

**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 RESPONSE BRIEF

PUBLIC VERSION

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The FTC identifies no credible path for the U.S. x-ray project to clear the outstanding decisional hurdles needed to obtain ultimate PLC approval, particularly in light of the serious and worsening financial, business, and technological problems. Defendants have documented these numerous impediments with detailed facts, whereas the FTC airily asserts that these problems could somehow be fixed, or that Synergy's management and the company's board of directors would have waved them off because they had hopes of success. In effect, the FTC asks the Court to substitute the FTC's own untested business judgment for that of Synergy. But the question is what Synergy actually would do but for the merger, not what the FTC thinks it could or should do. On that question, the evidence — both the pre-merger, regular course documents and the testimony at the hearing — uniformly confirms that Synergy would not have made a decision to risk over \$40 million on an x-ray roll-out in the U.S.

A. The U.S. X-Ray Business Model Failed To Meet Key Financial Requirements.

The FTC offers only a cursory discussion of the financial objectives governing Synergy's capex investments, and how U.S. x-ray failed to meet them. *See* FTC Br. at 13-15. The FTC never mentions, let alone addresses, key financial requirements like ROCE and the cash payback period. While the FTC acknowledges IRR, it does so only fleetingly on page 14 of its brief. It offers no defense of the accounting error that improperly doubled the IRR of the x-ray business case. Hr'g Tr. at 694:3-695:6. The FTC also continues its hearing strategy of substituting its own business judgment for that of Synergy by replacing the 10-year IRR requirement with terminal IRR. Unlike acquisitions, *see id.* at 687:1-21, and regardless of what the FTC in its business wisdom may prefer, Synergy consistently applies the 10-year IRR requirement for capex projects like U.S. x-ray because “[i]t's difficult even to forecast ten years, let alone any longer than that,” and Synergy's “investors are quite short term in nature,” usually looking about “three years” into the future. *Id.* at 659:19-660:7.

Rather than appropriately addressing these issues in a substantive way, the FTC attempts to dismiss these realities with several false generalities. First, the FTC misrepresents that the financial requirements “appear nowhere in Synergy’s pre-merger documents.” FTC Br. at 2; *see also id.* at 13-15. This is flatly wrong. Every one of the key financial requirements is thoroughly documented in regular course business documents that long pre-date both the September SEB meeting and the October merger announcement. *See, e.g.*, JDX2859; JDX1640 at 1; JDX2870 at 7; JDX3646 at 1-5 (Sources JDX2864-69, JDX2871). Mr. Hill explained at length that the 15% IRR requirement is set out in a policies and procedures manual enumerating group financial hurdle rates. *See Hr’g Tr.* at 655:25-668:7 (discussing JDX2859). As Mr. Hill noted, this document expressly “defines the 15 percent IRR.” *Id.* at 657:16-20. The same policy manual defines the group-wide ROCE and cash payback requirements. *See* JDX2859 at § 9.3.3 (ROCE), § 9.3.4 (cash payback). Mr. Hill marched through report after report that documented, over a period of years, the need for investments of the business units to satisfy a 30% ROCE goal to achieve a company goal of 15%. *See* JDX2864 at 10-11 (July 2011); JDX2865 at 8 (September 2011); JDX2866 at 10 (October 2011); JDX2867 at 11 (November 2011); JDX2868 at 9 (December 2011). As Mr. Hill summarized, he “ha[s] stated [the 30% ROCE requirement] to the businesses regularly.”¹ *Hr’g Tr.* at 670:15.

The pre-merger documents also confirm the undisputed testimony that investment proposals must undergo a rigorous black hat financial review that, among other things, assesses

¹ Moreover, pre-merger documents specifically related these financial considerations to businesses in the Americas, *see* JDX2867 at 11 (2011 finance director’s report listing the Americas as needing improvement on ROCE); *Hr’g Tr.* at 673:19-23 (noting that “[t]he Americas was falling short” on ROCE), and to Synergy’s x-ray business at Däniken, *see* JDX2871 at 2 (January 2013 finance director’s report noting ROCE deficiency of Däniken); *Hr’g Tr.* at 675:21-676:16 (noting that report “highlight[s] here that Däniken has underperformed . . . where their ROCE fell from 7.9 percent to 4 percent, which is extremely poor”).

the proposal against these key metrics. *See* JDX2869 at 4; Hr’g Tr. at 678:10-679:23 (Hill noting that document “highlight[s] that all major capital expenditure projects need to be put through a thorough black hat process before they get approved”). And Mr. Hill showed, by a “list of approved business cases” since 2011, that these financial metrics are consistently implemented in practice. *See* JDX3647 (Source JDX2876); Hr’g Tr. at 695:23-696:10. That collection confirms that Synergy’s actual business practices conform to its routinely documented financial requirements. *See* JDX3647; Hr’g Tr. at 695:23-707:23 (Mr. Hill discussing approved projects since 2011).²

The FTC argues that ordinary course documents do not support the fact that the well established financial requirements would apply to this project. The FTC’s claim is demonstrably wrong,³ and the opposite question should be posed to the FTC: “Please point to the documents, either pre-merger or after the fact, suggesting that the PLC Board was willing to exempt the x-ray project from any of these common-sense standards.” No such documents exist.

Second, the FTC claims that Synergy would not apply its ordinary financial targets to this project because Synergy had “full knowledge” of them while attempting to develop a business case. FTC Br. at 5. This is a non sequitur. The fact that the business team knew about obstacles and continued trying to overcome them hardly suggests that the targets were not applicable. To the contrary, it confirms the uniform testimony at the hearing that the business team, the SEB,

² The FTC’s legal premise that the hearing testimony of business executives should be discounted is also wrong in the context of an “actual potential competition” claim. *See FTC v. Atl. Richfield Co.*, 549 F.2d 289, 295 (4th Cir. 1977) (“In *Falstaff [Brewing Co.]*, 410 U.S. 526 (1973), the Supreme Court did not disturb the district court’s finding that Falstaff was not an actual potential entrant while at the same time indicating that the district court relied almost solely on management’s post-acquisition statements that Falstaff would not enter de novo.”).

³ Contemporaneous notes of the September 14, 2014 SEB meeting attribute to Dr. Steeves the statement, “[e]conomics not yet right — need to look @ again,” and note that Mr. McLean alluded to the “[d]ifficult[y of] get[ting] a baseload customer.” PX00655 at 47-48.

Mr. Hill, and the PLC Board all understood that these problems needed to be fully addressed before the project could ever be considered for approval.

Third, the FTC argues that all of Synergy's various decision makers would ignore the company's ordinary financial requirements because "U.S. x-ray represents a long-term, strategic investment" and the company hoped to "become the leading global sterilization provider." FTC Br. at 13. The idea that a company like Synergy would disregard basic business considerations and spend tens of millions of dollars on a massive new project in the hope that it would pan out in the "long-term," or because it was a "top-down" project in which Dr. Steeves was interested, FTC Br. at 1, 3-4, is divorced from business reality, and is unsupported by any documents or testimony. The FTC's view that U.S. x-ray represented a strategic investment of long-term importance is also refuted by the fact that Synergy sought no payment for it in the merger negotiations. Hr'g Tr. at 783:22-25 (Walter Rosebrough noting that "if somebody thinks they have something worth a lot of money, they ask you to pay for it").

Every decision maker who testified at the hearing explained that the importance of these financial metrics was, if anything, magnified here compared to ordinary investments, because of the sheer size of the investment, the unusually large risk associated with attempting to bring a long available but unaccepted sterilization modality to the U.S., and the company's disappointing prior experience at Däniken. *See, e.g., id.* at 225:17-228:13 (Steeves), 290:10-292:10, 361:6-21 (McLean), 465:3-466:3 (Baroudel), 661:14-662:17, 680:19-681:7, 682:16-684:11, 691:1-20 (Hill). Dr. Steeves himself, despite his interest in x-ray, quickly communicated to Mr. McLean after the September SEB meeting that the financials were poor — *i.e.*, they would not be approved by either the SEB or ultimately the PLC Board. *See* PX00215. And it is particularly implausible that Synergy, with global operations, would have sacrificed the economics of the

entire company in a speculative and risky *Field of Dreams* pursuit involving one technology in one business segment in one country.

Fourth, the FTC argues that the September 2014 presentation recognized the financial difficulties with the project and thus contemplated a “gradual[]” growth, reliance on non-medical customers, and cannibalization of Synergy’s existing e-beam revenue while the project progressed. FTC Br. at 8-9. But this simply restates the problem. The recognition of slow prospects for growth and insufficient x-ray demand produced an IRR falling “far short of [the] 15 percent,” which itself was overstated because it double-counted Synergy’s existing e-beam revenues. Hr’g Tr. at 686:15-19, 694:3-695:6.

B. Customer Commitments Were Required, But Were Not Obtained.

The FTC does not deny that committed, take-or-pay customer contracts are a standard prerequisite to approvals of Synergy investments. Instead, it resorts to imagining a non-existent exception for what would have been the largest greenfield investment in the company’s history, *see id.* at 696:15-697:5, 698:1-3, and exaggerating the customer interest.

First, the FTC relies on Joyce Hansen’s testimony that Johnson & Johnson, having now received international regulatory approvals for sterilizing a single product with x-ray, is “prepared” to move that product to x-ray. FTC Br. at 11-12. This reliance on the J&J Surgicel product is misplaced. J&J received U.S. regulatory approval for Surgicel last fall, but in nine months has done nothing to transition Surgicel to x-ray processing in the U.S. (likely because J&J manufactures and sterilizes Surgicel outside the continental U.S., and there is no evidence to suggest that J&J intends to relocate sterilization of Surgicel to facilities far away from where it is manufactured).⁴ Additionally, as with previous J&J expressions of interest in x-ray dating to at

⁴ To transfer Surgicel or any other product to x-ray, J&J would need, following determination of the facility location, to “say[], okay, of the products in this region, which ones

least as early as 2012, Ms. Hansen's testimony and her actions taken prior to working with the FTC are the definition of "non-committal." *See* JDX1186 at 1-2; JDX1188 at 2; Hr'g Tr. at 47:21-48:20, 57:12-62:16, 63:24-64:22, 67:9-68:8. It took J&J more than three years to complete validation testing and obtain regulatory approvals for Surgicel, *see* Hr'g Tr. at 75:2-6. During this time, J&J has not started x-ray validation testing for any other product, *see id.* at 79:17-20, and the company has never undertaken the "full analysis" it would need to do to figure out which other products, if any, might be suitable for x-ray. *Id.* at 67:16-21.

Second, the FTC claims that Synergy never sought commitments from customers. *See* FTC Br. at 9-11. Yet it is hardly difficult to understand that a path to a take-or-pay commitment must be built on steps that first develop interest, gradually move to stronger expressions of intent, and finally reach contractual commitments. *See* Hr'g Tr. at 591:13-25; Berger IH Tr. at 149:1-22. And J&J certainly understood what Synergy ultimately wanted. Victor Baran, Synergy's primary contact at J&J, testified that he was [REDACTED] [REDACTED] " Baran Dep. at 62:11-14.

Third, as it does with regard to the financial metrics, the FTC argues that the customer commitment requirement must not have applied to this investment because the company "understood all along that [it was] unlikely to obtain binding customer commitments before investing in initial facilities." FTC Br. at 2. This argument turns the evidence on its head. The

(continued...)

would be good for [it] to switch, which ones would [it] want to switch, and then start looking at the functionality studies, . . . and then [it] can transfer that information and do final finished validation for that site because [it] ha[s] to validate the site from a regulatory submission standpoint." Hr'g Tr. at 68:16-69:8. It would also need to consider the price. *See id.* at 103:18-23. None of these issues have begun to be addressed with respect to Surgicel. *See id.* at 67:9-21, 77:9-80:6. J&J has not even moved Surgicel to x-ray processing at Däniken, near where the product is currently manufactured. *See id.* at 76:15-77:8.

FTC offers no explanation why this issue would have been repeatedly discussed if it was not a critical requirement, and no document or testimony suggests that the difficulty in obtaining sufficient baseload customers through contractual commitments would be grounds for waiving the requirement and creating an otherwise unacceptable risk profile.

C. The Availability of Technologically Adequate X-Ray Equipment Was Highly Uncertain.

The FTC offers no meaningful answer to the ongoing and deepening technological barriers and uncertainties faced by Synergy. The FTC merely recites the history of IBA's efforts to produce a satisfactory duo x-ray machine, and concludes that IBA can resolve any technological challenges simply because IBA thinks it can. FTC Br. at 12-13 ("IBA was convinced that the TT1000 could meet the requirements."). IBA's expressions of confidence fall far short of providing a reasonable expectation on the part of Synergy's decision makers that IBA could resolve the outstanding issues, let alone within a reasonable time and without significantly increasing costs. IBA's professed confidence is particularly unsatisfying given

(a) [REDACTED] *compare, e.g.*, PX00237 at 2-3; Hr'g Tr. at 582:7-12, *with* PX00548 at 1; PX00415 at 3; JDX2200 at 2; Hr'g Tr. at 625:14-22 (b) IBA's own characterization of the proposed equipment as [REDACTED] *see* JDX1042 at 29; Bol Tr. at 95:6-17, 196:4-14, and (c) IBA's previous work at Däniken, where IBA's equipment took years to pass acceptance testing, *see* Hr'g Tr. at 423:10-19.

D. The X-Ray Project Failed To Satisfy The Requirements Of Synergy's Remaining Evaluation And Approval Processes.

While the FTC does not dispute that further decisional procedures were necessary before any U.S. x-ray project could have been approved by Synergy, it neither discusses them nor attempts to show how, given the deteriorating realities faced by the team, the project could have

navigated SEB approval, sign-off following a black hat financial review, and, ultimately, discretionary approval by the PLC Board. The FTC's discussion of the Synergy decisional process addresses only the few preliminary steps that had already occurred.

The FTC characterizes the SEB's approval of the strategy and the PLC Board's authorization of a down payment as "significant" steps. FTC Br. at 4-5. But the PLC Board's down payment authorization merely created "an option to buy" IBA equipment with no obligation on the part of Synergy. Hr'g Tr. at 730:5-18 (Hill); *see also id.* at 223:1-18, 260:8-15 (Steeves). And the PLC Board's approval of the down payment (which Synergy never, in fact, made, *see id.* at 258:12-14 (Steeves); Hill IH Tr. at 131:3-132:2) expressly provided that it was not approving the business case, *see* PX00574 at 10. If the FTC was correct in arguing that the risk profile and financial metrics for the project as presented to the SEB in September were acceptable, the PLC board would have approved the business case at that time rather than expressly reserving the decision.

Nor, critically, does the FTC make any attempt to satisfy this Court's requirement of a showing that entry by Synergy would have been approved but for the merger "within a reasonable period, reasonable time frame." Hr'g Tr. at 790:17-791:2. The various financial, business, and technological hurdles to ultimate PLC Board approval were growing more acute in the months since the SEB presentation in September 2014. Even under the flawed September strategy, construction of the initial facilities would not have been complete until 2016. *See* JDX2471 at 15-16; PX00275 at 5, 37. Because the business team did not present a U.S. x-ray proposal to the PLC Board in time to be included in its primary capex budgeting session in February of this year, that timing has been pushed even further down the road, with no discernible answer to when the obstacles could have been overcome, if ever, and in what form

given the errors (e.g., TT300 vs. TT1000, IRR double-counting) and weaknesses (e.g., still no support for revenues) in the September plan. The FTC points to nothing tangible in the future that would timely resolve all of the financial and technical problems that have arisen since then, or that would suggest that all the outstanding decisional processes could have concluded in the reasonable future in light of them. On the technology side, even if IBA's optimism panned out, testing would not have been completed until 2016, *see* PX00549 at 1, and it is not reasonable to imagine that the PLC Board would have approved a business case before these basic technological requirements were fully resolved.

E. The FTC's Remaining Efforts to Misdirect the Court's Attention Are Wrong and Irrelevant.

The FTC devotes a section of its brief to Synergy's interim report of financial results for March through September 2014. FTC Br. at 5-6. The FTC quotes three sentences, each of which was factually accurate at the time and was consistent with Synergy's position in this case. None of them (alone or together) supports the conclusion that Synergy had somehow publicly committed to building one or more x-ray facilities in the U.S., and certainly not on any particular timeframe, which is what the FTC would have the court believe.

These sentences were not the highlight or featured item of the report, but rather were extracted from a 25-page document providing updates and status information on a wide variety of operations and initiatives.⁵ The update was accurate and conveyed that with respect to x-ray "there was an aspiration and trying to see a scal[.]able investment" Hr'g Tr. at 498:11-18

⁵ It is worth noting that Synergy did not make its x-ray plans the subject of an affirmative press release the way it did with other commitments, some of which were significantly smaller. For example, on August 13, 2014, Synergy released an announcement with the headline "Synergy Health plc Invests £18 million (US \$30 million) to expand global Applied Sterilisation Technology capacity", JDX3492, whereas no similar announcement was ever made regarding x-ray (and the August 13 release makes no mention of x-ray).

(Baroudel), but scrupulously avoided providing any specifics or guidance as to the building of x-ray facilities in the U.S. precisely because Synergy had not yet committed to doing so.

In focusing on these statements made in November, the FTC ignores that the U.S. x-ray situation deteriorated significantly after this report was written. As shown in defendants' opening brief (at 8, 12-13), the financial and technological problems with the U.S. x-ray business case worsened and became more intractable over the course of the ensuing months, and the business team's inability to secure customer commitments became even clearer. *See e.g.*, PX00548 at 1; PX00549 at 1; JDX1970 at 1; JDX2858 at ¶ 63; JDX2450 at 2; Hr'g Tr. at 422:18-423:1, 582:7-12, 623:18-624:14; McEvoy Tr. at 125:9-18.

The FTC also makes its oft-repeated argument that Synergy terminated the U.S. x-ray project in response to the FTC investigation. *See* FTC Br. at 6-7. This assertion is belied by substantial contemporaneous documents and hearing testimony regarding the financial, customer and technology problems that only worsened since the September 2014 SEB meeting. Even if the FTC's investigation had influenced the timing of Synergy's decision to end the project, that is not the question at issue. The question is whether Synergy would have entered the U.S. with x-ray within a reasonable time but for the merger. Overwhelming evidence reveals that the answer was, and remains, "no." *See* Hr'g Tr. at 226:23-229:9. Whether the FTC's investigation caused the business leaders to scrutinize the project sooner or more than they otherwise would have, is irrelevant because the ultimate decision would have been the same in any event.

CONCLUSION

The FTC has failed to carry its burden of establishing a likelihood that Synergy would have entered the U.S. with x-ray within a reasonable time period. The Court should deny the preliminary injunction.

Dated: September 4, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

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