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

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| **FEDERAL TRADE COMMISSION,**<br>Plaintiff,<br>v.<br>**STERIS CORPORATION, *et al*.,**<br>Defendants. | No. 1:15-cv-1080<br>The Hon. Dan A. Polster |

**OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION**

# TABLE OF CONTENTS

# TABLE OF AUTHORITIES

**Page**

**CASES**

**STATUTES**

**OTHER AUTHORITIES**

Defendants STERIS Corporation and Synergy Health plc oppose Plaintiff Federal Trade Commission's motion for a preliminary injunction. The Commission relies on a legally invalid antitrust theory that it also cannot prove because the prospect of Synergy's x-ray entry was bogged down, perhaps forever, by daunting financial and technological impediments.

In an ordinary merger challenge, the Commission would argue that the merger will somehow reduce competition, *i.e.*, that, either immediately or incipiently, it will have some adverse effect on existing competition in the relevant market. Not so here. The Commission attempts to resurrect a theory—the oxymoronically titled "actual potential competition" theory—that courts overwhelmingly have refused to adopt. Under this theory, no diminution in competition need be proved if the Commission can instead prove that the merger would reduce some *future increase* in competition. The Supreme Court has consistently refused to approve this theory, which runs counter to the text of the Clayton Act, and lower courts have overwhelmingly rejected cases brought under it. No circuit has even considered applying this theory to a merger since the early 1980s. And even if it could conceptually support a preliminary injunction, the Commission would face a substantially heightened burden of proof at trial, which it cannot possibly satisfy.

The most basic predicate for an "actual potential competition" claim would be unequivocal proof that, without the merger, Synergy would have entered the United States with x-ray. Here, the Commission makes no showing that entry was or is likely. It relies on highly generalized claims about the possible utility of x-ray technology, on hedged declarations it obtained from customers expressing "interest" in x-ray, and on Synergy's considerations of an entrepreneurial and entirely prospective project. But entrepreneurial projects must eventually pass muster against concrete financial and business criteria, including capital expenditure

("CAPEX") budgeting, revenue commitments and projections, and degree of risk. Here, Synergy had not even developed a concrete business plan for its management team (the Senior Executive Board ("SEB")) or its governing board ("PLC Board") to consider for approval; meanwhile, major pieces of the strategy were falling apart. Any viable plan, had it existed, would have been subjected to a rigorous, de novo financial analysis by a senior finance team and to discretionary review by the PLC Board, which has sole authority to approve projects of this magnitude. The tentative investment model that was presented to the SEB in September 2014 abysmally failed several of Synergy's long-held minimum standards for capital investment.

The absence of a viable business plan was no accident. One could not have been developed, at least for the foreseeable future, because Synergy's analysis of potential entry revealed numerous insurmountable impediments. Binding customer commitments were necessary, particularly since no customer currently uses x-ray in the U.S.; yet none would commit due to substantial uncertainties, risks, and costs of converting to this sterilization modality. And Synergy requires anticipated ten-year internal rates of return ("IRRs") on capital projects to be at least 15%; yet the September model had a projected IRR of only 6.51%—and even that number was overstated. Moreover, Synergy was forced to abandon the x-ray machine it had budgeted because the equipment supplier had rescinded its promises that the machine could perform consistent with the model's assumptions, and no technologically adequate and existing substitute was ever confirmed to replace it. Indeed, the CAPEX for the project, which was already larger than any other project in Synergy's history, kept increasing despite the CEO's and SEB's insistence that it be reduced. Synergy's experience at its x-ray plant in Däniken, Switzerland, which operates at [redacted] capacity and generates a [redacted] the medical product segment around which the entire x-ray strategy was based,

confirms the difficulties Synergy would face in gaining such customers in the U.S.

X-ray technology may one day play a role in the U.S., but its near wholesale absence from the U.S. today is not an accident. X-ray has not yet been shown to be economically competitive with existing sterilization methods, particularly given the expensive and burdensome conversion costs for medical devices. Synergy's diligent but failed efforts to solve those obstacles cannot be the basis to prevent this merger.

There is no ground for any question about the lawfulness of this merger, and the Commission certainly cannot meet the heightened burden of proof needed under its dubious legal theory. The Court should deny the injunction.

## BACKGROUND

This is a case about a proposed merger between STERIS and Synergy, two companies that operate primarily in different geographies (STERIS in the United States and Synergy outside the country), a merger that neither the Commission nor the defendants contend will harm U.S. competition as it exists today. Tellingly, STERIS placed no value on Synergy's x-ray project in evaluating the merger.

The proposed merger will be strongly pro-competitive. The transaction will create a company with unified global sterilization offerings. While offering global services is not a prerequisite to competing in the U.S. sterilization industry (there are at least 29 small contract sterilization companies in the U.S. and they serve some of the largest sterilization customers), some customers would benefit from an integrated, global company. Because of this customer demand, the post-merger company will be better able to compete with the largest company in the industry, Sterigenics. The post-merger company will also have more resources to invest in research and business development, including being better positioned to explore ways to reduce

industry dependence on cobalt-60, which is used in gamma sterilization, and using Synergy's existing e-beam facilities to conduct testing for customers, [redacted]

Synergy purchased an existing x-ray facility in Däniken in 2012 and since then has explored bringing the sterilization modality to the U.S. On September 17, 2014, one of the Synergy x-ray project's team leaders, Gaet Tyranski, made a presentation to the SEB to build two to five facilities over the next three or more years in the U.S. (with only two locations actually specified), in the hope that two would become operational in 2016, at a cost of [redacted] million just for the first two facilities ([redacted] million per site). To prepare a financial model for the investment and predict revenues, Synergy's x-ray project team, under the leadership of Andrew McLean, simply assumed that, if Synergy built *all five of the hypothetical facilities*—a [redacted] million investment—it might capture 15% of the contract and in-house gamma sterilization market and yield an IRR for the first two plants of 6.51%. The model that was presented also optimistically assumed that those two facilities would fill to nearly 100% capacity by their seventh year of operation.

The next day, Synergy's CEO, Richard Steeves, himself a longstanding proponent of x-ray technology, observed that "the financial work" in the presentation "was poor and doesn't provide the robustness and confidence necessary" for such a significant undertaking. This reaction was not surprising. The [redacted] million estimated CAPEX for the first two facilities was at least twice as high as the CAPEX for any approved Synergy greenfield or capital expansion in the last five years. And, a supposed 6.51% IRR—itself well below Synergy's required 15% IRR threshold (and far lower than the expected IRR for any other project approved in the last five

years)—was completely unrealistic, especially because Synergy had been unable to secure any customer commitments to actually use x-ray.

Steeves's, and ultimately Synergy's, reluctance was well-founded in light of Synergy's own experience with Däniken. Synergy predicted that Däniken x-ray would succeed. [redacted] Däniken operates [redacted].

While allowing the business team to continue pursuing the strategy, the SEB instructed it to reduce the [redacted] million CAPEX and improve the financials, which would be required before the PLC Board would even consider approving the project. The business team tried to do so, and continued its efforts to obtain customer commitments, to no avail.

As it turned out, the September SEB meeting was the high water mark for Synergy's U.S. x-ray planning. Problems immediately arose in three key areas, any one of which likely would have doomed the project, but that together assured its failure.

First, Synergy requires binding customer commitments before expending significant resources on investments, particularly with a greenfield project. Despite Synergy's past and renewed efforts to obtain them, *not a single customer* would commit to using a future x-ray project.

[redacted], which had long been considered the best prospect, would not even sign an entirely non-binding letter of interest, instead conditioning its so-called "interest" even further to remove any hint of commitment. Other customers refused altogether. Without any commitments, the presumed revenues behind the already-low IRR expectations were at complete risk.

Second, Synergy learned in late 2014 that the technology upon which the proposal and costs were based ([redacted]), could not meet Synergy's production needs. [redacted]

Third, as Synergy tried to flesh out its guesses of costs used in the model, it learned that they would be far higher (*e.g.*, facilities and equipment). Thus, CAPEX, rather than decreasing as the SEB had demanded, was moving up.

In all, the "plan" presented at the September 17, 2014 SEB meeting fell apart piece by piece. Not surprisingly, it was never even presented to the financial review team or to the PLC Board for approval. Had it been, there would have been substantial, additional financial scrutiny, which would have exposed even more errors in the preliminary assumptions. For example, the expected revenue calculations double-counted the business Synergy would have transferred from one of its facilities in Lima, Ohio to one of its proposed x-ray facilities, artificially inflating the already inadequate expected IRR.

Even if Synergy had eventually found ways to reduce the CAPEX, developed an actual working machine [redacted], convinced customers to commit to this new sterilization technology, formulated a business plan that met the company's minimum financial targets, withstood the PLC Board's scrutiny, and somehow secured PLC Board approval, entering the U.S. with x-ray would not have succeeded. X-ray has not yet been shown to be commercially viable or economically competitive with other existing sterilization methods, particularly given the expense and burden customers must bear in switching from their already proven sterilization

modality. Indeed, [redacted] believes that x-ray will not develop over the short or medium-term in the United States. [redacted]

[redacted]

## ARGUMENT

## I. THE COMMISSION CANNOT SUCCEED ON THE MERITS.

### A. The Commission's So-Called "Actual Potential Competition" Theory Is Not A Justiciable Antitrust Theory And Cannot Support A Preliminary Injunction.

The Commission does not allege that the merger will reduce existing competition in any way. Rather, it claims that the merger will prevent Synergy from entering the U.S. market and creating new, future competition. (FTC Br. 12-13.) But the antitrust laws are concerned with transactions that substantially "lessen competition," 15 U.S.C. § 18, not with mandating that parties affirmatively generate new, additional competition. The Commission's legal theory is baseless, and would require denial of the preliminary injunction even if the Commission were able to prove clearly Synergy's imminent entry.

In keeping with the plain statutory language, the Supreme Court has long held that only a reduction in "pre-existing substantial competition" can render a merger unlawful. *Int'l Shoe Co. v. FTC*, 280 U.S. 291, 298 (1930). By itself this precedent squarely forecloses the Commission's "actual potential competition" theory, which is predicated solely on speculated effects upon hypothetical future competition.[1] Indeed, when the Supreme Court was presented with the opportunity to revisit its precedent and authorize the "actual potential competition" theory, the

[1] Congress ratified the *International Shoe* limitation by enacting the Celler-Kefauver amendments to the Clayton Act, which broadened Section 7 in unrelated ways (to include situations where the acquiring and acquired entities are in the same market even if not head-to-head competitors, *see Brown Shoe Co. v. United States*, 370 U.S. 294, 345 (1962), but left in place the "lessen competition" limitation construed by the Supreme Court in *International Shoe* to refer to pre-existing competition. Congress was well aware of *International Shoe* and cited it approvingly in another context. *See* H.R. Rep. No. 1191, 81st Cong., 1st Sess. 7 (1949).

Court declined to do so, twice reserving the question whether it should expand its precedents to embrace an "actual potential competition" cause of action. *See United States v. Marine Bancorporation*, 418 U.S. 602, 625-26 (1974); *United States v. Falstaff Brewing Corp.*, 410 U.S. 526, 537 (1973).

The Supreme Court's refusal to embrace the "actual potential competition" cause of action makes perfect sense because, as it noted, it would render unlawful mergers that "leave competition in the marketplace exactly as it was, neither hurt nor helped." *Id.* at 537; *accord FTC v. Atl. Richfield Co.*, 549 F.2d 289, 293 (4th Cir. 1977) (noting that the theory "simply prevents an increase in competition that would otherwise take place"). But the antitrust laws do not mandate the affirmative creation of new competition. For instance, if a monopoly in a market exists simply due to "historic accident," the law does not require parties to take steps to generate new competition. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004) (stating principle in monopolization context).

Following the Supreme Court's unwillingness to adopt the legal theory the Commission asserts in this case, those courts of appeals to consider the theory have overwhelmingly refused to adopt it, accepting it only arguendo in order to find that the government would lose even if it were a valid theory. *See Tenneco, Inc. v. FTC*, 689 F.2d 346, 347-50 (2d Cir. 1982); *United States v. Siemens Corp.*, 621 F.2d 499, 506 (2d Cir. 1980); *BOC Int'l, Ltd. v. FTC*, 557 F.2d 24, 25 (2d Cir. 1977); *Atl. Richfield Co.*, 549 F.2d at 294-95.[2] The Commission itself once admitted

[2] Commentators have been similarly harsh in their judgment of the theory. Lewis A. Kaplan, *Potential Competition and Section 7 of the Clayton Act*, 25 Antitrust Bull. 297, 314-317 (1980) ("the actual potential entrant doctrine should be rejected as inconsistent with the language and the congressional purpose of [S]ection 7"); Richard A. Posner, *Antitrust Policy and the Supreme Court: An Analysis of the Restricted Distribution, Horizontal Merger and Potential Competition Decisions*, 75 *Colum. L. Rev*. 282, 323 (1975) (criticizing the theory on various grounds); James Rahl, Applicability of the Clayton Act to Potential Competition, 12 *ABA Section*

that "[t]he actual potential competition doctrine represents a rather peculiar theory of competitive injury" because it "postulates that a merger or acquisition may prevent the relevant market from *becoming* as competitive as it might otherwise become." *In re B.A.T. Indus., Ltd.*, No. 9135, 1984 WL 565384, at *3 (FTC Dec. 17, 1984).

The Commission makes no effort to engage these points, or to argue for the doctrinal propriety of its legal theory. Its only support is a bare citation to a single decision, *Yamaha Motor Co. v. FTC*, 657 F.2d 971, 977 (8th Cir. 1981), (FTC Br. at 6), which accepted the theory without addressing the governing Supreme Court case law or other authorities on this point. No other circuit has followed *Yamaha* in the 34 years since the decision. *See Fraser v. Major League Soccer, L.L.C.*, 284 F.3d 47, 70 (1st Cir. 2002) ("To our knowledge only one circuit has expressly applied [S]ection 7 so broadly." (citing *Yamaha*)). Nor does the Commission's reference to "incipient" threats to competition support its theory. (FTC Br. at 6.) That uncontroversial principle means only that the Court may consider the long-term effects of the merger, even if competition is not lessened quickly. As the Court explained in *United States v. Phila. Nat. Bank*, 374 U.S. 321 (1963), Section 7 "requires not merely an appraisal of the *immediate* impact of the merger upon competition, but a prediction of its impact upon competitive conditions in the *future*; this is what is meant when it is said that the amended

(continued…)

*of Antitrust L*. 128, 142-43 (1958) (doctrine attempts the "neat trick" of "treat[ing] an election not to augment competition as a lessening of competition," which is "plainly not authorized by the language of the statute"; Frank H. Easterbrook, *Toehold Acquisitions and the Potential Competition Doctrine*, 40 *U. Chi. L. Rev*. 156, 181 (1972) ("The Clayton Act, by its terms, reaches only those actions that decrease competition, not those that fail to increase competition."). Even proponents of the theory have acknowledged it to be highly problematic. Andrew Joskow, *Potential Competition: The Bell Atlantic-NYNEX Merger*, 16 Rev. Indus. Org. 185, 189 (2000) (former chief economist of DOJ Antitrust Division admitting that the theory requires "an excess of psychoanalysis" that has rendered it "so rare as to make the whole notion virtually absent from antitrust").

s[ection] 7 was intended to arrest anticompetitive tendencies in their 'incipiency.'" *Id.* at 362. That the Court may consider the long-term effects on competition from a merger does not mean that a merger may be blocked that will not lessen competition at all, whether in the near term or the more distant future, but merely prevent or reduce a postulated future increase in competition.

In short, the Commission's legal theory makes no sense as a matter of antitrust law or policy, contravenes long-settled Supreme Court precedent that the Supreme Court has pointedly declined to upset, and has not been adopted by any circuit in the modern era of antitrust jurisprudence. But even if there were any lingering doubt over whether the Commission's legal theory could potentially be valid, the Court need not reach it, because even if it had been cognizable it still could not support preliminary injunctive relief.

Several circuits have questioned whether the government may ever obtain a preliminary injunction in an "actual potential competition" case even if the theory were cognizable. The Fourth Circuit has explained that "[t]he novelty of the doctrine and the absence of definitive authority sanctioning it and defining its parameters could well serve as a basis for denial of a preliminary injunction under § 13(b), since it is difficult, if not impossible, to determine FTC's chances of ultimate success when the law is so uncertain and the parameters of the doctrine obscure." *Atl. Richfield*, 549 F.2d at 293-94. The Second Circuit similarly noted that "some respected authorities have voiced understandable doubt" over whether "the theory of elimination of actual potential competition may be the basis of preliminary injunctive relief." *Siemens Corp.*, 621 F.2d at 506. While neither decision needed to decide that question definitively—because the government lost on other grounds—this is simply an application of the ordinary principle that courts may refuse preliminary injunctions on novel and undeveloped theories. *See, e.g.*, *Fair Housing in Huntington Comm. Inc. v. Town of Huntington, N.Y.*, 316 F.3d 357, 366 (2d

Cir. 2003); *Walmer v. U.S. Dep't of Def.*, 52 F.3d 851, 855-56 (10th Cir. 1995).

The case against predicating preliminary injunctive relief on the "actual potential competition" theory has only grown stronger since the Second and Fourth Circuits raised the question back in the 1970s and early 1980s. Antitrust jurisprudence has undergone decades of development in the interim, and, indeed, the Supreme Court has increasingly cabined over-expansive applications of the antitrust laws during those intervening years, without in any way developing the contours of this putative theory. Those cases' warnings that the "actual potential competition" theory was too vague and ill-defined to support a preliminary injunction have accordingly grown far stronger during that time.

### B. The Commission Could Not Prove Its Case Under The Theory Even If It Had Stated A Claim.

Even if the Commission had relied on a valid legal theory, and even if that theory could have supported a preliminary injunction as a matter of law, the Commission would still have to adduce unequivocal proof of entry and heightened proof of anticompetitive effects. The Supreme Court in *Marine Bancorporation*, without adopting the "actual potential competition" theory, explained that its rarity in the cases stemmed from the fact that "[u]nequivocal proof that an acquiring firm actually would have entered de novo but for a merger is rarely available." 418 U.S. at 624. This presupposes an unequivocal proof standard, because the sentence would make no sense if a lesser showing could suffice.

Thus, lower courts have recognized that *Marine Bancorporation* imposes an "unequivocal proof standard" on any "actual possible competition" plaintiff. *See Atl. Richfield*, 549 F.2d at 294-95 (noting that *Marine Bancorporation* "impl[ies] that the standard is one of 'unequivocal proof' in a case where only actual potential competition is claimed"); *see also Siemens Corp.*, 621 F.2d at 507 n.7 (citing cases supporting "clear proof of likelihood of entry"

standard) (internal quotation marks omitted). The Commission itself has strongly suggested that entry must be "virtually certain" in "the near future." *B.A.T. Indus.*, 1984 WL 565384, at *4.[3]

The Commission acknowledges that it must show it is "likely to succeed" on the merits of its Section 7 challenge. (FTC Br. 5.) *See Munaf v. Geren*, 553 U.S. 674, 690 (2008) ("a party seeking a preliminary injunction must demonstrate, among other things, 'a likelihood of success on the merits'"). But it ignores that "the burdens at the preliminary injunction stage track the burdens at trial." *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 429 (2006). Accordingly, if a party must meet a particular level of proof at trial, it must satisfy a corresponding level of proof at the preliminary injunction stage. *See Ashcroft v. ACLU*, 542 U.S. 656, 666 (2004). Thus, in this Section 13(b) case, the Commission must show a likelihood of success in establishing unequivocal proof of entry. The Commission cannot come close to meeting this burden.

### 1. The Commission Cannot Unequivocally Demonstrate That Synergy Is An Actual Potential Entrant.

The core predicate for any "actual potential competition" theory is a showing that a party to the transaction would unequivocally have entered the market but for the merger. Yet in this case, the evidence supports the opposite conclusion, and the Commission's allegations are hypothetical at best. The Commission relies most heavily on vague generalities about the

[3] Ignoring this clear authority and its own *B.A.T.* decision, the Commission disputes the propriety of this "unequivocal proof" standard. But its sole support is the claim that there is a circuit split on the issue, and it hedges by asserting that it has "satisfie[d] all of the[] standards." (FTC Br. at 10 n.63.) Its cases do not establish such a split. *Tenneco* found that the Commission had failed even a simple probability standard, and thus had no occasion to resolve whether a stronger showing was needed. 689 F.2d at 353. Same with *Mercantile Texas Corp. v. Bd. of Governors of Fed. Reserve Sys.*, 638 F.2d 1255 (5th Cir. 1981), where the agency had failed even to make required findings. *Id.* at 1265-66. And *Yamaha* noted that the entry showing was "considerably more definite" than a precedent case, obviating any need to define the precise required burden. 657 F.2d at 980 n.12.

promise and potential of x-ray technology, wholly apart from the particular business decision faced by Synergy. When it does address Synergy's decision-making, it does so in an extremely conclusory way, reciting several steps taken by Synergy personnel in evaluating or advocating a U.S. x-ray entry, but making no effort to show how those steps fit into Synergy's larger decisional process, or that they sufficed to make a decision to go forward in any way likely. Indeed, the Commission does not even mention that entry would require: (1) a new business plan involving critically different assumptions, including realistic cost and pricing assumptions, solid revenue predictions underpinned by committed revenues through customer commitments and validated technology; and (2) further de novo review and authorization by the PLC Board.

There can be no dispute about one key fact: Synergy never approved such entry. Instead, the Commission is forced to rely on a series of unsubstantiated assumptions that Synergy's hypothetical U.S. entry would have occurred at some indeterminate time in certain indeterminate locations. This hypothetical entry, the Commission alleges, would have resulted in hypothetical competitive effects. And all of this presupposes that the agency is able to predict the future behavior of other market participants, the likelihood of entry or expansion by incumbents or new entrants (either contract sterilizers or customers), and the substitution patterns and role of new or improved sterilization technologies over the next decade. The Commission has not only failed to show entry to be unequivocal, or "virtually certain" as its own precedent recognizes, but it could not satisfy even an ordinary likelihood standard.

**a. No Plan Sufficient For PLC Board Review Had Even Been Developed.**

The Commission's entry narrative relies heavily on the SEB's September 2014 response to a U.S. x-ray presentation, which the Commission correctly and vaguely characterizes as having "approved the x-ray *strategy*." (FTC Br. 11 (emphasis added).) But the SEB simply

authorized ongoing work on developing a business case for a potential x-ray plan (*see, e.g.*, Ex. 1, at 239:9-243:3; Ex. 2, at 148:23-149:17), and, in any event, it is the PLC Board, not the SEB, that had to approve the investment case and funding for a [redacted] million project (which would have risen to [redacted] million including all five of the plants in the strategy rather than just the budgeted two). (*See* Ex. 3, at 16; Ex. 4, at 10, 14.) Capital projects at Synergy proceed through several stages of business development and financial analysis. First, a local project team must develop a business case for the project. (*See* Ex. 5, at 17:16-18:3, 18:19-19:18.) At this stage, local teams are "empowered to . . . be visionary and entrepreneurial" (*Id.* at 182:20-183:16), and discuss "concepts," without regard to whether they constitute fully formed business cases, and to present such concepts to the SEB. (Ex. 6, at 226:16-227:18.) The SEB, in turn, can approve a high-level strategy for development, noting issues that must be resolved. (*See id.* at 221:17-222:11, 227:21-230:10.) Until such a project offers realistic budget and revenue commitments that would satisfy Synergy's standards for capital expenditures ("CAPEX"), any such first-stage presentations to the SEB are merely "progress [reports] as to what [the team is] working on and what their thoughts are." (*Id.* at 227:19-228:12.)

If a project team reaches a "final business case" for a proposed investment, it proceeds to the second stage. A senior business finance team, working under Gavin Hill, the Group Finance Director, performs a thorough, de novo financial review of the project. (*See* Ex. 5, at 19:2-18, 20:13-25, 108:4-109:1, 182:20-183:16.) This independent "model audit" or "black hat review" occurs only once the project team's business case has documented "a revenue line underpinned by guaranteed contracts with customers," and shows "the capital down to a point where [the project] was going to deliver [Synergy's] financial targets." (*Id.* at 182:20-183:16.) During this black hat review, Hill and his team aggressively "challenge[] the assumptions and review[] the

model" underlying the first-stage business case. (*Id.* at 20:17-25.) Hill's team "test[s the model] for integrity," ensures that "the financial modeling is correct" and that "there[ are] no errors in the numbers," and audits the model's assumptions on revenues and costs, particularly to ensure that "those revenues [we]re backed up by secure contracts." (*Id.* at 108:5-109:1.) All of this is a necessary predicate to consideration of the project by the PLC Board (*see id.* at 20:17-25), which is the ultimate decisionmaker for "any capital expenditure in excess of [redacted] million," (Ex. 7, at 46). The company views these detailed second-stage re-analyses as necessary to ensure "that the business case is robust and [that] the assumptions have been tested" by company-wide experts. (Ex. 8, at ¶ 28; *see also* Ex. 6, at 169:21-170:3.)

Synergy's consideration of U.S. x-ray never came close to undergoing second-tier review, let alone pass muster under that review by Hill's team and proceed to the PLC Board. The "x-ray strategy" to which the Commission refers (FTC Br. 11) was nothing more than "an aspiration" or an "ambition." (*See* Ex. 9, at 151:4-9; Ex. 10, at 1 (stating that the x-ray project's "investment case" would not be finalized before the "November strategy session").) It expressed a desire to obtain 15% of the U.S. gamma market *over a six year period* and with [redacted] additional plants that were not even remotely modeled in the strategy presentation. (*See* Ex. 11, at 2-3, 18-32, 34, 41-48; Ex. 8, at ¶ 64.) But this "top-down number" had "no substance behind [it] other than hey, there's market research here that shows there's a big market . . . . [L]et's go after 15 percent market share." (Ex. 12, at 197:21-198:9.) [redacted] (*See* Ex. 8, at ¶ 4; Ex. 13, at 149:18-25; Ex. 14, at 121:21-122:8; Ex. 2, at 116:20-118:16; Ex. 3, at 17.) The aspirational target also ignored well-known regulatory obstacles to conversion between sterilization modalities and well-known customer

reluctance to change sterilization modalities.[4]

The concept presented to the SEB used a similarly "pie-in-the-sky estimate" for construction costs; "nobody had done any real homework . . . to justify those numbers." (Ex. 15, at 198:23-199:15; *see also* Ex. 16, at 2 (noting "uncertainty on some of the CAPEX items").) The revenue projections had no analytical justification for assuming that they would have any application to an x-ray business model. And even the modeled revenues were "just assumptions" because there were "no committed revenue streams." (Ex. 17, at 1; *see also* Ex. 2 at 137:8-21; Ex. 18, at 141:1-9.) For that reason alone, "there [was] a limit to how insightful" the modeled scenarios were. (Ex. 17, at 1.) These failures were not lost on the SEB. (*See* Ex. 3, at 18 (Hill was "surprised that the financial model did not look better;" Steeves "had concerns that the economics were not right;" and Coward "suggested that rapid work needed to be done to build up the cost base from scratch"—all three sit on the PLC Board).) The presentation thus was simply "an update" rather than an actual investment plan. (Ex. 10, at 1; Ex. 5, at 160:11-23, 182:16-183:16.)

Contrary to the Commission's insinuation, the SEB did not in any way approve a CAPEX expenditure on the plan, nor could it. It mandated further investigation and development. (*See* Ex. 1, at 201:12-24, 244:10-15, 244:22-245:6 ("[T]hey had a mandate to continue to answer the questions that had not been answered in the previous four years together"); Ex. 2, at 148:20-149:14; Ex. 18, at 137:1-5.) Indeed, the SEB noted ongoing deficiencies that needed to be cured. Because the IRR in the proposal, 6.51%, was well below the minimum corporate requirement of 15%, the SEB directed the team to reduce CAPEX to improve IRR and to obtain firm customer

[4] *See* Ex. 19, at 2 (noting customer concern about "*regulatory barriers* for changing sterilizers and more so about changing between technologies" (emphasis in original)); Ex. 20, at 9, 17; Ex. 21, at 2; Ex. 22; Ex. 23; Ex. 24, at 1-2; Ex. 25; Ex. 33, at 100:6-16.

commitments to shore up the risks in predicting future revenue. (*See* Ex. 26 ("the financial work yesterday was poor"); Ex. 27, at 10 (noting that "further work was being done," particularly to "driv[e] down the cost of each build, to improve ROCE"); Ex. 28, at 4 (noting efforts "to bring down the cost of the investment in the facilities" was ongoing); Ex. 29, at 137:2-138:7; Ex. 5, at 118:13-24; Ex. 2, at 148:20-149:14; Ex. 18, at 61:22-23 ("[T]o make our business case and get our funding, we needed to have commitments."); Ex. 1, at 194:8-195:3; Ex. 8, at ¶ 5; Ex. 6, at 85:3-8; Ex. 29, at 86:8-10.)

McLean explained that any such future approvals would be contingent on the successful resolution of the SEB's concerns, and he communicated that message to his team. (*See* Ex. 30, at 1; Ex. 31, at 12; Ex. 14, at 174:13-22.) As a result of these deficiencies, the project team understood that the SEB "had not approved the business case" but had instead "approved . . . the ongoing development of the business cases." (Ex. 2, at 148:20-149:14; *see* Ex. 32, at 1; Ex. 18, at 36:6-14; Ex. 33, at 162:8-12, 164:10-16.)

Even the presentation that the team prepared for the November 2014 SEB meeting was "just . . . an update" and not part of a "formal approval process." (Ex. 34, at 1 (noting that there were "6 areas for [the team] to provide an update on": location selection, financial review, technical evaluations, CAPEX reductions, product testing, and network overlay with STERIS); *see also* Ex. 18, at 210:22-24; Ex. 35, at 1 (stating that, with respect to the project's budgets, "nothing has been approved by the SEB at this time" and that "what [the team] provided [to the SEB] was for information purposes only").) After this meeting, the team again heard about the need to "reduce [CAPEX] and . . . increase . . . customer commitments." (*See* Ex. 18, at 211:3-12.) The team did not know when, if ever, the SEB would approve the x-ray project. (*See* Ex. 36, at 1.) Unless the project team resolved the SEB's concerns, the project would never proceed

to a second-stage de novo black-hat review, let alone consideration by the PLC Board. (*See* Ex. 6, at 221:17-222:11.)

**b. No Viable Plan Could Have Been Developed, Because Essential Requirements Could Not Be Satisfied.**

Not only was there no extant business plan to proceed through the Synergy deliberative processes, but there was no realistic prospect for such a plan emerging. Critical financial deficiencies were simply not proving solvable. Thus, the case for U.S. x-ray entry was not merely undeveloped, but could never have been adopted under Synergy's long-held business practices. These financial deficiencies are particularly significant in light of Synergy's real-world experience attempting to market x-ray technology at its plant in Däniken. [redacted] X-ray at [redacted]. (*See* Ex. 37, at 2-3; Ex. 23, at 1-2 (Däniken shows that x-ray in U.S. [redacted]

**i. The Project Had No Customer Commitments.**

The PLC Board requires committed customer revenues before it will approve any expansion, particularly a greenfield project. (*See* Ex. 1, at 194:8-195:3 (Synergy "will not build [a facility] without having contracts in place to underpin the economics"); Ex. 8, at ¶ 5 ("repeated and consistent calls for focusing on . . . strong customer commitment."); Ex. 6, at 85:3-8 (customer commitment requirement is "business 101").) Both the SEB and the PLC Board require committed customer revenues before they will authorize construction of a new facility. (*See* Ex. 29, at 86:8-10 ("[F]or the SEB and the plc board to authorize a new facility, we

would need committed customer revenue."); Ex. 18, at 61:22-23 ("[T]o make our business case and get our funding, we needed to have commitments.").) This commitment requirement is absolute. (*See* Ex. 38 (Synergy has never approved a greenfield project without committed revenue); Ex. 6, at 95:16-24; Ex. 18, at 88:18-22.)

The bedrock requirement of contracted customer commitments is necessary to avoid duplicating "historic projects that have under-performed their business cases." (Ex. 8, at ¶¶ 4-5, 49, 59-60.) Because a project without committed revenue is inherently risky, the PLC Board has rejected several such projects even though they exceeded the IRR hurdle rate. For example, [redacted] (Ex. 8, at ¶ 39; *see also* Ex. 6, at 157:4-16.) Without committed customers, these projects carried an unacceptable level of "risk that revenue (and therefore returns) could materially differ from the business case." (Ex. 8, at ¶¶ 3-4, 59-60.)

While the customer commitment requirement is critical to every Synergy investment, its importance was magnified here because x-ray sterilization is virtually absent from the United States. "[M]edical and pharmaceutical customers" are reluctant "to switch sterilization technologies and to undertake the necessary FDA re-certification," and "not a single medical or pharmaceutical company us[es] x-ray sterilization in the U.S. today." (Ex. 8, at ¶ 63; *see also* Ex. 23, at 1-2.) Those two areas are particularly important for revenue. (*See* Ex. 29, at 112:7-13.)

Even after being presented with concrete pricing proposals, "not one potential customer

was willing to sign a binding letter of intent" to commit to Synergy's U.S. x-ray proposal. (Ex. 39, at ¶ 10.) Some customers refused to sign even nonbinding letters of intent.[5] After "twenty months of strenuous and coordinated effort," "there [wa]s no reasonable prospect of customer acceptance for Synergy's X-ray project." (Ex. 39, at ¶¶ 3-4; Ex. 40, at 18; Ex. 41, at 1-2; Ex. 8, at ¶ 63.)

Indeed, many significant potential customers affirmatively disclaimed interest in Synergy x-ray sterilization.[6] Customers offered a variety of explanations. Some expressed uncertainties about the adequacy of x-ray sterilization.[7] Others expressed fears of regulatory costs.[8]

Other potential customers were concerned about the economics of x-ray sterilization. Many expressed concerns about pricing.[9] And others feared substantial cost and delay in

[5] *E.g.*, Ex. 42, at 1 ( ); Ex. 43 ( ); Ex. 44, at 1-3 ( ); Ex. 45 ( ).

[6] *See, e.g.*, Ex. 46 ( ) ); Ex. 47, at 1 ( ) ); Ex. 43, at 1 ( ); Ex. 49 ( ) Ex. 50, at 1 ( ) is Ex. 51 ( ); Ex. 52 ( ) ( ); Ex. 53 ( ); Ex. 54 ( ) ( ); Ex. 55 ( ); Ex. 56 ( ).

[7] Ex. 56 ( ) ( ; Ex. 55 (" "); Ex. 40, at 18 ( ); Ex. 57 ( ) .

[8] Ex. 49 ( ); Ex. 54 ( ).

[9] *See, e.g.*, Ex. 54 ( ) ).

switching modalities.[10] As an official at [redacted] put it, all of these obstacles [redacted] (Ex. 59, at 1.)

In the face of this wholesale failure to obtain binding commitments, the Commission contends that Synergy's marketing efforts nonetheless met with "resounding" success because it obtained some non-binding "letters of interest" from potential customers. (FTC Br. 11.) But "interest" is not commitment, and these customers' statements provided no comfort to Synergy. The Commission, for example, touts a letter of interest of [redacted]. (FTC Br. at 11 (citing Ex. 60).) But that letter states only that [redacted] (*Id.*) [redacted] told Synergy that it did not foresee changing its sterilization method [redacted] (Ex. 46.) Far from providing "resounding" support, this company's statements convey skepticism. *See United States v. Sungard Data Sys., Inc.*, 172 F. Supp. 2d 172, 183 (D.D.C. 2001) (rejecting customer statements because "several customers who were interviewed by one party then changed their position when interviewed by the opposing party"). [redacted] similarly told the Commission that it was concerned about the merger because x-ray's entry [redacted] by providing access to a [redacted]. (Ex. 61, at ¶ 18.) But when deposed, [redacted]. (Ex. 62, at 170:13-171:25; *see also id.* at 132:17-133:8, 135:9-137:23, 140:18-23, 151:16-24, 156:15-158:2.)

The Commission's reliance on [redacted]s purported interest is similarly flawed: in its

[10] Ex. 53 ([redacted]) [redacted]; Ex. 49 ([redacted]); Ex. 58, at ¶ 10 ([redacted]).

deposition, [redacted] stated that it would not even begin the process of [redacted] in the near future. (Ex. 63, at 208:24-209:2 [redacted] 217:19-219:3 ([redacted] 339:4-15 ([redacted]); *see also* Ex. 64, at 61:23-62:10 (from his view in [redacted] procurement, [redacted] That puts the qualifications in [redacted]'s letter of interest front and center. (*See* Ex. 65 (letter of interest "intended to be a means of communicating our interest . . . and is not intended to commit [redacted]").) Indeed, the Commission ignores that [redacted] watered down even the nonbinding letter of interest that Synergy asked it to sign because, as it told Synergy at that time, it did [redacted] and wanted to instead say only [redacted] (Ex. 66, at 1 (emphasis added); Ex. 63, at 177-97, 182:24-185:19 ([redacted] told McLean by phone that [redacted]

Testimony from every customer deposed in this case underscores how non-committal and preliminary their x-ray interest was (and remains), consistent with their hedged language in the declarations the Commission obtained from them.[11] Some of these customers changed the

[11] *See, e.g.*, Ex. 67, at 73-77, 82-97, 104 (would not sign non-binding letter of interest or commit to testing any products [redacted]; Ex. 63, at

Commission's drafts of their declarations to ensure the language was appropriately non-committal.[12] And, when [redacted] was asked about language in its declaration stating that [redacted] the Commission objected to the "speculation." (Ex. 68, at 135-37.) The Commission is correct, of course—all of the declarations the Commission drafted for customers include speculation regarding whether they would use x-ray sterilization in the U.S. and under what circumstances.

During the July 2014 SEB meeting, McLean informed the SEB "that despite there being

(continued…)

107-10, 112-18, 130 [redacted] Ex. 69, at 58-59, 61-66, 139-40, 143-44 ( [redacted] ; Ex. 62, at 132-36, 148-57, 167-71 ( [redacted] Ex. 63, at 177-86, 189-92 ( [redacted] Ex. 70, at 159-66 ( [redacted] Ex. 71, at 81-84, 94-95 ( [redacted] ; Ex. 72, at 93-98, 106-07, 114-15 [redacted] Ex. 73, at 132-33, 180 [redacted]

[12] *See, e.g.*, Ex. 67, at 125-28, 135-38, 141, 164 (made multiple changes to Commission's draft, including modifying language stating [redacted] x. 73, at 177-79 [redacted]

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." (Ex. 74, at 13.) At the time, McLean wanted the SEB to understand that "customers . . . were not committing and they were not going to commit." (Ex. 29, at 102:13-21). In response to McLean's report, Steeves noted that "a key point was to convince a number of Global Key Accounts to want to be involved and to support Synergy in the project so as to give them a competitive advantage." (Ex. 75, at 13.)

At the September 2014 SEB meeting, McLean reiterated that the team did "not have a single committed customer" and that he did not "see any prospect of a single committed customer." (Ex. 29, at 116:8-21; *see also* Ex. 40, at 18 (McLean "noted that it was difficult to get a base load customer to bear any risk of X-ray given that it [was] new and unproved in the US").) Despite the team's concerted efforts over a period of months, "even up until [Synergy] cancel[ed] the project [the team] did not even have the prospect of a committed customer." (Ex. 29, at 115:9-14; *see also* Ex. 8, at ¶ 63; Ex. 41, at 1-2 ("[N]o customers have committed to the technology and we do not have any prospects of customers who are likely to undertake a commitment.").) By that time, potential customers declined to commit, including "a clear and definitive no" from [redacted], which had been believed to be the very "best prospect for x-ray." (Ex. 29, at 164:21-23; Ex. 63, at 182:24-185:16 ([redacted] told McLean [redacted] could not commit to [redacted] Ex. 76.) Synergy had "exhausted the list of potential customers for U.S. X-ray" and it had "obtained no results." (Ex. 39, at ¶ 4.) This total absence of customer commitments precluded any business plan ultimately developed in the project from proceeding to the second-stage black hat analysis. (*See* Ex. 5, at 19:2-18, 20:13-25, 108:4-109:1, 182:20-183:1; Ex. 6, at

221:17-222:11.)

**ii. No Business Plan Could Have Been Approved Due To The Inadequacy Of the Project's IRR Numbers.**

Barring exceptional circumstances, the PLC Board would not approve funding for a discretionary capital expansion or greenfield project unless the project could project a 10-year IRR of at least 15%. (*See* Ex. 8, at ¶¶ 7-8, 11, 17; Ex. 5, at 79:10-22; Ex. 2, at 131:18-132:2.) While Synergy has, on rare occasions, funded projects with slightly lower IRRs, these projects always involved "special factors, such as heightened assurance of customer commitment or revenue where there is little to no downside to the projected financial metrics within the business case."[13] (Ex. 8, at ¶ 9.) The 15% minimum IRR was well established and uncontroversial. It was communicated internally. (*See* Ex. 77, § 9.3.2 ("The Group target IRR on all investments is 15%.").) And it was announced to lenders externally. (*See* Ex. 78, at 1 ("For new contracts [Synergy tends] to use a hurdle rate of a 15% post tax IRR.").) It was also a requirement that investors expect of Synergy investments. (*See* Ex. 5, at 82:5-9; Ex. 6, at 82:6-23.) In short, the 15% "hurdle rate" was "very well-known, accurately communicated, and strictly adhered to." (Ex. 29, at 106:17-21; *see also* Ex. 12, at 111:1-15; Ex. 80, at 1 ("Work a model . . . with minimum IRR post tax of 15%."); Ex. 2, at 135:12-16 (stating that 15% is the "standard rate . . . established by Gavin [Hill] and group finance" for "investment projects").)

[13] For example, the [redacted] business case was funded with a ten-year IRR of [redacted]% "because (i) the revenue was committed with minimal risk, and (ii) the business case excluded the impact of volume from any new customers, which would improve the financial metrics to above our hurdle rates." (Ex. 8, at ¶ 42; Ex. 38.) Synergy may also make an exception for "projects required for health and safety . . . and regulatory compliance," although even those exceptional projects are "assessed under [the] same hurdle rates." (Ex. 8, at ¶ 9.) The [redacted] was funded with a ten-year IRR of [redacted]% because "[redacted] was required to: (i) close the risk of noncompliance associated with the lack of product segregation, (ii) mitigate the risk of damaging customer products due to lack of storage space, and (iii) eliminate [a] health and safety concern [to] warehouse operators." (*Id.* at ¶ 43; Ex. 38.)

The U.S. x-ray project would have been "by far the largest greenfield capital project Synergy ha[d] ever undertaken," but it "fail[ed] Synergy's internal financial hurdles by far," and was thus "fundamentally inconsistent with Synergy's funding standard and practices." (Ex. 8, at ¶ 3(C); *see also* Ex. 31, at 2 ("This will be the largest organic growth project, in terms of both capital expenditure and reach, ever undertaken by Synergy Health."); Ex. 81, at 1). It "showed a 10-year IRR of only 6.5% for the combined proposed plaints in Texas and Indiana." (Ex. 8, at ¶ 64). And even these unsatisfactory numbers were improperly inflated. The business team obtained them only by including e-beam revenues it believed would have been transferred from Synergy's existing Lima, Ohio e-beam facility. These revenues would have eventually been excluded by the finance team, which would have driven down the IRR even lower than 6.5%. (*See* Ex. 8, at ¶ 64; Ex. 6, at 68:6-18.)

The x-ray project thus could never "meet Synergy's financial hurdles for capital projects and offer[ed] no reason to deviate from them." (Ex. 8, at ¶ 67; Ex. 6, at 19:2-18, 20:13-25, 108:4-109:1). For this reason alone "neither the SEB nor plc Board would approve the U.S. x-ray project." (Ex. 8, at ¶ 67; *see also* Ex. 41, at 2 ("[T]he business case will not meet the financial hurdle rates required by SEB and then plc Board . . . .").)

**iii. Unacceptably High CAPEX Figures Precluded The Approval Of Any Business Plan.**

Following the September 2014 presentation, the SEB directed the x-ray team to reduce the project's anticipated capital costs. (*See* Ex. 26 (explaining that "the financial work yesterday was poor and doesn't provide the robustness and confidence necessary" to justify the project); *see also* Ex. 31, at 12 ("The SEB identified the following as key actions and objectives to be addressed: Further reduce CAPEX by at least $1.5MM . . . ."); Ex. 29, at 99:6-11; Ex. 12, at

123:21-124:13, 128:1-14, 134:10-13; Ex. 8, at ¶ 3(C)).)[14]

But these CAPEX reductions were never realized. To the contrary, despite the best efforts of the business team, the project's economics only worsened after the September 2014 meeting. This occurred for several reasons.

First, Synergy's initial guesses on the combined costs of the facility and shielding "went up significantly" once actual proposals from contractors were considered. (Ex. 15, at 198:21-199:6.) On October 23, 2014, a contractor provided estimates for the cost of building the facilities in Indiana and Texas. (Ex. 82.) Based on those estimates, Frampton determined that the CAPEX for the two planned x-ray facilities had *increased* by approximately $2.5 million. (*See* Ex. 83, at 10.)

Second, and as described more fully below, the one part of the September proposal that seemed the most certain—the use of [redacted] machine—began to unravel. By the end of 2014, it was becoming increasingly clear that the [redacted] would not handle the workload in the model. This meant that either the modeled revenues would have to be reduced or that a larger machine would have to be accounted for in the model. (*See* Ex. 84, at 2 (stating that "we need to update our CAPEX models"); Ex. 85, at 1 (stating that "the model has capex for a [redacted] but revenues assuming 400kW power").)

Synergy and [redacted] tried to address the technology issue and the discussions eventually revolved around the larger [redacted] machine with various configuration options allowing it to meet Synergy's needs. But the configuration of the larger and more expensive machine was effectively a hypothetical unit that had never been designed, built, tested or priced. (Ex. 86, at 1-

[14] There is disagreement among Synergy personnel whether the $1.5 million was accurate or should have been higher, but subsequent events would make the question irrelevant—costs for the project were only going up.

2 (describing modifications to [redacted] as "less risky option" but also developing "mitigation strategies" if it failed to achieve 10 MeV e-beam); *see also* Ex. 87, at 1.)

Thus, the Synergy team could not be confident either that the price was final or that the technology would work as anticipated. Because price discussions were ongoing when the project was canceled, (*see* Ex. 33, at 200:14-19), Synergy was never certain about the machine's final cost. This result was especially problematic because, at the September 2014 SEB meeting, Tyranski specifically identified machine costs from [redacted] as an area where it might be "possible to cut $2m" of CAPEX. (Ex. 40, at 18.)

In short, deep and persistent financial infirmities prevented the development of any approvable plan.

**c. Synergy Lacked The Technological Means To Enter, Because No Extant X-Ray Machine Has Proved Adequate For Its Needs.**

Synergy could not enter the U.S. market unless it had the technological means to do so. *See Tenneco, Inc.*, 689 F.2d at 355. But, in addition to facing increasing costs for the needed technology, it also faced persistent and worsening technological problems. There simply proved to be no existing x-ray [redacted] shown to be sufficient to meet Synergy's needs.

The [redacted] in the September 2014 business update needed to process products in both x-ray and e-beam modalities, *i.e.*, as a duo system, which McLean viewed as essential to the project's success:

> [W]e cannot make the economics work without the e-beam (duo system). Simple as that. We need the duo system as we will be transferring base load volumes from our Americas e-beam network across these sites which will make them financially viable much more early. More simply said, if we . . . do not have the e-beam to supplement, the economic case completely collapses and we may as well cancel the meeting tomorrow.

(Ex. 88, at 1; *see also* Ex. 13, at 147:11-20, 148:15-149:6.)

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This required a machine able to generate 7 MeV in x-ray mode and 10 MeV in e-beam mode. (*See* Ex. 89, at 1.) In addition, the machine needed at least 400 kW of power in x-ray mode to achieve the volume throughput necessary to reach the x-ray team's revenue projections. (*Id.*; *see also* Ex. 90; Ex. 15, at 231:21-232:25; Ex. 85, at 1; Ex. 91, at 1 ("The ideal system for us will be 400kW, 10MEV e-beam, and 7MEV x-ray." (sic throughout)); Ex. 90; Ex. 92, at 8; Ex. 13, at 134:14-18; Ex. 15, at 234:11-16 (noting that this particular technology "ha[d] never been done before").) Synergy required these specifications in part because it intended "to run [the] system the majority of the time in the X-ray mode." (Ex. 93, at 1; Ex. 21, at 2 (stating that the team's "primary intent [was] x-ray, with a little e-beam to improve flexibility and profitability"); Ex. 13, at 158:23-160:14.) Because the [redacted] could not deliver 400 kW in x-ray mode as initially promised, (Ex. 93, at 1), and because [redacted] could not deliver 10 MeV in e-beam mode (Ex. 94, at 1-2), Synergy's project required a new custom configuration from [redacted].

This additional customization, however, introduced significant technological uncertainty. On December 8, 2014, [redacted] told Tyranski that "we are developing the offering for the [redacted] that would be able to operate at 10 MeV for E-Beam processing along with its high power 7 MeV X-Ray capacity." (Ex. 95, at 1.) [redacted] circulated a "draft copy" of the scope of work on the [redacted] on January 9, 2015, characterizing it as "still to be validated by both parties." (Ex. 96.) [redacted] then retracted the document six days later, recognizing that he had made a number of errors and asking Synergy to "trash that one." (Ex. 97, at 1.) The next day, McEvoy described [redacted]'s materials to Tyranski as "mumbo jumbo," (Ex. 98, at 1), and Tyranski wrote [redacted] to let him know that, in the absence of sufficient documentation from [redacted], the meeting at Däniken planned for January 20-21 would be "more of a technical discussion vs

contractual." (Ex. 99, at 1.) [redacted] replied that "the technical configuration needs to be better defined, which impacts the scope/price and also what is written into the" purchase agreement. (Ex. 100, at 1.) But Synergy could not define the technical configuration because it did not have customer commitments and therefore did not know what products its machines would need to process. (Ex. 15, at 161:14-162:3; Ex. 18, at 221:6-222:3; Ex. 33, at 29:21-30:10; Ex. 14, at 77:7-13 ("[T]here [were] a lot of details not finalized into our user requirement specification that was necessary for [redacted] to complete their proposal to us."); Ex. 101, at 1 (noting outstanding deliverables from Synergy to [redacted] regarding "scan height, conveyor, system power, etc." and relaying that [redacted] "would rather not . . . quote more system options until [Synergy is] firm on the design").)

In short, Synergy had no grounds for confidence that any technologically sufficient machine existed. Neither Synergy nor any other reasonable business would have sunk close to $6 million apiece into two as yet non-existent machines with untested capabilities.

**d. Synergy Certainly Cannot Enter Now.**

Synergy was nowhere close to resolving all of the financial, decisional, and technological impediments to entry when the project ended. These problems grew worse over time, and the Commission offers no explanation how any of them (let alone all of them) would have simply vanished in time for a quick entry into the U.S. market.

What is all the more clear, however, is that Synergy will not enter the U.S. market with x-ray in the foreseeable future *now* if the merger were enjoined. All of the foregoing problems remain at least as severe today as when the project ended. Intervening developments have rendered entry even more unlikely. Negotiations with [redacted] have been halted and Synergy's option to [redacted] has lapsed. (*See* Ex. 13, at 161:12-162:6; Ex. 33, at 201:18-202:5.)

The project team has disbanded. (*See* Ex.79, at 1; Ex. 2, at 45:15-46:1; Ex. 102, at 18:11-21.) And Synergy has told customers and vendors, such entry would not succeed. (*See, e.g.*, Ex. 112.) Even if the Commission had somehow been able to show that Synergy would have entered *but for* the merger, that would still not justify an injunction today if such entry had been rendered impossible by intervening events, because an injunction would not result in any entry or any enhancement of competition.

**2. Any Entry By Synergy Would Not Yield Pro-Competitive Effects.**

The Commission must also show by heightened proof that Synergy's potential entry "offer[s] a substantial likelihood of ultimately producing deconcentration of th[e] market or other significant pro-competitive effects." *Marine Bancorporation, Inc.*, 418 U.S. at 629-630; *see Tenneco, Inc.*, 689 F.2d at 352 (same). An entry is "unlikely to have a significant impact unless [the entrant] eventually accumulates a market share sufficient to challenge the dominance of the established firms." *Mercantile Texas Corp. v. Bd. of Governors of Fed. Reserve Sys.*, 638 F.2d 1255, 1270 (5th Cir. 1981). In addition, "[i]f there are numerous potential competitors waiting in the wings, elimination of [one company] as one potential entrant would not be significant." *Id.* at 1267; *see Atl. Richfield Co.*, 549 F.2d at 299.

Here, the Commission cannot establish that any hypothetical entry by Synergy into the x-ray market would produce any significant deconcentration or pro-competitive effects. The evidence shows that x-ray sterilization would not achieve significant market share, and Synergy was not specially situated to enter, such that its elimination as a potential competitor is or would be significant.

**a. The Commission's Proposed Market Definition Cannot Withstand Scrutiny.**

The Commission alleges two product markets that seemingly reflect a desire to hedge its

position about the product space in which to analyze hypothetical competitive effects: (1) a narrow market comprised of contract gamma and x-ray radiation sterilization sold to customers that cannot switch affected products to e-beam sterilization; and (2) a broader market for contract radiation sterilization that includes gamma, x-ray, and e-beam sterilization. In both putative markets, the Commission inexplicably excludes sterilization capacity by in-house providers and through EO sterilization. The Commission's hedged and incomplete product market definition cannot withstand scrutiny, especially over the ten-year time alleged entry and effects horizon envisioned by the Commission's complaint and their economic expert. (FTC Expert Report at 63, 81-86, 109.)

The Commission must prove the relevant market. *Ky. Speedway, LLC v. Nat'l Ass'n of Stock Car Auto Racing, Inc.*, 588 F.3d 908, 916 (6th Cir. 2009). "[T]he 'reasonable interchangeability' standard [is] [t]he essential test" and the hypothetical monopolist concept is the accepted method for determining "reasonable interchangeability." *Id.* at 917 (affirming exclusion of expert because he did not perform required test). In defining the market, courts require objective data such as econometric evidence. *See Menasha Corp. v. News Am. Mktg. In-Store, Inc.*, 354 F.3d 661, 664 (7th Cir. 2004); *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1173 (N.D. Cal. 2004) (rejecting sufficiency of expert testimony based on "no formal studies of price discrimination"). By contrast, courts consider "'subjective' testimony by customers . . . or by company officials" to be "often unreliable," not representative, and not significant enough to merit antitrust concern. Areeda & Hovenkamp, at ¶ 538; *see FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1054 (8th Cir. 1999); *United States v. Engelhard Corp.*, 126 F.3d 1302, 1306 (11th Cir. 1997); *U.S. v. Sungard Data Sys., Inc.*, 172 F. Supp. 2d 172, 183, 192 (D.D.C. 2010). The Commission cannot and has not identified any empirical basis to exclude

EO sterilization and in-house sterilization—which collectively account for almost 60 percent of U.S. sterilization services (Defs.' Expert Report at 11)—particularly over the Commission's multi-year time horizon.

To the extent the Commission is relying on a "practical indicia" approach to support its putative markets, it is mistaken. (*See* FTC Br. at 7; FTC Expert Report at 30-34, 41-48.) That approach properly "come[s] into play only after . . . evaluating 'the reasonable interchangeability of use or the cross-elasticity of demand'" using the hypothetical monopolist test. *Ky. Speedway*, 588 F.3d at 918 (emphasis added). In addition, the Commission's theorizing relies extensively on general statements. (*See* FTC Br. at 7-8; FTC Expert Report at 30-34, 41-48.) For example, the Commission points to customer statements that it is difficult to build in-house facilities, (FTC Expert Report at 31), yet [redacted] did just that. (Ex. 104, at 1.) [redacted] is even exploring in-house x-ray. (*See* Ex. 63, at 139:6-140:5 (explaining [redacted] has [redacted] Ex. 126 ("[redacted]).) The Commission's failure to rely on objective evidence and "revealed" as opposed to "stated" preferences (Defs.' Expert Report at 15) is unsurprising: because its novel theory turns on a "lessening" of potential future competition, there is no real-world, non-speculative U.S. qualitative or quantitative information to rely upon in support.

Second, the Commission's exclusion of in-house sterilization from the relevant market makes no sense given the significance of that business. Many U.S. medical device manufacturers operate in-house sterilization facilities.[15] Vertically integrated firms can and

[15] They include: [redacted]

should be deemed market participants when there is direct evidence that captive producers exert a competitive impact on "merchant suppliers." *See* Horizontal Merger Guidelines, § 5.1 (2010). For example, in *United States v. SunGard Data Systems, Inc.*, 172 F. Supp. 2d 172 (D.D.C. 2001), the D.C. District Court explained that "[c]ourts have generally recognized that when a customer can replace the services of [an external product] with an internally-created [] system, their 'captive output' (i.e., the self-production of all or part of the relevant product) should be included in the same market." *Id.* at 386. Here, in-house sterilization capacity should be included in the relevant market because, as reflected in record testimony and documents, in-house providers have and will continue to exert competitive constraints on contract sterilization providers by taking, or credibly threatening to take, significant volume in-house and by competing directly with contract sterilizers for third party volumes.

In-house sterilization continues to be a significant competitive constraint and source of churn. In 2015, [redacted]% of Steris' lost business was to in-house competition. (Ex. 106, at 11 (showing [redacted] sterilization losses in FY15 were to in-house competition—[redacted]).) [redacted], which accounted for approximately [redacted]. These sales accounted for approximately [redacted] percent of [redacted]'s total gamma sterilization business in FY 2014. (Ex. 107, at 54:10-19, 55:23-56:1; *see also* STERIS's ODMSrt database, produced to the FTC as STERISFTC00000213.) According

(continued…)

[redacted](Defs.' Expert Report at Appx. A.)

to some, in-house sterilization [redacted] (Ex. 109, at 4.) Companies with in-house sterilization are continuing to invest in their in-house facilities (Ex. 104, at 1 (noting [redacted])), and companies have in the past and could in the future sell in-house capacity to third parties. (Ex. 110, at 3-4 ([redacted]); Ex. 62, at 143-144 ([redacted]).) Given the evidence of customer switching from contract gamma sterilization to in-house sterilization, there is no basis in the record for excluding in-house sterilization from a properly-defined relevant market.

In order to establish a discernible and significant group of customers vulnerable to price discrimination, *see* Merger Guidelines, at 6-7, 10, the Commission must provide something more than that the defendants "somehow" are "able to determine" the key features of some of their customers. *Oracle*, 331 F. Supp. 2d at 1173; *Sungard*; 172 F. Supp. 2d at 189. Here, the Commission assigns significance to allegations that suppliers individually negotiate prices with customers and that some customers reportedly cannot switch from gamma to e-beam. (FTC Br. at 7-8; FTC Expert Report at 44-47.) Notably missing from the Commission's complaint or its expert economist reports is evidence that suppliers are engaged in price discrimination today that would be redressed by the Commission's hypothetical entry and effects resulting from Synergy's x-ray entry. The Commission seems to conflate differential pricing with price discrimination; the fact that suppliers may individually negotiate with customers and charge them different prices is not indicative of market power if those prices are driven by differences in costs (*e.g.*, different dose rates). The Commission has not and cannot identify any means by which sterilization providers reliably and effectively identify targeted customers, nor has the

Commission identified how many such customers exist nor the magnitude of their contract gamma purchases. Further, even customers with similar products use different modalities or can switch modalities over time. (Defs.' Expert Report at 27-28 (tissues sterilized with gamma or e-beam); Ex. 19, at 5 ( sterilizes tissue with e-beam); Ex. 107, at 54:3-7 ( moves volume from gamma to e-beam).)

Finally, the Commission alleges that the relevant geographic markets are the areas within approximately 500 miles of each of the five locations where Synergy allegedly would have built an x-ray sterilization plant. The Complaint identifies the following locations: (Compl. at ¶ 52.) Even assuming it is appropriate to analyze this transaction in the context of regional markets, identifying legally defensible geographic markets for these hypothetical sites presents a significant challenge, especially for the locations—characterized by the Commission with no more specificity than at a state ( ) and regional level ( ). The lack of precision is not surprising: for these three hypothetical sites, the Synergy x-ray team conducted no financial modeling and no detailed assessment of potential locations.

**b. X-Ray Would Not Now Achieve Significant Market Share.**

The evidence shows that any Synergy x-ray entry would not achieve a significant market share. Currently, the only use of commercial x-ray sterilization technology in the U.S. is one facility that sterilizes the mail. (Ex. 111, at ¶ 15; Defs.' Expert Report at 30.) And there is nowhere to go: As , which has a significant interest in encouraging the development of x-ray sterilization, has told the Commission, " (Ex. 112, at 2.) This is not surprising given the

extremely limited demand for x-ray sterilization: Customers have repeatedly proven unwilling to switch from gamma sterilization to x-ray sterilization, for a number of reasons, including the substantial cost and delay of switching modalities. To the extent customers expressed interest in switching at all, it was due to potential cost savings, but Synergy's projected x-ray price far exceeds existing gamma sterilization prices.

The Commission's contrary argument is based on rosy and unsupported predictions of 15% market penetration on the part of those persons within Synergy who advocated for x-ray and on vague and unrealistic customer statements. The Commission notably does not grapple with the failure of the real world to live up to such pie-in-sky puffery.

**i.**

Synergy's experience with . The Däniken x-ray equipment ordinarily runs at of capacity. (Ex. 113, at 49:1-9.) Business development was plagued by (Ex. 114, at 1; *see* Ex. 115, at 3-4; Ex. 88 Ex. 2, at 118:11-16 ; Ex. 23 ("if we push ahead and build without proper baseload customer(s) in the U.S. it is to our peril . . . it could be a complete disaster").) As a result of the failure to attract

customers, Däniken was [redacted] (Ex. 116, at 3.)

At first, Synergy was able to convert some low-margin, non-medical, non-pharmaceutical customers to x-ray sterilization. [redacted] (Ex. 113, at 83:3-20). [redacted]. (Ex. 117, at 1 ("At the same time there has been a push to fill the X-Ray partly from the same customer base, and as a result there has been some [redacted] Synergy also tried a [redacted]. (Ex. 118, at 12-13.)

Synergy executive Andrew McLean acknowledged in May 2014, that [redacted] (Ex. 23, at 1.) But at the end of the day, only [redacted] medical, pharmaceutical, and labware customers—the type of customers that dominate the sterilization marketplace—switched from gamma to x-ray in 2014, representing [redacted]% of the total medical, pharmaceutical, and labware sterilization revenue at Däniken. (Ex. 119 (for [redacted] total customers switched, representing [redacted]% of Däniken sterilization revenue).)

**c. Synergy Was Not Specially Situated To Enter With X-Ray.**

In addition to failing to show that Synergy's entry into the U.S. x-ray sterilization space would have significant pro-competitive effects, the Commission also cannot show that Synergy possesses entry advantages not shared by other potential entrants, such that its elimination as a hypothetical entrant would have a meaningful effect on future competition. *Mercantile Texas*

*Corp. v. Bd. of Governors of Fed. Reserve Sys*., 638 F.2d 1255, 1267 (5th Cir. 1981); *F.T.C. v. Atl. Richfield Co.*, 549 F.2d 289, 299 (4th Cir. 1977). First, Synergy does not own or control any intellectual property, technology, or know-how related to x-ray sterilization, nor does Synergy possess any contract rights that would prevent others from entering. Neither Synergy's x-ray plant at Däniken nor its evaluation plans for x-ray in the U.S. confer any durable advantage on Synergy as an entrant. And while Synergy [redacted], but the agreement expired in March 2015. (Ex. 123; Ex. 124, at 82-83.) As a result, with or without the transaction, [redacted] remains free to market and sell its x-ray equipment for use in the United States. (Ex. 121, at 33.)

Second, Synergy's local presence in the U.S. is not significant, and this minimal presence confers no particular advantage to Synergy with respect to x-ray entry. With a de minimis share in U.S. sterilization (Ex. 1, at 234:5-6), Synergy is not materially larger, from a capacity perspective, than many other contract sterilization firms in North America, including Iotron, E-BEAM Services, and NUTEK, and these suppliers were able to achieve their current shares quickly. (Ex. 125, at 192:25-193:5.) Notably, Synergy achieved its limited U.S. presence only within the past few years, and entirely through acquisition.

Third, there is no evidence in the record to support a conclusion that a global presence is essential to accomplish x-ray expansion in the United States. Mediscan, Iotron, and NUTEK [redacted] are examples demonstrating that companies with fewer facilities and less international exposure could enter with x-ray. For example, Mediscan, the in-house subsidiary of Greiner, a medical device company, recently purchased IBA x-ray equipment to use in two facilities in Austria. (Ex. 127, at ¶ 7.) Similar to Mediscan, sterilization customers in the U.S., including those that operate in-house sterilization facilities for other modalities (gamma, e-beam,

and/or EO), could potentially expand into x-ray if there were a viable business case for doing so, particularly over the same multi-year time period as the alleged Synergy entry and effects. In fact, [redacted]. (Ex. 63, at 139:6-140:5 (explaining [redacted] has [redacted]); Ex. 126.) In addition, [redacted] (Ex. 128, at ¶¶ 3, 12.) The Commission's expert defensively makes much of the fact that Nutek is facing eminent domain action regarding a facility, (FTC Supp. Exp. Report at 34-35), but that is a distraction: Nutek's CEO stated that [redacted] (Ex. 129, at 11:7-17.) If the Commission's theory is true and there is demand for x-ray sterilization services in the U.S. at some indeterminate time in the future, then incumbent contract or in-house providers would see the profit opportunity and enter or expand their provision of x-ray services. Synergy's Däniken experience demonstrates that, despite years of efforts, [redacted] x-ray to sterilize medical devices and pharmaceutical products. [redacted]

**d. The Commission's Contrary Arguments Do Not Withstand Scrutiny.**

The Commission points to three types of alleged facts to counter all of the foregoing evidence. First, the Commission claims that Synergy would obtain 15% of the U.S. x-ray market and set off a "street fight" between STERIS and Sterigenics. (FTC Br. at 13; FTC Expert Report at 90-95.) Second, it claims that customers viewed Synergy's entry as important. (FTC Br. at 14; FTC Expert Report at 95-99.) Third, it claims that Synergy has "enormous entry advantages." (FTC Br. at 15; FTC Expert Report 111-21.) All three are wrong.

[redacted]. (*See* Ex. 116, at 3 [redacted]; *supra* Part I.B.1.a.) Despite Synergy's pre-acquisition forecasts that Däniken's x-ray plant would be at [redacted]% by FY2015 and [redacted]% by FY2016, (*see* Ex. 130, at 14 (Table 3.10)), its capacity was [redacted] (*i.e.*, [redacted]% to [redacted]%) by the end of FY2015, (*see* Ex. 8, at ¶ 4). Of that fractional utilization, less than just [redacted] percent of the FY2015 x-ray sterilization revenue at Däniken was attributable to the targeted medical devices and pharmaceuticals product segment, (*see* Ex. 8, at ¶ 4), which account for [redacted]% of all gamma revenue in the U.S. (of which Synergy's U.S. entry model depended on capturing a 15% share) (*see* Ex. 11, at 3). The Synergy officials that the Commission cites also predicted that they could make the business case for x-ray. They never did. (*See supra* Part I.B.1.) The Commission is mistaking the puffery or hopes of businesspeople pitching a project and salespeople touting a service with reasoned analysis based on objective data. *See, e.g.*, *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1054 (8th Cir. 1999) (rejecting business testimony inconsistent with basic facts).

The Commission's reliance on customer statements is similarly misplaced. The customers that the Commission claims are deeply concerned about the loss of x-ray have not committed to x-ray at any point. (*See supra* Part I.B.1.b.i.) And some of them have distanced themselves from their vague statements to the Commission. *See id.*; *Sungard Data Sys., Inc.*, 172 F. Supp. 2d at 183 (rejecting customer statements because "several customers who were interviewed by one party then changed their position when interviewed by the opposing party" and "[c]ustomer responses were also often vague").

Finally, the Commission's assertion of "enormous" entry advantages is unsupported. The

Commission points to Synergy's alleged two-year entry planning and customer cultivation. But the customer cultivation produced no binding customer commitments. (*See supra* at Part I.B.1.b.i.) And Synergy's planning is hardly an advantage, because in that time Synergy was not able to solve the business case problems that prevented it from entering. (*See supra* at Part I.B.1.) The Commission's expert observes that Synergy is a big company and claims that Däniken was a good dry-run for testing products. (FTC Expert Report at 112-114.) But bigger is not always better in this industry: there are more than 29 small U.S. contract sterilization providers, and some of the biggest customers, such as [redacted] and [redacted], use them. (Ex. 131, at ¶ 11 ([redacted]); Ex. 132, ¶ 7 ([redacted]).) Mediscan's entry in Austria and Nutek's entry in California also prove that size is not disqualifying. (*See supra* at I.B.2.) [redacted]. (*See supra* at I.B.2.b.i.) And it has not been used as some sort of dress rehearsal. Indeed, [redacted] tested a product at Däniken and then still refused to commit to x-ray sterilization in the U.S., and it is not using x-ray for products sterilized at Däniken. (Ex. 131, at ¶ 18 ([redacted] used Däniken for testing [redacted]).)

* * *

X-ray sterilization is a costly technology with unproven demand. [redacted] The Commission cannot show that Synergy's entry into the U.S. through x-ray sterilization was likely to obtain market share and thus have significant pro-competitive effects.

## II. THE EQUITIES SUPPORT DENIAL OF PRELIMINARY RELIEF.

As shown above, *see supra* at pages 3-4, this merger will generate substantial pro-

competitive effects in convenience to customers of a globally integrated sterilization company, and improved opportunities for research and development that will provide substantial long-term benefit to customers. On the other side of the balance, the Commission offers none of the traditional harms that can result from genuinely anticompetitive mergers. (*E.g.*, Ex. 134, at 130-31; Ex. 107, at 309-10). Even if the Commission's theory premised on the speculated reduction of postulated *future* gains in competition had any legal merit any such speculative, contingent future harms would be outweighed by the concrete and immediate public benefits of the merger. *See, e.g.*, *FTC v. Weyerhauser Co.*, 665 F.2d 1072, 1083 (D.C. Cir. 1981) (noting need to weigh benefits "that may be lost by a merger blocking preliminary injunction, whether or not those benefits could be asserted defensively in a proceeding for permanent relief").

Moreover, unlike the typical merger case, this merger could close during the pendency of the Commission's administrative proceedings without causing any harm to competition during the pendency of the case. Not even the Commission contends that Synergy will enter the U.S. market, or take steps toward doing so, while this case is being litigated. Therefore, there is less reason to preliminarily enjoin this merger than others. To be sure, preliminary injunctive relief can also be premised on the difficulties of unwinding a completed merger, but here, too, the unique context of this case counsels against the Commission's ordinary equities arguments, because the Commission has made no showing that it would be as difficult to undo a merger of parties that are largely geographically distinct from each other (or simply to require an x-ray technology or discrete operational spin-off) than it would be in a traditional merger case involving the integration of companies operating together in the same jurisdictions.

## CONCLUSION

The Commission cannot possibly prove its case, let alone with the required level of

unequivocal proof. The Court should deny the motion for a preliminary injunction.

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Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on August 8, 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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