

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO, EASTERN DIVISION**

an administrative proceeding on the merits scheduled to begin on October 28, 2015, which the Commission already has initiated pursuant to Sections 7 and 11 of the Clayton Act, 15 U.S.C. §§ 18, 21, and Section 5 of the FTC Act, 15 U.S.C. § 45. The administrative proceeding will determine the legality of the Merger, subject to judicial review by a federal Court of Appeals, and will provide all parties full opportunity to conduct discovery and present testimony and other evidence regarding the likely competitive effects of the Merger.

I.

NATURE OF THE CASE

1. Defendants are the second- and third-largest sterilization companies in the world, while Sterigenics International, Inc. ("Sterigenics") is the largest. Sterilization is a critical final step in the manufacture of many healthcare products, as it is necessary to eliminate bacteria and other microorganisms living on or within products and is required by the U.S. Food and Drug Administration ("FDA").
2. Steris is the largest provider of gamma radiation sterilization services in the United States with fourteen facilities, as well as ten ethylene oxide ("EO") gas sterilization facilities. Sterigenics also operates fourteen gamma sterilization facilities in the United States, along with ten EO facilities, and one electron-beam ("e-beam") radiation facility. Sterigenics also operates gamma, e-beam, and EO facilities outside the United States. Synergy operates more than three dozen contract sterilization facilities, including numerous gamma sterilization facilities outside of the United States, and currently offers only e-beam and EO sterilization services in the United States. Absent the proposed Merger, Synergy planned to [REDACTED]

[REDACTED] and [REDACTED]

[REDACTED] If consummated, the Merger would allow Steris to insulate itself against this competitive threat, which would have targeted Steris and Sterigenics' customers, especially its core gamma sterilization customers, and resulted in lower prices, improved quality, and increased choice for contract sterilization.

3. There are three primary methods of sterilization currently used in the United States: gamma radiation, e-beam radiation, and EO gas. Customers choose sterilization methods based on each product's physical characteristics and packaging, the volume of products requiring sterilization, and the capabilities of each sterilization modality. Gamma radiation sterilizes by exposure to a radioactive isotope, Cobalt 60. Gamma radiation has deep penetration capabilities and is favored by customers that need to sterilize dense products, such as implantable medical devices, and products with heterogeneity of density, such as products packaged in large quantities. E-beam, a second type of radiation sterilization, does not penetrate as deeply as gamma radiation, though it can be effective for low-density products sterilized in low volumes. EO is a non-radiation form of sterilization that exposes products to gas to kill unwanted organisms. EO is effective only if gas diffuses freely through packaging and makes contact with all product surfaces requiring sterilization.
4. X-ray radiation sterilization will be a close substitute for gamma sterilization. X-ray sterilization offers comparable, and possibly superior, depth of penetration, allowing it to compete for products that customers currently sterilize economically with gamma radiation. For many products, x-ray is the only functional alternative to gamma because



of the limitations of e-beam sterilization. According to Synergy, [REDACTED]

- [REDACTED]
5. The relevant product market in which to analyze the effects of the Merger is no broader than contract radiation sterilization services. EO sterilization is not an economical and practical substitute for contract radiation sterilization services, because EO gas can leave a harmful residue on products, making it unsuitable for many healthcare customers. EO sterilization also requires the use of specialized, breathable packaging and faces significant restrictions in how densely products can be packed into boxes and how those boxes can be configured in the sterilization chamber, limiting the types and volumes of products that can effectively use EO. It typically takes longer to complete than radiation sterilization as well. Thus, EO sterilization is properly excluded from the relevant market.
  6. A small number of medical device manufacturers use their own in-house sterilization facilities to sterilize a portion of their products. In-house sterilization is properly excluded from the relevant market because only the largest suppliers of medical devices and other products can cost-effectively sterilize any portion of their products in-house. Performing gamma sterilization internally makes economic sense only if a company produces or distributes a very large volume of product (generally in excess of [REDACTED] cubic feet of product annually) at a single facility. Very few companies produce the single-location volume required to justify the large upfront investment and ongoing costs associated with establishing and operating in-house sterilization. Industry trends show that medical device manufacturers and other customers are shifting more of their sterilization needs to contract providers, rather than using more in-house sterilization.



Even those that have in-house capabilities rely on contract sterilizers to provide some portion of their sterilization needs as well as back-up sterilization services in the event the in-house facilities temporarily shut down.

7. Today, e-beam is an uneconomical alternative for the vast majority of products that are sterilized with gamma radiation. Indeed, although e-beam has been available for thirty years, it still represents only about [REDACTED] of all contract radiation sterilization services sold in the United States while gamma accounts for the remaining [REDACTED]. At current prices, the amount of product that customers would likely switch to e-beam sterilization in the face of a small, but significant and non-transitory increase in price ("SSNIP") for contract gamma sterilization services would be small. However, some customers are concerned about the availability and pricing of gamma sterilization in the future due to questions about the supply of Cobalt 60. As a result, e-beam may become a closer economic substitute to gamma in the future than it is today. Thus, the relevant market is no broader than contract radiation sterilization.
8. The competitive impact of the proposed merger will be most pronounced for customers that would not switch to e-beam even if gamma sterilization prices were to increase by substantially more than a SSNIP. Thus, there is also a relevant market for contract gamma and x-ray sterilization services sold to targeted customers that would not switch to e-beam in the event of a SSNIP.
9. Customers purchase gamma sterilization services from suppliers located near their manufacturing or distribution sites in order to minimize transportation costs and turnaround times. The relevant geographic markets initially affected by the proposed transaction are the areas that Synergy would have served through its planned x-ray

facilities in the [REDACTED] area and [REDACTED] which were set to open in [REDACTED]. Synergy also planned to begin operating x-ray plants in [REDACTED] [REDACTED] by [REDACTED]. All [REDACTED] Synergy plants would have competed directly with nearby Steris facilities.

10. The Merger will result in substantial competitive harm in all [REDACTED] relevant markets, each of which is already highly concentrated under the Merger Guidelines and case law. The [REDACTED] million market for all contract radiation sterilization services surrounding [REDACTED] [REDACTED] currently has an HHI level of over [REDACTED] while the other [REDACTED] markets— [REDACTED]—are also highly concentrated with HHIs ranging from at least [REDACTED] to more than [REDACTED]. Analyzing the impact of the merger in the [REDACTED] market for contract gamma and x-ray sterilization services sold to targeted customers, which has [REDACTED] million in sales, yields an HHI of approximately [REDACTED]. Similarly, each of the other [REDACTED] geographic areas has an even higher current concentration level in a market for contract gamma and x-ray sterilization services sold to targeted customers.
11. Synergy, although a significant competitor outside the United States, is a small U.S. contract radiation player today because it offers only e-beam sterilization services. Synergy is an actual potential entrant with its x-ray sterilization business, which would substantially augment its competitive significance. Synergy's entry with contract x-ray services would reduce concentration substantially in each relevant market and result in other procompetitive effects.
12. Synergy's U.S. x-ray strategy has been [REDACTED] years in the making. In 2012, Synergy's founder and CEO, Dr. Richard Steeves determined that the company should develop a

U.S. x-ray business to differentiate itself from the other major contract sterilization suppliers to enable it to become the number one global provider of contract sterilization services. Since then, Synergy has taken numerous steps to further that plan. By

September 2014, Synergy's Senior Executive Board ("SEB") [REDACTED]

[REDACTED] the PLC Board (Synergy's Board of Directors) [REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED] the development team had secured numerous letters of interest from significant customers, and the team had transitioned from planning to implementation.

13. Synergy's proposed merger with Steris was announced on October 13, 2014. In the weeks following, Synergy [REDACTED] [REDACTED]  
[REDACTED]  
[REDACTED] and that the New Steris would

need to approve the x-ray strategy after the deal closed.

14. In January 2015, the FTC issued Second Requests to Steris and Synergy that made clear that the FTC's investigation was focused on Synergy's efforts to enter the United States with x-ray. In February, the head of Synergy's sterilization business, Andrew McLean,

[REDACTED] While Mr. McLean claimed [REDACTED]

[REDACTED] customers remain interested in x-ray as an alternative to gamma, and in Synergy as an alternative to Sterigenics and Steris. In actuality, Synergy

[REDACTED] in an effort to salvage the sale to Steris.



15. Synergy's U.S. x-ray entry would have had a large and lasting competitive impact, and a de-concentrating effect, in each relevant market. Synergy recognized that filling the facilities would take time because Synergy would be introducing a new technology to the market and because customers must validate some of their products for sterilization in the new x-ray facilities. Synergy conservatively expected its U.S. x-ray sterilization business to grow to a [REDACTED] share of U.S. contract gamma sterilization sales. Synergy's executives anticipated that the [REDACTED] Synergy assigned a [REDACTED] that Steris and Sterigenics would [REDACTED] Customers, including some of the world's largest medical device companies, share Synergy's expectation that its x-ray entry would provide them with an important alternative to contracting with Steris and Sterigenics for gamma sterilization services.
16. New entry or expansion is not likely to prevent the anticompetitive effects of the transaction—Synergy has entry advantages in x-ray that no other firm can match, including its global scale, a reputation as a quality service provider, a head-start of several years, and, as of the date of the transaction, a ten-year exclusive agreement with the [REDACTED] of commercially viable x-ray sterilization machines. No other firm is attempting to enter the United States with x-ray sterilization services capable of competing effectively with gamma sterilization.
17. New entry with e-beam sterilization is expensive and time consuming and would not prevent the anticompetitive effects of the Merger for targeted contract gamma and x-ray sterilization customers. Entry into gamma is extraordinarily costly, difficult, and time

consuming, and is unlikely because of the uncertain future availability and pricing of Cobalt 60, and the demanding regulatory environment.

18. Defendants cannot show that efficiencies resulting from the Merger will offset the Merger's anticompetitive effects. Most of the cost savings that Defendants claim will result are neither verifiable nor merger-specific, nor likely to be passed on to customers. According to the executive tasked with evaluating potential efficiencies, Steris's purported cost savings figures [REDACTED]

## II.

### BACKGROUND

#### A.

#### **Jurisdiction and Venue**

19. This Court's jurisdiction arises under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and 28 U.S.C. §§1331, 1337, and 1345. This is a civil action arising under Acts of Congress protecting trade and commerce against restraints and monopolies, and is brought by an agency of the United States authorized by an Act of Congress to bring this action.
20. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), provides in pertinent part:
- Whenever the Commission has reason to believe—
- (1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and
  - (2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the

interest of the public — the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or a preliminary injunction may be granted without bond . . .

21. Steris and Synergy are, and at all relevant times have been, engaged in activities in or affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.
22. Steris is incorporated in and transacts substantial business in the Northern District of Ohio and is subject to personal jurisdiction therein. Synergy transacts substantial business in the Northern District of Ohio and is subject to personal jurisdiction therein. Venue, therefore, is proper in this district under 28 U.S.C. § 1391 (b) and (c) and 15 U.S.C. § 53(b).

**B.**

**Defendants**

23. Defendant Steris is a publicly traded corporation organized under the laws of Ohio with headquarters in Mentor, Ohio. Steris provides contract sterilization services in the United States and infection prevention and surgical products and services in more than sixty countries around the world. Steris had total revenues of over \$1.6 billion in 2014, of which [REDACTED] derived from contract gamma sterilization services performed at facilities in Ohio, California, Illinois, Massachusetts, New Jersey, New York, Puerto Rico, South Carolina, Texas, and Utah.



24. Defendant Synergy is a publicly traded company registered in the United Kingdom, with its headquarters in Swindon, Wiltshire, United Kingdom. Synergy provides contract sterilization services in more than a dozen countries, as well as sterilization services for reusable surgical instruments and linen servicing for hospitals. Synergy had global revenues of approximately \$590 million in 2014. Outside of the United States, Synergy's AST business offers contract gamma, x-ray, e-beam, and EO sterilization services. In the United States, Synergy Health U.S. Holdings Inc. is headquartered in Tampa, Florida. Synergy currently offers U.S. e-beam sterilization services at facilities in Ohio, California, Colorado, and Pennsylvania and EO sterilization in Florida, which earned [REDACTED] and [REDACTED] respectively, in 2014.

C.

**The Merger and the Commission's Response**

25. On October 13, 2014, Steris and Synergy signed an Agreement and Plan of Merger ("Merger Agreement"), pursuant to which Steris would acquire all shares of Synergy in a transaction valued at \$1.9 billion.
26. Defendants submitted premerger notification forms to the FTC pursuant to the Hart-Scott-Rodino Act on November 7, 2014, and refiled on December 10, 2014. The Commission issued Requests for Additional Information ("Second Requests") to the parties on January 9, 2015. The purpose of the Second Requests and the Commission's investigation was to allow the Commission to assess whether it has "reason to believe" that the Merger may violate the antitrust laws. Defendants requested, received, and availed themselves of modifications to the Second Requests by agreeing that the

Commission's investigation is not discovery (or the functional equivalent thereof) for the purposes of any administrative or federal court proceeding relating to the Merger.

27. On April 15 2015, Defendants certified substantial compliance with their Second Requests, triggering a thirty-day statutory waiting period before they could consummate the Merger. Defendants subsequently agreed not to close the Merger before June 2, 2015.
28. On May 28, 2015, by a unanimous vote, the Commission found reason to believe that Defendants' have executed a Merger Agreement in violation of Section 5 of the FTC Act, and that the Merger, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the FTC Act. A plenary administrative trial on the merits of the merger will begin on October 28, 2015. After an initial decision by an Administrative Law Judge, the Commission will determine the legality of the Merger under Section 7 of the Clayton Act and Section 5 of the FTC Act, and an appropriate remedy if it finds liability. Under Section 11(c) of the Clayton Act, 15 U.S.C. §21(c), Defendants may appeal an adverse Commission decision directly to any U.S. Court of Appeals within whose jurisdiction Defendants reside or conduct business.
29. Also on May 28, 2015, the Commission authorized staff to commence this federal court proceeding under Section 13(b) of the FTC Act. This action seeks to enjoin Defendants from consummating the Merger pending resolution of the Commission's proceeding, and any appeals, in order to minimize interim harm to competition and preserve the Commission's ability to grant an adequate remedy if it concludes that the Merger is unlawful. Absent an order from this Court, Defendants will be free to close their transaction after 11:59 p.m. on June 1, 2015.

III.

**THE RELEVANT PRODUCT MARKETS**

30. The relevant product market in which to analyze the effects of the Merger is no broader than the market for contract radiation sterilization services. The effects of the Merger can also be analyzed properly in a narrower market for the sale of contract gamma and x-ray sterilization services to targeted customers that cannot economically or functionally switch to e-beam sterilization. Defining the relevant product market broadly or narrowly does not change the fact that Steris, Synergy, and Sterigenics are the only significant market participants or that substantial anticompetitive effects will result from the Merger.

A.

**Background on Contract Radiation Sterilization Services**

31. Contract radiation sterilization services include gamma, x-ray, and e-beam sterilization services provided by third parties.

**Contract Gamma Sterilization Services**

32. Gamma sterilization involves exposing products to Cobalt 60, a highly radioactive isotope, to kill microorganisms located on or within products and packaging. As Cobalt 60 decays, it emits energy in the form of photons, which do not have mass or an electric charge, allowing them to penetrate deeply into dense material.
33. Gamma sterilization is ideal for large volumes of dense products, such as large totes of medical devices, because it can penetrate several feet deep into containers. Gamma irradiators run continuously because Cobalt 60 emits radiation constantly and cannot be turned off. To prepare products for gamma sterilization, contract sterilizers transfer them



to irradiation containers, called totes, and place the containers near the Cobalt 60 source, exposing the products to gamma radiation for a set amount of time. The totes range in size from forty to seventy cubic feet, which is significantly larger than the containers used in the e-beam sterilization process. Typically, a batch of products sterilized using gamma radiation has a total turnaround time of about three to four days, including the time required to receive a shipment, irradiate it, and send it back to a customer's facility.

34. In the United States, there are a large number of products that can only be sterilized cost-effectively using contract gamma sterilization services. Steris's website includes a guide for their customers of products "where Gamma Irradiation is the Method of Choice." These include labware products; soft tissues that are recovered from donor cadavers, processed in boxes, and shipped on dry ice; liquids; filled media plates; products with a high moisture content; wet dressings that are temperature sensitive or hermetically packaged; prep pads; serums; devices or device components that are designed with occluded areas; filled syringes; and certain biological products. Other products that gamma sterilization is best suited for include products contained in impermeable packaging, orthopedic implants, surgical stents, single-use medical supplies, and many products sterilized efficiently in large batches. Gamma sterilization is particularly well-suited for these products, as well as other products of dense or varied and complex construction, because gamma radiation passes more easily through these materials than e-beam particles.

#### **Contract X-ray Sterilization Services**

35. X-ray sterilization uses a very high-powered electron beam machine to produce x-ray radiation. Historically, x-ray sterilization has not been used in the United States, in large

part because no machine existed that was capable of sterilizing products as cost effectively as gamma or other sterilization methods. Recently, however, IBA has developed equipment that can perform x-ray sterilization at a cost comparable to, and possibly lower than, gamma sterilization. IBA's accelerators have made x-ray sterilization a commercially viable alternative for products that are currently sterilized with gamma radiation.

36. X-ray sterilization combines the best features of e-beam and gamma sterilization. It offers the depth of penetration of gamma radiation, which makes it suitable for sterilizing dense products and packaging, and the quick turnaround times of e-beam sterilization. X-ray sterilization may provide significant advantages over gamma sterilization. It requires shorter processing times than gamma sterilization, providing potential inventory management advantages. It can also process multiple products with different dose requirements in the same irradiation cycle, making it more efficient than gamma sterilization. X-ray sterilization is also well-suited for processing large batches of products, and, because it uses electricity rather than Cobalt 60, x-ray does not raise many of the environmental and regulatory issues of gamma sterilization. Synergy expects that x-ray will offer quicker turnaround times, less oxidation and discoloration on plastic products, and less temperature-based damage than gamma.

#### **Contract E-beam Sterilization Services**

37. E-beam sterilization uses electrically powered accelerators to produce high-energy electron beams to kill unwanted microorganisms. The unique characteristics of the e-beam irradiation process often make it the most effective method for sterilizing small volumes of low-density, homogeneous products. E-beam machines are more efficient

than using Cobalt 60 because they can be turned on and off as needed, which ensures that they produce radiation only when they are in use. Small batches of products can often be sterilized more quickly with e-beam irradiation than gamma irradiation; an e-beam machine can sterilize some products in only a few minutes.

38. The primary drawback of e-beam sterilization is that the radiation produced does not penetrate nearly as deeply as gamma radiation, and products sterilized with e-beam radiation must be placed into smaller containers than those used in gamma sterilization. These containers are about twice the size of a copy paper box and can only hold approximately two cubic feet of product, so products delivered from customers must be loaded into small totes and exposed to e-beam radiation one box at a time. For products that are packed in dry ice, such as human tissue, the products must be unpacked from their boxes before being sterilized with e-beam. For large volumes of products, the e-beam loading process requires considerably more handling than gamma sterilization, and e-beam sterilization is not a cost-effective option for denser products. Indeed, according to customers, for many dense products, such as liquids and orthopedic implants, sterilization with e-beam technology is simply “impossible” and “[not] a viable option.” Because of the significant differences between the two methods of radiation sterilization, e-beam sterilization is not a cost-effective or practical substitute for most products that currently use gamma sterilization services.

**B.**

**The Market for Contract Radiation Sterilization Services**

39. Today, gamma sterilization accounts for [REDACTED] of radiation sterilization services sold in the United States, and e-beam the remaining [REDACTED]. The majority of products currently

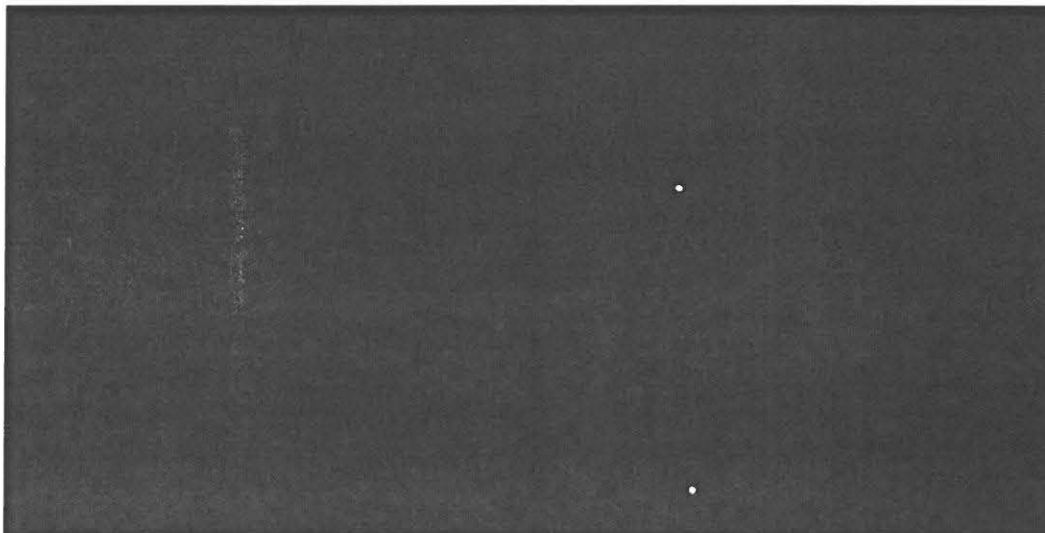


sterilized in the United States using contract gamma sterilization services currently cannot be sterilized practically using any other method of sterilization. Contract x-ray sterilization services would compete directly with contract gamma sterilization services, and may compete with e-beam to some extent. Therefore, it is appropriate to include x-ray in the relevant market for contract radiation sterilization services.

40. Customers currently do not view e-beam sterilization as a functional or economical substitute for gamma (or x-ray) sterilization for the majority of products. Nor do Steris or Sterigenics [REDACTED]

[REDACTED] For this reason, there is little switching between the two sterilization methods.

41.



[REDACTED] However, Synergy estimates that only [REDACTED] of current gamma sterilization volume could theoretically switch to e-beam sterilization. Neither of these estimates shows how much volume actually would switch in the face of a SSNIP. In fact, because of the limitations of e-beam, a SSNIP today would not induce customers to switch a significant volume of products from gamma sterilization to e-beam sterilization.

42. In the future, it is possible that, if contract gamma sterilization is more expensive or capacity constrained due to Cobalt 60 supply issues, there could be some switching to e-beam sterilization. Because of the possibility that contract e-beam sterilization services may become a competitive option for more contract gamma customers in the future, it may be appropriate to include contract e-beam services in the relevant product market.

43. Both x-ray and gamma sterilization services are suitable for the same high-density, heterogeneous products. X-ray sterilization services will likely be able to sterilize a number of products as well as, or better than, the gamma sterilization services these products rely on today, including: orthopedic implants, liquids, other dense products, impermeable packaging, and boxes of products that have varying densities. According to Synergy personnel, [REDACTED]

[REDACTED] Thus, Synergy's x-ray strategy was to take market share from gamma sterilization. Current gamma sterilization customers confirm that x-ray is a substitute for gamma.

**EO Sterilization Is Not a Substitute for Radiation Sterilization Services**

44. EO sterilization is properly excluded from the relevant product market. The technical differences between EO sterilization and gamma sterilization are substantial, and very few products can be cost effectively sterilized using both methods of sterilization. Accordingly, customers would not switch from radiation sterilization to EO in the face of a SSNIP for contract radiation sterilization services. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

45. Unlike radiation sterilization methods, EO sterilizes products by exposing them to a toxic gas that kills unwanted organisms. EO is a carcinogenic gas that is poisonous to humans. The EO sterilization process involves a number of steps, including placing the product in a chamber, filling the chamber with EO gas, degassing the chamber after sterilization, and aerating the product to remove or reduce EO residue on the product. EO sterilization requires that the design of products and packaging allow EO gas to move freely over material requiring sterilization. Thus, products must be packaged in permeable material and loaded in a configuration that allows the EO gas to reach all surfaces. The volume, density, and overall configuration of the load can limit gas exposure and removal after processing. The EO sterilization process also exposes products and packaging to a range of pressures at an elevated temperature, so products must be designed to withstand this environment. Even when EO could theoretically be used to sterilize some products, the process often takes significantly longer than other sterilization methods because products that have been exposed to EO must be quarantined for a period of days until all the gas has dissipated and no or acceptable levels of residue remain on the product.

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

46. In-house gamma sterilization services are properly excluded from the relevant product market. Most customers cannot use in-house gamma sterilization to meet any of their needs cost effectively, and customers do not rely on in-house gamma sterilization facilities to satisfy all of their requirements. A minimum of approximately [REDACTED] cubic feet of gamma-sterilized product annually at a single production or distribution facility is required to justify moving sterilization for a given facility in-house. Generally, only large medical device manufacturers produce sufficient volumes at a single location



to justify the large upfront investment and ongoing expenses of opening and operating an in-house gamma facility. Small customers are not capable of bringing gamma sterilization in-house economically, and no in-house sterilizer in the continental United States sells excess capacity to its competitors. Thus, only approximately 20% of gamma sterilization is performed in-house. Further, industry trends show that medical device manufacturers and other customers are shifting more of their sterilization needs to contract providers, rather than using more in-house sterilization.

47. There are substantial regulatory and practical barriers to establishing a gamma facility in the United States. Moreover, it is likely to become more difficult to justify establishing in-house gamma sterilization capabilities in the future because there are questions about the future availability and supply of Cobalt 60. Those concerns have become more acute since Sterigenics, through its acquisition of Nordion, Inc. ("Nordion") in 2014, became the sole supplier of Cobalt 60. [REDACTED]
- [REDACTED]
- [REDACTED]

48. Customers would not increase the volume of products sterilized with in-house gamma sterilization by an amount sufficient to make a SSNIP for all contract gamma sterilization services unprofitable. Even large customers that have in-house sterilization capabilities require contract gamma sterilization services as backup when their facilities are down, as well as contract services in areas where they do not produce enough product to justify an in-house facility. Further, even if some customers would switch some of their volume to in-house facilities in response to a SSNIP, a hypothetical monopolist could still profitably

increase prices by price discriminating against the majority of customers who cannot economically switch to in-house.

C.

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

49. The anticompetitive effects of the Merger will be most significant in the market for contract gamma and x-ray sterilization services sold to customers that cannot economically or functionally switch affected products to e-beam sterilization. As Steris noted in a presentation to the FTC, [REDACTED]

50.

[REDACTED]

[REDACTED] Thus, contract gamma sterilization providers can target and effectively price discriminate against customers that make products that cannot economically or functionally use any method of sterilization other than gamma radiation, charging them higher prices than customers that could cost-effectively use other means of sterilization.

51. While customers could switch some portion of products currently utilizing contract gamma sterilization services to e-beam sterilization, especially if future prices for

contract gamma sterilization increase as a result of Cobalt 60 supply issues, that group is likely relatively small. For those products that cannot switch from contract gamma sterilization services—e.g., dense medical devices, products that contain liquid, and products that are sterilized efficiently in large containers—e-beam sterilization providers will not constrain the prices of contract gamma sterilization service providers. Nor will the possibility of utilizing an in-house sterilization facility constrain contract gamma sterilization prices. Only contract x-ray sterilization services would provide competition against the contract gamma services that these customers must use today. Thus, even if a SSNIP to *all* contract gamma sterilization and x-ray customers would be unprofitable because some customers would switch to e-beam sterilization, a hypothetical monopolist of contract radiation sterilization services could profitably impose a SSNIP on targeted customers that cannot switch.

#### IV.

##### THE RELEVANT GEOGRAPHIC MARKETS

52. The relevant geographic markets in which to analyze the competitive effects of the Merger are the areas within approximately [REDACTED] miles of each of the [REDACTED] locations where Synergy planned to build an x-ray sterilization plant: [REDACTED]
- [REDACTED]
- [REDACTED]
53. Contract radiation sterilization providers compete for customers generally located within approximately [REDACTED] miles of their plants. Contract radiation sterilization customers are located throughout the country, but most strongly prefer to purchase services in the areas



around their manufacturing and distribution sites in order to minimize transportation costs and turnaround times. Transportation costs can be a significant part of the total cost of contract sterilization, and the delay and added cost of shipping a product away from a company's supply chain and back again can create significant logistical issues and become cost prohibitive. However, some customers may be able to use sterilization providers that are beyond this radius if the provider has a facility near its regular shipping routes. Contract radiation sterilization companies therefore locate their plants near the customers for which they expect to compete and evaluate competition and set prices regionally.

54.

[REDACTED]

[REDACTED]

55. In the first phase of its entry into the United States, Synergy planned to build [REDACTED] x-ray facilities: [REDACTED]

[REDACTED]

[REDACTED]

56. Synergy's [REDACTED] x-ray sterilization facility would compete directly with Steris's [REDACTED] facilities. Synergy identified potential customers for this facility throughout [REDACTED] including in [REDACTED]

[REDACTED] as well as in [REDACTED] and [REDACTED]

[REDACTED] Synergy planned to open its [REDACTED] x-ray plant in [REDACTED]

57. Synergy's [REDACTED] x-ray facility was also set to open in [REDACTED]. This facility, which would compete with Steris's [REDACTED] and [REDACTED] [REDACTED] planned to target key customers throughout [REDACTED].
58. In the second phase of its rollout, Synergy planned to build additional x-ray sterilization facilities in [REDACTED] in [REDACTED]. [REDACTED] Synergy's [REDACTED] x-ray plant would compete with Steris's [REDACTED] facilities. Its [REDACTED] x-ray facility would compete with Steris's [REDACTED] [REDACTED] plant. And Synergy's [REDACTED] facility would compete with Steris's [REDACTED] plants in [REDACTED].
59. After building all [REDACTED] x-ray facilities, Synergy would have a plant within [REDACTED] miles of the supply chain of the vast majority of U.S. sterilization customers.

V.

MARKET STRUCTURE

60. Steris and Sterigenics are currently the only providers of contract gamma sterilization services and the leading providers of radiation sterilization services. When the proposed Merger was announced, Synergy had begun implementing its strategy to bring a disruptive product to the U.S. contract sterilization market. Synergy's entry into the United States with contract x-ray sterilization services would compete directly with Steris and Sterigenics' contract gamma businesses, and would produce substantial consumer benefits that no other market participant or potential entrant could replicate.

**A.**

**Market Participants**

**Contract Gamma Sterilization Services**

61. Steris has twelve gamma sterilization facilities in the United States: Ontario, California; Libertyville, Illinois (three separate facilities); Northborough, Massachusetts; Wippany, New Jersey; Chester, New York; Groveport, Ohio; Vega Alta, Puerto Rico; Spartanburg, South Carolina; El Paso, Texas; and Sandy, Utah. Steris achieved [REDACTED] in revenues from contract sterilization services in 2014, with approximately \$ [REDACTED] coming from its U.S. contract gamma sterilization operations.
62. Sterigenics, the largest contract sterilization services provider in the world, and the only other U.S. contract gamma sterilization provider, is headquartered in Oak Brook, Illinois. It has fourteen U.S. gamma sterilization facilities located in the United States: West Memphis, Arkansas; Corona, California; Gilroy, California; Hayward, California; Tustin, California; Gurnee, Illinois; Schaumburg, Illinois; Rockaway, New Jersey; Salem, New Jersey; Charlotte, North Carolina; Haw River, North Carolina; Westerville, Ohio; Fort Worth, Texas; and Mulberry, Florida. In 2014, Sterigenics earned an estimated [REDACTED] from its U.S. contract gamma sterilization facilities.

**Contract X-ray Sterilization Services**

63. Synergy is the third major global provider of contract sterilization services, but does not offer contract gamma sterilization services in the United States. Synergy had a well-developed strategy to enter the United States with contract x-ray sterilization services that would have competed with contract gamma sterilization services. Outside of the United



States, Synergy already owns and operates a facility in Däniken, Switzerland, that performs both gamma and x-ray sterilization services.

64. Prior to the proposed Merger, Synergy expected to win a [REDACTED] share of U.S. contract gamma sterilization services revenue. Synergy expected that its first [REDACTED] x-ray facilities in the [REDACTED] areas would earn a combined \$[REDACTED] in [REDACTED] and \$[REDACTED] million in [REDACTED], by which time all [REDACTED] of its facilities would be operational. Synergy forecasted its annual x-ray revenues to reach \$[REDACTED] million.
65. Some small e-beam sterilization services providers, like [REDACTED], may attempt to provide x-ray sterilization services [REDACTED], but these firms will not be able to compete with gamma sterilization services because, [REDACTED]. Instead, they will be relegated to small-scale x-ray sterilization for a limited group of customers.

#### Contract E-beam Sterilization Services

66. Synergy is the leading provider of contract e-beam sterilization services in the United States with e-beam facilities located in San Diego, California; Denver, Colorado; Saxonburg, Pennsylvania; and Lima, Ohio. Synergy earned \$[REDACTED] million from its U.S. e-beam contract sterilization services in 2014. [REDACTED]
67. Sterigenics operates an e-beam facility in San Diego, California, that generated approximately [REDACTED] in sterilization sales in 2014. Sterigenics also operates a

facility in Bridgeport, New Jersey, that is dedicated to sterilizing U.S. mail with e-beam and a low-power x-ray machine. The Bridgeport facility generated [REDACTED] in 2014.

68. Steris does not currently provide e-beam sterilization services in the United States, but it also is [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

69. There are several smaller providers of e-beam sterilization serving the United States that operate one or two locations.

- E-BEAM Services Inc. ("E-BEAM Services"), headquartered in Cranbury, New Jersey, has two contract e-beam sterilization services facilities, one in Cranbury and the other in Lebanon, Ohio. Medical device customers are skeptical of working with E-BEAM Services for sterilization, however, citing a lack of technical expertise. Steris characterizes E-BEAM Services as being limited to industrial irradiation of wire, cable, and tubing. In 2014, E-BEAM Services earned approximately [REDACTED] in revenue from e-beam sterilization services.
- Nutek operates a contract sterilization facility in Hayward, California. In 2014, the company earned approximately [REDACTED] in revenue from contract e-beam sterilization services. [REDACTED]  
[REDACTED] Nutek lacks the expertise and efficiency of Steris, Sterigenics, and Synergy.
- Iotron Industries Canada, Inc. ("Iotron") is a Vancouver, British Columbia, company that opened a contract e-beam sterilization facility in Columbia City, Indiana, in 2012. In 2014, the company's revenues from the Indiana facility approached [REDACTED] of which approximately [REDACTED] were attributable to medical device and other healthcare related sterilization. Iotron serves mostly non-medical customers because medical device and other companies question its technical expertise and experience with their products. Even though Steris has four gamma sterilization facilities serving the area, Steris Isomedix's Vice President of Sales and Marketing could not name a single customer that it has ever lost to Iotron.
- Avantti Medi Clear is based in Tijuana, Mexico, [REDACTED]  
[REDACTED]

██████████. The company has been working for █████ years to establish that facility but has no sales at this time.

**B.**

## Market Concentration

70. Each relevant market is currently highly concentrated under the Horizontal Merger Guidelines and relevant case law, and Synergy's U.S. x-ray strategy would have resulted in substantial de-concentration and procompetitive effects in each relevant market.
71. The Horizontal Merger Guidelines and courts measure concentration using the Herfindahl-Hirschman Index ("HHI"). HHI levels are calculated by totaling the squares of the market shares of each firm in the relevant market. Changes in HHI levels are the difference between pre- and post-merger HHI levels. Under the Horizontal Merger Guidelines, a relevant market is "highly concentrated" if it has an HHI level of 2,500 or more. In highly concentrated markets, the Horizontal Merger Guidelines view changes in the HHI level of 200 points or more as evidence that a merger should be presumed likely to create or enhance market power, unless Defendants rebut this presumption by submitting persuasive evidence showing the merger is unlikely to enhance market power.
72. In the approximately \$ [REDACTED] million Midwest market for contract radiation sterilization services, the current HHI is over [REDACTED]. The [REDACTED] other relevant markets where Synergy plans to establish x-ray sterilization facilities, [REDACTED] [REDACTED] are also highly concentrated, with HHIs of more than [REDACTED] respectively.
73. Each relevant market for contract gamma and x-ray sterilization services sold to targeted customers is also highly concentrated. There are only two suppliers of contract gamma sterilization services today, and absent the Merger, Synergy's x-ray sterilization would



provide a third alternative. The high market concentration for these targeted customers is evidenced by the high concentration for contract gamma sterilization services: in the \$ [REDACTED] million contract gamma sterilization business in the [REDACTED] area, the current HHI level is approximately [REDACTED]. In the other [REDACTED] areas where Synergy plans to enter, concentration levels are even higher, ranging from more than [REDACTED] to at least [REDACTED]. The market shares and concentration levels in gamma markets are a good proxy for the market shares and concentration in gamma/x-ray markets for targeted customers.

## VI.

### ANTICOMPETITIVE EFFECTS

74. The anticompetitive effects of the Merger arise from the elimination of the likely future competition from Synergy's deployment of x-ray sterilization in the United States. Steris and Sterigenics are two of the three significant contract radiation sterilization providers and the only two contract gamma providers in the United States in each of the geographic markets at issue. Synergy, as the only major worldwide sterilization company without a gamma offering in the United States, was on the verge of entering with what it considered to be a disruptive sterilization technology, x-ray, that would allow it to compete directly for Steris and Sterigenics' customers.
75. By October 2014, just days before the announcement of the Merger, Synergy determined that it would have [REDACTED] operating by [REDACTED]. Synergy envisioned building a total of [REDACTED] sites and achieving broad mainstream adoption of x-ray sterilization technology by [REDACTED].

76. Synergy also considered the competitive impact its entry would have on U.S. gamma sterilization competitors, and concluded that Steris and Sterigenics would [REDACTED] [REDACTED] With the proposed acquisition, there will be no [REDACTED] nor will this promising sterilization technology be available to U.S. sterilization customers.

A.

**Synergy Was Entering the Relevant Markets Prior to the Merger**

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

77. In 2012, months after Synergy's acquisition of the x-ray facility in Däniken, Switzerland, the company's founder and CEO, Dr. Richard Steeves, proposed a plan to launch x-ray sterilization in the United States to [REDACTED] [REDACTED] This plan, Dr. Steeves explained in an April 2013 Synergy leadership conference, was [REDACTED]

- [REDACTED]
78. In May 2013, Dr. Steeves told Synergy's board of directors (the "PLC Board") that the x-ray launch in the United States had become a [REDACTED] [REDACTED] The following month, [REDACTED] [REDACTED] Before Mr. McLean had even started his job, Dr. Steeves told him that he was [REDACTED] and that

[REDACTED]

[REDACTED] Mr. McLean worked on the x-ray project from his first day on the job.

The X-ray Plan Ramp-Up

79. In 2014, the Synergy x-ray team took the project from the conceptual stage to the planning and implementation phase.

80. The team worked with [REDACTED] to configure equipment to be used and, on September 15, 2014, reached an agreement with [REDACTED] for the exclusive right to [REDACTED] x-ray technology in the United States. [REDACTED]

[REDACTED]

[REDACTED]

81. The x-ray team also worked to cultivate customer interest to support the business case and procured letters of interest ("LOIs") from many customers in August and September 2014. Key customers like [REDACTED]

[REDACTED] and [REDACTED] all submitted LOIs, as did [REDACTED]

[REDACTED] and [REDACTED]



82. The team prepared a business case for the [REDACTED] facilities based on a detailed analysis of the U.S. regional markets. On September 17, 2014, Synergy's SEB [REDACTED] [REDACTED] There are seven members of the SEB: Synergy's CEO (Dr. Steeves); Synergy's COO (Adrian Coward); Synergy's Group Finance Director (Gavin Hill); Synergy's Group Company Secretary; CEO of the AST business (Mr. McLean); an executive from Synergy's healthcare services division; and a human resources executive.

[REDACTED] The details of the strategy presented to the SEB [REDACTED]

[REDACTED] This presentation:

- Sought [REDACTED] and [REDACTED]
- Identified the [REDACTED] to be opened in [REDACTED] and [REDACTED]
- Explained that Synergy [REDACTED]
- Stated that [REDACTED] would be to [REDACTED] and [REDACTED]
- Described [REDACTED] to be to [REDACTED] and [REDACTED]

83. The same day, Mr. McLean emailed the x-ray team that the SEB had [REDACTED]

[REDACTED]

[REDACTED]

84. The day after the SEB meeting, September 18, 2014, Synergy's PLC Board met and discussed the U.S. x-ray strategy. Dr. Steeves, Mr. Coward, and Mr. Hill, all members of the SEB, are three of the seven members of the PLC Board; three of the four remaining members are outside directors, and one is the Non-Executive Chairman of the PLC Board. Mr. Coward explained that [REDACTED]

[REDACTED]

[REDACTED] He requested that the PLC Board [REDACTED]

[REDACTED] Dr.

Steeves also explained to his fellow PLC Board members that, with [REDACTED]

[REDACTED]

[REDACTED] The PLC Board approved [REDACTED]

[REDACTED]

85. After the September SEB and PLC Board meetings, the U.S. x-ray project was renamed [REDACTED] and implementation of the x-ray plan began. Synergy expanded the size of the team to [REDACTED] employees, including personnel from operations, engineering, accounting, and maintenance to assist through construction and start-up of operations. On October 7, 2014, Mr. McLean brought the team together for a [REDACTED]

[REDACTED]

[REDACTED] The slide presentation that opened

the meeting stated that:

- [REDACTED]

- [REDACTED]

The slides also cautioned that, [REDACTED]

86. The Merger of Synergy and Steris was announced less than a week later, on October 13, 2014.

Synergy's Actions Post-Merger Announcement

87. In the weeks following the announcement of the deal, Synergy recognized that [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED] As Mr. Tyranski wrote a week after he learned of the transaction, [REDACTED]  
[REDACTED] The Synergy x-ray team also recognized that [REDACTED]  
[REDACTED] Thus, Synergy [REDACTED]  
[REDACTED]  
[REDACTED] but acknowledging that the [REDACTED]  
[REDACTED]

88. The PLC Board, in its November 2014 meeting, [REDACTED]  
[REDACTED] because [REDACTED]  
[REDACTED]  
[REDACTED]

89. Synergy's management continued to believe that [REDACTED]  
[REDACTED]



- [REDACTED] Synergy's senior management expected to [REDACTED] while acknowledging that they would [REDACTED]
- [REDACTED]
90. [REDACTED] The [REDACTED] team leader created a detailed timeline describing each step needed to begin operations at the [REDACTED] x-ray facility by [REDACTED] the [REDACTED]
- [REDACTED]
- [REDACTED] The agreement with [REDACTED] reached on [REDACTED] was memorialized in writing and executed on [REDACTED] giving Synergy [REDACTED]
- [REDACTED]
- [REDACTED] The [REDACTED] [REDACTED] was pushed back from [REDACTED] to [REDACTED] to accommodate the anticipated closing of the Steris transaction.
91. The x-ray strategy continued to have the open support of Synergy leadership. The plan to enter the United States with [REDACTED] facilities, followed on by [REDACTED] additional facilities, was incorporated into the FY 2016 Strategic Plan for the AST business. In a November 4, 2014, statement to investors attached to a security filing, Synergy reported:

We are pleased to announce that we have signed an agreement with IBA for X-ray technology to be deployed in the United States, supplemented by our in-house knowledge and expertise. Our X-ray services are now the fastest growing of our AST technologies, driven by the higher levels of quality, favourable economics and faster processing speed, which helps our customers to reduce their working inventories. Most recently the first FDA approval of a Class III medical device was achieved by one of our major global customer partners, paving the way for further conversions.

**Synergy's Actions After the FTC Issued Second Requests**

92. On January 9, 2015, the FTC issued Second Requests to Defendants specifically requesting documents and information relating to potential competition between their x-ray and gamma sterilization businesses.

93. At a February 19, 2015, meeting with FTC staff, Mr. McLean announced that [REDACTED]

94. On February 24, 2015, Mr. McLean executed a declaration to evidence this [REDACTED] using an [REDACTED] as a pretext for doing so. As support for that [REDACTED] Mr. McLean attached copies of e-mails he personally received just days before. That evening, Mr. Tyranski wrote the x-ray team leaders:

[REDACTED]  
[REDACTED] Mr. Tyranski  
planned to [REDACTED] The  
next day, they informed [REDACTED] that Synergy would be [REDACTED] Peter  
Grief, a Project Endurance team member, recognized that it was [REDACTED] but  
he was [REDACTED]

**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 expected its x-ray entry would have a large and lasting competitive impact. Synergy expected to win a [REDACTED] share of all of the contract gamma sterilization business of Steris and Sterigenics in the United States.

96. Synergy projected approximately \$[REDACTED] million in sales for its [REDACTED] x-ray facility in [REDACTED] increasing to approximately \$[REDACTED] million annually by [REDACTED]. Synergy planned to target [REDACTED] among others, all of whom have expressed interest in converting product to x-ray and who are currently Steris and/or Sterigenics customers.
97. To provide a sense of the magnitude of the de-concentrating effect that Synergy's x-ray entry would have produced, it is informative to calculate future nationwide HHI levels with and without the Merger based on Synergy's ordinary course documents, even though the markets here are local. Synergy's x-ray entry, at a minimum, would reduce the HHI for U.S. contract radiation sterilization by more than [REDACTED] points. For contract gamma sterilization, Synergy's x-ray entry would, at a minimum, reduce the HHI by approximately [REDACTED] points.
98. To provide a sense of the magnitude of the de-concentrating effect that Synergy's x-ray entry would have produced on a local level, it is informative to calculate future HHI levels for the [REDACTED] facility, which would have opened in [REDACTED]. Based on Synergy's revenue projections, in [REDACTED] the HHI would have decreased, at a minimum, by more than [REDACTED] points in the market for contract radiation services and by at least [REDACTED] points in the contract gamma/x-ray market.
99. [REDACTED] documents confirm that Synergy's [REDACTED]  
[REDACTED]
  - [REDACTED]
  - [REDACTED]



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

100. Synergy expected to enter the highly concentrated relevant markets and win the business of the incumbents' highest value customers. Synergy knew that, in response to its entry, Steris and Sterigenics would vigorously defend their businesses and fight to keep their core gamma customers by, among other things, lowering prices.
101. Synergy designed its x-ray strategy to [REDACTED]  
[REDACTED] In response to its entry, Synergy expected Steris and Sterigenics to [REDACTED]  
[REDACTED] In the face of this competitor response, which Synergy described as [REDACTED]  
[REDACTED] Synergy planned to set its x-ray rates at a level that [REDACTED]. Synergy also planned to exploit [REDACTED]  
[REDACTED]
102. Synergy officials called the U.S. x-ray strategy [REDACTED] and anticipated a [REDACTED]  
[REDACTED] Even after Defendants announced the Merger, Synergy executives continued to tout x-ray's competitive potential. In a November 2014 email, Synergy's CEO told Steris's CEO that [REDACTED]  
[REDACTED]
103. Mr. Tyranski, Synergy's AST President, testified that the [REDACTED] for Synergy's U.S. x-ray strategy was [REDACTED] which Synergy planned to [REDACTED]  
[REDACTED] He acknowledged that [REDACTED] would be the [REDACTED]  
[REDACTED] Similarly, Synergy's AST

Business Analyst testified that [REDACTED]

He explained that Synergy [REDACTED] because [REDACTED]

104. Dr. Steeves testified that Synergy [REDACTED]

Dr. Steeves concluded that [REDACTED]

[REDACTED] given Synergy's goal of [REDACTED]

105. Customers, including some of the [REDACTED], share Synergy's expectation that its x-ray entry would provide them with an alternative to contracting with Steris and Sterigenics for gamma sterilization services. Customers believe that Synergy's x-ray services would compete directly with Steris and Sterigenics' gamma sterilization offerings and could be a potentially superior alternative to gamma sterilization. Moreover, many customers state that they would consider validating new

products for x-ray sterilization and switching a portion of their products that are currently sterilized with contract gamma radiation to Synergy's x-ray sterilization when it becomes available.

106. Some customers are concerned that, because Sterigenics controls the limited supply of Cobalt 60, their gamma sterilization prices may rise significantly in the future. Thus, these customers are interested in moving their business to x-ray sterilization if Synergy enters, to protect themselves from these anticipated gamma sterilization price increases.
107. Customers anticipate that their purchases of x-ray sterilization services will grow incrementally. Synergy understood that [REDACTED] and therefore expected [REDACTED]. Despite the time and costs required to switch to x-ray, many customers state that they are willing to switch current and/or future products due to the benefits of contract x-ray sterilization. In fact, even though Synergy has not yet opened a facility in the United States, J&J already invested \$ [REDACTED] to validate its Class III medical device, Surgicel, with Synergy's x-ray sterilization services. The FDA approved x-ray sterilization for Surgicel in September 2014.
108. Other companies, including [REDACTED], have also tested sample products at Däniken to determine the feasibility and effects of using x-ray sterilization on their products, and several more are interested in doing so. [REDACTED] and others have been in recent discussions with Synergy regarding the possibility of validating their FDA Class III products at Synergy's Däniken, Switzerland, x-ray facility.
109. Numerous significant purchasers of contract gamma sterilization services have expressed concern that, if Defendants consummate the Merger, the substantial competitive benefits



of Synergy's U.S. x-ray entry will never materialize. Customers have explained that having the credible threat of switching to an independent Synergy's x-ray sterilization services would provide them greater bargaining leverage when negotiating contract gamma sterilization prices with Steris and Sterigenics. Even more valuable to these customers is the prospect of a sterilization option that promises to be a superior technology, with better performance, greater efficiency, and possibly lower prices. Customers fear that, if the Merger closes, terminating Synergy's independent entry with x-ray sterilization services will deprive them of these substantial price and non-price benefits.

110. Customers have also expressed concern that Steris likely has significantly less incentive to bring competitive x-ray sterilization services to the United States than an independent Synergy. Moreover, even if the combined company were to proceed with some form of U.S. x-ray rollout, customers would lose the benefits of having an independent alternative to Steris's gamma sterilization services.

## VII.

### **ENTRY WILL NOT PREVENT THE MERGER'S COMPETITIVE HARM**

111. Neither new entry nor expansion by existing firms would be timely, likely, or sufficient to offset the anticompetitive effects of the Merger. Entry by a new gamma or e-beam sterilization provider would not prevent the harm created by Steris acquiring Synergy and preventing Synergy's independent entry into the U.S. x-ray sterilization business. No other firm could enter the United States with x-ray sterilization services that would recreate the benefits that Synergy's entry would have provided.

A.

**Barriers to Entry for X-ray Sterilization Services**

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

112. Synergy is the firm best positioned to enter the relevant markets with x-ray sterilization services. Synergy's desire to be a global supplier of contract sterilization services provides it with an incentive to enter the United States with x-ray sterilization services that no other firm in the world shares. Today, Synergy is small player in the U.S. contract radiation sterilization services business because the only radiation sterilization that it provides is e-beam, so it cannot compete for the vast majority of customers' business. X-ray is the only technology that can compete directly for all gamma sterilization customers, especially those that need to sterilize large volumes of dense products.
113. At the time Synergy executed the Merger Agreement, it had already devoted over two years to its U.S. x-ray entry strategy, and was in the implementation phase. It acquired the Däniken, Switzerland, x-ray sterilization facility in 2012, and has operated it for more than two years, developing an expertise with x-ray sterilization on a commercial scale. Synergy viewed the Däniken facility as a [REDACTED] [REDACTED] For well over a year, customers had been sending products to Däniken for x-ray testing so they could validate products for sterilization at the U.S. x-ray facilities as soon as they became available.
114. At the time of the Merger Agreement, Synergy had also secured a unique technological advantage: exclusive access to IBA's x-ray machines. No other x-ray machine available today can economically achieve the power generation and throughput capabilities of

IBA's machines and compete effectively with contract gamma sterilization services. In fact, Synergy's Däniken facility manager testified that [REDACTED]

[REDACTED] He further estimated that it would take [REDACTED] [REDACTED] to develop technology that could achieve what [REDACTED] machines can do today. At the time of the Merger announcement, [REDACTED] had agreed [REDACTED]

[REDACTED] Synergy viewed that [REDACTED]

115. No potential entrant could replicate the substantial benefits that Synergy's entry into the United States with x-ray sterilization services would have provided. No potential x-ray entrant has the ability to compete as effectively as Synergy would have. In order to enter the United States and compete as effectively as Synergy, a potential entrant would need to win the business of large medical device manufacturers that prefer to sterilize most of their products with the three major sterilization suppliers. Steris, Sterigenics and Synergy have the experience and scale and scope of operations to meet the needs of large medical device manufacturers effectively and economically. No potential entrant has the reputation or size of operations that these large customers require. Nor does any potential entrant have access to an x-ray plant like Synergy's Däniken facility, where it could test and validate products for potential customers. In addition, no company has an agreement with IBA to use its x-ray equipment, and [REDACTED]. Finally, any firm seeking to



enter the United States with x-ray sterilization services would be two or more years behind where Synergy was at the time it executed the Merger Agreement with Steris.

116. No firm is currently working to enter the United States with x-ray sterilization services that could compete as effectively as Synergy. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] Some companies have contemplated

[REDACTED]

[REDACTED]; however, [REDACTED] could not compete effectively or economically with contract gamma sterilization as Synergy planned to do with its high-power x-ray machines. [REDACTED], like e-beam machines, lack the penetration and throughput capabilities to sterilize large volumes of dense products. Only gamma sterilization and high-power x-ray sterilization services can sterilize these products economically and effectively.

#### **B.**

##### **Barriers to Entry for Gamma Sterilization Services**

117. Entry by establishing a gamma sterilization plant is extraordinarily difficult and time consuming, and is very unlikely to occur in a timely fashion, if ever. Despite the growth in demand for gamma sterilization services, no contract provider has built a new gamma sterilization facility in the United States in over fifteen years. The barriers to entry for a gamma sterilization facility are significant. Establishment of a commercial-scale gamma sterilization business requires a substantial sunk investment, significant technical

expertise, and regulatory authorizations that are difficult or impossible to obtain. Strict regulations govern gamma sterilization facilities because of the safety and environmental risks associated with storage of large volumes of radioactive material, and future legislative restrictions threaten to prohibit opening a new gamma facility in the United States altogether.

118. It is expensive to build and operate a gamma sterilization facility. The initial capital investment to build a single plant is between \$ [REDACTED] and \$ [REDACTED]. Further, to compete effectively for gamma sterilization business, an entrant would likely have to establish at least two facilities to be able to ensure that services are not interrupted during routine or unexpected shutdown periods.
119. Even more significant than the capital investment required are the regulatory barriers to entry. Cobalt 60 is an unsafe material that poses considerable environmental and health risks, so its procurement, handling, and storage are heavily regulated. The Nuclear Regulatory Commission and the International Atomic Energy Agency regulate the design of gamma sterilization facilities and the shipping of Cobalt 60. The Environmental Protection Agency and state agencies also regulate environmental safety aspects of handling and storing Cobalt 60 at gamma sterilization facilities. Because of this strict regulatory regime, building and licensing a gamma sterilization facility can take years, if future plant construction will be permitted at all.
120. In addition to the high cost and challenging regulatory environment, the future of gamma sterilization in general is uncertain. According to the CEO of Synergy's AST business,

[REDACTED]

██████████ The future availability of Cobalt 60 is also unpredictable, and the prices for this essential input are expected to increase. A new gamma sterilization entrant would have to secure Cobalt 60 from Sterigenics, with which it would also have to compete. The many obstacles to gamma sterilization entry contributed to Synergy's decision to pursue entry with x-ray technology, rather than gamma, to target the U.S. gamma sterilization business.

C.

**Barriers to Entry for E-beam Sterilization Services**

121. E-beam sterilization entry is time-consuming, expensive, difficult, and would not prevent the competitive harm from the proposed transaction. It takes at least ██████ years to plan and open an e-beam sterilization facility, and may take significantly longer. For example,

██  
██

██████. After building a sterilization plant, a potential entrant would need to secure customers willing to use its facility. Most customers need to test and validate their products with a potential e-beam sterilization provider before committing to use its services. It is difficult, and sometimes impossible, to conduct such testing before an e-beam facility is operational. Opening a new e-beam sterilization facility typically costs between ██████████ million upfront, including the costs for obtaining a building, a conveyor system, an electron accelerator, and required shielding equipment. Customers, even smaller localized ones, generally require contract e-beam sterilization providers to offer backup facilities for times when an e-beam machine is unavailable, whether for maintenance or in case of mechanical failure. Thus, an entrant would likely have to build



a facility with multiple e-beam machines or multiple facilities to enter and compete effectively for any significant amount of business.

122. Even if it were possible to enter the market in a timely fashion with e-beam sterilization services, such entry would not prevent the anticompetitive harm from the Merger. The evidence shows that there is a large universe of contract gamma sterilization customers that cannot switch to e-beam, but would switch to x-ray if it were available. E-beam entry would not affect the ability of contract gamma or x-ray sterilization providers to target these customers for price increases. Moreover, there is no evidence that any small fringe e-beam sterilization firm, or a *de novo* entrant, is likely to expand or enter the market in a significant manner. As Steris explains:



As a result, these fringe providers have been unable to grow beyond a tiny share, collectively, of contract radiation sterilization services.

123. The only company likely to enter into the e-beam sterilization business in the future and have a significant market impact is



VIII.

**EFFICIENCIES WILL NOT COUNTERACT THE MERGER'S COMPETITIVE HARM**

124. Extraordinary merger-specific efficiencies are necessary to outweigh the Merger's likely significant harm to competition in the relevant markets. Defendants cannot demonstrate cognizable efficiencies sufficient to outweigh the substantial competitive harm likely to result from the Merger.
125. The cost savings that Defendants claim will result are not verifiable, nor are they merger-specific or likely to be passed on to customers. According to the executive tasked with evaluating potential efficiencies, Steris's purported cost savings figures [REDACTED]
- [REDACTED]

IX.

**LIKELIHOOD OF SUCCESS ON THE MERITS AND NEED FOR RELIEF**

126. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), authorizes the Commission, whenever it has reason to believe that a proposed merger is unlawful, to seek preliminary injunctive relief to prevent consummation of a merger until the Commission has had an opportunity to adjudicate the merger's legality in an administrative proceeding. In deciding whether to grant relief, the Court must balance the likelihood of the Commission's ultimate success on the merits against the public equities, using a sliding scale. The principal equity in cases brought under Section 13(b) is the public's interest in effective enforcement of the antitrust laws. Equities affecting only Defendants' interests cannot tip the scale against a preliminary injunction.

127. The Commission is likely to succeed in proving in the administrative proceeding that the effect of the Merger may be substantially to lessen competition or tend to create a monopoly in violation of Section 7 of the Clayton Act or Section 5 of the FTC Act. In particular, Complaint Counsel for the Commission is likely to succeed in demonstrating, among other things, that:

- a. The Merger would have anticompetitive effects in the markets for contract radiation sterilization services, and narrower markets therein, in the [REDACTED]  
[REDACTED]  
[REDACTED]
- b. Substantial and effective entry or expansion into these markets would not be likely, timely, or sufficient to offset the anticompetitive effects of the Merger; and
- c. Any efficiencies that Defendant may assert will result from the Merger are speculative, not merger-specific, and are, in any event, insufficient as a matter of law to justify the Merger.

128. Preliminary relief is warranted and necessary. Should the Commission rule, after the administrative trial, that the Merger is unlawful, reestablishing the *status quo* would be difficult, if not impossible, if the Merger has already occurred in the absence of preliminary relief. Allowing the Merger to close before the completion of the administrative proceeding would cause irreparable harm by enabling the combined firm to begin altering Synergy's operations and business plans, accessing Synergy's sensitive business information, eliminating key Synergy personnel, and stalling Synergy's x-ray roll out efforts. In the absence of relief from this Court, substantial harm to competition would occur in the interim.



129. Accordingly, the equitable relief requested here is in the public interest.

WHEREFORE, Plaintiff respectfully requests that this Court:

- a. Temporarily restrain and preliminarily enjoin Steris from acquiring Synergy, all or in part, or from taking any further steps to consummate the Merger, or otherwise effecting a combination of Defendants Steris and Synergy, consistent with Plaintiff's Proposed Order;
- b. Retain jurisdiction and maintain the *status quo* until resolution of the administrative proceeding that the Commission has initiated; and
- c. Award such other and further relief as the Court may determine is appropriate, just, and proper.

Dated: May 29, 2015

Respectfully submitted,

[signed filed]

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*Attorneys for Plaintiff Federal Trade Commission*

**CERTIFICATE OF SERVICE**

I hereby **CERTIFY** that, on the 29th day of May, 2015, I filed the foregoing Complaint for Temporary Restraining Order and Preliminary Injunction with the Clerk of the Court.

  
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I hereby **CERTIFY** that, on the 29th day of May, 2015, I served the foregoing Complaint for Temporary Restraining Order and Preliminary Injunction on the following counsel for Defendants via electronic mail:

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