

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

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

STERIS CORPORATION, *et al.*,

Defendants.

No. 1:15-cv-1080

The Hon. Dan A. Polster

DEFENDANTS' POST-HEARING BRIEF ON SYNERGY NON-ENTRY

PUBLIC VERSION

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The Court has requested briefing on the single question of whether the evidence shows a probability that Synergy Health plc would have entered the U.S. market by building one or more x-ray facilities within a reasonable period. No rational public company would have done so when confronted with the challenges, uncertainties, and feeble financial returns faced by Synergy. The FTC cannot demonstrate a probability of Synergy's near-term entry. The FTC's case focused on *when* the project ended, not on whether it would have overcome the substantial obstacles to corporate approval within any reasonable time. Layers of uncertainty surrounded the project to the very end and, without the merger, approval by the Board of Directors (the "PLC Board") for a \$40 million investment (for only the first phase) was likely never to come. The FTC's failure to establish these fundamental preconditions to the purported actual potential competition theory precludes a reasonable likelihood of success on the merits.

The preliminary model first presented to the Synergy management team (the "SEB") in September of 2014, even with its utterly speculative assumptions, fell far short of the standard benchmarks for Synergy approval. Consequently the SEB sanctioned only the x-ray market strategy; it did not provide, nor could it have provided, the required PLC Board approval for a \$40 million investment case. The complete investment case, including a final financial model that addressed the numerous problems in the September version, would have required (1) SEB endorsement, (2) a rigorous "black hat" financial review by the finance department, and ultimately (3) PLC Board review and approval. The September 2014 financial model, which had not been reviewed by the finance department, was contemporaneously characterized by Synergy's CEO as "poor" and lacking in the "robustness and confidence" necessary for a future approval. Any prospects for eventual approval fell apart as additional financial, technological, and business obstacles arose through the end of 2014 and into the new year.

There is no basis to conclude that Synergy would have relaxed or abandoned its financial standards for what would have been the largest capital investment for a greenfield or expansion project in the company's history. An independent Synergy Director and Synergy's CFO both testified that Synergy would have applied heightened scrutiny to the x-ray project due to its risk profile and the company's desire to avoid replicating, on an even larger scale, the hugely disappointing results with x-ray at Däniken.

The FTC's focus on whether its investigation played a role in the company's termination decision is misplaced; the project was ended for wholly legitimate reasons, and in any event the question is whether anything would have changed the woeful risk and financial profile of the project. On this critical issue, the FTC simply assumes that the Synergy management team and PLC Board would have approved the project (i) although it failed to meet key financial hurdles (internal rate of return, return on capital employed, payback period) that had been clearly communicated, both internally and externally; (ii) with no binding customer commitments, despite Synergy's longstanding requirement for "baseload" customers/upfront committed revenues; (iii) with escalating costs, despite a mandate from the September 2014 meeting to reduce capex; and (iv) with new, unproven x-ray equipment, despite knowing that the supplier's earlier assurances about a different machine were unreliable. Even if somewhat accelerated by the FTC's inquiry, the outcome was inevitable and near-term. Defendants do not need to prove a negative – that Synergy would not have entered, let alone when the project would have ended; rather, the FTC must prove that entry was likely in the near future. It cannot meet that burden.

I. THE FTC HAS FAILED TO PROVE LIKELY ENTRY BY SYNERGY.

A. Däniken Demonstrated That X-Ray Technology Carried Heightened Risk.

Synergy's experience with its x-ray plant in Däniken provides a critical overlay to its consideration of U.S. x-ray. *See, e.g.*, Hr'g Tr. at 194:13-198:22, 382:25-383:11, 393:21-394:2,

683:9-684:1. When Synergy acquired the Däniken x-ray and gamma facility in 2012, the x-ray facility was using █████ of its capacity, PX00423 at 30 (Table 3.10); Hr’g Tr. at 195:4-5, 654:10-19, but the investment case assumed that it would reach █████ capacity utilization by FY2015, and █████ by FY2016, PX00423 at 30; Hr’g Tr. at 655:1-8. The investment case also assumed that Synergy could make the facility profitable by shifting the product mix from industrial customers to Synergy’s preferred medical and pharmaceutical products. These hopes proved unrealistic. *See* JDX3594 at 3; JDX1883 at 4; Hr’g Tr. at 281:18-21, 303:13-23, 393:13-15, 459:1-6, 655:17-22, 676:3-677:14. The actual utilization, near the midpoint of Synergy’s 2016 fiscal year, is only 25% to 30% capacity. Hr’g Tr. at 655:9-16.¹ Moreover, the x-ray business includes far fewer medical and pharmaceutical products (less than █████) than the adjacent gamma plant (more than █████). *See* JDX3644; Defs.’ Expert Report at 14-15, Ex. 8; JDX2612; JDX2858 at ¶ 4; Hr’g Tr. at 197:13-198:13, 391:2-15. Synergy’s experience at Däniken is a cautionary tale about x-ray, and Synergy is determined to ensure that any future x-ray investments are less costly and better supported by actual, as opposed to assumed, revenues from healthcare customers. *See* Hr’g Tr. at 393:21-394:16, 465:5-16, 683:2-684:11.

B. Synergy Sought To Develop A Viable X-Ray Business Plan.

Motivated by his belief in x-ray sterilization, and following the consolidation of cobalt-60 supplies in the hands of Sterigenics, a competing contract sterilization provider, Synergy’s CEO, Dr. Richard Steeves, decided to explore the possibility of commercial x-ray sterilization in the U.S. and elsewhere, *see* JDX1424 at 1; Hr’g Tr. at 157:4-24, 213:5-12, 372:2-20, although this was an “intuitive[.]” judgment not based on financial analysis, PX00095 at 2. In 2013, he tasked

¹ Had Synergy not forced some customers from the gamma side of the operation (which was at capacity) to switch to x-ray, JDX1510 at 1; JDX2858 at ¶ 4; Hr’g Tr. at 382:25-384:20, its x-ray would be operating at only █████ capacity, JDX1510 at 1.

Andrew McLean, the head of Synergy's AST business, with resolving key impediments to its success: (1) developing efficient and cost-effective technology; (2) developing a business plan to require significantly less capex than Däniken; and (3) overcoming customer reluctance to switching sterilization modalities. *See* Hr'g Tr. at 195:18-197:9, 202:5-203:20, 213:5-12.

In May 2014, Mr. McLean provided an update to the SEB about a possible U.S. x-ray project. *See* JDX1511 at 13; Hr'g Tr. at 378:11-379:10. He explained the ongoing work, but made clear his "broken record" concern that difficulties in obtaining take-or-pay contracts from sterilization customers would hinder the viability of the project. JDX1510 at 1; *see* JDX1511 at 13; Hr'g Tr. at 379:3-10; 381:23-382:8. Such contracts, where customers agree to process a volume of products or to pay as if they had, are the standard measure of customer commitment. *See* Hr'g Tr. at 203:16-20, 204:21-206:1. At the next SEB meeting in July 2014, the executives saw a more detailed update on U.S. x-ray, but it still did not contain Synergy's standard financial modeling for capital investments. *See* PX00101 at 12-13. Mr. McLean again warned the SEB that, despite interest in U.S. x-ray, customers remained unwilling to commit. *See id.* at 13; Hr'g Tr. at 214:21-215:9. Following that meeting, Mr. McLean asked U.S. AST head, Gaet Tyranski, to develop a strategy and financial case by exploring locations, equipment, and other considerations for possible x-ray expansion. *See* PX00898; Hr'g Tr. at 503:16-505:16. Mr. Tyranski and his team continued efforts to foster customer interest, with the ultimate goal of securing baseload customers and binding commitments. Hr'g Tr. at 404:3-405:12.

Mr. Tyranski's September 2014 presentation to the SEB sought approval for a strategy that contemplated offering both x-ray and e-beam sterilization at two facilities, with another two to be built starting in FY2016. JDX2471 at 15-18; PX00104 at 4. Construction costs for the first two plants were assumed to be about \$20 million each. PX00104 at 21; Hr'g Tr. at 587:16-19.

No financial models for the subsequent contemplated facilities were ever prepared. Hr’g Tr. at 313:22-314:4, 693:9-23.

C. The U.S. X-Ray Business Model Failed To Meet Required Criteria.

The SEB did not have the authority to approve capital expenditures of the magnitude required for the project. *See* PX00895 at 46; Hr’g Tr. at 446:25-447:23, 609:1-15, 647:23-648:6. But it did approve the general x-ray strategy, which allowed the business team to continue trying to develop a satisfactory business model. *See* Hr’g Tr. at 237:13-25, 257:19-258:5, 419:8-420:14. Everyone involved understood that the present model fell far short of what would be needed to obtain sign-off from the SEB, a favorable recommendation from the company’s central finance office, and ultimately approval by the PLC Board. *See* JDX1746 at 1; PX00194 at 12; PX00215; Hr’g Tr. at 609:11-610:3; McEvoy IH Tr. at 174:13-22; Berger IH Tr. at 211:3-12.

Because the financial proposal fell “woeful[ly]” short on a variety of grounds, Gavin Hill, Synergy’s Group Finance Director and member of the SEB and PLC Board, considered the September presentation a mere “progress update” rather than a fully formed business plan. Hr’g Tr. at 683:2-684:1; *see* JDX2260 at 1; Hr’g Tr. at 692:11-18; Hill IH Tr. at 160:11-23, 182:16-183:16. Dr. Steeves approved of the strategy, but contemporaneously expressed strong concerns about the economics, telling Mr. McLean that the financial work “was poor and [did not] provide the robustness and confidence necessary” for approval. PX00215. Adrian Coward, Synergy’s Chief Operating Officer, opined “that rapid work” was needed “to build up the cost base.” JDX2471 at 18.

The business team, for its part, acknowledged that the plan presented to the SEB was far from satisfactory or rigorous. Hr’g Tr. at 405:25-406:18, 407:10-408:15, 408:20-409:17, 411:3-412:2, 415:5-18, 593:16-594:3, 595:15-596:2, 597:2-22, 598:18-599:4; Tyranski IH Tr. at 197:21-198:9; Fry IH Tr. at 198:23-199:15. The model assumed that Synergy would quickly

obtain 15% of the U.S. contract and in-house radiation sterilization gamma market, PX00104 at 3, 5, a number lacking any support or analysis, *see* Hr’g Tr. at 407:10-408:4; Tyranski IH Tr. at 197:21-198:9. It assumed that the first two plants would be working at nearly 100% capacity within the first six years, PX00104 at 27; JDX2471 at 18, despite the absence of any customer commitments and despite Synergy’s experience with very weak x-ray demand at Däniken, *see* Hr’g Tr. at 411:3-412:10. And its estimates for construction costs and timing were “pie-in-the-sky” guesses. Fry IH Tr. at 198:23-199:15. Even these optimistic and unsupported numbers produced an internal rate of return (“IRR”) of only 6.51%, PX00104 at 32; Hr’g Tr. at 417:17-19, 603:14-604:13, far below the 15% required by the PLC Board, *see* JDX1858 at ¶¶ 7-8, 11, 17; JDX2859 at § 9.3.2; JDX2863 at 1; Hr’g Tr. at 599:22-600:4, 685:25-686:19.

Accordingly, Dr. Steeves instructed Mr. McLean to continue developing the business plan and to improve the finances. *See* Hr’g Tr. at 226:23-228:13, 251:25-256:12, 257:19-298:5, 420:1-14. Mr. McLean, in turn, told his team that future approvals would hinge on the successful resolution of these concerns. *See* JDX1746 at 1; PX00144 at 12; Hr’g Tr. at 609:11-610:3, 610:7-23, 612:6-19; McEvoy IH Tr. at 174:13-22. None of these requirements was ever satisfied; to the contrary, financial prospects for U.S. x-ray continued to deteriorate. *See, e.g.*, Hr’g Tr. at 422:18-423:1, 424:15-426:2, 631:16-24.

1. The September 2014 Model Failed Key Financial Requirements.

Synergy must allocate its limited capital among many more proposed investments than it can fund each year. *See* Hr’g Tr. at 453:4-454:7, 648:7-14, 650:17-24. It has developed a set of financial metrics to allow it to invest in projects that maximize returns while minimizing risk. *See* JDX2859; Hr’g Tr. at 656:11-657:15, 665:21-666:5, 668:3-19, 662:3-6. If a proposed investment does not satisfy these expectations, it will not be approved. Hr’g Tr. at 652:2-8.

One “extremely important measure” required by the PLC Board is an adequate expected

ten-year IRR. *Id.* at 416:12-15, 599:22-600:4, 657:6-20. This metric “show[s] whether a project is going to generate shareholder value and deliver as [Synergy’s] shareholders expect.” *Id.* at 657:13-15. Barring “exceptional circumstances” not present here,² the PLC Board will not approve funding for a discretionary capital expansion or greenfield project without a ten-year IRR of at least 15%. JDX1858 at ¶¶ 7-8, 11, 17; Hr’g Tr. at 659:17-660:7, 700:21-701:1. This has been communicated internally within Synergy and externally; investors expect that rate of return on Synergy’s investments. *See* JDX2859 at § 9.3.2; Hr’g Tr. at 416:12-15, 657:6-20.

Mr. Hill observed at the September meeting that the 6.51% IRR in the model was “extremely low,” “very poor,” and “far short of [the] 15 percent” threshold. Hr’g Tr. at 683:4-684:1, 686:15-19; *see id.* at 417:20-23. Worse still, it included a calculation error that essentially doubled its size. *Id.* at 694:3-695:6. He discovered “that [the business team] had double-counted” revenues, treating as new revenue business that in fact was assumed simply to transfer from Synergy’s own Lima, Ohio, e-beam facility. *Id.* at 694:3-14. Correcting this error and making it consistent with the company’s financial procedures “reduce[d] the internal rate of return from six percent to three percent,” a rate that Mr. Hill observed is better suited for investing in government bonds. *Id.* at 694:15-695:6.

Another critical financial metric is the Return on Capital Employed (“ROCE”). This is “one of the most important measures for the business, because it is used very extensively by investors,” and is essential to Synergy’s capital-intensive business. *Id.* at 665:7-13. Synergy has “worked extremely hard” to increase its aggregate ROCE from approximately 10%, when Mr. Hill joined, toward a target of 15%. *Id.* at 670:2-10; 674:16-24. The current group ROCE is

² The IRR requirement could be relaxed where necessary for health and safety, to meet regulatory requirements, or to prevent the potential loss of a customer. *See* Hr’g Tr. 701:10-13 (Malaysia), 702:13-703:1 (China JV facility), 703:5-6 (health and safety, regulatory).

12.4%. *Id.* at 669:3-670:1. To reach the group ROCE of 15%, Mr. Hill has established a business level ROCE goal of 30% for all investments. JDX2864 at 10; JDX2865 at 8; JDX2866 at 10; JDX2867 at 11; JDX2868 at 9; Hr’g Tr. at 670:11-15.

The September model, even in the most optimistic of circumstances, would not hit Synergy’s target “until year seven, which is a long way out.” Hr’g Tr. at 688:12-21. This ROCE deficiency in such a large project would have had reportable consequences for the group’s aggregate ROCE. *See id.* at 698:16-24. It would have lowered the group ROCE from 12.4% to 11.8%, “and [Synergy] would not recover,” again, even optimistically, to the preexisting 12.4% level for six years. *Id.* at 698:10-19. That seemingly small effect would have reversed several years of efforts and triggered an obligation to advise shareholders “why the company was investing in a project that was reducing” its ROCE. *Id.* at 698:20-24.

Another important and documented criterion for a Synergy investment is cash payback, which refers to how quickly the company will recoup its working capital from an investment. *See id.* at 667:9-13. Synergy’s target cash payback for all investments is no longer than five years. JDX2859 at § 9.3.4; Hr’g Tr. at 667:22-668:2, 770:23-771:13. Like all the other financial metrics, the September U.S. x-ray project fell well short of this target, with a pay-back period of 7.7 years. JDX1775 at 35; Hr’g Tr. at 771:10-24.

Despite vigorous efforts by Mr. Tyranski’s business team, the economics of the U.S. x-ray project only worsened after September 2014. Synergy’s initial guesses about the costs of the facility and shielding were much too low. *See Fry IH Tr.* at 198:21-199:6. And no solutions were ever found for the other financial and technological problems. *See Hr’g Tr.* at 226:10-22, 408:23-409:17, 422:6-423:1, 425:16-21.

2. The Project Never Obtained Any Customer Commitments.

Financial measurements are important, but if they are predicated on revenue not

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supported by committed customers, the entire plan is at risk and Synergy will reject it. *See* JDX2858 at ¶¶ 3, 39, 59-60; Hr’g Tr. at 394:17-395:7, 408:20-409:17, 465:3-466:3. The PLC Board thus requires firm customer commitments to approve any discretionary capital expansion or greenfield project. *See* JDX2858 at ¶¶ 38-42, 44-45, 48, 50-57, 59-60; JDX2876; Hr’g Tr. at 203:12-25, 221:10-222:6, 315:10-22, 465:9-16, 475:15-24. It has rejected projects lacking adequate customer commitments even with IRRs well above 15%. For example, the PLC Board rejected a proposed investment in [REDACTED] [REDACTED] despite ten-year IRRs near 25% for this reason. *See* JDX2876; JDX2858 at ¶¶ 59-60. It also twice rejected a [REDACTED] [REDACTED] with an IRR well over 15%. *See* JDX2235 at 2; JDX2858 at ¶ 39; JDX1818. [REDACTED] particularly instructive, because, after these rejections, the business team went on to obtain take-or-pay contracts, and the PLC Board then approved the project. *See* JDX1818 at 1; JDX2858 at ¶ 39.

Customer commitments were especially important to U.S. x-ray. First, Däniken showed the risk that x-ray facilities may not obtain adequate business in terms of revenue or product mix. *See* JDX1510 at 1-2; PX00819 at 6-7; Hr’g Tr. at 197:11-198:3, 286:23-287:6, 290:10-291:6, 393:21-394:2. And second, the proposal involved a sterilization method that, while long available, was almost entirely absent from the U.S., had no demonstrated U.S. market demand by medical device or pharmaceutical customers, and would need to overcome known regulatory barriers and customer reluctance. *See* JDX2858 at ¶ 63; JDX1510 at 1-2; Hr’g Tr. at 360:23-361:21, 362:20-363:24, 369:20-370:14, 381:5-22; Hill Tr. at 157:4-16.

Throughout 2014, Mr. Tyranski’s team solicited customer interest in U.S. x-ray. *See* Hr’g Tr. at 549:5-550:23. By the time of the September 2014 SEB meeting, a few potential customers had expressed general interest, but none had committed. *See* JDX2471 at 18; Hr’g Tr.

at 314:12-21; McLean IH Tr. at 116:8-21. Indeed, none ever did. *See* Hr’g Tr. at 365:4-14, 368:10-17, 399:10-12.

A handful of customers did agree to sign non-binding letters of interest (“LOIs”). For example, Joyce Hansen of Johnson & Johnson signed an LOI, but only after rejecting a draft provided by Synergy and using a substitute that failed even to refer to types of products or volumes to be considered for x-ray. *See* JDX1186 at 1-2; PX00826 at 2; Hr’g Tr. at 55:16-69:17. The letter, which is expressly non-committal, cites the “barriers” that would impede a switch to x-ray and concedes that J&J did not conduct a “full analysis” of candidate products. JDX1188; Hr’g Tr. at 58:4-6. Ms. Hansen testified that J&J still has not done a “full analysis” for U.S. x-ray. Hr’g Tr. at 67:9-21. David Silor of Zimmer made clear that his company’s “interest” in x-ray did not extend to having taken any concrete steps toward determining if it could or should adopt that technology. *Id.* at 142:5-144:4. Mr. Silor agreed that this interest amounted to nothing more than a vague sense that “it might be a good idea,” or “[m]ight be nice to have.” *Id.* at 143:16-24. Neither J&J nor Zimmer came close to committing to U.S. x-ray.³

Although completely non-committal, these were the best responses, which is why the FTC cherry-picked those two to testify at the hearing. Far more prospects refused to sign even non-binding LOIs. *See, e.g.*, JDX2506 at 1 (refusing to sign an LOI because “not sure how X-Ray could help” [REDACTED]); PX00290 at 1 (noting that [REDACTED] “would not sign an LOI at this time”). And many customers refused even to *discuss* x-ray with Synergy. *See, e.g.*, JDX1637 at 1 ([REDACTED] could not even “consider” x-ray without a demonstration of improved pricing over gamma); JDX2421 at 1 ([REDACTED] opining that “X-ray simply has not proven to

³ Ms. Hansen testified that J&J recently received global approvals to sterilize one product, Surgicel, with x-ray. Hr’g Tr. at 42:4-7. She offered no indication that J&J would consider sterilizing Surgicel in the mainland U.S. That product is manufactured in Switzerland and Puerto Rico. *Id.* at 76:15-23.

have any significant benefit over the big three forms of sterilization to warrant real interest”).

Other potential customers never even responded to Synergy inquiries about x-ray. *See, e.g.*, PX00150 (██████████); PX00159 (██████████); PX00164 (██████████); PX00165 (██████████).

By the time Synergy canceled the x-ray project, it had exhausted the list of potential customers for U.S. x-ray and had attained no concrete results. *See* JDX2692. Not one customer committed to x-ray. JDX2858 at ¶ 63; JDX2450 at 2; *see* Hr’g Tr. at 208:15-208:22, 399:10-12, 365:1-14, 368:10-17, 466:10-19, 529:22-530:9. Customers had no clear reason to undertake the significant transaction costs, regulatory hurdles, delays, and uncertainties associated with such a move. *See, e.g.*, JDX2421 at 1; JDX2446 at 1; JDX2477; Hr’g Tr. at 360:23-361:21, 362:20-363:24, 421:5-7. These responses were particularly significant given that the September model “assumed premium pricing”; it would be unrealistic to imagine that this “highly ambitious and optimistic” assumption could be realized without commitments and in the face of repeated warnings by customers that they would not consider x-ray unless the price was *lower* than gamma pricing. JDX1637 at 1; JDX1775 at 14; Hr’g Tr. at 290:10-291:6, 690:4-691:11.

Every Synergy witness who testified at the hearing made clear that the wholesale absence of firm customer commitments would, by itself, have precluded PLC Board approval. *See* Hr’g Tr. at 221:10-222:6 (Steeves), 419:2-7 (McLean), 465:7-466:3 (Baroudel), 529:11-530:9 (Tyranski), 680:19-681:12 (Hill). It is inconceivable that Synergy would have invested \$40 million for two x-ray plants, let alone the far greater amounts required to complete the additional facilities contemplated by the September 2014 model, without substantial revenue commitments ensuring that they would be financially viable and fare better than the x-ray site at Däniken. *See* JDX1510 at 1; Hr’g Tr. at 696:15-24. And even if Synergy had somehow managed to obtain

take-or-pay commitments to support the revenue assumptions (even from a large global customer), this would merely have supported the insufficient IRR, ROCE, and cash return of the model; it would not have improved those financial deficiencies. *See* Hr’g Tr. at 603:17-604:13.

3. The Availability Of Technologically Adequate X-Ray Equipment Became Increasingly Uncertain Over Time.

The one piece of the September plan that seemed at the time to be more than guesswork was the equipment—IBA’s Rhodotron TT300. Hr’g Tr. at 424:17-18, 427:22-25; Fry IH Tr. at 234:8-16. IBA’s typical TT300 had “duo” capabilities; it could run either e-beam or x-ray. Hr’g Tr. at 295:7-12, 322:4-14, 361:24-362:7, 419:18-23, 423:20-424:14, 582:4-12. But the greater capacity was on the e-beam side. *See* JDX1975 at 1. A duo machine was essential to the business model under consideration, because it assumed significant e-beam revenue for years. *See* PX00819 at 5; JDX1775 at 25, 27; JDX1722 at 1; Hr’g Tr. at 406:7-18. However, because Synergy primarily needed x-ray at these plants, the Rhodotron had to have more x-ray than e-beam capacity, *see* JDX1975 at 1; JDX1760 at 2 (slide 20); Hr’g Tr. at 582:20-583:12; Bol Tr. at 158:23-160:14, which presented a novel technological challenge for IBA, *see* Hr’g Tr. at 361:22-362:9, 576:22-577:15; Fry IH Tr. at 234:8-16.

The IBA machines had to satisfy several power requirements; they needed 400 kW and 7 MeV for x-ray, and 100 kW and 10 MeV for e-beam. JDX1920 at 1; PX00548 at 1; Hr’g Tr. at 582:20-23. The TT300 design could not reach the 400 kW requirement, but IBA promised to redesign the TT300. *See* Hr’g Tr. at 582:7-12, 614:23-615:18. In late 2014, [REDACTED]

[REDACTED] *See, e.g.,* JDX1978 at 1. [REDACTED], *see* PX00237 at 1, 3, but [REDACTED]

[REDACTED] PX00548 at 1; PX00415 at 3; JDX2200 at 2; Hr’g Tr. at 625:14-22.

That did not put the issue to rest. Like the TT300, the larger machine still required reengineering and reconfiguration. *See* Hr'g Tr. at 426:5-427:5, 627:6-14. [REDACTED]

[REDACTED]
PX00549 at 1. [REDACTED]

[REDACTED] JDX1042 at 29; Bol Tr. at 95:6-17, 196:4-14. Mr. Tyranski, who was overseeing the discussions with IBA, understandably did not feel very assured [REDACTED] *See* Hr'g Tr. at 577:6-15, 629:8-11; *see also* Hr'g Tr. at 426:22-427:9.

In order to design, build, test and price the machine, IBA needed additional specifications. *See* JDX1970 at 1; McEvoy Tr. at 76:24-77:25, 122:11-21; Fry IH Tr. at 161:12-162:3; Berger IH Tr. at 220:6-222:3; McEvoy IH Tr. at 29:21-30:19. These come from customers, and address the dimensions, type, dose and other details of the processed products. *See* PX01316 at 1; McEvoy Tr. at 76:24-77:25, 122:11-125:8. [REDACTED]

[REDACTED] McEvoy Tr. at 125:9-18. [REDACTED]

[REDACTED] *See* Hr'g Tr. at 422:18-423:1, 623:18-624:14, 626:21-627:2. This uncertainty was never resolved. *See* JDX1970 at 1; PX00240 at 3; McEvoy IH Tr. at 200:5-22. Even if the TT1000 had ultimately proved feasible, Synergy could not be assured that its budgeted expenditures for the IBA Rhodotrons were realistic. *See* JDX2200 at 3; PX00549 at 1.

D. The X-Ray Project Could Never Satisfy The Requirements Of Synergy's Remaining Evaluation And Decisional Processes.

Once a business strategy is approved by the SEB, the team must resolve outstanding deficiencies in the business plan, such as those discussed in the preceding sections. *See* Hr'g Tr. at 680:19-682:11. If the team is able to develop the plan into a form that is sufficiently concrete

and rigorous, it must undergo a thorough, de novo financial review, known as a “black hat” process, by the Group Finance Director, Mr. Hill, and his central finance team. *Id.* at 221:10-222:2; *see id.* at 471:20-472:21, 680:19-682:11. The PLC Board mandated the black hat review process because of concerns over investment forecasts that had not been met in past investments, *see* JDX2583 at ¶¶ 25, 28, including, in particular, Däniken, *see id.* at ¶ 28.

The black hat process would include review by experienced and senior Synergy financial personnel. *See* Hr’g Tr. at 221:10-222:2, 412:16-413:7, 448:12-450:25, 677:24-679:9, 681:2-682:11. Recognizing the possibility that local business teams could become advocates for a project, the process was designed to provide rigorous, dispassionate financial evaluation by disinterested financial experts. *See id.* at 221:10-222:2, 448:12-450:25, 678:21-679:5. The U.S. x-ray project never came up for a black hat review, because the financials failed on their face and such a review would have been pointless. *See id.* at 418:20-420:14; 706:16-707:16. If those initial financial problems had ever been resolved, the project would still have had to survive a black hat review. *See id.* at 450:25-452:4, 707:16-707:23. And even then, surviving the black hat process only makes a proposal eligible to compete against other project proposals; it does not guarantee funding. *See id.* at 449:8-450:4, 472:22-473:9, 661:22-662:6. The PLC Board must prioritize among financially acceptable projects to select those projects that maximize expected returns while minimizing risk. *See id.* at 447:20-449:7, 661:22-662:6. The future competing demands for capex, which cannot be predicted, add another layer of significant uncertainty to whether any project would be funded. *See id.* at 227:8-228:13, 453:1-456:2. Moreover, alternative capital project proposals from the hospital sterilization business often come with committed revenues and higher IRR, which would make them more appealing than an x-ray proposal. *See id.* at 228:6-10, 691:12-692:7.

E. Synergy Has Terminated The U.S. X-Ray Project, Thus Precluding Entry In The Foreseeable Future.

The FTC must demonstrate how Synergy would have overcome the financial, technical and customer obstacles that stood in the way of approval. It must show that the SEB, Mr. Hill, and ultimately the PLC Board would have approved spending its entire discretionary capex budget for the year, over \$40 million, for the first two sites of this project. There simply is no basis for such a conclusion. The revenues are still completely at risk despite vigorous efforts to get customer commitments. The IRR has gone from very bad to nearly non-existent when the double counting of revenues is corrected. The capex amount is going up, not down. The technology has gone from seemingly solid to unknown. Even the larger (and more expensive) version of the equipment deemed necessary in January was a dream rather than a reality.

By March 2015, everyone involved in the U.S. x-ray project was acutely aware both of the deep financial, revenue, and technological problems it faced, and the fact that these problems had grown worse since they had arisen. *See, e.g., id.* at 226:23-229:13. The ongoing consumption of time and resources demanded by the FTC's merger investigation may have been one of the considerations discussed when Synergy decided, for a host of sound business reasons, not to expend further resources on the doomed project. But the evidence at the hearing showed unambiguously that even if Synergy had continued with the project for additional months (or even years), there was no realistic prospect for making a compelling case to the PLC Board for approval of the investment, especially when compared to other potential opportunities in Synergy's AST, HSS and Linen businesses. *See, e.g., id.* at 221:10-222:6.

CONCLUSION

The FTC has failed to meet its burden of proving that entry was even possible in the reasonable future, let alone probable. The Court should deny the preliminary injunction.

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Respectfully submitted,

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I hereby certify that on August 28, 2015, a copy of the foregoing was filed electronically with the Clerk of the United States District Court for the Northern District of Ohio, Eastern Division using the CM/ECF system, causing it to be served on all registered users to be noticed in this matter, including:

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