious interference with contract, conspiracy and aiding and abetting. Those state-law claims are so related to the claims within the Court's original jurisdiction that they form part of the same case or controversy under Article III of the United States Constitution. This Court has supplemental jurisdiction over these claims pursuant to 28 U.S.C. § 1367(a).

21. Venue is proper in this district under 28 U.S.C. §§ 1391(c) and 1400(b).

22. Defendants are subject to this Court's specific and general personal jurisdiction pursuant to due process and/or the Delaware Long Arm Statute, *see* 10 Del. C. § 3104. Defendants have availed themselves of Delaware corporate law. In addition, on information and belief, Defendants have engaged in substantial business in this forum, including: (i) at least a portion of the infringements alleged herein; (ii) targeting business activities towards consumers in the United States, including Delaware, through at least commercial Internet sites; and/or (iii) regularly doing or soliciting business, engaging in other persistent courses of conduct, or deriving substantial revenue from goods and services provided to individuals in Delaware.

23. Robert is also subject to the personal jurisdiction of this Court under 6 Del. C. § 18-109(a) based on his management and/or material participation in the management of Turbett Surgical, the allegations against him focus on the performance of his duties and obligations as a manager of Turbett Surgical, the resolution of this matter is bound up in Delaware law and Delaware's strong interest in providing a forum for disputes relating to whether and how the managers of Delaware LLC's are discharging their management functions.

24. Robert is also subject to the personal jurisdiction of this Court under the Delaware Long Arm Statute, 10 Del. C. § 3104(c), based upon his having formed a Delaware entity, Turbett Surgical, and his having conspired with and/or having been aided and abetted by, this Delaware entity.

FACTUAL BACKGROUND

Snyders Invent Multiple Tray Sterilization System Called SCORES

25. Modern surgery typically requires a large number of surgical instruments stored and sterilized in individual trays. For example, the average knee replacement operation requires approximately twelve trays containing the surgical instruments needed for this operation.

26. Coming into 2009, the customary procedure was to sterilize each tray individually, including the steps of washing each tray individually, inspecting each instrument carefully, re-assembling instruments into the tray, wrapping each tray individually with a specially manufactured disposable wrap, taping and labeling each tray individually and then placing the wrapped, taped and labeled tray on a load cart that is inserted into an autoclave where steam is introduced at very high temperatures to sterilize the contents of the trays. After allowing sufficient time in the autoclave to sterilize the contents of the load cart and for those contents to dry, the cart is removed from the sterilizer chamber and sequestered for a minimum of 60 minutes while the wrapped trays cool down and become dry to touch. Once each wrapped tray is at room temperature, it can be transferred to another cart to be moved to sterile storage or delivered to the OR for use. When wrapped trays are brought to the OR, prior to the commencement of surgery the exterior of each wrapped tray must be inspected for defects, the tray is then unwrapped, and then the wrapper must be re-inspected in front of a light source for holes prior to the contents being allowed to be placed on the sterile field (the "surgical back table"). Each tray also bears a chemical indicator of the sterilization status of the tray and the chemical indicator itself must be inspected. Most important in this process is inspection of the wrapper to be certain there is no breach in the package integrity. Holes and tears in wraps occur all too frequently.

27. This sterilization process is time-consuming and inefficient. Wrapping (sometimes facilitated with extra materials including corner protectors and linen to prevent

damage to the wrap), taping, and labeling is expensive – both material and labor. Wrap inspection in the OR is mandatory and costly. Published estimates of OR cost per minute range from $28 - $180. Much more important is the risk to patient safety posed by undetected compromised sterility and/or the potential delays caused by the detection of a breached sterile wrap and the time it takes to replace or re-sterilize those needed instruments.

28. Barry and Clarence Snyder invented a solution for these problems: the first-ever multiple surgical tray sterilization system called the SCORES cabinet (short for Self-Contained Operating Room Equipment Sterilization) involving a mobile cabinet into which multiple trays containing procedure-specific surgical instruments are loaded, sterilized, stored and transferred on its own cart to the OR. The SCORES system eliminated the time-consuming, expensive and potentially hazardous steps of wrapping, taping, labeling, sterilizing, storing, and finally delivering to the OR and inspecting multiple surgical trays individually. The SCORES cabinet is widely regarded as the foundational technology for mobile sterilization of multiple surgical trays.

29. The Snyders formed AmMed for purposes of producing and distributing the SCORES cabinets and related filters and accessories.

30. Shortly thereafter, on May 6, 2009, the Snyders filed U.S. Patent Application No. 12/387,683 for a patent on the SCORES sterilization system, which the U.S. Patent and Trademark Office granted approximately four years later as U.S. Patent No. 8,454,901, dated June 4, 2013 (the "SCORES patent").

Snyders and AmMed Engage Robert Turbett to Promote the SCORES Business

31. By early 2011, the Snyders and AmMed had designed and manufactured SCORES units that implemented their patent-pending inventions. They had begun the process of obtaining FDA clearance to market and sell SCORES units via a Section 510(k) premarket

submission. They required assistance promoting sales into hospitals and attracting capital to scale marketing, sales, production and distribution to commercially profitable levels.

32. At or about the same time, AmMed engaged Robert to act as an authorized promoter of SCORES units as well as assist with commercialization efforts generally, including fund raising.

33. Robert had been working as a sales representative for companies selling surgical instruments to hospitals, but he had no experience or knowledge regarding processes used by hospitals to sterilize surgical instruments, nor did he have any experience or knowledge regarding the design, testing, or manufacturing of sterilization devices or systems and the process for obtaining government clearance to sell sterilization devices or systems.

34. Robert nonetheless viewed AmMed and multiple surgical tray sterilization systems as a potentially lucrative business opportunity. He expected to receive compensation from AmMed for his services, including, at least, commissions on sales and possibly also consideration for sourcing additional investment into AmMed. The relationship was based on verbal communications, principally between Robert and Barry, and their email communications. The expectation was that Robert and AmMed would enter into more formal written agreement as AmMed's business developed.

35. On December 29, 2011, Barry sent Robert an email titled "NDA" attaching a Confidentiality Agreement between AmMed and Robert, a true and correct copy of which is attached as Exhibit A. On information and belief, Robert signed the agreement. As discussed below, Keenan entered into the same agreement with AmMed.

36. AmMed introduced Robert to prospective hospital accounts developed prior to his engagement, including proprietary and confidential information on specific account requirements

and pricing, and Robert sought to make commercial sales of SCORES units, filters and related accessories into these accounts.

37. In December 2012, Barry and his nephew Travis White provided on-site training on SCORES units to Robert, Mauzerall and another sales representative Tom Plis. The training occurred at St. Peter's University Hospital in Albany, New York. Robert received specific instructions on hospital sterilization processes, use and operation of the SCORES units, how to adjust the units, how to set up the units to interface with the hospital's autoclave, what to say and what not to say during a sales presentation, pricing strategy, and the instructions to give the hospital for use (IFUs) of SCORES units, and observed Barry conduct an In Service meeting with a hospital account.

38. On behalf of AmMed, Robert developed new hospital accounts in New York, Pennsylvania, Massachusetts and New Jersey, engaged and trained sales representatives to serve these territories, and managed hospital accounts in these territories.

39. AmMed paid sales commissions to Robert, including a specific percentage of the revenue received by AmMed on SCORES units purchased by St. Peters University Hospital in early 2013.

40. Robert also participated directly in most if not all facets of the process of obtaining FDA clearance to market and sell SCORES units under the FDA's 510(k) Premarket Notification rules, which the FDA granted to AmMed on July 26, 2012.

41. In early 2012, Robert was involved in developing the protocol for human factors testing required by the FDA, including the instructions for use (IFUs) to be used by the hospital. Robert communicated directly with Farm Design, the consultant engaged by AmMed to design, conduct and report the testing subject to strict confidentiality requirements. He attended the

testing conducted pursuant to the protocol and reviewed and suggested revisions to the test results.

42. On information and belief, AmMed disclosed to Robert all sterilization-related testing done for AmMed on a confidential basis by SPS Medical and Moog/Ethox in 2010 and 2011. The disclosures included test protocols and applicable industry and government standards covering the testing and test results on at least five subjects (*i.e.* sterility assurance levels, thermal profiles and steam penetration, drying, barrier integrity and transport and shelf life).

43. On information and belief, AmMed disclosed to Robert all submissions made to the FDA in 2011 and 2012 to obtain 510(k) clearance. These submissions were made by AmMed's regulatory consultant, David Furr, whose internal communications with AmMed, on information and belief, also were disclosed by AmMed to Robert. These disclosures in the submissions and communications with Furr included hundreds of pages of non-public and confidential information, including FDA inquiries regarding potential deficiencies in AmMed's 510(k) notification, SCORES unit's designs and specifications, and performance testing of the SCORES units such as the aforementioned testing by Moog/Ethox, Farm Design and SPS Medical.

44. Robert was copied on communications by Barry and Keenan presenting the SCORES technology to medical device distributor Stryker, with the expectation that Stryker might be interesting in licensing the technology. On information and belief, AmMed or Barry disclosed to Robert in confidence additional copies of SCORES performance testing and then-pending 510(k) submissions as part of AmMed's discussions with Stryker.

45. Ultimately, Barry, Clarence and AmMed could not agree with Robert to reduce the terms of their prior agreement(s) to a formal written contract. Robert gave Barry and Sam

written notice on October 7, 2013 that, effective as of that date, Robert and his companies and partners would not be involved in the promotion of AmMed products. In the same communication, Robert acknowledged the need to return AmMed's proprietary sales and promotional materials (and said that he and his associates would do so). Robert also reserved his claim for compensation for his efforts to introduce licensing or potential investment partners, citing his introduction of Keenan to Barry as discussed in the next section.

AmMed Discloses to Robert its Trade Secret Technology and Confidential Information

46. During the aforementioned meetings and communications, AmMed disclosed in confidence to Robert at least the following trade secret information ("Trade Secret Technology") and types of confidential Information ("Confidential Information") pertaining to the design, manufacture, FDA clearance, marketing and sales of SCORES units, filters and accessories, multiple tray sterilization system technology, and related intellectual property:

a. Non-public inventions and supporting disclosures in pending patent applications, including U.S. Patent Applications 12/387,673, filed May 6, 2009 and 13/944,875, filed July 17, 2013;

b. Subject matter that might not be covered in pending patent applications, including U.S. Patent Applications 12/387,673, filed May 6, 2009 and 13/944,875, filed July 17, 2013;

c. SCORES units' Instructions For Use (IFU) including improved IFU for multiple tray sterilization systems developed through the human factors testing on SCORES units;

d. Protocols for validating performance of multiple tray sterilization systems sufficient to obtain FDA 510(k) clearance, including:

1) Methodology for analyzing microbial barrier properties;

2) Methodology for verifying sterilization efficacy;

3) Methodology for demonstrating adequate steam sterilization/heat penetration of the cabinet;

4) Methodology for determining proper drying time;

5) Methodology for determining transport and shelf life over 7/30 days;

6) Methodology for demonstrating safety and performance of transfer cart; and

7) Methodology for using human factors testing to validate usability of the multiple surgical instrument tray systems in both OR and sterile processing department.

e. Methodology for combining filters to achieve FDA-compliant microbial barrier properties;

f. Non-public submissions and content of 510(k) Premarket Notification for SCORES units;

g. Improvements to the SCORES transfer cart, including modification of wheel base and improved autoclave docking and transfer cart self-locking features;

h. Pricing strategies for SCORES units, filters and accessories; and

i. The identity and cost of vendors and consultants competent and available to provide performance testing and FDA clearance approval.

47. The Trade Secret Technology and Confidential Information was generally not known or readily accessible and was maintained in confidence by AmMed. AmMed derived independent economic value from keeping this Trade Secret Technology and Confidential Information in confidence. The Snyders, AmMed, Keenan and Mauzerall developed the Trade Secret Technology and Confidential Information over years of investing substantial time, effort, expense, and research. At the time that AmMed began initial efforts to market and sell the FDA-cleared SCORES units, the market for multiple surgical tray sterilization systems was just emerging and AmMed, Keenan and Mauzerall were at the forefront of this market.

48. During all pertinent times, reasonable steps have been taken to maintain the secrecy of the Trade Secret Technology and Confidential Information. AmMed consistently sought NDAs from its outside vendors as reflected in its communications with Keenan and its independent testing centers. Further, Robert knew or reasonably should have known that the information disclosed by the Snyders, AmMed, Keenan and Mauzerall, and any of the vendors, consultants or investors with whom they associated to commercialize multiple tray sterilization products was confidential and proprietary.

49. Progressive is the owner by sale and transfer of the entire right, title and interest in the Trade Secret Technology and Confidential Information.

AmMed Engages the Services of Keenan and Mauzerall

50. Robert, through his business partner Joe Brown, introduced Keenan to Barry and AmMed as someone who could assist with the licensing or sale of the SCORES technology.

51. Keenan and her company, Phoenix, had access to individuals with expertise in healthcare, in particular with interests in the market for improvements in orthopedic, cardiac and hospital processes. Based upon her conversations with Barry, Keenan believed her market

contacts would be interested in the SCORES technology and she agreed to begin soliciting strategic licensing or acquisition partners in return for a percentage of gross proceeds on any such transaction.

52. On October 24, 2011, Keenan signed AmMed's Confidentiality Agreement. A true and correct copy of the form signed by Keenan, as well as excerpted copies reflecting Keenan's execution of the agreement, are attached as Exhibits B-1 and B-2, respectively. Pursuant to this agreement, AmMed agreed to furnish Keenan with "confidential or proprietary information or trade secrets" and to allow AmMed's suppliers, customers, employees and representatives to disclose this information to Keenan. Keenan, in turn, agreed to maintain the confidentiality of and to not disclose all such information. The agreement concludes: "This agreement shall be binding upon and inure to the benefit of the parties, their successors and assigns."

53. On information and belief, AmMed required all potential investors, promoters and distributors to sign the Confidentiality Agreement, including the aforementioned request that Robert sign the Confidentiality Agreement.

54. On November 13, 2011, Barry approved the entry by AmMed into a Consulting Services Agreement with Keenan's company, Phoenix. Pursuant to this agreement, Keenan began promoting potential licenses of SCORES technology by companies interested in distributing SCORES units. Keenan's active participation in the aforementioned presentation to Stryker is an example of the services provided by Keenan to AmMed.

55. At approximately this same time, Keenan and Mauzerall had been discussing the possibility of starting a consulting firm specifically for Process Improvement/Efficiency Generation for hospitals and medical practices.

56. Keenan introduced Mauzerall to Barry in the summer of 2012, thinking AmMed's SCORES units and related cost saving, efficiencies and improved patient safety might be a good focus for their nascent business. She was right. Mauzerall's conversations with Barry convinced her that the multiple tray sterilization technology implemented in SCORES units dwarfed any other ideas she had for her business with Keenan.

57. Mauzerall participated in the aforementioned SCORES unit hospital trial at St. Peter's University Hospital in December 2012. From there she was given verbal authorization to sell and market SCORES units in New York and New Jersey. She and her company PMBS also attended national and local trade conferences as AmMed's authorized "distributor" during 2013. These efforts, including a sale to an account in Oregon, convinced AmMed that Mauzerall could sell SCORES units. On November 3, 2013, AmMed and PMBS entered into their first written distribution agreement, pursuant to which PMBS was recognized as AmMed's exclusive "Distributor" in twelve (12) states, District of Columbia, Puerto Rico, and the Virgin Islands. As discussed below, the agreement was modified shortly thereafter to give PMBS an exclusive license for North America.

Keenan and Mauzerall Invent Improvements to Multiple Tray Sterilization Systems: the '143, '093 and '972 Patents

58. Mauzerall and Keenan conceived of and jointly developed with Barry and Clarence the improvement of placing a vent or vents and associated filter or filters on any panel of the sterilization cabinet, not just at the top or bottom.

59. Mauzerall and Keenan also conceived of and jointly with Barry and Clarence improved methods for loading, sterilizing and delivering SCORES-type sterilization cabinets to the operating room from the hospital's sterile processing department and back again.

60. On July 17, 2013, AmMed filed U.S. Patent Application 13/944,875 ("the '875 application") providing the written description and figures supporting claims for patent protection on these improvements. Keenan and Mauzerall are co-inventors along with Barry and Clarence Snyder of claims for which patents have issued based on these disclosures.

61. The claims in the '875 application were granted patent protection in U.S. Patent No. 9,616,143 ("the '143 patent"), issued April 11, 2017, and entitled "Mobile Apparatus and Method for Sterilizing One or More Surgical Trays with Integrable Transfer and Storage System". A copy of the '143 patent is attached as Exhibit C.

62. A continuation of the '875 application seeking protection of additional inventions supported by the disclosures in the '875 application was filed on January 20, 2017. The claims in this continuation application, U.S. Pat. Application 15/411,361 were granted protection in U.S. Patent No. 9,694,093 ("the '093 patent"), issued July 4, 2017, and entitled "Mobile Apparatus and Method for Sterilizing One or More Surgical Trays with Integrable Transfer and Storage System". A copy of the '093 patent is attached as Exhibit D.

63. Keenan and Mauzerall also invented improvements to the design of the floor of the sterilization cabinet to better drain water and other condensate remaining after the sterilization process.

64. PMBS filed for patent protection on these improvements in U.S. Pat. Application 15/831,144 ("the '144 application"), which through a chain of continuation applications claims the benefit of U.S. Provisional Application No. 62/053,338 filed on September 22, 2014.

65. The claims in the '144 application were granted patent protection in U.S. Patent No. 10,111,972 ("the '972 patent"), issued on October 30, 2018, and entitled "Mobile

Sterilization Apparatus and Method for Using the Same". A copy of the '972 patent is attached as Exhibit E.

66. Collectively, the '143 patent, '093 patent and '972 patent are the "Asserted Patents".

67. Progressive is the owner by assignment of the entire right, title and interest in the Asserted Patents, including without limitation the owner by assignment of the entire right, title and interest in any patent or patent application whose ownership is or may be necessary in order to enforce any rights in the Asserted Patents. Among other things, Progressive is the owner by assignment of the entire right, title and interest in U.S. Patent Nos. 9,724,439; 9,833,524; 9,439,992; and 9,808,545 (sometimes referred to as the "PMBS Prior Patents").

AmMed Declares Bankruptcy; Progressive Acquires AmMed's Intellectual Property and Sells an Improved Multiple Tray Sterilization System called the CUBE

68. On or about January 9, 2014, Mauzerall's company, PMBS, entered into a License and Distribution Agreement with AmMed ("AmMed – PMBS License Agreement"), pursuant to which AmMed granted to PMBS, among other things, an exclusive and irrevocable license to all of AmMed's intellectual property and to purchase, manufacture, market, distribute and sell SCORES units, filters and accessories in the United States, Canada, Puerto Rico and the Virgin Islands.

69. After the AmMed – PMBS License Agreement was entered, disputes arose between AmMed, PMBS and their respective affiliates regarding the marketability of SCORES units. For these and other reasons, AmMed was not receiving sufficient royalty income to sustain active operations. On August 22, 2014, AmMed filed for bankruptcy protection under Chapter 11 of the Bankruptcy Code on August 22, 2014.

70. Pursuant to a Mediation Settlement Agreement ("MSA") entered into on or about January 30, 2015 and the proposed Plan of Liquidation incorporating the MSA filed on February 26, 2015, and as later approved in the bankruptcy court's Order Confirming Plan of Liquidation ("the Plan") entered on December 21, 2015, AmMed sold and transferred substantially all of its tangible and intangible assets to Progressive.

71. Under the Plan, Progressive acquired free and clear of any and all liens and interests all of AmMed's intellectual property relating in any way to SCORES units technology, including without limitation the SCORES patent, all AmMed rights in any then-pending patent applications, all AmMed trade secrets, and all of AmMed's legal or equitable interests in any other confidential information or intellectual property relating to surgical instrument sterilization. Progressive thereby acquired free and clear of any and all liens and interests AmMed's Trade Secret Technology and Confidential Information.

72. The only AmMed assets excluded from what was sold and transferred to Progressive under the Plan consisted of cash, bank deposits and marketable securities and abandoned physical property in the form of company car(s), trailers, office supplies and an autoclave. AmMed dissolved effective March 4, 2016, reporting in its Articles of Dissolution that "COMPANY SOLD."

73. Progressive currently markets and sells an improved multiple tray sterilization system, the MTS300 System, also referred to as the CUBE or the SteriCUBE System. The CUBE sterilization cabinet, transfer cart, and related filters and accessories ("CUBE units") are based on SCORES technology and patented improvements to the SCORES technology owned by Progressive, including the Asserted Patents.

74. While the FDA has cleared the CUBE for commercial marketing, sales and distribution, Progressive is still a nascent medical device company that has had to overcome numerous litigated disputes regarding marketing and intellectual property rights to its technology, while at the same time designing and developing an improved sterilization system, obtaining government clearance for this system, and re-introducing its product to national medical device distributors whose support is crucial to its success. Having fought to bring itself to the cusp of achieving significant commercial success, Progressive has discovered that its efforts to-date have been significantly impeded by Robert's and Turbett Surgical's theft of Progressive's intellectual property and that these impediments must be removed if Progressive is to succeed.

Discovery of Theft

75. The first trade show where the CUBE was exhibited (as an FDA cleared medical device) was the AORN (Association of periOperative Registered Nurses) show in Anaheim, California in April 2016. Keenan and Mauzerall were on-site beginning April 3, 2016 and at or around that time another distributor at the show advised them that Robert was at the show and exhibiting a potentially competing multiple tray sterilization system from Turbett Surgical. At that time the Turbett product had no name but it has since been called "the POD". This was the first time they saw and could confirm that Robert had begun to sell a competing device, and it was also the first knowledge of any kind of the POD's design and operation.

76. At the time, none of the Asserted Patents had yet been issued. Plus, Keenan, Mauzerall and Progressive were still two years away from resolving all disputes with their business partners regarding intellectual property implemented first in SCORES units and then in CUBE units. They nonetheless began to research the POD as best they could from publicly

available information.

Robert and Turbett Surgical Misappropriated the Trade Secret Technology and Confidential Information

77. Over an extended period of time, what Keenan, Mauzerall and Progressive began to suspect, and ultimately determined, was that the POD had several features that embodied and/or were derived from the Trade Secret Technology and the Confidential Information that had been disclosed in confidence to Robert.

78. Investigation revealed that Robert and Turbett Surgical disclosed and used certain Trade Secret Technology and Confidential Information in the course of making non-public submissions to obtain FDA clearance to market the POD under Section 510(k).

79. Investigation revealed that Robert and Turbett Surgical disclosed and used certain Trade Secret Technology and Confidential Information in its IFU and other instructions given to users of the POD.

80. Investigation revealed that Robert and Turbett Surgical disclosed and used certain Trade Secret Technology and Confidential Information in the course of marketing and selling the POD.

81. Investigation revealed that Robert founded and formed Turbett Surgical as a Delaware limited liability company on September 20, 2013, which was several weeks before Robert advised Barry and AmMed on October 7, 2013 that Robert was terminating his promotion of SCORES units. On information and belief, the formation of the Delaware entity was intended to further a scheme to covertly develop a competing sterilization system using AmMed's, Keenan's and Mauzerall's inventions, trade secrets and confidential information and beat them to market with this competing product; and the Delaware entity did in fact further

these conspiratorial goals.

82. Investigation revealed that Robert advised Barry and AmMed on or about February 26, 2013 that "We have reps primed in: . . . Delaware." On information and belief, Robert and Turbett Surgical covertly redirected the sales representatives "primed" in Delaware away from SCORES units to market and promote the POD to hospitals, surgery centers and surgical staff in Delaware and these sales and marketing efforts have continued up through the present.

Turbett Surgical Infringes the '143, '093 and '972 Patents

83. The applications pending as of the time of the AORN show have since issued as the Asserted Patents, and Turbett Surgical infringes one or more claims in these patents.

The '143 patent

84. The '143 patent discloses, in one embodiment, a mobile sterilization system for receiving and sterilizing a plurality of surgical instruments or trays of surgical instruments, for use in a sterile field in an operating room. The mobile sterilization system includes a cabinet with an interior sterilization area, into which a sterilization agent can be introduced to sterilize the surgical trays and instruments. The system further includes a transfer cart onto which the cabinet can be positioned for movement to and from an autoclave, into which the cabinet is placed so that its contents may be exposed to the sterilization agent, typically steam. After the sterilization process is complete, the cabinet is removed from the autoclave and at the appropriate time moved into the operating room, at which point the cabinet can be opened and the trays and/or instruments removed. The '143 patent thereby provides an apparatus that eliminates many of the repetitive steps currently required to prepare and deliver instruments to the sterile field.

The '093 patent

85. The ‘093 patent describes, in one embodiment, a method of sterilizing surgical trays containing surgical instruments, using a cabinet sized to receive the surgical trays. The method includes the steps of loading surgical tray(s) containing surgical instruments into the cabinet’s interior sterilization chamber and then securing the cabinet into a sealed configuration. The cabinet is positioned at a sterilization location adjacent to an autoclave using a transfer cart, which is then locked relative to the autoclave. The cabinet is then moved from the transfer cart into the autoclave where the surgical instruments are sterilized within the cabinet’s interior sterilization chamber. After the sterilization process is complete, the cabinet is removed from the autoclave and positioned on the transfer cart. The transfer cart can then be released from the autoclave and the cabinet can be moved from the sterilization location using the transfer cart. In one embodiment, a security structure is applied to the cabinet to ensure that the cabinet remains in the sealed configuration until the surgical instruments are to be used.

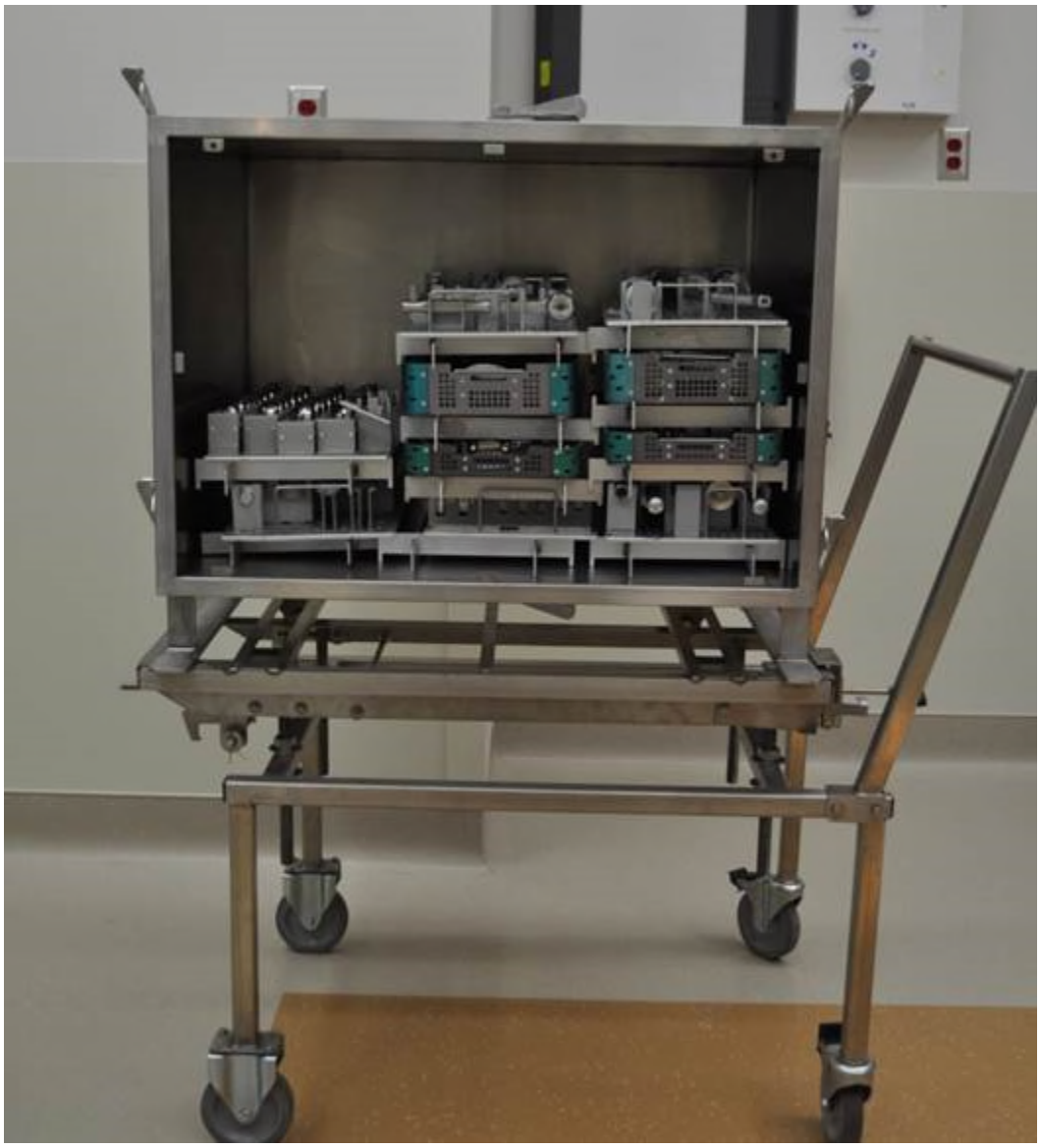
The ‘972 Patent

86. The ‘972 patent describes, in one embodiment, a cabinet for sterilizing surgical equipment or a surgical tray. The sterilization cabinet comprises a plurality of panels forming a chamber with an opening for insertion of the surgical equipment or tray. One of the panels is a floor panel at a bottom of the chamber, the floor panel having a lowest point. Another of the panels is a door that can close the opening to create a closed, sealed configuration. At least one of the panels has a vent formed therein that allows passage of a sterilization fluid into the chamber. An entirety of the floor panel is pitched such that any liquid condensate formed during the sterilization process is directed by gravity towards the lowest point in the floor panel. The cabinet also includes a filter in communication with the lowest point in the floor panel, such that condensate flowing on the floor panel passes through the filter. Also provided is at least one

supporting structure removably positioned within the chamber and configured for supporting the surgical equipment or the surgical tray above the floor panel.

Turbett Surgical's Infringement of the '143, '093, and '972 Patents

87. Turbett Surgical makes, uses, sells and offers for sale in the United States a system (the "POD unit") comprising a reusable cabinet (the "POD cabinet") used for packaging, transporting and holding of surgical instruments prior to, during and after sterilization of the cabinet and its contents in an autoclave. The system also includes a loading and delivery cart (the "POD cart") to be used with the POD cabinet. An example of the POD unit is shown in the image below.



88. Turbett Surgical also provides specific instructions to purchasers of the POD unit as to how it is to be used.

89. The POD unit and its use is described both on Turbett Surgical's website at http://www.turbettsurgical.com and in Turbett Surgical's instructions for using the system, attached as Exhibits F and G, respectively.

90. Turbett infringes the Asserted Patents at least by making, using, selling and

offering for sale the POD unit, which falls within the scope of one or more of the claims of the Asserted Patents as shown in more detail below. Turbett further infringes indirectly by active inducement, specifically intending that its customers, including hospitals, surgery centers and associated surgical staff, directly infringe one or more claims of the Asserted Patents, either by using the infringing POD unit *per se* or by using Progressive's patented sterilization methods in connection with the use of the POD as shown in more detail below.

FIRST CAUSE OF ACTION

Infringement of '143 Patent

(Against Turbett Surgical)

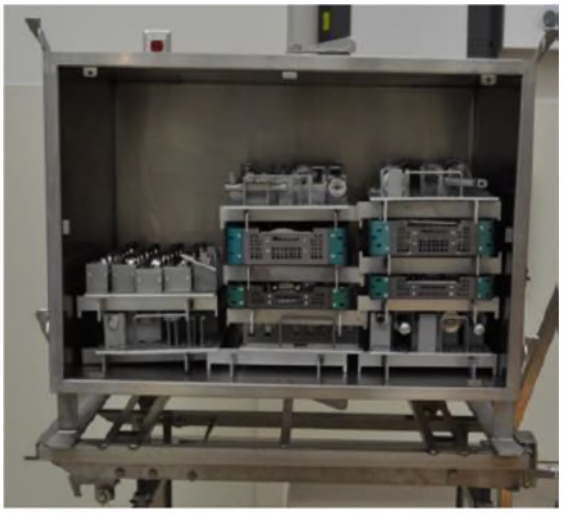
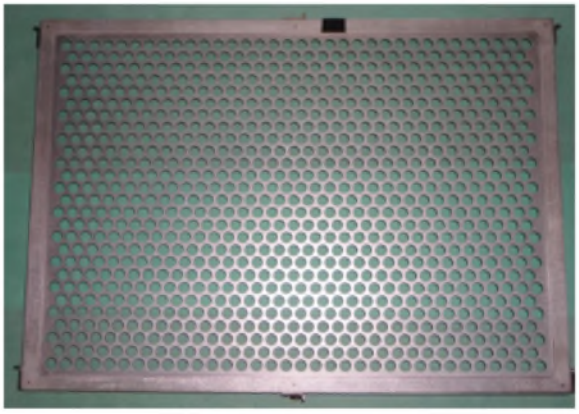
91. Progressive repeats, realleges, and incorporates hereunder by reference the allegations contained in all of the above paragraphs.

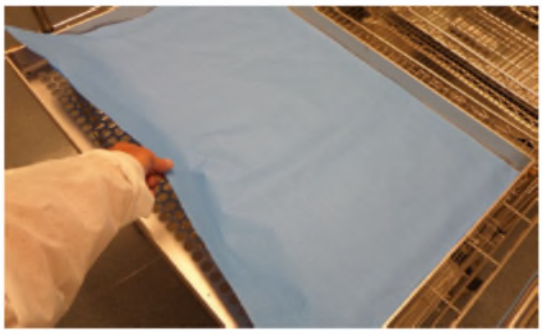
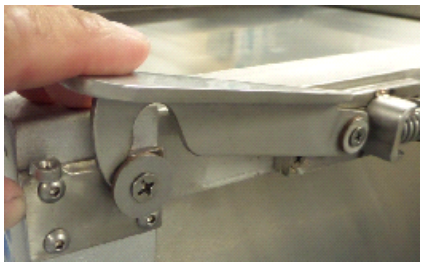
Direct Infringement

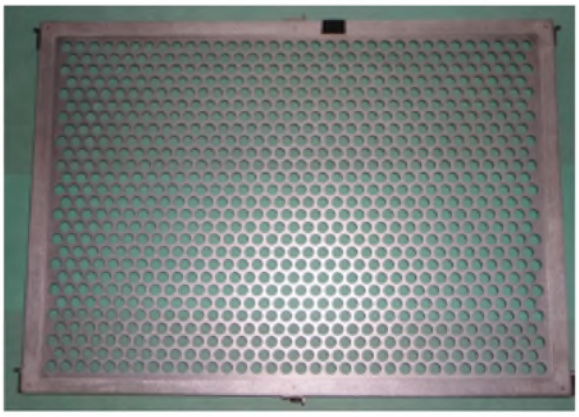
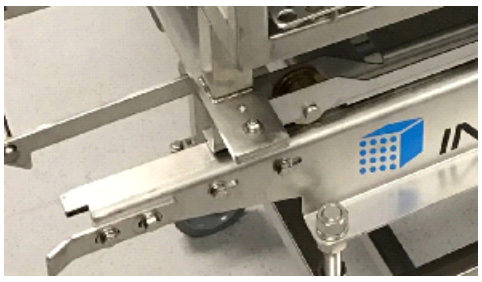
92. Turbett Surgical has directly infringed, and continues to directly infringe, literally and/or under the doctrine of equivalents, one or more claims of the '143 patent by, among other things, making, using, importing, offering for sale, or selling the POD unit, which is covered by at least claims 1, 2, 10, 11, 12, 13, 17, 26, 27, 28, 29 and 33 of the '143 patent.

93. One example of Turbett Surgical's infringement of the '143 patent is shown in the following table**:**

US 9,616,143	The POD unit
1. A mobile sterilization system for sterilizing a plurality of surgical trays and for movement from an autoclave, the mobile sterilization system comprising:	The POD unit is used for packaging, transporting and holding of instruments prior to, during and after sterilization. It is indicated for enclosing multiple uncovered, vented instrument delivery trays. (Ex. G pg. 1)
a cabinet comprising a plurality of panels having a first panel and a second panel surrounding a cabinet floor,	The POD cabinet comprises a plurality of panels having a first panel (the "outer door") and a second panel (e.g. one of the side panels

	or the roof panel) surrounding a cabinet floor. (Ex. G pg. 4 and Ex. F pg. 2)   Outer Door
where at least the first panel is removably coupleable to the second panel with a gasket there between, such that when coupled the first panel and second panel form a seal to define an interior sterilization area sized to receive the plurality of surgical trays,	The outer door is removably coupleable to the side and roof panels. Turbett filter cartridges are comprised of filtration paper with a built in gasket. A filter cartridge is loaded into the door, which is then removably coupled to the other panels with the gasket there between, to define an interior sterilization area sized to receive the plurality of surgical trays. “Place a single Turbett Surgical filter cartridge into the door.”

	 "10. Place door onto front of container, and close the **SIX** latches. Latches are located two on each side, one on top center, one on bottom center"  (Ex. G pgs. 2 – 8, Ex. F)
where a sterilization agent can be introduced to the inner sterilization area to sterilize the plurality of surgical trays	The POD cabinet in use is placed in an autoclave (aka sterilizer) and a sterilization agent can enter the inner sterilization area through the holes in the door and through the filter cartridge to sterilize the plurality of surgical trays. "4. … push the container into the sterilizer until it is completely within the sterilizer. 5. Unlock cart from sterilizer and pull empty cart away from sterilizer." (Ex. G pg. 6) "4. Run the sterilizer for the validated cycle." (Ex. G pg. 7)
where the first panel can be uncoupled from the second panel to provide access to the interior area;	The door can be uncoupled to provide access to the interior area. "3. Remove the six integrity locks, and open each of the six latches. Latches are located at each front corner, one top center and one bottom center.

	4. Remove the outer door with filter, pulling the top away first." (Ex. G pg. 8) 
at least one opening in at least one of the plurality of panels to allow flow of the sterilization agent from an exterior of the cabinet directly to the interior sterilization area;	The door has a plurality of openings to allow flow of the sterilization agent from an exterior of the POD cabinet directly to the interior sterilization area (Ex. G pg. 2)  Outer Door
a transfer cart frame that supports at least one rail, where the cabinet is moveably positionable on at least one rail such that the cabinet can be moved between the autoclave to the transfer cart;	The POD cart includes a transfer cart frame that supports at least one rail, onto which the POD cabinet is moveably positionable such that the cabinet can be moved between the autoclave and the POD cart. 

	"5. At the end of the cycle, roll cart into place, engage cart lock to sterilizer, confirm tracks are aligned, and lock wheels. … 6. Roll transfer carriage with container onto the cart. Ensure that transfer carriage locks to the cart." (Ex. G pg. 7)
at least one retaining mechanism on the transfer cart frame, where the at least one retaining mechanism releasably engages the cabinet to secure the cabinet to the transfer cart during movement of the transfer cart; and	The POD unit includes at least one transfer carriage lock for releasably engaging the POD cabinet to secure the POD cabinet to the POD cart during movement of the POD cart. "4. Release the transfer carriage lock, and push the container into the sterilizer until it is completely within the sterilizer." (Ex. G pg. 5) "6. Roll transfer carriage with container onto the cart. Ensure that transfer carriage locks to the cart." (Ex. G pg. 7)
where a lower portion of the transfer cart frame is configured to permit movement of the transfer cart.	The lower portion of the transfer cart frame includes wheels to permit movement of the POD cart. "1. Unlock wheels, and roll cart to sterilizer." (Ex. G pg. 6)

Induced Infringement

94. 35 U.S.C. § 271(a) provides that "whoever without authority…uses any patented invention…infringes the patent." Accordingly, use of a patented apparatus by the purchaser or other end user of the patented apparatus is direct infringement of the patent by the purchaser/end user.

95. Since at least the date of service of this Complaint, Turbett Surgical has had actual knowledge of the '143 patent, as well as knowledge that the POD unit infringes one or more claims of the '143 patent.

96. With this knowledge, Turbett Surgical knowingly has induced, and continues to induce, direct infringement by its customers, including hospitals, surgery centers and associated surgical staff, which are using the infringing POD unit to sterilize surgical instruments.

97. Turbett Surgical specifically intended to encourage its customers to engage in infringing use of the POD as manifested by its web site and other promotional literature, the IFUs it distributes with the POD, its presentations at trade shows such as AORN, after- its sales maintenance and support, its FDA 510(k) premarket notification of intent to market the accused POD and on information and belief the instructions and directions provided by Robert, Turbett Surgical and their representatives during in service or other on-site meetings with customers encouraging infringing uses of the POD.

98. Turbett Surgical's knowing and intended direction to others, including its customers, is causing indirect infringement under 35 U.S.C. § 271(b) of at least claims 1, 2, 10, 11, 12, 13, 17, 26, 27, 28, 29 and 33 of the '143 patent.

Willful Infringement, Damages and Injunctive Relief

99. The infringement of the '143 patent by Turbett Surgical has been, since at least the date of service of this Complaint, and continues to be, deliberate, willful, and knowing, or with deliberate indifference, entitling Progressive to treble damages.

100. Progressive has been, and continues to be, damaged and irreparably harmed by the infringement of Turbett Surgical, which will continue unless this Court enjoins Turbett Surgical and those acting on its behalf or under its control.

101. Progressive, under 35 U.S.C. § 284, seeks damages adequate to compensate for the infringement of Turbett Surgical.

102. As a consequence of Turbett Surgical's willful infringement of the '143 patent,

Progressive is entitled to enhanced damages pursuant to 35 U.S.C. § 284.

103. The Court should declare this an exceptional case under 35 U.S.C. § 285, entitling Progressive to recover attorneys' fees.

SECOND CAUSE OF ACTION

Infringement of the '093 Patent

(Against Turbett Surgical)

104. Progressive repeats, realleges, and incorporates hereunder by reference the allegations contained in all of the above paragraphs.

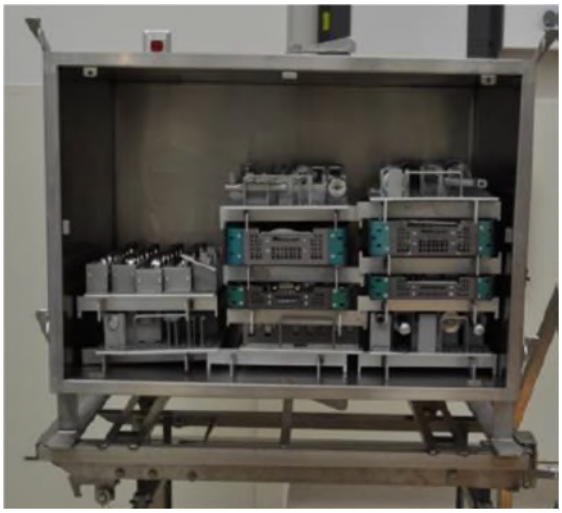
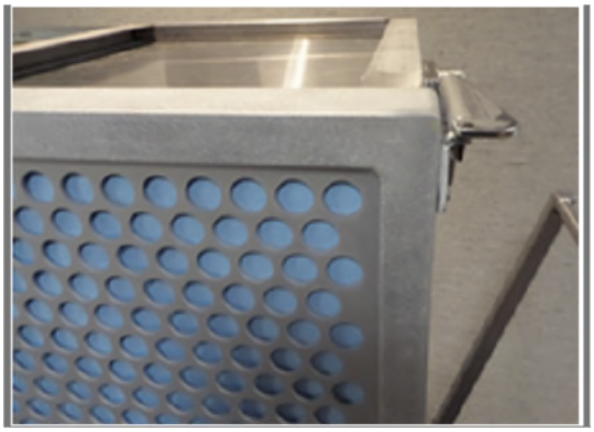
Direct Infringement

105. Turbett Surgical has directly infringed, and continues to directly infringe, literally and/or under the doctrine of equivalents, one or more claims of the '093 patent by, among other things, using the sterilization methods covered by at least claims 1, 2, 3, 5, 6, 7, 8, 9, 10, 12, 13, 14, 15, 16, 17, 18 and 19 of the '093 patent.

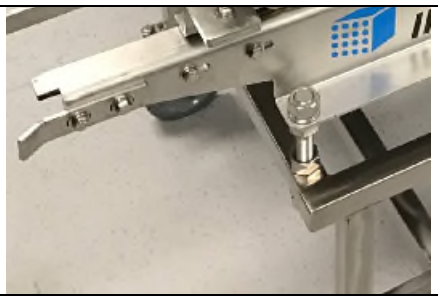
106. More specifically, Turbett Surgical's direct infringement of the '093 patent has been by practice of the claimed method to obtain FDA clearance, in in-service trials, for testing of the POD unit and for development and testing of the methods of using the POD unit.

107. One example of Turbett Surgical's infringement of the '093 patent is shown in the following table:

US 9,694,093	The Turbett method
1. A method of sterilizing at least one surgical tray containing surgical instruments using a cabinet, where the cabinet is sized to receive the at least one surgical tray within an interior sterilization chamber, where the cabinet can be configured between an open configuration allowing for insertion and removal of at least one surgical tray into the interior sterilization chamber and a sealed	The POD cabinet is used for packaging, transporting and holding of instruments prior to, during and after sterilization. It is indicated for enclosing multiple uncovered, vented instrument delivery trays. (Ex. G pg. 1) The POD cabinet can be configured between an open configuration allowing for insertion and removal of at least one surgical tray into the interior sterilization chamber and a sealed

configuration where the at least one surgical tray cannot be removed, the method comprising:	configuration where the at least one surgical tray cannot be removed. (Ex. F pgs. 1 & 2)   
configuring the cabinet in the open configuration;	After preparation and cleaning as specified on page 3 of Exhibit G, the POD cabinet is in the open configuration.
loading the at least one surgical tray containing surgical instruments into the interior sterilization chamber;	At least one surgical tray containing surgical instruments is then loaded into the interior sterilization chamber. (Ex. F pg. 3)

	
securing the cabinet into the sealed configuration;	The POD cabinet is then secured into the sealed configuration. "9. Place outer door on work table, outer side down. Place a single Turbett Surgical filter cartridge into the door. The filter is friction fit for assembly. 10. Place door onto front of container, and close the **SIX** latches. Latches are located two on each side, one on top center, one on bottom center" (Ex. G pg. 5)
positioning the cabinet at a sterilization location adjacent to an autoclave using a transfer cart,	The POD cabinet is then positioned at a sterilization location adjacent to an autoclave using the POD cart. "1. Unlock wheels, and roll cart to sterilizer. 2. Dock cart to sterilizer, engaging sterilizer cart lock and ensuring tracks are aligned." (Ex. G pg. 6)
where the transfer cart is adjustable to permit leveling of the cabinet to the autoclave;	The POD cart is adjustable to permit leveling of the POD cabinet to the autoclave via screw threads located at the corners of the cart:

	
locking the transfer cart relative to the autoclave;	The POD cart is locked relative to the autoclave. "2. Dock cart to sterilizer, engaging sterilizer cart lock and ensuring tracks are aligned. 3. Confirm cart is locked to sterilizer by pulling back on cart." (Ex. G pg. 6)
transferring the cabinet from the transfer cart into an autoclave while the transfer cart is locked relative to the autoclave,	The POD cabinet is transferred from the POD cart into an autoclave while the POD cart is locked relative to the autoclave. "**Do not proceed to load container unless cart is locked to sterilizer** 4. Release the transfer carriage lock, and push the container into the sterilizer until it is completely within the sterilizer." (Ex. G pg. 6)
where the cabinet or transfer cart includes mechanical guides to guide the transfer cart into the autoclave;	The POD cabinet includes guide rails and the cart includes flanged wheels.  "2. Dock cart to sterilizer, engaging sterilizer cart lock and ensuring tracks are aligned." (Ex. G pg. 6)
sterilizing the surgical instruments within the interior sterilization chamber;	The surgical instruments are sterilized within the interior sterilization chamber. "4. Run the sterilizer for the validated cycle." (Ex. G pg. 7)
positioning the cabinet onto the transfer cart while the cabinet is in the sealed configuration;	The POD cabinet is then positioned onto the POD cart while the cabinet is in the sealed configuration.

	"5. At the end of the cycle, roll cart into place, engage cart lock to sterilizer, confirm tracks are aligned, and lock wheels. … 6. Roll transfer carriage with container onto the cart. Ensure that transfer carriage locks to the cart" (Ex. G pg. 7)
releasing the transfer cart relative to the autoclave; and	The POD cart is released relative to the autoclave. "7. Disengage cart from sterilizer..." (Ex. G pg. 7)
relocating the cabinet from the sterilization location using the transfer cart.	The POD cabinet is relocated from the sterilization location using the POD cart. (Ex. G pg. 7) "7. … unlock wheels, and move entire unit to a draft free area to cool."

Induced Infringement

108. Turbett Surgical has infringed and continues to infringe indirectly by active inducement, specifically intending its customers, including hospitals and surgery centers and their surgical staff, to directly infringe one or more claims of the '093 patent.

109. Since at least the date of service of this Complaint, Turbett Surgical has had actual knowledge of the '093 patent, as well as knowledge that the POD unit is used to practice the methods claimed and taught in the '093 patent.

110. With this knowledge, Turbett Surgical knowingly has induced, and continues to induce, direct infringement of the '093 patent by its customers, including hospitals and surgery centers and their surgical staff, that have been and are continuing to sterilize surgical instruments using the POD unit as directed by Turbett Surgical. Upon information and belief, when Turbett Surgical sells the POD unit, it provides training and/or instruction specifying how the POD unit is to be used, including but not limited to the "Turbett Surgical Container" instructions attached

as Exhibit G. Consequently, Turbett Surgical has intentionally caused, urged, encouraged or aided action by its customers to practice the methods claimed and taught in the '093 patent resulting in direct infringement.

111. Turbett Surgical has had, and continues to have, the specific intent that its customers practice the methods claimed and taught in the '093 patent.

112. Turbett Surgical's knowing and intended direction to its customers, including hospitals and surgery centers and their surgical staff, is causing indirect infringement under 35 U.S.C. § 271(b) of at least claims 1, 2, 3, 5, 6, 7, 8, 9, 10, 12, 13, 14, 15, 16, 17, 18 and 19 of the '093 patent.

Willful Infringement, Damages and Injunctive Relief

113. The infringement of the '093 patent by Turbett Surgical has been, since at least the date of service of this Complaint, and continues to be, deliberate, willful, and knowing, or with deliberate indifference, entitling Progressive to treble damages.

114. Progressive has been, and continues to be, damaged and irreparably harmed by the infringement of Turbett Surgical, which will continue unless this Court enjoins Turbett Surgical and those acting on its behalf or under its control.

115. Progressive, under 35 U.S.C. § 284, seeks damages adequate to compensate for the infringement of Turbett Surgical.

116. As a consequence of Turbett Surgical's willful infringement of the '093 patent, Progressive is entitled to enhanced damages pursuant to 35 U.S.C. § 284.

117. The Court should declare this an exceptional case under 35 U.S.C. § 285, entitling Progressive to recover attorneys' fees.

///

///

THIRD CAUSE OF ACTION

Infringement of the '972 Patent

(Against Turbett Surgical)

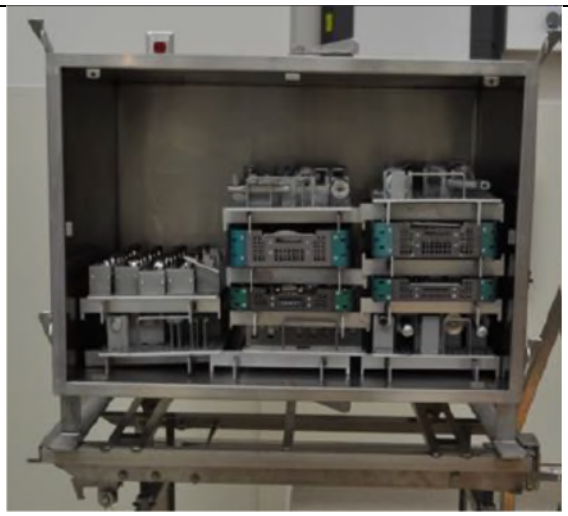
118. Progressive repeats, realleges, and incorporates hereunder by reference the allegations contained in all of the above paragraphs.

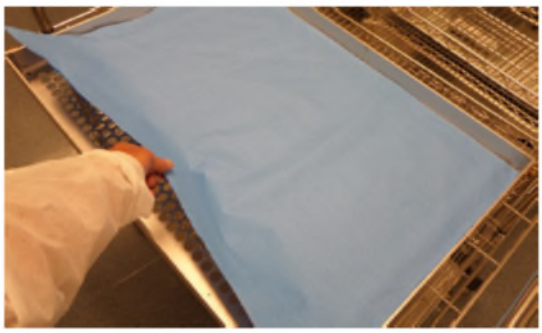
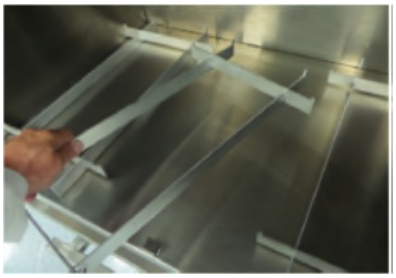
Direct Infringement

119. Turbett Surgical has directly infringed, and continues to directly infringe, literally and/or under the doctrine of equivalents, one or more of claims of the '972 patent by, among other things, making, using, importing, offering for sale, or selling the POD unit, which is covered by at least claims 14, 15, 16 and 18 of the '972 patent.

120. One example of Turbett Surgical's infringement of the '972 patent is shown in the following table:

US 10,111,972	The POD unit
14. A sterilization unit for sterilizing surgical equipment or a surgical tray, the sterilization cabinet comprising:	The POD cabinet is used for packaging, transporting and holding of instruments prior to, during and after sterilization. It is indicated for enclosing multiple uncovered, vented instrument delivery trays. (Ex. G. pg. 1)
a plurality of panels forming a chamber with an opening for insertion of the surgical equipment or the surgical tray into the chamber,	The POD cabinet comprises a plurality of panels forming a chamber with an opening for insertion of the surgical equipment or the surgical tray into the chamber (Ex. F pgs. 2 - 4)

	
where at least one of the plurality of panels is a floor panel at a bottom of the chamber, the floor panel having a lowest point;	The POD cabinet has a floor panel at a bottom of the chamber, the floor panel having a lowest point.
at least pane comprising a door, where the door is configured to close the opening to create a closed configuration in which the at least one door seals the chamber;	A Certificate of Correction has been filed to correct "at least pane" to "at least one panel." At least one panel of the POD cabinet is a door that is configured to close the opening to create a closed configuration in which it seals the chamber (Ex. G pgs. 2 & 4)  Outer Door
a vent formed in at least one of the plurality of panels that allows passage of a sterilization fluid therethrough;	The outer door has a vent formed therein that allows passage of a sterilization fluid therethrough, see image in cell directly above.
wherein an entirety of the floor panel is pitched such that any liquid condensate is directed by gravity towards the lowest point in the floor panel;	The entirety of the floor panel of the POD cabinet is pitched such that any liquid condensate is directed by gravity towards the lowest point in the floor panel.

a filter in fluid communication with the lowest point in the floor panel such that any condensate flowing on the entirety of the floor panel passes through the filter; and	A filter is positioned in the door over the vent, which is placed onto the front of the POD cabinet. The filter is in fluid communication with the bottom row of holes in the door such that any condensate flowing on the entirety of the floor panel passes through the filter. "Place a single Turbett Surgical filter cartridge into the door."  "10. Place door onto front of container, and close the **SIX** latches. Latches are located two on each side, one on top center, one on bottom center" (Ex. G pg. 5)
at least one supporting structure removably positioned within the chamber and configured for supporting the surgical equipment or the surgical tray above the floor panel.	The POD cabinet includes at least one supporting structure removably positioned within the chamber and configured for supporting the surgical equipment or the surgical tray above the floor panel. "3. Place divider into container. Dividers help ensure airflow. **Failure to place dividers could lead to wet loads**  4. Place instrument tray on top of divider, ensuring it is level." (Ex. G pg. 4)

Induced Infringement

121. 35 U.S.C. § 271 (a) provides that "whoever without authority … uses…any patented invention… infringes the patent." Accordingly, use of a patented apparatus by the purchaser or other end user of the patented apparatus is direct infringement of the patent by the purchaser/end user.

122. Since at least the date of service of this Complaint, Turbett Surgical has had actual knowledge of the '972 patent, as well as knowledge that the POD unit infringes one or more claims of the '972 patent.

123. With this knowledge, Turbett Surgical knowingly has induced, and continues to induce, direct infringement by its customers, including hospitals, surgery centers and associated surgical staff, which are using the infringing POD unit to sterilize surgical instruments.

124. Turbett Surgical specifically intended to encourage its customers to engage in infringing use of the POD as manifested by its web site and other promotional literature, the IFUs it distributes with the POD, its presentations at trade shows such as AORN, after- its sales maintenance and support, its FDA 510(k) premarket notification of intent to market the accused POD and on information and belief the instructions and directions provided by Robert, Turbett Surgical and their representatives during in service or other on-site meetings with customers encouraging infringing uses of the POD.

125. Turbett Surgical's knowing and intended direction to others, including its customers, is causing indirect infringement under 35 U.S.C. § 271(b) of at least claims 14, 15, 16 and 18 of the '972 patent.

Willful Infringement, Damages and Injunctive Relief

126. The infringement of the '972 patent by Turbett Surgical has been, since at least

the date of service of this Complaint, and continues to be, deliberate, willful, and knowing, or with deliberate indifference, entitling Progressive to treble damages.

127. Progressive has been, and continues to be, damaged and irreparably harmed by the infringement of Turbett Surgical, which will continue unless this Court enjoins Turbett Surgical and those acting on its behalf or under its control.

128. Progressive, under 35 U.S.C. § 284, seeks damages adequate to compensate for the infringement of Turbett Surgical.

129. As a consequence of Turbett Surgical's willful infringement of the '972 patent, Progressive is entitled to enhanced damages pursuant to 35 U.S.C. § 284.

130. The Court should declare this an exceptional case under 35 U.S.C. § 285, entitling Progressive to recover attorneys' fees.

FOURTH CAUSE OF ACTION

Misappropriation of Trade Secrets, 6 Del. C. §§ 2001-2009

(Against Turbett Surgical and Robert Turbett)

131. Progressive repeats, realleges, and incorporates hereunder by reference the allegations contained in all of the above paragraphs.

132. Progressive owns all right, title, and interest in the Trade Secret Technology disclosed to Robert.

133. Since it acquired ownership and control of the Trade Secret Technology, Progressive has maintained it in confidence and except for the unauthorized disclosures that are the subject of this lawsuit it has not been generally known nor has it been readily accessible. Progressive has derived independent economic value from keeping the Trade Secret Technology confidential. Building on the efforts of the Snyders, AmMed, Keenan and Mauzerall, Progressive

has continued to develop the Trade Secret Technology over years of investing substantial time, effort, expense, and research.

134. At all relevant times, Progressive has taken reasonable steps to maintain the secrecy of the Trade Secret Technology. Progressive has continued the practice of its predecessor AmMed of consistently obtaining NDAs from its outside vendors. Further, Robert and Turbett Surgical knew or reasonably should have known that the Trade Secret Technology disclosed in confidence to Robert by the Snyders, AmMed, Keenan and Mauzerall, and any of the vendors, consultants or investors with whom they associated to commercialize multiple tray sterilization products was confidential and proprietary. Robert's and Turbett Surgical's knowledge and understanding in this regard has not changed up through the present time.

135. At all relevant times, the Trade Secret Technology possessed by AmMed and then Progressive were trade secrets as defined by Delaware Uniform Trade Secrets Act ("DUTSA"), 6 Del. C. § 2001(4). As described above, Robert was provided confidential access to such trade secret information through his access to the Trade Secret Technology. The proprietary business and technical information of Progressive, i.e., the Trade Secret Technology that Robert accessed, constitutes trade secrets because Progressive, as described herein, derived independent economic value from that information and keeping that information secret; such information is not generally known nor readily ascertainable by proper means from other persons who can obtain economic value from its disclosure or use; and because the information was the subject of reasonable efforts to maintain its secrecy by AmMed and then Progressive.

136. At all relevant times, Robert knew that he had acquired the Trade Secret Technology under circumstances giving rise to a duty to maintain the secrecy of these trade secrets, and Turbett Surgical knew that it had acquired the Trade Secret Technology under

circumstances giving rise to a duty to maintain the secrecy of these trade secrets and/or that these trade secrets were derived from or through a person (Robert) who owed a duty to maintain the secrecy of the trade secrets.

137. Defendants have improperly used and disclosed the Trade Secret Technology without consent.

138. Defendants improperly used and disclosed the Trade Secret Technology, and information derived from these trade secrets, in the planning of, design of, FDA clearance of, purported patenting of, marketing of, and sale of at least Turbett Surgical's POD, filters and accessories.

139. As a proximate cause of Defendants' trade secret misappropriation, Progressive has suffered damages in an amount to be proven at time of trial, but which are substantial and in excess of the minimum jurisdiction for an unlimited civil case of this Court.

140. Defendants' misappropriation of the Trade Secret Technology is willful and malicious.

141. Progressive is entitled to recover actual and treble damages, unjust enrichment, attorneys' fees, and the costs of this litigation pursuant to DUTSA, 6 Del. C. § 2003(a) and (b) and injunctive relief pursuant to DUTSA, 6 Del. C. § 2002.

FIFTH CAUSE OF ACTION

Breach of Fiduciary Duty – Agency Relationship

(Against Robert Turbett)

142. Progressive repeats, realleges, and incorporates hereunder by reference the allegations contained in all of the above paragraphs.

143. Progressive owns all right, title, and interest in the Confidential Information

disclosed to Robert.

144. Since it acquired ownership and control of the Confidential Information, Progressive has maintained it in confidence and except for the unauthorized disclosures that are the subject of this lawsuit the Confidential Information has not been generally known nor has it been readily accessible. Building on the efforts of the Snyders, AmMed, Keenan and Mauzerall, Progressive has continued to develop the Confidential Information over years of investing substantial time, effort, expense, and research.

145. At all relevant times, Progressive has taken reasonable steps to maintain the secrecy of the Confidential Information. Progressive has continued the practice of its predecessor AmMed of consistently obtaining NDAs from its outside vendors. Further, Robert and Turbett Surgical knew or reasonably should have known that the Confidential Information disclosed in confidence to Robert by the Snyders, AmMed, Keenan and Mauzerall, and any of the vendors, consultants or investors with whom they associated to commercialize multiple tray sterilization products was confidential and proprietary. Robert's and Turbett Surgical's knowledge and understanding in this regard has not changed up through the present time.

146. By its words and conduct, AmMed acknowledged that Robert would act for the company and subject to its control in regard to obtaining FDA clearance of the SCORES units, marketing, sales and promotion of SCORES units, and seeking to obtain additional funding and capital for AmMed.

147. Robert, by his words and conduct, manifested his assent to act on behalf of AmMed and its successors and assigns with respect to these undertakings and to do so subject to their control.

148. As a result of their relationship, Robert owed AmMed and its successors and

assigns the fiduciary duty to act loyally for their benefit, including the specific duties 1) not to use their property for Robert's own benefit or those of a third party, and 2) not to use or communicate their confidential information for Robert's own purposes or those of a third party.

149. Robert breached his fiduciary duties in one or more of the following ways:

a. Misappropriated the Confidential Information for his own benefit and that of his business interests by improperly using and disclosing the Confidential Information and information derived from the Confidential Information, in the planning of, design of, FDA clearance of, purported patenting of, marketing of, and sale of at least Turbett Surgical's POD and its filters and accessories.

b. Misappropriated the Confidential Information for his own benefit and that of his business interests by disclosing and communicating it to third parties.

150. AmMed and its successors and assigns did not consent to Robert's unlawful disclosure and use of their confidential information.

151. Progressive is AmMed's successor and assign based upon the bankruptcy court's Order Confirming Plan of Liquidation entered December 21, 2015, pursuant to which Progressive was deemed to have acquired substantially all of AmMed's tangible and intangible assets, including all of AmMed's patents, trade secrets, confidential information and any other intellectual property rights relating to sterilization systems, and, further, pursuant to which AmMed dissolved effective March 4, 2016, stating in its Articles of Dissolution that as a result of the bankruptcy "COMPANY SOLD," and, further, pursuant to which the founders and managing members of AmMed (and the inventors of the underlying SCORES technology) agreed not to compete with Progressive.

152. Alternatively, Progressive is AmMed's successor and assign under the

Confidentiality Agreement(s) that on information and belief were entered into between AmMed and Robert.

153. Progressive, as AmMed's successor and assign, has been harmed as a direct and proximate result of Robert's conduct.

154. The aforementioned acts of Robert are willful, malicious and fraudulent.

155. Progressive is entitled to actual damages, trebled damage, attorneys' fees and costs for Robert's willful conduct, and to injunctive relief.

SIXTH CAUSE OF ACTION

Aiding and Abetting

(Against Turbett Surgical and Robert Turbett)

156. Progressive repeats, realleges, and incorporates hereunder by reference the allegations contained in all of the above paragraphs.

157. Robert has committed the wrongful acts of trade secret misappropriation and breach of fiduciary duties arising out of an agency relationship.

158. Turbett Surgical had knowledge of Robert's wrongful acts based upon Robert serving as Turbett Surgical's controlling member and principal manager.

159. Turbett Surgical knowingly and substantially participated in or provided substantial assistance for Robert's wrongful acts.

160. Turbett Surgical has committed the wrongful acts of trade secret misappropriation.

161. Robert had knowledge of Turbett Surgical's wrongful acts based upon Robert serving as Turbett Surgical's controlling member and principal manager.

162. Robert knowingly and substantially participated in or provided substantial

assistance for Turbett Surgical's wrongful acts.

163. Turbett Surgical and Robert are jointly and severally liable for harm to Progressive resulting from Robert's wrongful acts.

164. Robert's and Turbett Surgical's participation or assistance in the unlawful acts of the other was willful and malicious.

165. Progressive is entitled to actual damages, trebled damage, attorneys' fees and costs for Turbett Surgical's willful conduct, and to injunctive relief.

SEVENTH CAUSE OF ACTION

Conspiracy to Misappropriate Trade Secrets and Confidential Information

(Against Turbett Surgical and Robert Turbett)

166. Progressive repeats, realleges, and incorporates hereunder by reference the allegations contained in all of the above paragraphs.

167. Robert and Turbett Surgical together agreed upon and implemented a conspiracy to use the Trade Secret Technology and Confidential Information to make a multiple tray sterilization system and to do so before any or all of Keenan, Mauzerall, AmMed or Progressive could get a competing system to market.

168. In furtherance of the conspiracy, Robert misappropriated and unlawfully disclosed the Trade Secret Technology and Confidential Information to Turbett Surgical.

169. In furtherance of the conspiracy, Robert misappropriated and unlawfully used the Trade Secret Technology and Confidential Information.

170. In furtherance of the conspiracy, Robert breached fiduciary duties to AmMed and its successors and assigns by unlawfully misappropriating the Trade Secret Technology and Confidential Information for his own benefit and that of his business interests and/or by

disclosing and communicating it to Turbett Surgical or other third parties.

171. Central to the conspiracy was the covert formation of Turbett Surgical for purposes of furthering the scheme of misappropriating and unlawfully using the Trade Secret Technology and Confidential Information to develop and promote the sale of a multiple tray sterilization system that came to be called the POD.

172. As proximate result of the conspiracy, Progressive has been harmed.

173. Turbett Surgical and Robert are jointly and severally liable for harm to Progressive resulting from the conspiracy.

174. Robert's and Turbett Surgical's conduct was willful and malicious.

175. Progressive is entitled to actual damages, trebled damage, attorneys' fees and costs for Turbett Surgical's willful conduct, and to injunctive relief.

EIGHTH CAUSE OF ACTION

Breach of Contract

(Against Robert Turbett)

176. Progressive repeats, realleges, and incorporates hereunder by reference the allegations contained in all of the above paragraphs.

177. On information and belief, on or about December 29, 2011 Robert and AmMed, and its successors and assigns, entered into the Confidentiality Agreement, a true and correct copy of which is attached hereto as Exhibit A.

178. The Confidentiality Agreement provides "[t]his agreement shall be binding upon and inure to the benefit of the parties, their successors and assigns." Progressive is AmMed's successor and assign.

179. Under the Confidentiality Agreement, Robert was obligated to, *inter alia,* (i) hold

any and all confidential information, including Confidential Information and Trade Secret Technology, he obtained from AmMed confidential and secret; (ii) use the Confidential Information and Trade Secret Technology solely and exclusively for the contemplated purpose of the Confidentiality Agreement, which is "seeking the undersigned as a potential investor in the company"; and (iii) refrain from disclosing any and all Confidential Information and Trade Secret Technology to any third party absent agreement from the third party to be bound by the terms of the Confidentiality Agreement and approval of the disclosure by AmMed, and/or its successors and assigns.

180. AmMed did all, or substantially all, of the essential things which the Confidentiality Agreement required it to do, except those which were waived, excused or rendered impossible of performance.

181. All conditions required by the Confidentiality Agreement for Robert's performance had occurred.

182. Robert breached the Confidentiality Agreement by (i) failing to hold AmMed's Confidential Information and Trade Secret Technology confidential and secret; (ii) using the Confidential Information and Trade Secret Technology for purposes other than the contemplated purpose of the Confidentiality Agreement; (iii) failing to refrain from disclosing any and all Confidential Information and Trade Secret Technology to any third party without agreement from any third party to be bound by the Confidentiality Agreement and without approval by AmMed and/or is successors and assigns.

183. In the alternative, to the extent Robert did not breach any term of the Confidentiality Agreement, he breached the covenant of good faith and fair dealing by unfairly interfering with Progressive's right to receive the benefit of the contract. The parties

contemplated that one of the benefits of the Confidentiality Agreement is Robert's safeguarding of the Confidential Information and Trade Secret Technology. Progressive did not receive this benefit as a direct and proximate result of Robert's breach of such covenant.

184. As a direct and proximate result of Robert's breaches of the Confidentiality Agreement (or, alternatively, of the covenant of good faith and fair dealing), Progressive has suffered damages, and Robert has been unjustly enriched, in an amount to be determined at trial.

185. Robert's breaches have caused and continue to cause Progressive irreparable harm that cannot be fully redressed through damages alone. An injunction as set forth herein is necessary to provide Progressive with complete relief.

NINTH CAUSE OF ACTION

Tortious Interference with Contract

(Against Turbett Surgical)

186. Progressive repeats, realleges, and incorporates hereunder by reference the allegations contained in all of the above paragraphs.

187. A valid contract existed between AmMed, and its successors and assigns, and Robert, namely the Confidentiality Agreement. Progressive is AmMed's successor and assign.

188. Turbett Surgical was aware of the existence of a valid contract between AmMed, and its successors and assigns, and Robert, namely the Confidentiality Agreement.

189. Turbett Surgical intentionally took actions that were intended to and did induce a breach or disruption of the Confidentiality Agreement, including (within a few months of Turbett's departure from AmMed) developing the POD product; seeking FDA clearance to market the POD under Section 510(k); offering the POD for public sale; disclosing and using the Trade Secret Technology and Confidential Information in its IFU and to users of the POD; and

disclosing and using the Trade Secret Technology and Confidential Information in the course of marketing and selling the POD.

190. There was no legal justification for the actions of Turbett Surgical.

191. As a direct and proximate result of the actions of Turbett Surgical, Progressive has suffered damages, and Turbett Surgical has been unjustly enriched, in an amount to be determined at trial.

TENTH CAUSE OF ACTION

Breach of Quasi Contract/Unjust Enrichment

(Against Robert Turbett)

192. Progressive repeats, realleges, and incorporates hereunder by reference the allegations contained in all of the above paragraphs.

193. To the extent there is no enforceable express or implied-in-fact contract between Robert and AmMed, and its successors and assigns, with respect to the Confidential Information and Trade Secret Technology, Progressive alternatively pleads breach of a quasi-contract and is entitled to recovery thereunder, as AmMed's successor and assign.

194. AmMed, and its successors and assigns, have conferred material benefits on Robert, namely access to its Confidential Information and Trade Secret Technology, which Robert requested, received, accepted and fully enjoyed the benefit thereof.

195. Robert has knowledge of the benefits conferred by AmMed, and its successors and assigns.

196. Robert has accepted and/or retained the benefits, including by accessing, using, retaining and disclosing to third parties AmMed's Confidential Information and Trade Secret Technology.

197. Robert has failed to pay any value for the Confidential Information and Trade Secret Technology of AmMed and its successors and assigns.

198. Extant circumstances make it unjust for Robert to retain the benefits without fully and fairly compensating Progressive, as AmMed, and its successors and assigns, have fulfilled their obligations to Robert under the quasi contract by providing Robert access to AmMed's Confidential Information and Trade Secret Technology, in reliance upon Robert's representations to fulfill his obligations.

199. Robert has been unjustly enriched at the expense of AmMed, and its successors and assigns, in an amount to be proven at trial.

ELEVENTH CAUSE OF ACTION

Misappropriation of Trade Secrets, Defend Trade Secret Act, 18 U.S.C. 1836 *et seq.*

(Against Robert Turbett and Turbett Surgical)

200. Progressive repeats, realleges, and incorporates hereunder by reference the allegations contained in all of the above paragraphs.

201. Progressive owns all right, title, and interest in the Trade Secret Technology disclosed to Robert.

202. Since it acquired ownership and control of the Trade Secret Technology, Progressive has maintained it in confidence and except for the unauthorized disclosures that are the subject of this lawsuit, the Trade Secret Technology has not been generally known nor has it been readily accessible. Progressive has derived independent economic value from keeping the Trade Secret Technology confidential. Building on the efforts of the Snyders, AmMed, Keenan and Mauzerall, Progressive has continued to develop the Trade Secret Technology over years of investing substantial time, effort, expense, and research.

203. At all relevant times, Progressive has taken reasonable steps to maintain the secrecy of the Trade Secret Technology. Progressive has continued the practice of its predecessor AmMed of consistently obtaining NDAs from its outside vendors. Further, Robert and Turbett Surgical knew or reasonably should have known that the Trade Secret Technology disclosed in confidence to Robert by the Snyders, AmMed, Keenan and Mauzerall, and the vendors, consultants or investors with whom they associated to commercialize multiple tray sterilization products was confidential and proprietary. Robert's and Turbett Surgical's knowledge and understanding in this regard has not changed from first disclosure to them and through the present time.

204. At all relevant times, the Trade Secret Technology possessed by AmMed and then Progressive constituted trade secrets as defined by the Defend Trade Secrets Act, 18 U.S.C. § 1839(3). As described above, Robert was provided confidential access to such trade secret information through his access to the Trade Secret Technology. The proprietary business and technical information of Progressive, i.e., the Trade Secret Technology that Robert accessed, constitutes trade secrets because Progressive, as described herein, derived independent economic value from that information and from keeping that information secret; such information is not generally known nor readily ascertainable by proper means from other persons who can obtain economic value from its disclosure or use; and because the information was the subject of reasonable efforts to maintain its secrecy by AmMed, and then Progressive.

205. At all relevant times, Robert knew that he had acquired the Trade Secret Technology under circumstances giving rise to a duty to maintain the secrecy of these trade secrets, and Turbett Surgical knew that it had acquired the Trade Secret Technology under circumstances giving rise to a duty to maintain the secrecy of these trade secrets and/or that these

trade secrets were derived from or through a person (Robert) who owed a duty to maintain the secrecy of the trade secrets.

206. At all relevant times, the Trade Secret Technology was related to a product or service used in interstate commerce, including the Defendant's commercialization of multiple surgical tray sterilization technology in the form of the POD and other related products and accessories with the objective of supplying hospitals and healthcare facilities in national and international markets.

207. The Trade Secret Technology has not been disclosed before the enactment of the DTSA on May 11, 2016 with respect to at least the design, manufacture, FDA clearance, marketing and sales of SCORES units, filters and accessories, multiple tray sterilization system technology, and related intellectual property relating to:

a. Subject matter that might not be covered in pending patent applications, including U.S. Patent Applications 12/387,673, filed May 6, 2009 and 13/944,875, filed July 17, 2013;

b. Negative know-how and other non-public information relating to the development of the SCORES units' Instructions For Use (IFU) including improved IFU for multiple tray sterilization systems developed through the human factors testing on SCORES units;

c. Protocols for validating performance of multiple tray sterilization systems sufficient to obtain FDA 510(k) clearance, including:

1) Methodology for analyzing microbial barrier properties;

2) Methodology for verifying sterilization efficacy;

3) Methodology for demonstrating adequate steam sterilization/heat

penetration of the cabinet;

4) Methodology for determining proper drying time;

5) Methodology for determining transport and shelf life over 7/30 days;

6) Methodology for demonstrating safety and performance of transfer cart; and

7) Methodology for using human factors testing to validate usability of the multiple surgical instrument tray systems in both OR and sterile processing department.

This category of trade secrets encompasses negative know-how regarding the protocols to be used and the know-how regarding the combination of specific protocols required to validate a mobile system for sterilizing multiple trays of surgical instruments.

d. Methodology for combining filters to achieve FDA-compliant microbial barrier properties;

e. Non-public submissions and content of 510(k) Premarket Notification for SCORES units;

f. Pricing strategies for SCORES units, filters and accessories; and

g. The identity and cost of vendors and consultants competent and available to provide performance testing and FDA clearance approval.

208. In addition, whether any or all of the Trade Secret Technology was disclosed prior to the enactment of the DTSA and/or was not secret, Progressive's trade secrets include the combination of separate categories of Trade Secret Technology to create a process for

successfully commercializing a mobile system for sterilizing multiple trays of surgical instruments. This combination has not been disclosed.

209. Defendants have misappropriated by continuing use on and after the enactment of the DTSA on May 11, 2016 the non-disclosed Trade Secret Technology.

210. Defendants' misappropriation of the Trade Secret Technology is willful and malicious.

211. Progressive is entitled to recover actual and treble damages, unjust enrichment, attorneys' fees, and the costs of this litigation pursuant to DTSA, 18 U.S.C. § 1836(b)(3)(B) and injunctive relief pursuant to DTSA, 18 U.S.C. § 1836(b)(3)(A).

TWELFTH CAUSE OF ACTION

False Advertising – Violation of Lanham Act, 15 U.S.C. § 1125

(Against Turbett Surgical)

212. Progressive repeats, realleges and incorporates hereunder by reference the allegations contained in all of the above paragraphs.

Market Opportunity

213. Progressive, on its own or through its license and distribution agreement with PMBS, competes directly with Turbett Surgical in the market to supply mobile systems for sterilizing multiple trays of surgical instruments.

214. The relevant customers are hospitals and health care facilities who, for each surgery, have trays of surgical instruments that need to be loaded, sterilized, stored and delivered to the OR from the sterile processing department and then returned to the sterile processing department following surgery.

215. These customers are most interested in purchasing sterilization systems that

address time-consuming, inefficient and expensive sterilization processes while protecting against the threat to patient safety posed by undetected or compromised breaches in sterile wrapping.

216. Mobile systems for multiple surgical tray sterilization are directly responsive to these customer requirements. They eliminate the time-consuming, expensive and potentially hazardous steps of wrapping, taping, labeling, sterilizing, storing and finally delivering to the OR and then inspecting individual trays of surgical instruments.

217. There are significant market opportunities for legitimate suppliers of these multiple surgical tray sterilization systems. The projected number of hospitals and healthcare facilities interested in these systems is in the thousands and the great majority of the customer base have not yet made the initial transition to a multiple tray sterilization system from legacy single tray sterilization systems. Suppliers chosen for this initial transition have a much greater opportunity to sell additional systems and related filters and accessories into the same customer. The projected revenues for this market are conservatively estimated as hundreds of millions.

FDA Regulation

218. The design, development, manufacture, marketing and sale of Progressive's and Defendants' competing mobile systems for multiple surgical tray sterilization, the CUBE or SteriCUBE (by Progressive) and the POD (by Turbett Surgical), respectively, is regulated by the FDA.

219. PMBS (acting as the exclusive licensee of AmMed's, and subsequently Progressive's, intellectual property) at the time as the licensee of Progressive's predecessor AmMed) and Turbett Surgical submitted a 510(k) notifying the FDA of the intent to bring devices implementing their multiple tray sterilization systems to market. These submissions were

required to demonstrate to the FDA that the device to be marketed was at least as safe and effective as, or substantially equivalent to, a previous legally marketed device. The legally marketed device to which equivalence is drawn is commonly known as the "predicate" device. Both submissions cited the Snyders' and AmMed's SCORES system as the predicate device in their respective 510(k) submissions.

220. Before the systems could be marketed and sold, the FDA had to issue an order in the form of a letter finding the system to be substantially equivalent to the predicate device. The FDA issued such an order with respect to both the CUBE and the POD, thereby "clearing" the devices for commercial distribution.

221. These systems may only be labeled and promoted for uses cleared by the FDA. Labeling is considered to be any written material which accompanies, supplements, or explains the product. Labeling includes the Instructions for Use (IFUs) that accompany the CUBE and the POD. Labeling also includes the IFUs provided by the manufacturers of the surgical instruments sterilized in the CUBE or POD. Promotion means all proactive activities (written, oral or otherwise) that directly or indirectly market, sell or support product sales and use, or that contribute to the sales growth of a company's products. For example, the FDA views promotion as including written labeling and advertising materials, interactions with sales representatives, company websites, dissemination of journal articles, and, in some cases, trade show presentations, physician training, and reimbursement advice.

222. The FDA's clearance of the CUBE and the POD was contingent upon, among other things, the FDA finding that the labeling of these systems accurately reflected the safety and effectiveness data presented as part of Progressive/PMBS's and Defendants' respective 510(k) submissions.

223. Any significant change in labeling or that otherwise affects any condition of a device previously cleared by the FDA requires a new 510(k) submission where the change is deemed significant. An example of such a significant change, per the FDA's online explanation of its 510(k) procedures, is where "[o]perations, such as sterilization, could alter the condition of the device." *See* FDA, Premarket Notification 510(k) at https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k#who.

224. "Off-label" is a term describing instructions for the use of a cleared medical device that are not specified in the IFUs or other labeling approved by the FDA. It is any use that is not in the FDA's cleared indications for use.

225. Good medical practice and the best interests of the patient require that hospitals and physicians use FDA cleared devices consistent with FDA approved uses and IFUs and other labeling and do not engage in off-label uses.

226. The national organizations that are directly interested in the sterilization of surgical instruments, including Association of periOperative Registered Nurses (AORN), International Association of Healthcare Central Service Materiel Management (IAHCSMM), Center for Disease Control and Prevention (CDC), and Association for the Advancement of Medical Instrumentation (AAMI) all require that suppliers of sterilization systems must follow the IFUs of the surgical instrument manufacturers.

Dry Time is a Material Consideration

227. As part of the sterilization process, multiple uncovered trays of surgical instruments are loaded into a cabinet (e.g. Progressive's CUBE cabinet or Defendants' POD cabinet) and the cabinet is then placed into an autoclave for sterilization.

228. A typical load in a medium to large sterilization chamber (autoclave) takes approximately 60 minutes to run. This includes a Conditioning Cycle of about 15 minutes (to get the sterilizer up to temperature), followed by a Sterilization Cycle typically 4-10 minutes, followed by a Dry Cycle of 30 minutes or more. During the Sterilization Cycle pre-vacuum steam is then introduced into the cabinet for purposes of sterilizing the contents of the cabinet.

229. Validation testing and the IFUs submitted to the FDA for Progressive's CUBE, the Defendants' POD and the Snyders' SCORES system, used a minimum four minute exposure (Sterilization Cycle) to introduce pre-vacuum steam at 270°F. The FDA validated and approved the four minute/270°F Sterilization Cycle for all these systems and their IFUs.

230. Following the Sterilization Cycle, the cabinet remains in the autoclave for drying time, which ensures the removal by evaporation or drainage of all condensate (i.e. liquid water) resulting from the sterilization cycle. Incomplete or prematurely ending the dry time cycle poses the significant risk of the cabinet and/or the instrument trays and/or individual medical devices retaining moisture which can render the contents unsterile. In fact, the SCORES units, the original multiple tray sterilization containers, experienced moisture retention issues and the company performed a voluntary recall. Millions of dollars were spent perfecting the design of the SteriCUBE System that served as the replacement device for the SCORES units that were removed from the marketplace. Of particular note is that the SCORES units had filters in the lower portion of the cabinet that, when moisture was retained on the filter, the moistures served as a pathway through which contaminants can travel back into the cabinet thereby compromising sterility and endangering the safety of the patient. This moisture was not always visible hours after retrieving the cabinet from the autoclave as over time the moisture could evaporate. This was of greater significance since undetected contamination is an even greater threat to patient

safety. At least if there is visible moisture when the OR technicians open the cabinet to retrieve the contents, they would reject the instruments as being contaminated, thus delaying the surgical procedure but not necessarily endangering the patient. This is why it is imperative that the contents of the autoclave are retrieved only after thorough drying. This is why each manufacturer of instruments validates their own systems and specifies in their respective IFUs the minimum sterilization times and dry times (e.g., Zimmer – 4 min. sterilization/30 minute minimum dry time; Stryker – 4 min. sterilization/30 minute minimum dry time; Biomet – 4 min. sterilization/30 minute minimum dry time).

231. Validation testing and the IFUs submitted to the FDA for Progressive's CUBE, the Defendants' POD and the Snyders' SCORES system used a 30 minute dry time. The FDA reviewed the data showing a 30 minute dry time validation and approved the 30 minute dry time for all these systems and their IFUs.

232. On information and belief, no surgical instrument manufacturer whose devices are sterilized in a multiple tray sterilization system has obtained FDA approval for a dry time less than 30 minutes in a multiple tray sterilization container. On information and belief, there is at least one orthopedic vendor with minimum dry time of only 20 minutes but even this vendor has not validated a shorter dry time nor have they obtained FDA clearance for this shorter dry time in a multiple tray sterilization container.

233. On information and belief, the FDA has never validated or approved a dry time of less than 30 minutes in connection with the sterilization of surgical instruments in a multiple tray sterilization system.

234. Any change in the operation of a multiple tray sterilization system or its IFU or other labeling to shorten dry time is a significant change, one which potentially compromises the

sterility of the contents of a cabinet, and therefore requires a new 510(k) submission seeking FDA approval of the changes.

False Advertising

235. Turbett Surgical has repeatedly made the literally false or impliedly false statements in its commercial advertising that the POD has a validated 10 minute dry time.

236. Defendants distributed at the AORN Surgical Conference and Expo in April 2017 and the IAHCSMM Annual Conference in May 2017 and possibly at other conferences as well the following postcard:

237. Robert also repeatedly published online articles in which he made literally false or impliedly false statements that the POD was validated for safe and effective operating using a 10 minute dry time:

Your New Choice in Processing Instruments,
By Robert Turbett, President at Turbett Surgical
Published May 2, 2017

https://www.linkedin.com/pulse/your-new-choice-processing-instruments-robert-turbett/

With our new 10 minute dry time validation, we increase your sterilizer throughput capability by 45%, so you can handle all the work that is being sent to you. Instrument turnaround time can be reduced dramatically. We help you do a much better job with your two customers- the patient, and the OR.

Sterile Processing – How to Help Your Team and Befriend the Operating Room at the Same Time,
By Robert Turbett, President at Turbett Surgical
Published May 3, 2017

https://www.linkedin.com/pulse/sterile-processing-how-help-your-team-befriend-room-same-turbett/

Instrument sets can be turned over much quicker - and utilizing the new validated 10 minute dry time, instruments can be returned to the OR in record time.

Instrument Pod Saves Time at AAOS 2018 New Orleans
By Robert Turbett, President at Turbett Surgical
Published March 11, 2018

https://www.linkedin.com/pulse/instrument-pod-saves-time-aaos-2018-new-orleans-robert-turbett/

Surgeons were impressed with this, and in tune with our 4/10 validation that doubles sterilizer throughput in the Sterile Processing department- and gets the equipment back to the OR sooner.

Turbett Surgical is Heading to IAHCSMM!,
By Robert Turbett, President at Turbett Surgical
Published April 15, 2018

https://www.linkedin.com/pulse/turbett-surgical-heading-iahcsmm-robert-turbett/

The past year has given us a lot of experience and success implementing our validated 4/10 cycle, doubling the sterilizer throughput. This is letting SPD's with just two sterilizers perform as if they had four!

238. Robert also published numerous articles online in which he made the literally false or impliedly false statement that the POD was validated for safe and effective operation reducing the dry time by 20 minutes. For example:

Eliminate Surgical Delays Due to Holes in Wrap,
By Robert Turbett, President at Turbett Surgical
Published May 11, 2018

https://www.linkedin.com/pulse/eliminate-surgical-delays-due-holes-wrap-robert-turbett/

The economic improvement can't be ignored. By using the Instrument Pod, turnover time is reduced by as much as 20 minutes, making hospitals as efficient as surgicenters. That time savings on a three surgery day leads to enough time to add a procedure. That's the equivalent of adding 250 hours/ 32 surgical days to each operating room dedicated to using the Instrument Pod.

239. On information and belief, the purported validation was not based on credible and reliable testing.

240. The purported validation statements, when viewed in context, falsely imply that the validation was of a fully loaded POD to a maximum of 15 trays or 375 lbs.

241. The purported validation statements, when viewed in context, falsely imply that the POD could be safely and effectively operated using a 10 minute dry time and/or by reducing the 30 minute dry time cycle by 20 minutes.

242. These validation statements are contradicted by the POD's 510(k) submission claiming substantial equivalence to a predicate device, the Snyders' SCORES cabinet, which was validated and approved by the FDA for a 30 minute dry time.

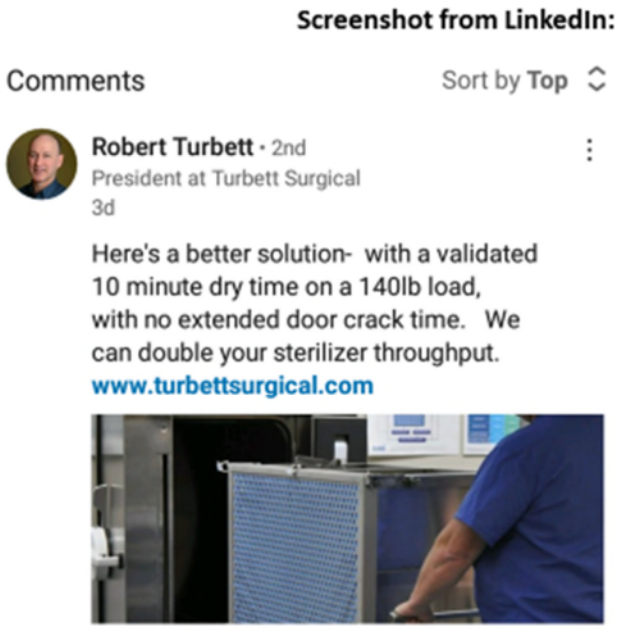
243. These validation statements are contradicted by the IFU approved by the FDA for use with the POD, which provides the "Turbett Surgical Container was validated using: **270**

degree F (132 C) Pre-vacuum cycle with an exposure of **4 minutes** and a dry time of **30 minutes**. (See Exh. G. (emphasis in original).)

244. On information and belief, the FDA has not cleared the POD for use with a 10 minute dry time nor has the FDA approved any IFU distributed with the POD for a 10 minute dry time.

245. Further evidence that these validations statements are literally false or impliedly false is that almost two years after Defendants began this advertising campaign they qualified their earlier claims to limit the application of the 10 minute dry time to loads of 140 lb. or less, i.e., to loads less than 40% of the maximum capacity of the POD cabinet. On or about January 20, 2019, Robert posted the following statement on his LinkedIn account:

Screenshot from LinkedIn:



246. Alternatively, the statements that the POD has been validated for a 10 minute dry time are misleading in at least the following respects:

a. Misrepresenting that the validation was presented to and approved by the FDA when in fact this has not occurred.

b. Misrepresenting that the use of a dry time of 10 minutes complies with the IFUs of surgical instrument manufacturers when in fact this has not occurred.

c. Mispresenting and withholding from hospitals and healthcare facilities that the 10 minute dry time is an off-label use.

d. Misrepresenting that the purported validation was based on credible and reliable testing when, in fact, this had not occurred.

e. Misrepresenting that the validation was of a fully loaded POD to a maximum of 15 trays or 375 lbs when, in fact, this had not occurred.

f. Misrepresenting that the POD could be safely and effectively operated using a 10 minute dry time and/or by reducing the 30 minute dry time cycle by 20 minutes when, in fact, this is not the case.

247. Defendants have continued up through the present to widely disseminate and promote the POD to target hospital and healthcare facility customers as having a validated 10 dry time.

248. In April 2019, Defendants began distributing a so-called "retrospective study" prepared by Dr. Brian McGrath. Dr. McGrath, on information and belief, is an investor in Turbett Surgical and a co-inventor with Robert on at least one of Turbett Surgical patents or patent applications (although these bias-inducing factors are not disclosed in the study). The study, which is reproduced below, purports to analyze POD-sterilized surgical instruments used in 2,100 orthopaedic joint replacement procedures. The study purports to reduce time in the autoclave when using the POD from 60 to 30 minutes, which, allowing for a conditioning time of approximately 15 minutes, means that the POD was being operated off-label using a 10 minute dry time. The study touts the "outcome" of achieving a "70% time savings dry time" (referring to the approximate reduction from 30 minutes to 10 minutes for dry time). The study also specifically refers to repeatedly processing 300 pounds of instrumentation in the POD,

contradicting the 2019 statement purporting to limit the abbreviated dry time validation to loads of no more than ***140 lbs***.

Use of A Novel Sterilization Process for Surgical Instruments

Our Team

Brian McGrath, M.D.
Professor of Orthopaedics, University at Buffalo Jacobs School of Medicine and Biomedical Sciences
UBMD Orthopaedics & Sports Medicine

Juliette Mader, RN BSN
Director Perioperative Services
Kaleida Health- Buffalo General Medical Center, Gates Vascular Institute

Nancy Schoolfield, BA, CHL, CIS, CRCST, ST
Campus Director – Sterile Processing
Kaleida Health- Buffalo General Medical Center/Gates Vascular Institute/ John Oishei Children's Hospital

Mary Beyers-Thoring, MS, MBA
Research Manager, Dept. of Orthopaedics
Kaleida Health/Buffalo General Medical Center
SUNY at Buffalo

Preparation and Planning

The Kaleida Health Hospital System was expanding the number of operating rooms from 20 to 40. The expansion included ORs for different procedures including vascular and pediatric. The sterile processing department (SPD) management was requested to evaluate a sterilized pod system that was a new and more efficient sterile processing method (Figure 1). An eighteen month trial was set up to evaluate the sterile pod system for orthopedic joint procedures.
The evaluation would include sterile processing instruments in the standard method versus the new pod system.
The standard methods decontamination, cleaning, inspection, high level disinfection/sterilization. 1. The instruments are then systematically placed into custom metal sterilization trays wrapped in blue paper secured with autoclave indicator tape placed in the autoclave for 60 min then properly cooled (Figure 2).

Figure 1 Pod System

Figure 2 Blue paper wrap versus the pod

Preparation and Planning (cont.)

2. Instruments are placed in custom metal containers and secured with a lock which has an indicator to verify the sterilization process. Once cooled placed on case charts for use in the operating room.
The **sterile pod method,** method 3 The first steps of cleaning are the same. Instruments are placed in there custom trays but there is no wrapping in blue paper. The trays are put directly into the sterile pod which has filter that changes color after sterilization. There is no additional lifting of individual trays once they are in the pod. The autoclave time is only 30 minutes and you don't have to wait for cooling. The pod is brought to the OR when the instruments are needed. The sterile seal is released in the OR and the instruments trays are placed onto the OR tables. There are not 10 + pans to individually open.

Implementation

In the first 6 month evaluation period we introduced 4 sterile pods into the sterilization process. The sterile pod is a five sided steel box with a front dual aluminum removable vented inner and out door. A single use double layer paper filter is placed between the 2 vented doors. Six spring loaded latches allow the inner and outer doors to be removed for loading and unloading. The entire assembly is on a 4 wheeled cart. The sterile pod can hold up to 12 instrument trays (370 lbs. max). There is no need for sterile wrapping or rigid containers (Figure 1). The transition to the use of the sterile pods was seamless. Throughout the 18 month evaluation period an additional 12 sterile pods were introduced.

Figure 3a: 30 containers of instruments to lift if not using the pod system

Figure 3b: Sterile pod system, 10 instrument trays, no containers

Figure 4a Loading unsterile instruments into the pod

Figure 4b Unloading sterile instruments in the OR.

Evaluation Period	# of Procedures	# of S pods	Ratio of S pods/old sterilization	Tray prep time old min	Tray prep S pod min	Cleanup time old min	Cleanup time S pod min	Transfer trays to case cart old min	Transfer trays to case cart S pod min	Time savings per procedure min	Total time savings Minutes, Hours
First 6 months	670	4	30%/66%	18	3	60	30	3	0	48	6830, 113.8
Second 6 months	710	10	30%/66%	18	3	60	30	3	0	48	10220, 267
Third 6 months	710	10	30%/66%	18	3	60	30	3	0	48	35446, 489.8

Outcome

During the 18 month period the sterile pods were used for 2100 orthopaedic joint replacement procedures. Processing time (time form decontamination to OR available), costs, # of lifts, processing time, sterilization "incidents", and durability were evaluated (Table 1)
- Processing time 45 min less for sterile pod
  - 20% time saving prior to autoclaving
  - 70% time savings dry time
  - 10% time savings no transfer needed to case cart
- No difference in cost of disposable materials
- 300 less pounds lifted per case set up (Figure 3a,b)
- 0.1 % sterilization issues pods, 0.5% for standard method
- Sterile pod 1 latch failure, 1 outer door repair
- Standard method multiple rigid containers needed refurbishing to manufacturers specifications

Implications for Perioperative Nursing

The Sterile Pod System improved the processing of surgical instruments for our joint replacement cases. Our meticulous evaluation of time savings, cost reduction, safety and ease of use were carefully considered in this trial (Figure 4a,b). We had a time savings of 45 minutes which over the course of a standard shift can allow enough time to add an additional surgical procedure. Sterile incidences were <5% in all groups. The most common breech was with large irregular instruments in the blue paper wraps. The sterile pod system eliminated this issue.
There was a 300 lbs. reduction in the amount of weight SPD staff lift per joint replacement case since the instruments are only lifted once into the pod and the pod is on a wheeled cart. We believe this reduction in strain to the staff will result in fewer injuries and a decrease in lost work. Our next study will track and report additional experience for other types of cases as well as look at lose work due to job injury.

249. The statements made in the study incorporate and repeat the misleading promotion of the POD as validated for a 10 minute dry time. The statements in the study are misleading in at least the following respects:

a. Misrepresenting that the validation was presented to and approved by the FDA when in fact this has not occurred.

b. Misrepresenting that the use of a dry time of 10 minutes complies with the IFUs of surgical instrument manufacturers when in fact this has not occurred.

c. Mispresenting and withholding from hospitals and health care facilities that the 10 minute dry time is an off-label use.

d. Misrepresenting that the purported validation was based on credible and reliable testing when, in fact, this had not occurred.

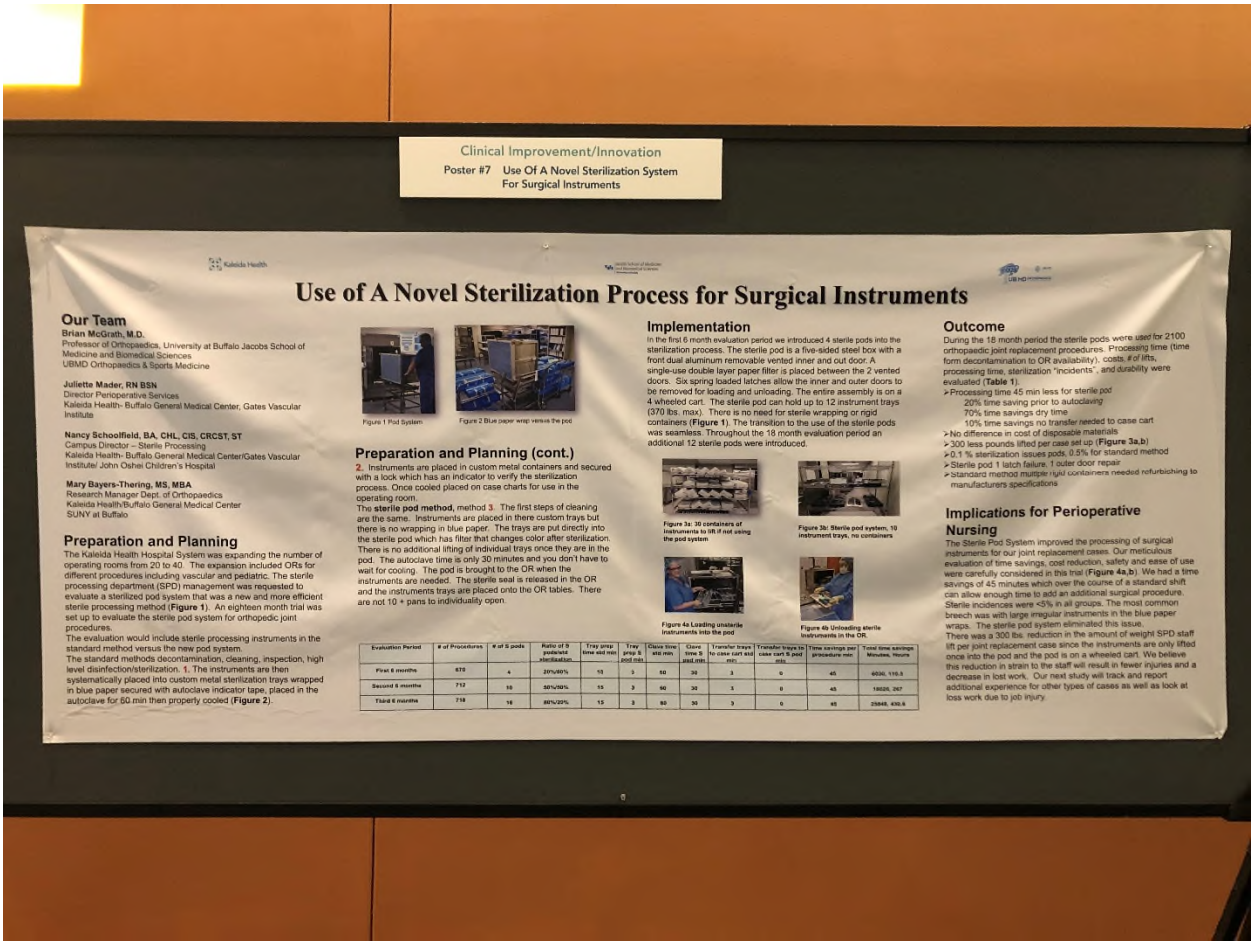
e. Misrepresenting that the validation was of a fully loaded POD to a maximum of 15 trays or 375 lbs when, in fact, this had not occurred.

f. Misrepresenting that the POD could be safely and effectively operated using a 10 minute dry time and/or by reducing the 30 minute dry time cycle by 20 minutes when, in fact, this is not the case.

g. Misrepresenting that the study was credible and reliable based on it having been conducted by independent professionals when in fact the principal author had conflicts of interest based on his financial ties to Turbett Surgical.

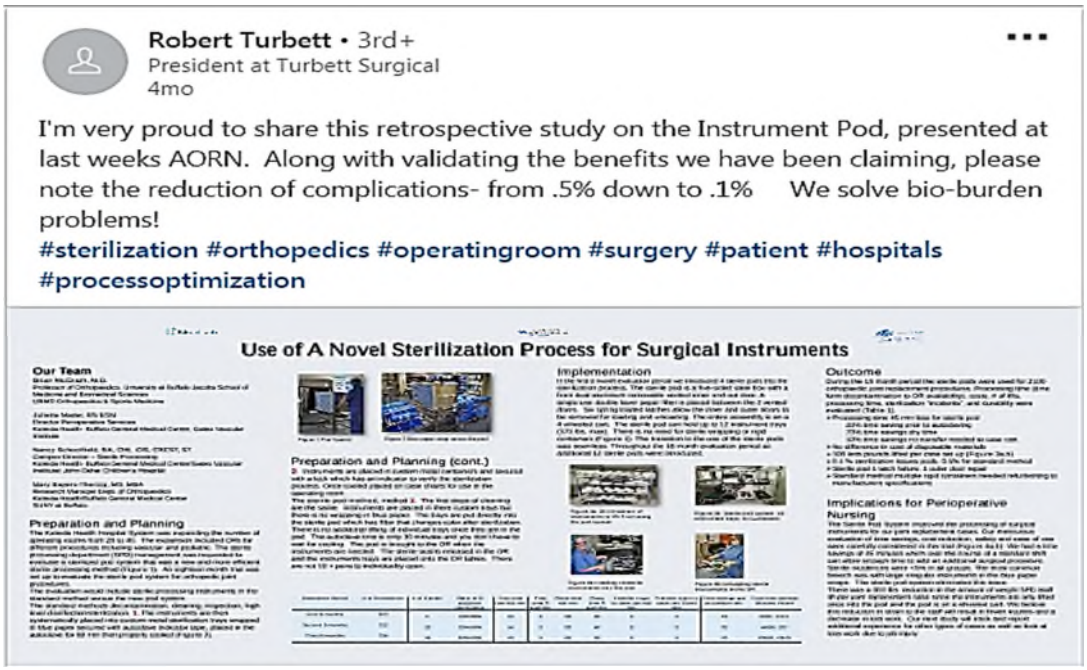
h. Misrepresenting that the thousands of patients whose surgeries were performed with instruments sterilized in the POD using off-label dry times were properly notified and consented to the off-label procedure and attendant potential health and contamination risks, when in fact this was not the case.

250. Robert published the study and its misleading statements at the AORN trade conference in April 2019. The following is an oversize poster containing an image of the study that was displayed at the conference:

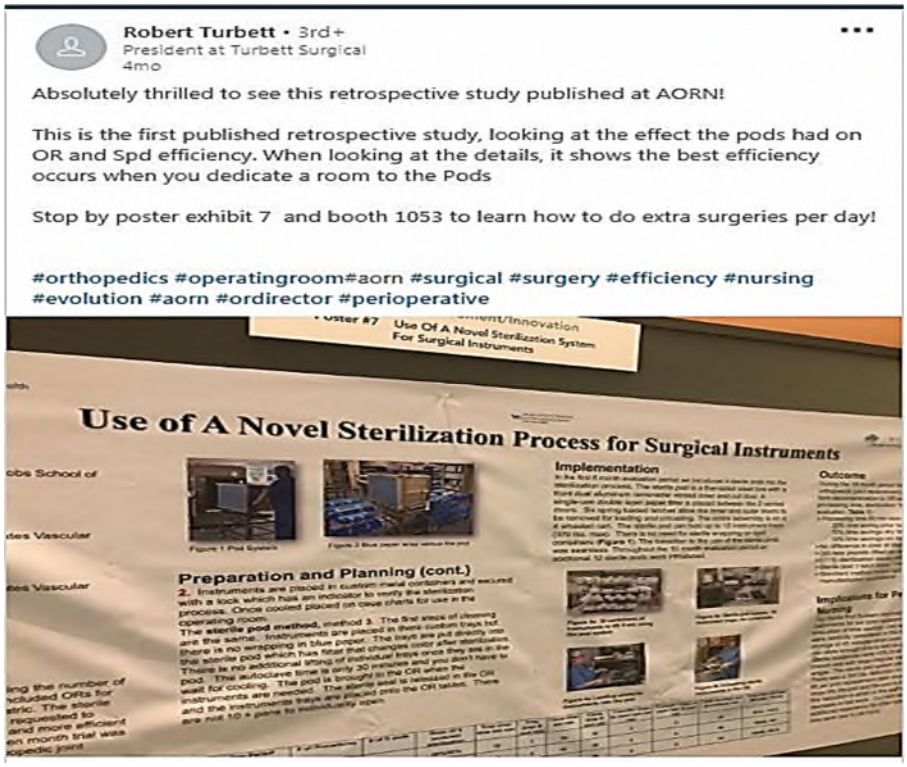


251. Robert has repeatedly posted and republished the study online, including at least the following:

https://www.linkedin.com/posts/robert-turbett-ba85b246_retrospective-study-2100-surgeries-with-the-activity-6524034083696316416-G-G7



https://www.linkedin.com/posts/robert-turbett-ba85b246_orthopedics-surgical-surgery-activity-6520406525499056128-CHIR



252. The Defendants' misleading statements are material to hospitals and healthcare facilities and have in fact caused or continue to cause these customers to hold false impressions. That the statements are material and that the relevant customers would hold these impressions is demonstrated by the customers' understanding and expectation that Defendants are complying with relevant regulations and standards, including: FDA procedures requiring 510(k) approval of significant changes to labeling, particularly labeling changes relating to sterilization and potential contamination hazards; best medical practices compelling physicians and hospitals to avoid off-label uses; and national trade association guidelines requiring suppliers of sterilization systems to follow the IFUs of surgical instrument manufacturers. Moreover, the statements at issue speak to a key factor, drying time, that is a significant contributor to the time and expense incurred by the customers, not to mention the source of significant liability for patient injury if not performed to FDA validated and manufacturer validated IFUs.

253. The literally false, impliedly false and/or misleading statements made by or on behalf of Turbett Surgical have harmed and will continue to harm Progressive. The ability to reduce dry time is a material factor in the purchasing decision of the relevant customer. As Defendants' own advertisements demonstrate, a reduction in dry time of even a few minutes, let alone 20, can save hundreds of hospital man hours and allow hundreds of additional surgeries, providing huge cost-savings as well as revenue. While Progressive is competing fairly and spending significant time and money obtaining the requisite FDA clearance of changes to its IFUs and operating procedures to use a reduced dry time cycle, Defendants have obtained the unfair head start of promoting their product as already having the approval of the FDA and complying with the IFUs of surgical instrument manufacturers. As a result, Defendants have placed hundreds of their systems with customers, diverting profits and market share from

Progressive. In addition, Defendants' false or misleading statements have harmed PMBS' ability to successfully market and distribute the CUBE as Progressive's licensed distributor in the United States, Canada, Puerto Rico and the Virgin Islands. (Progressive succeeded AmMed as licensor of SCORES technology and related improvements to PMBS.) The Defendants' false or misleading advertising is one more instance of misconduct by Defendants that has impeded Progressive's ability to successfully overcome years of challenges to its rightful ownership of foundational technology on mobile systems for sterilizing multiple surgical trays and successfully commercialize this technology.

254. Progressive is entitled to recover actual and treble damages, attorneys' fees, and the costs of this litigation pursuant to 15 U.S.C. § 1117 and injunctive relief pursuant to 15 U.S.C. § 1116.

THIRTEENTH CAUSE OF ACTION

Deceptive Trade Practices, 6 DEL. CODE ANN §§ 2531 et seq.

(Against Turbett Surgical)

255. Progressive repeats, realleges and incorporates hereunder by reference the allegations contained in all of the above paragraphs.

256. Turbett Surgical has engaged in deceptive trade practices through its false, misleading or deceptive statements including that (a) the POD is validated for use with 10 minute dry time; (b) the FDA has validated and approved the POD for use with a 10 minute dry time; (c) manufacturer IFUs have been validated and approved for use with a 10 minute dry time; (d) withholding from relevant customers that Defendants are promoting off-label use of the POD; and (e) misrepresenting that there are independent and credible studies supporting safe and effective operation of the POD with a 10 minute dry time.

257. Turbett Surgical's false, misleading or deceptive statements, individually or taken together, are likely to cause confusion, deception, or misunderstanding and violate 6 DEL. CODE ANN. § 2532(a)(1)-(3), (5), (7)-(8), and (12).

258. Progressive is entitled to damages, trebled, attorneys' fees and costs for Turbett Surgical's willful conduct, and to injunctive relief pursuant to 6 DEL. CODE ANN. § 2533.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter:

1. A decree preliminarily and permanently enjoining Defendants, their principals, officers, directors, employees, agents, successors, assigns, and all persons in active concert with them:

a. from infringing, and contributing to or inducing others to infringe, the '143, '093, and '972 patents, including without limitation immediately ceasing any and all marketing, sales, and distribution of POD units, filters and related accessories, pursuant to 35 U.S.C. § 283.

b. from making false and misleading statements in violation of the Lanham Act and Delaware state law, including without limitation from making any direct or indirect representation that Turbett Surgical's POD has a validated 10 minute dry time, that the FDA has reviewed and approved a 10 minute dry time for use with the POD, that manufacturers IFUs allow the use of a 10 minute dry time with the POD, and that the "retrospective study" independently confirmed that a 10 minute or other reduced dry time is a safe and effective use of the POD pursuant to 15 U.S.C. § 1116 and 6 DEL. CODE ANN. §§ 2523, 2533.

c. from engaging in any deceptive trade practices, pursuant to 6 DEL. CODE ANN. § 2533.

d. from using or disclosing any trade secrets and confidential and proprietary information regarding Progressive or its predecessors and assigns.

e. requiring the return of all trade secrets and confidential and proprietary information regarding Progressive or its predecessors and assigns.

2. A judgment in favor of Plaintiff that Defendants have infringed, contributed to, and/or induced the infringement of one or more claims of each of the '143, '093, and '972 patents;

3. A judgment and order requiring Defendants to pay Plaintiff its damages, costs, expenses, and prejudgment and post-judgment interest for Defendants' infringement of the '143, '093, and '972 patents as provided under 35 U.S.C. § 284;

4. An award to Plaintiff for enhanced damages resulting from the knowing, deliberate, and willful nature of Defendants' prohibited conduct with notice being made at least as early as the date of the filing of this Complaint, as provided under 35 U.S.C. § 284;

5. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiff its reasonable attorneys' fees;

6. A judgment and order requiring Defendants pay Plaintiff's damages, treble damages, attorneys' fees, and the costs for misappropriation of trade secrets, false advertising, deceptive trade practices, breach of fiduciary duties, breach of express and quasi-contract, tortious interference with contract, aiding and abetting, and conspiracy; and

7. Any and all other relief to which Plaintiff may show itself to be entitled.

DEMAND FOR JURY TRIAL

Plaintiff, under Rule 38 of the Federal Rules of Civil Procedure, requests a trial by jury of

///

///

///

///

///

any issues so triable by right.

Respectfully submitted,

Dated: September 24, 2020

By: Patricia S Rogowski

Patricia Smink Rogowski (Del. Bar No. 2632)
ROGOWSKI LAW LLC
501 Silverside Road, Suite 11
Silverside Carr Executive Center
Wilmington, DE 19809
pat@rogowskilaw.com
Phone: (302) 893-0048

David C. Bohrer (Cal. Bar No. 212397)
(*pro hac vice*)
Francois deVilliers (Cal. Bar No. 183631)
(*pro hac vice*)
Bridget R. O'Hara (Cal. Bar No. 313945)
(*pro hac vice*)
GREENFIELD SOUTHWICK LLP
55 S. Market Street, #1500
San Jose, CA 95113
dbohrer@greenfieldlaw.com
Phone: (408) 995-5600

Attorneys for Plaintiff,
Progressive Sterilization, LLC

CERTIFICATE OF SERVICE

The undersigned attorney certifies that on September 24, 2020 she caused the foregoing to be served by electronic mail on counsel of record.

By: */s/ Patricia S. Rogowski*

Patricia Smink Rogowski (Del. Bar No. 2632)
ROGOWSKI LAW LLC
501 Silverside Road, Suite 11
Silverside Carr Executive Center
Wilmington, DE 19809
pat@rogowskilaw.com
Phone: (302) 893-0048