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SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF LOS ANGELES, CENTRAL DISTRICT

BC 689984

HENRI PAUL FAUCHER, individually and as Successor in Interest to CARL J. MARAVILLA, Decedent,

Plaintiff,

v.

LIVANOVA DEUTSCHLAND, GMBH (f/k/a SORIN GROUP DEUTSCHLAND GMBH), LIVANOVA HOLDING, USA, INC., (f/k/a SORIN GROUP USA, INC.), KAISER FOUNDATION HEALTH PLAN, INC., KAISER FOUNDATION HOSPITALS, and SOUTHERN CALIFORNIA PERMANENTE MEDICAL GROUP, jointly and

Case No. [redacted]

COMPLAINT FOR DAMAGES

1) Strict Liability – Design Defect
2) Strict Liability – Manufacturing Defect
3) Strict Liability – Failure to Warn
4) Negligence
5) Loss of Consortium
6) Medical Negligence
7) Wrongful Death
8) Survival Action

JURY TRIAL DEMANDED

By Fax

CIT/CASE: ~~BC686574~~
LEA/DEF#: BC689984 PDR

RECEIPT #: CCH465980105
DATE PAID: 01/10/18 03:52 PM
PAYMENT: $435.00 310
RECEIVED:
CHECK: $435.00
CASH: $0.00
CHANGE: $0.00
CARD: $0.00

6/26/19
7/10/19
1/11/21

01/16/2018

individually,

Defendants.

Plaintiff Henri Paul Faucher, individually as the surviving Husband and successor in interest to Carl Maravilla, brings this action against Defendants LivaNova Deutschland, GmbH (f/k/a Sorin Group Deutschland GmbH) and LivaNova Holding USA, Inc. (f/k/a Sorin Group USA, Inc.)[1], Kaiser Foundation Health Plan, Inc., Kiser Foundation Hospitals, and Southern California Permanente Medical Group, and hereby alleges as follows:

THE PARTIES

1. Plaintiff Henri Faucher is a resident of California, residing in Redondo Beach, County of Los Angeles, CA 90254. Plaintiff brings this action individually, and as the surviving spouse and successor in interest to Carl Maravilla, deceased, pursuant to California Code of Civil Procedure §§ 377.30 & 377.60 *et seq.*

2. Defendant Sorin Group Deutschland GbmH ("Sorin GmbH") is a foreign corporation with its headquarters in Munich, Germany. Sorin GmbH is a wholly owned subsidiary of LivaNova, PLC. Sorin GmbH designed, tested, assembled, manufactured, marketed, distributed, and/or sold the Sorin 3T Heater-Cooler Device that was used in Mr. Maravilla's open-heart surgery on November 2, 2015.

3. Defendant Sorin Group, USA, Inc. ("Sorin USA") is a Delaware Corporation with its principal place of business at 14401 West 65th Way, Arvada, Colorado 80004. Sorin USA is a wholly owned subsidiary of LivaNova, PLC. Sorin USA designed, tested, assembled, manufactured, marketed, distributed, and/or sold the Sorin 3T Heater-Cooler Device that was used in Mr. Maravilla's open-heart surgery on November 2, 2015. Sorin USA is a registered corporation with the

[1] The Sorin entities recently underwent a name change. Plaintiff will refer to these entities by their names that were in use during the time period relevant to this action, as Sorin Group Deutschland, GmbH, and Sorin Group USA, Inc.

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California Secretary of State. Sorin USA's registered agent in California is CT Corporation System, residing at 818 W 7th St., Suite 930, Los Angeles, California 90017.

4. Defendant Kaiser Foundation Health Plan, Inc., is and has at all relevant times been an entity doing business Los Angeles County, California. Its principal place of business is located at 1526 North Edgemont Street, Los Angeles, California 90027.

5. Defendant Kaiser Foundation Hospitals is and has at all relevant times been an entity doing business in Los Angeles County, California. Its principal place of business is located at 1526 North Edgemont Street, Los Angeles, California 90027.

6. Defendant Southern California Permanente Medical Group is and has at all relevant times been an entity doing business Los Angeles County, California. Its principal place of business is located at 1526 North Edgemont Street, Los Angeles, California 90027.

7. On October 9, 2017, Counsel for Plaintiff sent a Notice of Intent to Sue letter to all Kaiser entities pursuant to California Code of Civil Procedure § 364.

JURISDICTION AND VENUE

8. Personal Jurisdiction exists over Sorin GmbH and Sorin USA (collectively, "Sorin") pursuant to California Civil Procedure Code § 410.10 (the "long-arm" statute) and federal due process standards because Sorin regularly conducted business in California and maintained systematic and continuous contact with California. Furthermore, Sorin designed, tested, assembled, manufactured, marketed, distributed, and/or sold the Sorin 3T Heater-Cooler Device that was used in Mr. Maravilla's open-heart surgery on November 2, 2015. Upon information and belief, Sorin sold the Sorin 3T Heater-Cooler Device directly to Kaiser Permanente Los Angeles Medical Center in Los Angeles County, California, where Mr. Maravilla's open-heart surgery took place.

9. Personal Jurisdiction exists over Kaiser Foundation Health Plan, Inc.,

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Kaiser Foundation Hospitals, and Southern California Permanente Medical Group (collectively, "Kaiser") because Kaiser's conduct that gave rise to this action took place in Los Angeles County, California, and because Kaiser Foundation Health Plan, Inc., Kaiser Foundation Hospitals, and Southern California Permanente Medical Group each have their principal place of business within the state of California.

10. Venue is proper in this Court under California Code of Civil Procedure § 395 because Los Angeles County is the place where the injury causing Mr. Maravilla's death occurred, and pursuant to § 395.5 because Los Angeles County is the place where the Defendants' obligation and/or liability arose.

FACTUAL ALLEGATIONS

11. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

12. The Sorin 3T Heater-Cooler Device ("Sorin 3T") is intended to provide temperature-controlled water to heat exchanger devices (cardio-pulmonary bypass heat exchangers, cardioplegia heat exchangers, and thermal regulating blankets) to warm or cool a patient during cardio-pulmonary bypass procedures lasting six (6) hours or less. The Sorin 3T is not intended to come into contact with the patient.

13. The Sorin 3T is a Class II Medical Device that is subject to the Food and Drug Administration's ("FDA") Section 510(k) Premarket Notification process.

14. Prior to commercialization of the Sorin 3T in the United States, Sorin submitted a 510(k) Premarket Notification of intent to market the Sorin 3T with the Department of Health and Human Services. A letter from the FDA dated June 6, 2006, informed Sorin that the FDA determined the Sorin 3T to be substantially equivalent to legally marketed predicate devices that do not require a premarket approval (PMA) application.[2]

[2] The 510(k) approval is attached as Ex A. All exhibits are incorporated as referenced herein.

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15. Following the 510(k) approval in 2006, and at all relevant times, Sorin was in the business of designing, licensing, manufacturing, distributing, marketing, advertising, selling, and/or delivering the Sorin 3T into the stream of commerce in the United States and California, including marketing, selling, and/or delivering the Sorin 3T that was used in Mr. Maravilla's heart surgery.

16. At all relevant times, Sorin was required to develop and test safe cleaning/disinfection protocols for the Sorin 3T, and to provide safe cleaning/disinfection instructions in the Sorin 3T's labeling and Instructions for Use ("IFU").

17. The development and testing of the cleaning/disinfection procedures conducted by Sorin was done without consideration for the presence of mycobacteria, and the instructions for cleaning/disinfecting the Sorin 3T in the IFU and elsewhere were insufficient to properly disinfect the Sorin 3T from the presence of mycobacteria.

18. Between April 11 and April 13, 2011, the FDA conducted an inspection of Sorin GmbH's manufacturing facility. Upon information and belief, this is the same facility that designed, manufactured, and/or assembled the Sorin 3T that was used in Mr. Maravilla's open-heart surgery on November 2, 2015.

19. The FDA's 2011 Establishment Inspection Report found several issues related to the cleaning/disinfecting of the Sorin 3T. Specifically, the inspector found that (i) the design inputs do not include an input for the cleaning of the water tank to prevent bacterial growth; (ii) the design output includes a cleaning procedure for the U.S., but requires the use of agents that are not available in the U.S.; (iii) the design verification was not performed in relation to the U.S. cleaning IFU; (iv) risk analysis does not include possible contamination from water held in the tank in relation to the patient, operating room, or operation; and (v) design changes were not adequately verified.

20. On November 18, 2016, The European Centre for Disease Prevention

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and Control ("ECDC") reported that cases of infection caused by Mycobacterium chimaera ("M. chimaera") in patients who had recently undergone open-heart surgery had been reported in seven European countries (France, Germany, Ireland, the Netherlands, Spain, the UK and Switzerland).[3] The ECDC reported that the outbreaks began in 2011.

21. Based upon these outbreaks in Europe, the FDA's inspection, and their own investigation and testing, Sorin knew or should have known in 2011 of the association between non-tuberculous mycobacterium ("NTM") infections and the use of the Sorin 3T when used in open-heart surgeries.

22. Upon information and belief, on or around January 2014, Sorin received notification from a hospital that at least one patient suffered an infection following an open-heart surgery in which the Sorin 3T was used. The hospital proceeded to test all Sorin 3T units, and found that all units were contaminated with bacteria.

23. On or around July 14, 2014, Sorin issued an "Important Information" letter to hospitals that had purchased the Sorin 3T.[4] The letter warned that "Some cardiac surgery patients have been infected with a slow growing *Mycobacterium chimaera*." The letter further stated that "during the investigation work it has been identified that some hospitals' heater cooler devices are contaminated."

24. On or around August 6, 2014, Sorin USA filed a MAUDE adverse event report with the FDA.[5] The event description was reported as follows:

> "The 15 pts have tested positive +afb for an atypical mycobacterium infection. All infections have been surgical site infections. The investigation is still on-going. The common denominator for the cardiac surgeries is the profusion machine. The machine has been cultured and found to have the mycobacterium in the water."

25. Upon information and belief, on or around August 2014, Sorin GmbH

[3] The ECDC report is attached as Ex. B.
[4] The Important Information Letter is attached as Ex. C.
[5] The MAUDE report is attached as Ex. D.

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performed its own investigation in its manufacturing facility. That investigation revealed the presence of mycobacteria on Sorin 3T units at the manufacturing facility. Upon information and belief, this is the facility that manufactured the Sorin 3T used in Mr. Maravilla's open-heart surgery on November 2, 2015. However, the results of this investigation were not made public until nearly two years later, when the FDA issued a Safety Communication on June 1, 2016.

26. On or around June 15, 2015, Sorin issued a Field Safety Notice related to Mycobacterium risk and the Sorin 3T. The Field Safety Notice warned as follows:

> "Without vigilant performance of the disinfection and maintenance procedures per the Instructions for Use, organisms can multiply in a heater cooler device and potentially form biofilm. The biofilm provides an opportunity for bacteria, including Mycobacteria, to colonize within the device. Once colonized, there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source for contamination. Although water from the heater cooler device is not intended to contact the patient directly, fluid leakage from the device or aerosolization generated by a contaminated water circuit during device operation may create conditions in which organisms could potentially contact the patient and subsequently contaminate the surgical site."

27. The June 15, 2015 Field Safety Notice also included an updated IFU, which provided updated cleaning and disinfection procedures. However, these updated cleaning/disinfecting procedures were still ineffective and failed to properly clean and disinfect the Sorin 3T.

28. On or around July 15, 2015, Sorin issued a Class 2 Recall of the Sorin 3T. Sorin reported the reason for the recall as, "Potential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per Instructions for Use."[6]

29. By the time the Class 2 recall and Field Safety Notice were issued, Sorin knew, or should have known, that design and/or manufacturing defects in the Sorin

[6] The July 15, 2015 Class 2 Recall Notice is attached as Ex. G.

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3T rendered the device prone to colonization and transmission of bacteria, including Mycobacteria, regardless of the cleaning and/or disinfection procedures used.

30. On or around August 24 to August 27, 2015, the FDA conducted a follow-up investigation at the Sorin manufacturing facility. The FDA's 2015 investigation noted that several problems continued to exist related to lack of a validated cleaning and disinfecting process for the Sorin 3T. This was the same or similar problem that the FDA identified in its 2011 inspection.

31. On or around October 15, 2015, the FDA issued a Safety Communication in regard to the Sorin 3T.[7] That Safety Communication stated that between January 2010 and August 2015, that FDA had received thirty-two (32) Medical Device Reports of patient infections associated with the Sorin 3T.

32. On December 29, 2015, the FDA sent a Warning Letter to the C.E.O. of LivaNova, the parent company of Sorin GmbH and Sorin USA.[8] The Warning Letter stated that several violations of the Food, Drug, and Cosmetic Act ("FDCA") were present with respect to the Sorin 3T, including, among other things, the following:

a. That the Sorin 3T devices are adulterated within the meaning of section 501(h) of the FDCA, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation of title 21, Code of Federal Regulations (CFR), part 820.

b. Failure to establish and maintain procedures for the identification, documentation, validation, or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i).

[7] The October 15, 2015 Safety Communication is attached as Ex. H.
[8] The Warning Letter is attached as Ex. I.

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c. Failure to adequately update the cleaning and disinfection IFU after receiving complaints of patient death due to infections caused by the Sorin 3T. The updated cleaning and disinfection test does not demonstrate an adequate verification or validation of the new cleaning IFU because the acceptance criteria do not demonstrate an adequate level reduction for bacteria. Additionally, Puristeril is not available in the U.S., and therefore Sorin recommends substituting Clorox, but the test report does not demonstrate the amounts of Clorox described in the IFU are equivalent to Puristeril.

d. Failure to validate a process, with a high degree of assurance and approval according to established procedures, where process results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a).

e. Failure to adequately develop, implement, and maintain written MDR (Medical Device Research) procedures, as required by 21 CFR 803.17.

33. On or around April 18, 2016, EuroSurveillance published an article entitled, "Contamination during production of heater-cooler units by *Mycobacterium chimaera* potential cause for invasive cardiovascular infections: results of an outbreak investigation in Germany, April 2015 to February 2016" (the "EuroSurveillance article").[9]

34. The EuroSurveillance article reported the following:

> "Invasive infections with *Mycobacterium chimaera* were reported in patients with previous open chest surgery and exposure to contaminated heater-cooler units (HCUs) . . . Clinical infections occurred in five male German cases over 50 years of age (range 53–80). Cases had been exposed to HCUs from one single manufacturer during open chest surgery up to five years prior to onset of symptoms. During

[9] The EuroSurveillance article is attached as Ex. J.

> environmental investigations, *M. chimaera* was detected in samples from used HCUs from three different countries and samples from new HCUs as well as in the environment at the manufacturing site of one manufacturer in Germany. Our investigation suggests that at least some of the *M. chimaera* infections may have been caused by contamination of HCUs at manufacturing site."

35. Upon information and belief, the "single manufacturer" referred to by the EuroSurveillance article is Sorin, and the manufacturing site is Sorin's facility in Munich, Germany. Upon information and belief, this is the site where the Sorin 3T used in Mr. Maravilla's November 2, 2015 surgery was manufactured.

36. On or around June 1, 2016, the FDA issued another Safety Communication in regard to the Sorin 3T. That Safety Communication stated, "Testing conducted by [Sorin] in August 2014 found *M. chimaera* contamination on the production line and water supply at the 3T manufacturing facility. Units from this facility can be found worldwide."

37. On or around July 2016, Sorin issued at least one MAUDE adverse event report after a hospital continued to find mycobacteria, including mycobacteria avium complex and mycobacteria intracellular complex, on the Sorin 3T. The hospital had strictly followed the updated IFU cleaning/disinfecting procedure since August 2015.[10]

38. On or around October 13, 2016, the Center for Disease Control and Prevention ("CDC") issued a Health Advisory in regard to the Sorin 3T and the risk of infection after surgery.[11]

39. The CDC Health Advisory advised hospitals to notify patients who underwent open-heart surgey involving a Sorin 3T that the device was potentially contaminated, stating that information indicated the devices "were likely contaminated with the rare bacteria *Mycobacterium chimaera* during manufacturing."

[10] The adverse event report is attached as Ex. K.
[11] The CDC Health Advisory is attached as Ex. L.

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40. The CDC Health Advisory went on to state the following:

> "[The] CDC in collaboration with National Jewish Health completed a whole-genome sequencing analysis and results demonstrate that M. chimaera isolates from patients with heater-cooler associated infections and from the 3T heater-cooler devices from several U.S. hospitals (in Pennsylvania and Iowa) are all highly related to each other. This evidence for likely point-source contamination of the 3T heater-cooler devices is consistent with recent reports from Europe [links omitted] that describe matching of M. chimaera sequences from environmental isolates at the device production site in Germany and isolates from patients and devices in Europe."

41. On or around October 13, 2016, the FDA issued an updated Safety Communication regarding M. chimaera infections association with the Sorin 3T.[12] The updated Safety Communication echoed the CDC's finding that results of testing done by the CDC and National Jewish Health "strongly suggest that the tested 3T devices had a common source of *M. chimaera* contamination."

42. The design and manufacturing defects in the Sorin 3T allowed bacteria, including NTM and M. chimaera, to colonize and multiply within the water and component parts of the device. Bacteria was then able to reach the surgical site and cause infection, as it did during Mr. Maravilla's surgery, through aerosolization, fluid leakage, or by other means.

43. Sorin knew or should have known of this risk before 2011, and clearly knew of the risk by 2014, when its *own investigation* revealed that the Sorin 3T devices were contaminated with mycobacteria at the manufacturing facility. Despite knowledge of the risk to patients and others, Sorin continued to manufacture, assemble, distribute, advertise, and/or sell the Sorin 3T to hospitals in the United States, including California.

FACTS ABOUT NONTUBERCULOUS MYCOBACTERIA (NTM)

44. Plaintiff incorporates by reference each and every allegation in this

[12] The October 13, 2106 Updated Safety Communication is attached as Ex. M.

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Complaint, as if fully set forth herein.

45. Nontuberculous mycobacteria, or NTM, are bacteria that are typically not harmful, but can be harmful, especially in persons with weakened immune systems, or persons who have recently undergone vascular grafting, prosthetic valve surgery, or other types of invasive surgery.

46. Because NTM are slow growing, it can take months or years for symptoms to materialize after exposure.

47. The symptoms of an NTM infection are very general, including fevers, chills, nausea, and weight loss, among others. These symptoms also make an NTM infection difficult to diagnose in early stages.

48. Mycobacterium chimaera, or M. chimaera, is a sub-species of NTM. Like other NTM infections, M. chimaera may cause serious illness and/or death.

FACTS SPECIFIC TO CARL MARAVILLA

49. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

50. On or around November 2, 2015, Mr. Maravilla underwent aortic valve replacement (an open-heart procedure) at Kaiser Permanente Los Angeles Medical Center in Los Angeles County, California.

51. During Mr. Maravilla's open-heart surgery, the Sorin 3T was used to cool and re-warm Mr. Maravilla.

52. M. chimaera bacteria from the Sorin 3T used in Mr. Maravilla's procedure reached the surgical site and Mr. Maravilla's open-heart through aerosolization, fluid leakage, or by other means.

53. In the months following his surgery, Mr. Maravilla appeared to be doing very well, and had resumed his normal, active lifestyle.

54. On or around October 15, 2016, Mr. Maravilla returned to a Kaiser facility in Harbor City, California, with complaints of fever, fatigue, chills, night sweats, loss of appetite and weight loss, and others.

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55. Following his October 15, 2016 visit, healthcare professionals at Kaiser ordered various blood cultures and other lab tests.

56. Between October 15, 2016, and January 26, 2017, Mr. Maravilla made numerous return visits to Kaiser facilities to follow-up on his lingering and worsening illness.

57. At no point during the time period from October 15, 2016 to January 26, 2017 did Kaiser warn Mr. Maravilla, Mr. Faucher, Mr. Maravilla's physicians or other healthcare providers that Mr. Maravilla had been exposed to M. chimaera during his November 2, 2015 open-heart surgery.

58. On or around January 26, 2017, Mr. Maravilla was admitted to St. Joseph Hospital in Denver, Colorado while he was visiting family in the area. Mr. Maravilla reported to the emergency department at St. Joseph Hospital at the recommendation of physicians at Kaiser following abnormal lab results that had been obtained earlier that day.

59. On or around January 28, 2017, Mr. Maravilla was discharged from St. Joseph Hospital in order to return to Los Angeles and be admitted at Kaiser Permanente Los Angeles Medical Center. In his discharge summary, physicians at St. Joseph Hospital noted that Mr. Maravilla should be considered for a mycobacterium avium intracellulare/ mycobacterium avium complex (MAI/MAC) test.

60. On or around January 31, 2017, following an infectious disease consult, physicians at Kaiser finally suspected that Mr. Maravilla was suffering from an M. chimaera infection due to his exposure to the Sorin 3T during his open-heart surgery on November 2, 2015. At this time, acid-fact bacilli (AFB) cultures were ordered.

61. On or around February 8, 2017, a liver biopsy confirmed that mycobacterium—presumed to be M. chimaera—had disseminated to Mr. Maravilla's liver. It was at this time that anti-mycobacterial antibiotics were started.

62. By the time Mr. Maravilla began antibiotic treatment on or around

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February 8, 2017, the M. chimaera infection had disseminated throughout his body and was causing multisystem organ failure.

63. Despite treatment, Mr. Maravilla's condition worsened. On March 7, 2017, he returned home for home hospice care. Mr. Maravilla died within hours of returning home on March 7, 2017 as a result of his disseminated M. chimaera infection.

64. On or around March 17, 2017, partial 16s rRNA gene sequencing confirmed that Mr. Maravilla had been suffering from an M. chimaera infection.

COUNT I

Strict Liability – Design Defect

(On Behalf of Henri Faucher as the surviving spouse and successor in interest to Carl Maravilla, against Sorin Group Deutschland GmbH and Sorin Group USA, Inc.)

65. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

66. At all relevant times, Sorin was engaged in the design, development, testing, manufacture, assembly, promotion, marketing, and/or sale of the Sorin 3T that was used in Mr. Maravilla's November 2, 2015 open-heart surgery.

67. The Sorin 3T was defective at the time that it was designed, manufactured, assembled, and sold. The Sorin 3T was defective in that its design prevented it from being properly and consistently cleaned and disinfected based on the accompanying IFU and other labels, instructions, or cleaning procedures, thus rendering the Sorin 3T unsafe for use by Kaiser Permanente Los Angeles Medical Center, and Mr. Maravilla in his November 2, 2015 open-heart surgery.

68. The Sorin 3T used by Kaiser Permanente Los Angeles Medical Center in the surgery of Mr. Maravilla was expected to reach, and did reach, Kaiser Permanente Los Angeles Medical Center and Mr. Maravilla, the intended consumer and ultimate consumer, without substantial change to the condition in which it was sold by Sorin.

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69. At the time the Sorin 3T left the possession of Sorin, the Sorin 3T was defective, and its condition made it unreasonably dangerous for Mr. Maravilla and others who may have been exposed to the device at Kaiser Permanente Los Angeles Medical Center. The Sorin 3T was defective because its design allowed bacteria, including mycobacteria, to collect and multiply and to form biofilm in the device. Said bacteria could subsequently come into contact with vulnerable patients and others in the operating room, or to infect other areas of the operating room, through aerosolization, fluid leakage, or other means.

70. Sorin intended for the Sorin 3T to be used in heart surgeries (among others) at Kaiser Permanente Los Angeles Medical Center, like the one Mr. Maravilla had on November 2, 2015. Sorin knew or should have known that the Sorin 3T would be used by patients like Mr. Maravilla at Kaiser Permanente Los Angeles Medical Center.

71. The Sorin 3T was used by Kaiser Permanente Los Angeles Medical Center for Mr. Maravilla's surgery in the manner in which it was intended, thus it was reasonably foreseeable that the Sorin 3T would be used in Mr. Maravilla's surgery.

72. At all relevant times, neither Plaintiff nor Mr. Maravilla could have discovered the design defects associated with the Sorin 3T through the exercise of due diligence, nor could they have been expected to perceive the danger posed by the Sorin 3T. Thus, the dangerous condition of the Sorin 3T was unknowable to Plaintiff or Mr. Maravilla.

73. The Sorin 3T, as designed by Sorin, transmitted bacteria, including M. chimaera, directly to patients undergoing invasive surgery, including Mr. Maravilla, through aerosolization, fluid leakage, or by other means.

74. The foreseeable risks of transmitting bacteria to patients undergoing invasive surgery, including Mr. Maravilla, far outweigh any utility of using the Sorin 3T. The foreseeable risks also far outweigh any cost of designing, manufacturing,

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and producing an alternative design of the Sorin 3T that is not defective.

75. Mr. Maravilla had a reasonable expectation that the Sorin 3T would not be unreasonably dangerous and defective, and that the device would not cause him to contract the M. chimaera bacteria.

76. The use of the Sorin 3T during Mr. Maravilla's open-heart surgery on November 2, 2015, was the cause-in-fact of his injuries, specifically, his contraction of M. chimaera, and his subsequent pain and suffering, disability, and death.

77. As a direct and proximate result of using the Sorin 3T system during his open-heart surgery on November 2, 2015, specifically the defective design of the device, Mr. Maravilla suffered catastrophic injury, pain and suffering, disability, and death.

78. As a result of the foregoing, Plaintiff and Mr. Maravilla incurred damages, both economic and non-economic, including, *inter alia*, medical expenses, future medical expenses, loss of earnings, including future earnings and loss of earning capacity, pain and suffering, inconvenience, mental suffering, emotional distress and other damages in an amount not yet determined but for which California law provides a remedy.

COUNT II

Strict Liability – Manufacturing Defect

(On Behalf of Henri Faucher as the surviving spouse and successor in interest to Carl Maravilla, against Sorin Group Deutschland GmbH and Sorin Group USA, Inc.)

79. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

80. At all relevant times, Sorin was engaged in the design, development, testing, manufacture, assembly, promotion, marketing, and/or sale of the Sorin 3T that was used in Mr. Maravilla's November 2, 2015 open-heart surgery.

81. The Sorin 3T was defective at the time that it was designed, manufactured, assembled, and sold. The Sorin 3T was defective in that its design

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and manufacture prevented it from being properly and consistently cleaned and disinfected based on the accompanying IFU and other labels, instructions, or cleaning procedures, thus rendering the Sorin 3T unsafe for use by Kaiser Permanente Los Angeles Medical Center, and unsafe for use in Mr. Maravilla's open-heart surgery on November 2, 2015.

82. The Sorin 3T's was further defective in its manufacture, in that the device was exposed to the M. chimaera bacteria at the time that the device was manufactured. This occurred because M. chimaera was present at Sorin's manufacturing facility where the Sorin 3T, including the Sorin 3T used in Mr. Maravilla's surgery, was designed, manufactured, and/or assembled.

83. The Sorin 3T used by Kaiser Permanente Los Angeles Medical Center in the surgery of Mr. Maravilla on November 2, 2015, was expected to reach, and did reach, Kaiser Permanente Los Angeles Medical Center and Mr. Maravilla, the intended consumer and ultimate consumer, without substantial change to the condition in which it was sold by Sorin.

84. At the time the Sorin 3T left the possession of Sorin, the Sorin 3T was defective, and its condition made it unreasonably dangerous for Mr. Maravilla and others who may have been exposed to the device at Kaiser Permanente Los Angeles Medical Center. The Sorin 3T was defective because its design and manufacture allowed bacteria, including mycobacteria, to collect and multiply and to form biofilm in the device. In fact, the M. chimaera bacteria was present on the Sorin 3T at the time it left Sorin's manufacturing facility. Said bacteria could subsequently come into contact with vulnerable patients and others in the operating room, or to infect other areas of the operating room, through aerosolization, fluid leakage, or other means.

85. Sorin intended for the Sorin 3T to be used in heart surgeries (among others) at Kaiser Permanente Los Angeles Medical Center, like the one Mr. Maravilla had on November 2, 2015. Sorin knew or should have known that the

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Sorin 3T would be used by patients like Mr. Maravilla at Kaiser Permanente Los Angeles Medical Center.

86. The Sorin 3T was used by Kaiser Permanente Los Angeles Medical Center for Mr. Maravilla's surgery in the manner in which it was intended, thus it was reasonably foreseeable that the Sorin 3T would be used in Mr. Maravilla's surgery.

87. At all relevant times, neither Plaintiff nor Mr. Maravilla could have discovered the manufacturing defects associated with the Sorin 3T through the exercise of due diligence, nor could they have been expected to perceive the danger posed by the Sorin 3T. Thus, the dangerous condition of the Sorin 3T was unknowable to Plaintiff or Mr. Maravilla.

88. The Sorin 3T, as designed by Sorin, transmitted bacteria, including M. chimaera, directly to patients undergoing invasive surgery, including Mr. Maravilla, through aerosolization, fluid leakage, or by other means.

89. The foreseeable risks of transmitting bacteria to patients undergoing invasive surgery, including Mr. Maravilla, far outweigh any utility of using the Sorin 3T.

90. Sorin failed to prevent the Sorin 3T from being manufactured, assembled, and/or prepared to be distributed in a manner that would have prevented the device from being contaminated while on the production line or elsewhere while in Sorin's possession or control.

91. Sorin manufactured, assembled, and/or sold the Sorin 3T with NTM including M. chimaera, present in and/or on the device. The contamination occurred on the production line or elsewhere while in Sorin's possession or control.

92. Sorin's failure to ensure proper sanitation in the workplace, failure to ensure proper workmanship, failure to ensure adequate testing of component parts, and/or failure to ensure adequate labeling for the Sorin 3T caused the Sorin 3T to be manufactured in a manner that made the device defective and unreasonably

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dangerous.

93. Mr. Maravilla had a reasonable expectation that the Sorin 3T would not be unreasonably dangerous and defective, and that the device would not cause him to contract the M. chimaera bacteria.

94. The use of the Sorin 3T during Mr. Maravilla's open-heart surgery on November 2, 2015, was the cause-in-fact of his injuries, specifically, his contraction of M. chimaera, and his subsequent pain and suffering, disability, and death.

95. As a direct and proximate result of using the Sorin 3T system during his open-heart surgery on November 2, 2015, specifically the defective manufacture the device, Mr. Maravilla suffered catastrophic injury, pain and suffering, disability, and death.

96. As a result of the foregoing, Plaintiff and Mr. Maravilla incurred damages, both economic and non-economic, including, *inter alia*, medical expenses, future medical expenses, loss of earnings, including future earnings and loss of earning capacity, pain and suffering, inconvenience, mental suffering, emotional distress and other damages in an amount not yet determined but for which California law provides a remedy.

COUNT III

Strict Liability – Failure to Warn

(On Behalf of Henri Faucher as the surviving spouse and successor in interest to Carl Maravilla, against Sorin Group Deutschland GmbH and Sorin Group USA, Inc.)

97. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

98. At all relevant times, Sorin was engaged in the design, development, testing, manufacture, assembly, promotion, marketing, and/or sale of the Sorin 3T that was used in Mr. Maravilla's November 2, 2015 open-heart surgery.

99. The Sorin 3T was defective at the time that it was designed, manufactured, assembled, and sold. The Sorin 3T was defective in that its design

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and manufacture prevented it from being properly and consistently cleaned and disinfected based on the accompanying IFU and other labels, instructions, or cleaning procedures, thus rendering the Sorin 3T unsafe for use by Kaiser Permanente Los Angeles Medical Center, and unsafe for use in Mr. Maravilla's open-heart surgery on November 2, 2015.

100. The Sorin 3T was further defective and unreasonably dangerous in that the "IFU" and other labels and materials failed to adequately warn hospital staff, patients, and others, about the Sorin 3T's serious risk of causing infection from aerosolization and/or fluid leakage from the device, which can lead to serious infections and death.

101. At all relevant times, Sorin was aware of the Sorin 3T's defects which caused the unreasonably dangerous condition.

102. The Sorin 3T was in a defective condition at the time it left Sorin.

103. Sorin failed to timely and adequately warn hospitals/healthcare providers and patients of the serious risks associated with the Sorin 3T, including, but not limited to:

a. That the Sorin 3T was contaminated with NTM, specifically M. chimaera, at the time the device was manufactured;

b. That the Sorin 3T could harbor and grow bacteria, including M. chimaera;

c. That the bacteria, including M. chimaera, can reach the surgical site during an operation through aerosolization, fluid leakage, and/or other methods.

104. Further, Sorin failed to adequately and timely provide cleaning and disinfecting procedures that ensured that the Sorin 3T would not continue to be contaminated with bacteria, including M. chimaera.

105. Mr. Maravilla had a reasonable expectation that the Sorin 3T would not be unreasonably dangerous and defective, that Sorin provided all proper warnings

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and IFU regarding the Sorin 3T, and that the device would not cause him to contract the M. chimaera bacteria.

106. If Plaintiff or Mr. Maravilla had been made aware of the significant risks of NTM and M. chimaera infection associated with the use of the Sorin 3T, Mr. Maravilla would not have consented to use of the Sorin 3T during his November 2, 2015 surgery.

107. The use of the Sorin 3T during Mr. Maravilla's open-heart surgery on November 2, 2015, was the cause-in-fact of his injuries, specifically, his contraction of M. chimaera, and his subsequent injury, pain and suffering, disability, and death.

108. As a direct and proximate result of using the Sorin 3T system during his open-heart surgery on November 2, 2015, and as a result of Sorin's failure to warn, Mr. Maravilla suffered catastrophic injury, pain and suffering, disability, and death.

109. As a direct and proximate cause of Sorin's failure to warn Kaiser Permanente Los Angeles Medical Center, Mr. Maravilla, Plaintiff, the FDA, and the public about the significant risk of NTM and M. chimaera infection from use of the Sorin 3T in surgery, Mr. Maravilla suffered catastrophic injury, pain and suffering, disability, and death.

110. As a result of the foregoing, Plaintiff and Mr. Maravilla incurred damages, both economic and non-economic, including, *inter alia*, medical expenses, future medical expenses, loss of earnings, including future earnings and loss of earning capacity, pain and suffering, inconvenience, mental suffering, emotional distress and other damages in an amount not yet determined but for which California law provides a remedy.

COUNT IV

Negligence

(On Behalf of Henri Faucher as the surviving spouse and successor in interest to Carl Maravilla, against Sorin Group Deutschland GmbH and Sorin Group USA, Inc.)

111. Plaintiff incorporates by reference each and every allegation in this

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Complaint, as if fully set forth herein.

112. Sorin owed a duty of reasonable care to Plaintiff, Mr. Maravilla, the public, and all foreseeable users of the Sorin 3T, including patients, when it designed, tested, assembled, manufactured, marketed, distributed, and sold the Sorin 3T into the stream of commerce. This duty of reasonable care required Sorin to assure that the product was in full compliance with FDA and other regulations, and was not defective or unreasonably dangerous for its intended purpose and other foreseeable uses.

113. Sorin breached this duty of care by designing, testing, assembling, manufacturing, marketing, distributing, and selling the Sorin 3T in a manner that made the device defective and unreasonably dangerous for its intended and foreseeable use. This defect stems from the Sorin 3T's propensity to permit the colonization and growth of bacteria, including NTM and M. chimaera, and the ability of said bacteria to reach the surgical site through aerosolization, fluid leakage, or other means.

114. Sorin further breached this duty by allowing the Sorin 3T devices, including the device used in Mr. Maravilla's open-heart surgery, to become contaminated with NTM and M. chimaera while still in Sorin's possession and control, and then sold to the end user without being disinfected.

115. Sorin owed Plaintiff and Mr. Maravilla a duty of reasonable care to discover these defects and to timely warn the FDA, Kaiser Permanente Los Angeles Medical Center, Plaintiff, and Mr. Maravilla about these defects.

116. Sorin failed to timely warn the FDA, Kaiser Permanente Los Angeles Medical Center, Plaintiff, and Mr. Maravilla about these defects, thereby breaching its duty of care.

117. Sorin owed a duty to Plaintiff, Mr. Maravilla, all foreseeable users, and the general public to develop, test, and produce a cleaning and disinfecting procedure to be included in the IFU that adequately eliminated the presence of NTM and M.

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chimaera from the Sorin 3T.

118. Sorin failed to develop, test, and produce a cleaning and disinfecting procedure that adequately eliminated the presence of NTM and M. chimaera from the Sorin 3T, thereby breaching its duty of care.

119. Sorin owed a duty to Plaintiff, Mr. Maravilla, all foreseeable users, and the general public to issue a timely recall of all Sorin 3T units in use throughout the United States and abroad when Sorin became aware that the Sorin 3T unites had become contaminated at Sorin's manufacturing facility.

120. Sorin breached this duty by failing to timely recall all Sorin 3T devices, despite Sorin's knowledge that the devices had been exposed to the M. chimaera bacteria and were possibly contaminated.

121. As a direct and proximate cause of Sorin's breach of duty, Mr. Maravilla became infected with M. chimaera as a result of bacteria from the Sorin 3T reaching the surgical site—at his open chest—on November 2, 2015.

122. As a direct and proximate cause of Sorin's breach of duty, Mr. Maravilla became seriously ill with an M. chimaera infection resulting in catastrophic injury, pain and suffering, disability, and death.

123. As a result of the foregoing, Plaintiff and Mr. Maravilla incurred damages, both economic and non-economic, including, *inter alia*, medical expenses, future medical expenses, loss of earnings, including future earnings and loss of earning capacity, pain and suffering, inconvenience, mental suffering, emotional distress and other damages in an amount not yet determined but for which California law provides a remedy.

COUNT V

Loss of Consortium

(On Behalf of Henri Faucher, individually, against all Defendants)

124. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

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125. Plaintiff Henri Faucher was entitled to the care, comfort, companionship, services, and consortium of his husband, Carl Maravilla.

126. As a direct and proximate result of the negligence, carelessness, and willful and wanton conduct by Sorin and Kaiser as outlined herein, Mr. Maravilla contracted an M. chimaera infection, fell severely ill, became disabled, and died as a result of his infection.

127. As a result of the injuries to Carl Maravilla, Henri Faucher was, and will continue to be, deprived of care, comfort, companionship, services, and consortium of his Husband.

128. As a result of the foregoing, Henri Faucher incurred damages related to the loss of Carl Maravilla's services, society, and companionship that he would have received in the usual course of married life, and other damages reasonable under the circumstances for which California law provides a remedy.

COUNT VI

Medical Negligence

(On Behalf of Henri Faucher, as the surviving spouse and successor in interest to Carl Maravilla, against Kaiser Foundation Health Plan, Inc., Kaiser Foundation Hospitals, and Southern California Permanente Medical Group)

129. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

130. By the time that Mr. Maravilla first reported to Kaiser with early symptoms of M. chimaera on October 15, 2016, Kaiser knew or should have known that Mr. Maravilla was at risk of contracting the M. chimaera bacteria given his exposure to the bacteria during his open-heart surgery on November 2, 2015, *especially* given that his exposure occurred at the Los Angeles Medical Center, within the Kaiser Permanente health system.

131. In fact, on October 13, 2016—just two days before Mr. Maravilla first reported to Kaiser with his early symptoms—the CDC issued a "Health Advisory"

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advising hospitals, including Kaiser, to alert patients who may be at risk of M. chimaera infection due to exposure to the Sorin 3T during open-heart surgery.

132. Kaiser owed a duty to inform and to warn Plaintiff, Mr. Maravilla, his physicians and/or his other healthcare providers that Mr. Maravilla had been exposed to the M. chimaera bacteria during his November 2, 2015 surgery, that he may be infected with the M. chimaera bacteria, and that said bacteria should be considered as a cause of his symptoms. This information should have been disseminated to the appropriate persons on or before October 15, 2016.

133. Despite its knowledge of Mr. Maravilla's exposure, Kaiser failed to inform or warn Plaintiff, Mr. Maravilla, or his physicians and other healthcare professionals that Mr. Maravilla had been exposed to the M. chimaera bacteria, and that Mr. Maravilla may be suffering from an M. chimaera infection.

134. Kaiser's failure to disseminate its knowledge of Mr. Maravilla's exposure to the M. chimaera bacteria constituted a breach of its duty to Plaintiff and Mr. Maravilla, and fell below the applicable standards of care.

135. Kaiser promotes itself as a "smarter" healthcare system with "a connected team" of caregivers.[13] Part of this connectivity stems from Kaiser's electronic health record system, which allows caregivers at Kaiser to access the same records and schedule for a given patient.

136. Upon information and belief, this electronic health record system enables Kaiser to send an alert, such as a message or a warning, to the front of a patient's chart. This technology was available at all relevant times and would have allowed Kaiser to alert all of Mr. Maravilla's healthcare providers that he had been exposed to M. chimaera and to be mindful of any symptoms of an M. chimaera infection.

137. As a direct and proximate cause of Kaiser's failure to timely disseminate

[13] See the "Why KP" tab on Kaiser's website, available at https://healthy.kaiserpermanente.org/why-kp.

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its knowledge of Mr. Maravilla's exposure to M. chimaera, Mr. Maravilla's physicians did not suspect that he was suffering from an M. chimaera infection until around January 31, 2017, approximately 3.5 months after Mr. Maravilla first reported to Kaiser with symptoms of an M. chimaera infection.

138. As a direct and proximate cause of Kaiser's failure to timely disseminate its knowledge of Mr. Maravilla's exposure to M. chimaera, Mr. Maravilla's physicians failed to diagnose his M. chimaera infection until after he had begun to suffer multisystem organ failure. At this point, Mr. Maravilla was almost certainly past the point of possible recovery.

139. Had Kaiser timely disseminated its knowledge of Mr. Maravilla's exposure to M. chimaera, Mr. Maravilla's physicians would have known to test for and treat the M. chimaera infection beginning in October of 2016.

140. If Mr. Maravilla's physicians had begun treatment in October or November of 2016, it is more likely than not that Mr. Maravilla would have survived his M. chimaera infection.

141. Kaiser's failure to timely disseminate its knowledge of Mr. Maravilla's exposure to M. chimaera was a direct and proximate cause of his physician's failure to diagnose Mr. Maravilla's M. chimaera infection until after a point at which Mr. Maravilla was beyond saving, and therefore was a direct and proximate cause of Mr. Maravilla's catastrophic injury, pain and suffering, disability, and death.

142. As a result of the foregoing, Plaintiff and Mr. Maravilla incurred damages, both economic and non-economic, including, *inter alia*, medical expenses, future medical expenses, loss of earnings, including future earnings and loss of earning capacity, pain and suffering, inconvenience, mental suffering, emotional distress and other damages in an amount not yet determined but for which California law provides a remedy.

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COUNT VII

Wrongful Death

(Against all Defendants)

143. Plaintiff incorporates by reference each and every allegation in the Complaint, as if fully set forth herein.

144. Plaintiff is the surviving spouse and successor in interest to Carl Maravilla, Decedent.[14]

145. Mr. Maravilla's death and damages, and Mr. Faucher's injury and damages, were caused by the wrongful acts and omissions of Defendants.

146. As a result of the death of Mr. Maravilla, Plaintiff was and continues to be deprived of love, companionship, comfort, affection, society, solace, and moral support of Mr. Maravilla.

147. Plaintiff is entitled to recover economic and non-economic damages against all Defendants for wrongful death directly, proximately, and legally caused by Defendants' negligent and reckless conduct, including the actions, errors, and omissions of Defendants.

COUNT VIII

Survival Action

(Against all Defendants)

148. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

149. As a direct and proximate cause of Defendants' conduct, as outlined above, Mr. Maravilla suffered injury, pain and suffering, and disability prior to his death, resulting in pain and suffering, mental anguish, loss of capacity of the enjoyment of life, hospital and other medical expenses, loss of earnings and loss of earning capacity prior to his death.

[14] The Declaration of Successor in Interest is attached as Ex. N.

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150. Plaintiff, as successor in interest to Mr. Maravilla, brings this claim for damages on behalf of Mr. Maravilla's heirs, as Mr. Maravilla may have maintained himself prior to his death.

151. Plaintiff, as successor in interest to Mr. Maravilla, further pleads all survival damages allowed by statute and law in the state of California.

ACTUAL DAMAGES

152. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

153. As a direct and proximate result of the acts, omissions, and violations of Defendants as alleged herein, Plaintiff has suffered injuries and damages. Plaintiff seeks compensation from Defendants for injuries including, but not limited to:

a. Pain and suffering, including mental suffering and emotional distress;

b. Loss of earnings, including loss of future earning and loss of earning capacity;

c. Loss of consortium damages incurred by Mr. Faucher;

d. Medical bills and expenses, including funeral expenses;

e. Any and all such further relief to which Plaintiff may be entitled under the law.

PUNITIVE DAMAGES

154. Plaintiff incorporates by reference each and every allegation in the Complaints, as if fully set forth herein.

155. Defendants' conduct as described above demonstrates a willful and wanton disregard for the safety of Mr. Maravilla and other patients exposed to the Sorin 3T.

156. Defendants' negligence, carelessness, recklessness, and maliciousness in this case warrants an award of punitive damages in favor of Plaintiff under California Civil Code § 3294.

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157. At this time, Plaintiff makes his Punitive Damages demand against the Sorin Defendants only. Plaintiff intends to seek a Court Order permitting punitive damages to be sought against the Kaiser Defendants in a timely fashion pursuant to California Code of Civil Procedure § 425.13(a).

PRAYER FOR RELIEF

158. Plaintiff incorporates by reference each and every allegation in this Complaint, as if fully set forth herein.

159. Plaintiff requests the Court to enter judgment against the Defendants, jointly and individually, for a reasonable amount in accordance with the injuries and damages listed above, and other damages which the Court deems just, together with interests, costs, and disbursements incurred herein.

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DEMAND FOR JURY TRIAL

Plaintiff hereby requests a jury trial on all issues raised in this Complaint.

Dated: January 10, 2018

WALKUP, MELODIA, KELLY & SCHOENBERGER

By: _____

KHALDOUN A. BAGHDADI
JASLEEN SINGH

and

JOHNSON BECKER PLLC

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