

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

STERIS CORPORATION, et al.,

Defendants.

Case No. 1:15-cv-1080

Hon. Dan Aaron Polster

**ANSWER OF DEFENDANT
SYNERGY HEALTH PLC**

Defendant Synergy Health plc (“Synergy”), by and through its undersigned counsel, responds below to the Complaint dated May 29, 2015. As initial matter, the premise of the Complaint – that, but for the merger between STERIS Corporation (“STERIS”) and Synergy, Synergy would have constructed X-ray radiation sterilization plants in the United States, and that the merger is therefore anticompetitive – is erroneous both in fact and in its application of the U.S. antitrust laws. The Federal Trade Commission’s (the “Commission”) challenge to the merger is based on a faulty and speculative factual premise and is unsupported by established antitrust doctrine.

To the extent the Complaint's preamble requires a response, Synergy denies the allegations contained therein, except Synergy admits that the Commission has petitioned this Court for a temporary restraining order and preliminary injunction enjoining the Defendants from consummating their proposed merger; admits, on information and belief, that the Commission, by a vote of 5-0, commenced an administrative proceeding regarding the merger; and admits that the administrative trial is currently scheduled to begin on October 28, 2015.

I. NATURE OF THE CASE

1. Synergy admits the allegations contained in Paragraph 1, but specifically denies that "the world" is a relevant market for purposes of the Complaint. Synergy avers that it competes vigorously with a diverse group of competitors both in the U.S. and globally.

2. Synergy admits that it operates more than three dozen contract sterilization facilities globally, including gamma facilities outside the United States, and that, with respect to contract sterilization modalities it currently offers only e-beam and EO sterilization services in the United States. Synergy lacks sufficient knowledge to be able to admit or deny the allegations in Paragraph 2 pertaining to STERIS and Sterigenics. Synergy otherwise denies the allegations contained in Paragraph 2. Synergy avers that the Commission's selective quotation of unidentified written material offered without context is misleading as framed, and Synergy respectfully refers the Court to the quoted documents.

3. Synergy admits that gamma, e-beam, and EO are the three primary methods of sterilization currently used in the United States. Synergy also admits that gamma radiation sterilizes by exposure to Cobalt 60 and that EO is a non-radiation form of sterilization that exposes products to gas. Synergy lacks sufficient knowledge to admit or deny the allegations of Paragraph 3 concerning how customers choose sterilization modalities. Synergy denies the

remaining allegations in Paragraph 3. Synergy avers that E-beam can and does compete with gamma radiation as a sterilization modality and that E-beam is an appropriate alternative sterilization method for most products being sterilized by gamma in the United States today.

4. Synergy admits the allegations contained in Paragraph 4 that X-ray is a substitute for gamma radiation offering comparable depth of penetration. Synergy otherwise denies the allegations contained in Paragraph 4 and avers that E-beam is a functional and economically viable alternative sterilization method to gamma for most applications. Synergy avers that the Commission's selective quotation of unidentified written material offered without context is misleading as framed, and Synergy respectfully refers the Court to the quoted documents.

5. Paragraph 5 contains legal conclusions to which no response is required. To the extent that Paragraph 5 contains factual allegations, Synergy denies the allegations contained in Paragraph 5. Synergy specifically denies that EO sterilization takes longer to complete than radiation sterilization and that EO gas leaves harmful residue on products.

6. Synergy admits that some medical device manufacturers with in-house sterilization facilities also utilize contract sterilization services. The rest of Paragraph 6 contains legal conclusions to which no response is required. To the extent that Paragraph 6 contains factual allegations, Synergy denies all other allegations contained in Paragraph 6. Synergy avers that it competes for medical device manufacturers' sterilization business against their use of existing in-house sterilization facilities and the threat of increased utilization or expansion of such facilities.

7. Synergy lacks sufficient information to respond to allegations regarding the concerns of unidentified customers about the availability and pricing of gamma sterilization. The rest of Paragraph 7 contains legal conclusions to which no response is required. To the

extent that Paragraph 7 contains factual allegations, Synergy denies all other allegations contained in Paragraph 7. Synergy avers that E-beam is less expensive than gamma radiation and is an economical alternative for most products that are sterilized with gamma radiation.

8. Paragraph 8 contains legal conclusions to which no response is required. To the extent that Paragraph 8 contains factual allegations, Synergy denies the allegations contained in Paragraph 8.

9. As Synergy does not operate any gamma radiation facilities in the United States, Synergy lacks sufficient information to respond to the allegations contained in Paragraph 9 concerning customer purchases of gamma sterilization services domestically. Synergy admits that, in the past, it considered constructing X-ray facilities in the United States, including in the geographic areas identified. The rest of Paragraph 9 contains legal conclusions to which no response is required. To the extent that Paragraph 9 contains factual allegations, Synergy denies all other allegations contained in Paragraph 9.

10. Paragraph 10 contains legal conclusions to which no response is required. To the extent that Paragraph 10 contains factual allegations, Synergy denies the allegations contained in Paragraph 10. Synergy avers that the Merger Guidelines do not necessarily mirror, and do not substitute for, controlling case law.

11. Synergy admits that it has significant operations abroad and that it is a small contract sterilization provider in the United States offering E-beam sterilization services. Synergy avers that it also offers EO sterilization services in Florida. The rest of Paragraph 11 contains legal conclusions to which no response is required. To the extent that Paragraph 11 contains factual allegations, Synergy denies all other allegations contained in Paragraph 11.

12. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Synergy denies all other allegations contained in Paragraph 12. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

13. Synergy admits the allegations contained in Paragraph 13 that its proposed merger with STERIS was announced on October 13, 2014. Synergy admits that its exploration of potential X-ray entry into the United States continued for some weeks thereafter. Synergy denies the remaining allegations in Paragraph 13.

14. Synergy admits that the FTC issued Second Requests to STERIS and Synergy in January 2015. Synergy denies all other allegations contained in Paragraph 14. Synergy avers that insufficient customer support was, in fact, one of the reasons that Synergy terminated its United States X-ray entry plans.

15. Synergy lacks sufficient information to admit or deny the allegations in Paragraph 15 concerning customers' expectations. The rest of Paragraph 15 contains legal conclusions to which no response is required. To the extent that Paragraph 15 contains factual allegations, Synergy denies all other allegations contained in Paragraph 15. Synergy avers that the Commission's selective quotation of unidentified written material or communications, offered

without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents.

16. Synergy admits that it has global operations and a reputation as a quality service provider. The rest of Paragraph 16 contains legal conclusions to which no response is required. To the extent that Paragraph 16 contains factual allegations, Synergy denies all other allegations contained in Paragraph 16. Synergy avers that IBA is not the world's only supplier of commercially viable X-ray sterilization machines. Synergy further avers, on information and belief, that other domestic firms (including Nutek Corporation ("Nutek") and Iotron Industries Canada, Inc. ("Iotron")) are attempting to enter or are already offering X-ray sterilization services in the United States in competition with gamma sterilization.

17. Synergy admits that there is uncertainty regarding the future availability and pricing of Cobalt 60 and that Cobalt 60 is a regulated substance. The rest of Paragraph 17 contains legal conclusions to which no response is required. To the extent that Paragraph 17 contains factual allegations, Synergy denies all other allegations contained in Paragraph 17. Synergy avers that of the four sterilization modalities, E-beam is the least expensive to build and that the addition of E-beam capacity in the United States would reduce the cost of gamma sterilization for domestic customers.

18. Synergy lacks information sufficient to admit or deny the unspecified statements by an unidentified STERIS employee. Synergy avers that the Commission's selective quotation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents. The rest of Paragraph 18 contains legal

conclusions to which no response is required. To the extent that Paragraph 18 contains factual allegations, Synergy denies all other allegations contained in Paragraph 18.

II. BACKGROUND

A. Jurisdiction

19. Paragraph 19 contains legal conclusions to which no response is required. To the extent that Paragraph 19 contains factual allegations, Synergy admits that the Commission purports to bring this action pursuant to the statutes cited, admits that the Commission is an agency of the United States, and denies all other allegations in Paragraph 19.

20. Synergy admits the allegations contained in Paragraph 20.

21. Paragraph 21 contains legal conclusions to which no response is required. To the extent that Paragraph 21 contains factual allegations, Synergy admits the allegations in Paragraph 21.

22. Paragraph 22 contains legal conclusions to which no response is required. To the extent that Paragraph 22 contains factual allegations, Synergy admits the allegations in Paragraph 22.

B. Respondents

23. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 23 regarding STERIS' revenues. On information and belief, Synergy admits all other allegations contained in Paragraph 23.

24. Synergy admits the allegations contained in Paragraph 24.

C. The Merger and the Commission's Response

25. Synergy admits the allegations contained in Paragraph 25.

26. Paragraph 26 contains legal conclusions to which no response is required. To the extent that Paragraph 26 contains factual allegations, Synergy admits the allegations in Paragraph 26.

27. Paragraph 27 contains legal conclusions to which no response is required. To the extent that Paragraph 27 contains factual allegations, Synergy admits the allegations in Paragraph 27.

28. Paragraph 28 contains legal conclusions to which no response is required. To the extent that Paragraph 28 contains factual allegations, Synergy admits that, on information and belief, on May 28, 2015, the Commission, by a unanimous vote, commenced an administrative proceeding regarding the merger, and admits that the administrative trial is currently scheduled to begin on October 28, 2015. Synergy otherwise denies the allegations contained in Paragraph 28 and specifically denies that the merger violates the FTC Act or the Clayton Act.

29. Paragraph 29 contains legal conclusions to which no response is required. To the extent that Paragraph 29 contains factual allegations, Synergy admits, on information and belief, that, on May 28, 2015, the Commission authorized staff to commence this federal court proceeding, and that this action seeks to enjoin Defendants from consummating their merger. Synergy denies all other allegations in Paragraph 29.

III. THE RELEVANT PRODUCT MARKET

30. Paragraph 30 contains legal conclusions to which no response is required. To the extent that Paragraph 30 contains factual allegations, Synergy denies the allegations contained in Paragraph 30.

A. Background on Contract Radiation Sterilization Services

31. Synergy admits the allegations contained in Paragraph 31, except to the extent that those allegations imply that in-house sterilization services are not part of the relevant market.

Contract Gamma Sterilization Services

32. Synergy admits the allegations contained in Paragraph 32.

33. Synergy denies the allegations contained in the first sentence of Paragraph 33. Synergy admits all the other allegations contained in Paragraph 33.

34. Synergy avers that STERIS' website speaks for itself and respectfully refers the Court to STERIS' website, once the cited portion is identified, for a complete and accurate description of its contents. Synergy denies the allegations contained in Paragraph 34 regarding the number of products that can only be sterilized using contract gamma sterilization services. Synergy avers that E-beam can be used cost-effectively to sterilize most products that are sterilized with gamma radiation.

Contract X-ray Sterilization Services

35. Synergy admits that X-ray sterilization uses a high-powered electron beam machine to produce X-ray radiation and that IBA has developed equipment that can perform X-ray sterilization. Synergy denies all other allegations contained in Paragraph 35.

36. Paragraph 36 contains legal conclusions to which no response is required. To the extent that Paragraph 36 contains factual allegations, Synergy denies the allegations contained in Paragraph 36.

Contract E-beam Sterilization Services

37. Synergy admits the allegations contained in Paragraph 37 except to the extent Paragraph 37 contains opinions or legal conclusions to which no response is required, and to the

extent that Paragraph 37 implies that E-beam can only be used to sterilize small volumes of low-density, homogenous products. Synergy avers that E-beam can be used to sterilize most products that are sterilized with gamma radiation.

38. Synergy denies the allegations contained in Paragraph 38 that E-beam is not a cost-effective option for sterilizing denser products and that E-beam is not a cost-effective or practical substitute for sterilizing most products that are currently sterilized with gamma radiation. To the contrary, Synergy avers that E-beam can be used to sterilize most products that are sterilized with gamma radiation. Synergy lacks information sufficient to admit or deny the unspecified statements by unidentified customers. The rest of Paragraph 38 contains legal conclusions to which no response is required. To the extent that Paragraph 38 contains factual allegations, Synergy denies all other allegations contained in Paragraph 38. Synergy avers that the Commission's selective quotation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents.

B. The Market for Contract Radiation Sterilization Services

39. Synergy admits that contract X-ray sterilization services, if offered in the United States, would compete with, among others, gamma and E-beam sterilization services. The rest of Paragraph 39 contains legal conclusions to which no response is required. To the extent that Paragraph 39 contains factual allegations, Synergy denies all other allegations contained in Paragraph 39. Synergy avers that E-beam can be used to sterilize most products that are sterilized with gamma radiation.

40. Synergy denies the allegations contained in Paragraph 40 that there is little switching between E-beam and gamma sterilization methods. Synergy lacks information

sufficient to admit or deny the unspecified views of unidentified customers. Synergy avers that the Commission's selective summation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the summarized documents, once identified, for a complete and accurate description of their contents. [REDACTED]

[REDACTED]

41. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 41 regarding STERIS' gamma sterilization capacity and future plans. Synergy also lacks information sufficient to admit or deny the unspecified statements by an unidentified STERIS employee. Synergy avers that the Commission's selective quotation of unidentified written material or communications from both Synergy and STERIS, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents. The rest of Paragraph 41 contains legal conclusions to which no response is required. To the extent that Paragraph 41 contains factual allegations, Synergy denies all other allegations contained in Paragraph 41.

42. Synergy denies the allegations contained in Paragraph 42 to the extent that they imply that E-beam is not currently a competitive option for contract gamma customers. Synergy admits all other allegations contained in Paragraph 42, except to the extent that Paragraph 42 contains legal conclusions to which no response is required.

43. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 43 concerning the unspecified views of unidentified customers. Synergy avers that the Commission's selective summation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the

summarized documents, once identified, for a complete and accurate description of their contents. Similarly, Synergy avers that the Commission's selective quotation of unidentified written material or communications from Synergy personnel, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents. Synergy denies the remaining allegations contained in Paragraph 43.

EO Sterilization Is Not a Substitute for Radiation Sterilization Services

44. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 44 concerning STERIS' purported views regarding the impact of nearby EO sterilization facilities and STERIS' marketing efforts. Synergy avers that the Commission's selective summation of unidentified written material or communications from STERIS personnel, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the summarized documents, once identified, for a complete and accurate description of their contents. The rest of Paragraph 44 contains legal conclusions to which no response is required. To the extent that Paragraph 44 contains factual allegations, Synergy denies all other allegations contained in Paragraph 44.

45. Synergy denies the allegations contained in Paragraph 45 that EO sterilization takes significantly longer than other sterilization methods, and to the extent that they imply that EO sterilization is only "theoretical." To the contrary, Synergy avers that EO sterilization is widely used and is quicker than typical gamma sterilization. Synergy admits the other allegations contained in Paragraph 45.

In-House Sterilization Is Not a Viable Substitute for Most Customers

46. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 46 regarding the purported number of cubic feet of gamma-sterilized product annually

required to justify in-house gamma sterilization, whether any in-house sterilizer in the continental United States sells excess sterilization capacity, and the percentage of gamma sterilization performed in-house. On information and belief, Synergy admits that most in-house gamma sterilization facilities are operated by large medical device manufacturers. Synergy further admits that its contract sterilization customers do not rely on in-house gamma sterilization facilities to satisfy all of their sterilization requirements. The rest of Paragraph 46 contains legal conclusions to which no response is required. To the extent that Paragraph 46 contains factual allegations, Synergy denies all other allegations contained in Paragraph 46.

47. On information and belief, Synergy admits the allegations contained in Paragraph 47 that there are regulatory barriers to establishing a gamma facility in the United States, that Sterigenics acquired Nordion, Inc. (“Nordion”) in 2014, that there are questions about the future availability and supply of Cobalt 60, and that Sterigenics sells gamma sterilization services. Synergy denies all other allegations contained Paragraph 47 and avers that there is a robust resale market for partially used Cobalt 60 pencils, which are available from suppliers other than Nordion, and that medical device manufacturers in the United States continue to add in-house radiation capacity, including E-beam capacity.

48. Synergy admits the allegations contained in Paragraph 48 that some customers with in-house sterilization capabilities use contract sterilization services as backup when their facilities are down and in areas where they do not have an in-house facility. The rest of Paragraph 48 contains legal conclusions to which no response is required. To the extent that Paragraph 48 contains factual allegations, Synergy denies all other allegations contained in Paragraph 48.

C. The Market for Contract Gamma and X-ray Sterilization Services Sold to Targeted Customers

49. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 49 concerning STERIS' presentation to the Commission. Synergy avers that the Commission's selective summation of unidentified written material or communications from STERIS, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the summarized documents, once identified, for a complete and accurate description of their contents. The rest of Paragraph 49 contains legal conclusions to which no response is required. To the extent that Paragraph 49 contains factual allegations, Synergy denies all other allegations contained in Paragraph 49.

50. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 50 concerning STERIS' and Sterigenics' actual customer negotiations and negotiation strategies. The rest of Paragraph 50 contains legal conclusions to which no response is required. To the extent that Paragraph 50 contains factual allegations, Synergy denies all other allegations contained in Paragraph 50. Synergy avers that E-beam can be used to sterilize most products that are sterilized with gamma radiation.

51. Synergy admits the allegations contained in Paragraph 51 that customers could switch some portion of products currently utilizing contract gamma sterilization services to E-beam sterilization. The rest of Paragraph 51 contains legal conclusions to which no response is required. To the extent that Paragraph 51 contains factual allegations, Synergy denies all other allegations contained in Paragraph 51.

IV. RELEVANT GEOGRAPHIC MARKETS

52. Paragraph 52 contains legal conclusions to which no response is required. To the extent that Paragraph 52 contains factual allegations, Synergy denies the allegations contained in Paragraph 52.

53. Synergy admits the allegations contained in Paragraph 53 that most contract radiation sterilization customers seek to minimize transportation costs and turnaround times in seeking contract sterilization. Synergy also admits that customers may use sterilization providers more than 500 miles away from a customer's plants if the sterilization provider has a facility near the customer's regular shipping route. Synergy lacks sufficient information to admit or deny the allegation concerning where contract sterilization companies may decide to locate their plants. Synergy denies all other allegations contained in Paragraph 53.

54. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 54 concerning how other contract sterilization providers set pricing. With regard to its own practices, Synergy denies the allegations of Paragraph 54.

55. [REDACTED]

[REDACTED] Synergy denies all other allegations contained in Paragraph 55.

56. Synergy admits that it identified users of sterilization services located near Decatur, Indiana. Synergy denies all other allegations contained in Paragraph 56.

57. Synergy denies the allegations contained in Paragraph 57.

58. Synergy denies the allegations contained in Paragraph 58.

59. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 59 concerning the supply chain of the vast majority of U.S. sterilization customers. Synergy denies the other allegations contained in Paragraph 59.

V. MARKET STRUCTURE

60. On information and belief, Synergy admits the allegations contained in Paragraph 60 that STERIS and Sterigenics are currently the only providers of contract gamma sterilization services in the United States. Synergy denies all other allegations contained in Paragraph 60.

A. Market Participants

Contract Gamma Sterilization Services

61. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 61 regarding STERIS' revenues. On information and belief, Synergy admits all other allegations contained in Paragraph 61.

62. Synergy lacks information sufficient to admit or deny the allegations contained in Paragraph 62 regarding Sterigenics' revenues. On information and belief, Synergy admits all other allegations contained in Paragraph 62.

Contract X-ray Sterilization Services

63. Synergy denies the allegations contained in Paragraph 63 that it had a well-developed strategy to enter the United States with contract X-ray sterilization services, and that those services would have competed with contract gamma sterilization services. Synergy admits all other allegations contained in Paragraph 63.

64. Synergy denies the allegations contained in Paragraph 64.

65. Synergy admits the allegations contained in Paragraph 65 that third party sterilization service providers, like Nutek, may attempt to provide X-ray sterilization services. On information and belief, Synergy avers that such activity is already underway. Synergy denies all other allegations in Paragraph 65.

Contract E-beam Sterilization Services

66. Synergy admits the allegations contained in Paragraph 66, except that it denies that [REDACTED]

67. On information and belief, Synergy admits the allegations contained in Paragraph 67 that Sterigenics operates a contract E-beam sterilization facility in San Diego, California. Synergy lacks information sufficient to admit or deny all other allegations contained in Paragraph 67.

68. On information and belief, Synergy admits the allegations contained in Paragraph 68 that STERIS does not currently provide E-beam sterilization services in the United States. Synergy lacks information sufficient to admit or deny all other allegations contained in Paragraph 68.

69. On information and belief, Synergy admits the allegations contained in Paragraph 69 that E-beam contract sterilization services are offered by 1) E-BEAM Services Inc. in Cranbury, New Jersey and Lebanon, Ohio, 2) Nutek in Hayward, California, and 3) Iotron in Columbia City, Indiana. Synergy denies the allegations contained in Paragraph 69 that Nutek lacks experience and efficiency and denies the implication that Iotron lacks the technical expertise to serve medical device manufacturers. Synergy lacks information sufficient to admit or deny all other allegations contained in Paragraph 69. Synergy avers that the Commission's selective quotation and summation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents.

B. Market Concentration

70. Paragraph 70 contains legal conclusions to which no response is required. To the extent that Paragraph 70 contains factual allegations, Synergy denies the allegations contained in Paragraph 70.

71. Synergy admits that the HHI is used by the Commission as a measure of purported concentration and avers that the Horizontal Merger Guidelines issued by the Antitrust Division of the United States Department of Justice and the Federal Trade Commission on August 19, 2010, speak for themselves. Synergy further avers that the Horizontal Merger Guidelines do not necessarily mirror, and do not substitute for, controlling case law. The rest of Paragraph 71 contains legal conclusions to which no response is required. To the extent that Paragraph 71 contains factual allegations, Synergy denies all other allegations contained in Paragraph 71.

72. Paragraph 72 contains legal conclusions to which no response is required. To the extent that Paragraph 72 contains factual allegations, Synergy denies all other allegations contained in Paragraph 72. Synergy specifically denies that contract radiation sterilization services and the geographic markets identified constitute relevant markets.

73. Paragraph 73 contains legal conclusions to which no response is required. To the extent that Paragraph 73 contains factual allegations, Synergy denies all other allegations contained in Paragraph 73. Synergy specifically denies that “contract gamma and x-ray sterilization services sold to targeted customers” constitute a relevant market.

VI. ANTICOMPETITIVE EFFECTS

74. Synergy admits the allegations contained in Paragraph 74 that it is a worldwide sterilization company without a gamma offering in the United States and, on information and

belief, that STERIS and Sterigenics are the only two contract gamma sterilization providers in the United States. The rest of Paragraph 74 contains legal conclusions to which no response is required. To the extent that Paragraph 74 contains factual allegations, Synergy denies all other allegations contained in Paragraph 74. Synergy specifically denies that there is any likely future competition arising from Synergy's deployment of X-ray sterilization in the United States.

75. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy admits that, at one time, certain Synergy personnel explored the possibility of building X-ray sterilization facilities in the United States. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Synergy denies all other allegations contained in Paragraph 75.

76. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 76.

A. Synergy Was Entering the Relevant Markets Prior to the Merger

The Early Stages of Synergy's U.S. X-ray Plan

77. Synergy admits that it acquired an X-ray facility in Däniken, Switzerland. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 77.

78. Synergy admits that Andrew McLean joined Synergy in June 2013 as Vice President of Global AST Business Development and that Mr. McLean was responsible for Synergy's initiative to explore potential X-ray sterilization entry in the United States. Synergy

avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations in Paragraph 78.

The X-ray Plan Ramp-Up

79. Synergy denies the allegations contained in Paragraph 79.

80. Synergy denies the allegations contained in Paragraph 80.

81. Synergy admits the allegations contained in Paragraph 81 that it [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Synergy denies all other allegations in Paragraph 81.

82. [REDACTED]

[REDACTED]

[REDACTED] and that Synergy's SEB includes the members identified. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 82.

83. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized document, once identified, for a complete and accurate description of its contents. Synergy denies all other allegations contained in Paragraph 83.

84. [REDACTED] that the plc board includes the individuals identified, and that [REDACTED]

[REDACTED] Synergy avers that its documents speak for themselves and respectfully refers the Court to the summarized documents, once identified, for a complete

and accurate description of their contents. [REDACTED]

[REDACTED] Synergy denies all other allegations contained in Paragraph 84.

85. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Synergy avers that its documents speak for themselves and respectfully refers the Court to the summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations in Paragraph 85.

86. Synergy admits the allegations contained in Paragraph 86.

Synergy's Actions Post-Merger Announcement

87. Synergy admits that, after consummation of the proposed merger of Synergy and STERIS, the merged entity could make a decision whether to continue exploring the introduction of X-ray technology in the U.S. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 87.

88. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 88.

89. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 89.

90. [REDACTED]

[REDACTED] Synergy avers that its documents speak for themselves and respectfully refers the Court to the referenced and summarized documents, once fully identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 90.

91. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 91.

Synergy's Actions After the FTC Issued Second Requests

92. Synergy admits the allegations contained in Paragraph 92.

93. [REDACTED]

[REDACTED] Synergy denies all other allegations contained in Paragraph 93.

94. Synergy admits that Mr. McLean executed a declaration on February 24, 2015 and that, [REDACTED]

[REDACTED] Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once fully identified, for a complete and accurate description of their contents. Synergy further avers that the Commission's selective quotation of unidentified written material offered without context is misleading as framed. Synergy denies all other allegations contained in Paragraph 94.

B. Synergy's U.S. X-ray Entry Would Result in Substantial Procompetitive Effects

**Synergy's Entry Would Have a Significant
De-concentrating Effect on the Relevant Markets**

95. Synergy avers that its documents speak for themselves and respectfully refers the Court to the summarized documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 95.

96. Synergy denies the allegations contained in Paragraph 96.

97. Paragraph 97 contains legal conclusions and argument to which no response is required. To the extent that Paragraph 97 contains factual allegations, Synergy denies the allegations contained in Paragraph 97. Synergy specifically denies that contract radiation sterilization and/or contract gamma sterilization constitute relevant product markets.

98. Paragraph 98 contains legal conclusions and argument to which no response is required. To the extent that Paragraph 98 contains factual allegations, Synergy denies the allegations contained in Paragraph 98. Synergy specifically denies that contract radiation services and/or contract gamma/x-ray market constitute relevant product markets.

99. Synergy lacks information sufficient to admit or deny the unspecified statements by an unidentified Sterigenics employee. Synergy avers that the Commission's selective quotation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 99.

**Synergy's X-ray Entry Would Have Created Substantial Price
and Non-Price Benefits for Customers**

100. Synergy denies the allegations contained in Paragraph 100.

101. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once fully identified, for a complete and accurate description of their contents. Synergy further avers that the Commission's selective quotation of unidentified written material offered without context is misleading as framed. Synergy denies all other allegations contained in Paragraph 101.

102. Synergy avers that its documents speak for themselves and respectfully refers the Court to the quoted and summarized documents, once fully identified, for a complete and accurate description of their contents. Synergy further avers that the Commission's selective quotation of unidentified written material offered without context is misleading as framed. Synergy denies all other allegations contained in Paragraph 102.

103. Synergy avers that its executives' testimony speaks for itself and respectfully refers the Court to the complete transcripts of the identified executives' testimony for a complete and accurate transcription of the same. Synergy further avers that the Commission's selective quotation of testimony offered without context is misleading as framed. Synergy denies all other allegations contained in Paragraph 103.

104. Synergy avers that Mr. Steeves' testimony speaks for itself and respectfully refers the Court to the complete transcript of Mr. Steeves' testimony for a complete and accurate transcription of the same. Synergy further avers that the Commission's selective quotation of testimony offered without context is misleading as framed. Synergy denies all other allegations contained in Paragraph 104.

105. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 105 regarding the purported statements of unidentified customers. Synergy admits that many customers would have to validate their products for X-ray sterilization before they could switch

those products over from gamma radiation sterilization. Synergy denies all other allegations contained in Paragraph 105.

106. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 106 regarding the purported concerns of unidentified customers.

107. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 107 regarding the statements and activities of unidentified customers. Synergy admits the allegations contained in Paragraph 107 regarding Synergy's understanding that it would take significant time, cost, and effort for customers to switch from gamma to X-ray sterilization. Synergy further admits that Johnson & Johnson has obtained FDA approval for Surgicel. Synergy avers that, [REDACTED]

[REDACTED]
[REDACTED] Synergy denies all other allegations contained in Paragraph 107.

108. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 108 concerning other entities' intentions. [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Synergy denies all other allegations contained in Paragraph 108.

109. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 109 regarding the purported concerns and statements of unidentified customers.

110. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 110 regarding the purported concerns and statements of unidentified customers.

VII. ENTRY WILL NOT PREVENT THE MERGER'S COMPETITIVE HARM

111. Paragraph 111 contains legal conclusions and argument to which no response is required. To the extent that Paragraph 111 contains factual allegations, Synergy denies the allegations contained in Paragraph 111.

A. Barriers to Entry for X-ray Sterilization Services

Synergy Has X-ray Entry Advantages Unmatched by Any Other Firm

112. Synergy admits that it is a small player in the U.S. contract radiation sterilization services business and that it provides E-beam and EO in the United States. Synergy denies all other allegations contained in Paragraph 112.

113. Synergy admits that, at the time Synergy executed the merger agreement with STERIS, Synergy had been operating its Däniken, Switzerland X-ray sterilization facility for approximately two years and had considered the possibility of entering the U.S. with X-ray.

[REDACTED]

[REDACTED]

[REDACTED] Synergy denies all other allegations contained in Paragraph 113.

114. Synergy admits that, at the time of the merger agreement, Synergy had reached an agreement with IBA. Synergy avers that the IBA agreement speaks for itself and respectfully refers the Court to the IBA agreement for a complete and accurate description of its contents. Similarly, Synergy avers that the testimony of the Däniken facility manager speaks for itself and respectfully refer the Court to the complete transcript of the testimony in question for a complete and accurate transcription of the same. Synergy denies all other allegations contained in Paragraph 114.

115. Synergy admits that it has the experience needed to meet the needs of large medical device manufacturers effectively and economically. On information and belief, Synergy

also admits that no company has an agreement with IBA to use its X-ray equipment in the United States. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 115 regarding STERIS and Sterigenics, and IBA's purported beliefs. Synergy denies all other allegations contained in Paragraph 115.

116. On information and belief, Synergy admits that other E-beam sterilization service providers in the United States have contemplated converting their E-beam sterilization machines into X-ray sterilization machines. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 116 regarding the conclusions purportedly reached by [REDACTED]. Synergy denies all other allegations contained in Paragraph 116.

B. Barriers to Entry for Gamma Sterilization Services

117. On information and belief, Synergy admits that no contract gamma sterilization provider has built a new gamma sterilization facility in the United States in over fifteen years. On information and belief, Synergy avers that in-house gamma sterilization facilities have been constructed and that contract gamma sterilization providers have added capacity at their existing facilities in the United States in the last fifteen years. Synergy also admits that regulations govern gamma sterilization facilities. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 117 regarding the purported threat of future legislative restrictions. Synergy denies all other allegations contained in Paragraph 117.

118. Synergy denies the allegations contained in Paragraph 118. [REDACTED]
[REDACTED]

119. Paragraph 119 contains opinions and legal conclusions to which no response is required. To the extent that Paragraph 119 contains factual allegations, Synergy admits the allegations contained in Paragraph 119.

120. Synergy admits that the prices of Cobalt 60 are likely to increase because of Sterigenics' ownership of Nordion. Synergy avers that its documents and its executives' testimony speak for themselves and respectfully refers the Court to the quoted and summarized documents and/or testimony, once identified, for a complete and accurate description of their contents and/or transcription. Synergy further avers that the Commission's selective quotation of unidentified written material and/or testimony offered without context is misleading as framed. The rest of Paragraph 120 contains opinions and legal conclusions to which no response is required. To the extent that Paragraph 120 contains factual allegations, Synergy denies the allegations contained in Paragraph 120.

C. Barriers to Entry for E-beam Sterilization Services

121. Synergy admits that a potential E-beam entrant would need to secure customers willing to use its facility and that customers would need to test and validate their products with a potential E-beam sterilization provider before committing to use its services. Synergy lacks information sufficient to admit or deny the allegations in Paragraph 121 regarding the length of time an unnamed firm seeking to open an E-beam sterilization facility has been planning to enter or when it expects to begin operations. Synergy denies all other allegations contained in Paragraph 121. [REDACTED]

122. Synergy lacks information sufficient to admit or deny the unspecified statements by an unidentified STERIS employee. Synergy avers that the Commission's selective quotation

of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 122.

123. Synergy lacks information sufficient to admit or deny the unspecified statements by an unidentified STERIS employee. Synergy avers that the Commission's selective quotation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 123.

VIII. EFFICIENCIES WILL NOT COUNTERACT THE MERGER'S COMPETITIVE

HARM

124. Paragraph 124 contains legal conclusions and argument to which no response is required. To the extent that Paragraph 124 contains factual allegations, Synergy denies the allegations contained in Paragraph 124.

125. Synergy lacks information sufficient to admit or deny the unspecified statements by an unidentified STERIS employee. Synergy avers that the Commission's selective quotation of unidentified written material or communications, offered without context, is misleading as framed, and Synergy respectfully refers the Court to the quoted documents, once identified, for a complete and accurate description of their contents. Synergy denies all other allegations contained in Paragraph 125.

IX. LIKELIHOOD OF SUCCESS ON THE MERITS AND NEED FOR RELIEF

126. Paragraph 126 contains legal conclusions to which no response is required. To the extent that Paragraph 126 contains factual allegations, Synergy denies the allegations in Paragraph 126.

127. Synergy denies the allegations contained in Paragraph 127, and specifically denies that contract radiation sterilization services constitute a relevant product market, that the geographic areas identified constitute relevant geographic markets, and that there are significant barriers to entry for the provision of sterilization services.

128. Synergy denies the allegations contained in Paragraph 128, and specifically denies that Synergy has any existing “x-ray roll out efforts,” which could be “stall[ed]” if the merger proceeds.

129. Paragraph 129 contains legal conclusions to which no response is required. To the extent that Paragraph 129 contains factual allegations, Synergy denies the allegations contained in Paragraph 129. Synergy avers that the Commission is not entitled to any of the relief requested and respectfully requests that Synergy be awarded the costs incurred in defending this action, and any and all other relief as the Court may deem just and proper.

AFFIRMATIVE DEFENSES

Synergy asserts the following defenses, without assuming the burden of proof on such defenses that would otherwise rest with the Commission:

FIRST DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE

The relief sought is contrary to the public interest.

THIRD DEFENSE

The alleged relevant geographic market definitions fail as a matter of law.

FOURTH DEFENSE

The Complaint fails to adequately allege a relevant product market.

FIFTH DEFENSE

The Complaint fails to allege harm to competition.

SIXTH DEFENSE

The Complaint fails to allege harm to any consumers.

SEVENTH DEFENSE

The Complaint fails to allege harm to consumer welfare.

EIGHTH DEFENSE

The alleged harm to potential competition is not actionable.

NINTH DEFENSE

The Commission cannot show that, even if it succeeds in blocking the proposed merger, Synergy will ever provide contact X-ray sterilization services in the United States.

TENTH DEFENSE

The combination of the Defendants' businesses will be procompetitive. The merger will result in substantial merger-specific efficiencies, cost synergies, and other procompetitive effects that will directly benefit consumers. The benefits greatly outweigh any and all proffered anticompetitive effects.

OTHER DEFENSES

Synergy reserves the right to assert any other defenses as they become known to Synergy.

Dated: June 12, 2015

Respectfully submitted,

DLA PIPER LLP (US)

By: s/ Laura M. Kam
PAOLO MORANTE
Paolo.Morante@dlapiper.com
STEVEN E. LEVITSKY
Steven.Levitsky@dlapiper.com
1251 Avenue of the Americas, 27th Floor
New York, NY 10020
Tel: 212.335.4500
Fax: 212.606.5101

DAVID H. BAMBERGER
David.Bamberger@dlapiper.com
JULIE GRYCE
Julie.Gryce@dlapiper.com
500 Eighth Street, NW
Washington, DC 20004
TEL: 202.799.4000
FAX: 202.799.5000

LAURA M. KAM
Laura.Kam@dlapiper.com
2525 East Camelback Road, Suite 1000
Phoenix, AZ 85016
TEL: 480.606.5100
FAX: 480.606.5101

Attorneys for Defendant Synergy Health plc

CERTIFICATE OF SERVICE

I hereby certify that on June 12, 2015, I caused the attached document to be electronically transmitted to the Clerk's Office using the CM/ECF System for filing and transmitted a Notice of Electronic Filing to the following CM/ECF registrants:

Michael Moiseyev
Tara Reinhart
Daniel K. Zach
Peter Colwell
FEDERAL TRADE COMMISSION
400 7th St., SW
Washington, DC 20024
mmoiseyev@ftc.gov
treinhart@ftc.gov
dzach@ftc.gov
pcolwell@ftc.gov

*Counsel for Plaintiff
Federal Trade Commission*

John M. Majoras
JONES DAY
Street Address:
325 John H. McConnell Blvd., Suite 600
Columbus, OH 43215-2673
Mailing Address:
P.O. Box 165017
Columbus, OH 43216-5017
jmmajoras@jonesday.com

Louis K. Fisher
Michael S. Fried
Geoffrey S. Irwin
Tara Lynn R. Zurawski
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001-2113
lkfisher@jonesday.com
msfried@jonesday.com
gsirwin@jonesday.com
tzurawski@jonesday.com

Nelson Fitts
WACHTELL, LIPTON, ROSEN & KATZ
51 West 52 Street
New York, NY 10019
NOFitts@WLRK.com

Counsel for Defendant STERIS Corporation

s/ April Natzke
April Natzke