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

FEDERAL TRADE COMMISSION	)
	)
Plaintiff,	)
v.	)

INTRODUCTION

Defendants do not dispute that, in September 2014, Synergy's Senior Executive Board approved the U.S. x-ray strategy, the plc Board approved down payments for two IBA x-ray systems, and Synergy created a team that began implementing the x-ray strategy.[1] Synergy and IBA executed an exclusivity agreement,[2] and in November 2014 Synergy informed investors that the agreement was "for x-ray technology to be deployed in the United States."[3] These undisputed facts alone are sufficient to demonstrate that it is probable that Synergy would have entered the United States with x-ray sterilization technology within a reasonable time frame.

The evidence further establishes that since 2012 U.S. x-ray entry has been a top-down strategic investment of crucial importance to Synergy's goal of becoming the world's leading provider of contract sterilization services.[4] Synergy built in to its entry plan a lesson learned from its experience at Däniken, that initial revenues would come from non-medical products as medical device customers sought regulatory approvals for use of x-ray.[5] Synergy had generated significant interest in x-ray in the United States,[6] and was testing potential U.S. customers' products at Däniken,[7] when executives learned that the Federal Trade Commission ("FTC") was concerned about the potential effects of the Steris acquisition on Synergy's plans for x-ray.[8] Only then did Synergy AST CEO Andrew McLean and AST for the Americas President Gaet Tyranski

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[1] Steeves (Synergy) Hrg. Vol. 1 at 237:13-21; PX00574-010; Tyranski (Synergy) Hrg. Vol. 2 at 523:6-524:10; PX01410.
[2] Tyranski (Synergy) Hrg. Vol. 3 at 612:20-613:5.
[3] PX00580-004.
[4] Steeves (Synergy) Hrg. Vol. 1 at 151:21-156:7; PX00092-034.
[5] McLean (Synergy) Hrg. Vol. 2 at 308:11-15; Tyranski (Synergy) Hrg. Vol. 2 at 514:1-4, 518:22-519:5; PX00571-005 ("Focus will now turn to the industrial customers that can assist with early stage business to overcome regulatory delays.").
[6] PX00601 (Hansen (J&J) Decl. ¶ 19); PX00605 (Spang (Haemonetics) Decl. ¶ 16); PX00606 (Snyder (DCIDS) Decl. ¶ 13); PX00610 (Silor (Zimmer) Decl. ¶ 16-18); PX00611 (Elliott (Amniolife) Decl. ¶ 17); PX00625 (Zheng (Thermo Fisher) Decl. ¶ 22); PX00615 (Wilson (CTS) Decl. ¶ 23); PX00616 (Thome (St. Jude) Decl. ¶ 12); PX00617 (Irwin (Covidien) Decl. ¶ 15); PX00618 (Kook (Baxter) Decl. ¶ 8-9).
[7] *See, e.g.*, PX01272-001.
[8] McLean (Synergy) Hrg. Vol. 2 at 340:17-341:2.

"kill" the x-ray entry strategy.[9] As Mr. Tyranski wrote on February 24, 2015: "this whole FTC inquiry is going down a rat-hole . . . we cannot proceed for the Americas."[10]

In the face of this incontrovertible evidence, Defendants argue that the capital expenditure would not have been approved because, they say, Synergy could not have overcome certain financial hurdles. But the purported hurdles were never impediments and appear nowhere in Synergy's pre-merger documents. The Synergy SEB and plc Board understood all along that they were unlikely to obtain binding customer commitments before investing in initial facilities.[11] Defendants likewise exaggerate issues that arose in technical discussions with IBA, but Synergy's internal documents and IBA's testimony reveal little concern that IBA could deliver the x-ray systems Synergy required at an acceptable price. Antitrust is skeptical of, and accords little weight to, the self-serving testimony of company officials with a vested interest in the proposed transaction.[12] This is particularly true where, as here, that testimony contradicts contemporaneous evidence and finds support only in made-for-litigation documents.

Potential customers continue to express interest in Synergy's U.S. x-ray business.[13] Indeed, the "big fish" of medical device customers, Johnson & Johnson ("J&J"), is prepared to move its Surgicel product to x-ray, "paving the way for further conversions."[14] Even plc Board member Constance Baroudel recognizes that Synergy still has "an advantage, an interest" in deploying x-ray in the United States.[15]

ARGUMENT

I. X-RAY IS A TOP-DOWN, STRATEGIC INVESTMENT THAT PROGRESSED SIGNFICANTLY BEFORE THE STERIS TRANSACTION WAS ANNOUNCED.

A. X-ray in the United States is crucial to achieve Synergy's goal to become the world's leading contract sterilization provider.

Dr. Richard Steeves first posed the idea of entering the United States with x-ray at a joint strategy session between the SEB and the plc Board in October 2012.[16] Dr. Steeves knew that "Synergy cannot create competitive advantage over its competitors by offering purely EO, gamma or electron beam services."[17] He sought to differentiate Synergy from Sterigenics and Steris with x-ray.[18] Synergy knew that x-ray sterilization's advantages over gamma would be valuable to customers,[19] and would allow it to compete successfully in the United States.[20]

When Dr. Steeves hired Mr. McLean, he specifically identified developing x-ray as a "game changer" in the United States as a top priority.[21] The SEB discussed in July 2013 that, even though "x-ray may give lower returns, it was critical for the global strategy of the group."[22] After Sterigenics topped Synergy's bid for Nordion, Dr. Steeves saw an opportunity for Synergy to expand its U.S. business with x-ray "as quickly as possible."[23] Synergy's strategy was to transform the U.S. radiation sterilization business, moving gamma business to x-ray by capitalizing on customer concerns about the future availability and pricing of Cobalt-60.[24]

Senior management drove the x-ray strategy. Dr. Steeves delegated leadership of the

[16] PX00092-034; Steeves (Synergy) Hrg. Vol. 1 at 151:21-156:7.
[17] PX00092-034; Steeves (Synergy) Hrg. Vol. 1 at 154:23-155:1.
[18] PX00092-034; Steeves (Synergy) Hrg. Vol. 1 at 151:21-156:7.
[19] PX00275-007; *see also* Tyranski (Synergy) Hrg. Vol. 2 at 514:5-516:2.
[20] PX00092-034; Steeves (Synergy) Hrg. Vol. 1 at 151:21-156:7.
[21] PX00095-002; Steeves (Synergy) Hrg. Vol. 1 at 156:8-158:8.
[22] PX00891-005; McLean (Synergy) Hrg. Vol. 2 at 275:8-276:14.
[23] Steeves (Synergy) Hrg. Vol. 1 at 159:21-160:22.
[24] PX00275-003, -007; Steeves (Synergy) Hrg. Vol. 1 at 160:4-22; Tyranski (Synergy) Hrg. Vol. 2 at 512:23-513:3; Tyranski (Synergy) Hrg. Vol. 3 at 641:22-642:6.

strategy to Mr. McLean, whom he promoted to CEO of the global AST business in April 2014.[25] Mr. McLean, a member of the SEB,[26] has profit and loss responsibility for the worldwide sterilization business.[27] Gaet Tyranski, President of AST Americas, has profit and loss responsibility for the AST business in that region.[28] He and his team implemented the strategy.[29]

B. The SEB and the plc Board granted significant approvals in September 2014.

Membership on the SEB and plc Board overlaps: Dr. Steeves, Gavin Hill (Group Finance Director), and Adrian Coward (Chief Operating Officer) sit on both.[30] All three had intimate knowledge of the detailed SEB-level discussions of the U.S. x-ray strategy when they attended plc Board meetings at which x-ray was discussed. Both the SEB and the plc Board members received numerous detailed reports on the x-ray strategy.[31]

On September 17, 2014, the SEB approved the strategy to build an initial two x-ray sterilization facilities in the United States.[32] Afterward, Mr. McLean wrote:

> Most importantly, our x-ray strategy was approved this week during our Board meeting. We are going to completely transform how irradiation sterilization is done in the US and we have a compelling value proposition to support that, hence our Board having the confidence to make a very large capital investment to underpin a new nation-wide network.[33]

[25] Steeves (Synergy) Hrg. Vol. 1 at 157:7-158:8; McLean (Synergy) Hrg. Vol. 2 at 269:20-270:5.
[26] McLean (Synergy) Hrg. Vol. 2 at 269:22-24.
[27] McLean (Synergy) Hrg. Vol. 2 at 270:9-12.
[28] Tyranski (Synergy) Hrg. Vol. 2 at 502:16-503:13.
[29] McLean (Synergy) Hrg. Vol. 2 at 293:22-294:2.
[30] Steeves (Synergy) Hrg. Vol. 1 at 150:13-151:1.
[31] *See, e.g.*, PX00114-003; PX00099-012-013; PX00101-012-013; PX01408-005-014; PX00113-003; PX00571-003-004; PX00897-002-003; PX00893-001; McLean (Synergy) Hrg. Vol. 2 at 281:25-283:2, 284:11-285:17, 311:25-312:15, 356:9-357:4.
[32] Steeves (Synergy) Hrg. Vol. 1 at 237:13-21; s*ee also* PX00347-001; PX00191-001; PX00955-001; PX00808-001.
[33] PX00922-001. McLean also wrote of the SEB approval: "Clearly this is a major achievement, and marks the true beginning of what I believe will be a fundamental change to the way in which products are sterilized in the long term future in the US." McLean (Synergy) Hrg. Vol. 2 at 321:9-21; PX00271. McLean described that "what we're going to do in partnership [with IBA] will be a big disruption to the U.S. irradiation market." McLean (Synergy) Hrg. Vol. 2 at 324:10-13.

On September 18, 2014, the plc Board, including Dr. Steeves, Mr. Hill, and Dr. Coward, approved down payments for IBA x-ray/e-beam systems.[34]

The members of the SEB and the plc Board knew in September that customer commitments supporting x-ray in the United States would be unlikely. Mr. McLean made that clear to the SEB in May and July 2014.[35] They knew that the financial model for the x-ray plan forecasted an internal rate of return ("IRR") including terminal value of 15.85 percent and a 10-year IRR of 6.51 percent.[36] They knew that the capital expenditure for the first two facilities would be roughly $40 million.[37]

With full knowledge of information that Defendants now characterize as barriers to the deployment of x-ray, the SEB approved the U.S. x-ray strategy and the plc Board approved the IBA down payments.[38] Following the approvals, Synergy created the Project Endurance implementation team, which convened in Tampa for a three-day kick-off meeting and then began to execute the first two phases of the strategy, including "building and start[ing] operation of at

signed an agreement with IBA for X-ray technology to be deployed in the United States, supplemented by our in-house knowledge and expertise."[41] This referred to the exclusivity arrangement executed on October 30, 2014.[42] The Interim Results also highlighted that "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.[43] The public filing—reviewed, revised, and signed by Dr. Steeves[44]—explained that "[o]ur X-ray services are now the fast

killing X-ray for the U.S."[51] Synergy's Peter Greif responded: "Definitely a switch but not surprised based on Andrew's approach with the FTC."[52] The only rationale Mr. Tyranski provided for "killing" x-ray was the pending investigation.

Also on February 24, 2015, Mr. McLean asked Vic Baran of J&J to write a letter stating that the business case for x-ray was not compelling to J&J and to include cost assumptions that would make J&J's business case appear less compelling than Mr. Baran had estimated.[53] Mr. Baran provided the requested letter because Mr. McLean said that he needed it for Synergy management.[54] The next day, Mr. McLean cited that letter as evidentiary support for the declaration he provided to the FTC attesting to the termination of the U.S. x-ray plan.[55]

During the hearing in this case, Defendants adduced testimony from their own executives that Synergy would not have approved the capital expenditure necessary for the first two x-ray facilities.[56] Yet, Defendants did not offer a single contemporaneous business record that supported their key assertions.[57] That is because Synergy's business records tell a very different story. Thus, it is not surprising that courts give little weight to the kind of self-serving, post-acquisition testimony upon which Defendants' assertions rely here.[58] As shown in this Section, Synergy's business records are devoid of the *post hoc* concerns highlighted in the testimony of Synergy executives, and are replete with evidence that Synergy probably would have entered the United States with x-ray, but for the proposed buy-out.

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[51] PX00863-001. Mr. Tyranski testified that the FTC inquiry "was bogging the entire team down" and admitted that the FTC inquiry was the only factor he cited in his email about the U.S. project's demise. Tyranski (Synergy) Hrg. Vol. 3 at 570:10-24.

[52] PX00863-001.

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A. Synergy's entry plan contemplated growing the medical device business gradually, and a lack of commitments from customers was not an impediment.

1. Synergy targeted non-medical customers and e-beam volume from its Lima facility to base load the new facilities.

Synergy understood from its experience with Däniken that converting different types of products to x-ray would take different amounts of time, with Class III medical devices taking longest.[59] Synergy recruited customers that make non-medical products to use x-ray sterilization and make the Däniken facility profitable.[60] In addition to medical devices, Synergy sterilized products at Däniken like packaging and lab-ware, which have lower regulatory requirements to switch sterilization modalities.[61] In the United States, Synergy planned to sterilize these types of products as well as products like Zimmer's Class II medical devices that would take less time to convert to x-ray than Class III devices like J&J's Surgicel.[62] Synergy understood that it would be easiest to convince customers to convert new products to x-ray sterilization and factored this in to its x-ray strategy.[63]

In preparation for the September 2014 SEB presentation, Mr. McLean instructed Mr. Tyranski to analyze potential medical device customers as well as non-medical device (termed

delays."[65] The intention was to load the new x-ray facilities with industrial products first with medical devices to follow.[66] The SEB understood this on September 17, 2014.[67] The strategy to load the new x-ray facilities with non-medical device customers initially is consistent with Synergy's Däniken experience.[68]

Synergy also planned to move existing e-beam business from its aging facility in Lima,[69] Ohio, as part of its x-ray entry plan.[70] The e-beam business would provide base revenues to the new Midwest dual x-ray/e-beam facility as medical device customers were developed and their products validated for x-ray.[71]

"obtain as many as possible" by the first week of September.[74] Tyranski led by example, writing to device manufacturers: "Synergy is in the final stages of gaining board approval for wholesale investments in X-Ray capacity in the Americas as an alternative to gamma in the US, at comparable pricing."[75] He attached a form LOI, which made clear that Synergy was not seeking binding revenue commitments.[76] Mr. Tyranski encouraged his team to send similar emails and obtain similar LOIs.[77]

Following the September 2014 SEB approval, Mr. Tyranski and his team continued soliciting LOIs as well as product testing at Däniken; they did not solicit take-or-pay contracts.[78] Synergy sought to have products tested at Däniken to foster "widespread adoption, momentum," and to allow potential customers to start work toward regulatory approvals ahead of construction of U.S. facilities.[79] As of December 2014, "[x]-ray technology proliferation [was] accelerating with multiple US-based customers, both medical and non-medical, now testing at our Däniken, Switzerland facility in anticipation of US capacity availability in late 2016."[80] Until Mr. McLean set out to justify his termination of the x-ray plan in late February 2015, customers wersedg at o15,4.solicitBe

report that several large device manufacturers—including Thermo Fisher and Zimmer—had tested or were proposing to test products at Däniken.[83] These (and other) customers continued to express interest in x-ray, and remain interested in U.S. x-ray sterilization.[84]

3. "Big Fish" J&J now has regulatory approvals and is preparing to use x-ray, which will lead to conversion of more products by more customers.

Johnson & Johnson has a strong relationship with Synergy at multiple sterilization sites, and that relationship will continue.[85] In September 2014, J&J reported that it had received FDA approval to have Surgicel, a Class III medical device, sterilized with x-ray.[86] Although J&J had been in discussions with Synergy about using x-ray sterilization beginning in 2016,[87] J&J could not switch Surgicel from gamma to x-ray until it received regulatory approvals from all of the jurisdictions where Surgicel is sold.[88] Joyce Hansen, J&J's Vice President for Sterility Assurance, learned that J&J received those regulatory approvals during the week of August 10, 2015.[89] J&J intends to sterilize Surgicel with x-ray.[90]

Synergy expected the approval for x-ray sterilization of Surgicel to "pave the way" for additional product conversions.[91] Conversions to x-ray would follow because, as Mr. McLean said, J&J is "the big fish. If we got that big fish, others would follow. They are a key opinion

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[83] PX01272-001; Tyranski (Synergy) Hrg. Vol. 3 at 553:14-555:8. This was just three weeks prior to Tyranski's email "killing x-ray for the U.S." Tyranski (Synergy) Hrg. Vol. 3 at 554:15-25.
[84] *See supra*, n.6.
[85] Hansen (J&J) Hrg. Vol. 1 at 69:24-70:6. Synergy and J&J have worked together on x-ray sterilization for several years. Hansen (J&J) Hrg. Vol. 1 at 40:2-41:10.
[86] Hansen (J&J) Hrg. Vol. 1 at 41:11-19; PX00852-002.
[87] Hansen (J&J) Hrg. Vol. 1 at 42:13-24. Ms. Hansen understood from Mr. McLean that Synergy planned to bring x-

leader. They are highly regarded and respected."[92] With "the big fish" ready to move forward with x-ray, it is likely that additional customers learning of J&J's move would follow.

B.

the TT1000 could meet the requirements.[103] Synergy expected that pricing would be in line with the assumptions of its business model[104] and understood that pricing would decrease through negotiations with IBA.[105] As of February 6, 2015, Mr. Tyranski confirmed that it was Synergy's plan to move forward with the modified TT1000.[106] Less than three weeks later, IBA was surprised and shocked to learn that Mr. McLean had ended the U.S. x-ray plan.[107]

C. There is an absence of evidence that financial hurdles would have prevented entry.

Two plc Board members testified that a project's financials are only one factor influencing the likelihood of a project's approval.[108] But even to the extent Synergy has financial targets for capital projects, it was unlikely to reject U.S. x-ray based on its financial targets given the strategic significance of the project. In an

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SEB and plc Board encouraged management to continue U.S. x-ray.[111] Consistent with this imperative, Defendants cannot point to a single document that U.S. x-ray approval was contingent on a certain IRR or CAPEX.[112]

Moreover, the forecasted financial returns of U.S. x-ray are attractive. Though the short-term returns are challenged by the gradual nature of the business ramp-up, the returns over the life of the assets exceed Synergy's stated IRR threshold of 15 percent.[113] Metrics for both the near-term and life of the assets are presented to the SEB and plc Board.[114] Mr. Hill admitted that

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that the annual capital budget could not accommodate this project ignores that other large strategic projects (BeamOne: £26 million; Däniken: €48 million; Nordion: $800 million (bid)) had comparable or larger price tags.[122] Also, any important project could be funded through ordinary credit lines.[123]

Finally, in the reams of analyses relating to the x-ray project, in the hundreds of e-mails, and in the SEB and plc Board minutes, there is not a single mention of a requirement that customer commitments must be obtained for the project to move forward. This purported requirement was not applied to the much larger Däniken acquisition,[124] nor was it applied to the U.S. x-ray plan. Given the substantial interest in x-ray,[125] Synergy could confidently, if not conservatively, estimate revenues to underlie the x-ray facilities.[126]

CONCLUSION

For the foregoing reasons, the FTC respectfully requests that this Court find that: (1) it is probable that Synergy would have entered the U.S. market by building one or more x-ray sterilization facilities within a reasonable time frame; and (2) it is likely that the FTC will succeed in proving the merits of its claim under Section 7 of the Clayton Act, and, accordingly, that the Court grant a preliminary injunction.

[122] Hill (Synergy) Hrg. Vol. 3 at 725:2-5, 756:2-757:4.
[123] Hill (Synergy) Hrg. Vol. 3 at 757:5-11; PX00791 (Hill Depo.) at 231:20-23.
[124] Hill (Synergy) Hrg. Vol. 3 at 714:14-17; PX00423-019; PX00791 (Hill Depo.) at 249:22-250:5.
[125] *See supra*, n.6.
[126] PX00215-001; McLean (Synergy) Hrg. Vol. 2 at 325:16-327:7.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby **CERTIFY** that on August 28, 2015, a copy of the foregoing Plaintiff Federal Trade Commission's Post-Hearing Brief was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system ("CM/ECF") to all parties indicated on the electronic filing receipt. Parties may access this filing via the Court's CM/ECF system.

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