

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION
OFFICE OF ADMINISTRATIVE LAW JUDGES



In the matter of

Steris Corporation
a corporation,

and

Synergy Health PLC,
a corporation.

Docket No. 9365

**ANSWER AND DEFENSES OF RESPONDENT
STERIS CORPORATION**

Pursuant to Rule 3.12 of the Federal Trade Commission’s (“Commission”) Rules of Practice for Adjudicative Proceedings, Respondent STERIS Corporation (“STERIS”), by and through its attorneys, admits, denies, and avers as follows with respect to the Administrative Complaint (“Complaint”) filed by the Commission as follows:

STERIS lacks knowledge of and excludes for purposes of its answer, any information contained in or related to highly confidential information or documents provided by Synergy in connection with the FTC’s investigation of the proposed transaction between STERIS and Synergy that was disclosed only to counsel. To the extent not specifically admitted in the following paragraphs, the allegations in the Complaint are denied.

INTRODUCTORY STATEMENT

STERIS states that the premise of the Complaint – that, but for the merger between erroneous both e1wfact and e1wip6Sapplication of thg p.S. e9pitrust laws. Thg Commission’s challenge to the merger is based on awfaultywfactual premise and es contrary to well-established e9pitrust doctrine.

I. NATURE OF THE CASE

1. STERIS admits that it is the second-largest provider of contract rayruc118.i.-o service6Se1wing world, and that Sayrugenics is the largest provider of contract rayruc118.i.-oservice6S in the world, but denies that the world is a relevant market for purposes of the Complaint. STERIS avers that Synergy’s United States operations are smaller than STERIS and Sterigenics, and Synergy is not materially larger, from a capacity perspective, than many other contract

and irrelevant to any valid theory of antitrust liability. Upon information and belief, STERIS avers that Synergy also offers EO sterilization in the U.S. STERIS denies the remaining

II. BACKGROUND

A. Jurisdiction and Venue

19. STERIS admits the allegations set forth in paragraph 19 of the Complaint.
20. STERIS admits the allegations set forth in paragraph 20 of the Complaint.

B. Defendants

21. STERIS denies that \$127.5 million of its 2014 revenues derived from contract gamma sterilization services performed at facilities

be used cost-effectively to sterilize most products that are sterilized with gamma radiation. STERIS denies the remaining allegations set forth in paragraph 28 of the Complaint.

Contract X-ray Sterilization Services

29. STERIS admits that x-ray sterilization uses a high-powered electron beam machine to produce x-ray radiation. STERIS admits that, historically, x-ray sterilization has not been used in the United States. STERIS avers that there are many reasons x-ray sterilization has not been used, and the fact that no machine existed that was capable of sterilizing products as cost effectively as gamma or other sterilization methods is but one reason. STERIS further avers that no x-ray machine historically existed or currently exists that is capable of sterilizing products as cost effectively as gamma or other sterilization methods. STERIS denies the remaining allegations set forth in paragraph 29 of the Complaint.

30. STERIS admits that x-ray is theoretically capable of the depth of penetration of gamma radiation. STERIS admits x-ray raises different regulatory issues than gamma sterilization. STERIS avers that e-beam can be used to sterilize most products that are sterilized with gamma radiation. STERIS denies the remaining allegations set forth in paragraph 30 of the Complaint.

Contract E-beam Sterilization Services

31. STERIS admits the allegations set forth in paragraph 31 of the Complaint except to the extent that the allegations imply that e-beam can only be used to sterilize small volumes of low-density homogeneous products. STERIS avers that e-beam is currently used to sterilize large volumes of such products as well. STERIS avers that e-beam can be used to sterilize most products that are sterilized with gamma radiation. STERIS denies the remaining allegations set forth in paragraph 31 of the Complaint.

32. STERIS denies the allegations set forth in Paragraph 32 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. STERIS avers that e-beam can be used to sterilize most products that are sterilized with gamma radiation. STERIS lacks knowledge or information sufficient to form a belief as to unspecified statements by unidentified customers and therefore denies those allegations. STERIS avers that the FTC's selective quotation of unidentified written material or communications, offered without context, is misleading as framed in the Complaint, and STERIS respectfully refers the Court to the quoted documents, if identified, for a complete and accurate description of their contents. STERIS denies the remaining allegations contained in Paragraph 32.

B. The Market for Contract Radiation Sterilization Services

33. STERIS admits that today, gamma sterilization accounts for 85% of radiation sterilization services sold in the United States, and that e-beam accounts for the remaining 15%. STERIS avers that e-beam can be used to sterilize most products that are sterilized with gamma radiation, and that e-beam's share of radiation sterilization services sold in the United States has been increasing over time. The last sentence of paragraph 33 contains a legal conclusion to

39. STERIS denies that EO sterilization often takes significantly longer than other

STERIS denies the remaining allegations set forth in paragraph 44 of the Complaint. STERIS avers that e-beam can be used to sterilize most products that are sterilized with gamma radiation.

45. STERIS admits the allegations contained in Paragraph 45 that customers could switch some portion of products currently utilizing contract gamma sterilization services to e-beam sterilization. STERIS denies the remaining allegations set forth in paragraph 45 of the Complaint.

IV. RELEVANT GEOGRAPHIC MARKETS

46. The FTC's allegation of the relevant geographic market constitutes a legal conclusion to which no response is required. To the extent a response is deemed required, STERIS denies that allegation. STERIS denies all other allegations in paragraph 46 of the Complaint.

47. Upon information and belief, STERIS admits that transportation costs and turnaround times are among the factors considered by customers in choosing services. STERIS also admits that a customer may use sterilization providers more than 500 miles away from that customer's plants if the sterilization provider has a facility near the customer's regular shipping route. Upon information and belief, STERIS admits that contract radiation sterilization companies locate their plants near the customers for which they expect to compete. STERIS denies all other remaining allegations set forth in paragraph 47 of the Complaint.

48. STERIS lacks knowledge or information sufficient to form a belief as to how other contract sterilization providers set pricing, and therefore denies those allegations. STERIS denies the remaining allegations set forth in paragraph 48 of the Complaint.

49. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 49 of the Complaint, and therefore denies them.

50. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 50 of the Complaint, and therefore denies them.

51. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 51 of the Complaint, and therefore denies them.

52. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 52 of the Complaint, and therefore denies them.

53. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 53 of the Complaint, and therefore denies them.

V. MARKET STRUCTURE

54. On information and belief, STERIS denies that STERIS and Sterigenics are currently the only providers of contract gamma sterilization services in the United States. STERIS lacks knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 54 of the Complaint, and therefore denies them.

62. STERIS admits the allegations set forth in paragraph 62 of the Complaint, but

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

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

71. STERIS admits that Synergy acquired an x-ray facility in Däniken, Switzerland. STERIS lacks knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 71, and therefore denies them.

72. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 72 of the Complaint, and therefore denies them.

The X-ray Plan Ramp-Up

73. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 73 of the Complaint, and therefore denies them.

74. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 74 of the Complaint, and therefore denies them.

75. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 75 of the Complaint, and therefore denies them.

76. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 76 of the Complaint, and therefore denies them.

77. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 77 of the Complaint, and therefore denies them.

78. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 78 of the Complaint, and therefore denies them.

79. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 79 of the Complaint, and therefore denies them.

80. STERIS admits that the proposed merger of Synergy and STERIS was announced on October 13, 2014. STERIS lacks knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 80 of the Complaint, and therefore denies them.

Synergy's Actions Post-Merger Announcement

81. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 81 of the Complaint, and therefore denies them.

82. STERIS avers that Synergy's 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. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 82 of the Complaint, and therefore denies them.

83. STERIS avers that Synergy's 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. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 83 of the Complaint, and therefore denies them.

84. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 84 of the Complaint, and therefore denies them.

85. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 85 of the Complaint, and therefore denies them.

Synergy's Actions After the FTC Issued Second Requests

86. STERIS admits the allegations set forth in paragraph 86 of the Complaint, but avers that x-ray sterilization does not currently compete with gamma sterilization in the United States.

87. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 87 of the Complaint, and therefore denies them.

88. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 88 of the Complaint, and therefore denies them.

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

89. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 89 of the Complaint, and therefore denies them.

90. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 90 of the Complaint, and therefore denies them.

91. STERIS denies the allegations set forth in paragraph 91 of the Complaint.

92. STERIS denies the allegations set forth in paragraph 92 of the Complaint.

93. STERIS lacks knowledge or information sufficient to form a belief as to allegations set forth in paragraph 93 of the Complaint, and therefore denies them.

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

94. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 94 of the Complaint, and therefore denies them.

95. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 95 of the Complaint, and therefore denies them.

96. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 96 of the Complaint, and therefore denies them.

97. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 97 of the Complaint, and therefore denies them.

98. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 98 of the Complaint, and therefore denies them.

99. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 99 of the Complaint, and therefore denies them.

100. Upon information and belief, STERIS admits that some customers have indicated they are concerned about the effect of Cobalt 60 supply on gamma sterilization prices in the future. STERIS avers that the FTC's clearance of the Sterigenics-Nordion transaction in 2014 has contributed to this uncertainty and potential volatility. STERIS denies the remaining allegations set forth in paragraph 100 of the Complaint.

114. STERIS lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 114 of the Complaint, and therefore denies them.

C. Barriers to Entry for E-beam Sterilization Services

115. STERIS lacks knowledge or information sufficient to form a belief as to whether an unspecified firm seeking to open a single e-beam sterilization facility has been planning to enter for approximately four years, and still does not expect to begin operations until the fall of 2015, and therefore denies those allegations. STERIS admits that a potential entrant would need to secure customers and that most customers need to test and validate their products with a potential e-beam sterilization provider before committing to use its services. STERIS avers that the cost to construct an e-beam sterilization facility is dependent on numerous factors, and lacks knowledge or information sufficient to form a belief as to the FTC's alleged cost for constructing an e-beam sterilization facility, and therefore denies that allegation. STERIS lacks knowledge or information sufficient to form a belief as to unspecified customer requirements and the alleged effect on entrants, and therefore denies those allegations. STERIS denies the remaining allegations set forth in paragraph 115 of the Complaint.

116. STERIS lacks knowledge or information sufficient to form a belief as to whether any small fringe e-beam sterilization firm or *de novo* entrant is likely to expand to enter the e-beam sterilization market in a significant manner in an unspecified timeframe under unspecified market conditions, and therefore denies that allegation. STERIS lacks sufficient knowledge or information sufficient to form a belief as to whether small e-beam providers have been unable to grow beyond a small share of contract radiation sterilization services because e-beam processing companies have had limited success converting gamma customers, and therefore denies that allegation. STERIS avers that the FTC's selective quotation of unidentified written material or communications, offered without context, is misleading as framed in the Complaint, and STERIS respectfully refers the Court to the quoted documents, if identified, for a complete and accurate description of their contents. STERIS denies the remaining allegations set forth in paragraph 116 of the Complaint.

117. STERIS avers that the FTC's selective quotation of unidentified written material or communications, offered without context, is misleading as framed in the Complaint, and

EIGHTH DEFENSE

The alleged harm to potential competition is not actionable

NINTH DEFENSE

The FTC cannot show that, even if it is successful in blocking the proposed merger, that 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. These benefits greatly outweigh any and all proffered anticompetitive effects.

ELEVENTH DEFENSE

The FTC fails to allege a time frame for the alleged anticompetitive effects.

RESERVATION OF RIGHTS TO ASSERT ADDITIONAL DEFENSES

STERIS has not knowingly or intentionally waived any applicable defenses, and it reserves the right to assert and rely upon other applicable defenses that may become available or apparent throughout the course of the action. STERIS reserves the right to amend, or seek to amend, its answer or affirmative defenses.

NOTICE OF CONTEMPLATED RELIEF

WHEREFORE, STERIS requests that the Commission enter judgment in its favor as follows:

- A. The Complaint be dismissed with prejudice;
- B. None of the Complaint's contemplated relief issues to the FTC;
- C. Costs incurred in defending this action be awarded to STERIS; and
- D. Any and all other relief as the Commission may deem just and proper

Dated: June 18, 2015

Respectfully submitted,

/s/ John M. Majoras

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Counsel for Defendant STERIS Corporation

CERTIFICATE OF SERVI

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Notice of Electronic Service

I hereby certify that on June 18, 2015, I filed an electronic copy of the foregoing STERIS Answer to FTC Part 3 Complaint, with:

D. Michael Chappell
Chief Administrative Law Judge
600 Pennsylvania Ave., NW
Suite 110
Washington, DC, 20580

Donald Clark
600 Pennsylvania Ave., NW
Suite 172
Washington, DC, 20580

I hereby certify that on June 18, 2015, I served via E-Service an electronic copy of the foregoing STERIS Answer to FTC Part 3 Complaint, upon:

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