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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of, **STERIS CORPORATION** **and** **SYNERGY HEALTH PLC,** **Respondents.**	**Docket No. 9365**

RESPONDENTS' MOTION TO THE COMMISSION TO WITHDRAW MATTER FROM ADJUDICATION

Respondents STERIS Corporation and Synergy Health PLC (collectively, "Respondents"), pursuant to Commission Rule 3.26(c), 16 C.F.R. § 3.26(c), move to withdraw the above-captioned matter from adjudication. On September 24, 2015, a judge of the United States District Court for the Northern District of Ohio, the Honorable Dan Aaron Polster, denied the motion of the Federal Trade Commission (the "Commission") for a preliminary injunction pending adjudication of the administrative proceeding in this matter. Trial in the administrative litigation is set to begin in less than a month, on October 28, 2015. Withdrawal of the matter is required under Rule 3.26(c), because the motion is timely filed following the denial of a Commission request for a preliminary injunction in this case.

This motion is based on the concurrently-filed memorandum of points and authorities, and Respondents have also submitted a proposed order.

Dated: October 1, 2015

Respectfully Submitted,

/s/ John M. Majoras
John M. Majoras
JONES DAY
Street Address:
325 John H. McConnell Blvd., Suite 600
Columbus, OH 43215-2673
Mailing Address:
P.O. Box 165017
Columbus, OH 43216-5017
Telephone: (614) 469-3939
Facsimile: (614) 461-4198
Email: jmmajoras@jonesday.com

Geoffrey S. Irwin
Kerri Ruttenberg
Louis K. Fisher
Michael S. Fried
Tara Lynn R. Zurawski
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001-2113
Telephone: (202) 879-3939
Facsimile: (202) 626-1700
Email: gsirwin@jonesday.com
Email: kruttenberg@jonesday.com
Email: lkfisher@jonesday.com
Email: msfried@jonesday.com
Email: tzurawski@jonesday.com

Counsel for Defendant STERIS Corporation

/s/ David H. Bamberger
David H. Bamberger
Julie A. Gryce
DLA Piper LLP (US)
500 8th Street, N.W.
Washington, D.C. 20004
Email: david.bamberger@dlapiper.com
Email: Julie.gryce@dlapiper.com

Paolo Morante
Steven E. Levitsky
DLA Piper LLP (US)
1251 Avenue of the Americas, 27th Floor
New York, NY 10020
Email: paolo.morante@dlapiper.com
Email: steven.levitsky@dlapiper.com

Laura M. Kam
DLA Piper LLP (US)
2525 East Camelback Road, Suite 1000
Phoenix, AZ 85016-4232
Email: laura.kam@dlapiper.com

Counsel for Defendant Synergy Health PLC

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MEMORANDUM IN SUPPORT OF RESPONDENTS' MOTION TO THE COMMISSION TO WITHDRAW MATTER FROM ADJUDICATION

Respondents STERIS Corporation ("STERIS") and Synergy Health PLC ("Synergy") submit this memorandum in support of their motion to withdraw this matter from adjudication pursuant to Commission Rule 3.26(c). Under that rule, a timely motion filed following a district court denial of preliminary injunctive relief automatically results in "withdraw[al of] the matter from adjudication 2 days after such a motion is filed[.]" 16 C.F.R. § 3.26(c). After conducting a three day hearing featuring live testimony from eight witnesses, and considering a voluminous documentary record and extensive pre- and post-hearing briefing by the parties, the Honorable Dan Aaron Polster of the United States District Court for the Northern District of Ohio issued a 41-page ruling that denied the motion of the Federal Trade Commission (the "Commission") for a preliminary injunction, and concluded that the Commission is not likely to prevail in an administrative proceeding challenging the merger of STERIS and Synergy.

This development exemplifies the circumstances that the Commission has found warrant discontinuing administrative proceedings. The district court's ruling, which is highly fact-

intensive and case-specific, is amply supported by extensive findings, and documented with copious citations to the record. The district court's decision identifies insurmountable hurdles the Commission would face on the merits if it attempted to litigate its claims through the administrative process and subsequent appellate review. And all five factors that the Commission considers in determining whether to continue administrative litigation after the denial of a preliminary injunction weigh in favor of discontinuance in the present case. Should the administrative proceedings be ended now, the Commission would avoid the significant expense that otherwise would be incurred during the administrative trial. Further, the merger will be closed when the administrative proceedings are concluded, making the identification of any practicable and effective remedy particularly problematic. The Commission should withdraw the case as a matter of course under Rule 3.26(c), and for the reasons discussed below, STERIS and Synergy respectfully request that the Commission exercise its discretion not to continue the proceedings.

BACKGROUND

The Commission commenced the instant administrative proceeding on May 28, 2015 with the filing of an administrative complaint (the "Complaint"). The Commission also authorized Complaint Counsel to file a nearly identical complaint (the "PI Complaint") seeking a temporary restraining order and preliminary injunction pending the administrative proceeding in the United States District Court for the Northern District of Ohio, under section 13(b) of the Federal Trade Commission Act, 15 U.S.C. § 53(b). (Dkt. No. 5.)[1] Both the Complaint and the PI Complaint alleged that the proposed acquisition of Synergy by STERIS would violate Section

[1] Unless otherwise indicated, docket entries refer to those in the district court proceeding, *FTC v. STERIS Corp.*, No. 1:15-CV-1080 (DAP) (N.D. Ohio).

7 of the Clayton Act, 15 U.S.C. § 18. The Administrative Law Judge (the "ALJ") in the administrative proceeding is scheduled to conduct an evidentiary hearing in the case beginning on October 28, 2015.

The Commission predicated its challenge to the merger on the "actual potential competition" theory of merger liability, under which a postulated reduction or prevention of new, future competitive benefits, can render a merger unlawful, as opposed to an actual lessening of existing competition found in most litigated merger cases. The Commission alleged that the STERIS/Synergy merger would run afoul of this theory because it had purportedly caused Synergy to abandon a strategy to enter the United States with x-ray sterilization technology. The Commission claimed that this future entry would have resulted in Synergy competing for a portion of the sterilization business in parts of the United States, and would have produced new procompetitive benefits in those markets.

The evidentiary record before the district court consisted of more than 2,000 exhibits, including deposition transcripts, investigational hearing transcripts, business records of STERIS, Synergy, and their customers, and sworn declarations of various party and non-party witnesses. This record was supplemented by a three-day hearing, held between August 17 and August 19, 2015, as well as extensive pre- and post-hearing briefing from the parties. On September 24, 2015, the district court issued a 41-page opinion denying the Commission's request for preliminary injunctive relief, resting upon a series of detailed findings of fact.[2] Requiring only that the Commission "raise [merits] questions" sufficiently "serious . . . to make them fair ground for" further administrative proceedings (Op. at 6 (internal quotation marks omitted)), the district

[2] The district court's opinion is found at Dkt. No. 84, and it is cited hereinafter as "Op. at __." It is also attached hereto as Exhibit A.

court nonetheless held that "the FTC has failed to show, by a preponderance of evidence, that it is likely to succeed on the merits in the upcoming administrative trial." Op. at 41. In particular, it held that the Commission had failed to "show a likelihood of proving at trial that, absent the merger, Synergy probably would have entered the U.S. contract sterilization market by building one or more x-ray facilities in the U.S. within a reasonable period of time," which is an essential predicate of the Commission's "actual potential competition" theory of harm. Op. at 28.

The Court explained that the merger "had no significant impact on Synergy's plans for U.S. x-ray," and that Synergy abandoned its consideration of entering the U.S. with x-ray for independent financial and business reasons that rendered the strategy entirely unsound. Op. at 27. To wit, the Court concluded that "the evidence unequivocally shows that the problems that plagued the development of x-ray sterilization as a viable alternative to gamma sterilization in 2012 . . . were the same problems that justified termination of the project in 2015: the failure to obtain customer commitments and the inability to lower capital costs." Op. at 40.

The Commission elected not to file any motion for a stay or other relief pending appeal within the seven days prescribed by the governing rule 3.26. *See* FTC Rule 3.26(b)(1), 16 C.F.R. § 3.26(b)(1). As such, STERIS and Synergy timely file this motion seven days after the district court's judgment. *See id.*

ARGUMENT

The Commission has determined that where, as here, a district court denies preliminary injunctive relief pending an administrative challenge to a merger, "the determination to continue a merger challenge in administrative litigation is not, and cannot be, either automatic or indiscriminate." *FTC Admin. Litig. Following the Denial of a Preliminary Injunction: Policy Statement*, 60 Fed. Reg. 39741, 39742 (Aug. 3, 1995) (the "Policy Statement"). "[A]utomatic

pursuit of administrative litigation following denial of a preliminary injunction is not required to serve the public interest." *Id.* at 39743.

The Commission has specifically identified a district court's finding of a failure to show a likelihood of success on the merits as particularly important to the analysis of whether continuation of administrative proceedings remains in the public interest. Where, as here, the district court has applied the "serious question" standard for likelihood of success (Op. at 6), the Commission has announced that a finding of no likelihood of success on the merits will "itself raise serious questions about whether the Part 3 case should continue." *FTC Interim Final Rules With Request For Comment*, 74 Fed. Reg. 1804, 1812 (Jan. 13, 2009).

In conjunction with this overarching consideration, the Commission has elected to consider five factors in determining whether to continue administrative proceedings after the denial of preliminary injunctive relief by a district court:

> (i) the factual findings and legal conclusions of the district court or any appellate court; (ii) any new evidence developed during the course of the preliminary injunction proceeding; (iii) whether the transaction raises important issues of fact, law, or merger policy that need resolution in administrative litigation; (iv) an overall assessment of the costs and benefits of further proceedings; and (v) any other matter that bears on whether it would be in the public interest to proceed with the merger challenge.

Id. at 1811.

Cessation of administrative proceedings may be appropriate under this test even where "some factors suggest the Commission should continue its challenge[.]" Statement of Commissioners Leibowitz, Kovacic, and Ramirez*, Lab. Corp. of Am., et al.*, FTC Dkt. No. 9345, at 1 (Apr. 21, 2011) ("*LabCorp* Statement"). Indeed, termination of the administrative proceedings may also be appropriate even if the Commission "continue[s] to have reason to believe that [the challenged merger] will result in anticompetitive effects[.]" *Id.* at 1; *see also id.* at 2 (same).

Here, the district court has definitively found that the Commission is unlikely to succeed in establishing a core factual prerequisite for its legal theory in this case; namely, it found that Synergy would not have entered the U.S. sterilization market with x-ray technology but for the merger. And all five of the factors identified in the Commission's Policy Statement favor terminating the administrative proceedings now, saving the expenditure of substantial public money and resources, and avoiding both litigation risk and the limitations on available remedies addressed to an already-completed merger. The Commission should, accordingly, grant the motion, withdraw this case from adjudication, and determine that continuation of the administrative proceedings would not be in the public interest.

I. THE DISTRICT COURT'S THOROUGH AND DETAILED FINDINGS OF FACT SHOW THAT THE COMMISSION IS NOT LIKELY TO SUCCEED ON THE MERITS OF THE CASE.

The district court surveyed the extensive evidence presented by both parties and offered detailed findings showing that the Commission had failed to establish a likelihood of proving one of the threshold and essential elements of its case, namely "whether, absent the acquisition, the evidence shows that Synergy probably would have entered the U.S. contract sterilization market by building one or more x-ray facilities within a reasonable period of time." Op. at 7. As the Commission acknowledges, the question whether Synergy would have entered the U.S. sterilization market with x-ray but for the merger is a key requirement to its case, because the Commission's "actual potential competition" theory requires proof that the "competitor 'probably' would have entered the market" if it had not been for the challenged transaction. Op. at 6. As such, the district court's detailed factual findings in favor of STERIS and Synergy cannot be ignored, and weigh strongly in favor of discontinuance.

A. The District Court Found That The Commission Had Failed To Establish A Likelihood That Synergy Would Have Entered The U.S. Contract Sterilization Market With X-Ray But For The Merger.

The district court compiled an extensive, twenty-page distillation of the relevant facts, replete with citations to documents and witness testimony. Op. at 7-26. Following this summary of the evidence, the district court turned to a point-by-point evaluation of the issues, and ruled that the Commission had proffered insufficient evidence to carry its burden as to the crucial factual question whether Synergy would have entered the U.S. with x-ray but for the merger.

The district court concluded that the evidence of entry was insufficient "in at least three ways." Op. at 27. First, the district court found that U.S. x-ray entry had not been approved by the necessary decision-making bodies within the Synergy corporate structure. Op. at 27. Not only had the Synergy PLC board of directors failed to approve such entry, but "[i]n fact, no business plan was presented to the PLC Board for approval." Op. at 28. And even as Synergy's Senior Executive Board approved moving forward with developing a general x-ray strategy, it expressed "considerable concern over the numbers in [the] business model." Op. at 18. Synergy's CEO, Dr. Richard Steeves, for example, voiced concern that the "economics were not right and . . . needed to be looked at again" (Op. at 18), and those problems were never resolved. In short, the district court recognized that Synergy clearly understood that "the business plan had not been approved and [that] there were significant obstacles . . . to overcome in order to win approval." Op. at 27.

Second, the district court held that the potential merger with STERIS "had no significant impact" on Synergy's U.S. x-ray considerations. Op. at 27. Following STERIS's announcement of the proposed merger, the district court noted that "work on the U.S. x-ray project continued unabated." Op. at 19. Synergy executives "continued to mobilize the employees . . . to try to obtain customer buy-in, to try to bring down the cost of the new facilities, and to work with IBA

to develop a dual-capability machine of sufficient power to meet Synergy's needs." Op. at 27. The district court found that these were "legitimate effort[s] by Synergy employees who really wanted the project to succeed." Op. at 39. But "the failure to obtain customer commitments and the inability to lower capital costs" proved insurmountable to the business team and justified the project's termination. Op. at 40.

Third, the district court noted that it was Andrew McLean, Synergy's CEO of Applied Sterilization Technologies and Laboratories (Op. at 4), who terminated Synergy's U.S. x-ray aspirations, not Synergy's CEO, Dr. Steeves. Op. at 27. Dr. Steeves had hired Mr. McLean, at least in part, to lead the U.S. x-ray project. Op. at 10. After Synergy's failed attempt at acquiring Nordion, Dr. Steeves instructed Mr. McLean to "redouble his efforts and do everything he could to try and get this to work." Op. at 10. Mr. McLean threw in the towel notwithstanding that instruction from his boss because "after serious consideration of all the business factors involved" (Op. at 40), he "concluded that there was little to no likelihood of obtaining [board] approval" (Op. at 27).

The district court found that the evidence showed a wide variety of reasons why U.S. x-ray was simply not viable for Synergy in the foreseeable future. From the beginning, Synergy's "directors understood that they faced three significant obstacles in bringing this new technology to the U.S. market: lowering the capital costs, understanding the regulatory hurdles involved in transitioning from gamma to x-ray sterilization, and convincing gamma customers to accept and, more importantly, *support* this new technology." Op. at 8 (emphasis in original). Synergy was simply unable to make progress on these fronts.

The district court held that "the most significant reason Synergy opted to discontinue the U.S. x-ray project was lack of customer commitment." Op. at 28. "Synergy's corporate practice

is to secure take-or-pay contracts from customers before making significant capital investments." Op. at 28. Here, there were no such contracts. Despite making best efforts to obtain such an agreement from each of almost 200 Synergy customers, the district court noted that "Synergy could not identify a single customer who would provide the financial commitment required to build x-ray sterilization facilities in the United States." Op. at 29. Johnson & Johnson ("J&J"), long-believed to be the best candidate for commitment, declined despite a 50% cost savings. *See* Op. at 15.

The district court also found that the capital costs previously estimated to implement the U.S. x-ray marketplace entry were persistently inaccurate, further hardening key decision-makers against proceeding. Op. at 35. The evidence demonstrated, and the district court found, that Synergy evaluates the expected financial performance of proposed capital projects by reference to "a series of metrics[] or hurdle rates." Op. at 12 (internal quotation marks omitted). These metrics include a targeted 15% internal rate of return ("IRR"), a targeted 15% return on capital employed ("ROCE"), and a maximum five-year cash payback (i.e., the period of time it takes for a project to repay its initial cash outlay). Even if all of these metrics were satisfied, the district court noted that a project would not be guaranteed approval. Op. at 14. Rather, Synergy would also consider the project's risk profile and strategic fit in evaluating the investment. Op. at 12-14. Indeed, the risk profile assumes paramount importance where, as here, the capital expenditure "would consume the company's entire annual discretionary budget." Op. at 13. The PLC Board would also consider whether the project fit within the company's "overall strategy," how it aligned with or impacted "shareholder expectations," and how it compared to other projects Synergy might otherwise be able to undertake. Op. at 14.

To evaluate financial criteria like these, Synergy required a detailed financial review of its investments. But the U.S. x-ray project never went through such a second-tier financial evaluation (Op. at 11-12), because, without committed customer revenue, "the model just wasn't ready," Op. at 29. Without this second-level "black hat" financial review and firm customer commitments memorialized in take-or-pay contracts, the district court found that the U.S. x-ray project was ineligible for approval. Op. at 12, 29. Absent demonstrated demand for the service, any business model was doomed. Op. at 29.

The project could not have been approved in any event because, as the district court found, the "business model failed every one of the metrics Synergy uses to rank capital investments." Op. at 35. The project offered, at best, a 6.51% IRR and a 7.7-year cash payback. Op. at 17. It would also drag down the company's ROCE, which would "raise red flags for shareholders." Op. at 36. And these figures were generated by unsupported assumptions about revenue, market share, price, and capacity, as well as by an accounting error that double-counted revenues. Op. at 36. In short, "the business model [was] the product of guesswork and assumptions," Op. at 36, and, even then, it failed to meet Synergy's minimum requirements. Moreover, "[a]s the effort to develop a financial model that more accurately represented the economic realities advanced, the numbers got worse instead of better." Op. at 35. Building costs increased by $2.5 million per site, and it became clear the project would require the more expensive TT1000 Rhodotron, not the initially budgeted TT300. Op. at 35. And the numbers do not capture the growing uncertainty that any x-ray sterilization machine could meet Synergy's business needs. Op. at 22-24. The machine Synergy needed "had never been designed, built, tested or priced." Op. at 35. As such, "[t]he only certainty about the proposed machine was that it would cost considerably more than the initial business model estimate[d]." Op. at 35.

The district court found that these insurmountable challenges, *not* the pending merger with STERIS or the Commission's investigation thereof, caused Synergy to abandon its U.S. x-ray aspirations. Op. at 39. Moreover, the district court's decision carries special weight here. It was based on an adjudication after trial of historical facts, rather than technical antitrust issues within the Commission's area of expertise. The decision also demonstrates that this is not a close case, stating that "the evidence shows the opposite" of the Commission's factual premise "in at least three ways" (Op. at 27) and that, "[i]n the end, the evidence unequivocally shows" that legitimate business reasons "justified termination of the [x-ray] project" (Op. at 40 (emphasis added)). The evidence simply does not support the Commission's claim, essential to its theory, that Synergy would have entered the U.S. x-ray marketplace had it not been for the contemplated merger with STERIS.

B. The District Court Based This Determination On Its Evaluation Of An Extensive Evidentiary Record, And Further Proceedings Will Not Enhance The Evidentiary Record.

The district court came to these conclusions following an extensive, three-day hearing, and after evaluating a voluminous evidentiary record. Before it initiated the administrative proceeding and the federal court lawsuit, the Commission conducted a lengthy investigation lasting more than six months, in which it interviewed and obtained declarations from dozens of third parties, held sixteen investigational hearings of STERIS and Synergy employees, and obtained more than 3,000,000 documents from STERIS and Synergy.

In the course of the district court proceeding, the Commission developed vast amounts of additional discovery. Sixteen third parties and twenty-three employees of Synergy and STERIS were deposed. The Commission also obtained more than 5,000 additional documents from the parties. And it submitted numerous declarations and other materials from its investigation to the district court in support of its motion for a temporary restraining order and preliminary injunction.

STERIS and Synergy opposed that motion with detailed citations to voluminous record materials. As noted above, the evidentiary record before the district court ultimately consisted of more than 2,000 exhibits.

Where, as here, a district court has reviewed a robust evidentiary record and denied a preliminary injunction after finding no likelihood of success on the merits, any continued disagreement with the result of the district court's decision should not justify continuation of the case. In *Labcorp*, the Commission "continue[d] to have reason to believe that LabCorp's acquisition . . . w[ould] likely have anticompetitive effects," but it nonetheless discontinued administrative proceedings following a district court denial of an injunction. *LabCorp* Statement, at 2. And the Commission has terminated administrative proceedings following the denial of a preliminary injunction even where it had found that the district court had "made numerous factual and legal errors that contributed to what [the Commission] believe[d] was an erroneous decision." Statement of the Commission, *In re Paul L. Foster, et al.*, FTC Dkt. No. 9323, at 3 (Oct. 3, 2007) ("*Foster* Statement"). The Commission in that case recognized that before it engages in "lengthy and resource-intensive administrative litigation . . . , there must be support for the conclusion that the additional expense will improve the evidentiary record." *Id.* In particular, the Commission must examine "whether the record before the district court was deficient in any serious respect[,]" because that inquiry is "essential to understand whether the court's errors resulted from a flawed record or simply from a mistaken view of a sufficient record." *Id.* In *Foster*, the Commission concluded that even though the record was short of a fully developed trial record, the Commission had not been prevented from presenting any important evidence regarding the potential impact of the merger to the district court. As such,

the court's ruling was based in that case on essentially the same evidence that would likely be considered in the administrative proceeding.

Here, the district court unquestionably afforded the Commission ample opportunity to develop and present its full case, developed from both the parties and non-parties. The Commission has never suggested that the record is in any way deficient or flawed. To the contrary, the record is voluminous and comprehensive. On the basis of that extensive record, and given the opportunity for the Commission to present its very best evidence, the district court concluded that the Commission could not demonstrate a likelihood of success on the merits. The Commission should, accordingly, elect not to pursue further administrative proceedings.

C. In Light Of Its Ruling On The Entry Issue, The District Court Did Not Even Reach Other Required Showings That The Commission Would Need To Make To Establish Liability.

Because the district court found that the Commission had not demonstrated a likelihood that Synergy would have entered the U.S. x-ray sterilization market but for the merger with STERIS, the court did not need to assess the viability of the other factual predicates the Commission would need to establish to prevail on liability in the administrative proceeding. The district court did not address (a) whether the Commission had proved properly defined product and geographic markets; (b) whether Synergy's entry into the U.S. x-ray market, if it occurred, would have given rise to significant pro-competitive benefits in those markets; or (c) the viability of the "actual potential competition" theory as a matter of law. Each of these issues was hotly contested and extensively briefed; each would serve as a significant additional obstacle that the Commission would need to overcome in a full administrative adjudication. These other outstanding issues underscore that the infirmities identified by the district court will be only part of the Commission's problems in the event that it pursues a full administrative trial.

II. NEW EVIDENCE DEVELOPED DURING THE DISTRICT COURT LITIGATION SUPPORTS TERMINATING THE ADMINISTRATIVE PROCEEDINGS.

The evidence developed during the district court litigation further undermines the Commission's factual case, and strongly supports the district court's findings while supporting the grounds for discontinuing the administrative proceedings.

The district court cited facts developed following the issuance of the complaint. For example, one of the contested issues in the case involved the performance of a European x-ray facility owned by Synergy in Däniken, Switzerland. STERIS and Synergy argued that the x-ray performance at this plant was poor, and that this was one of the reasons why Synergy did not ultimately choose to pursue a U.S. x-ray plan. The district court agreed, finding based on evidence that, even today, "Däniken's x-ray facility is running at only 25% capacity[.]" Op. at 26. Moreover, the composition of that small operation is sub-optimal; most of that 25% consists of less lucrative "non-medical products, and the non-medical business is not the business Synergy prefers to attract." Op. at 34. The business Synergy wants—medical device business—accounts for just "2% of Daniken's overall x-ray business." Op. at 34. Just as importantly, even with the passage of several months since the Complaint was issued, the technology that Synergy would have needed to pursue a U.S. x-ray plan still has not been developed. Op. at 26 (finding that "there is no dual x-ray/e-beam sterilization machine in existence that operates at a 400kW capacity").

Live testimony at the hearing also supported the district court's findings in key respects. As but one example, a critical issue underlying the entry issue was the reason why Synergy stopped considering a possible entry into the U.S. with x-ray. On this question, the district court specifically cited and credited testimony by Gaet Tyranski, President of Synergy's U.S. sterilization operations, explaining the basis for the timing of the x-ray project's termination,

noting that it was related to the fact that the upcoming fiscal year's budget needed to be finalized and that customer interest had not adequately developed. Op. at 26.

The district court also credited testimony of Mr. McLean, Synergy's CEO of applied sterilization technologies, on another important issue, namely, the reason why no x-ray business plan was ever subjected to required "black hat" financial review. Mr. McLean explained, and the district court accepted, that this had not occurred because the x-ray team's model simply was not sufficiently developed to undergo such scrutiny. Op. at 29.

Another issue in the case involved the extent of U.S. customer interest in x-ray technology, because Synergy would obviously be unlikely to enter the U.S. with such technology without assurance that it would have customers to support such an investment. On this issue, the district court found that testimony from the Commission's own witnesses underscored the absence of customer commitment to the project. As the Court explained, testimony from the Commission's customer witnesses from J&J and Zimmer, "demonstrate[d] that their interest in x-ray sterilization in the United States was primarily academic." Op. at 30. David Silor of Zimmer testified that, "to this day, Zimmer has been unable to conduct any x-ray feasibility studies at all." Op. at 31. Mr. Silor also testified about the various steps required for conversion from gamma to x-ray sterilization: "The product would need to be tested, then the conversion would need to be approved by the FDA and the foreign counterpart in any foreign country where the product would be sold, then the site would have to be qualified; and then product would have to be put through the facility for validation." Op. at 32. Similarly, he explained that "Zimmer would have to do a dose mapping study, a dose setting validation, get the subdose verification level, perform sterility testing on the product, modify the manufacturing routers to indicate that

the company is using x-ray instead of gamma, make the FDA submissions on Class 3 medical devices, and perform material shelf-life studies and packaging shelf-life studies." Op. at 37.

Even at the hearing, these witnesses remained non-committal to x-ray technology and admitted that they had done none of the work required to facilitate a transition to x-ray. When Joyce Hansen was asked what J&J would do if Synergy opened an x-ray facility in the U.S. tomorrow, "[h]er response was that both parties would have to go through another series of hoops before [J&J would process there], i.e., J & J would have to get regulatory approval for the site, Synergy would have to go through installation and operational qualification, and J & J would have to put its product through the facility and conduct validation testing before sterilizing Surgicel there." Op. at 37. Similarly, "Zimmer ha[d] not evaluated the potential use of x-ray as a sterilization method for the products it manufactures, it ha[d] not performed any feasibility testing with x-ray sterilization, it ha[d] not evaluated whether x-ray performs better than gamma for its products, it ha[d] not discussed pricing for x-ray sterilization with anyone at Synergy, and it ha[d] not analyzed the cost of switching [] from gamma to x-ray sterilization in any formal way." Op. at 37. Put simply, although hand-selected by the FTC to support its case, neither company was willing to commit to the technology.[3] There has been no material change in these circumstances since the hearing.

[3] Ms. Hansen testified at the hearing that J&J's Surgicel product had recently received global approval for x-ray sterilization. Yet the district court noted that even following this approval Ms. Hansen had explained that "both parties would have to go through another series of hoops before" J&J could make any decision even as to that one product. Op. at 37.

III. THE TRANSACTION IMPLICATES NO IMPORTANT ISSUES OF FACT, LAW OR POLICY WARRANTING CONTINUATION OF THE ADMINISTRATIVE PROCEEDING.

Where, as here, the district court's denial of a preliminary injunction is fact-intensive and its legal discussion does "little more than recite established principles of competition law," *Foster* Statement, at 3-4, ending the administrative proceedings is particularly warranted. The district court's 41-page ruling in this case exemplifies this sort of fact-based decision; it cites a mere six cases. Even those authorities are cited only for generalized background standards against which Clayton Act claims are assessed. *See* Op. at 5-6. Instead, the district court's decision was based on the Commission's failure to establish the core *factual* predicate for its case, as described above. Because of its ruling on entry, the district court did not reach the only significant legal issue in the case, namely, the validity of the Commission's "actual potential competition" theory as a matter of law, and as such it expressly "assumed" the validity of the Commission's theory. Op. at 6.

The factual issues that scuttled the Commission's case here will not arise in other cases. The question whether a particular company (here, Synergy) would have elected to pursue a business plan but for a merger is entirely case-specific. There is thus no danger to the Commission that the district court decision in this case will materially affect future matters, either doctrinally or otherwise. This is yet another reason why discontinuation of the administrative complaint is warranted. *See Foster* Statement, at 4 (dismissing administrative complaint where "[t]he district court's opinion [denying the Commission's request for a preliminary injunction] . . . should have little precedential value beyond the specific facts of this case").

The Commission itself appears to have acknowledged that this matter does not involve the adjudication of any important factual or legal issues, because it has declined to seek a stay or

other relief pending any appeal of the district court's ruling in time to block consummation of the transaction. This provides an additional basis to conclude that the third prong of the test supports ending the administrative proceeding.

IV. THE COST OF FURTHER PROCEEDINGS OUTWEIGHS ANY POTENTIAL BENEFITS.

In order for the Commission to prevail on the merits in the administrative trial, it must meet a substantially higher burden of proof than the one it failed to satisfy in the preliminary injunction case in the district court. Statement of the Commission, *In re Arch Coal, Inc., et al*., FTC Dkt. No. 9316, at 8 (June 13, 2005) (Commission bears "a higher standard of proof" in administrative trial on the merits as compared with preliminary injunction motion). Whereas in the district court the Commission needed only to show a reasonable likelihood of success warranting maintaining the status quo to permit the administrative case to proceed, in the underlying administrative trial (and in appellate proceedings following such litigation) the Commission would need to make an actual rather than merely probable showing of liability.

Meanwhile, this case has proven to be extremely expensive by any yardstick. Prior to commencing the administrative and federal court lawsuits, the Commission undertook more than six months of investigation, in which it interviewed dozens of third parties, held sixteen investigational hearings of STERIS and Synergy employees, and obtained more than 3,000,000 documents from STERIS and Synergy. In the course of the district court proceeding, the Commission deposed sixteen third-parties and twenty-three employees of Synergy and STERIS, and obtained more than 5,000 additional documents from the parties. The Commission submitted voluminous materials from this investigation to the district court in support of its motion for a preliminary injunction—these herculean efforts did not persuade the district court to

grant the motion. And those resources would continue to climb if the case were to move forward to a full trial before the administrative law judge.

In short, the Commission would need to expend substantial additional resources preparing for and participating in a lengthy administrative trial and appeals, in the face of the district court's detailed analysis as to why the evidence belies the Commission's factual contentions. Such a significant investment of public resources on a case the Commission is so unlikely to win counsels in favor of ending the proceeding under the fourth factor that the Commission considers. *See LabCorp* Statement, at 2 (where "the potential benefits of proceeding relative to the costs" are low, termination of administrative litigation is warranted).

V. DISCONTINUATION OF THE ADMINISTRATIVE PROCEEDING IS IN THE PUBLIC INTEREST.

Terminating the administrative proceedings now, before more public resources are expended, would serve the Commission's policy goals and the public interest. Commissioner Olhausen recently observed that "the Commission has not pursued a Part III proceeding following a PI loss in federal court for twenty years." *A SMARTER Section 5: Remarks of Maureen K. Ohlhausen*, Sept. 25, 2015, Chamber of Commerce, at 17, https://www.ftc.gov/system/files/documents/public_statements/804511/150925smartersection5.pdf. Halting the part 3 proceedings at this point in time would promote uniformity with prior precedent, comport with policy considerations currently under consideration by the Commission, and promote uniformity of outcomes between Commission and DOJ merger cases. *See id.* at 10.

Moreover, because the Commission has elected not to pursue any stay preventing the parties from consummating their merger, even if it were somehow to prevail in the administrative case, its remedy would require efforts to unwind an already completed merger of STERIS and Synergy. The Commission has noted that "the difficulty of fashioning relief if the

Commission were to find a violation" under such circumstances "significantly limits the potential benefits of proceeding relative to the costs." *LabCorp* Statement at 2. These concerns are fully applicable to this case, where it will be difficult to separate the two companies once the merger has been consummated, as the Commission has recognized.

CONCLUSION

For the reasons set forth herein, STERIS and Synergy respectfully request that the Commission grant the Motion to Withdraw the Matter from Adjudication.

Dated: October 1, 2015

Respectfully Submitted,

/s/ John M. Majoras

John M. Majoras
JONES DAY
Street Address:
325 John H. McConnell Blvd., Suite 600
Columbus, OH 43215-2673
Mailing Address:
P.O. Box 165017
Columbus, OH 43216-5017
Telephone: (614) 469-3939
Facsimile: (614) 461-4198
Email: jmmajoras@jonesday.com

Geoffrey S. Irwin
Kerri Ruttenberg
Louis K. Fisher
Michael S. Fried
Tara Lynn R. Zurawski
JONES DAY
51 Louisiana Avenue, N.W.
Washington, D.C. 20001-2113
Telephone: (202) 879-3939
Facsimile: (202) 626-1700
Email: gsirwin@jonesday.com
Email: kruttenberg@jonesday.com
Email: lkfisher@jonesday.com
Email: msfried@jonesday.com

Email: tzurawski@jonesday.com

Counsel for Respondent STERIS Corporation

/s/ David H. Bamberger
David H. Bamberger
Julie A. Gryce
DLA Piper LLP (US)
500 8th Street, N.W.
Washington, D.C. 20004
Email: david.bamberger@dlapiper.com
Email: julie.gryce@dlapiper.com

Paolo Morante
Steven E. Levitsky
DLA Piper LLP (US)
1251 Avenue of the Americas, 27th Floor
New York, NY 10020
Email: paolo.morante@dlapiper.com
Email: steven.levitsky@dlapiper.com

Laura M. Kam
DLA Piper LLP (US)
2525 East Camelback Road, Suite 1000
Phoenix, AZ 85016-4232
Email: laura.kam@dlapiper.com

Counsel for Respondent Synergy Health PLC

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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of, **STERIS CORPORATION** **and** **SYNERGY HEALTH PLC,** **Respondents.**	**Docket No. 9365**

[PROPOSED] ORDER

Upon consideration of Respondents' Motion to the Commission to Withdraw Matter from Adjudication, any opposition thereto, and the Commission being fully informed,

IT IS HEREBY ORDERED, that Respondents' Motion is GRANTED.

IT IS FURTHER ORDERED, pursuant to Rule 3.26(c) of the Commission Rules of Practice, that this matter in its entirety be, and hereby is, withdrawn from adjudication.

By the Commission.

_____

Donald Clark, Secretary

Date: _____

CERTIFICATE OF SERVICE

I hereby certify that on October 1, 2015, I caused the foregoing to be electronically filed with the Secretary of the Commission using the Federal Trade Commission's e-filing system, causing it to be served on all registered users to be noticed in this matter, including:

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

Counsel for Plaintiff Federal Trade Commission

David H. Bamberger
Julie A. Gryce
DLA Piper LLP (US)
500 8th Street, N.W.
Washington, D.C. 20004
Email: david.bamberger@dlapiper.com
Email: Julie.gryce@dlapiper.com

Paolo Morante
Steven E. Levitsky
DLA Piper LLP (US)
1251 Avenue of the Americas, 27th Floor
New York, NY 10020
Email: paolo.morante@dlapiper.com
Email: steven.levitsky@dlapiper.com

Laura M. Kam
DLA Piper LLP (US)
2525 East Camelback Road, Suite 1000
Phoenix, AZ 85016-4232
Email: laura.kam@dlapiper.com

Counsel for Defendant Synergy Health PLC

/s/ John M. Majoras
John M. Majoras

Counsel for Defendant STERIS Corporation

EXHIBIT A

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

FEDERAL TRADE COMMISSION,	)	**CASE NO. 1:15 CV 1080**
	)	
Plaintiff,	)	**JUDGE DAN AARON POLSTER**
	)	
vs.	)	**OPINION AND ORDER**
	)	
STERIS CORPORATION, et al.,	)	
	)	
Defendants.	)	

On May 29, 2015, the Federal Trade Commission (FTC) filed a Complaint for Temporary Restraining Order and Preliminary Injunction against Defendants Steris Corporation (Steris) and Synergy Health plc (Synergy). (Doc #: 1.) The FTC asked the Court to grant immediate injunctive relief under Section 13(b) of the Clayton Act to prevent Steris from acquiring its alleged potential competitor, Synergy, on June 1, 2015. The parties agreed to maintain the status quo pending an expedited hearing on the motion for preliminary injunction and the Court's ruling. An administrative proceeding on the merits is scheduled to begin on October 26, 2015.

I.

Defendants Steris and Synergy are the second- and third-largest sterilization companies in the world, the largest provider being Sterigenics International LLC (Sterigenics). Sterilization of many healthcare and healthcare-related products is a critical final step in their manufacture; it

is required by the Food and Drug Administration (FDA) to eliminate microorganisms living on or within the manufacturers' products before those products are distributed to end-users in the United States. Foreign regulatory bodies require sterilization of these same products when sold in foreign countries. Only a small number of manufacturers sterilize their own products: the bulk of sterilization is contracted to suppliers like Steris,[1] Synergy and Sterigenics.

Three primary methods of contract sterilization are currently used in the United States: gamma radiation, e-beam radiation, and ethylene oxide gas (EO). Customers choose sterilization methods based on their products' physical characteristics and packaging. Gamma sterilization, which sterilizes by exposing products to the radioactive isotope Cobalt-60, is the most effective and economical option for most healthcare products because of its penetration capabilities. It is the only viable option for dense products (e.g., implantable medical devices) and products packaged in larger quantities. E-beam sterilization, 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. It represents only 15% of all contract radiation sterilization in the United States. EO is a non-radiation form of sterilization that exposes products to gas to kill unwanted organisms. It is effective only if gas diffuses freely through packaging and makes contact with all product surfaces requiring sterilization.

Steris, with twelve gamma facilities across the country, is one of only two U.S. providers of contract gamma sterilization services. Sterigenics, the other gamma provider, operates fourteen U.S. gamma facilities and two U.S. e-beam facilities. Together, these two firms

[1]In 1997, Steris acquired a medical sterilization company called Isomedix. (Hr'g Tr. 152 (Steeves).) Today, Steris' contract sterilization business is often referred to as Steris Isomedix.

account for approximately 85% of all U.S. contract sterilization services. Synergy, a British company, is the largest provider of e-beam services in the United States,[2] but operates more than thirty-six contract sterilization facilities, primarily gamma facilities, outside the United States. Of particular note are Synergy's two contract sterilization facilities located in Daniken, Switzerland (Daniken): a gamma facility and an x-ray facility. The Daniken x-ray sterilization facility is the only facility in the world providing x-ray sterilization services on a commercial scale.

The FTC alleges that, prior to the proposed merger announced on October 13, 2014, Synergy had been planning to enter the U.S. with an emerging x-ray sterilization technology it hoped would disrupt the current duopoly in the U.S. contract sterilization market, competing directly with Steris' and Sterigenics' gamma sterilization services. According to the FTC, x-ray sterilization is a competitive alternative to gamma sterilization because it has comparable, "and possibly superior," depth of penetration and turnaround times. (Compl. ¶ 4, Doc #: 1.) The FTC claims that, if consummated, the merger would allow Steris to insulate itself against competition with its gamma business. Synergy's planned x-ray sterilization facilities would have targeted Steris' and Sterigenics' gamma sterilization customers, providing them with options for contract sterilization and resulting in lower prices and improved quality.

After months of investigation, the FTC filed this case several days before the proposed merger was to close, contending that the acquisition of Synergy by Steris would violate Section 7 of the Clayton Act, which prohibits mergers "the effect of [which] may be substantially to lessen

[2]Synergy acquired its U.S. contract sterilization facilities from BeamOne LLC in April 2011. (Tr. 148.)

competition, or to tend to create a monopoly." 15 U.S.C. §§ 18, 45. The FTC sought injunctive relief under Section 13(b), which authorizes the Court to grant preliminary relief if, after considering the FTC's likelihood of success on the merits and weighing the equities, such relief would serve the public interest. 15 U.S.C. § 53(b).

On June 1, 2015, the Court held a teleconference with counsel to determine how to proceed most efficiently in this matter. As a result of discussions, the parties agreed to file a Stipulation and Order wherein Defendants agreed not to consummate the proposed merger until at least four business days after the Court rules on the FTC's motion for a preliminary injunction. (Doc #: 7.) The parties also agreed to provide the Court with a joint proposed expedited schedule for litigating that motion, which the Court issued. (Doc #: 24.)

The Court held a three-day hearing beginning August 17, 2015, during which the following witnesses testified: Joyce Hansen, Vice President of Sterility Assurance at Johnson and Johnson (J & J); David Silor, Principal Sterilization Associate at Zimmer Biomed Orthopedics (Zimmer); Dr. Richard M. Steeves, founder and CEO of Synergy; Andrew McLean, Synergy's CEO of Applied Sterilization Technologies (AST) & Laboratories; Constance Baroudel, one of the outside directors on Synergy's PLC Board; Gaet Tyranski, Synergy's President, AST for the Americas; Gavin Hill, CFO of Synergy; and Walter Roseborough, CEO of Steris. The parties filed simultaneous post-hearing briefs and response briefs. (Doc ##: 77, 78, 80, 81.) The Court, having listened to the evidence and reviewed the briefs, issues this ruling.

(Continued on next page)

II.

Section 7 of the Clayton Act provides that

> No person engaged in commerce or in any activity affecting commerce shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of another person engaged also in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the county, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.

15 U.S.C. § 18. Section 13(b) of the Clayton Act provides that

> [u]pon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, . . . a preliminary injunction may be granted . . . .

15 U.S.C. § 53(b).

"Section 7 is 'designed to arrest in its incipiency . . . the substantial lessening of competition from the acquisition by one corporation of the whole or any part of the stock' or assets of a competing corporation." *United States v. Dairy Farmers of Am., Inc.*, 426 F.3d 850, 858 (6th Cir. 2005) (alteration in original) (quoting *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 589 (1957)). In enacting this statute, Congress was concerned with probabilities, not certainties. *Id.* (citing *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962)). As District Judge David A. Katz recently explained,

> The "only purpose of a proceeding under Section 13[(b)] is to preserve the status quo until the FTC can perform its function." *FTC v. Food Town Stores, Inc.*, 539 F.2d 1339, 1342 (4th Cir. 1976). The ultimate determination as to a Section 7 violation of the Clayton Act is an "adjudicatory function [ ] vested in the FTC." *Id.*

FTC v. Promedica Health System, Inc., No. 3:11 CV 47, 2011 WL 1219281, at *53 (N.D. Ohio Mar. 29, 2011) (alteration in original). Under 15 U.S.C. § 25, the FTC is authorized to seek an

injunction to enforce Section 7, and it carries the burden of proving a Section 7 violation by a preponderance of the evidence. *See, e.g., U.S. v. H&R Block, Inc.*, 833 F.Supp.2d 36, 48-49 (D.D.C. 2011) (citing 15 U.S.C. § 25).

To show a likelihood of success under Section 13(b), the FTC must "raise questions going to the merits so serious, substantial, difficult and doubtful as to make them fair ground for thorough investigation, study, deliberation and determination by the FTC in the first instance, and ultimately by the Court of Appeals." *F.T.C. v. Promedica*, 2011 WL 1219281, at *53, (quoting *FTC v. Butterworth Health Corp.*, 946 F.Supp. 1285, 1289 (W.D. Mich. 1996), *aff'd*, 121 F.3d 708 (6th Cir. 1997)).

According to the FTC, the "actual potential entrant" doctrine specifically addresses this factual scenario: where a potential entrant (i.e., Synergy) merges with a firm already competing in the market (i.e., Steris) and the effect lessens future competition. The FTC asserts that the acquisition of an actual potential competitor violates Section 7 if (1) the relevant market is highly concentrated, (2) the competitor "probably" would have entered the market, (3) its entry would have had pro-competitive effects, and (4) there are few other firms that can enter effectively. (Mem. in Supp. of Mot. for TRO and Prelim. Inj. 6 n.40, Doc #: 5-1.)

Defendants challenge the actual potential entrant doctrine, arguing that it has long been disfavored by numerous courts including the Supreme Court. However, the FTC has clearly endorsed this theory by filing this case, and the administrative law judge will be employing it during the proceeding beginning October 26. Accordingly, in deciding the likelihood of success on the merits, the Court will assume the validity of this doctrine.

Prior to the August 2015 hearing, the Court directed counsel to focus their attention at the hearing on the second prong of the actual potential entrant doctrine, i.e., whether, absent the acquisition, the evidence shows that Synergy probably would have entered the U.S. contract sterilization market by building one or more x-ray facilities within a reasonable period of time. For the reasons that follow, the Court concludes that the FTC has failed to carry its burden.

III.

In 2000, Dr. Richard M. Steeves, a biochemistry doctor with a business background, purchased a facility with a controlled environment for the purpose of manufacturing products to prevent surgeons from acquiring HIV. (Hr'g Tr. 188-89 (Steeves).)[3] In 2007, Dr. Steeves acquired a small business in medical device sterilization, which became Synergy. (Id.) Synergy quickly grew from a privately held company with an annual revenue of £750,000 to a publicly traded company with an annual revenue of approximately £440,000,000 today. (Id. at 189.)

The first time Dr. Steeves came across x-ray sterilization technology was at an international radiation conference in 2011. (Hr'g Tr. 194.) Daniken, the only company in the world providing x-ray sterilization services on a commercial scale, made a presentation on this new technology that piqued Dr. Steeves' interest. (Id.) He found that the technology worked, but generally dismissed it "because all the talk at the conference was this was an expensive white elephant." (Id.)

In 2012, Leoni Studer, the company that owned Daniken, put it up for sale. (Hr'g Tr. 194 (Steeves).) Dr. Steeves had one of his senior directors conduct due diligence to determine whether the business would be worth acquiring. (Id. at 194-95.) He learned that Daniken had

[3]Citation to "Hr'g Tr." refers to the August 2015 Hearing Transcript, Doc #: 72.)

two components: a gamma facility and an x-ray facility. (Id. at 195.) At that time, Daniken's gamma facility was running at 75% capacity, while the x-ray facility was running at 22%. (SH-00968554; PX00423-030.) Synergy reached a valuation the directors thought workable based on the gamma business supporting the x-ray business and, "importantly, what we were expecting in terms of a change in interest in x-ray." (Id. at 195.) This predicted increase in customer interest in x-ray was based on the fact that J & J, one of the world's leading manufacturers of medical devices, pharmaceutical and consumer packaged goods, was about to begin the process of making the change from gamma to x-ray sterilization for one of its products (i.e., Surgicel, a blood-clotting agent) at the Daniken facility—setting what Dr. Steeves believed would be "an industry trend" away from gamma and towards x-ray sterilization. (Id.) At the same time, the directors understood that they faced three significant obstacles in bringing this new technology to the U.S. market: lowering the capital costs, understanding the regulatory hurdles involved in transitioning from gamma to x-ray sterilization, and convincing gamma customers to accept and, more importantly, *support* this new technology. (Id. at 195-96.) Based on forecasts predicting the x-ray facility would reach 52% capacity by fiscal year 2015 and 64% by fiscal year 2016, Synergy decided to purchase Daniken. ((SH-00968554; PX00423-030; Hr'g Tr. 653-55 (Hill).)

Synergy's management hierarchy consists of two main boards. (Hr'g Tr. at 148, 190 (Steeves).) The Senior Executive Board (SEB) runs the day-to-day operations, generates business strategies, and makes decisions on investments up to £10,000,000 (approximately $15.5 million). (Id.) As a publicly traded company, Synergy also has a PLC Board of Directors that represents the shareholders, defines the company's business and investment strategies, and

ensures that the company's operational and financial performance respects the shareholders' interests. (Hr'g Tr. 446 (Bouradel), 645 (Hill).) The PLC Board consists of 4 outside directors and 3 inside directors. (Id. at 150 (Steeves).) Together, they have responsibility for governance, signing off on strategy developed by the SEB, and investments over £10,000,000. (Id. at 190.)

At the annual meeting of the combined SEB and PLC boards held in October 2012, Dr. Steeves made a presentation on x-ray technology and Synergy's recent acquisition of Daniken. (Hr'g Tr. 151-55 (Steeves).) Dr. Steeves observed that Synergy could not compete in the U.S. market for contract sterilization services with its gamma, e-beam and EO services, given that Steris and Sterigenics held 83 % of the radiation market and 90% of the EO market. (Id. at 152-53.) He believed that Synergy could only compete with Steris and Sterigenics in the U.S. market by introducing its new x-ray sterilization technology, acquired via its acquisition of Daniken. (Id. at 153.) He pointed out that there were five main hubs in the United States where radiation sterilization is performed, and he hypothesized that Synergy could build a facility in each of those hubs with the prospect of taking more than $120 million of revenue away from Steris and Sterigenics. (Id. at 154.) He recommended that Synergy endeavor to reach an exclusivity agreement with IBA, the only manufacturer of x-ray equipment in the world that could make a machine powerful enough to sterilize medical devices on a commercial scale, to build up to five facilities in the U.S. (Id. at 155.)

Dr. Steeves made a similar presentation to the top Synergy leaders in a conference held in April 2013. (Hr'g Tr.155-56 (Steeves).) Two days later, he hired Andrew McLean to lead the design and project teams for the AST division, beginning in June 2013. (Id. at 157; PX00095-001.) In a letter to McLean dated May 15, 2013 (before McLean came onboard), Dr. Steeves

updated McLean on the status of various AST businesses. (PX00095-001.) With regard to x-ray at Daniken, Dr. Steeves noted his concern over "slow customer conversions." (Id.) However, Dr. Steeves considered x-ray at Daniken to be a "potential game changer" in the U.S. contract sterilization market. (PX00095-002; Hr'g Tr. 157 (Steeves), 274 (McLean).) Although Synergy hadn't run the numbers on x-ray in the United States, he commented that "intuitively I think it could be lower cost than gamma, and would beat the gamma service on every other operating metric. This is one of the key projects I would like you to lead through the design team." (PX00095-002.) In April 2014, McLean was promoted to CEO of AST and Laboratories. (Hr'g Tr. 156 (Steeves).)

McLean was tasked with presenting the U.S. x-ray team's strategy to the combined boards at the November 2013 meeting. (Hr'g Tr. 211 (Steeves).) McLean never made that presentation, however, as it was around that time that Nordion, the world's leading supplier of Cobalt-60 (the energy source for gamma radiation sterilization) and one of only two Cobalt-60 suppliers in North America, became available for acquisition. (Id. at 211-12 (Steeves), 461-62 (Bouradel).) Both Steris and Sterigenics participated in a bidding war for Nordion beginning in the fall of 2013 that culminated in an announcement, on March 31, 2014, that Sterigenics entered into a definitive agreement to acquire Nordion.

Now concerned about Cobalt-60 supply in the hands of Sterigenics and motivated by his belief in x-ray technology, Dr. Steeves decided to explore fully the concept of commercial x-ray sterilization in the U.S. and other parts of the world. (Hr'g Tr. 213 (Steeves).) He directed Andrew McLean to "redouble his efforts and do everything he could to try and get this to work, sort out the three issues that he needed to address in order to allow [Synergy] to bring it in the

United States." (Id.) Those issues are the same impediments Synergy faced when it purchased Daniken: (1) developing a business plan requiring significantly less capital than the 18 million euros it cost Leoni Studer to build Daniken, (2) overcoming customer reluctance to switch sterilization modalities, and (3) obtaining revenue commitments from a base load of customers in the form of take-or-pay contracts. (See also Hr'g Tr.195-197, 202-203 (Steeves).)

Synergy's corporation has three businesses: AST, hospital sterilization services, and a linen business. (Hr'g Tr. 646-47 (Hill).) Synergy has an annual maintenance budget of $40 million, and a discretionary budget of $25 to $40 million for investment purposes. (Id. at 650.) The competition for discretionary cash among the businesses has led Synergy to establish a formal process for deciding which projects to fund.

The first phase of the process is aspirational; a Synergy business (e.g., AST) will come up with an idea for a capital project, and do the research to determine whether it can make a business case that supports the investment of discretionary capital. (Hr'g Tr. 678 (Hill); see also 206 (Steeves) ("[M]ost of the ideas I think probably come from me and my team.").) The project team enters the results of its research into a template, designed by Synergy CFO Gavin Hill, which outputs numbers, or metrics, commonly used by corporations when deciding whether to invest significant capital. (Hr'g Tr. 660-61 (Hill).) The project team will present the business case to the SEB for approval, and may return to the SEB several times before the concept is approved. Once the SEB approves the business case, but before it is submitted to the PLC Board, the business model must undergo a rigorous review by Hill and his corporate finance team, known within the corporation as the "black hat" review. (See generally Hr'g Tr. 206-08, 221 (Steeves); 412-13, 418 (McLean); 446-450 (Bouradel); 678-682 (Hill).) When the business

case is sufficiently "robust," the black hat review commences. (Id. at 681 (Hill).)

The black hat process "is a management term for a two-part review." (Hr'g Tr. 648 (Hill).) The first component is the financial review of "the assumptions underpinning the business case." (Id. at 678-79.) According to Hill, the project team needs to understand what underpins the revenues, benchmark the costs against other facilities, consider the return on sales, and, generally, make sure that the team has thoroughly done its homework and put together a comprehensive business model. (Id. at 679-680.) The second part of the review is the commercial review. It covers a number of areas such as the contracts underpinning the revenues (e.g., take-or-pay contracts, termination clauses, penalty payments) and all aspects of risk (e.g., pension, insurance). (Id. at 680-81.) The black hat review must conclude, and the SEB must approve, the business model before it is presented to the PLC Board. (Id. at 681, 707).

There are a series of metrics, or "hurdle rates," that Hill's team uses to evaluate and compare the expected financial performance of proposed capital projects—measures commonly used by corporations when ranking investments. (Hr'g Tr. 652 (Hill).) Among the metrics is the internal rate of return (IRR), which Synergy targets as 15%. (Id. at 656-675; JDX2859-001, Synergy Group Policies and Governance Manual ¶ 9.3.2.) The IRR is the expected rate of growth from a project over a period to time (Hr'g Tr. 656 (Hill).) It is the cash that is left over after the taxes and operating costs have been removed, which can then be reinvested in the business. (Id. at 659) Synergy considers a project's IRR over a period of seven to ten years maximum, because investors typically have a short-term perspective, with a three-year horizon. (Id. at 659-661.) That a project has an IRR of 15% does not guarantee that it will be approved by the PLC Board. (Id. at 661.) Just as important is the risk profile. (Id. at 662.) Hill testified

that the risk profile is especially important where, as here, Synergy would be considering a capital expenditure (CAPEX) that would consume the company's entire annual discretionary budget. (Id.) Any financial impact from that investment would have a reportable effect on the company's earnings. (Id.)

Another metric is the return on capital employed (ROCE), which Synergy targets at 15%. (JDX2859-002 ¶ 9.3.3; Hr'g Tr. 664 (Hill).) It is the ratio of operating profit to shareholder funds and long-term debt, or a measure of how well the company converts invested capital into profit. (Id.) While the IRR looks at future cash flows, ROCE is a single figure calculation in a single year. (Hr'g Tr. 664 (Hill).) Hill testified that he looks at ROCE as "one of the most important measures for the business . . . as there is an extremely strong correlation between [ROCE] and a company's share price." (Id. at 665.) Under Gavin Hill's five-year leadership, Synergy's ROCE has increased from 10% to 12.4%. (Id. at 669-671.) His short-term goal for Synergy is to reach 15%, and then 20%. (Id. at 668.) To get to 15% ROCE at a company level, Hill requires the businesses, such as AST, to deliver a 30% ROCE. (Id. ("Once you take account of regional costs that are in the business, central overhead that is part of running the business, and good will, we have a large amount of good will on our balance sheet, you then get to 15 percent.").)

Another metric is cash payback, which is the period of time it takes for the operating cashflows of the investment to repay the initial capital outlay. (JDX2869-002 ¶ 9.3.4.) Synergy's target cash payback on all investments is 5 years. (Id.; Hr'g Tr. 667-68 (Hill).)

And last, but certainly not least, Synergy requires revenue commitments from customers who will use the facilities. (Hr'g Tr. 201-02 (Steeves), 680-81 (Hill).) These commitments

typically take the form of take-or-pay contracts in which the customer agrees to provide a volume of products for Synergy to sterilize at some point in the future. (IH Hr'g Tr. 62 (Baran).)[4] In the event the customer does not provide those products, it still has to pay for the services. (Id.) These agreements verify that there is a demand for the services, and support the business cases seeking PLC Board approval. (Hr'g Tr. 208-09 (Steeves), 680-81 (Hill).)

Even if a business model satisfies all the metrics, there is no guarantee the PLC Board will approve it. As Constance Baroudel testified, "the finances are important, but it is also the overall strategy that is important," along with consideration of "shareholder expectations." (Hr'g Tr. 473 (Baroudel).) Furthermore, the PLC Board may not reach a consensus on approving the project. (Id.) Gavin Hill testified,

> So if you ask me would you potentially consider a project that maybe just didn't quite hit your hurdle rates but it was guaranteed to deliver, I may say yes, . . . because I know exactly where we are going to be, and I would much rather that over a project that had a much higher potential return but there was huge speculation in the assumptions and could actually deliver a negative return.

(Hr'g Tr. 691 (Hill).) Additionally, the size of the project matters. (Id.) In a project as large as the U.S. x-ray business case, little risk would be tolerated as Synergy would have to forego "many other projects." (Id.)

In May 2014, McLean made a presentation to the SEB, updating the board on the progress of the U.S. x-ray project. The minutes from that presentation show that McLean continued to analyze "as agreed in the previous SEB meeting" the building of combined e-beam and x-ray facilities; determined the location of Sterigenics U.S. facilities and identified the products being sterilized there; and narrowed to eight the number of U.S. locations under

[4]Citation to "IH TR." refers to the Investigative Hearing Transcript.

consideration. (PX00099-012, -013.) Again, he expressed his "concern with proceeding with this course of action, as it would be difficult to guarantee getting take or pay contracts to support the financial model for building these facilities." (Id.) In a subsequent letter dated May 29, 2014 to Synergy's COO, Dr. Adrien Coward, McLean further explained his concerns over the project:

> I know I sound like a broken record on this but the message does not seem to be cutting through. . . . The fact of the matter is that building an x-ray facility today would not guarantee conversions tomorrow. As an example Daniken x-ray is only ~25% capacity utilized after more than 3 years. If we did not force customers to move from Daniken and our other gamma sites, then capacity utilization would be only 10%. These are the facts and if we push ahead and build without a proper baseload customer(s) in the US it is to our peril. And of course we do not have the same footprint in the US that would allow us to "force" customers to convert and cross validate and indeed our competitors would be doing everything possible to stop that occurring, creating further delays and barriers. No one is more enthusiastic about getting an x-ray footprint in the US than myself, however it could be a complete disaster.

(JDX1510-001); Hr'g Tr. 379-385 (McLean).)

A more detailed presentation of the U.S. x-ray strategy was presented to the SEB by McLean's subordinate, Chris Fry, in July 2014. (PX00101.) The minutes of the meeting show, among other things, that McLean again raised his concern over the lack of customer financial backing for the project. (PX00101-013.) He reported that "despite there being a lot of interest from customers about [Synergy] building X-ray facilities in America none had yet given an indication that they would be willing to enter into a long term take or pay contract." (Id.) By way of example, he pointed out that "J & J had declined the opportunity to enter into such a contract despite the fact that they were saving 50% of costs and it was only a two-year payback period for the revalidation costs [due to] concern about the risk." (Id.) With regard to x-ray sterilization of medical devices, he observed that "the big concern was the impact of treatment on the form and function of the device." (Id. See also Hr'g Tr. 214-15 (Steeves).) At the

conclusion of the meeting, it was agreed that McLean would present a formal business case at the September 2014 SEB meeting. (PX00101-013.)

Following the July 2014 meeting, McLean tasked Gaet Tyranski, President of AST for the Americas, with preparing the September 2014 presentation. (Hr'g Tr. 511 (Tyranski).) McLean directed Tyranski to generate as many customer letters of interest as possible by the first week in September, to identify two potential U.S. building sites taking into consideration the location of the headquarters, manufacturing, or distribution facilities of the largest medical device manufacturers, and to identify the products manufactured there. (Id. at 504-05.)

In a report circulated to board members prior to the September 2014 meeting, McLean reported that, while a number of major medical manufacturers (J & J, Community Tissue, BD, Stryker Orthopedics, and Bayer) had signed letters of interest in x-ray sterilization services in the U.S., he still had difficulty getting anyone to "bear the risk" of x-ray given that it was new and unproven in the United States. (Hr'g Tr. 307-08 (McLean) (citing PX5771 at 5).) Two days before the September 2014 SEB Meeting, McLean reported to Dr. Steeves and Dr. Coward that he had reached an oral agreement with IBA in which IBA would agree to provide dual x-ray/e-beam sterilization equipment to Synergy exclusively for 10 years for its U.S. operations, provided Synergy would make down payments on the first two x-ray facilities by the end of October 2014.

On September 17, 2014, Tyranski presented the business plan to the SEB. (PX00104-0003 to -00076.) The presentation sought approval for a strategy offering dual x-ray/e-beam sterilization at a network of four to five facilities in the United States. (PX00104-0004, -0027.) Phases 1 and 2 called for the construction of two facilities, one in Indiana and one in Texas, that

would be in operation by fiscal year 2016. (PX00104-0007, -0021.) Phase 2 called for the construction of two to three more facilities beginning in fiscal year 2016, with an expected completion date in fiscal years 2017 or 2018. (PX00104-0007.) The presentation contemplated an investment of approximately $20.2 million for each plant— meaning a capital investment of more than $40 million was required for the first phase of the proposed project alone. (Hr'g Tr. 587 (Tyranski); PX00104-0005; JDX2471-016.).

The September 2014 business plan indicated that the first two plants would offer a combined IRR of 6.51%, and a cash pay-back period of 7.7 years. (PX00104-0037.) The revenue assumptions in the plan were based on achieving a target of 15% of the U.S. gamma market after completion of all five plants (i.e., fiscal year 2018). (PX00104-0005, -0007.) The plan assumed that customers would pay a lower cost for x-ray ($2.50 per cubic foot) versus gamma ($3 to $4). (PX00104-0034.) And it assumed that the first two plants would achieve nearly 100% capacity utilization by the end of year 6.

In fact, the only number that was locked down in this business model were the revenues from the volume of products Synergy planned to transfer from its Lima, Ohio e-beam plant to the new plant for e-beam sterilization. (Hr'g Tr. 406 (McLean).) It was later discovered that the revenue from the Lima plant was counted twice. (Id. at 694-95 (Hill).) Correcting this accounting error reduced the IRR from 6.51% to 3%. (Id.) The evidence shows that all the other numbers upon which the business model was based were the product of guesswork and assumptions.[5] Even with an IRR of 6.5%, McLean knew the SEB would not approve the

[5]Since the team did not have any take-or-pay contracts, they could only guess at the volume of medical devices that might go through the facility. (Hr'g Tr. 405 (McLean).) The 15% market share number was an arbitrary number the team thought Synergy "might" be able to achieve "over a seven-to-ten year time frame." (Id. at 407.) The team plugged in some numbers to show

business model. (Id. at 418 (McLean).) And with an IRR of 6.5% *and* no customer commitments, McLean didn't bother to ask Hill to conduct a black hat review because he knew the model was not ready. (Id. at 418-19.) The business model was never presented to the PLC Board. (Hr'g Tr. 472-73 (Bouradel).)

While the evidence shows that the SEB approved the x-ray/e-beam strategy, the minutes of the meeting reflect considerable concern over the numbers in Tyranski's business model. (JDX2471-018.) Specifically, Gavin Hill commented that "he was surprised . . . the financial model did not look better. The output appeared to be the same as for a gamma facility but given the unproven nature of the technology it was considerably riskier, and it assume[d] that [Synergy] would be able to command a premium price for its services." (Id.) Dr. Steeves advised that he considered the strategy right, but "he had concerns that the economics were not right and that these needed to be looked at again." (Id.) Chris Fry advised that "some of the numbers in the model were guess work." (Id.) Dr. Coward "suggested that rapid work needed to be done to build up the cost base from scratch." (Id.) Yet again, McLean pointed out that "it was difficult to get a base load customer to bear any risk of X-ray given that it is new and unproved in the US." (Id.)

At the PLC Board meeting the next day, outside director Constance Baroudel asked for an update on AST's U.S. strategy. (PX00574-001.) Dr. Coward reported that Daniken, while increasing in capacity utilization, "was also undertaking more work for industrial [non-medical device] customers, as the regulatory process to allow [medical] devices to be sterilised using X-rays was taking longer than originally planned." (PX00574-002.) Dr. Steeves reported that

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that the facility would reach 100% capacity utilization "around year seven or so." (Id. at 411.)

McLean was "working on entering into an exclusivity agreement with IBA to ensure that Synergy was the only outsourced sterilisation provider [that] would supply X-ray equipment in the US." (PX00574-002.) However, "in order to secure this exclusivity it was likely that deposits of €300k each would need to be placed for two X-ray facilities before the end of the financial year." (Id.) Dr. Coward made clear that formal approval for the plan involving four facilities "was **not** being sought at this juncture, just for the deposits on two machines." (PX00574-010.) The PLC Board approved the down payments for the two facilities with IBA. (Id.)

On October 7, 2014, core team members from the United States and Europe attended a kickoff meeting in Florida during which Gaet Tyranski made a presentation he called "Project Endurance." (Hr'g Tr. 525 (Tyranski).) He noted that the U.S. x-ray strategy was approved by the SEB at the September 2014 meeting. (Id. at 526.) He also noted that the SEB identified key actions to be addressed, including further reduction of CAPEX by at least $1.5 million, further work on the facility locations, and finalizing the exclusivity agreement with IBA. (Id. at 527.) At the August 2015 hearing, Tyranski testified that, although he did not mention in his presentation that customer commitments would be needed in order for Project Endurance to go forward, it was understood based on his experience at Synergy. (Id. at 529.)

Less than one week later, on October 13, 2014, Steris announced its proposed merger with Synergy. Notwithstanding this announcement, evidence shows that work on the U.S. x-ray project continued unabated.

On October 21, 2014, Tyranski sent an email to his x-ray team stating that, with the exception of market development expense (e.g., "a Synergy branded new x-ray logo and

campaign when it will likely be Steris in a few months"), the x-ray project was proceeding as planned. (Hr'g Tr. 531-32 (Tyranski).)

On October 30, 2014, McLean reported that he had executed an option contract with IBA giving Synergy until March 31, 2015 (the end of Synergy's fiscal year), to sign purchase agreements with IBA. (Hr'g Tr. 331 (McLean.) McLean testified that, at that time, he was having standing meetings every two weeks with J & J, whose product Surgicel was recently approved by the FDA for x-ray sterilization, prodding them for a take-or-pay contract "or *any* project with J & J for x-ray in the United States." (Id. at 336.) He testified that "the weeks and months drew on and there was nothing." (Id.) Still, he had cause for optimism because J & J continued to express enthusiasm about x-ray, they complained about the sharp increase in prices for Cobalt-60, and there was concern in the industry over Cobalt-60 supply and tightening regulations over disposal of Cobalt-60 and EO residuals. (Id. at 305-07, 339 (McLean).)

On November 4, 2014, Synergy issued its Interim Results for the Six Months Ending 28 September 2014. (PX00580.) On page 4 of the 25-page document, the report provided, with regard to AST,

> 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.

(PX00580-004.)

In an earnings call held the next day, Dr. Steeves stated that AST had a really good half year, commenting that

> [t]he strongest growth has been in the Americas along with good growth in Europe from the new facility in Marcoule, France, our x-ray facility in Switzerland and the new capacity acquired with [the Bioster acquisition] . . . Looking forward, there are few further steps we are taking to support growth and including expanding our network in the U.S. as well as expanding the capacity of a number of our facilities around the world. We've also reach an agreement with IBA that will allow us to get started with x-ray in the U.S.

(PX01773-005.)

Meanwhile, Tyranski continued working on locking down numbers for the U.S. x-ray business model, explaining that, if the merger went through, he would just have to re-present his business model to the new combined Steris/Synergy SEB, and that they would probably not build an x-ray facility right next to a Steris gamma facility. (Id. at 532-33, 548-49 (Tyranski).)

The business plan proposed at the September 2014 SEB meeting anticipated that Synergy's e-beam facility in Lima, Ohio would be closed and that the products would be transferred to Synergy's new dual x-ray/e-beam facility. (Hr'g Tr. 539-540 (Tyranski).) On January 19, 2015, Tyranski sent an email to Gavin Hill asking him to sign a lease extension for the Lima facility (to October 2017), so that the new U.S. facility would have base load e-beam revenues while x-ray customers were being developed. (Id.; PX-01265-001.) Hill extended the lease. (Hr'g Tr. 540-41 (Tyranski).)

In November 2014, Tyranski sent Mark Berger, a business development manager, to the Dallas/Fort Worth area to visit numerous proposed locations for an x-ray facility, while Aldo Rodriguez, an accountant, continued discussions over economic incentives that would lower capital costs in building that facility. (Id. at 541-45.) Tyranski testified that the reason for this activity was to nail down costs so that he could present the best business case to the board for approval. (Id. at 545.) Tyranski himself continued discussions with the Miami Valley Research

Park in Dayton, Ohio, regarding incentives and grants that could be offered in locating a facility there—discussions that continued into February 2015. (Id. at 545-49; PX01270.) Tyranski testified that he could not make a decision on committing to a lease until he presented the business case to the SEB again. (Hr'g Tr. 548 (Tyranski).)

The evidence shows that, on October 9, 2014, Tyranski sent an email to his sales staff reminding them to continue to elicit customer letters of interest under the market development strategy and offering $500 bonuses to those who could get a customer to sign up to send their product to Daniken for x-ray testing by November 15, 2014. (Hr'g Tr. 549-551 (Tyranski); PX00244-001.) He subsequently extended the deadline another several months. (Hr'g Tr. 549 (Tyranski).)

The evidence also shows that, despite Synergy's best efforts to advance the x-ray project, news on the economic front worsened. The machine that formed the cornerstone of the September 2014 business plan was IBA's Rhodotron TT300. (Hr'g Tr. 423-28 (McLean); 555-567 (Tyranski).) IBA had represented that its Rhodotron TT300 was a combination x-ray/e-beam machine that could meet Synergy's needs. (Id. at 424 (McLean).) But in late 2014, IBA began expressing a lack of confidence in the TT300, proposing a reconfiguration of the TT1000 with a €250,000 increase in price.[6] (PX00240-003-004. Hr'g Tr. 562 (Tyranski), 422 (McLean).) While the TT300 provided both e-beam and x-ray services, the greater capacity was on the e-beam side. A machine that provided both services was critical to the September 2014 business model because it guaranteed considerable e-beam revenue for years (which would be

[6]The Rhodotron TT1000, the machine that ran x-ray at Daniken, was an x-ray-only machine.

satisfied by the movement of products from the Lima, Ohio e-beam plant to the new facility) while Synergy's U.S. x-ray business developed. (JDX1722-001; JDX1775 at 25, 27.) However, the ultimate goal driving the plan's economics was always the machine's x-ray capacity. (JDX1760-002 (Slide 20).) The machine needed to have more x-ray than e-beam capacity; it required 400 kW and 7 MeV for x-ray, and 100 kW and 10 MeV for e-beam. (JDX1920-001.) The TT300 could not achieve the 400kW power level, and there was no dual-purpose machine in existence capable of reaching those power levels. (Hr'g Tr. 582, 615 (Tyranski).) The evidence shows that the business plan with a 300kW machine would produce 25% less revenue than the TT1000 with 400kW. (PX00240-004.) According to McLean, the one thing he thought "should have been relatively simple just became more and more complex and more and more costly." (Hr'g Tr. 422-23.)

The uncertainty culminated in a meeting in January 2015 attended by principals from Synergy and IBA, during which IBA told Synergy that the price of the systems was "going up." (Hr'g Tr. 426 (McLean).) Tyranski testified that, at the time of that meeting, IBA's price for a TT1000 with 400kW capacity was €5.304 million and the cost of the machine constituted more than 25% of the capital cost for one facility. (Id. at 577-78 (Tyranski).)

In response to a question at the August 2015 hearing, whether IBA gave Synergy an estimate as to how long it would take to design, build and test the system, McLean responded,

> Well, that's—that's a question I never asked, because at that point, I'm getting quite frustrated and disillusioned with the whole thing. It is going nowhere. And in my point of view, if they have never built one, never tested one, did we want to be the guinea pig?
>
> And I remember discussions with my team saying, you know, do we want to be the experiment here in the U.S. and persuade and influence J & J and other top tier customers to come over to us and then have a failure? It had to work."

(Hr'g Tr. 426-27 (McLean).) When the Court asked Tyranski to gauge, in February 2015, his confidence level that IBA could produce the machine at the required power level, he responded, "Their story kept changing so I was skeptical. I was probably more than 50 percent confident that they could ultimately get there *over time*, but there were no guarantees." (Id. at 577 (Tyranski) (emphasis added).) It is undisputed that there is no machine in existence today that is capable of providing both x-ray/e-beam sterilization at the 400kW power level. (Id. at 425 (McLean), 577 (Tyranski).)

On February 24, 2015, McLean sent a declaration to the FTC stating that he was terminating Synergy's U.S. x-ray project, and listing the reasons for doing so. (JDX2655.) He described his team's "top-down, full-court" efforts, and failure, to solicit customer commitments. (Id. at ¶ 2.) He explained that Synergy's sales and marketing efforts began in July 2013, by identifying 185 leading medical device and pharmaceutical manufacturers as potential candidates for x-ray. (Id. at ¶ 6.) For those companies, Synergy began its marketing efforts with sales calls made in conjunction with sales of other AST products, explanatory brochures, webinars, live seminars, tours of Synergy plants, tours of Daniken, and phone calls. (Id. at ¶ 6.) Of those companies, Synergy targeted 34 as the best candidates to generate a viable processing volume to underpin the x-ray strategy. (Id. at ¶ 7.) This was necessary to guarantee the revenues needed for the business model to meet the minimum hurdle rates and obtain SEB and PLC Board approval. (JDX2655 ¶ 8.) McLean provided file folders for each of those companies with contemporaneous documentation of those efforts. (Id. at ¶ 9.) In anticipation of presenting a business case to the SEB in September 2014, the project team continued its efforts to obtain some form of customer commitment to support the business model. (Id. at ¶ 11.) All they were

able to obtain were around six nonbinding letters of interest. (Id.) Following the September 2014 SEB meeting, the project's marketing team continued efforts to obtain customer commitments, to no avail. (Id. at ¶ 12.) As no significant U.S. customers remained to be contacted, McLean concluded that "there [was] no reasonable prospect of customer acceptance for Synergy's X-ray project." (Id. at ¶ 4.)

Attached to McLean's declaration are emails from five of Synergy's top customers stating that they have no present intention of using x-ray sterilization: Covidien/Medtronics ("Although x-ray is interesting to the team, it is not a modality the Covidien Group with Medtronic is actively investigating today."), Boston Scientific ("Xray simply has not proven to have any significant benefit over the big three forms of sterilization to warrant real interest."), J & J ("Per our conversation today, the Business Case for J & J to support transfer of its U.S. gamma processed products (done by 3rd Parties) into a new xray facility near Memphis TN (J & J Distribution Center) does not appear to be compelling."), and Becton Dickinson ("The risk to reward ratio remains stubbornly favorable toward Co60 and Ebeam. . . . The costs in labor, material testing, submissions, reviews, etc., to switch to Xray could approach $400K per product family. Multiplied out by 100s, if not 1000s, for different designs and product families and the investment costs are staggering.") (Respectively, JDX2852, JDX2853, JDX2854, JDX2855.) McLean solicited these communications following his meeting with the FTC on February 17, 2015, when asked for evidence showing that customers had refused to back x-ray *in writing*. (Hr'g Tr. 399 (McLean).) McLean testified that if these customers had said they were really committed to x-ray in the United States, he would not have terminated the project.

> So I wanted to make sure. Remember that myself and my team had put a lot of time and effort, hard work into this, so I wanted to be sure. I asked a direct

question and I got a direct answer.

(Id. at 400.)

That same day, Gaet Tyranski sent an email to his team leaders. (PX00863-003.) Noting that "the FTC inquiry was going down a rat-hole," Tyranski advised, "I do think it's prudent to stop further spend on X-Ray Americas." (Id.) When asked at the August 2015 hearing what he meant by "going down a rat-hole," Tyranski responded, "[The FTC inquiry] was bogging the entire team down. It was burdensome." (Id. at 570.)

Tyranski, who had only been President of AST for the Americas since August 2014, was dealing with numerous other capital projects at the same time he was working on the business case for the U.S. x-ray project (i.e. building a facility in Saxonburg, Pennsylvania, working to obtain approval to build a facility in Northern California, and preparing a business case for greenfield sites in the Carribean). (Hr'g Tr. 585 (Tyranski).) Consequently, he spent no more than 30% of his time on the U.S. x-ray project. He testified that, in discussions with McLean over whether to terminate the project, they knew they were reaching the point where the budget for fiscal year 2016 needed to be set. (Id. at 575.) They were concerned about devoting millions of dollars to the U.S. x-ray project, considering customer interest had not advanced much, there were only a couple of customers sending product to Daniken for testing, and the cost base for the September 2014 business model was not improving. (Id.) They were also mindful that the $40 million investment for phase 1 of the project would consume Synergy's entire discretionary budget for the year. (Id. at 587.)

Today, Daniken's x-ray facility is running at only 25% capacity, and there is no dual x-ray/e-beam sterilization machine in existence that operates at a 400kW capacity.

IV.

The FTC contends that Synergy was poised to enter the U.S. market in Fall 2014 by constructing one or more x-ray facilities, and that the merger with Steris caused Synergy to abandon the effort. As a corollary, the FTC argues that documents created and testimony given after the merger was announced should be viewed with a high degree of suspicion. If the FTC is correct, the evidence should show that if the merger does not go through (either because the parties abandon it or a permanent injunction is issued), Synergy is likely to revive its plans and build one or more x-ray facilities in the U.S. in the near future.

In fact, the evidence shows the opposite in at least three ways. One, while Synergy's PLC Board had endorsed the concept of U.S. x-ray in September 2014, the business plan had not been approved and there were significant obstacles that McLean and Tyranski knew they needed to overcome in order to win approval. Two, the announced merger with Steris in October 2014 had no significant impact on Synergy's plans for U.S. x-ray. McLean and Tyranski continued to mobilize the employees under their direction to try to obtain customer buy-in, to try to bring down the cost of the new facilities, and to work with IBA to develop a dual-capability machine of sufficient power to meet Synergy's needs. Three, it was McLean, and not CEO Steeves, who made the decision in February 2015 to discontinue the U.S. x-ray project after he concluded that there was little to no likelihood of obtaining SEB approval, let alone approval from a combined Synergy/Steris board.

The evidence shows that, at the conclusion of the September 2014 SEB meeting, all that the SEB approved was the U.S. x-ray strategy. The SEB did not have the authority to approve discretionary capital expenditures of more than 10 million pounds. Nor did the PLC Board,

which *does* have the authority to approve discretionary capital expenditures over 10 million pounds, approve the September 2014 business plan. In fact, no business plan was presented to the PLC Board for approval. (Hr'g Tr. 221 (Steeves); PX00574-010.) All that Dr. Steeves requested, and the PLC Board approved, was the expenditure of 300,000 pounds each for down payments on the first two facilities, as that is what IBA demanded in order to enter an exclusivity agreement with Synergy.[7] (Hr'g Tr. 223 (Steeves); (PX00574-010.).)

In order to obtain injunctive relief, the FTC has to show a likelihood of proving at trial that, absent the merger, Synergy probably would have entered the U.S. contract sterilization market by building one or more x-ray facilities in the U.S. within a reasonable period of time. The Court concludes, for the following reasons, that the FTC has not met its burden.

A. Customer Commitments

The evidence at the hearing revealed that the most significant reason Synergy opted to discontinue the U.S. x-ray project was lack of customer commitment. According to the FTC, there is no documentation that Synergy solicited customer interest throughout 2014, and in any event, customers continue to be "interested in x-ray sterilization in the United States." (Doc #: 81 at 9.) The Court disagrees.

The evidence shows that Synergy's corporate practice is to secure take-or-pay contracts from customers before making significant capital investments, and this was certainly a significant capital investment. The first phase of the project alone required the expenditure of Synergy's entire annual discretionary budget ($40 million). Despite considerable effort on

[7]Bouradel testified at the August 2015 hearing that the PLC Board didn't even have to approve the down payments, as the total expenditure was less than 10 million pounds.

Synergy's part, as shown by the evidence and described in concise detail in McLean's declaration, not a single medical device customer would sign a take-or-pay contract, and only about 6 of the 185 customers Synergy initially targeted in its sales and marketing campaign would sign even a nonbinding letter of interest.

The evidence, in the form of minutes, emails and testimony, shows that McLean knew he had to obtain take-or-pay contracts or some form of financial commitments in order to support the U.S. x-ray business model; otherwise, the business model underpinning the x-ray strategy would not be approved by the SEB or the PLC Board. In fact, the evidence shows that McLean *repeatedly* raised his concern over the inability to obtain financial backing in any form at every SEB meeting at which the U.S. x-ray strategy was discussed, and expressed his frustration in correspondence with Dr. Coward. The evidence shows that, despite the level of interest expressed by a handful of healthcare products manufacturers in x-ray technology, Synergy could not identify a single customer who would provide the financial commitment required to build x-ray sterilization facilities in the United States. Absent the ability to demonstrate a demand for this service, McLean knew that any business model the x-ray team presented to the SEB or PLC Board would not have been approved. Indeed, McLean testified that he didn't bother to ask Gavin Hill to commence a black hat review of the model because the model just wasn't ready.[8]

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[8]Not only does the FTC challenge that a black hat review of the September 2014 business model would have ended the x-ray strategy, the FTC challenges whether Synergy really has a "black hat" process for reviewing business models at all. However, all of Synergy's witnesses who were questioned about the process testified consistently, if in varying detail, about how the corporate finance team conducts its review of proposed capital projects. (Hr'g Tr. 221 (Steeves); 412-13, 418 (McLean); 448-450 (Bouradel); 678-682 (Hill).) Even the FTC conceded that there is documentary evidence referencing the process. (See Doc #: 81 at 2 n.5.) Regardless of what the corporate financial team's review process is called, there cannot be serious dispute that the type of financial review the team conducts (and the metrics it uses) to evaluate capital investments is not standard business practice in the industry.

McLean knew that the September 2014 model, with one exception, was not based on anything more than assumptions (e.g., premium pricing, revenues, market share). (Hr'g Tr. 406-418 (McLean).)

The testimony of the FTC's own witnesses, Joyce Hansen of J & J and David Silor of Zimmer, demonstrates that their interest in x-ray sterilization in the United States was primarily academic. As Hansen testified, she preferred to remain "totally noncommittal" to Synergy until a laundry list of factors were resolved: a decision on where the x-ray facilities would be located in the United States, what machine would be used, which J & J products might benefit from x-ray sterilization, the volume of those products, the completion of functionality studies, and the approval of regulatory agencies in all countries where the x-ray-sterilized products would be sold.

The evidence shows that after McLean asked Hansen for something in writing to support the business model he was preparing to present to the SEB in September 2014, Hansen submitted a letter expressing, *at best*, lukewarm interest. (JDX1188-022.) After articulating a few reasons why x-ray sterilization is "of interest" to J & J, she explained that the primary barrier in transitioning from gamma to x-ray sterilization is "the additional work required to support the physical / functional product testing, regulatory authority submissions, and personnel time and resources for these activities." (Id.) She concluded that "this letter of interest is intended to be a means of communicating our interest in pursuing the use of X-ray processing *in the future*, and is not intended to commit J & J to processing a volume of product in a facility with Synergy Health." (Id. (emphasis added).)

The evidence shows that Hansen well knew how take-or-pay contracts work and the need for volume commitments before building new facilities. When asked about J & J's Albuquerque, New Mexico gamma sterilization facility, Hansen agreed that, in evaluating whether it made sense to build a new facility, J & J would have to consider how much volume would be put through the facility before building it, otherwise it would not be a good use of J & J's capital. (Hr'g Tr. 71-72 (Steeves).) Furthermore, the evidence shows that J & J had previously entered into a $2.8 million take-or-pay contract with Synergy to build an e-beam sterilization facility in Ireland. (Id. at 204-05.) By the time the plant was completed, another medical device company had apparently built a better device than the product J & J intended to put through the facility, and J & J wrote off the entire investment, leaving Synergy empty-handed. So, Synergy had to rely on the $2.8 million to support its investment until it could bring in additional customers. (Id.)

David Silor, Principal Sterilization Associate at Zimmer, testified that he had discussed x-ray sterilization in the U.S. with Synergy for the past two years. (Hr'g Tr. at 116.) But shortly after Zimmer had agreed to conduct a feasibility study at Daniken, Zimmer initiated a major quality remediation project at the FDA's request. (Hr'g Tr. at 119.) Consequently, its resources were shifted to support those efforts and, to this day, Zimmer has been unable to conduct any x-ray feasibility studies at all. (Hr'g Tr. at 119.)

B. Why No Take-Or-Pay Contracts: Customer Concerns

The evidence shows that the problem obtaining customer commitments had nothing to do with the merits or benefits of x-ray sterilization. Sterilization represents only about 3% of the cost of the medical device. (Hr'g Tr. 381.) This means that even if Synergy could promise a

customer a 30% price savings over gamma sterilization for a product, the conversion would only reduce the product's cost by 1%. On the other side of the ledger was the significant cost of conversion, estimated to be $250,000 to $500,000 per product. (Id. at 438.) The product would need to be tested, then the conversion would need to be approved by the FDA and the foreign counterpart in any foreign country where the product would be sold, then the site would have to be qualified; and then product would have to be put through the facility for validation. As J & J found out, this conversion process could take several years. And if a manufacturer of a medical device had been on the market for ten to forty or more years, it is likely that the regulatory standards for testing and approving these products would have gotten tighter, and the product may no longer be in compliance. (Hr'g Tr. 371-72 (McLean).) Furthermore, any x-ray facilities built in the United States would need contingency processing options, i.e., other qualified facilities where products could be sterilized if the facility needed repair. (Id. at 361.) There are no existing x-ray sterilization facilities in the United States; Synergy's would be the first. A problem in Synergy's facility could leave a customer with no readily-available alternative for sterilizing its products, and any mistake could jeopardize a manufacturer's business reputation and, consequently, its business.

In fact, the documentary evidence shows that on February 24, 2015, despite the considerable efforts of McLean and his team to obtain some kind of customer support endorsing the U.S. x-ray business model, not one customer was willing to do so. There are four emails from leading manufacturers of medical and pharmaceutical products (Covidien/Medtronics, Boston Scientific, J & J, Becton Dickinson) expressing their reasons for not signing up for the U.S. x-ray project, e.g., there is no significant benefit in x-ray sterilization over the other

sterilization modalities, the risk-to-reward ratio favors the other modalities, and the cost of transitioning multiple products from gamma to x-ray is staggering. This was correspondence McLean solicited following his meeting with the FTC on February 17, 2015, when asked for documentary evidence showing that customers had rejected x-ray.

At the August 2015 hearing, the FTC made much of the fact that McLean had solicited J & J's email and had asked Vic Baran, who wrote the email, to go back and look at the numbers again because they did not reflect the numbers McLean had previously discussed with Joyce Hansen regarding the costs involved in obtaining validation, product stability, product functionality and regulatory filings. Vic Baran then sent McLean an email with revised numbers. McLean testified that the costs in the email accurately reflected his discussions with Joyce Hansen and the FTC never called Vic Baran to the stand. In any event, the FTC did not challenge the other emails which clearly showed a lack of interest on the part of industry leaders in backing x-ray sterilization of their products at this time.

The evidence shows that Synergy itself had previously undertaken the black hat process for building a new x-ray sterilization facility in Bradford, U.K. When the Bradford gamma sterilization facility was running out of capacity, Synergy's AST team decided to present two business models to the SEB: one for building a gamma facility and one for building an x-ray facility. (Hr'g Tr. 372 (McLean.) The business models showed that the gamma financials were superior to the x-ray financials, and the project team could not drum up one customer who was willing to back the x-ray business model. (Id. at 373.) In the end, because Synergy had to do "the right thing by [its] shareholders," it built a new gamma facility with higher capacity at the Bradford site. (Id.)

Synergy's experience at Daniken only added to these concerns for several reasons. First, the predicted growth in medical product x-ray sterilization (i.e., 52% capacity by fiscal year 2015) never materialized. Today, Daniken's x-ray facility runs at 25% capacity utilization. Second, most of Daniken's x-ray business is processing non-medical products, and the non-medical business is not the business Synergy prefers to attract. (Hr'g Tr. 385 (McLean) (Synergy's core competence is working "in a highly regulated environment, where you have to deliver an exceptional quality," and the volume is stable with guaranteed revenues.) The evidence shows that over 80% of the product going through Daniken's gamma facility is medical; in contrast, only 5 to 6% of the product going through Daniken's x-ray facility is medical. (Id.) Furthermore, the medical device x-ray business at Daniken is paltry; the $100,000 generated represents only about 2% of Daniken's overall x-ray business. (Id. at 389-393.) The evidence shows that Synergy was unsuccessful in getting its existing gamma customers to convert to x-ray. When Synergy tried to leverage this conversion by telling its Daniken gamma customers that there was little or no remaining capacity at the gamma facility, the customers responded by threatening to go to a competitor's gamma facility. (Id. at 383.) McLean testified, "at one point, we were sterilizing soil, earth, at Daniken x-ray to get product through. That's not what we want." (Id. at 385.)

There was nothing McLean and Tyranski could do to change this paradigm. And of course, any further price reduction Synergy might offer to incentivize its customers would result in lower profit margins and IRR for Synergy.

C. Capital Costs

The evidence shows that, despite Synergy's best efforts, it was unable to harness the capital costs to build x-ray facilities in the United States. Synergy has only $25 to $40 million per year to spend on capital projects. The cost of building two x-ray facilities was estimated to be well over that budget. Because this investment would consume the entire annual discretionary capital budget, little risk could be tolerated. It was clearly incumbent on the project team to lock down real numbers, obtain customer commitments, and lessen capital costs. In short, this particular investment, given its enormity, was a "bet the farm" proposition for Synergy.

As the effort to develop a financial model that more accurately represented the economic realities advanced, the numbers got worse instead of better. The evidence shows that, from the September 2014 board meetings, shortly before the merger was announced, until late February 2015, when the project was abandoned, Synergy's estimates on the cost of building the facilities increased by $2.5 million once actual proposals from contractors were considered. (Invest. Hr'g Tr. 198-199 (Fry); SH00483971 at 10.) By early 2015, it became clear IBA had lost confidence that the TT300, the dual x-ray/e-beam machine on which the team's September 2014 business model was based, would deliver the required 400kW capacity. And the TT1000 with dual x-ray/e-beam technology had never been designed, built, tested or priced. The only certainty about the proposed machine was that it would cost considerably more than the initial business model estimates.

The evidence also shows that the September 2014 business model failed every one of the metrics Synergy uses to rank capital investments. With a few exceptions, the PLC Board

generally will not approve funding a discretionary capital investment without an IRR of 15%.[9] The September 2014 business model showed a 6.51% IRR—a number that included a significant accounting error that reduced the projected IRR to 3%. The erroneous IRR was reached by double-counting revenues from the Lima, Ohio plant, and it was the only number in the business model that was not the product of guesswork and assumptions. The evidence also shows that Synergy's target for ROCE was 15%. To reach this goal, the business seeking discretionary funds (e.g., AST) would have to show a ROCE of 30%. The business model presented at the September 2014 meeting would not hit the target until year 7, lowering the current company ROCE from 12.4% to 11.8%: a reportable consequence that, though seemingly small, would raise red flags for shareholders. (Hr'g Tr. 688, 698 (Hill).) Another metric the model failed to meet was cash payback. Synergy's target cash payback for all investments is no longer than five years. The September 2014 business model reflected a cash payback period of 7.7 years.

D. The Prospect of Building X-ray Facilities in the United States

According to the FTC, the current "interest" that a few customers have expressed in x-ray technology, plus the fact that some healthcare products manufacturers have recently sent a few products to Daniken for testing, shows that Synergy was poised to build x-ray sterilization facilities in the United States in the foreseeable future. The evidence of the FTC's own witnesses shows otherwise.

Hansen was asked at the hearing, if Synergy opened an x-ray sterilization facility in the U.S. tomorrow, would J & J send Surgicel to that facility for sterilization? (Hr'g Tr. 77

[9]The evidence shows that this standard could be relaxed where necessary for health and safety, to meet regulatory requirements, or to prevent the potential loss of a customer. (Hr'g Tr. 701 (Malaysia); 702- 703 (China facility); 703 (health and safety, regulatory).)

(Hansen).) Her response was that both parties would have to go through another series of hoops before doing so, i.e., J & J would have to get regulatory approval for the site, Synergy would have to go through installation and operational qualification, and J & J would have to put its product through the facility and conduct validation testing before sterilizing Surgicel there. (Id.)

Silor testified that Zimmer has not evaluated the potential use of x-ray as a sterilization method for the products it manufactures, it has not performed any feasibility testing with x-ray sterilization, it has not evaluated whether x-ray performs better than gamma for its products, it has not discussed pricing for x-ray sterilization with anyone at Synergy, and it has not analyzed the cost of switching to from gamma to x-ray sterilization in any formal way.

Silor testified that, in order to use a new technology for sterilizing medical devices that does not exist here today, Zimmer would have to do a dose mapping study, a dose setting validation, get the subdose verification level, perform sterility testing on the product, modify the manufacturing routers to indicate that the company is using x-ray instead of gamma, make the FDA submissions on Class 3 medical devices, and perform material shelf-life studies and packaging shelf-life studies. (Hr'g Tr. 130 (Silor).) He acknowledged that evaluating an alternative sterilization modality is a long-term project. (Id. at 131.)

E. The September 2014 Minutes

Much examination and cross-examination at the hearing was devoted to the accuracy of the September 2014 SEB meeting minutes. It is undisputed that Jonathan Turner, who was responsible for taking the minutes, did not transcribe the part of those minutes pertaining to the x-ray presentation until March 2015, when Dr. Steeves was preparing to meet with the FTC over

the proposed merger, and he realized that the portion of the September 2014 meeting minutes addressing the x-ray team's presentation was missing.

The evidence shows that Turner kept his minutes in a 195-page notebook, which he used to transcribe the minutes. The FTC challenged the credibility of the minutes because they were not taken verbatim from Turner's notes. However, as Dr. Steeves pointed out during his testimony, the entire SEB board was there, along with one of Synergy's outside directors, and there is no doubt that the presentation was given, the discussion took place, and the minutes that are contained in the middle of Turner's handwritten book "exist and are real." (Hr'g Tr. 246 (Steeves).) In addition, the presentation of the September 2014 SEB meeting is part of the record, and the testimony solicited at the hearing corroborated the minutes.

F. The November 2014 Earnings Call and Interim Report

The FTC contends that the following statements Synergy reported in November 2014 effectively show that Synergy had publicly committed to building two x-ray facilities in the U.S.: "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," "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 [of products from gamma sterilization to x-ray]," and "[o]ur 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." (Pl. FTC's Post-Hr'g Br. at 6-7. Doc #: 78.) However, the fact that they were reported after the merger was announced shows that no one at Synergy viewed the proposed merger with Steris as an impediment to its U.S. x-ray strategy. (Hr'g Tr. 225 (Steeves) (noting, three weeks after the

announcement, that he was trying to support the x-ray team and drum up some enthusiasm for the team's efforts "to get customers aligned with what we were trying to do in the United States." (Id.)

G. Timing

The FTC contends that it is the FTC's investigation—and not the numerous business reasons just articulated and supported by evidence—that caused Synergy to "kill" x-ray in the United States. The Court disagrees.

The timing of the decision to pull the plug on the U.S. x-ray project may actually be the best evidence that it was done for legitimate business reasons, as opposed to anti-competitive ones. If the merger with Steris was going to prevent Synergy from entering the U.S. market, Synergy would have stopped working on the U.S. x-ray project as soon as the merger was announced in mid-October 2014. Instead, following the September 2014 meetings, Synergy, led by McLean and Tyranski, continued to go all out to try to win SEB support for the business plan, and ultimately PLC approval,. The x-ray team continued to court customers, signing them up to get their products tested at Daniken. The team continued their detailed discussions with IBA on the appropriate machine. They made road trips to scout out sites, soliciting incentives from the various cities. The evidence demonstrates that this was not a sham to convince the FTC that Synergy wanted to enter the market; it was legitimate effort by Synergy employees who really wanted the project to succeed, but recognized the hurdles they needed to overcome to win approval. The fact that McLean and Tyranski decided to terminate the project in February 2015, four months after the merger was announced and in the midst of the FTC's investigation,

supports the conclusion that this was a decision reached by the project managers after serious consideration of all the business factors involved.

More likely, the last thing Synergy would have done, if the Steris merger was driving its U.S. x-ray strategy, would have been to pull the plug immediately after meeting with the FTC staff in January 2015 and hearing their objections to the merger, as Synergy had to know that doing so would only have solidified the FTC's position that the merger was driving the decision. Synergy could have kept its x-ray efforts going in order to convince the FTC that the merger with Steris was not going to prevent its entry into the U.S. market.

If Synergy had terminated the U.S. x-ray project when it entered talks with Steris, or when the merger was announced in October 2014, the Court might view this scenario differently. However, the evidence shows that the negotiations between Steris and Synergy had no effect whatsoever on the work of Synergy's U.S. x-ray team. The team continued to seek take-or-pay contracts from customers and there is evidence that Synergy incentivized that effort financially. The team continued to crunch the numbers in the business model, to negotiate concessions with states where they considered building the facilities, and to work diligently with IBA on the machine that would meet Synergy's needs.

In the end, the evidence unequivocally shows that the problems that plagued the development of x-ray sterilization as a viable alternative to gamma sterilization in 2012, when Dr. Steeves purchased Daniken, were the same problems that justified termination of the project in 2015: the failure to obtain customer commitments and the inability to lower capital costs.

(Continued on next page)

V.

Because the Court finds that the FTC has failed to show, by a preponderance of evidence, that it is likely to succeed on the merits in the upcoming administrative trial, its Motion for Preliminary Injunction (**Doc #: 5**) is hereby **DENIED**.

IT IS SO ORDERED.

/s/ Dan A. Polster September 24, 2015
Dan Aaron Polster
United States District Judge

Notice of Electronic Service

I hereby certify that on October 01, 2015, I filed an electronic copy of the foregoing Respondents' Motion to the Commission to Withdraw Matter from Adjudication, 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 October 01, 2015, I served via E-Service an electronic copy of the foregoing Respondents' Motion to the Commission to Withdraw Matter from Adjudication, upon:

Louis Fisher
Jones Day
lkfisher@jonesday.com
Respondent

Michael Fried
Jones Day
msfried@jonesday.com
Respondent

Tara Zurawski
Jones Day
tzurawski@jonesday.com
Respondent

Geoffrey Irwin
Jones Day
gsirwin@jonesday.com
Respondent

John Majoras
Jones Day
jmmajoras@jonesday.com
Respondent

Kerri Ruttenberg
Jones Day
kruttenberg@jonesday.com
Respondent

Paolo Morante
Mr.
DLA Piper LLP (US)
paolo.morante@dlapiper.com
Respondent

David Bamberger
Mr.
DLA Piper LLP (US)
david.bamberger@dlapiper.com

Respondent

Steven Levitsky
Mr.
DLA Piper LLP (US)
steven.levitsky@dlapiper.com
Respondent

Laura Kam
DLA Piper LLP (US)
laura.kam@dlapiper.com
Respondent

Julie Gryce
DLA Piper LLP (US)
julie.gryce@dlapiper.com
Respondent

Tara Reinhart
Federal Trade Commission
treinhart@ftc.gov
Complaint

Thomas H. Brock
Federal Trade Commission
TBrock@ftc.gov
Complaint

I hereby certify that on October 01, 2015, I served via other means, as provided in 4.4(b) of the foregoing Respondents' Motion to the Commission to Withdraw Matter from Adjudication, upon:

Peggy Bayer Femenella
Attorney
U.S. Federal Trade Commission
pbayer@ftc.gov
Complaint

Lynda Lao
Attorney
U.S. Federal Trade Commission
llao1@ftc.gov
Complaint

Daniel Zach
Attorney
U.S. Federal Trade Commission
dzach@ftc.gov
Complaint

John Majoras
Attorney