Sekisui America Corporation et al v. Hart et al

2014 | Cited 0 times | S.D. New York | February 21, 2014

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK
----------)(SEKISUI AMERICA CORPORATION and SEKISUI MEDICAL CO., LTD.,

Plaintiffs, - against- RICHARD HART and MARIE LOUISE TRUDEL-HART,

Defendants.

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OPINION AND ORDER

12 Civ. 3479 (SAS)

(SHIRA A. SCHEINDLIN, U.S.D.J.: I. INTRODUCTION

Sekisui America Corporation ("SAC") and Sekisui Medical Co., Ltd. ("SMD") (collectively, "Sekisui") bring this action for breach of contract against Richard Hart and Marie Louise Trudel-Hart (the "Harts,,).l Sekisui alleges that the Harts breached representations and warranties set forth in Sections 4.12, 4.14(a), 4.14(c), and 4.14(d) ofthe parties' Stock Purchase Agreement ("SPA"). The Harts' alleged breaches fall into two categories: (1) breaches related to the failure ofAmerica Diagnostica, Inc. ("AD I") to comply with FDA regulations, known as

See Complaint 1. Sekisui's fraud claim was dismissed by this Court in an October 17,2012 Opinion and Order. See Dkt. No. 28.

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Quality System Regulations (“ QSRs”); and (2) breaches related to Femtelle, ADI’ s breast cancer prognosis assay. The Harts deny that they breached any provision of 2 the SPA and counterclaim that Sekisui breached Section 2.6(d) by failing to use commercially reasonable efforts to market Femtelle

and omitting to take actions to obtain FDA approval for Femtelle, thereby preventing ADI from maximizing Femtelle revenues. Both parties seek damages. 3

I held a bench trial from January 13 to January 17, 2014. The parties made post-trial submissions on January 31, 2014. Pursuant to Rule 52(a) of the Federal Rules of Civil Procedure, I make the following findings of fact and conclusions of law. In reaching these findings and conclusions, I heard the testimony, examined the documentary evidence, observed the demeanor of the witnesses, and considered the arguments and submissions of counsel. II. FINDINGS OF FACT

A. Background

1. The Parties

See Plaintiffs' Trial Memorandum of Law (" Pl. Mem.") at 1-2. 2 See Defendants' Supplemental Proposed Findings of Fact and 3 Conclusions of Law and Annotated and Abridged Original Proposed Findings of Fact and Conclusions of Law (" Def. Facts and Concl.") at 23-24. The Harts have abandoned their declaratory judgment counterclaim. See Trial Transcript (" Tr.") at 867:10-23 (Jonathan Kortmansky, Counsel for the Harts).

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In 1982, the Harts founded ADI, a Connecticut corporation engaged in the discovery, manufacture, and marketing of medical diagnostic products. ADI 4 manufactured and marketed products that were designated " Research Use Only" and products that could be used as in vitro diagnostics (" IVD"). ADI was the 5

parent company of a Canadian subsidiary, a German subsidiary, and a French subsidiary. ADI with its subsidiaries had a maximum of thirty-five employees. 6 7

The Harts are citizens and residents of Connecticut. Until Sekisui 8 acquired ADI, the Harts owned 95.94% of the existing and outstanding shares of common stock of ADI. Richard Hart served as the President and Chief Executive 9 Officer (" CEO") of ADI and oversaw the company' s operations. Hart left ADI in 10 April 2010 for medical reasons. 11

See Joint Pretrial Order (" JPTO") at 2. 4 See Tr. at 143:12-144:9 (Kevin Morrissey). 5 See Plaintiffs' Exhibit (" Pl. Ex.") 7 (August 2008 CrossTree 6 Confidential Memorandum).

See id. 7 See JPTO at 2. 8 See id. 9 See Tr. at 73:15-74:2 (Mamoru Takemura). 10 See Pl. Ex. 14 (6/23/10 Email from Hart to Mamoru Koseki); Pl. Ex. 11 15 (5/27/10 Email from Richard Hart to Jeffrey Ellis).

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SAC and SMD are wholly owned subsidiaries of Sekisui Chemical Co., Ltd. SAC is a corporation organized under Delaware law with its principal 12 place of business in New Jersey. SMD is a Japanese corporation with its 13 principal place of business in Tokyo. Sekisui engages in the research, 14 development, manufacture, sale, import, and export of plastic medical products. 15

2. FDA Regulations and Procedures Section 520(f) of the Food Drug & Cosmetic Act (the " Act") gives the FDA authority to prescribe regulations requiring that the methods, facilities, and controls used for the manufacture, packing, storage, and installation of medical devices conform to good manufacturing practices. In 1997, the FDA 16 promulgated the QSRs. Under the QSRs, medical device manufacturers should 17 " establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of" the

See JPTO at 2. 12 See id. 13 See id. 14 See Pl. Ex. 48 (April 2009 KPMG Valuation Study). 15 See 21 U.S.C. § 360j(f). 16 See 21 C.F.R. § 820.1. 17

QSRs. Failure to comply with the QSRs renders a device " adulterated" under the 18 Act. 19

The QSRs are flexible regulations. According to the FDA, the QSRs are " an umbrella . . . that specifies general objectives rather than methods." 20 Because the QSRs " must apply to so many different types of devices, the regulation does not prescribe in detail how a manufacturer must produce a specific device." Instead, " the regulation provides the framework that all manufacturers 21 must follow by requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device . . . ." 22

The FDA advises its inspectors to " use good judgment in determining compliance with the [QSRs], keeping in mind that it is an umbrella . . . and all

21 C.F.R. § 820.5. This system is known as the Quality Management 18 System (" QMS"). See Tr. at 602:16-19 (Carrie Kuehn).

21 C.F.R. § 820.1(a). 19 FDA Investigations Operations Manual (" IOM") §5.6.2. The Court 20 takes judicial notice of the IOM and other widely available FDA publications because the facts therein are " not subject to reasonable dispute" and " can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2).

Defendants' Exhibit (" Def. Ex.") 8M (61 Fed. Reg. 52602). 21 IOM § 5.6.2. 22

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requirements may not apply or be necessary." Furthermore, inspectors should 23 " not insist that a manufacturer meet non-applicable requirements." Inspectors 24 should recognize that at small firms " division of work is at a minimum, with one person often assembling and testing the finished device." As such, " blueprints or 25 engineering drawings could be adequate procedures," and " several requirements can be met with a single procedure." 26

To determine compliance with the QSRs, the FDA conducts an Establishment Inspection (" EI"). An EI is an inspection of a medical device 27 manufacturing firm' s facilities and records. During an EI, the inspector 28 interviews the firm' s management responsible for the QMS. Inspectors use a 29 " top-down" approach to evaluate a firm' s system for addressing quality in four main areas: Management Control, Corrective and Preventive Actions (" CAPA"),

Id. 23 Id. 24 Id. § 5.6.7. 25 Id. 26 See 21 U.S.C. § 374. 27 See id. 28 See FDA Guide to Inspections of Quality Systems, Quality System 29 Inspection Technique (" QSIT") at 14-15. The Court takes judicial notice of QSIT, an FDA publication available at its website.

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Design Controls, and Production and Process Controls. Nonconformities must be 30 addressed through the CAPA process. CAPAs come from a company' s own 31 monitoring process, regulatory inspections, customer audits, and internal audits. 32

After the EI, the inspector may issue a Form 483, which may include " inspectional observations." Inspectional observations are not " final [FDA] 33 determination[s] regarding [a firm' s] compliance." Moreover, inspectors must 34 not report opinions, conclusions, or conditions as " violative" because " [t]he determination of whether any condition is violative is an agency decision made after considering all circumstances, facts and evidence, involving discussions with management . . . ." The inspector then discusses the Form 483 with the 35 manufacturer' s senior management. The firm may respond at that time or send a 36

See id. at 7-8. 30 See id. at 48. 31 See id. at 25. 32 Def. Ex. 4Q (FDA Transparency Sheet). 33 Def. Ex. D (6/23/05 FDA Form 483 issued to ADI); Def. Ex. E 34 (6/22/11 FDA Form 483 issued to ADI).

IOM § 5.2.3.3. 35 See QSIT at 30. 36

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corrective action plan to the FDA shortly thereafter. 37

The Director of the relevant field office considers the Form 483 observations, the inspector' s narrative of the inspection — the Establishment Inspection Report (" EIR") — and the firm' s

responses to the Form 483 observations. The Director then classifies the inspection as no action indicated 38 (“ NAI”), voluntary action indicated (“ VAI”), or official action indicated (“ OAI”). 39

An NAI is appropriate “ when no objectionable conditions were found during the inspection or the significance of the documented objectionable conditions found does not justify further action.” A VAI is given “ when 40 objectionable conditions or practices were found that do not meet the threshold of regulatory significance.” An OAI occurs when “ significant objectionable 41 conditions or practices were found and regulatory action is warranted to address the establishment’ s lack of compliance.” After issuing an OAI, the FDA may 42

See Tr. at 215:2-9 (Morrissey); Def. Ex. V (7/7/11 Letter from Joseph 37 Azary, ADI’ s Director of Quality Assurance and Regulatory Affairs, to the FDA).

See Def. Ex. 4Q. 38 See id. 39 Id. 40 Id. 41 Id. 42

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send a Warning Letter. Because a Warning Letter is “ informal and advisory,” it 43 communicates “ the agency’ s position on a matter, but does not commit the FDA to taking enforcement action.” 44

An inspection is “ closed” when “ a final decision has been made not to take [administrative] action or such action has been taken and the matter has been concluded.” Thus, when the FDA closes an action, it is satisfied with the results 45 of the inspection and the firm’ s responses. 46

B. Pre-Acquisition Events

1. 2004 and 2005 FDA Inspections Since at least 2004, ADI has manufactured and sold products regulated by the FDA and has therefore been subject to the QSRs. In 2004, the 47 FDA inspected ADI’ s facilities. After the inspection, the FDA sent ADI a 48 Warning Letter, stating that “ [t]he inspection revealed that [ADI’ s] devices are

See FDA Regulatory Procedures Manual § 4-1-8. 43 Id. § 4-1-1. 44 21 C.F.R. §20.64(d)(3). See also Tr. at 585:14-17 (Kuehn). 45 See Def. Ex. X (1/7/09 Morgan Lewis Preliminary Legal Due 46 Diligence Report).

See Tr. at 264:25-265:2 (Hugh Fryer); id. at 485:5-12 (Bhavna 47 Gaikwad).

See Pl. Ex. 197 (10/15/04 FDA Warning Letter). 48

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adulterated under [the Act], in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the [QSRs]." The letter noted that it " is not intended to be an all-inclusive 49 list of the deficiencies at [ADI]," and that it is ADI' s " responsibility to ensure adherence to each applicable requirement of the Act and FDA regulations." 50

In June 2005, FDA returned to ADI for a follow-up inspection. The 51 FDA found that " [ADI] has completed corrections on several previous observations and is in the process of completing all others." Specifically, the 52 FDA noted improvement in ADI' s training program, standard operating procedures (" SOPs"), device master records (" DMRs"), device history files (" DHFs"), 53 54 validation processes, and more. 55

Id. 49 Id. 50 See Def. Ex. B (10/17/05 FDA EIR). 51 Id. 52 A DMR " include[s], or refer[s] to the location of" the specifications 53 and production processes for manufacturing a device, quality assurance procedures, packaging, and labeling instructions. 21 C.F.R. § 820.181.

A DHF " contain[s] or reference[s] the records necessary to 54 demonstrate that the design was developed in accordance with the approved design plan[.]" Id. § 820.30.

See Def. Ex. B. 55

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Nevertheless, the FDA observed that (1) " [p]rocedures to ensure that equipment is routinely checked are not established, documented, and implemented;" (2) " procedures that describe the review and disposition process for nonconforming products were not complete;" and (3) " calibration procedures do not include provisions for remedial actions." However, the FDA noted that " all 56 three of these observations were being addressed by [ADI] and draft SOPs were in the process as [] observed." In October 2005, the FDA released the EIR to ADI, 57 closing the inspection. Thus, I find that the FDA considered ADI to be in 58 material compliance with the QSRs at that time.

2. Intertek Audits Interek is a private inspection, product testing, and certification company that operates internationally. Interek audits firms for compliance with 59 the International Organization of Standardization (" ISO"). Intertek auditors 60 conduct a comprehensive review of quality management system documentation

Id. 56

Id. 57 See id. 58 See Intertek website (Jan. 1, 2013), http://www.intertek.com. I take 59 judicial notice of the public information on the Intertek website and in the ISO Standards Catalogue.

See id. 60

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and then an on-site review. An ISO on-site inspection is similar to an FDA 61 inspection. Like an FDA inspector, the ISO auditor examines the firm' s QMS, 62 management responsibility, training, product design and development process, internal audits, CAPAs, and procedures for recalling non-conforming products. 63

If the auditor finds the firm compliant with ISO standards, Intertek grants ISO certification. ISO 13485:2003 sets forth the international standard for 64 medical device manufacturers' quality management systems, and is similar to the QSRs. In fact, the FDA specifically sought to make the QSRs " consistent, to the 65 extent possible" with ISO 13485:2003. In addition, the FDA has instituted a 66 pilot program that acknowledges ISO certification as evidence of compliance with the QSRs. 67

See Def. Ex. L (3/24/06 Intertek Systems Certification QMS 61 Checklist).

See Def. Ex. P (4/16/09 Intertek Systems Certification Audit Report). 62 See id. 63 See Intertek website. 64 See ISO Standards Catalogue, ISO 13485:2003. 65 Def. Ex. 8M. 66 See Tr. at 592:7-25 (Kuehn). 67

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Intertek audited ADI six times during the relevant period. The first 68 audits took place in March and April 2006. On March 23 and 24, 2006, Intertek 69 reviewed all of ADI' s QMS documentation. After finding ADI' s documents ISO 70 compliant, Intertek returned to ADI for an on-site inspection. ADI was certified 71 as ISO 13485:2003 compliant. Intertek noted that it had " verified [the] quality of 72 [ADI' s] internal audits." It found that ADI had " [g]ood use of customer 73 complaints, internal audits, [and] corrective and preventative actions [CAPAs], and [that] management review [] continually improve[d]." 74

On February 5, 2007, Intertek conducted a review of ADI documents to determine whether ADI also complied with the Canadian Medical Devices Conformity Assessment System (" CMDCAS"). On March 21, 2007, Intertek 75

The SPA refers to January 1, 2006 through the April 20, 2009 as the 68 relevant period for the representations and warranties at issue. See SPA § 4.14.

See Def. Ex. L; Def. Ex. M (4/27/06 Intertek Systems Certification 69 Audit Report).

See Def. Ex. L. 70 See Def. Ex. M. 71 See id. 72 Id. 73 Id. 74 See Def. Ex. N (3/21/07 Intertek Systems Certification Audit Report). 75

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conducted an on-site surveillance audit for continued ISO 13485:2003 certification and a CMDCAS upgrade. ADI was re-certified and upgraded. 76 77

On April 8 and 9, 2008, Intertek conducted a surveillance audit and extended ADI' s ISO certification. On April 14, 15, and 16, 2009 — four days 78 before Sekisui acquired ADI — Intertek audited ADI and granted ISO re- certification. Intertek noted that (1) " [t]he Management System was found to be 79 effectively implemented in spite of the minor nonconformities cited;" (2) " [the QMS continues to improve;" (3) " six sets of batch records were audited [and] found to be complete;" (4) " all [manufacturing] records reviewed were found to be complete;" (5) " [calibration] records of eight devices were sampled and found acceptable." Given the similarity between ISO 13485:2003 and the QSRs, I find 80 the Intertek audits highly probative of whether ADI materially complied with FDA regulations during the relevant period.

3. Supplier Audits The FDA requires manufacturers to evaluate suppliers from whom

See id. 76 See id. 77 See Def. Ex. O (4/9/08 Intertek Systems Certification Audit Report). 78 See Def. Ex. P (4/16/09 Intertek Systems Certification Audit Report). 79 Id. 80

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they purchase devices or components. Manufacturers may not purchase from 81 suppliers who are not compliant with the QSRs. 82

Two medical device manufacturers — ADI' s customers — audited ADI during the relevant period. On December 10, 2007, Siemens Dade Behring (" Siemens") found that ADI had " [v]ery clear structured written procedures." 83 Siemens noted that " [t]he support by the ADI staff was excellent" and that " [a]ll documentation required by auditors was shown." 84

On September 3, 2008, Trinity Biotech audited ADI for compliance with the QSRs and ISO 134:85:2003. Trinity Biotech found that ADI: (1) 85 properly documented design inputs and outputs; (2) had an adequate design verification including design reviews, testing, and validations; (3) conducted risk analysis; (4) had an adequate document control system and properly maintained records; (5) properly handled raw materials; (6) had procedures to ensure that only acceptable materials were used to manufacture products; (7) established, documented, and maintained procedures for traceability; and (8) documented

See 21 C.F.R. § 820.50. 81 See id. 82 Def. Ex. T (12/10/07 Siemens Audit Report) . 83 Id. 84 See Def. Ex. S (9/3/08 Trinity Biotech Supplier Audit Report). 85

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equipment and process validations. 86

4. Audit by the State of Connecticut Connecticut law requires in-state medical device manufacturers to register with the Connecticut Department of Consumer Protection, Drug Control Division. As such, Sekisui' s regulatory attorneys, Morgan, Lewis & Bockius LLP 87 (" Morgan Lewis"), urged ADI to register. On April 1, 2009, Connecticut 88 inspected ADI in connection with its application for a license, which was granted seven days later. 89

5. Other Observations About ADI' s Compliance Sekisui' s regulatory affairs expert, Carrie Kuehn, testified that ADI was not in compliance with the QSRs during the relevant period. At the outset, I note that Kuehn has never conducted or even witnessed an FDA inspection or an ISO audit. Her training is limited to attending regulatory conferences and reading 90

See id. 86 See Def. Ex. X. 87 See id. 88 The State of Connecticut did not issue an inspection report. 89 See Tr. at 576:17-577:7 (Kuehn). 90

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relevant guidance materials. 91

Nonetheless, Kuehn repeatedly testified that ADI' s documents differed from what she would expect to see in an FDA-compliant company. The FDA 92 expects each company to implement a QMS tailored to its size and risk-level. The 93 QSRs provide a " framework" for companies to develop their own internal procedures. While Kuehn might have implemented the QSRs differently than 94 ADI, her opinion does not render ADI non-compliant.

Moreover, Kuehn' s methodology is flawed. Her conclusions are based on a review of documents, at least one of which she misread. The documents were 95 provided by Sekisui' s counsel at least four years after the relevant time period. 96 Although she interviewed four ADI employees, she failed to speak with key

See id. at 593:6-18 (Kuehn). 91 See, e.g., id. at 602:15-20, 608:25-609:1-2, 620:14-25 (Kuehn). 92 See IOM § 5.6.7. 93 See Def. Ex. 8M. 94 See Tr. at 697:16-21 (Kuehn). 95 See id. at 648:2-13 (Kuehn). In addition, the documents she reviewed 96 may not have included all relevant documents. See Sekisui v. Harts, 945 F. Supp. 2d 494, 509-10 (S.D.N.Y. 2013) (finding that Sekisui willfully destroyed the Electronically Stored Information (" ESI") of Richard Hart, Leigh Ayres, and possibly others at ADI).

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compliance managers, such as Leigh Ayres. Thus, I cannot credit Kuehn' s 97 opinions over the contemporaneous conclusions of the FDA inspectors, ISO auditors, and customer auditors that visited ADI, interviewed management, and reviewed key documentation. These teams of experienced auditors and inspectors concluded that any flaws in ADI' s procedures were not sufficiently material to deny ISO certification, take FDA regulatory action, or stop purchasing ADI products.

Numerous fact witnesses also testified about ADI' s perceived non- compliance. Hugh Fryer, an ADI research and development scientist, testified that ADI improperly extended and/or failed to record expiration dates in a batch record for Product 822. He also stated that no document indicated that ADI performed 98 validation testing before extending the dates. Although Fryer manufactured 99 products, he did not testify that he was involved with the manufacture of Product 822. Thus, his testimony is based solely on a review of the documents in the 100 batch record. Even if the records indicate that this particular kit failed to meet

See id. at 745:16-20 (Kuehn). 97 See id. at 284:1-5, 290:6-294:13 (Fryer). 98 See id. at 290:20-25 (Fryer). 99 Nor does Fryer' s name appear on the batch record or any document 100 associated with Product 822. See Pl. Ex. 210 (Product 822 Lot 72401 Batch Records); Pl. Ex. 211 (Product 822 Lot 72405 Batch Records); Pl. Ex. 215 (Product 822 SOPs).

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specifications, I do not know whether ADI conducted further testing. Because Fryer lacked personal knowledge as to this kit, Fryer' s testimony is limited to his statement that " we don' t know what was actually done." Moreover, I excluded as 101 hearsay Fryer' s statement that the practice of improperly extending expiration dates was " widespread" at ADI. 102

Kevin Morrissey, ADI' s post-acquisition President and Chief Operating Officer (" COO"), also testified about aspects of ADI' s purported non- compliance, including its inadequate facilities and environmental controls. For 103 the following reasons, I do not find Morrissey a credible witness. Morrissey arrived at ADI on March 31, 2010, a year after the closing date, and assumed the position of Director of Manufacturing. He was promoted to President and COO in 104 October 2010. In 2011, Fryer began to suspect that Morrissey was spying on his 105 emails. Fryer wrote an email to himself — assuming Morrissey would read it — 106 stating, " You have caused us an undue amount of problems with your overblown

Tr. at 291:24-25 (Fryer). 101 Id. at 299:10-21 (Fryer). 102 See id. at 201:11-22 (Morrissey). 103 See id. at 141:1-13 (Morrissey). 104 See id. at 141:14-20 (Morrissey). 105 See Tr. at 361:21-25 (Fryer). 106

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claims. I think FDA would not be pleased with making up expertise then blaming other problems on your lack of knowledge." In another email, Fryer wrote, " You 107 really aren' t fooling any of us. Joe [Azary] is sick of your strange interpretations of FDA regs. But continue on this path; you make the rest of us look like geniuses." 108 Morrissey was fired in 2012 after several ADI employees complained about his incompetence. 109

Moreover, although he testified about finding expired raw materials, Morrissey could not establish that ADI had used them to manufacture any product during the relevant period. The record contains no evidence of any customer 110 complaint, recall, or notification to the auditors or customers regarding the use of expired materials during the relevant period. In fact, the record shows that the manufacture and sale of products using expired materials occurred — if at all — after the acquisition, on Sekisui' s watch. 111

Finally, Bhavna Gaikwad, also a research and development scientist at

Def. Ex. 6A (12/25/11 Email from Fryer to Fryer). 107 Def. Ex. 6B (1/4/12 Email from Fryer to Fryer). 108 See Tr. at 366:14-21 (Fryer). 109 See id. at 158:1-159:10 (Morrissey). 110 See id. at 242:18-20 (Morrissey). Accord Def. Ex. 3Z (4/26/10 Email 111 from Kathleen Georgelos to David Teicher, regarding use of expired biotin).

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ADI, testified about other aspects of ADI' s non-compliance, such as insufficient employee training. Both Gaikwad and Fryer also testified that ADI recorded the 112 design process for each product in lab notebooks, rather than maintaining DHFs. 113 However, throughout the relevant period, auditors and inspectors evaluated ADI' s employee training, use of expired materials, creation of batch records, adequacy of DHFs, implementation of design control procedures, and more, and found material compliance with the QSRs and ISO. For example, in 2008, Trinity Biotech reported that raw materials at ADI are " quarantined until evaluated for conformance to specifications . . . [,] labeled with status and adequately controlled . . . [, and] nonconforming material [is] segregated, identified, and reviewed for disposition[.]" To the extent that these witnesses disagree with the auditors' 114 conclusions, I credit the auditors.

6. 2007 Femtelle 510(k) Submission Medical device manufacturers who wish to market their products in the United States must submit a 510(k) to the FDA for pre-market approval. Each 115

See Tr. at 484:9-22 (Gaikwad). 112 See id. at 485:13-486:5 (Gaikwad); id. at 270:23-271:8 (Fryer). 113 Def. Ex. S. 114 See 21 C.F.R. § 807.87 115

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submission goes to a primary reviewer who may ask for more information. The 116 manufacturer has 30 days to respond, but the FDA can grant an extension of up to 180 days if needed. If the manufacturer fails to provide the information by the 117 deadline, the FDA considers the submission withdrawn. If the submission is 118 withdrawn, the manufacturer must restart the process by submitting a new 510(k). 119

Femtelle is a breast cancer diagnostic assay developed in the 1990s and sold in Europe by ADI' s German subsidiary. ADI planned to market Femtelle in 120 the United States. On February 7, 2007, ADI submitted a Femtelle 510(k) to the 121 FDA. On March 30, 2007, the FDA sent a letter requesting more information 122 including the data from Femtelle' s analytical studies. ADI requested a 180 day 123 extension to gather the materials. The FDA granted the extension, but ADI was 124

See Tr. at 425:10-23, 426:4-16 (Timothy Ulatowksi). 116 See 12 C.F.R. § 807.87. See also Tr. at 436:7-13 (Ulatowski). 117 See 12 C.F.R. § 807.87. 118 See Tr. at 449:12-20 (Ulatowski). 119 See Pl. Ex. 7. See also Tr. at 783:14-16 (Guy Erb). 120 See JPTO at 3. 121 See Pl. Ex. 22 (1/31/09 Letter from Hart to Jonathan Kahan, attaching 122 the 2007 Femtelle Application).

See id. 123 See id. 124

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unable to collect the materials in time. ADI requested a second 180 day 125 extension but continued to have difficulty producing the data. On May 18, 2008, 126 the FDA deemed the submission withdrawn. 127

C. The Acquisition

1. Due Diligence Period In early 2008, the Harts began seeking a buyer for ADI. Crosstree 128 Capital Partner (" Crosstree") served as ADI' s financial advisor. In February 129 2008, Crosstree drafted a Confidential Memorandum (" CM") to provide to potential buyers. The CM discussed Femtelle without making any financial projections. 130 131 In August 2008, Crosstree updated the CM to include Femtelle projections. 132 However, the CM clearly stated:

See id. 125 See id.; Pl. Ex. 36 (2/28/08 Email from Hart to Manfred Schmitt). 126 See Pl. Ex. 22. 127 See Pl. Ex. 247 (1/25/08 Email from Ellis to Hart). 128 See JPTO at 2. 129 See Pl. Ex. 240 (2/20/08 Email from Ellis to Hart, attaching the 130 February 2008 CM).

See id. 131 See Pl. Ex. 7 (August 2008 CM). 132

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This [CM] does not constitute an offer to sell or the solicitation of an offer to purchase [ADI]' s securities, and it should not and may not be relied upon in connection therewith. Any offer of [ADI' s] securities will be offered only through definitive documents prepared specifically for that purpose. [I]nterested parties must conduct their own independent, in-depth investigation and analysis of [ADI] and the information set forth in this CM and any other . . . communication . . . . 133 In October 2008, Crosstree sent Sekisui a copy of the CM. On 134 January 7, 2009, Sekisui' s accountant, KPMG, provided a due diligence report that included ADI' s financial information through October 31, 2008. On the same 135 date, Morgan Lewis provided a Preliminary Legal Due Diligence Report. 136 Morgan Lewis reported that ADI had no significant product quality issues, that Interek had granted certification, and that the FDA was satisfied with ADI' s responses to its 2004 and 2005 observations. 137

On January 31, 2009, Hart provided Hogan and Hartson LLP — the Harts' FDA attorneys — with a copy of ADI' s 2007 Femtelle submission and related documentation. After discussing the 2007 submission with Hogan and

Id. 133 See id. 134 See Pl. Ex. 21 (1/7/09 KMPG Due Diligence Draft). 135 See Def. Ex. X. 136 See id. 137

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Hartson, Morgan Lewis requested a copy. I find no evidence to suggest that 138 either Hogan and Hartson or Hart — whose email was willfully destroyed by Sekisui — failed to provide Morgan Lewis with the information it requested. 139

On December 10, 2008, Sekisui sent ADI a Letter of Interest, stating that Sekisui, " along with [its] investment banker (Savvian), outside counsel (Morgan Lewis), and accountants (KPMG), are prepared to commence this effort immediately and to dedicate significant resources to the . . . transaction . . . ." 140 The parties executed the letter, stating that Sekisui would pay $25.5 million for ADI, an additional two million dollars if Femtelle received FDA clearance by June 30, 2009, and earn-out payments of up to nine million dollars if Femtelle reached certain revenue targets. In the letter, Sekisui proposed a due diligence period of 141 at least seventy-five days. Sekisui had until the April 20, 2009 closing date — 142

See Pl. Ex. 245 (2/12/09 Email exchange between Hart and Dan 138 Crosby, an attorney at Withers Bergman).

Furthermore, during discovery, Sekisui produced a copy of the 2007 139 submission and related documentation, which had been stored in the document room at ADI. See Def. Ex. 5H. Thus, I conclude that Morgan Lewis — and Sekisui — received the 2007 submission and related documentation during the due diligence period. Sekisui offered no testimony that it did not receive

the submission and documentation.

Pl. Ex. 2 (12/10/08 Sekisui Letter of Interest to ADI). 140 See id. 141 See id. 142

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nearly five months after it sent the letter — to complete its due diligence. 143

2. Sekisui' s Valuation of ADI Mamoru Takemura, Sekisui Medical' s General Manager of International Marketing, testified that Sekisui was interested in acquiring ADI as a platform for selling diagnostic products in the United States and found Femtelle attractive. On February 6, 2009, Sekisui' s financial advisor, GCA Savvian 144 (" Savvian") advised Sekisui not to make any up front payment for Femtelle. As 145 Savvian noted, " Realization of Femtelle value has a certain level of uncertainty and hence, it is possible to employ Earn Out Method payment . . . ." 146

To obtain board approval, Sekisui modeled three projections for the value of ADI: (1) including highest Femtelle revenue payments from the earn-out, (2) including lowest Femtelle revenue payments from the earn-out, and (3) without Femtelle at all. On February 9, 2009, the board approved the acquisition. 147 148

See SPA ¶ 6.14. 143 See Tr. at 50:20-51:14 (Takemura). 144 See Def. Ex. 2M (2/9/09 Savvian Report) (English translation). 145 Id. at 6. 146 See Tr. at 65:20-67:1 (Takemura); Pl. Ex. 49 (3/27/09 Excel 147 spreadsheet analyzing expansion of Sekisui' s diagnostic business).

See Tr. at 112:3-6 (Takemura). 148

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Takemura testified that the board would not have approved the acquisition without projecting Femtelle to achieve at least the lowest revenue payments. However, I 149 am troubled by Takemura' s insistence that Sekisui did not rely on the Savvian report. Sekisui' s analysis — computing the value of ADI first without Femtelle 150 and then with Femtelle earn-out potential — closely tracks Savvian' s. I find that 151 Seksui' s board presentation is clearly derived from the Savvian report.

Sekisui submitted other evidence in an attempt to show that the purchase price included Femtelle. First, Exhibit A of the SPA purportedly revealed that the purchase price must have included Femtelle because the Harts would receive nothing for Femtelle unless it generated millions of dollars in revenue for Sekisui. Further, the Harts' earn-out potential was capped at a certain amount 152 each year even if Femtelle revenues were significantly higher than expected. 153 Second, Sekisui introduced a Purchase Price Allocation (" PPA") prepared by

See id. at 68:9-69:1 (Takemura). 149 See id. at 126:8-13 (Takemura) (testifying that he did not look " too 150 carefully" at the report and that it was not " used as a basis for making our decision in the company").

See Pl. Ex. 49; Def. Ex. 2M. 151 See SPA at Ex. A (Schedule of Femtelle Revenue Based Payments). 152 See id. 153

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KPMG, which valued Femtelle at $7.65 million of the purchase price. Based on 154 this evidence, Sekisui' s damages expert, Guy Erb, opined that the purchase price included the prospective value of Femtelle. 155

As an initial matter, the PPA proves nothing about Sekisui' s valuation of Femtelle at the time of the acquisition. KPMG prepared the PPA six months after the closing for " financial and tax reporting purposes[.]" The PPA presents 156 the " fair value of the Subject Assets between a hypothetical willing buyer and a hypothetical willing seller in an assumed transaction on an assumed valuation date." It notes — in an important disclaimer — that " the price at which the 157 Subject Assets might be sold in a specific transaction between specific parties on a specific date might be significantly different from the fair value expressed in our report." Moreover, the PPA relies on and incorporates the Femtelle projections in 158

See Pl. Ex. 48 (10/1/09 KPMG Valuation Study). 154 See Tr. at 837: 11-15 (Erb). 155 Pl. Ex. 48. 156 Id. 157 Id. 158

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the CM. Both the CM and the SPA expressly disclaim these projections. 159 160

Furthermore, what Sekisui perceived as Femtelle' s value is irrelevant to what Sekisui actually paid for it. Based on Exhibit A, Sekisui certainly believed Femtelle would generate millions of dollars. But as a sophisticated investor, Sekisui sought a deal that would allow it to avoid the risk of loss. Thus, the SPA expressly allocated payments for Femtelle only if certain contingencies occurred. First, Sekisui would pay two million dollars if the FDA approved Femtelle by November 20, 2009. Second, Sekisui would pay an earn-out in each year from 161 2010 through 2013 if Femtelle reached certain revenue targets. Consistent with 162 Savvian' s advice, Sekisui obtained an excellent deal in which it would be handsomely rewarded if Femtelle was successful but shielded if it was a loser. In short, Sekisui has not established what portion of the purchase price — if any — was allocated to Femtelle.

3. The SPA and the Closing

See id. 159 See Pl. Ex. 7; SPA § 4.29 (" The representations and warranties set 160 forth in this [SPA] supercede and replace all prior statements, representations, projections, forecasts, warranties, and other understandings . . . including the projections set forth in the [CM] relating to [ADI] . . . .").

See SPA § 2.6. 161 See id. at Ex. A. 162

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On March 5, 2009, the parties voluntarily executed the SPA, stating that Sekisui would purchase all outstanding shares of ADI for $25.5 million. 163 When they signed the SPA, Sekisui and the Harts were both represented by counsel. The deal closed on April 20, 2009. In the SPA, the Harts represented 164 165 and warranted, in relevant part:

4.12 The buildings, plants leasehold improvements, structures, facilities,

equipment and other property and assets . . . are (a) sufficient to conduct . . . the Business . . . , [and] (b) conform in all material 166 respects to all Laws . . . relating to their construction, use and 167 operation . . . 168 4.14 (a) [ADI] and its Subsidiaries are, and have since January 1, 2006

been, in compliance in all material respects with all applicable Laws. . . (c) [ADI] holds all Permits which are required under the applicable Laws for the Products currently marketed by [ADI] . . . and the 169

See id. ¶ 2.2. 163 See JPTO at 2. 164 See id. 165 The " Business" means " the business of ADI and its subsidiaries, 166 including the in vitro diagnostic business." SPA § 1.1.

As defined, " Laws" means FDA regulations, including the QSRs, 167 codified at 21 C.F.R. § 820. See id. § 1.1.

Id. § 4.12. 168 " Products" is defined as " any products currently or formerly 169 manufactured, sold, distributed, provided, shipped or licensed, or any services

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conduct of [ADI' s] testing, manufacturing, marketing, sales and distribution for the Products . . . All (i) correspondence with Governmental Entities related to the Products, (ii) Product Registrations and associated records and correspondence (together with all supporting documentation), (iii) data and information relating to non-clinical and clinical testing of Products, (iv) promotional literature and advertising materials . . . relating to the Products, (v) design history files, complaints, medical device reports, medical device reports event files, correction and removal reports, and (vi) memoranda or records . . . documenting decisions not to file a 510(k) pre-market notification with respect to any of

the Products have been maintained in all material respects in accordance with sound business practices and complete and correct copies . . . have been made available to [Sekisui] by [ADI]. (d) [ADI' s] Products are not misbranded or adulterated within the meaning of the [Act]. . . . Since January 1, 2006, the Company has not received from the FDA (i) any notice of inspectional observation, including Form 483, or a warning letter, or (ii) any correspondence or any other communication from FDA . . . that could be reasonably expected to have a Material Adverse Effect. 170 Next, Sekisui represented and warranted, in relevant part,: 2.6 (d)(i)(A) [Sekisui] shall undertake commercially reasonable efforts

to market or sell, or to cause the marketing and sale of the Femtelle Product, including . . . submitting to the FDA . . . submissions and filings for uses of the Femtelle Product that are reasonably related to those provided for in the Femtelle Clearance . . . [and] (B) not willfully take any actions, or omit to take any actions, with the intent of preventing the Business from meeting the Femtelle

rendered" by ADI or its subsidiaries. Id. § 4.11.

Id. § 4.14. " Material Adverse Effect" means " any change, event, or 170 effect that . . . has or would reasonably be expected to have a material adverse effect (a) on the assets, liabilities, condition (financial or otherwise) or results of operations of [ADI], taken as a whole." Id. § 1.1.

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Revenue targets . . . or that could reasonably be expected to impair the ability of [ADI] to maximize Femtelle Revenues . . . . 171 The SPA also set forth certain rights of the parties, in relevant part: 6.14 [ADI] and [the Harts] shall . . . afford [Sekisui] complete access

upon reasonable prior notice . . . to [ADI' s] officers, employees, agents, properties, books and records . . . , and shall furnish [Sekisui] with all financial, operating and other data and information as [Sekisui] may reasonably request. 172 9.1 Notwithstanding any right of any party, whether or not exercised,

to investigate the affairs or the accuracy of the representations and warranties contained herein . . . , each party hereto has the right to rely fully on the representation, warranties, covenants, and agreements of each other party contained herein. 173 Further, pursuant to Section 7.2(e)(vii) of the SPA, Hart executed an employment agreement with ADI that allowed him to " terminate his employment . . . for any or no reason" during the two year period. 174

D. Post-Acquisition Events

1. Observations About ADI' s Compliance Hart remained CEO of ADI until early 2010 when he left

for medical

Id.§ 2.6(d). 171 Id.§ 6.14. 172

Id.§ 9.1. 173 Pl. Ex. 6 (Hart' s Employment Agreement). 174

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reasons. During that time, the day-to-day operations of ADI remained the 175 same. Morrissey testified that shortly after the acquisition, he discovered 176 problems with ADI' s QMS, including insufficient SOPs, storage of expired raw materials, and incomplete batch records. Morrissey hired Jose Campo, a private 177 auditor at Advanced Quality Solutions (" AQSOL"), who reported significant quality system deficiencies at ADI. In response, Sekisui devised an extensive 178 remediation plan. 179

Once again, I do not credit Morrissey' s testimony that extensive remediation was required. First, Morrissey' s assessment may have been influenced by his relationship with Campo. Morrissey had hired Campo as an auditor in the past, and, after Morrissey was fired from ADI, Campo hired Morrissey as an auditor at AQSOL. Second, a wealth of evidence suggests that Morrissey' s 180

See Pl. Ex. 14; Pl. Ex. 15. 175 See Tr. at 76:8-78:3 (Takemura). ADI continued to exist as an 176 independent entity until 2012 when it was absorbed into Sekisui Diagnostics. See id. at 44:24-45:3 (Takemura).

See id. at 157:20-158:4, 161:14-19, 164:25-165:17, 168:19-23 177 (Morrissey).

See id. at 173:2-19, 177:11-14 (Morrissey); Pl. Ex. 46 (May 2010 178 AQSOL Audit Report); Pl. Ex. 84 (June 2010 AQSOL Audit Report).

See Pl. Ex. 53 (June 2010 Quality System Improvement Plan). 179 See Tr. 142:10-15 (Morrissey). 180

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understanding of FDA regulations was poor and that Campo' s evaluation of ADI' s QSM was extreme. In fact, based on Morrissey' s own admission, ADI had DHFs 181 when he arrived at ADI. Third, post-acquisition audits and inspections showed 182 that ADI was in material compliance. On June 8, 2010, Intertek conducted a surveillance audit and re-certified ADI as ISO and CMDCAS compliant. On 183 March 29, 2011, Intertek conducted another audit and renewed ADI' s certification. 184

On June 20-22, 2011, two years after the acquisition, the FDA inspected ADI. The FDA made four

observations: (1) complaints were not 185 adequately documented; (2) there was no CAPA documentation prior to July 23, 2010; (3) procedures to control environmental conditions were not adequately established; and (4) schedules for adjustment, cleaning, and other equipment

See Def. Ex. 6B; Def. Ex. 5Z (3/27/11 Risk Reduction Actions Chart) 181 (stating that " Jose [Campo]' s extreme view of ADI' s quality system" is causing " panic in our lawyers"); Def. Ex. 6C (6/10/12 Email from Azary to Fryer). See also Tr. at 361:7-20 (Fryer) (stating that Azary and others shared his view about Morrissey' s incompetence).

See Tr. at 157:15 (Morrissey). 182 See Def. Ex. Q (6/8/10 Intertek Systems Certification Audit Report). 183 See Def. Ex. R (3/29/11 Intertek Systems Certification Audit Report). 184 See Def. Ex. C (8/29/11 FDA EIR). 185

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maintenance were not adequately established. On July 7, 2011, ADI wrote a 186 letter to the FDA attaching a " plan and status with regards to each observation noted on the 483." ADI noted that " [t]he corrective actions will be completed within 187 the month of July 2011." ADI further explained that " ADI has had a [CAPA] 188 procedure since 2006" and that " [c]orrective actions were taken but were addressed in a decentralized manner using other processes within the quality system." The 189 FDA then closed the inspection and released the EIR. 190

In September 2012, two years after Sekisui began its purported remediation, Siemens found ADI " noncompliant to ISO 13485 and FDA standards . . . ." Thus, if ADI was non-compliant in 2012, the fault likely lies with Sekisui, 191 not ADI.

2. 2009 Femtelle 510(k) Submission On March 17, 2009, after the parties had signed the SPA but before the

See Def. Ex. E. 186 Def. Ex. V. 187 Id. 188 Id. 189 See Def. Ex. C. 190 Id. 191

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closing, ADI submitted another Femtelle 510(k). On May 27, 2009, the FDA 192 requested additional information regarding Femtelle' s studies and device history. 193 In the letter, the FDA requested " line data of all three [Femtelle] studies in extractable format," " a more detailed description of the linearity study," and " data to demonstrate the minimum amount of tumor cell content required to perform an acceptable assay." The FDA acknowledged that ADI had already provided the 194 line data " as an image in a PDF document." 195

In January 2010, the FDA wrote another letter requesting " data to support that the test adds value

over other clinical variables" and " line data including all clinical covariates information." On March 26, 2010, ADI sent the 196 FDA a report compiling " all of the data pertaining to the [Femtelle] study" in Germany. Robert Greenfield, an ADI employee, then tried to obtain the missing 197

See JPTO at 3. 192 See Pl. Ex. 24 (5/27/09 Letter from FDA to ADI). 193 Id. 194 Id. 195 Pl. Ex. 26 (1/15/10 Email from Reena Philip, FDA Associate Director, 196 to David Teicher, ADI' s Director of Technical Affairs).

Pl. Ex. 28 (3/26/10 Email from Teicher to Philip). 197

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data from researchers in Germany. Manfred Schmitt, one of the researchers, 198 responded, " [W]e have all the original data of each of the patients . . . " 199 Greenfield then asked Schmitt only for the " raw numbers" underlying the data set provided to the FDA. 200

On May 11, 2010, the FDA requested the " data to support that the test adds value over other clinical variables." On May 17, 2010 Greenfield informed 201 his colleagues that ADI had information to show that it was " using the same sources for raw materials [for Femtelle] today as [it was] back to 1988 . . . ." On May 19, 202 2010, Greenfield again contacted the German researchers, explaining that if Femtelle failed in the United States, " [w]e may only be able to market it as an IVD in Europe under CE marking." In June 2010, ADI had to reduce the number of 203 patients relied on in the submission. On June 2, 2010, Schmitt told Greenfield, 204

See Pl. Ex. 42 (5/4/10-6/10/10 Email exchange between Greenfield 198 and Manfred Schmitt).

Id. 199 Id. 200 Pl. Ex. 30 (5/11/10 Email from Philip to Teicher). 201 Def. Ex. 2I (5/26/10 Email from Greenfield to Gaikwad, Teicher, 202 Fryer, Morrissey, Koseki, and Michael Smirnov).

Pl. Ex. 43 (5/19/10 Email from Greenfield to Schmitt). 203

See Pl. Ex. 39 (6/2/10 Email from Schmitt to Greenfield). 204

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" You will get a final statement from us very soon, regarding the 153 patients in focus of the FDA. [F]or some of these patients, we do not have data . . . ." 205

In addition to the missing data, ADI was concerned about missing batch records from Femtelle' s DHF. In a June 2010 conference call, ADI asked 206 the FDA if it could proceed with the filing without the batch records. The FDA 207 responded, " [e]ven if you lost the batch records due to your

site change, the Principal Investigator of your clinical validation study should have the information . . . . You could collect the information from them, for your records." There is no 208 evidence that the FDA told ADI that Femtelle would not be approved without certain batch records.

Nevertheless, ADI concluded that it would not be able to get missing clinical data and batch records to the FDA by the July 14, 2010 deadline. Fryer 209 also voiced concern that continuing to seek 510(k) clearance would invite an FDA

Id. 205 See Pl. Ex. 222 (6/1/10 Email from Greenfield to Fryer, Koseki, 206 Morrissey, and Teicher).

See Def. Ex. 2L (6/2/10 Email from Greenfield to Koseki, Morrissey, 207 Teicher, Fryer, Smirnov, attaching minutes from call with FDA).

Pl. Ex. 29 (6/28/10 Email from Philip to Teicher). 208 See Def. Ex. 2L; Pl. Ex. 143 (Minutes for ADI' s 6/25/10 Femtelle 209 Direction Meeting).

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audit. Thus, in June 2010, Sekisui decided to withdraw the submission. 210 211

Sekisui' s FDA expert, Timothy Ulatowski, testified that he agreed with the decision to withdraw the submission. Ulatowski opined that ADI was missing 212 too much " critical information" to obtain 510(k) clearance by the deadline. 213 While I find Ulatowski' s testimony credible, it is not particularly relevant to Sekisui' s breach claims, as discussed below.

3. Subsequent Efforts to Market Femtelle After withdrawing the 2009 Femtelle 510(k) submission, Sekisui continued its efforts to achieve 510(k) clearance. ADI employees tried to recreate 214 the DHF and other data. In September 2011, Fryer traveled to Germany to 215 retrieve the clinical data, but did not succeed. Sekisui concluded that it required 216

See Pl. Ex. 143. 210 See Tr. at 80:25-81:7 (Takemura). 211 See id. at 473:2-9 (Ulatowski). 212 Id. at 472:15-473:1 (Ulatowski: " In my experience . . . reviewing 213 hundreds of 510(k) [submissions], time was up.").

See Pl. Ex. 93 (8/29/11 Femtelle Regulatory Gap Analysis). 214 See Tr. at 332:9-333:2 (Fryer); Pl. Ex. 93. 215 See id. at 410:6-411:1 (Fryer). 216

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new clinical studies in the United States to compile the data. 217

In 2011, while Sekisui was still attempting to obtain the clinical data and recreate DHFs, Fryer reported to KPMG that there was a seventy percent chance of obtaining sufficient data, and an eighty percent chance of success on the Femtelle project if Sekisui could do so. Ultimately, however, Sekisui determined 218 that the new clinical studies would cost $3.2 million and take more than three years to complete. Given the cost of the studies, the uncertainty of ever receiving FDA 219 clearance, and the increased competition in the breast cancer diagnostic market, Sekisui decided not to submit another Femtelle 510(k). 220 III. APPLICABLE LAW 221

To recover for breach of contract under New York law, a plaintiff must prove by a preponderance of the evidence, " (1) the existence of a contract between [the plaintiff] and th[e] defendant; (2) performance of the plaintiff' s obligations

See id. at 334:8-11 (Fryer). 217 See Def. Ex. 2E (6/30/11 KPMG Initial Information Request). 218 See Def. Ex. 4J (11/19/12 KPMG Follow-up Information Request). 219 See id. 220 The Court has subject matter jurisdiction over this case based on 221 diversity pursuant to 28 U.S.C. § 1332. Venue is proper under 28 U.S.C. § 1391(b). See JPTO at 2. The SPA states that New York law governs interpretation of the contract. See SPA § 10.6.

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under the contract; (3) breach of the contract by th[e] defendant; and (4) damages to the plaintiff caused by th[e] defendant' s breach." To recover on their 222 counterclaim, the Harts must prove breach by a preponderance of the evidence. 223 There is no dispute that a valid contract exists, that Sekisui paid the purchase price under the SPA, and that the deal closed on April 20, 2009. 224 IV. CONCLUSIONS OF LAW

A. Sekisui' s Claim

1. Sekisui Failed to Prove that the Harts Breached Any

Provision of the SPA Related to FDA Noncompliance Sekisui alleges that the Harts breached: (1) Section 4.14(a) because ADI failed to comply with the QSRs; (2) Section 4.14(c) because ADI lacked DHFs for its products; (3) Section 4.14(d) because non-compliance with the QSRs renders products adulterated; and (4) Section 4.12 because ADI' s facilities and equipment failed to comply with the QSRs. I conclude that Sekisui has not met its burden. 225

Diesel Props S.R.L. v. Greystone Bus. Credit II LLC, 631 F.3d 42, 52 222 (2d Cir. 2011). Accord Mandarin Trading Ltd. v. Wildenstein, 16 N.Y.3d 173, 182 (2011). The parties do not dispute the validity of the contract.

See Raymond v. Marks, 116 F.3d 466, 466 (2d Cir. 1997). 223 See JPTO at 2. 224 See Plaintiffs'

Combined Proposed Findings of Fact and Conclusions 225 of Law (“ Pl. Facts and Concl.”) at 51.

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First, Sekisui failed to prove that the Harts breached Section 4.14(a) because the QSRs “ leave it up to the manufacturer to institute a quality control system specific to the medical device it produces to ensure that such device is safe and effective.” I conclude that during the relevant period, ADI’ s QMS was 226 commensurate with its size and risk level.

While ADI may not have been an exemplar of regulatory compliance, it met the FDA’ s requirements. Rather than seeking perfection, the FDA expects manufacturers to investigate and correct non-conformities through their CAPA systems. The evidence established that ADI had a CAPA system during the 227 relevant period. Thirteen contemporaneous audits and inspections concluded that 228 ADI responded appropriately to non-conformities. Sekisui may not hold ADI to a higher standard than the FDA requires.

Similarly, Sekisui has failed to prove a breach of Section 4.14(d) because ADI was in material compliance with QSRs and, thus, no product was “ adulterated” as of the closing date. Sekisui does not allege any misbranding. 229

Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 279 (E.D.N.Y. 2009). 226 See 21 C.F.R. § 820.100. 227 See Def. Ex. B, Def. Ex. M, Def. Ex. V, Def. Ex. C. 228 See 21 U.S.C. § 351(f) (“ A drug or device shall be deemed to be 229 adulterated if . . . the methods used in, or the facilities or controls used for, its

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Next, Sekisui has failed to prove a breach of Section 4.14(c), which required the Harts to maintain required documentation, including DHFs, in accordance with “ sound business practices.” A DHF need only “ contain or 230 reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan . . . .” The audits and inspections 231 reflect that ADI adequately maintained DHFs and other documentation at the time of the acquisition. 232

Finally, Sekisui has failed to prove a breach of Section 4.12, warranting that ADI’ s facilities and equipment are sufficient to conduct business. 233 In isolation, I would be troubled by the FDA’ s 2011 observations about ADI’ s inadequate equipment and environmental conditions. But ADI promptly 234 responded with a detailed plan to correct the problems, and the FDA closed the

manufacture, packing, storage, or installation are not in conformity with [the QSRs].”).

SPA § 4.14(c). 230 21 C.F.R. § 820.30. 231 See Def. Ex. B; Def. Ex. S. 232 See SPA § 4.12. 233 See Def. Ex. C. 234

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inspection. Thus, the FDA must have concluded that ADI met its expectations. 235

I further conclude that no post-acquisition remediation was required. Although Morrissey urged Sekisui to spend hundreds of thousands of dollars to remediate perceived problems, multiple post-acquisition Intertek audits and an FDA inspection showed that ADI was already in compliance. In fact, ADI was not 236 found non-compliant until two years after Sekisui' s purported remediation had begun. Therefore, Sekisui is not entitled to any remediation damages. 237

2. Sekisui Failed to Prove that the Harts Breached Any

Provision of the SPA Related to Femtelle Sekisui next argues that the Harts breached Sections 4.14(c) and (d) with respect to the Harts' contractual representations regarding Femtelle. Section 4.14(c) states that " [a]ll . . . data . . . relating to non-clinical and clinical testing of Products . . . [and] design history files . . . have been maintained in material respects in accordance with good business practices." Sekisui' s theory is that ADI failed 238 to maintain sufficient Femtelle clinical data and DHFs to support its 510(k)

See id.; Def. Ex. V. 235 See Def. Ex. C; Def. Ex. Q; Def. Ex. R. 236 See Def. Ex. T. 237 SPA § 4.14(c). Sekisui asserts that " Products" include Femtelle 238 because Femtelle was being manufactured and sold by ADI' s German subsidiary at the time of the acquisition. See Pl. Facts and Concl. at 7, 53.

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submission. Relying on Ulatowski, Sekisui argues that because of this missing 239 information, the Femtelle 510(k) was destined to fail. 240

Sekisui' s theory is riddled with problems. First, the SPA does not require ADI to maintain the Femtelle data and DHFs in the United States given that Femtelle is manufactured and sold only in Europe. Sekisui has failed to show that the Femtelle data and DHFs were not maintained in Germany in accordance with " good business practices" — a term not defined in the SPA. Second, Ulatowski 241 did not opine that Femtelle was destined to fail. He testified only that ADI would not be able to submit the critical information by the FDA' s deadline. In any 242 event, Ulatowski' s testimony says nothing about how ADI maintained the information in Germany, and is, thus, irrelevant to the breach claim. Third, even if batch records were missing, ADI had all the necessary information about Femtelle' s design history available in either lab notebooks or in certificates of analysis. In 243 any event, DHFs can be maintained in accordance with " good business practices" See Pl. Facts and Concl. at 53-54. 239

See id. at 38. 240 SPA § 4.14(c). 241 See Tr. at 472:15-473:1 (Ulatowski). 242 See Def. Ex. 2I (ADI report

stating that certain notebook pages and 243 certificates can demonstrate that ADI was using " the same sources for raw materials [for Femtelle in 2010] as [it was] back in 1988").

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without batch records. According to the FDA, DHFs need only " reference the records necessary to demonstrate" the design history of a product. Thus, the 244 good business practices do not necessarily require ADI to maintain batch records for Femtelle.

Sekisui' s theory under Section 4.14(d) fares no better. Section 4.14(d) states, " [s]ince January 1, 2006, [ADI] has not received from the FDA . . . any correspondence or any other communication from FDA . . . that could be reasonably expected to have a Material Adverse Effect." A " Material Adverse Effect" must 245 impact " the assets, liabilities, condition (financial or otherwise) or results of operations of [ADI], taken as a whole." Sekisui' s theory is that the Harts 246 withheld numerous communications from the FDA about deficiencies in the 2007 Femtelle submission. Because these communications allegedly revealed the low 247 likelihood that Femtelle would ever obtain FDA clearance, they could have had a material adverse effect. 248

As an initial matter, I have already found that the Harts provided

See 21 C.F.R. § 820.30(j)(emphasis added). 244 SPA § 4.14(d). 245 Id. § 1.1. 246 See Pl. Facts and Concl. at 55. 247 See id. 248

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Morgan Lewis with a copy of the 2007 Femtelle 510(k) and related documentation during due diligence. Morgan Lewis discovered that ADI submitted an unsuccessful 510(k) in 2007, discussed it with Hogan and Hartson, and advised Sekisui to proceed with the closing. In the SPA, ADI warranted that it would 249 furnish Sekisui with " all . . . information as [Sekisui] may reasonably request." I 250 conclude that it did so. If Sekisui was dissatisfied with the information it received, it should not have closed.

Moreover, Femtelle was attractive to Sekisui because of its " future potential," not its value on the closing date. By Sekisui' s own admission, 251 " Femtelle had no contribution to [ADI' s] revenue and earnings" at the time of the acquisition. Thus, Femtelle' s fate had no effect — materially adverse or 252 otherwise — on ADI' s existing assets, liabilities, condition or operation. 253

Finally, although Femtelle may have been the driving force behind the acquisition, both Sekisui and ADI knew that Femtelle' s fate was uncertain. Thus,

See Pl. Ex. 245, Pl. Ex. 2. 249 SPA § 6.14. 250 Tr. at 54:9 (Takemura). 251 Id. at 544:16-18 (Ellis). 252 See

Recticel Foam Corp., Inc. v. Bay Indus., Inc., 128 Fed. App' x 253 798, 800 (2d Cir. 2005) (noting that a new " account of what the [target] company [i]s worth" does not have a material adverse effect on an acquiring company).

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the parties structured a deal that rewarded Sekisui with a substantial upside if Femtelle succeeded and no downside if it failed. Even if ADI had breached the SPA with regard to warranties relating to Femtelle, Femtelle' s value is inherently uncertain because neither the CM nor the PPA provides a reliable basis for ascertaining its dollar value. Therefore, consistent with the law of the case, even 254 if the Harts breached the SPA — which Sekisui has failed to prove — I could not award any portion of the purchase price as damages for ADI' s failure to obtain FDA approval of Femtelle.

B. The Harts' Counterclaim Is Dismissed Because the Harts Failed to

Prove that Sekisui Breached Section 2.6(d) of the SPA The Harts allege that Sekisui breached Section 2.6(d), which warrants that Sekisui will (1) take " commercially reasonable efforts" to market and sell Femtelle, and (2) " not . . . omit to take any actions, with the intent of preventing [ADI] from meeting Femtelle Revenue targets . . . or that could reasonably be expected to impair [ADI' s ability] to maximize Femtelle Revenues." The Harts 255 have not proven that Sekisui breached this term of the SPA. First, the Harts

Sekisui v. Harts, No. 12 Civ. 3479, 2012 WL 5039682, at *6 254 (S.D.N.Y. Oct. 17, 2012) (granting in part and denying in part the Harts' motion to dismiss and finding that the SPA limits Sekisui' s damages " in the event that Femtelle does not obtain FDA approval" because in that event Sekisui is excused from paying earn-outs).

SPA § 2.6(d). 255

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presented no evidence establishing the objective standard for " commercially reasonable efforts" in the FDA-regulatory context or explained how Sekisui deviated from that standard. In fact, Sekisui undertook considerable efforts to 256 bring Femtelle to market, including re-creating files and traveling to Germany to obtain data. Sekisui diligently strived for Femtelle clearance until 2011 when it 257 realized that the necessary studies would be prohibitively expensive and time- consuming. Even if Sekisui had paid for the studies, they would not have been 258 completed until 2014 — a year after the earn-out period had ended. Second, the 259 Harts have submitted no evidence that Sekisui omitted to take any actions with the intent of preventing ADI from meeting Femtelle revenue targets. In fact, Sekisui would have made millions of dollars if Femtelle reached the targets. Thus, I 260 conclude that Sekisui pursued FDA approval as long it practically could.

See MBIA Ins. Corp. v. Patriach Partners VIII, LLC, 950 F. Supp. 2d 256 568, 617 (S.D.N.Y. 2013) (requiring evidence to define the " commercially reasonable" standard for a particular industry); B.D.G.S., Inc. v. Balio, 8 N.Y.3d 106, 113 (2006) (relying on expert testimony regarding bank practices on check endorsement for purposes of commercial reasonableness analysis).

See Tr. at 332:9-333:2 (Fryer); Pl. Ex. 93. 257 See Def. Ex. 4J. 258 See Pl. Ex. 5 (Schedule for Femtelle Revenue Payments, SPA Ex. A). 259 See id. 260

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C. The Harts' Motion for Sanctions Under 28 U.S.C. § 1927 Is Denied

The Harts request sanctions under Section 1927, alleging that Sekisui brought this case in bad faith. Section 1927 provides: 261

Any attorney or other person admitted to conduct cases in any court of the United States . . . who so multiplies the proceedings in any case unreasonably and vexatiously may be required by the court to satisfy personally the excess costs, expenses, and attorneys' fees reasonably incurred because of such conduct. 262 To impose sanctions, a court must find that the challenged claim was (i) " without a colorable basis" and (ii) " brought in bad faith, i.e., motivated by improper purposes such as harassment or delay." " Although both findings must 263 be supported by a high degree of specificity, bad faith may be inferred only if actions are so completely without merit as to require the conclusion that they must have been undertaken for some improper purpose such as delay." 264

Under this standard, I find that sanctions are not warranted. Without a doubt, Sekisui' s willful destruction of the ESI of two key ADI employees has raised

See Tr. at 849:22-852:12 (Franklin Velie, Counsel for the Harts). 261 28 U.S.C. § 1927. 262 Enmon v. Prospect Capital Corp., 675 F.3d 138, 143 (2d Cir. 2012) 263 (internal quotation marks omitted).

Id. 264

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serious concerns about credibility. Nevertheless, I am required to resolve all 265 doubts in favor of Sekisui' s counsel. Although I have rejected their arguments, 266 Sekisui' s counsel made colorable claims, and there is no proof that counsel bought this action in bad faith. I therefore deny the Harts' motion for sanctions against 267 Sekisui' s counsel. V. CONCLUSION

For the foregoing reasons, Sekisui' s claims and the Harts' counterclaim are dismissed with prejudice. Sekisui is ordered to pay $83,408.36 to

Sullivan & Worcester LLP in attorneys' fees pertaining to the Harts' spoliation

On August 15, 2013, I ruled that Sekisui " willfully destroyed" the ESI 265 of Hart and Ayres and granted the Harts' motion for sanctions in the form of an adverse inference instruction. See Sekisui, 945 F. Supp. 2d at 509-10. While inferring that the missing ESI is favorable to the Harts would reinforce my conclusions, I need not do so here. Even without the missing ESI, the evidence at trial was plainly insufficient to prove by a preponderance of the credible evidence that the Harts' breached the SPA. Because I decided Sekisui' s claim on other grounds, the adverse inference instruction is moot.

See Perez v. Posse Comitatus, 373 F.3d 321, 324 (2d Cir. 2004) 266 (finding that on a motion for sanctions, the court must " resolve all doubts in favor of the [pleadings] signer") (internal citation omitted).

See Salovaara v. Eckert, 222 F.3d 19, 34 (2d Cir. 2000) (" A 267 distinction must be drawn between a position which is merely losing, and one which is both losing and sanctionable.") (internal citation omitted).

51 motion, which I granted in an opinion dated August 15, 2013. 268

The Clerk of the Court is directed to prepare a judgment and to close this case.

... """"

. . . . ShiraA:. Scheindlin U.S.D.l. Dated: New York, New York

February 21,2014

268 The Harts requested a fee of$166,816.71. However, "[t]he district court retains discretion to determine ... what constitutes a reasonable fee. '" Millea v. Metro-North R.R. Co., 658 F.3d 154,166 (2d Or. 2011) (internal quotation marks omitted). It may sometimes be necessary "to make across-the-board percentage cuts in hours as a practical means of trimming fat from a fee application." Green v. City a/New York, 403 Fed. App'x 626, 630 (2d Cir. 2010) (internal quotation marks omitted). I find the Harts' fee request excessive because it includes the cost of general litigation preparation and other work unrelated to the missing ESI ofHart and Ayres. Thus, a reduction of fifty percent is warranted to eliminate excessive time charges.

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- Appearances -

Sekisui America Corporation et al v. Hart et al

2014 | Cited 0 times | S.D. New York | February 21, 2014

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