IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MEXTEL, INC., et al.	:	
	:	
Plaintiffs,	:	**CIVIL ACTION**
	:	
v.	:	**01-CV-7308**
	:	
AIR-SHIELDS, INC., et al.	:	
	:	
Defendants.	:	
_____	:	
	:	
HILL-ROM MANUFACTURING, INC., et al.	:	
	:	
Counterclaim Plaintiffs,	:	
	:	
v.	:	
	:	
MEXTEL, INC., et al.	:	
	:	
Counterclaim Defendants.	:	

MEMORANDUM AND ORDER

Presently before the Court are Plaintiffs' Motion for Partial Summary Judgment In Favor of Plaintiffs' Contract Claims and Dismissal of Defendants' Contract Counterclaims (Doc. No. 64), filed on April 14, 2004, and all responses and supplemental briefs thereto; Plaintiffs' Second Motion for Partial Summary Judgment With Respect to the Dismissal of Patent Defenses and Counterclaims (Doc. No. 66), filed on April 14, 2004, and all responses and supplemental briefs thereto; Defendant's Motion for Summary Judgment on Plaintiffs' Amended Complaint and Count IX of Defendants' Counterclaim (Doc. No. 74), filed on April 14, 2004, and all responses

and supplemental briefs thereto; Defendants' Motion to Strike Portions of Plaintiffs' Opening Brief in Support of Their First Motion for Partial Summary Judgment, First Declaration of Vedran Skulic, First Declaration of Novela Skulic, and Plaintiffs' Statement of Undisputed Material Facts in Support of Their First Motion for Partial Summary Judgment (Doc. No. 82), filed on May 6, 2004, and all responses and supplemental briefs thereto; and Defendants' Motion to Strike Portions of the Affidavit of Oleh V. Bilynsky, Third Declaration of Vedran Skulic, and Declaration of Harry Gugnani (Doc. No. 87), filed on May 19, 2004, and all responses and supplemental briefs thereto.

I. Factual and Procedural History

The genesis of this litigation stems from an arrangement between the parties for the development and supply of component medical devices. Defendant Air Shields, Inc., the successor in interest to defendant Hill-Rom Manufacturing Inc. ("Hill-Rom"),[1] a holding company that provides products and services for the health care industry, and plaintiff Mextel, Inc. ("Mextel"), an Illinois-based designer and manufacturer of electronic assemblies, entered into a "Development and Supply Agreement" on December 7, 1996. The Development and Supply Agreement was made retroactive to October 1995. It was supplemented with an "Addendum to the OEM Supply Agreement of October 1, 1995," which the parties executed on February 20, 1997, and by an "Amendment to the Development and Supply Agreement," which the parties executed on December 16, 1997. (See Addendum and Amendment, attached as Ex. 2 and 3 to Pl. App.). Collectively, these three documents shall be referred to as the "Agreement."

A. The Agreement

[1] Throughout the opinion, this Court refers to Hill-Rom, and its successors, including Air-Shields, collectively as "Hill-Rom."

The Agreement required Mextel to design, manufacture, and supply an electronic controller for use in the Hill-Rom's Isoletee, model C2HS infant incubator (the "C2000 incubator"). The C2000 incubator is a neonatal incubator, which, as defined by federal regulation, is a "device consisting of a rigid boxlike enclosure in which in an infant may be kept in a controlled environment for medical care . . . ." See 21 C.F.R. § 880.5400. The C2000 is used for critically ill newborn premature babies. (See March 28, 1998 Summary of Findings, at FDA00246). The standard model of the C2000 consists of a hood/shell assembly, a heater, a controller, a sensor module, two skin temperature probes, an air temperature probe, and an air flow probe. (Id.). The electronic controller in the C2000 incubator is the "brain" of the device, controlling the incubator's operations and ensuring that the heating, humidity, and oxygen systems operate effectively and according to programmed specifications. (Id.; see Pl. Mot. For SJ., at 2).

Pursuant to the Agreement, Mextel was required to comply with specific design, manufacturing, supply, and regulatory obligations. First, with respect to design obligations, Mextel was required, *inter alia*, to design the product in accordance with performance specifications prescribed by the Agreement; to provide validation of the product design to enable Hill-Rom to obtain FDA marketing clearance for the infant incubators; and to use its "best efforts" to design and provide validation of the product. (See Agreement, at ¶ 2.1(a); ¶ 2.1(b); ¶ 2.4(a)). Second, with respect to manufacturing obligations, Mextel was required to manufacture the controller in accordance both with manufacturing and quality assurance specifications prescribed by the Agreement and with good manufacturing practices ("GMPs") under the United States Food, Drug, and Cosmetic Act of 1938 (the "Act") and its attending regulations. (Id., at ¶

6.1(a)-(b)). Third, with respect to supply obligations, Mextel was required, prior to shipment, to examine all controllers in accordance with the quality assurance procedures prescribed by the Agreement and to provide a written confirmation that the products conformed to product design specifications; to submit to quality assurance audits, as prescribed by the Agreement; to maintain all manufacturing records, including lot histories and device master records; and to provide copies of these records to Hill-Rom quarterly for all products manufactured in that quarter. (Id., at ¶¶ 9.3, 9.4, 8.2). Finally, with respect to regulatory obligations, Mextel agreed to provide Hill-Rom "with any assistance reasonably required" in connection with the generation and development of data necessary to obtain FDA approval to market the incubator. (Id., at ¶ 11.2).

In exchange for Mextel's development and supply of the controllers, Hill-Rom agreed to use Mextel as its exclusive supplier. (See Agreement, at ¶ 6.2). As such, Hill-Rom contracted to purchase a minimum of 8000 controllers throughout the life of the Agreement. (See Addendum to Agreement, at ¶ 2). The Agreement established an arrangement by which Hill-Rom would submit purchase orders to Mextel for the supply of the controllers. (Id., at ¶ 9.7). Purchase orders were required to be placed at least fourteen weeks prior to the requested date of the shipment. (Id., at ¶ 9.9). Hill-Rom was required to pay Mextel within forty days from the date of shipment of the controllers. (Id., at ¶ 9.6). Hill-Rom also agreed to compensate Mextel for services associated with the development of the controller, including a non-recurring engineering charge and reasonable out-of-pocket travel expenses in connection with services performed under the Agreement. (Id., at ¶ 2.2).

To ensure the exclusivity of the arrangement, Hill-Rom extended several representations and warranties to Mextel. (Id., at ¶ 15.1). In ¶ 15.1(c), Hill-Rom represented and warrantied that it:

> is not currently a party to any agreement or undertaking, oral or written, that would, in any manner be inconsistent with the rights herein granted to MEXTEL to design, develop and SUPPLY a PRODUCT and shall not enter into any such agreement or understanding, oral or written, during the term of the Agreement, nor, during the term of this Agreement, directly or indirectly, engage in any activity that would, in any manner, be inconsistent with the right herein granted to MEXTEL to design, develop and SUPPLY a PRODUCT, except as specifically authorized herein.

(Id., at ¶ 15.1(c)).

1. Recalls

The Agreement contained a provision expressly allocating liability for costs in the event of a "recall" of Hill-Rom's products using the controller. This provision stated that:

> In the event of a recall of any Air-Shields products that use PRODUCT [the controller] supplied by MEXTEL hereunder, when it is determined that such an event is caused by PRODUCT malfunction and not by specification or requirement change, MEXTEL shell [sic] repair or replace all such PRODUCTS. Whether it is claimed that PRODUCT is causing such an event or not, AIR-SHIELDS will indemnify, defend, and hold MEXTEL, its current directors, officers, employees, and agents harmless from and against any and all claims, liability, product and warranty liability, loss, damages, costs, or expenses.

(See Agreement, at ¶ 10.2). The Agreement did not define the term "recall."

2. Duration and Termination

The duration of the Agreement was for four years, with automatic renewal "for successive one (1) year term [sic] unless sooner terminated . . . ." (See id., at ¶ 16). Although not expressly referenced in the duration clause, the Agreement provided, in a separate section marked "Termination," several ways for both Hill-Rom and Mextel to end its existence. (Id., at ¶¶ 18, 19).

Pursuant to ¶ 18.1 and ¶ 19.1, both parties enjoyed the right to terminate the Agreement upon the occurrence of certain enumerated events after providing sixty days written notice. (Id., at ¶ 18.1, 19.1). One of these enumerated events included the noticed party's failure to meet "any of its material obligations under the Agreement." (Id., at ¶ 18.1(c), 19.1(c)). Nonetheless, the noticed party retained a right to cure its default within sixty days after receipt of notice; and, if able to do so, the Agreement was to remain in effect. (Id.).

The Agreement also provided an additional mechanism by which Hill-Rom could terminate it:

> AIR-SHIELDS shall have the right to terminate the agreement at any time after giving sixty (60) days' written notice to MEXTEL if AIR-SHIELDS shall, in its sole discretion, determine either that the PRODUCTS are obsolete or that the infant incubators or infant radiant warmers into which such PRODUCTS are incorporated are obsolete.

(Id., at ¶ 18.2). This mechanism was exclusively reserved for Hill-Rom, and, in contrast to ¶ 18.1, did not trigger a right by Mextel to cure.

3. Applicable Law

The parties agreed that Pennsylvania law would apply to all disputes arising from the Agreement. (Id., at ¶ 27). The parties further consented to the exercise of personal jurisdiction by the federal and state courts of Pennsylvania. (Id.).

B. Design and Supply of the Sensor Module

In addition to designing, manufacturing, and supplying the controller, Mextel also designed and supplied to Hill-Rom a sensor module for use in the C2000 incubator. The sensor module was the subject of United States Patent 5, 957,830 ('830 patent), which was issued to plaintiff Vedran Skulic ("Skulic"), the founder and president of Mextel (collectively "plaintiffs"),

on September 8, 1999. (See '830 Patent, attached as Ex. B to Second Skulic Declaration).[2] The function of the sensor module was to measure the temperature, humidity, and oxygen inside the incubator, and then to feed the relevant data to the controller. (See Pl. Mot. For SJ., at 2).

The design and supply of the sensor module was not covered by the Agreement, which, according to its terms, applied only to the "electronic controller." (See Agreement, at ¶ 1.17). Instead, the sensor module was shipped pursuant to an informal arrangement between the parties, whereby Hill-Rom would issue purchase orders for controllers and/or sensor modules and Mextel would fill the purchase orders. (See Pl. Br. In Opp'n. to Def. Mot. For SJ., at 12; see also December 1, 1999 letter placing production hold on controllers and sensor modules, attached as Ex. 16 to Pl. Mot. For SJ.). Mextel supplied the sensor modules during the time when the Agreement was in existence. (See Purchase Orders, attached as Ex. 15 to Pl. Mot. For SJ.).

C. The Relationship

Between 1996 and December 1999, Mextel designed and shipped controllers and sensor modules to Hill-Rom for use in the C2000 incubator. In order to understand the collapse of this arrangement, and to frame the issues concerning liability and damages in the pending motions, it is necessary to provide: (i) a genealogical discussion of the regulatory requirements applicable to manufacturers of finished medical devices throughout the course of the parties' relationship; and (ii) a chronological recitation of the major events, correspondence, and regulatory problems associated with the C2000 incubator during the course of the parties' arrangement.

1. Regulatory Requirements

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[2] The '830 patent is one of two patents at issue in this litigation. The other patent, US Patent 5,707,006 (the "'006 patent"), was issued to Skulic on January 13, 1998. (See '006 Patent, attached as Ex. A to Second Skulic Declaration). The '006 patent covers a removable heater assembly for an infant incubator. (Id.).

The FDA initially issued market clearance for the C2000 incubator in July 1996. (See July 1996 Marketing Clearance letter, attached as Ex. 8 to Pl. Mot. For SJ.). The letter reiterated that, to maintain the right to market the C2000 incubator, Hill-Rom needed to comply with GMPs pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*., and that failure to comply with these practices could result in FDA action. (Id.).

The FDCA authorizes the FDA to promulgate regulations "requiring that the methods used in, and the facilities and controls used for the manufacture, pre-production design validation (including a process to access the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice . . . to assure that the device will be safe and effective and otherwise in compliance with this chapter." 21 U.S.C. § 360j(f)(1)(A) (West 2005). In 1976, the FDA promulgated a series of good manufacturing practice regulations, known as GMPs, that preemptively require manufacturers to build quality into their devices, rather than [to] permit a defective device to be distributed and used to treat patients." U.S. v. 789 Cases, More or Less, of Latex Surgeon's Gloves, 799 F.Supp. 1275, 1285 (D.P.R. 1992). These regulations apply to manufactures of finished medical devices. See 21 C.F.R. § 820.1(a). Manufacturers of medical device components, on the other hand, are exempt. Id. ("This regulation is not intended to apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidelines.").

By 1996, the year in which the Agreement was signed, GMPs had been promulgated in the following areas connected with the manufacture of medical devices: organization and personnel; buildings; equipment; control of components; production and process controls;

packaging and labeling control; holding, distribution, and installation; device evaluation; and records. See 21 C.F.R. Part 820. With respect to records, GMPs required (and continue to require) manufacturers to maintain product records during the design and expected life of the device. 21 C.F.R. §§ 820.180-198 (1996). Manufacturers were (and continue to be) required to keep the following: (i) a device master record ("DMR"), which includes device specifications, production process specifications, quality assurance procedures, and packing and labeling; (ii) a device history record ("DHR"), which ensures that the device was manufactured in accordance with the device master record by including the dates of manufacture, the quantity manufactured, the quantity released for distribution, and any control number used; and (iii) complaint files. Id.

On October 7, 1996, the FDA published the Quality System ("QS") regulation in the Federal Register. See Medical Devices; Current CGMP (CGMP) Final Rule; Quality System Regulation, 61 Fed. Reg. 52,602, 52,654 (Oct. 7, 1996) (to be codified at 21 C.F.R. pt 820). The QS regulation redefined GMPs, creating stricter standards for manufacturers of finished medical devices. Id. Although published in October 1996, the QS regulation did not take effect until June 1, 1997. Id. The QS regulation remains in effect today.

As part of the QS regulation, the FDA made verification and validation requirements part of GMPs. The QS regulation defines validation as "establishing by objective evidence that device specifications conform with user needs and intended use(s)." 21 CFR § 820.4(z). Verification is defined as "confirmation by examination and provision of objective evidence that specified requirements have been fulfilled." Id. § 820.4(aa).

The QS regulation implements verification and validation requirements through specific forms of controls, including design, production and process, and document controls. First, with

respect to design controls, the QS regulation requires manufacturers of medical devices to maintain procedures for verifying the device design, which must conform to designated output meets design input requirements, and for validating the device design, which must be performed on initial production units and which must ensure that devices confirm to designed user needs and intended uses. Id. § 820.30(a)-(j). The results of the design verification and validation must be documented. Id. § 820.30(f)-(g). Furthermore, a design history file ("DHF") must be established and maintained to demonstrate "that the design was developed in accordance with the approved design plan." Id. § 820.30(j).

Second, with respect to production and process controls, the QS regulation requires manufacturers to validate the production process with a high degree of assurance to ensure that a device confirms to its specifications, when such a process cannot be fully verified by subsequent inspections and tests. Id. § 820.75. The validation activities and results must also be documented. Id.

Third, the QS regulation imposes additional document controls and quality system controls, including the maintenance of a quality system record to document executive responsibility for, and commitment to, quality. Id. §§ 820.20, 820.40, 820.186.

2. Chronology of Events

Hill-Rom started placing orders for controllers from Mextel in 1996. (See First Declaration of Vedran Skulic, at ¶ 2). For each controller, Mextel kept "Certificates of Conformance" to certify that the product was manufactured in accordance with the specifications in the purchase order and tested according to the design specifications prescribed by the Agreement. (Id., at ¶ 23; see also Sample Certificates of Conformance, attached as Ex. 22 to Pl.

Mot. For SJ.). Nonetheless, regulatory concerns with the controller started to arise almost immediately.

In the summer of 1996, Hill-Rom started to request from Mextel documentation concerning the controller that was necessary for the C2000 incubator to comply with GMPs. On July 10, 1996, September 3, 1996, September 5, 1996, September 24, 1996, and October 11, 1996, Hill-Rom sent facsimile transmissions to Mextel demanding the immediate production of DMR documentation, DHR documentation, and verification and validation information for the controller and sensor module, and identifying the information necessary to satisfy the DMR and DHR requirements. (See Letters requested documentation, attached as Ex. 4B at Def. Mot. For SJ.). On November 5, 1996, plaintiff Skulic and a representative from Hill-Rom signed a certification statement indicating that complete DMR documentation had been developed for several models of the controllers, and that, although currently in an untidy and informal form, Mextel would deliver "complete" and "formalized" documentation by December 31, 1996. (See November 5, 1996 Certification, attached as Ex. 3A to Def. Mot. For SJ.).

In February 21, 1997, Hill-Rom again wrote to Mextel concerning the "lack of product device master record documentation" and an "unacceptable level of change controls existing between our respective firms." (See February 21, 1997 letter, attached as Ex. 4B to Def. Mot. For SJ.). The February 21, 1997 correspondence further asserted that "device master record documentation is past due and urgently requested." (Id.). On September 3, 1997, Hill-Rom sent a letter to Mextel concerning outstanding quality problems with the controller, including the lack of complete DMR documentation, and suggested that Hill-Rom was not "in a good position to withstand regulatory audit scrutiny by FDA" due to these problems. (See September 3, 1997

letter, attached as Ex. 4C to Def Mot. For SJ.). Indeed, the letter demanded that a complete DMR was to be provided to Hill-Rom and continuously maintained at both Mextel's and Hill-Rom's facilities. (Id.). Perhaps in response to these requests, on November 10, 1997, Skulic signed a letter on behalf of Mextel stating that Mextel "will fully cooperate with Air-Shields in an effort to implement QSR [QS] requirements." (See November 10, 1997 Letter, attached as Ex. 12A to Def. Mot. In Opp'n.).

In March 1998, an independent research organization, CriTech Research Inc. ("CriTech"), performed an on-site evaluation of Mextel's software verification and validation methodology, equipment, and records. (See CriTech Research Software Verification and Validation Assessment Report, attached as Ex. 28 to Pl. Mot. For SJ.). The final report indicated that Mextel was able to produce "a software source code." (Id.). However, the report concluded that components of the "Design History File" were missing and that "no documented evidence of Software Verification and Validation, nor of the expected work products of software development, was found during CriTech's on site assessment." (Id.). Indeed, as a result of the lack of documentation, CriTech issued a proposal on April 6, 1998, which was then later reissued on November 10, 1999, to Hill-Rom to "develop a Design History File for the Mextel controller integrated into the . . . Air Shields Isolette." (See CriTech Proposal, attached as Ex. 30 to Pl. Br. In Opp'n.).

In January and February 1998, the FDA started to actively monitor the regulatory compliance of the C2000 incubator, making unannounced inspections of Hill-Rom's facility in Hatboro, Pennsylvania (the "Hatboro facility"), where the C2000 incubator was manufactured. (See Certified FDA documents, attached as Ex. 14 to Def. Br. In Opp'n.). On March 26, 1998,

the FDA issued a "Form FDA 483" to Hill-Rom, listing observations of problems with the C2000 incubator, including a lack of software validation data, an incomplete DMR from the vendor of the controller and sensor module, and incomplete device history records for the C2000 incubator. (See March 26, 1998 Letter, attached as Ex. 14 to Def. Br. In Opp'n., at FDA 00286-291). Hill-Rom met with the FDA to discuss these findings. (See Utterback Aff., attached as Ex. 3 to Def. Mot. For SJ., at ¶ 3).

In response to this letter and meetings with the FDA, Hill-Rom issued an "Urgent Medical Device Notice/Recall" for the incubator on May 18, 1998, citing temperature fluctuations, humidity departures from set points, and air flow probe failures as the causes of the notice. (See May 18, 1999 Urgent Medical Device Notice/Recall, attached as Ex. 12 to Pl. Mot. For SJ.). This notice was issued in conjunction with and at the recommendation of the FDA. (See October 3, 2001 Memorandum Summarizing Recall, attached as Ex. 14 to Def. Br. In Oppn., at FDA 00293-00294). An FDA memorandum indicated that the reason for the May 18, 1998 notice was the C2000 incubator's "potential for causing serious injuries or deaths," specifying that the "unresolved problems were with regard to the controller and the humidity module." (Id., at 00294). The memorandum further identified overheating problems with the controller and humidity module, which increased the possibility that an infant in the C2000 could "dry out and experience respiratory distress." (Id., at 00295).

On June 18, 1998, Skulic sent Hill-Rom a letter contesting an accusation that Mextel was failing to help Hill-Rom fulfill FDA requirements. (See June 18, 1998 Letter, attached as Ex. 29 to Pl. Br. In Opp'n.). The letter stated that Mextel was available and willing to offer assistance in responding to FDA issues. (Id.).

On June 25, 1998, the FDA issued a "Warning Letter" to Hill-Rom. (See June 25, 1998 Warning Letter, attached as Ex. 21 to Pl. Mot. For SJ.). The warning letter found that "the C2000 devices are adulterated within the meaning of Section 501(h) of the FD&C Act in that methods used in, or facilities or controls used for, their manufacturing, packing, storage, or installation are not in conformance with the good manufacturing (CGMP) regulations" of the FDCA. (Id., at E22258). The warning letter provided a non-exhaustive list of twenty-four violations, including, *inter alia*, a failure to include information regarding component specifications in the DMR for the controller, the failure to include the primary history label and labeling for each product unit in the DHR, and the failure to assure that production processes for the controller conform to its specifications. (Id.). The warning letter noted that the controllers were associated with a 15% failure rate at incoming inspection and that the FDA's inspection "revealed significant deviations" from the GMPs. (Id., at E22259).

Immediately after the June 25, 1998 warning letter, Hill-Rom sent a letter to Mextel demanding rectification of several FDA observations related to the controller. (See June 30, 1998 letter, attached as Ex. 4D to Def. Mot. For SJ.). The June 30, 1998 letter stated that the "recall was largely driven by the lack of verification and validation of the controller software and the unacceptably high fallout rate during incoming inspection and test." (Id.). It also noted that Hill-Rom still had not received DMR materials, and that, if these materials were not provided, Hill-Rom would ask the FDA to directly inspect the DMR materials for the controller at Mextel's facility. (Id.).

In September 1998, Hill-Rom exercised its right under ¶ 9.4 of the Agreement and conducted a quality audit of Mextel's facility to ensure compliance with quality assurance

protocols. The Hill-Rom used the regulations promulgated by the FDA as the gauge to determine compliance. (See 1998 Quality Audit Report, attached as Ex. 4E to Def. Mot. For SJ.). The quality audit in September 1998 resulted in an overall survey score of 58.7%, and a conditional certification level grade for Mextel. (Id.).

On October 7 and 8, 1998, representatives from both Hill-Rom and Mextel with the agenda of "problem solving," which included discussions of the in-coming inspection failures of the controllers and sensor modules. (See Itinerary of October 7 and 8, 1998 Meeting, attached as Ex. 13 to Pl. Mot. For SJ.).

The FDA conducted another unannounced inspection of Hill-Rom's Hatboro facility in February 1999. Following this inspection, the FDA issued a second 483 letter to Hill-Rom on February 19, 1999. (See February 19, 1999 letter, attached as Ex. 14 to Def. Br. In Opp'n., at FDA00230-00285). The February 19, 1999 letter listed fourteen observations of problems with the C2000 incubator, including, *inter alia*, that "design verification did not confirm that the design output meets the design input requirements through software verification," that "actions needed to correct and prevent recurrence of nonconforming product and quality problems in regards to the control module are incomplete," and that "the DHR does not include or refer to the location of acceptance records which demonstrate the device is manufactured in accordance with the DMR." (See id.).

In April 1999, Hill-Rom conducted a second quality audit of Mextel's manufacturing facility to determine compliance with GMPs. (See April 1999 Supplier Survey Results, attached as Ex. 4F To Def. Mot. For SJ.). Again, Hill-Rom used the QS regulations as the template to determine quality audit compliance. The audit produced an overall survey score of 34%, with a

designated certification level of "unacceptable." (Id.). As a result of the low score, Hill-Rom demanded the submission of improvement plans to Hill-Rom's development team within thirty days of receipt of the survey. (Id.).

After the quality audit, Hill-Rom sent Mextel an April 27, 1999 letter, in which Hill-Rom referenced the poor certification level, listed many alleged deficiencies in Mextel's methodology and performance as a supplier of medical components, and threatened to terminate the Agreement if Mextel did not take "appropriate action." (See April 27, 1999 letter, attached as Ex. 4G to Def. Mot. For SJ.).

In October and November 1999, the FDA again conducted a series of inspections at Hill-Rom's Hatboro facility. On November 30, 1999, the FDA sent Hill-Rom a third 483 letter. (See November 30, 1999 Letter, attached as Ex. 14 to Def. Br. In Opp'n., at FDA00179-00181). The letter emphasized failures with respect to Hill-Rom's procedures for handling complaints associated with the C2000 incubator. (Id.). Complaints concerning the sensor module and controller were documented and reviewed by the FDA. (See Summary of Findings for November 30, 1999 Report, EIR Addendum, attached as Ex. 14 to Def. Br. In Opp'n., at 00178).

D. Termination

In February 1998, Hill-Rom contemplated the possibility of exiting the contractual arrangement with Mextel through a buy-out of Hill-Rom's remaining obligations. (See Estimate of Buyout, attached as Ex. 25 to Pl. Br. In Opp'n.). In July 13, 1998, Hill-Rom accepted a detailed quotation from Comtec Systems, Inc. ("Comtec") "for the development of a replacement controller" for the C2000 incubator. (See July 13, 1998 Letter, attached as Ex. 27 to Pl. Br. In Opp'n). Hill-Rom also accepted a proposal from Battelle to conduct a design and development

program for the re-design of the controller. (See Battelle Proposal, attached as Ex. 26 to Pl. Br. In Opp'n.).

Despite accepting quotations and proposals from new suppliers for the development of a replacement controller, Hill-Rom continued to place purchase orders for sensor modules and controllers through November 1999. (See Purchase Orders, attached as Ex. 14 to Pl. Mot. For SJ.). On December 16, 1999, however, Hill-Rom notified Mextel that it was placing a production hold on all sensors and controllers, with the exception of spares. (See December 16, 1999 Letter (dated December 1, 1999), attached as Ex. 16 to Pl. Mot. For SJ.; see Skulic's First Declaration, at ¶ 10). Shortly thereafter, Skulic asserts that he notified Hill-Rom that it would not ship any more products until outstanding invoices were paid. (See Skluic's First Declaration, at ¶ 10). Then, on December 28, 1999, Hill-Rom sent Mextel another letter purporting to terminate the Agreement, citing ¶¶ 18.1 and 18.2 as the justification for this right to terminate. (See December 28, 1999 Letter, attached as Ex. 17 to Pl. Mot. For SJ.). The December 28, 1999 letter declared that this termination was effective immediately. (Id.).

After purporting to terminate the Agreement, Hill-Rom met with the FDA in January 2000. (See Johnson Aff., attached as Ex. 3 to Def. Mot. In Opp'n., at ¶ 5-6). Hill-Rom issued a revised recall letter for the C2000 incubator on January 5, 2000, based in part on an overheating issue with the controller. (See October 3, 2001 FDA Memorandum, attached as Ex. 14A to Def. Br. In Opp'n., at FDA00292-FDA00295). Hill-Rom then replaced Mextel's controller with a replacement controller for every C2000 incubator. (See Johnson Aff., at ¶ 8). Hill-Rom also replaced Mextel's sensor module with a new sensor module. After the completion of this

process, Hill-Rom started to sell a new version of the C2000 incubator ("new C2000 incubator"), without the Mextel products, on the market.

E. Litigation

On December 28, 2001, plaintiffs filed a complaint, which was later amended on April 26, 2002. The amended complaint alleged eleven counts against Hill-Rom: breach of contract (Count I); quantum meruit (Count II); unjust enrichment (Count III); breach of implied covenant of good faith and fear dealing (Count IV); fraud and deceit (Count V); patent infringement (Count VI); misappropriation of trade secrets (Count VII); trade dress infringement (Count VIII); common law unfair competition (Count IX); one count against fictitious individuals incorporating the substance of each prior claim (Count X); and one count against fictitious corporations incorporating the substance of each prior claim (Count XI). On November 8, 2002, the Court dismissed Counts V, X, and XI for failure to state a claim, and dismissed Counts I-IV on behalf of Skulic. (Doc. No. 20).

The Court issued a scheduling order on October 17, 2002 requiring fact discovery to conclude by March 31, 2003. (Doc. No. 19). On March 10, 2003, the Court amended this order, extending the end date for factual discovery until June 30, 2003 and for expert discovery until September 31, 2003. (Doc. No. 22). On May 9, 2003, the Court amended the scheduling order for a second time, extending the deadline for fact discovery until August 29, 2003 and for expert discovery until November 30, 2003. (Doc. No. 24). On August 4, 2003, after plaintiffs' representation that neither party deposed any witnesses, the Court issued a third amended scheduling order, requiring all fact discovery to end by December 27, 2003 and all expert discovery to conclude by April 14, 2004. (Doc. No. 28), including the submission of expert

witness reports.

Subsequent to the issuance of the third amended scheduling order, Hill-Rom filed three motions to compel discovery responses and plaintiffs filed one motion. (Doc. No. 29, 30, 37). On December 19, 2004, the Court advised the parties to resolve their discovery disputes privately. (Doc. 38). The Court further extended the deadline to file specific motions to compel on particular discovery issues to January 15, 2004 and February 2, 2004, in the event the parties failed to privately resolve their discovery disputes. (Id.). Neither party filed a motion to extend the discovery deadlines or a motion to amend the August 4, 2003 scheduling order during this period.

The parties were unable to work out their discovery disputes, and Hill-Rom filed a motion to compel on January 15, 2004 (Doc. No. 39). Pursuant to its January 29, 2004 Order, the Court granted Hill-Rom's motion to compel and required plaintiffs to produce a copy of the electronic source code for the controller. On February 2, 2004, the Court again extended its deadline, from February 2, 2004 until February 27, 2004, for plaintiffs to file a motion to compel (Doc. No. 49) the production of allegedly privileged documents. On March 30, 2004, the Court resolved the plaintiffs' motion to compel in favor of Hill-Rom. (Doc. No. 59). Because none of the parties requested additional time for fact or expert discovery, the March 30, 2004 order enforced the existing August 4, 2003 scheduling order, officially closed the discovery period for fact and expert discovery, and demanded the filing of dispositive motions by April 14, 2004. (Id.).

On April 14, 2004, both sides filed summary judgment motions. (Doc. No. 63-74). This was followed by an array of briefs in opposition, reply briefs, statements of disputed and

undisputed material facts, and motions to strike.

II. Discussion

A. Motions to Strike

It is well-established that "only evidence which is admissible at trial may be considered in ruling on a motion for summary judgment." Countryside Oil Co., Inc. v. Travelers Ins. Co., 928 F.Supp. 474, 482 (D.N.J. 1995); see also Pamintuan v. Nanticoke Mem. Hosp.,192 F.3d 378, 388 (3d Cir. 1999); Fed. R. Civ. P. 56(e) (requiring affidavits in support of summary judgment motion to be made on personal knowledge, to set forth facts that would be admissible in evidence, and to show affirmatively that the affiant is competent to testify to such matters). Both parties challenge the admissibility of affidavits and documents attached to their opponents' motions.

1. Plaintiffs' Objections

Plaintiffs argue that the affidavits of Susan Reilly ("Reilly Affidavit"), James Utterback ("Utterback Affidavit"), and Otho Boone ("Boone Affidavit"), and the documents attached to the Utterback and Boone Affidavits, constitute inadmissible evidence that may not be relied upon to resolve Hill Rom's motion for summary judgment. (See Pl. Br. In Opp'n., at 5-8).

a. The documents attached to the Boone Affidavit and Utterback Affidavit are admissible.

Plaintiffs seek to strike the documents attached to the Boone and Utterback Affidavits because the documents are unauthenticated and because the letters do not constitute business records within the hearsay exception. (Id., at 7).[3] The Court rejects plaintiffs' motion.

[3] The documents attached to the Utterback Affidavit are attached as Exhibits A-C to the Boone Affidavit.

The documents attached to the Boone Affidavit are admissible. Mr. Boone is the custodian of domestic records of regularly conducted activity for Hill-Rom and its predecessors, including Air-Shields. (See Boone Aff., attached as Ex. 4 to Def. Mot. For SJ., at ¶ 2). Boone provides testimony to authenticate the documents–that they were made by a person with knowledge at or near the time of the occurrences of the matters set forth in the letters; that they were kept in the course of regularly conducted business activity as part of a regular business practice; and that they were made in the course of a regularly conducted business practice. See Fed. R. Ev. 902(11). Furthermore, to the extent that Hill-Rom seeks to introduce these documents for their truth-value, these authenticated documents meet the business records exception to the hearsay rule. See Fed. R. Ev. 803(6) (custodian may establish admissibility of records of regularly conducted business activities). Finally, plaintiffs cite no caselaw to support their position that letters kept in the course of regularly conducted activity fail to constitute a "memorandum, report, record, or data compilation" within the meaning of Federal Rule of Evidence 803(6).

b. The Utterback Affidavit is admissible.

Plaintiffs seek to strike the Utterback Affidavit on the basis that Mr. Utterback lacks personal knowledge of the testimony in his affidavit and on the basis that his testimony puts in issue communications relating to the FDA that were previously withheld by Hill-Rom on the basis of the attorney-client and work-product privilege. (See Pl. Br. In Opp'n., at 6-7). The Court rejects plaintiffs' motion.

The Utterback Affidavit is admissible. First, the Utterback Affidavit does not put in issue privileged communications between Mr. Utterback and his client to which plaintiffs were

previously denied access during discovery, such as communications embodying Mr. Utterback's direction of Hill-Rom's response to FDA investigations. Instead, the Utterback Affidavit refers to, and provides documents concerning, communications between Hill-Rom and the FDA, communications to which the attorney-client privilege does not attach. (See Utterback Aff., attached as Ex. 3 to Pl. Mot. For SJ., at ¶ 2-4); see 42 Pa. Cons. Stat. Ann. § 5928 (attorney-client privilege protects confidential communications between attorney and client). These documents were turned over in the course of discovery, rather than withheld through Hill-Rom's discovery logs. (See Def. Response to Mot to Compel, at 23-24) ("Hill-Rom has not withheld documents provided to the FDA").

Furthermore, the Court finds that Mr. Utterback, as in-house counsel for Hill-Rom, has knowledge of the factual averments in his affidavit. Fed. R. Civ. P. 56(e) (requiring affiant to set forth facts made on personal knowledge). Plaintiffs cite one lone example—Mr. Utterback's reference to the December 31, 1996 certificate statement in which Mextel promised to deliver formal DMR documentation--to support its contention that "Utterback's affidavit is largely not based on personal knowledge." (See Pl. Mot. In Opp'n., at 6). In contrast to plaintiffs' argument, Mr. Utterback does not testify to the circumstances behind the signing of the certificate statement, which occurred prior to his employment at Hill-Rom; but, instead, merely references the existence of the certificate statement in his discussion of Mextel's alleged failure to deliver pertinent DMR information to Hill-Rom both before and after the commencement of FDA investigations. (See Utterback Affidavit, at ¶ 3c). More importantly, assuming *arguendo* that Mr. Utterback's reference to the December 31, 1996 letter should be stricken, plaintiffs' general contention of lack of personal knowledge, without specific examples, fails as a matter of

law to render inadmissible the remaining testimony in the Utterback Affidavit. See Wright, Miller & Kane, 10B Federal Practice & Procedure § 2738, at 377 (3d ed. 1998) ("It follows that a motion to strike should specify the objectionable portions of the affidavit and the grounds for each objections. A motion asserting only a general challenge to an affidavit will be ineffective.").

c. The Reilly Affidavit is inadmissible.

Plaintiffs seek to exclude the affidavit of Susan C. Reilly, an expert in the field of regulatory compliance for the medical device and diagnostic industry, on the basis of Hill Rom's violation of discovery deadlines. (See Pl. Br. In Opp'n., at 5). The Court agrees.

Ms. Reilly was not designated as an expert witness prior to the close of expert discovery. Nor did Ms. Reilly file an expert report prior to the close of expert discovery. Hill-Rom's untimely introduction of Ms. Reilly's testimony in affidavit form at the summary judgment stage therefore violates the Court's August 4, 2003 scheduling order. (Doc. No. 28). Accordingly, after weighing the relevant factors, particularly the prejudice to plaintiffs, this Court finds that an appropriate sanction pursuant to Federal Rule of Civil Procedure 37(b)(2)(B) is to bar Ms. Reilly's testimony at trial, thereby making her affidavit inadmissible for purposes of Hill Rom's summary judgment motion. See, e.g., Oliver v. Ingber, 1998 WL 107299, at *2 (E.D. Pa. March 9, 1998) (excluding expert testimony at trial for failure to meet pre-trial deadline for exchange of expert witness information because defendant would have been prejudiced by allowance of expert testimony); Perkasie Ind. Corp. v. Advance Transformer, Inc., 143 F.R.D. 73, 77 (E.D. Pa. 1992) (excluding expert testimony for failure to comply with pre-trial scheduling order).

d. Conclusion

This Court finds the Utterback Affidavit, the Boone Affidavit, and the documents attached to these affidavits admissible as a matter of law. However, the Court grants plaintiffs' motion to strike the Reilly Affidavit.

B. Summary Judgment Motions

Plaintiffs and Hill-Rom have filed motions for summary judgment.

1. Standard

In considering a motion for summary judgment, the court must determine whether "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247 (1986); Arnold Pontiac-GMC, Inc. v. General Motors Corp., 786 F.2d 564, 568 (3d Cir. 1986). Only facts that may affect the outcome of a case are "material." Anderson, 477 U.S. 248. All reasonable inferences from the record are drawn in favor of the non-movant. See id. at 256.

The movant has the initial burden of demonstrating the absence of genuine issues of material fact. This "burden . . . may be discharged by 'showing' that there is an absence of evidence to support the non-moving party's case." Celotex Corp. v. Catreet, 477 U.S. 317, 323 (1986). Once this burden is discharged, the non-movant must then establish the existence of each element on which it bears the burden of proof. See J.F. Feeser, Inc. v. Serv-A-Portion, Inc., 909 F.2d 1524, 1531 (3d Cir. 1990). A plaintiff cannot avert summary judgment with speculation or by resting on the allegations in his pleadings, but rather must present competent evidence from which a jury could reasonably find in her favor. Anderson, 477 U.S. at 248;

Ridgewood Bd. of Educ. v. N.E. for M.E., 172 F.3d 238, 252 (3d Cir. 1999); Williams v. Borough of West Chester, 891 F.2d 458, 460 (3d Cir. 1989); Woods v. Bentsen, 889 F. Supp. 179, 184 (E.D. Pa. 1995).

2. Plaintiffs' Motion for Summary Judgment

Plaintiffs seek summary judgment with respect to certain breach of contract claims in Count I of the amended complaint, Hill-Rom's contract counterclaims, and Hill-Rom's patent defenses and counterclaims. (See Pl. Mots. For SJ.).[4]

A. Breach of Contract

Mextel's summary judgment motion alleges that Hill-Rom breached the Agreement in numerous ways.[5] First, Mextel claims that Hill-Rom refused to pay invoices from March 12, 1998 to January 12, 2000 covering controllers and sensor modules shipped to and accepted by Hill-Rom. (See Pl. Mot. For SJ., at 10-12). Second, Mextel claims that Hill-Rom refused to pay for unshipped products after placing purchase orders pursuant to the Agreement. (Id., at 12-13). Third, Mextel contends that Hill-Rom did not purchase the minimum of 8,000 controllers, as required by the Agreement, but, instead, purchased only 5,621 controllers. (Id., at 13-14).[6]

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[4] This Court addresses plaintiffs' summary judgment argument with respect to dismissing Hill Rom's patent defenses and counterclaims in the context of Hill Rom's summary judgment motion.

[5] Mextel notes that it has not moved for summary judgment on all its breach of contract allegations, including damages stemming from Hill-Rom's breach of its obligations to use plaintiff as the exclusive supplier for replacement controllers, from plaintiff's exclusive controller design and development rights, and from plaintiff's rights to other damages and attorney's fees. (See Pl. Mot. For SJ., at 10 n.2).

[6] As a threshold question, this Court must first determine what law to apply to the dispute. The Agreement calls for the application of Pennsylvania law. (See Agreement, at ¶ 27). Neither party has expressly determined whether the Pennsylvania Uniform Commercial Code ("UCC") applies to the Agreement. Article II of the Pennsylvania UCC applies to transactions involving the sale of goods. See 13 Pa. Cons. Stat. Ann. § 2-102 (Article II of UCC applicable to

i. The sensor module was not covered by the Agreement.

Mextel seeks summary judgment on its breach of contract claim with respect to the contract price both of delivered and of ordered, but undelivered sensor modules. (See Pl. Mot. For SJ., at 10-12). However, Mextel admits in its brief in opposition to Hill-Rom's summary judgment motion that the production and supply of sensor modules are not covered by the Agreement. (See Pl. Br. In Opp'n. to Def. Mot. For SJ., at 12).[7] Nor does Mextel supply alternative oral or written contracts between Mextel and Hill-Rom for the supply of sensor modules. See, e.g., Rototherm Corp. v. Penn Linen & Uniform Serv., 1998 WL 134222, at *3 (E.D. Pa. March 19, 1998) (granting summary judgment to defendant for plaintiff's failure to demonstrate the existence of contract between two parties, "an essential element of its claim for breach of contract"). Moreover, the accounting documentation Mextel submits as proof of its production and supply of sensor modules to Hill-Rom only identifies the date of shipping, rather than the type of products supplied to Hill-Rom. (See Ageing Accounts, attached as Ex. 5 and 7 to Pl. Mot. For SJ.). Without an express written or oral contract for the supply and purchase of sensor modules, Mextel is not entitled to summary judgment on a breach of contract theory as to

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"transactions in goods"). Although the Agreement covers the design, development, and manufacture of controllers, as well as the provision of other types of engineering services, its primary purpose is the supply/sale of these controllers to the Hill-Rom. (See Agreement, at ¶ 9). This Court concludes that Article II of UCC applies to the parties' breach of contract dispute. See Advent Systems Ltd. v. Unisys Corp, 925 F.2d 670 (3d Cir. 1991). This conclusion is further confirmed by the parties, who, in their respective briefs, both rely upon the Pennsylvania UCC as controlling law.

[7] Specifically, Mextel concedes that the production and supply of sensor modules to Hill-Rom was not covered by the Agreement, asserting instead that the sensor modules would be supplied to Hill-Rom pursuant to an informal arrangement by which Hill-Rom would place purchase orders both for controllers and sensor modules. (See Pl. Br. In Opp'n., at 12-13 ; see also December 1, 1999 Letter placing "all sensors and controllers" on hold, attached as Ex. 6 to Pl. Mot. For SJ.).

the cost of the shipped or unshipped sensor modules. See 13 Pa. Cons. Stat. Ann. § 2107(a) (contract for the sale of goods for the price of $500 or more is not enforceable by way of action or defense unless some writing indicating existence of contract for sale between parties and unless signed by party against whom enforcement is sought).

ii. Mextel is entitled to summary judgment on liability for Hill Rom's refusal to pay for controllers that it received and accepted; however, Mextel is not entitled to summary judgment for services received by Hill-Rom.

Mextel also asserts that it is entitled to summary judgment on Hill-Rom's failure to compensate Mextel for controllers shipped to Hill-Rom between March 12, 1998 and January 12, 2000, and for engineering services rendered to Hill-Rom in connection with the design and production of these products. (See Pl. Mot. For SJ., at 10-12). Mextel asserts that the contract price for the delivered products and services was $278,385. (Id.). Hill-Rom admits that outstanding invoices exist for certain shipments. However, Hill-Rom challenges the amount of products received and justifies non-payment on the basis that the products were non-conforming at the time of their receipt. (See Def. Br. In Opp'n., at 2-4).

a. Engineering Services

To support its claim for the value of engineering services rendered, Mextel relies upon the affidavit of Novela Skulic, an employee of Mextel who managed product orders, shipping, and invoicing between Mextel and Hill-Rom. (See First Skulic Declaration, at ¶ 2). However, Skulic's affidavit does not identify the type of "services" rendered. (Id. at ¶ 4). Moreover, Mextel has failed to identify under what provision of the Agreement it is entitled to the reasonable value of engineering services. See, e.g., Omicron Systems, Inc. v. Weiner, 860 A.2d 554, 564 (Pa. Super. Ct. 2004) (breach of contract requires plaintiff to establish existence of

contract, breach of duty imposed by contract, and resultant damages). Nor has Mextel provided an invoice detailing when engineering services were rendered, why these services were rendered, and the amount of these services. Thus, genuine issues of material fact exist as to whether Mextel provided engineering services to Hill-Rom, whether the Agreement covered these services, and the amount of those services.

b. Controllers

The shipment of controllers is governed by the Agreement, and, thus, by the Pennsylvania UCC. Under the Pennsylvania UCC, upon delivery of a commercial unit, a buyer may reject the whole, accept the whole, or accept any commercial units and reject the rest. See 13 Pa. Cons. Stat. Ann. § 2-601. An acceptance of goods occurs when the buyer either: (1) after a reasonable opportunity to inspect the goods signifies to the seller that the goods are conforming or that she will take or retain them in spite of their nonconformity; or (2) fails to make an effective rejection after a reasonable time for inspection. Id. § 2-606. The buyer must pay at the contract rate for any goods accepted. Id. § 2-607(a).

To make an "effective rejection," a buyer must notify the seller of the non-conforming nature of the goods "within a reasonable time after the delivery or tender of the goods." Id. § 2-602(a)-(b). The seller must then hold the goods "with reasonable care at the disposition of the seller for a time sufficient to permit the seller to remove them." Id. § 2-602((b).

(i) Liability

The Agreement required Hill-Rom to pay Mextel forty days from the date of shipment of the controllers, thereby setting the date for rejection of delivered controllers at a maximum of forty days. (See Agreement, at ¶ 9.6). It is indisputable that Hill-Rom immediately rejected a

number of incoming controllers for poor quality and then returned these products to Mextel to cure their defects. (See Wenstrup Aff., attached as Ex. 1 to Def. Br., at ¶ 8); (Ferrante Aff., attached as Ex. 6 to Def. Mot. For SJ., at ¶ 5); (Drinkwater Aff., attached as Ex. 4 to Def. Br., at ¶ 4) ("When Mextel products would arrive, they would be tested to determine if they worked correctly. If they did not, they would be returned to Mextel. As a general rule, when that occurred, Mextel was very uncooperative with Hill-Rom's efforts to get the problems corrected and the controller timely returned"). It is also indisputable that Hill-Rom "accepted" a number of Mextel's controllers by taking steps inconsistent with Mextel's ownership--Hill-Rom incorporated these controllers in the C2000 incubator, sold the C2000 incubator, and then failed to pay Mextel within forty days from the date of shipment (See Novela Skulic Declaration, at ¶¶ 3-5). See Comfort Springs Corp. v. Allancraft Furniture Shop, 67 A.2d 818, 820 (Pa. Super. Ct. 1949) (holding that "buyer's rights to reject goods must be exercised promptly and unequivocally and that complaint as to qualify [sic] while exercising dominion over the goods is not rejection"); Foell Packing Co. v. Harris, 193 A. 152 (Pa. Super. Ct. 1937) (resale of product constitutes act inconsistent with seller's ownership). Nor has Hill-Rom provided documentation to indicate that it effectively rejected those controllers that passed Hill-Rom's initial inspection test;[8] indeed, although Hill-Rom constantly notified Mextel of its general inability to demonstrate and document that the controller was manufactured in accordance with GMPs, Hill-Rom never notified Mextel in writing of particular defects with particular installments, nor offered to return

[8] In fact, as plaintiff points out, Hill-Rom's December 28, 1999 termination letter never suggested that the controllers received by Hill-Rom were non-conforming. (See December 28, 1999 Termination Letter).

allegedly defective controllers to Mextel.[9] See 13 Pa. Cons. Stat. Ann. § 2-602; see Julian C. Cohen Salvage Corp. v. Eastern Elec. Sales Co., 206 A.2d 331, 334 (Pa. Super. Ct. 1965) (buyer of 36,440 pounds of defective cable accepted cable when it failed to give written notice of rejection and never offered or attempted to return cable from warehouse). Accordingly, regardless of whether those controllers that passed the initial inspection test were non-conforming at the time of delivery, Hill-Rom "accepted" those controllers within the meaning of section 2-606 of the Pennsylvania UCC. Mextel is therefore entitled to summary judgment on its breach of contract claim for those controllers that Hill-Rom received and accepted, but for which Hill-Rom never paid.

(ii) Damages

Under the Pennsylvania UCC, "the buyer must pay at the contract rate for any goods accepted." See 13 Pa. Cons. Stat. Ann. § 2-607(a). However, several genuine issues of material fact exist as to the amount of damages.

Mextel has not provided the original purchase orders or supplemental documentation indicating how many controllers Hill-Rom ordered and accepted. Instead, Mextel provides accounting information in the form of "ageing detail reports" of accounts receivable, which identify the date of the invoice and the amount owed for the invoice. (See Ageing Detail Reports,

[9] Hill-Rom's arguments to the contrary are not persuasive. Hill-Rom argues that Mextel's controllers were not manufactured in accordance with GMPs, that Hill-Rom returned controllers because they did not pass initial inspections, and that the FDA "suggested" that Hill-Rom terminate its contract with Mextel in 1999. Hill-Rom claims that these acts, some initiated by Hill-Rom and some initiated by third parties, constitute a sufficient "rejection" of non-conforming controllers. (Def. Mot. For SJ., at 2-4). With respect to controllers received by Hill-Rom, this Court disagrees. Hill-Rom continued to place orders for controllers until December 1999, continued to use those controllers that passed the initial screening test in the C2000 incubator, and never indicated nor expressed in writing an intent to reject allegedly defective controllers that it received from Mextel. See 13 Pa. Cons. Stat. Ann. §2-602.

attached as Ex. 5 and 7 To Pl. Mot. For SJ.). This accounting information does not specify what types of goods were delivered, let alone whether the invoices were for the shipment of controllers. (Id.). Nor does the accounting information identify what goods Hill-Rom accepted, what goods Hill-Rom rejected through the initial screening test, and what products were immediately rejected and then cured, if at all, by Mextel. (Id.; see February 17, 1998 letter from Hill-Rom to Mextel discussing the return of a defective controller, attached as Ex. 40 to Pl. Mot. In Opp'n.). Accordingly, a genuine issue of material fact exists as to the number of controllers that were delivered to Hill-Rom and that were accepted within the meaning of section 2-615 of the Pennsylvania UCC.

By implication, a genuine issue of material fact also exists as to the actual amount owed for those controllers shipped to and accepted by Hill-Rom. Mextel provides invoices, along with the affidavit of Mextel's shipping and invoicing personnel, concluding that the total value of the unpaid invoices from March 12, 1998 until January 12, 2000 is $278,384.95. (See Novella Skulic Aff., at ¶ 4). Hill-Rom, however, has provided an affidavit from Mextel's manager of finance, Doreen Tierney, who states that the Hill-Rom's accounting department only retains a record of $106,664 in outstanding invoices. (See Tierney Aff., attached as Ex. 9 to Def. Br. In Opp'n. to Pl Mot. For SJ.). Accordingly, there is a genuine issue of material fact as to the total value of the unpaid controllers received by Hill-Rom.

iii. Hill-Rom properly terminated the Agreement pursuant to ¶ 18.2, and, therefore, Hill-Rom is entitled to summary judgment on Mextel's breach of contract claim for obligations that were executory at the time of Hill-Rom's termination of the Agreement.

Mextel also claims that it is entitled to summary judgment with respect to two obligations

that were outstanding when Hill-Rom first placed a "production hold" on ordered controllers on December 16, 1999 and then purported to terminate the Agreement on December 28, 1999. (See Pl. Mot. For SJ., at 12-13). First, Mextel asserts that Hill-Rom was required to pay for manufactured, but undelivered, controllers. (Id.). Second, Mextel asserts that Hill-Rom was required to purchase the minimum aggregate number of 8000 controllers over the course of the Agreement.[10] (See Addendum to Agreement, at ¶1). According to this logic, because Hill-Rom wrongfully repudiated its Agreement obligations by placing a production hold on all purchase orders and by impermissibly terminating the Agreement, Mextel is entitled to summary judgment on its contract claim for ordered but unshipped controllers and for unordered controllers. (Id.).[11]

Hill-Rom admits that it continued to place orders for controllers throughout the fall of 1999. (See Drinkwater Aff., attached as Ex. 4 to Def. Mot. For SJ., at ¶ 6). Hill-Rom also admits that it did not purchase the minimum number of controllers contemplated by the Agreement. (See Def. Br. In Opp'n. To Pl. Mot. For SJ., at 10; Tierney Aff., attached as Ex. 9 to Def. Br. In Opp'n., at ¶ 3). However, Hill-Rom rejects Mextel's characterization of the

[10] The February 20, 1997 Addendum to the Agreement states that Hill-Rom shall purchase a minimum of two thousand controllers per year during the term of the Agreement. (See Addendum, attached as Ex. 2 to Pl. Mot. For SJ., at ¶ 2). Mextel contends that Hill-Rom only purchased 5,621 controllers, and that, even if justified in terminating the contract, Hill-Rom was bound to purchase the remaining 2,379 controllers.(See Novela Skulic Declaration, at ¶ 6).

[11] Under the Pennsylvania UCC, an anticipatory repudiation of a performance not yet due permits the aggrieved party to resort to any remedy for the breach and to either suspend her own performance or to identify goods to the contract. 13 Pa. Cons. Stat. Ann. § 2-610. The measure of damages for the buyer's repudiation is the difference between the market price at the time of tender and the unpaid contract price and incidental damages, minus expenses saved in consequence of the breach. Id. § 2-708(a).

December 16, 1999 letter[12] placing a "production hold" on ordered controllers and the December 28, 1999 letter terminating the Agreement as an anticipatory repudiation of the Agreement. Instead, Hill-Rom asserts that Mextel's breach of contract claim with respect both to the unshipped controllers under the suspended purchase orders and to the unordered controllers must fail for any of three reasons: (i) Hill-Rom properly terminated the Agreement prior to the receipt of these products; (ii) Hill-Rom properly cancelled the Agreement pursuant to section 2-612 of the Pennsylvania UCC; and/or (iii) continued performance of the Agreement in December 1999 was impracticable.

The resolution of Mextel's summary judgment motion hinges on the characterization of Hill-Rom's December 1999 correspondence with Mextel either as an anticipatory repudiation of the Agreement or as a proper termination.[13] If no genuine issue of material fact exists that Hill-

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[12] The letter placing a "production hold" on ordered controllers is dated December 1, 1999, but, according to Skulic's First Declaration, was not issued by Hill-Rom until December 16, 1999. (See Skulic First Declaration, at ¶ 10).

[13] To the extent that Mextel's briefs raise this issue, the Court finds that the December 16, 1999 letter, standing alone, was not an "anticipatory repudiation" of Hill-Rom's obligations pursuant to § 2-610. Although the statutory text of the Pennsylvania UCC does not define the phrase "anticipatory repudiation," the commentary indicates that an "anticipatory repudiation" depends on the circumstances of the situation. Id., at comment 2. According to this commentary, an anticipatory repudiation may be evidenced by words or actions, and occurs when a party "reasonably indicates a rejection of the continuing obligation." Id. The rejection itself, however, must be "definite and unequivocal." Anderson on the Commercial Code § 2-610:16 (2004).

The December 16, 1999 letter does not meet this standard. This letter tersely states that, pursuant to an earlier telephone conversation between the parties, "all sensors and controllers are on 'Production Hold' with the exception of spares, which will be handled on an as-needed basis." (See December 16, 1999 Letter, attached as Ex. 6 to Pl. Mot. For SJ.). This letter does not indicate that Hill-Rom was no longer willing to perform under the Agreement, that Hill-Rom was refusing to pay for controllers that had been manufactured, that Hill-Rom was refusing shipment of controllers that had already been produced and manufactured, or that Hill-Rom was not going to continue to purchase controllers from Mextel in the future. In fact, through the reference to an earlier conversation, the December 16, 1999 letter does not clearly indicate that the production hold was a unilateral action taken by Hill-Rom. As such, the December 16, 1999 letter did not

Rom improperly repudiated its performance, then Mextel is entitled to the difference between the market price at the time of tender, on one hand, and the unpaid contract price and incidental damages, on the other hand, minus expenses saved in consequence of the breach. See 13 Pa. Cons. Stat. Ann. §§ 2- 608(a), 2-610. However, if Hill-Rom was correct in terminating the Agreement, or if continued performance under the Agreement was impracticable, then Hill-Rom's executory obligations under the Agreement were discharged, and Mextel is not entitled to summary judgment on its contract claims for the unshipped and unordered controllers. See id. §§ 2105(a)-(b) (effect of both "termination" and "cancellation" of sale of goods means that all executory obligations on both sides are discharged, but any right based on prior breach or performance survives). Furthermore, Hill-Rom may be entitled to summary judgment if Hill-Rom acted properly in terminating the Agreement due to Mextel's material breaches.

a. Hill-Rom terminated the Agreement pursuant to ¶ 18.2 in a procedurally and substantively proper manner, but failed to properly terminate the Agreement pursuant to ¶ 18.1(c).[14]

(i) Moment of Contractual Demise

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manifest a definite and unequivocal refusal to perform an obligation not yet due. See 13 Pa. Cons. Stat. Ann. § 2-610.

Nonetheless, the December 26, 1999 termination letter, when read in conjunction with the December 16, 1999 letter, connotes a clear refusal by Hill-Rom to perform under the Agreement. Consequently, to the extent that the December 26, 1999 letter improperly terminated the Agreement, Hill-Rom repudiated the contract within the meaning of 2-610 of the Pennsylvania UCC.

[14] The Court uses the term "termination" as employed in the Agreement: as covering all instances when a party properly puts an end to a contractual relationship. Nonetheless, the Court recognizes the distinction between "termination," which refers to when "either party puts an end to the contract otherwise than for its breach," and "cancellation," which refers to when "either party puts an end to the contract for breach by the other." See 13 Pa. Cons. Stat. Ann. § 2106(c)-(d). This distinction is important with respect to the remedies that are available the terminating or cancelling party. Id.

Before this Court determines whether Hill-Rom properly ended the contractual arrangement between the parties in December 1999, this Court must first address Mextel's contention that Hill-Rom impermissibly "decided to terminate the Agreement when it began to develop knock-offs of the Mextel controller and sensor module in 1998." (See Pl. Disputed Facts, at ¶ 14). In other words, Mextel argues that Hill-Rom "repudiated" the Agreement prior to December 1999 by surreptitiously violating its representation and warranty of exclusivity in ¶ 15.1(c), indeed, by "negotiating and contracting with third parties to copy plaintiffs' intellectual property and supply the component parts developed and manufactured by Mextel" (Pl. Undisputed Facts, at ¶7). As such, Mextel argues that this earlier breach, albeit unknown to Mextel at the time, discharged Mextel's obligations to perform under the Agreement. See 13 Pa. Cons. Stat. Ann. § 2-610(a) (anticipatory repudiation constitutes breach of contract and entitles seller to suspend performance); see also Ott v. Buehler Lumber Co., 541 A.2d 1143, 1145 (Pa. Super. Ct. 1988) ("the general rule is that a party who has materially breached a contract may not complain if the other party refuses to perform his obligations under the contract"); Oak Ridge Construction Co. v. Tolley, 504 A.2d 1343, 148 (Pa. Super. Ct. 1986) ("If a breach constitutes a material failure of performance, then the non-breaching party is discharged from all liability under the contract.").

Hill-Rom admits that it hired a third-party to design and develop a new controller. (Def. Mot. For SJ., at 21-22). However, Hill-Rom asserts that this relationship with a third-party did not violate the Agreement because the third-party never supplied controllers during the life of the contract. (Id.).

In ¶ 15.1(c) of the Agreement, Hill-Rom represented and warrantied that it:

> [i]s not currently a party to any agreement or undertaking, oral or written, that would, in any manner be inconsistent with the rights herein granted to MEXTEL to design, develop, and SUPPLY a PRODUCT and shall not enter into any such agreement or understanding, oral or written, during the term of the Agreement, nor, during the terms of this Agreement, directly or indirectly, engage in any activity that would, in any manner, be inconsistent with the right herein granted to MEXTEL to design, develop, and SUPPLY a PRODUCT, except as specifically authorized herein . . . .

(Id.). The clear language of ¶ 15.1(c) of the Agreement prohibits Hill-Rom from "design[ing], develop[ing], and supply[ing] a product" during the life of the contract. Id. The conjunction "and" precludes a breach of this provision if Hill-Rom only hired a third party to design and develop a replacement controller, without using this third party to supply the product. Id.

Mextel has provided evidence, to which Hill-Rom admits, that by June 1998, Hill-Rom was accepting detailed quotations and proposals from third parties to develop a replacement controller for the C2000 incubator. (See Comtec and Battelle Proposals, attached as Ex. 26-27 to Pl. Br. In Opp'n.). It is also true that Mextel could not have waived its right to discharge its obligations under the Agreement based upon Hill-Rom's alleged repudiation by continuing to perform, as Mextel was not aware of Hill-Rom's solicitation of these quotations and proposals. (See Vedran Skulic's Third Declaration, at ¶ 8); see also Keenan v. Scott Township Auth., 616 A.2d 751, 755 (Pa. Commw. Ct. 1992) (waiver requires "intentionally relinquishing or abandoning some known right, claim or privilege"); 13 Williston on Contracts § 39:22 (4th ed. 2004) (party charged with waiver of contractual breach must possess knowledge or notice of opponent's breach). However, Mextel provides no evidence to indicate that Hill-Rom contracted with a third party to *supply* a replacement controller in June 1998 or, then again, prior to Hill-Rom's attempt to terminate the Agreement in December 1999. As such, no evidence suggests that Hill-Rom breached ¶ 15(c) of the Agreement prior to December 1999. Therefore, Mextel

was not discharged of its obligations under the Agreement by virtue of Hill-Rom's solicitation of proposals for the design and manufacture of a replacement controller in 1998.

(ii) Contractual Termination of the Agreement

Hill-Rom relies upon two different contractual provisions to justify its termination of the Agreement. First, ¶ 18.1(b) gives Hill-Rom the right to terminate the Agreement "at any time after giving sixty (60) days' written notice to Mextel upon the occurrence of" Hill-Rom's failure to meet any of its material obligations under this Agreement. (See Agreement, at ¶ 18.1(b)). Paragraph 18.1(b) also gives Mextel the right to cure any material breach within sixty days after receipt of Hill-Rom's written notice. (Id.).

Second, ¶ 18.2 grants Hill-Rom the right to terminate the Agreement after providing sixty days written notice, if Hill-Rom "in its sole discretion, determine [sic] that the PRODUCTS are obsolete or that the infant incubators or infant radiant warmers into which such PRODUCTS are incorporated are obsolete." (See Agreement, at ¶ 18.2). Unlike ¶ 18.1, the decision to terminate under ¶ 18.2 resides solely within Hill-Rom's discretion, and does not require Hill-Rom to provide Mextel a right to cure the controller's obsolescence.

Mextel challenges the procedural and substantive propriety of Hill Rom's invocation of ¶ 18.1(b) and ¶ 18.2 to terminate the contract.

(a) Procedural Propriety

Under Pennsylvania law, "conditions precedent to a contract termination must be strictly fulfilled." Accu-Weather, Inc. v. Prospect Communications, Inc., 644 A.2d 1251, 1254 (Pa. Super. Ct. 1994); see also 13-68 Corbin on Contracts § 68.9 ("Notice within the designed time period is the condition precedent to the effective exercise of the power reserved. If a party who

has a power of termination by notice fails to give the notice in the form and at the time required by the Agreement, it is ineffective as a termination."). This rule leads to two important corollary rules, both of which are applicable to the resolution of this dispute. First, according to the Pennsylvania Supreme Court, notice to terminate a contract must be "clear and unambiguous," and "where the conduct of one having the right to terminate is ambiguous, he will be deemed not to have terminated the contract." Maloney v. Madrid Motor Corp., 122 A.2d 694, 696 (Pa. 1956); see also 17B C.J.S. Contracts § 446 ("A clear and unambiguous notice, timely given, and in the form prescribed by the contract, is essential to the exercise of an option to terminate the contract."). Second, notice provided after the contractual deadline for providing termination is ineffective to avoid renewal of a contract among sophisticated commercial entities pursuant to an automatic renewal provision. See, e.g., Otis Elevator Co. v. George Washington Hotel Corp., 27 F.3d 903, 909 (3d Cir. 1994) (holding under Pennsylvania law that failure to comply with ninety-day deadline for providing notice of termination prior to automatic renewal of contract renders termination ineffective, even without a showing of prejudice by noticed party).

Nonetheless, in contrast to ambiguous and/or untimely notice, Pennsylvania law relaxes in at least one instance the rule of strict compliance with condition precedents to contractual termination. Consistent with the "universally accepted rule," timely notice that purports to terminate the contract in a shorter amount of time than that stipulated in the termination clause effectively terminates the contract, but only after the expiration of the prescribed time within the termination clause. See, e.g., Shain v. Washington Nat'l Ins. Co., 308 F.2d 611, 614 (8th Cir. 1962) (J. Blackmun) ("it is the general rule that were a contract, whether it be for one for employment or for insurance or of a different kind, requires written notice of cancellation upon a

stated time, a notice failing to meet the time requirement, but otherwise appropriate, is nonetheless effective upon the lapse of the time required by the contract"); Wetherell v. Sentry Reinsurance, 743 F.Supp. 1157, 1176 (E.D. Pa. 1990) (applying Pennsylvania law and finding that notice of termination providing less time than required under reinsurance contract was effective at the conclusion of proper date as between sophisticated insurance companies and brokers); 14 Summ. Pa. Jur. 2d Ins. § 3:58 ("the fact that the notice contains a time limitation which is void because it is less than that required by the policy does not void the notice or make it inoperative; rather, the notice is effective, but is to be read as though it stated the proper date which would be allowed by the policy"). Of course, notice declaring termination in a shorter amount of time than that stipulated in the contract is effective only to the extent that it does not seek to circumvent or nullify other contractual precedents to termination. Accordingly, such notice is ineffective when the contract affords the noticed party the right, during the stipulated notice period, to cure the conditions that would negate the opposing party's right to terminate the contract. See, e.g., Luden's Inc. v. Local Union No. 6 of the Bakery, Confectionary, and Tobacco Workers, 805 F.Supp. 313, 317 (E.D. Pa. 1992), vacated and remanded on other grounds, 28 F.3d 347 (3d Cir. 1994) (general rule that termination notice is not rendered ineffective merely because it states shorter period than that required by Agreement carries exception where "the contract affords the noticed party the right during the stipulated period to bring about a condition which will negate the other party's right to terminate"); see also W.C. Crais III, Annotation, Effect of Attempt to Terminate Employment or Agency Contract Upon Shorter Notice Than That Stipulated in Contract, 96 ALR2d 272 (1964) (exception to general rule in context of terminating agency or employment contract is recognized in the "situation where the contract affords the

noticed party the right, during the stipulated notice period, to perform certain acts or bring into existence certain conditions which will nullify or negate his adversary's right to give effective notice").

(i) ¶ 18.1(b)

Hill-Rom asserts that it properly terminated the Agreement pursuant to ¶ 18.1(b). First, Hill-Rom argues that it satisfied its 60-day advance notice of termination when it sent Mextel the April 27, 1999 letter detailing all of the pending problems with the relationship, and advising Mextel that if they were not remedied, the Agreement could be terminated. (Def. Br. In Opp'n., at 5). Second, even if this did not constitute adequate notice, Hill-Rom contends that the December 26, 1999 termination letter was sufficient under the Agreement. (Id., at 5-8; Statement of Disputed Facts, at ¶ 10). Hill-Rom's arguments fail as a matter of law.

The April 27, 1999 letter failed to establish unequivocal notice of termination. See, e.g., Pomerantz v. Mutual Fire Ins. Co., 124 A. 139, 140 (Pa. 1924) ("If the notice be equivocal or not indicative of a present cancellation, but a mere intention or desire to cancel in the future, a cancellation will not be effected."); 16 Summa. Pa. Jur. 2d Commercial Law § 5:25 ("Notice to terminate a contract must be clear and unambiguous. Where a notice by Hill-Rom to terminate a contract is unclear and ambiguous it is not effective."). The letter listed various problems with Mextel's design and development of the controllers, including a failure to maintain good design controls and quality work standards, and then threatened that if Mextel "continues to conduct business in this manner, we will have to take appropriate action, which could include termination of Mextel as a developer/supplier as provided under the contract." (See April 27, 1999 letter, attached as Ex. 4G To Def. Mot. For SJ.). A threat of possible termination in the future does not

constitute clear and unambiguous notice. See Accu-Weather, 644 A.2d at 1255 (notice stating that termination of contract applies in "ninety-days," but that services may be "continued" on some later date, is unclear and ambiguous). Furthermore, Hill-Rom's continued performance under the Agreement, as evidenced by its placing of orders for Mextel's controllers in fall 1999, is inconsistent with a clear intent to terminate the contract. Id. (no legal notice of termination when party allegedly giving notice continues to perform under Agreement because continued performance gives "mixed and ambiguous" message).

It is equally evident that the December 28, 1999 letter, which purported to terminate the Agreement immediately, failed to comply with the contractually imposed conditions precedent to termination. (See December 28, 1999 Termination Letter, attached as Ex. 17 to Pl. Mot. For SJ.). First, the letter failed to provide sixty days notice of termination, as required by ¶ 18.1(b). (Id.). Second, and most importantly, the letter failed to give Mextel sixty days to cure the alleged breaches of the Agreement and to thereby maintain the parties' contractual relationship, as required by ¶ 18.1. (Id.). Instead, the letter sought to preempt this right to cure by immediately terminating the Agreement, a maneuver that was not permitted by the termination procedures of the Agreement. Accordingly, because Hill-Rom did not follow the conditions precedent to termination, thereby depriving Mextel of its right to nullify Hill-Rom's justifications for termination, the notice based upon ¶ 18.1(b) was ineffective. See, e.g., Luden's Inc., 805 F.Supp. at 323 n.15. Therefore, Hill-Rom was not excused from complying with the terms of the Agreement based upon its ¶ 18.1(b) notice of termination.

(ii) ¶ 18.2

Hill-Rom also claims that the December 28, 1999 letter properly terminated the

Agreement under ¶ 18.2 of the Agreement because the controller was "obsolete." (See Def. Br. In Opp'n., at 8). Although ¶ 18.2 required sixty days notice prior to termination, it did not provide Mextel the right to cure the controller's "obsolescence" within a designated time. (Id.).

Hill-Rom's purported termination under ¶ 18.2 was procedurally effective, but only after the expiration of sixty days from the mailing of the termination letter. See, e.g., Wetherell, 743 F.Supp. at 1176. Because Mextel did not have the contractual right to cure the reasons for Hill-Rom's determination of the controller's obsolescence, the only condition precedent with which Hill-Rom failed to comply was the provision of the contractually prescribed amount of sixty days notice. Unlike ¶ 18.1, therefore, the procedural appropriateness of Hill-Rom's purported termination under ¶ 18.2 of the Agreement is covered by the general rule that timely notice of termination allowing a period of time shorter than that stipulated in the contract is effective after the lapse of the stipulated time period. See, e.g., In re Best Film & Video Corp., 46 B.R. 861, 873 (E.D.N.Y. 1985). Accordingly, so long as Hill-Rom was justified in concluding that the controller was obsolete, the Agreement expired sixty days after mailing the December 28, 1999 notice of termination to Mextel.

(b) Substantive Propriety

The Court has concluded that the notice of termination pursuant to ¶ 18.1 was procedurally ineffective. However, because the notice of termination pursuant to ¶ 18.2 was procedurally appropriate, the Court now considers whether Hill-Rom was substantively justified as a matter of law in terminating the contract pursuant to ¶ 18.2. Importantly, however, the Agreement does not define the term obsolete, and, in fact, leaves the determination of the controller's obsolescence to the "sole discretion" of Hill-Rom. (See Agreement, at ¶ 18.2).

Hill-Rom construes "obsolete" in its colloquial sense, as an outmoded or outdated product. In support of its claim, Hill-Rom provides the testimony of Jan Wenstrup, the engineer responsible for the development of the C2000 incubator. (See Wenstrup Aff., attached as Ex. 1 to Def. Br., at ¶ 19). Wenstrup contends that by December 1999, the product was obsolete for several reasons. First, the controller contained an outdated computer processor that was introduced into the marketplace in the mid-1970's and that had limited expansion capabilities. (Id.). Second, the controller failed to comply with the initial product specifications by accommodating an interface function, which would have allowed the controller to interface with other devices in addition to the C2000 incubator. (Id.). Third, the controller was unable to accommodate a monitoring feature that would have allowed constant monitoring of a baby's vital signs while in the C2000 incubator. (Id.).

Mextel provides no direct testimony or other evidence to dispute Wenstrup's conclusion regarding the obsolescence of the controller. Instead, Mextel challenges the definition of "obsolete," contending that the parties' course of dealing establishes that the term "obsolete" means a product that is not marketable. (See Pl. Statement of Undisputed Facts, at ¶ 37). Using this definition, Mextel argues that the product could not have been obsolete because "between November of 1996 and December of 1999, Mextel manufactured and shipped to Air-Shields over 5000 controllers covered by the Agreement." (Id.). Mextel further argues that during this period, Hill-Rom repeatedly manifested a belief that the controllers were not obsolete. (Id.).

This Court must ascertain the mutual intent of the parties by examining the language of the Agreement. See, e.g., Duquesne Light Co. v. Westinghouse Elec. Corp., 66 F.3d 604, 613 (3d Cir. 1995) (applying Pennsylvania law). In ascertaining the mutual intent of the parties, the

Court must construe terms according to their ordinary usage and meaning. Id.; Raymark Industries Inc., v. Butera, Beausang, Cohen & Brennan, 1997 WL 746125, at *7 (E.D. Pa. Dec. 1, 1997) (applying Pennsylvania law). The term "obsolete," as defined in Webster's Collegiate Dictionary, means "no longer in use or no longer useful." (See Webster's Collegiate Dictionary, at 816 (1990)). This definition is echoed by Black's Law Dictionary, which defines "obsolete" as "no longer in general use; out-of-date." (See Black's Law Dictionary, at 1105 (7th ed. 1999). Furthermore, Webster's Third International Dictionary notes that the term "obsolete" may apply to any product that is out-of-date, regardless of whether that product is in use or not. (See Webster's New Third International Dictionary, at 1558 (1993)). Accordingly, in this context, the Court adopts both the legal and colloquial definition of "obsolete" as a product that is "out-of-date," even if that product is currently in use in some capacity. To be "obsolete" therefore, the controller need not have been unmarketable, although the controller's lack of marketability, its inability to be commercially distributed, would certainly establish its obsolescence.

Mextel provides no evidence to rebut Hill-Rom's testimony that the product was, in an objective sense, out-of-date by December 1999. Nor has Mextel provided any evidence to establish that Hill-Rom's decision to terminate the contract pursuant to ¶18.2 was made in bad faith, as a mere pretext for financial or other motivations unrelated to the product's technological outdatedness. Based upon the testimony of Wenstrup, and upon the Mextel's failure to provide evidence to the contrary, no jury could conclude that Hill-Rom's categorization of the product as obsolete in December 1999 was unreasonable. Indeed, although Hill-Rom continued to place orders for the controllers up to December 1999, the controllers lacked significant technological features required both by the original product specifications, such as the RS-232 interface and the

SPO2 monitoring system, and by technological advancements in the marketplace, such as a more advanced computer processor, thereby rendering the controller "out-of-date." (See Wenstrup Aff., at ¶ 19).

Furthermore, assuming *arguendo* that this Court accepts the strict definition of "obsolete" proffered by Mextel, as the state of being unmarketable, Hill-Rom was still justified in terminating the contract pursuant to ¶ 18.2 because no jury could conclude that Hill-Rom's belief in the unmarketability of the controller in December 1999 was unreasonable. Hill-Rom presents evidence that the controller presented numerous quality issues that hindered its marketability. For instance, Mextel's controller suffered from a failure rate of 21.8% for 1997 and 1998, as compared to a 6% failure rate for the replacement controllers for the time period April 30, 2001 through April 23, 2002. (See Ferrante Aff., attached as Ex. 6 to Def. Rsp. To Pl. Mot. For SJ., at ¶ 5). Based upon an analysis of warranty data, Mextel's controller also suffered from a field replacement rate of 15% between the period November 1996 and October 1999, as compared to a field replacement rate of 3% or lower for the replacement controller. (Id., at ¶¶ 6-7). Moreover, according to Wenstrup's testimony, "the rejection rate for incoming controllers from Mextel was . . . at an unacceptably high level, as were warranty claims related to the Mextel controller." (See Wenstrup Aff., attached as Ex. 1 to Def. Br., at ¶ 8). Richard Drinkwater, the buyer responsible for purchasing products and services from Mextel, also provides affidavit testimony that Mextel's "products were returned at an abnormally high, and ultimately, unacceptable level." (See Drinkwater Aff., attached as Ex.4 to Def. Br. In Opp'n., at ¶ 4).

Hill-Rom also provides evidence to justify a reasonable belief that, in addition to lacking the requisite level of quality, the product was *per se* unmarketable in December 1999 because the

continued distribution of C2000 incubators with Mextel's controllers would have subject Hill-Rom to FDA enforcement action. James Utterback, an in-house counsel for Hill-Rom who worked directly with the FDA between January 1998 and December 1999, offers affidavit testimony that Mextel's failure to provide verification, validation, and DMR documentation for the controller precluded Hill-Rom from complying with GMPs. See Utterback Aff., at Ex. 3 to Def. Mot. For SJ., at ¶ 3b-e). This, in turn, resulted in a warning letter from the FDA, a finding that the C2000 incubator was "adulterated," and two recalls of the C2000 incubator. (Id.). Utterback further testifies that the termination of the contract in December 1999 was the direct result of Hill-Rom's inability to comply with submissions required by the FDA in response to the FDA's complaints and warning letters received in 1998 and 1999. (Id.)

James Utterback's testimony is echoed by that of James Wenstrup and Timothy Johnson, Hill-Rom's vice-president of operations until February 2002. According to Wenstrup's testimony, interactions between the FDA and Hill-Rom involved problems with the controller; and specifically, Hill-Rom's inability to provide necessary DMR and verification and validation documentation to satisfy regulatory requirements for medical devices. (Wenstrup Aff., attached as Ex. 1 to Def. Br. In Opp'n., at ¶¶ 4-17). Moreover, according to Johnson's affidavit, Mextel's inability to provide information necessary for Hill-Rom to comply with FDA regulations, coupled with the investigations performed by the FDA in 1998 and 1999, led Hill-Rom "to conclude that there was a very real possibility that the FDA was going to take drastic action against Hill-Rom," such as a seizure of the C2000 inventory or an action to shut down Hill-Rom's Hatboro facility. (See Johnson Aff., at Ex. 3 to Def. Br. In Opp'n., at ¶ 4). Indeed, according to Johnson, "my interactions with the FDA in October and November [1999] led me to

conclude that a predominant concern the FDA had was with the C2000 controller." (Id. at ¶ 5).

Mextel cites the affidavit testimony of Vedran Skulic to rebut Hill-Rom's evidence that the product was unmarketable. Skulic's testimony references the fact that Hill-Rom purchased controllers between November 1996 and December 1999, even after the FDA warning letters and the two recalls. (See First Declaration of Vedran Skulic, at ¶ 35). Mextel also cites a December 10, 1996 letter from Hill-Rom to its employees stating that the C2000 "exceeds all other incubators on the market," and a February 1999 comparative review of three nursing incubators by the Medical Devices Agency favorably reviewing the C2000 incubator. (See Reports, attached as Ex. 23 to Pl. Mot. For SJ.). However, neither Skulic's testimony, nor the documents cited by Mextel, disputes the failure and replacement rate of the controller. Nor does this evidence render unreasonable Hill-Rom's belief that by December 1999, the FDA was preparing to take "drastic action" against Hill-Rom for problems related to the controller. Finally, Mextel fails to dispute the reasonableness of Hill Rom's belief that by December 1999, due to the lack of verification and validation and of DMR documentation, it was no longer safe to sell the controller on the market to consumers.

Based upon the available record, this Court holds as a matter of law that Hill-Rom was justified in providing notice to terminate the contract in December 2000 based upon ¶ 18.2 of the Agreement. No genuine issue of material fact exists to challenge the reasonableness of Hill-Rom's belief that the controller was "obsolete," both in the sense of being unmarketable and in the sense of being technologically outdated. Furthermore, regardless of whether Mextel was required to follow GMPs in the design and manufacture of the controller, and regardless of whether Mextel breached these practices, Hill-Rom's inability to provide the FDA with

necessary validation, verification, and DMR information rendered the controller unusable and unmarketable.

This Court further concludes that because Hill-Rom did not provide sixty days notice of the obsolescence of the controller, the termination of the contract did not become effective until Saturday, February 26, 2000, sixty days after the mailing of the December 28, 1999 letter. (See Agreement, at ¶ 24). Hill-Rom was required to perform its obligations under the contract until that date. However, the effective termination of the Agreement on February 26, 2000 discharged Hill-Rom's executory obligations, which included the purchase both of manufactured, but unshipped controllers and of the remaining controllers necessary to reach the minimum amount of 8000 controllers under the Agreement.

b. Cancellation of the Agreement[15]

Hill-Rom also contends that it properly cancelled the Agreement in December 1999 pursuant to the statutory authority of the Pennsylvania UCC. In support of its position, Hill-Rom characterizes the Agreement as an "installment contract," which the UCC defines as "one which requires or authorizes the delivery of goods in separate lots to be separately accepted . . ." 13 Pa. Cons. Stat. Ann. § 2-612(a). In turn, because the Agreement was an installment contract, the failure of past installments of controllers to substantially conform to commercial expectations and contractual specifications constituted a breach of the contract as a whole. Id. § 1-612(c)

[15] Mextel does not assert that ¶ 18.1(b) of the Agreement modified this statutory remedy by prescribing specific procedures for ending the Agreement upon the occurrence of material breaches, which is the definition of "cancellation" under the Pennsylvania UCC. See 13 Pa. Cons. Stat. Ann. § 2-106(d) (definition of "cancellation"). Because Mextel failed to raise this argument, and because the Court finds that Mextel was not entitled to cancel the Agreement in December 1999 pursuant to § 2-711(a) of the Pennsylvania UCC, the Court does not address this argument.

("Whenever nonconformity or default with respect to one or more installments substantially impairs the value of the whole contract there is a breach of the whole."). As the buyer, Hill-Rom was therefore entitled to cancel the contract and all unexecuted performances. Id. § 2-711(a) ("Where the seller fails to make delivery or repudiates or the buyer rightfully rejects or justifiably revokes acceptance then with respect to any goods involved, and with respect to the whole if the breach goes to the whole, the buyer may cancel . . . .").[16]

Hill-Rom's argument fails as a matter of law. Regardless of whether the earlier deliveries of controllers were non-conforming and regardless of whether they impaired the value of the Agreement as a whole, thereby giving Hill-Rom the right to treat the earlier nonconforming deliveries as complete breach, Hill-Rom's post-delivery conduct consistently reinstated the terms of the Agreement up to December 1999. See 13 Pa. Cons. Stat. Ann. § 2-612(c) (aggrieved party reinstates contract by accepting nonconforming installation without seasonably notifying of cancellation or demands performance as to future installments). For instance, there is no dispute that Hill-Rom accepted controllers in previous installments without notifying Mextel of its intent to cancel the Agreement. Furthermore, even after receipt of the allegedly non-conforming deliveries, Hill-Rom continued to demand shipments of additional controllers up until the point of cancellation in December 1999. See, e.g., Traynor v. Walters, 342 F.Supp. 455, 461 (M.D. Pa. 1972) (holding that buyer reinstated contract under Pennsylvania UCC by demanding delivery in future installments of yet undelivered trees, despite allegedly non-conforming aspects of first two deliveries of trees). By placing new purchase orders, Hill-Rom reaffirmed the contract and could

[16] This argument, if successful, insulates Hill-Rom from liability for damages for any breaches between December 1999 and the date of the termination of the Agreement, on February 26, 2000.

only have rejected the yet undelivered installments after delivery, rather than through a premature cancellation. See 13 Pa. Cons. Stat. Ann. § 2-612 comment 6 (although defects in prior installments are cumulative in effect, "if only the seller's security in regard to future installments is impaired, he has the right to demand adequate assurances of proper future performance but had not an immediate right to cancel the entire contract"). Accordingly, this Court holds that Hill-Rom was not entitled to cancel the Agreement pursuant to § 2-711 of the UCC.

c. Impracticability/Frustration of Purpose[17]

Hill-Rom also argues that it was not required to purchase unshipped controllers or to purchase the minimum number of controllers because the performance of these obligations was impracticable by December 1999. (See Def. Br. In Opp'n., at 9; Def. Mot. For SJ., at 16-17).

The Pennsylvania UCC provides a defense when performance "becomes commercially impracticable because of unforeseen supervening circumstances not within the contemplation of the parties at the time of contracting." See Comment 1 to 13 Pa. Cons. Stat. Ann. § 2-615. Section 2-615 excuses a seller from delay in delivery or non-delivery if "performance as agreed has been made impracticable by the occurrence of a contingency the non-occurrence of which was a basic assumption on which the contract was made or by compliance in good faith with any applicable foreign or domestic governmental regulation or order whether or not it later proves to be invalid." See 13 Pa. Cons. Stat. Ann. § 2-615. To invoke this defense, the seller "must notify the buyer seasonably that there will be delay or nondelivery." Id. § 2-615(c).

Although the defense of impracticability within the Pennsylvania UCC does not apply by its literal terms to buyers, Comment 9 to the provision indicates that the rationale for the

[17] Again, this argument, if successful, would insulate Hill-Rom for damages for any breaches between December 1999 and February 26, 2000.

exemption may apply to the buyer in certain instances. See Comment 9. One particular instance is "where the buyer's contract is in reasonable commercial understanding conditioned on a definite and specific venture or assumption, as, for instance, a war procurement subcontract known to be based on a prime contract which is subject to termination, or a supply contract for a particular construction venue." Id. Accordingly, this Court concludes that the defense of impracticability is available to buyers under the Pennsylvania UCC in the limited instances articulated in Comment 9.

The defense of impracticability is unavailable to Hill-Rom in this instance. Hill-Rom argues that Mextel's failure to design and manufacture the controller in accordance with FDA regulations made the continued purchase of controllers impracticable, as Hill-Rom would not have been able to resell the controllers in accordance with FDA regulations. (Def. Mot. For SJ., at 15-16). However, the alleged failure to design and manufacture the controller in accordance with FDA regulations was not an "unforeseeable supervening circumstance." See Pa. Cons. Stat. Ann. § 2-615, Comment 1; see also Restatement (Second) of Contracts § 264 (impracticability applies when supervening government action prohibits performance). Instead, Mextel's alleged failure to meet design specifications was foreseeable, a breach of the provisions the parties negotiated. Indeed, as evidenced by the termination procedures in ¶ 18 and ¶ 19 of the Agreement, the parties contemplated this type of material breach at the time of the formation of the contract, and expressly allocated the risk for such an occurrence by creating procedures to exit the Agreement in the event of such a breach. See Anderson on the Uniform Commercial Code § 2-615:42 ("In order to excuse performance, the contingency must be unforeseen and unusual, and mist be distinct from the risks and hazards of a foreseeable character).

Nor does Hill-Rom provide evidence of a supervening FDA action that prohibited the sale of the C2000 incubators with the Mextel controller. The record indicates that the FDA might have been contemplating action against Hill-Rom, but that no enforcement action was taken with respect to the C2000 incubators, and, more specifically, with respect to the controller manufactured by Mextel. Furthermore, although Hill-Rom alleges that it was unable to comply with government regulations, both parties were aware of the existence of FDA regulations at the time of contract formation and incorporated these regulations into the Agreement. Accordingly, Hill-Rom may not invoke section 2-615 of the Pennsylvania UCC to excuse Hill-Rom's obligations under the Agreement. See, e.g., Rohm & Hass Co. v. Crompton Corp., 2002 WL 1023435, at *7 (Pa. C. P. April 29, 2002) (seller's compliance with pre-existing consent decree that substantially increased costs in requirements contract does not make performance impracticable because compliance was foreseeable and not supervening).

3. Hill-Rom's Motion for Summary Judgment

Hill-Rom moves for summary judgment on the remaining counts in plaintiffs' amended complaint, and on Hill-Rom's counterclaims for breach of contract.

A. Breach of Contract Counterclaim

This Court has found that Hill-Rom breached the Agreement by failing to pay Mextel for delivered and accepted controllers and that Mextel reaffirmed the Agreement by continuing to deliver installments of controllers to Hill-Rom, despite lack of payment. This Court has also found that Hill-Rom's failure to follow the appropriate procedures rendered Hill-Rom's attempt to terminate the Agreement based upon ¶ 18.1(b) is ineffective, without deciding whether Hill-Rom was substantively justified in invoking ¶ 18.1(b). Nonetheless, as the Agreement did not

terminate until February 26, 2000, Hill-Rom may still recover damages for preceding breaches of the Agreement by Mextel. See 13 Pa. Cons. Stat. Ann. § 2-608(a) (when buyer accepts goods and gives notification pursuant to § 2-607(c), buyer may recover damages for any non-conformity of tender the loss resulting in the ordinary course of events from the seller's breach); see also Times Mirror Magazine, 103 F.Supp. 2d 711, 736 (S.D.N.Y. 2000) ("A non-breaching party who elects to continue to perform a contract may still sue later and recover damages solely for the *breach* of the Agreement, provided that it gives notice of the breach to the breaching party."); Restatement (Second) of Contracts § 246 comment b (party who tenders defective, but excused performance still liable "for damages for partial breach because of his defective performance").

Although Hill-Rom's counterclaim includes a laundry list of 24 alleged breaches, the Court will only address those breaches discussed in Hill-Rom's various briefs. (See Counterclaim, at ¶ 39(a)-(x)). First, Hill-Rom claims that Mextel breached ¶ 6.1 and ¶ 8.2 of the Agreement by failing to comply with GMPs, such as by failing to provide Hill-Rom with DMR documentation, to perform verification and validation and to provide Hill-Rom with verification and validation documentation, and to maintain for the life of the controller all manufacturing records. (See Def. Undisputed Facts, at ¶¶ 2-19). Second, Hill-Rom contends that Mextel breached ¶ 9.4 by failing to correct negative audit findings. (Id., at ¶¶ 20-24). Third, Hill-Rom argues that Mextel breached ¶ 2.1(b) by failing to provide Hill-Rom with information needed to obtain FDA marking clearance for the C2000. (Id., at ¶ 3).

1. Good Manufacturing Practices

Hill-Rom contends that Mextel breached ¶ 6.1 of the Agreement by failing to manufacture the controller in accordance with GMPs. (See Def. Mot. For SJ., at 2-7, 15-17).

Mextel, however, contends that it was not subject to GMPs as a matter of contract interpretation. Mextel contends that ¶ 6.1(b) did not require Mextel to comply with GMPs because these regulations expressly exempt "manufacturers of components or parts of finished devices." (Pl. Mot. For SJ., at 18). Instead, ¶ 6.1(b) merely indicates that "Mextel would comply with whatever obligations would be imposed on Mextel by the FDA Act." (Id.). Mextel contends that this interpretation is confirmed by Exhibit E to the Agreement, which states that Mextel "is not a medical device manufacturer and is not subject to FDA regulations." (Id.; see also Ex. E to Agreement, attached as Ex. 1 to Gugnani Declaration). Mextel further argues that ¶ 6.1(b) is prophylactic, "having been apparently copied from some other agreement." (Id., at 18).

This Court finds as a matter of law that Mextel contractually agreed to manufacture the controller in accordance with GMPs. (See Agreement, at ¶ 6.1(b)). The unambiguous language of ¶ 6.1(b) of the Agreement clearly imposes such a contractual obligation:

> The PRODUCTS manufactured by MEXTEL and sold to AIR-SHIELDS under this AGREEMENT shall be . . . (b) manufactured in accordance with good manufacturing practices under the ACT.

The obligation is presented in clear, mandatory terms, requiring Mextel to comply with all GMPs during the manufacture of controllers for the term of the contract. See, e.g., PBS Coals, Inc. v. Barnham Coal Co., 558 A.2d 562, 564 (Pa. Super. Ct. 1989) ("In determining the intent of parties to a written agreement, the court looks to what they have clearly expressed, for the law does not assume that the language of the contract was chosen carelessly."). It does not contain conditional or suppositional language, nor does it limit Mextel's private obligation to comply with GMPs to a hypothetical future date. Moreover, although Mextel is correct in pointing out that, as a "manufacturer of components or parts of finished devices," it was exempt from

compliance with GMPs pursuant to 21 C.F.R. § 820.1(a), this regulatory provision also states that "such manufacturers are encouraged to use appropriate provisions of this regulation as guidance." Id. The Agreement merely transforms this recommendation into a mandatory obligation in the private setting.

Mextel's reliance on Exhibit E and the statement that Mextel is "not a medical device manufacturer and is not subject to FDA regulations" as nullifying ¶ 6.1(b) is misplaced. Exhibit E only confirms that the contractual arrangement between the parties, and Mextel's agreement to comply with GMPs, would not subject Mextel to FDA action for failure to comply with FDA regulations. Exhibit E's declaration does not absolve Mextel of private liability for the contractual assumption of compliance with particular FDA regulations. Moreover, Exhibit E is only relevant with respect to the obligations imposed by ¶ 6.1(a) of the Agreement and other paragraphs in the contract that expressly reference or rely upon Exhibit E, such as the contractual prescription for confirming product conformance in ¶ 9.3. Indeed, to exempt Mextel from compliance with GMPs based upon the existence of Exhibit E would render the language of ¶ 6.1(b) mere surplusage, and the obligations imposed meaningless. See, e.g., Tenos v. State Farm Ins. Co., 716 A.2d 626, 631 (Pa. Super. Ct. 1998) (Pennsylvania contract law "does not permit words in a contract to be treated as surplusage."). Such an outcome would violate traditional principles of contract interpretation. See, e.g., Meeting House Lane, Ltd. v. Melso, 628 A.2d 854, 857-58 (Pa. Super. Ct. 1993) ("One part of a contract cannot be interpreted so as to annul another part, and a contract must be construed, if possible, to give effect to all of its terms.").

Because the language of the Agreement is clear and unambiguous, the Court need not

resort to extrinsic evidence to interpret ¶ 6.1(b).[18] See, e.g., Sabad v. Fessenden, 825 A.2d 682, 688 (Pa. Super. Ct. 2003) (unambiguous contract interpreted according to language selected by parties, while extrinsic evidence only appropriate to interpret ambiguous contractual terms). Consequently, the Court finds that Exhibit E only modifies ¶ 6.1(a), and not ¶ 6.1(b), and that, pursuant to the Agreement, Mextel was required to comply with GMPs during the manufacture of controllers.

a. DMR Documentation

Hill-Rom contends that Mextel breached ¶ 6.1(b) and ¶ 8.2 by refusing to generate and maintain DMR documentation, including device specifications, production process specifications, quality assurance procedures, and packing and labeling, and by refusing to provide Hill-Rom with DMR documentation on a quarterly basis. (Def. Br. In Opp'n., at 11-17; Def. Mot. For SJ., at 15-17). This Court agrees.

From 1996 until April 1999, Hill-Rom sent numerous letters to Mextel demanding DMR documentation, including an April 27, 1999 letter revealing Mextel's continued failure to generate and to provide DMR documentation for the controller. James Utterback, Hill-Rom's in-house counsel from September 1997 until September 2002, Jan Wenstrup, the engineer responsible for development of the C2000 incubator, Doug Spencer, the Vice-President and

[18] Nonetheless, the Court notes that the use of extrinsic evidence to interpret ¶ 6.1(b) of the Agreement confirms the Court's interpretation. According to David Ascher, Hill Rom's attorney who negotiated the Agreement with Mextel, the intent of ¶ 6.1 was to ensure that Mextel would manufacture the controller so that Hill-Rom could satisfy its regulatory obligations. (See Ascher Affidavit, attached as Ex. 13 To Def. Mot. For SJ., at ¶ 6). Although this conflicts with Skulic's understanding of the Agreement, any other interpretation would violate principles of common sense. After all, unless Mextel contractually assumed responsibility for complying with the QS regulation, Hill-Rom, as a regulated party, would have been unable to meet its obligations under the FDCA, thereby subjecting itself to perpetual enforcement action by the FDA and dooming the success of the C2000 incubator from the outset.

General Manager of Hill-Rom's Maternal and Infant Care Business Unit until June 22, 1999, and Timothy Johnson, the General Manager at the Hatboro manufacturing facility after 1999, all testify that Mextel never produced, made available, or supplied the information necessary to compile an appropriate DMR for the controller. (See Affidavits, attached as Ex. 1-4 to Def. Br. In Opp'n. and Ex. 3 to Def. Mot. For SJ.). Furthermore, FDA documentation, including the June 1998 Warning Letter, the March 1998 483 Letter, the February 1999 483 Letter, and the various inspection reports, confirmed that DMR documentation was lacking with respect to the controller. Finally, an independent audit conducted in April 1999 documented Mextel's lack of compliance with the QS regulations, including a finding of little or no documentation for design control, inspection and testing, and quality records. (See April 1999 Supplier Survey Results, attached as Exhibit 3C at Def. Mot. For SJ.).

Despite admitting that Skulic had no prior experience in designing or manufacturing components for medical devices regulated by the FDA, Mextel nonetheless contends that it maintained DMR documentation and provided copies of all manufacturing records for the life of the controllers. (See Gugnani Declaration, at ¶ 14; see Pl. Statement of Disputed Facts, at ¶ 9). To support this contention, Mextel relies upon: (i) Skulic's affidavit testimony; (ii) a November 5, 1996 certification statement, signed by representatives from Mextel and Hill-Rom, indicating that "complete device mast record documentation per 21 CFR § 820.181 has been developed of the models C2C-1 and C2C-1E Air-Shields Infant Incubator Controllers" and that DMR documentation "in its current form is adequate to provide functional and configuration traceability and to control production processes"; and (iii) a selection of certificates of conformance accompanying the shipment of various orders of controllers. (See Pl. Statement of

Disputed Facts, at ¶ 9; First Vedran Skulic Declaration, at ¶ 23).

Mextel's proffered evidence fails to raise a genuine issue of material fact. First, Mextel is correct in noting that the November 5, 1996 certification statement averred that DMR documentation in its current form, however "untidy and informal," is "adequate" to "provide functional and configuration traceability and to control production processes." (See November 5, 1996 Certification Statement, attached as Ex. 3A to Def. Mot. For SJ.). However, the November 5, 1996 certification statement does not make clear that Mextel possessed formal DMR documentation in compliance with GMPs. Nor does the certification statement indicate that Hill-Rom had access to, evaluated, or approved this form of DMR documentation. In fact, the certification statement suggests the opposite, codifying Mextel's obligation to provide formal DMR documentation to Hill-Rom by December 31, 1996. (Id.). Based upon subsequent correspondence, including the February 21, 1997, September 3, 1997, June 30, 1998, and April 27, 1999 letters from Hill-Rom to Mextel demanding DMR documentation, as well as the internal FDA documents and the testimony of Hill-Rom's quality assurance personnel, it is clear that Mextel never provided formal DMR documentation to Hill-Rom on December 31, 1996 or throughout the relationship.

Second, rather than supporting Mextel's position, Skulic's affidavit suggests ambiguity with respect to Mextel's compliance with GMPs. Skulic indicates that Mextel "comported its facilities and Product records as if it were subject to the FDA *to the extent possible* . . . ." (See First Declaration of Vedran Skulic, at ¶ 23) (emphasis added). Skulic also testifies that although Mextel was not subject to FDA regulations, Mextel "did internally comply with all such *substantive* good manufacturing processes." (Id., at ¶ 20) (emphasis added). Furthermore, Skulic

suggests lacking the resources and expertise to write the DMR, conceding that "my obligation was to assist in that endeavor, not to write the document." (Id., at ¶ 6). Finally, although Skulic suggests that Mextel "maintained all manufacturing records for the life of the controllers by serial number," Hill-Rom only provides two certificates of conformance as evidence of the existence of DMR documentation. (Id., at ¶ 23).

The certificates of conformance are signed by Mextel's representative, and certify that the controllers were produced "in accordance with the specifications" in Hill-Rom's purchase order and with the "Approved Design Specifications." (See Certificates of Conformance, attached as Ex. 22 to Pl. Mot. For SJ.; see also First Declaration of Skulic, at ¶ 23). The Certificates of Conformance also provide lot serial numbers, purchase order numbers, and customer part number and description. (Id.). The Certificates of Conformance were mandated by ¶ 9.3 of the Agreement, and confirm that the products confirm to quality assurance procedures and specifications identified in Exhibits E and F to the Agreement.

The certificates of conformance do not constitute DMR documentation within the meaning of the FDA regulations. Indeed, they do not contain: (i) device specifications, including appropriate drawings, composition, formulation, and component specifications; (ii) production process specifications, including the appropriate equipment specifications, production methods, production procedures, and production environment specifications; (iii) quality assurance procedures and specifications, including quality assurance checks used and the quality assurance apparatus used; and (iv) packaging and labeling specifications, including methods and processes. See 21 CFR § 820.181 (1995). In fact, the certificates of conformance do not even indicate that the products were produced in accordance with GMPs.

Based upon Hill-Rom's overwhelming evidence concerning Mextel's failure to provide DMR documentation, and based upon Mextel's inability to challenge this evidence, this Court concludes that Mextel breached ¶ 6.1(b) and ¶ 8.2 of the Agreement by failing to create, maintain, and provide Hill-Rom with DMR documentation. Hill-Rom is therefore entitled to summary judgment on counterclaims 39(h) and 39(j) with respect to DMR documentation.

b. Verification and Validation

Hill-Rom next argues that Mextel breached ¶ 6.1(b) and ¶ 8.2 by failing to generate and to provide verification and validation information for the controller. (See Def. Mot. For SJ., at 16-17). Mextel's alleged breach with respect to verification and validation takes two forms: (a) failure to provide access to the controller source code, which was necessary to enable Hill-Rom to conduct verification and validation and to establish the root causes for allegedly high warranty and failure rates for the Mextel controller; and (b) failure to conduct verification and validation for device design, to validate the production process, and to provide verification and validation records to Hill-Rom. (See Def. Statement of Disputed Facts, at ¶ 7; Def. Statement of Undisputed Facts, at ¶¶ 2-4).

i. Source Code

A genuine issue of material fact exists as to whether Mextel provided the controller source code to Hill-Rom. On one hand, Mextel contends that it did provide the source code to a third-party, Cri-Tech, which Hill-Rom hired to develop the verification and validation dossier for the C2000 controller in March 1998. A March 9, 1998 document identified by Mextel states that, despite numerous other failings, Mextel "presented" two components of the controller: the "software source and engineering notes/memos" (See March 9, 1998 CriTech Report, attached as

Ex. 28 to Pl. Br.). Furthermore, Skulic's affidavit states that he personally provided to Cri-Tech "the source code for the electronic controller software." (See Vedran Skulic's Third Declaration, at ¶ 8).

On the other hand, the March 9, 1998 document states that "Mextel still controls the critically needed software source." (See March 9, 1998 CriTech Report, attached as Ex. 28, at E09378). Furthermore, an affidavit from the president of Cri-Tech states that noone associated with CriTech has "received or taken any source code from Mextel, Inc., nor has CriTech given Hill-Rom a computer source code drafted by Mextel, Inc." (See Rajewski Aff., attached as Ex. 23, at ¶¶ 4-5). Accordingly, there is a general issue of material fact as to whether Mextel provided the source code to Hill-Rom, and, therefore, whether Mextel breached ¶ 6.1(b) of the Agreement.

ii. Verification and Validation Records

Verification and validation obligations for medical devices were promulgated pursuant to the QS Regulation on October 7, 1996. See 21 CFR Part 820 (1997). These regulations were made effective on June 1, 1997. Id. These obligations required manufacturers of medical devices to implement "design controls," such as establishing and maintaining procedures for verifying and validating the device design, establishing and maintaining a device history file, and documenting the results of the design verification and validation process. See 21 CFR § 820.30(f)-(j) (1997). These obligations also required manufacturers to implement "production and process controls," including validating the production process to establish by "objective evidence that a process consistently produces a result or product meeting its predetermined specifications." Id. § 820.70. Manufacturers were further required to maintain a Quality System

Record including or referring to the location of records concerning management responsibility. Id. § 820.186

No genuine issue of material fact exists that Mextel breached ¶ 6.1(b) by failing to comply with the verification and validation obligations of the QS regulation, particularly with respect to generating and maintaining appropriate documentation. First, Mextel admits that Hill-Rom continued to place orders for, and that Mextel continued to manufacture, controllers after June 1, 1997. (See First Skulic Declaration, at ¶ 10). Second, the contract mandated that Mextel comply with all GMPs, which, after June 1, 1997, included the QS regulations and its verification and validation requirements. (See Agreement, at ¶ 6.1(b)). Third, a body of evidence confirms that Mextel did not comply with these requirements. Hill-Rom sent letters on June 30, 1998 and April 27, 1999 demanding verification and validation documentation for the manufacture of controllers and reiterating Mextel's failure to implement design controls pursuant to 21 CFR § 820.30. (See June 30, 1998 Letter and April 27, 1999 Letter, attached as Ex. 4D and 4G to Def. Mot. For SJ.). James Utterback, Jan Wenstrup, and Doug Spencer testify that Mextel failed to provide Hill-Rom with verification and validation information for the controller, that Hill-Rom needed to employ, albeit unsuccessfully, a fixture test to validate incoming controllers against design specifications, and that failure to verify and validate the controller's design led to the 1998 and 1999 recall of the C2000 incubator. (See Utterback Aff., at ¶ 3(a)-(d); Wenstrup Aff., at ¶¶ 6-16; Spencer Aff., at ¶ 7). CriTech indicated in its March 9, 1998 Software Verification and Validation Assessment Report and in its November 10, 1999 Proposal that a design history file, as required by § 820.30(j), was lacking for the controller. (See CriTech Report, attached as Ex. 28 and 30 to Pl. Mot. For SJ.). Finally, documentation from the FDA,

including the March 26, 1998 and the February 19, 1999 letters, observed that verification and validation data, including a DHR, was lacking for the controller. (See March 26, 1998 and February 19, 1999 Letters, attached as Ex. 14 to Def. Br.).

Mextel fails to rebut this evidence, and, by relying on the misapprehension that it was not bound by the verification and validation requirements of the GMPs, concedes its failure to comply. For instance, Skulic admits throughout his Third Declaration that Mextel did not believe that it was contractually or legally responsible for generating or supplying verification and validation documentation, and that Mextel never generated or supplied such documentation. (See Third Skulic Declaration, at ¶¶ 7-9). Specifically, Mextel admits that it did not have "information relating to the design of the electronic controller," but that Hill-Rom continued to demand such information. (Id.). Accordingly, Hill-Rom is entitled to summary judgment on counterclaims 39(b), (h) and (j) with respect to Mextel's failure to comply with the verification and validation requirements of the QS regulation and to provide the appropriate verification and validation documentation to Hill-Rom.

2. Quality Audits

Paragraph 9.4 of the Agreement states that Mextel "shall permit an Air-Shields representative to inspect the facility at which Mextel manufactures PRODUCTS to conduct an audit to ensure compliance with quality assurance protocols of Exhibit F . . . ." (See Agreement, at ¶ 9.4). This paragraph further states that "within thirty (30) days of MEXTEL's receipt of AIR-SHIELD's audit report, MEXTEL shall commence and thereafter diligently complete the cure of any deficiencies noted therein." (Id.). Although no quality assurance protocols are listed in Exhibit F, Mextel submits that the parties meant to refer to Exhibit E as the list of the quality

assurance protocols.

A quality audit was conducted in September 1998 based upon Mextel's compliance with the QS regulations. The September 1998 audit resulted in an "overall survey score" of 58.7% and a "conditional" certification level grade by Hill-Rom. (See September 21, 1998 Letter, attached as Ex. 4E to Def. Mot. For SJ.). However, in April 1999, Hill-Rom conducted a second audit to determine compliance with the QS regulations. The second audit demonstrated a decline in a compliance rating from 58.7% to 34%. (See April 1999 Results, attached as Ex. 4F to Def. Mot. For SJ.). The certification level was listed as "unacceptable," with "improvement plans" necessary. (Id.). In turn, Hill-Rom sent Mextel a letter demanding that Mextel cure these deficiencies immediately, particularly with respect to design controls. (See April 27, 1999 Letter, attached as Ex. 4G to Def. Mot. For SJ.). Hill-Rom provides affidavit testimony from James Utterback that Mextel failed to cure any of the deficiencies noted in the reports within 30 days. (See Utterback Aff., at ¶ 3f).

Mextel characterizes these audits as "unreasonable demands for overly-detailed written procedures." (See Pl. Br., at 10). Mextel contends that, pursuant to the language of ¶ 9.4, the quality audit could only be conducted to ensure compliance with the protocols listed in Exhibit E, rather than with the QS regulations, to which Mextel was not subject as a manufacturer of a component product. (See Pl. Disputed Facts, at ¶ 20). Accordingly, because the quality audit performed by Hill-Rom imposed the requirements of the QS regulations, Mextel contends that it did not constitute a "quality audit" within the meaning of the Agreement, and, hence, that Mextel did not breach the contract by failing to remedy the deficiencies in the April 1999 audit report within 30 days. (Pl. Br. In Opp'n., at 10).

The Court agrees that the parties meant to refer to Exhibit E in ¶ 9.4 of the Agreement. The Court also agrees that ¶ 9.4 of the Agreement defined quality audit according to the specifications listed in Exhibit E, so that compliance with those specifications satisfied Mextel's obligations under ¶ 9.4. Nonetheless, because an overlap may exist between a quality audit conducted pursuant to Exhibit E and a quality audit conducted pursuant to the QS regulations, the Court concludes that a genuine issue of material fact exists as to whether Mextel met the requirements of Exhibit E during the April 1999 audit.[19] As such, a genuine issue of material fact exists as to whether Mextel failed to cure deficiencies identified in Exhibit E and referenced in the April 1999 audit report, particularly with respect to "in-process procedures" referenced in Exhibit E. Neither Mextel nor Hill-Rom is therefore entitled to summary judgment with respect to counterclaims based on ¶ 9.4 of the Agreement.[20]

3. Marketing Clearance

Hill-Rom asserts that Mextel breached ¶ 2.1(b) of the Agreement by failing to provide validation for the product design sufficient to obtain FDA marketing clearance. (See Answer, at ¶ 39(b)). Paragraph 2.1(b) of the Agreement states that Mextel shall "provide validation of the PRODUCT design sufficient to enable Air-Shields to obtain FDA marketing clearance for the infant incubators and infant radiant warmer incorporating the PRODUCT." Id. The Agreement does not defined the phrase "marketing clearance."

Mextel claims that a July 30, 1996 letter from the FDA provides the required "marketing

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[19] Vedran Skulic testifies that Mextel always met the "assurance specifications and protocols that were identified in Exhibit E to the Agreement." (Skulic's Third Declaration, at ¶ 15).

[20] Nonetheless, as discussed earlier, the failure to comply with QS regulations in April 1999 demonstrates a failure to comply with GMPs in breach of ¶ 6.1(b) of the Agreement.

clearance." The July 30, 1996 letter states:

> You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act [FDCA], include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

(See July 30, 1996 Letter, attached as Ex. 8 to Pl. Mot. For SJ.). Hill-Rom, however, interprets this letter as imposing a condition precedent to marketing clearance, so that marketing clearance could only occur upon compliance with the general control provisions of the FDCA.

This Court finds as a matter of law that the July 30, 1996 letter satisfies Mextel's obligation in ¶ 2.1(b) to provide validation of the product design sufficient to obtain "marketing clearance." The July 30, 1996 letter further states:

> This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that the FDA approves your device.

(Id.). This letter consequently constitutes an initial "marketing clearance," which satisfied Mextel's obligation under ¶ 2.1(b) of the Agreement. Thus, this Court grants summary judgment for Mextel with respect to counterclaims based on ¶ 2.1(b).

4. Remaining Counterclaims

Both Hill-Rom and Mextel seek summary judgment on Hill-Rom's remaining counterclaims, including counterclaims 39(a), (d)-(g), (j), (n)-(x). Because neither Mextel nor Hill-Rom has squarely addressed the merits of these remaining counterclaims, this Court denies each party's respective motion for summary judgment on these counterclaims.

5. Damages

As a result of Mextel's breaches, Hill-Rom seeks the costs associated with recalling Mextels' controller, with developing the replacement controller, with the costs of making FDA submissions, and with a loss of reputation in the marketplace. (See Br. In Opp'n. to Pl. Mot. For SJ., at 19). Hill-Rom claims that these costs flow from Mextel's alleged breaches and from the mitigation doctrine. (Id.). On the other hand, Mextel contends that the terms of the contract limit the remedies available to Hill-Rom and that Mextel is entitled to summary judgment with respect to Hill-Rom's request for each item of damages.

"An unjustified breach of a contract does not subject the breaching party to all remedies under contract law if the contract provides otherwise." John B. Conomos, Inc. v. Sun Co., Inc., 831 A.2d 696, 708 (Pa. Super. Ct. 2003); see 13 Pa. Cons. Stat. Ann. § 2-719 (agreement may limit or alter the measure of damages recoverable, with the underlying purpose that parties should be "left free to shape their remedies to their particular requirements"). Unless otherwise modified by contractual terms, a buyer who accepts non-conforming goods retains the right to sue for breach of contract, but must notify the seller of the breach within a reasonable time after she discovers or should have discovered the breach. Id. § 2-607. Upon doing so, the buyer may recover damages for any nonconformity of tender, including incidental and consequential damages. Id. § 2-714(a)-(b). Incidental and consequential damages are those damages that naturally and proximately flow from the breach or that were foreseeable at the time of contract formation. Id.; see, e.g., Fran B. Bozzo, Inc. v. Electric Weld Div., 435 A.2d 702, 709 (Pa. Super. Ct. 1980) (recoverable loss "must be one which ordinarily follows the breach of the sales contract in the usual course of events or one that reasonable men in the position of the parties would have foreseen as the probable results of that breach.")

a. Costs of FDA Submissions

In ¶ 11.1 of the Agreement, Hill-Rom agreed to "make, at its sole costs and expense, all necessary submissions to the FDA . . . ." (Id.). However, in the same paragraph, Mextel agreed to provide Hill-Rom "with any assistance reasonably requested by Hill-Rom in connection with the generation of any such test data [necessary for filings] as well as the preparation of the FDA and comparable foreign submissions." (Id.).

Hill-Rom claims that because Mextel's breaches led to FDA submissions, including submissions in response to agency inquiries, 483 observations, and warning letters, Mextel may not take advantage of Hill Rom's contractual obligation to pay for such submissions. (See Def. Br. In Opp'n., at 18). Mextel, on the other hand, contends that Mextel had no obligation to pay any costs of any regulatory event pursuant to the allocation of expenses within ¶ 11.1. (See Pl. Mot. For SJ., at 19).

The language of ¶ 11.1 clearly states that Hill-Rom was required to pay for all "necessary" submissions to the FDA. Id. Hill-Rom does not argue that the FDA submissions in response to various inquiries were not "necessary" within the meaning of ¶ 11.1. Nor does the language of ¶ 11.1 give Hill-Rom the discretion to limit this financial obligation to certain factual scenarios. Finally, Hill-Rom fails to cite applicable case law to support its view that ¶ 11.1's contractual allocation of the costs of regulatory submissions is voided by Mextel's breaches of the Agreement, particularly when Hill-Rom continued to reinstate the terms of the Agreement by accepting non-conforming products. Therefore, regardless of whether Mextel's failure to comply with GMPs caused Hill-Rom to make submissions to the FDA, Hill-Rom contractually agreed to assume liability for the costs of all regulatory submissions during the life of the Agreement.

b. Costs of Recalls

Hill-Rom requests summary judgment on the issue of damages for the cost of recalling Mextel's C2000 incubator. (Def. Mot. For SJ., at 19-21). Hill-Rom provides evidence that it initiated an "Urgent Medical Device Notice/Recall" pertaining to problems with the C2000 incubator in May 1998, and then issued a revised recall letter in January 2000. (See FDA Documentation, attached as Ex. 14 to Def. Br. In Opp'n., at FDA 00292-00295). Mextel, on the other hand, asks the Court to dismiss ¶ 40(b) of Hill-Rom's counterclaim on the basis of the allocation of costs in ¶ 10.2. (Pl. Mot. For SJ., at 19-20).

Although the Agreement does not define the term "recall," the Court finds from the language of the Agreement, from the context of the contractual arrangement, and from the objective of the arrangement that the parties intended to adopt the FDA's definition of "recall." See, e.g., Bethlehem Steel Corp. v. MATX, Inc., 703 A.2d 39, 42 (Pa. Super. Ct. 1997) ("intention of parties paramount and the Court will adopt an interpretation which under all circumstances ascribes the most reasonable, probable, and nature conduct of the parties, bearing in mind the objects manifestly to be accomplished") (internal quotations omitted). According to the FDA, most "recalls" of medical devices are voluntarily conducted by the manufacturer in accordance with 21 CFR Part 7. See FDA, *Medical Device Recalls and Corrections and Removals*, available at http://www.fda.gov/cdrh/devadvice/51.html#3 (as of January 25, 2005). This type of voluntary "recall" is defined as a "firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." 21 CFR § 7.3

(West) According to this definition, a "recall does not include a market withdrawal or a stock recovery." Id.

The Agreement contains a provision that applies to recalls of the controller:

> RECALLS: In the event of a recall of any AIR-SHIELDS products that use PRODUCT supplied by MEXTEL hereunder, when it is determined that such an event is caused by PRODUCT malfunction and not by specification or requirement change, MEXTEL shall repair or replace all such PRODUCTS. Whether it is claimed that PRODUCT is causing such an event or not, AIR-SHIELDS will indemnify, defend, and hold MEXTEL, its current directors, officers, employees, and agents harmless from and against any and all claims, liability, product and warranty liability, loss, damages, costs, or expenses.

(See Agreement, at ¶ 10.2).

Paragraph 10.2 of the Agreement allocates contractual risk and identifies that the appropriate remedy in the event of a recall is replacement or repair of the products. Id. In contrast to Hill-Rom's assertions, the "event" described in the Agreement refers to any form of a recall, rather than to a recall based expressly upon a product malfunction. Id. Thus, regardless of whether the controller caused the recall (ie., regardless of whether the recall was for a malfunction or not), Hill-Rom agreed to indemnify Mextel for the costs associated with that recall through ¶ 10.2.

Problematically, however, the remedy available to Hill-Rom pursuant to ¶ 10.2 is expanded by ¶ 21.2 of the Agreement. Rather than the replacement or repair of malfunctioning controllers, Mextel in ¶ 21.2 agreed to indemnify Hill-Rom for the costs of recalls that Hill-Rom incurred as a result of any "hardware failure" within the controller. (See Agreement, at ¶ 21.2). Thus, to the extent that ¶ 21.2 requires indemnification for the costs of recalls associated with hardware failures within the controller, it contradicts ¶ 10.2's obligation of Hill-Rom to indemnify Mextel for any costs incurred in connection with the recall of the controller.

Despite these two seemingly contradictory provisions, one harmonizing principle can be devised: Hill-Rom was required to indemnify, defend, and hold Mextel harmless for all damages or costs associated with the recall of the controller, when the recall was not caused by a hardware failure within the controller. In other words, Mextel is entitled to summary judgment on this issue of damages if the recall was not caused by a hardware failure; on the other hand, Hill-Rom *may* be entitled to summary judgment on the issue of damages if the recalls were caused by a hardware failure. With this interpretative overlay in mind, the Court finds several genuine issues of material fact that preclude granting summary judgment on this issue.

First, the Court finds that a genuine issue of material fact exists as to whether the May 18, 1998 urgent medical device notice was a "recall" within the meaning of ¶ 10.1 of the Agreement and FDA regulations.[21] It is true that a memorandum from the Philadelphia Branch of the FDA refers to the May 18, 1998 notice as a "recall notification." (See October 3, 2001 Memorandum Concerning Recall Termination Recommendation, at FDA 00292-00295). Nonetheless, the parties have failed to provide the Court with an appropriate factual or legal framework, including citations to the appropriate regulatory authority, to determine whether the May 18, 1998 urgent medical device notice and any accompanying action was a voluntarily "recall," as defined by the FDCA and within the meaning of ¶ 10.1 of the Agreement.

Second, a genuine issue of material fact exists as to whether the process by which Hill-Rom replaced controllers in every C2000 incubator in January 2000 was a "recall." While providing affidavit testimony to indicate that Hill-Rom commenced the process to replace C2000

[21] Mextel implicitly challenges the categorization of the May 18, 1998 notice as a "recall," noting that "this FDA 'recall' did not require Air-Shields [Hill-Rom] to reissue or replace its products as is classically understood by this term." (Pl. Mot. For SJ., at ¶ 20).

incubators using the Mextel controller in January 2000, Hill-Rom has failed to provide information relevant to that process, such as the alleged agreement with the FDA to replace such controllers, the procedures by which the event was accomplished, and the results of the process. (See Spencer Aff., at ¶ 8). As such, a genuine issue of material fact exists as to whether the January 2000 event meets the definition of "recall" within the meaning of the FDCA and ¶ 10.1 of the Agreement.

Finally, assuming *arguendo* that the May 18, 2000 urgent medical device notice and the January 2000 event that led to the replacement of controllers in the C2000 incubator were "recalls," the Court finds that a genuine issue of material fact exists as to whether the two recalls were caused by a hardware failure in the controller. Hill-Rom provides evidence that the controller suffered from a failure rate of 21.8% for 1997 and 1998, and from a field replacement rate of 15% between November 1996 and October 1999. (See Ferrante Aff., at ¶ 5-7). Furthermore, an October 3, 2001 Memorandum concerning the termination of the recalls, approved by the director of the Philadelphia Investigations Branch for the FDA, stated that the FDA issued to Hill-Rom a recall recommendation for the C2000 incubator in May 1998 and that the reason for the recall recommendation was the product's potential to cause serious injuries and deaths." (See October 3, 2001 Concerning Recall Termination Recommendation, attached as Ex. 14 to Def. Br. In Opp'n., at FDA 00292-00295). The October 3, 2001 Memorandum further states that "the unresolved problems were with regard to the controller and the humidity module," and particularly with regard to their failure to meet QS/GMP requirements. (Id.).

On the other hand, as Mextel points out, FDA inspection reports and 483 letters throughout 1998 and 1999 listed problems with components of the C2000 incubator independent

of the controller and with deficiencies in Hill-Rom's manufacturing process. (See id.). For instance, the November 30, 1999 inspection report lists specific problems with Hill-Rom's complaint handling procedures, and documents complaint occurrence for the humidity system as well as the controller. (See November 30, 1999 483 Letter, attached as Ex. 14 to Def. Br. In Opp'n., at FDA 00179-181). The March 26, 1998 inspection report, which precipitated the May 1998 notice, lists problems with the C2000's simulator, with Hill-Rom's complaint handling procedures and documentation, with a lack of oversight when problems are detected in the manufacturing of the C2000 incubator, and with Hill-Rom's quality system compliance. (See March 26, 1998 483 Letter, attached as Ex. 14 to Def. Br. In Opp'n., at FDA 00286-291). Furthermore, the requisite link between the malfunction of the incubator and the recalls is undermined by Mextel's contradictory position that the recall was not initiated because the controller failed to work properly, or "malfunctioned," but, instead, because Mextel failed to comply with regulatory requirements to verify that the controller would not malfunction. (See Def. Mot. For SJ., at 20).

Accordingly, because genuine issues of material fact exist as to whether Hill-Rom conducted recalls within the meaning of the FDCA, and, if so, as to whether the recalls were caused by a malfunction or hardware failure with the controller, neither party is entitled to summary judgment on the issue of recall damages.

c. Cost of Developing a Replacement Controller

Plaintiff contends that no basis exists for the recovery of costs incurred to develop and design a replacement controller. (See Pl. Mot. For SJ. For. SJ., at 20). However, the Agreement does not limit Hill-Rom's right to seek the costs of developing a replacement controller in the

event of Mextel's material breach of the Agreement. Furthermore, pursuant to the Pennsylvania UCC, a buyer, such as Hill-Rom, who accepts a non-conforming product, such as a controller that lacks DMR documentation and verification and validation analysis, may seek damages for the non-conformity, as well as incidental damages, which include "any commercially reasonable charges, expenses in connection with effecting cover," and consequential damages, which include damages that were "reasonably foreseeable" at the time of contract formation. See 13 Pa. Cons. Stat. Ann. § 2714; AM/PM Franchise Ass'n v. Atlantic Richfield Co., 584 A.2d 915, 921 (Pa. Super. Ct. 1990) (defining consequential damages).

Nonetheless, a genuine issue of material fact exists as to whether the costs associated with the development of a replacement controller flow from Mextel's breaches of the Agreement, particularly because Hill-Rom started soliciting proposals for a replacement controller in 1998 and has not documented the timing of particular expenses for the replacement controller. (See Comtec and Battelle Proposals, attached as Ex. 26-27 to Pl. Br. In Opp'n.). A genuine issue of material fact also exists as to whether Hill-Rom complied with the provisions of the Pennsylvania UCC permitting a recovery of incidental damages in such a situation. See 13 Pa. Cons. Stat. Ann. § 2-607 (requiring buyer who accepts goods and who seeks to recover for breach to notify seller of breach within reasonable time after she discovers or should have discovered breach). Accordingly, neither Hill-Rom nor Mextel is entitled to summary judgment on ¶ 40(d) of Hill-Rom's counterclaim.

d. Lost Profits From Reputation Damage

The Agreement does not limit Hill-Rom's right to recover consequential damages, including reputation damages. Section 2-715 of the Pennsylvania UCC permits the recovery of

loss of good will, including damage to reputation, and the loss of future profits as a result of that loss of good will. See, e.g., AM/PM Franchise Assoc. v. Atlantic Richfield Co., 584 A.2d 915, 926 (Pa. 1990) (holding that good will damages, including loss of business reputation, is available as consequential damages under sections 2-714 and 2-715 of the Pennsylvania UCC).

Hill-Rom offers only conclusory and speculative statements, without specific evidentiary support, that Hill-Rom's reputation suffered because of the problems with the Mextel controller and the process of replacing all C2000 incubators that contained a Mextel controller in 2000. (See Johnson Aff., at ¶ 8; Wenstrup Aff., at ¶ 3). Genuine issues of material fact therefore exist as to whether Hill-Rom suffered loss of reputation due to the alleged "recalls" of the C2000 incubator, and whether this loss of reputation flowed from Mextel's breaches of ¶ 6.1(b) and ¶ 8.2 of the Agreement. A genuine issue of material fact also exists as to the amount of such damages. See, e.g., Glenn Distributors Corp. v. Carlisle Plastics, Inc., 297 F.3d 294, 305 (3d Cir. 2002) (evidence of lost profits must be demonstrated to a fair degree of probability). Accordingly, neither Hill-Rom nor Mextel is entitled to summary judgment on ¶ 40(c) of Hill-Rom's counterclaim.

B. Counts II and III: Quantum Meruit and Unjust Enrichment

Counts II and III of the Mextel's complaint seek damages on the legal theories of quantum meruit and unjust enrichment. Hill-Rom seeks summary judgment on these claims, asserting that they may not survive because of the existence of the written contract.

Claims for quantum meruit and unjust enrichment presuppose the absence of a valid contract. See, e.g., Hershey Foods Corp v. Ralph Chapek, Inc., 828 F.2d 989, 1000 (3d Cir. 1987) (applying Pennsylvania law); Villoresi v. Femminella, 856 A.2d 78, 84 (Pa. Super. Ct.

2004) ("Where an express contract already exists to define the parameters of the parties' respective duties, the parties may avail themselves of contract remedies and an equitable remedy for unjust enrichment cannot be deemed to exist."). Mextel admits that the written agreement covers the electronic controller. However, Mextel contends that the sensor modules were not covered by the Agreement, and, thus, that Mextel's quantum meruit and unjust enrichment claims should survive with respect to the shipment of sensor modules.

The Agreement permitted Hill-Rom to submit purchase orders for the sale and purchase of "products." (See Agreement, at ¶ 9.1). The Agreement defines "products" as "the electronic controller" for Hill-Rom's infant incubators and infant radiant warmers. (Id., at ¶ 1.17). Thus, Mextel's production and shipment of the sensor modules to Hill-Rom was not expressly covered by the Agreement. Nor has Mextel identified any other contract, written or oral, for the design and supply of sensor modules to Hill-Rom. Hill-Rom is therefore not entitled to summary judgment with respect to Mextel's quantum meruit and unjust enrichment claims regarding the sensor modules.

C. Count IV: Breach of Implied Covenant of Good Faith and Fear Dealing

In its opposition brief, Mextel voluntarily withdraws Count IV of its amended complaint. (See Pl. Br. In Opp'n. to Def. Mot, at 1 n.1). Accordingly, this Court grants Hill-Rom's motion for summary judgment with respect to Mextel's claim for breach of the implied covenant of good faith and fear dealing.

D. Count VI: Misappropriation of Trade Secrets

Count VII of the amended complaint alleges that Hill-Rom misappropriated plaintiffs' source code that formed the software template for the plaintiffs' controller. (Am. Compl., at ¶¶

48-52). In their opposition brief, plaintiffs further allege that Hill-Rom stole the executable code and trade secrets relating to the sensor module. (Pl. Br. In Opp'n. to Def. Mot. For SJ., at 21-24).

A trade secret can be "any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it." Prudential v. Stella, 994 F.Supp. 318, 323 n. 2 (E.D. Pa. 1998). In order to prevail on a claim for misappropriation of trade secrets, plaintiffs must establish: (1) the existence of a trade secret; (2) which was communicated in confidence to Hill-Rom; (3) used by Hill-Rom in breach of that confidence; (4) to the detriment of the plaintiff. See, e.g., Moore v. Kulicke & Soffa Industries, Inc., 318 F.3d 561, 566 (3d Cir. 2003); Pennfield Precision, Inc. v. EF Precision, Inc., 2000 WL 1201381, at *3 (E.D. Pa. Aug. 15, 2000) (outlining elements).

1. Source Code

Hill-Rom implicitly agrees that the executable component of the source code for the controller, that hidden portion of the code encoded by the source code, is a "trade secret." (Def. Mot. For SJ., at 22-23; Def. Reply Br., at 6). However, Hill-Rom claims that there is no evidence to support the remaining elements of plaintiffs' cause of action--that plaintiffs communicated the source code to Hill-Rom and that Hill-Rom used that source code without plaintiffs' permission in its new incubator products. (Id.).

This Court agrees. Hill-Rom presents the testimony of Colin Jackson, the software project engineer for Comtec Systems, Inc. ("Comtec"), the company that contracted with Hill-Rom for the design and development of the replacement controller. (See Jackson Aff., attached as Ex. 8 to Def. Mot. For SJ.). According to Jackson, neither he nor anyone else at Comtec ever

used or had access to plaintiff's source code. (Id., at ¶¶ 3-5). Jackson further testifies that Comtec did not reverse engineer the replacement controller from plaintiffs' executable code and that Comtec never received a copy of plaintiffs' executable code from Hill-Rom. (Id.).

Jackson's testimony is reinforced by the testimony of Michael Mountain, Hill-Rom's in-house software engineer who amended the Comtec source code prior to its inclusion in the new C2000 incubator. (See Mountain Aff., attached as Ex. 9 to Def. Mot. For SJ.). Mountain's affidavit avers that work performed on the replacement controller was "done totally independent of any source code generated by Mextel." (Id., at ¶ 4). Specifically, Mountain testifies that neither he nor anyone working on the replacement controller software used any source code language from the original controller, reverse engineered any source code or executable code from the original controller, or used the source code from the original controller in designing the replacement controller. (Id., at ¶¶ 2-4).

Plaintiffs have failed to present any evidence to rebut this testimony, let alone to articulate a coherent theory as to how Hill-Rom misappropriated the source code.[22] Instead, plaintiffs attempt to establish the existence of a genuine issue of material fact by arguing: (i) that Hill-Rom has not produced the source code for the replacement controller in discovery, despite plaintiffs' production of the source code to Hill-Rom; and (ii) that plaintiffs worked directly with Hill Rom's engineers during the production of the plaintiff's electronic controllers. (Pl. Br. In Opp'n., at 21-23).

[22] Plaintiff seems to have withdrawn from its earlier position that CriTech's representative took plaintiff's source code for the controller on behalf of Hill-Rom. (See Answer to Interrogatory, attached as Ex. 5 to Def. Mot. For SJ., at 4). Nonetheless, Hill-Rom includes an affidavit from CriTech's president, who categorically denies misappropriating the source code. (See Rajewski Aff, attached as Ex. 23 to Def. Mot. For SJ., at ¶¶ 2-5).

Plaintiffs' factual disputes are not material to the elements necessary to establish a cause of action for trade secret misappropriation. See Jersey Central Power & Light Co. v. Lacey Township, 772 F.2d 1103, 1109 (3d Cir. 1985) (summary judgment motion not defeated by existence of factual dispute, but, instead, by existence of factual dispute *material* to resolution of claims). First, regardless of the veracity of plaintiffs' allegations concerning the production of the new source code during discovery, plaintiff has failed to put forth any evidence indicating that Hill-Rom used plaintiffs' source code to create the replacement controller. In fact, plaintiffs' admission that it failed to obtain Hill-Rom's source code for the replacement controller despite nearly two years of discovery is fatal to plaintiffs' cause of action; it reveals that plaintiffs will not be able to present evidence at trial, in the form of comparative analysis, that Hill-Rom used plaintiffs' trade secrets, indeed, that the new source code is identical to, or shares similar characteristics with, plaintiffs' source code. See, e.g., Block v. Blakely, 2004 WL 1902520, at *2 (E.D. Pa. Aug. 24, 2004) (summary judgment appropriate when plaintiff fails to make sufficient showing as to element of claim for trade secret misappropriation). Second, the fact that Hill-Rom's engineers worked with Skulic and Mextel's engineers to develop the controller does not establish that Hill-Rom's engineers had access to the source code, nor that they communicated the source code to a third-party to develop the replacement controller. Based upon the record before the Court, no reasonable juror could conclude that Hill-Rom misappropriated plaintiffs' source code.

2. Sensor Module

Plaintiffs argue in their opposition brief that Hill-Rom misappropriated trade secrets related to the sensor module. (See Pl. Br. In Opp'n. to Def. Mot. For SJ., at 22-23). Hill-Rom

claims that this argument is impermissible at this stage in the litigation because these factual allegations were never articulated in the amended complaint. (See Def. Reply Br., at 6-7). Hill-Rom further asserts that the record is devoid of any support for these allegations. (Id.).

This Court agrees that plaintiffs never asserted that Hill-Rom misappropriated trade secrets related to the sensor module in the amended complaint. See, e.g., Conley v. Gibson, 355 U.S. 41, 47-48 (1957) (complaint must "give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests"). Nonetheless, assuming *arguendo* that plaintiffs were entitled to raise this additional misappropriation claim at this point in the litigation, plaintiffs have failed to identify any evidence in support of their claim. Plaintiffs rely upon 48 documents produced by Hill-Rom to Da-Tech, the third party engaged by Hill-Rom to manufacture the new sensor module, to support their misappropriation claim. (See Da-Tech Documents, attached as Ex. 38 to Pl. Mot. For SJ., at DA 01513-27, DA 01550-75, and DA 02551-57). According to plaintiffs, these documents demonstrate that Hill-Rom provided and used plaintiffs' trade secrets, such as specifications, drawings, and other information, to manufacture the new sensor modules. (Id.).

These documents fail to support plaintiffs' misappropriation claim. Plaintiffs fail to document its ownership of the allegedly confidential information in the Da-Tech documents, such as by providing testimony or documentation that the material within the Da-Tech documents was used in the design, production, or manufacture of the original sensor modules. Indeed, many of the Da-Tech documents themselves indicate that the information is the property of Hill-Rom. (See Da-Tech Documents, at DA01513, DA01550, DA01559, DA02551). Nor do plaintiffs identify what information contained in the Da-Tech documents is a trade secret and

what alleged trade secrets were used by Hill-Rom and Da-Tech to produce the replacement sensor module. Plaintiffs, as the ultimate bearers of proof, have failed to meet their burden at the summary judgment stage of demonstrating a genuine issue for trial. Accordingly, this Court grants Hill-Rom's summary judgment motion as to the misappropriation claim with respect both to the sensor module and the controller.

E. Count VIII: Trade Dress Infringement

Plaintiffs voluntarily withdraw Count VIII of their amended complaint. (See Pl. Br. In Opp'n. to Def. Mot, at 1 n.1). Accordingly, this Court grants Hill Rom's motion for summary judgment with respect to plaintiffs' trade dress infringement claim.

F. Count IX: Unfair Competition

Plaintiffs do not identify the basis of their claim for unfair competition. Presumably, plaintiffs proceed on the theory that Hill-Rom was "passing off" plaintiffs' controller, trade secrets, and/or trademarks as that of Hill-Rom in the marketing and sale of the C2000 incubator. See, e.g., Restatement (Third) of Unfair Competition § 5 (1995) (liability for deceiving or misleading prospective purchasers by causing mistaken belief that defendant is manufacturer, producer, or supplier of plaintiff's goods or services); see also Scott Fetzer Co. v. Gehring, 288 F. Supp. 2d 696, 703 (E.D. Pa. 2003) (to prove unfair competition concerning trademarks under Pennsylvania common law, plaintiff must show that trademark is valid and legally protectable, that trademark is owned by plaintiff, and that defendant's use of the mark to identify goods and services is likely to create confusion concerning the origin of goods or services); Haymond v. Lundy, 2001 WL 15956, at *2-3 (E.D. Pa. Jan. 5, 2001) (outlining elements). Under Pennsylvania common law, the "essence" of the claim lies in the "deception practiced in 'passing

off' the goods of one for that of another." Pennsylvania State Univ. v. Univ. of Orthopedics, Ltd., 706 A.2d 863, 870 (Pa. Super. Ct. 1998). Indeed, the underlying purpose motivating the law of unfair competition is to prevent "substitution by deception." Id.

Hill-Rom offers evidence that there were never visible markings on the C2000 that identified Mextel as the manufacturer or designer of the controller or its software, therefore making it impossible for consumers to be confused as to the source of the replacement controller. (See Boone Aff., attached as Ex. 6 to Def. Mot. For SJ., at ¶¶ 3-5). Plaintiffs lone response to this argument is that the "misappropriation of Mextel's trade secrets also renders Air-Shields liable for unfair competition." (See Pl. Br. In Opp'n., at 24).

This Court has already granted Hill Rom's summary judgment motion on plaintiffs' claim for misappropriation of trade secrets, concluding that plaintiffs failed to establish Hill-Rom's impermissible use of plaintiffs' trade secrets in the design, manufacture, and sale of the new C2000 incubator. With respect to the unfair competition claim, plaintiffs have also failed to create a genuine issue of material fact that Hill-Rom unfairly passed off plaintiffs' products, trade secrets, or trademarks as its own. Nor have plaintiffs put forth any evidence of consumer confusion as to the origin or source of the replacement controller or of any other components of the new C2000 incubator. See, e.g., Haymond, 2001 WL 15956, at *3-4 (summary judgment appropriate when plaintiff fails to demonstrate likelihood of confusion among consumers); Polymer Dynamics, Inc. v. Bayer Corp., 2000 WL 1146622, at *8 (E.D. Pa. Aug. 14, 2000) (consumer confusion essential element of unfair competition claim under Pennsylvania common law). Consequently, the Court grants Hill Rom's motion for summary judgment with respect to the unfair competition claim in Count IX of the amended complaint.

G. Count VI: Patent Infringement

Defendant moves for summary judgment on plaintiffs' patent infringement claim. (Def. Mot. For SJ., at 18-22). A determination of patent infringement requires a two-step analysis. See PSC Computer Products, Inc. v. Foxconn Int'l., Inc., 355 F.3d 1353, 1357 (Fed. Cir. 2004). The court must first interpret the claims to determine their scope and meaning. Id. The court must then compare the properly construed claims to the allegedly infringing device. Id.

The burden is on the plaintiff to prove infringement by a preponderance of the evidence. Advanced Cardiovascular Sys., Inc. v. Scimel Like Sys. Inc., 261 F.3d 1329, 1336 (Fed. Cir. 2001). To establish infringement of a patent, "every limitation set forth in a claim must be found in an accused product or process exactly or by a substantial equivalent." Johnston v. Ivac Corp., 885 F.2d 1574, 1577 (Fed. Cir. 1989). An accused infringer is therefore "entitled to summary judgment, on the ground of non-infringement, by pointing out that the patentee failed to put forth evidence to support a finding that a limitation of the asserted claim was met by the structure in the accused devices." Johnston, 885 F.2d at 1578. General denials and conclusory statements are insufficient to meet the non-movant's burden. See Hodash v. Black Dog Drug Co., 786 F.2d 1136, 1141 (Fed. Cir. 1986).

Hill-Rom argues that it is entitled to summary judgment on plaintiffs' patent infringement claim for several reasons. First, Hill-Rom argues that the Court need not perform an initial claim construction of the '006 and '083 patents because the record lacks a basis for a reasonable juror to find by a preponderance of the evidence that a product possessed by Hill-Rom infringes on plaintiffs' patented devices. (See Def. Mot. For SJ., at 12-14, 18-19). Second, assuming that claim construction is necessary, Hill-Rom specifically contends that the '006 patent is not

infringed because the heater assembly in the C2000 lacks a mounting bushing. (Id., at 19-20). Third, Hill-Rom contends that even if the '830 patent is infringed, it is invalid because it was "on sale" more than one year prior to the filing of the patent application. (Id., at 20).

Hill-Rom first argues that the record fails to identify any basis to support plaintiffs' infringement claim—that Hill-Rom's sensor module and heater assembly in the new C2000 incubator infringe upon each and every limitation in various claims of the '006 and the '830 patents. Hill-Rom emphasizes that plaintiffs failed to provide answers to interrogatories, which asked plaintiff Skulic to identify the products that he contends infringe upon the '006 and '830 patents, to specify the claims of those patents that are infringed, and to explain how, on an element-by-element basis, those claims read on the accused products. (See Hill-Rom's Interrogatory Requests, attached as Ex. 14-15 to Def. Mot. For SJ.). Furthermore, Hill-Rom contends that because plaintiffs failed to inspect the replacement controller and sensor module during the requisite discovery period, despite numerous opportunities to do so, plaintiffs cannot identify what elements of Hill-Rom's new incubator are infringing. (See Letters to Plaintiffs' Counsel, attached as Ex. 16-19 to Def. Mot. For SJ.).

This Court agrees. Plaintiffs' lone response to Hill-Rom's motion is the testimony of the patentee. According to Skulic's Third Declaration, he inspected an Isolette C2000 incubator with replacement versions of the heater assembly, the controller, and the sensor module in a hospital in Evanston, Illinois. (See Vedran Skulic's Third Declaration, at ¶¶ 22-23). Skulic asserts that the inspected incubator "is consistent with all the documents produced in this case indicating that it is the current version of the C2000 being commercialized by Air-Shields." (Id., at 23). Skulic testifies that he was able to take apart the infringing C2000 incubator, and to review and

photograph the internal mechanisms of the sensor module and the heater assembly. Skulic concludes that the Isolette C2000 Incubator included "all the elements of one or more claims of both of my patents." (Id., at ¶¶ 25-26).

Skulic's testimony fails as a matter of law to overcome Hill-Rom's summary judgment motion. See, e.g., Johnson, 885 F.2d at 1578 (affidavit stating that grip mechanism of accused thermometer infringes upon claims 1, 2, 3, 4, 5, and 6 of the patent constitutes conclusory statement and fails to raise a genuine evidentiary dispute for jury). First, plaintiffs offer no specific evidence that the C2000 incubator inspected by Skulic was in fact the incubator sold by Hill-Rom. Rather than inspecting products that Hill-Rom made available, plaintiff investigated an incubator in a hospital that appeared "consistent" with what the exchanged documents indicated was Hill-Rom's product. (See Letters to Plaintiffs' Counsel For Scheduling of Inspection, attached as Ex. 16-19 to Def. Mot. For SJ.). Second, Skulic's photographs of the accused products are not accompanied by a factual description of the elements in the accused sensor module and heater assembly, of where these elements are located, or of their relationship to claims in the plaintiffs' patents. Third, Skulic's testimony relies upon conclusions without factual support. See, e.g., TechSearch LLC v. Intel Corp., 286 F.3d 1360, 1372 (Fed. Cir. 2002) ("infringement must be shown literally or equivalently for each limitation; general assertions of facts, general denials, and conclusory statements are insufficient to shoulder the non-movant's burden"). Specifically, Skulic's Third Declaration fails to provide any fact-based analytical comparison between the accused and patented products, let alone any evidence demonstrating how each limitation in the relevant claims for both the '006 patent and '863 patent is found in the accused products. See, e.g., McKeown v. Bayshore Concrete Products Cor., 2002 WL 914339,

at *2 (Fed. Cir. May 7, 2002) (granting summary judgment to defendant when plaintiff patentee relies on broad statements in his own affidavit alleging, without factual support, that "he has personally inspected [defendant's] products, compared them to the '020 patent, and found that the accused structures contain every element" of the infringed upon claim). In fact, with the exception of Claim 1 of the 006 patent,[23] Skulic fails to identify which claims are being infringed. What Skulic does present is the naked conclusion that the C2000 incubator "includes all the elements of one or more claims of both of my patents." (See Third Skulic Declaration, at ¶ 24). Such a statement, without more, fails to raise a genuine issue of material fact. McKeown, 2002 WL 914339, at *2 (unsupported, conclusive statements on the issue of infringement "are wholly insufficient to raise a genuine evidentiary dispute for trial"); see Fed. R. Civ. P. 56(e) (nonmoving party must "set forth *specific facts* showing that there is a genuine issue of trial") (emphasis added).

It is true that this Court has yet to offer a formal claim construction of the two patents. It is also true that an infringement analysis typically begins with claim construction. See, e.g., PSC Computer Products, 355 F.3d at 1357. However, the sequence of this process is not absolute,

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[23] Claim 1 of the '006 patent reads as follows:

> 1. An infant incubator heater assembly comprising:
>
> a mounting plate adapted for attachment to a base of an incubator;
> a mounting bushing mounted to said mounting plate;
> a heat radiator removably attached to said mounting bushing and having a plurality or radially extending fins; and
> a cartridge heater extending through said heat radiator in heat transfer relationship with said heat radiator and mounted to said mounting bushing.

(See '006 Patent, attached as Ex. 2 to Second Skulic Declaration and as Ex. 11 to Def. Mot. For SJ.).

and, in an effort to avoid advisory opinions, only terms that are disputed, thereby placing such terms actually in controversy in the infringement litigation, are construed. See, e.g., Unitherm Food Systems, Inc. v. Swift-Eckrich, Inc., 375 F.3d 1341, 1350 (Fed. Cir. 2004) (district court not obligated to construe undisputed claim terms prior to issuing summary judgment on invalidity); PSC Computer Products, 355 F.3d at 1357 (affirming district court's decision to not construe claims as first step of infringement analysis because their meaning was not disputed); Westvaco Corp. v. Viva Magnetics Ltd., 2002 WL 31052870, at *2 (S.D.N.Y. 2002).[24] Furthermore, the lack of an express claim construction by the Court does not absolve plaintiffs of their burden at the summary judgment stage to provide factual support for the conclusion that each and every limitation in the germane claims of the two patents reads on the accused devices. See Linear Tech. Corp. v. Impala Linear Corp., 379 F.3d 1311, 1325-1326 (Fed Cir. 2004) (because patent holder bears the burden of establishing infringement at trial, defendant need only

[24] The Court notes that in this instance, plaintiffs dispute only one term—the phrase "mounting bushing" in claim 1 of the '006 patent. (See Third Skulic Declaration, at ¶ 28-29). Resolution of this disputed construction is immaterial because plaintiffs have not met their burden of providing a factual analysis that the limitations in claim 1 of the '006 patent are infringed by Hill-Rom's heater assembly. Furthermore, Hill-Rom offers evidence, including an affidavit from Ronald Kolarovic, the senior electrical engineer of the new C2000 incubator, along with technical drawings of the new heater assembly unit, that the heater assembly for the new C2000 incubator lacks a mounting bushing, and, in fact, was purposefully designed to eliminate such an element. (See Kolarovic Aff., attached as Ex. 21 to Def. Mot. For SJ.). This analysis is also confirmed by US Patent 6,646,232 ("'232 patent"), which was issued for Hill-Rom's new heater assembly unit and which does not claim a mounting bushing for the device. (See Claim 1 of '232 Patent, attached as Ex. 13 to Def. Mot. For SJ.). Once again, plaintiffs fail to present any factual evidence to challenge this showing, with the exception of Skulic's general conclusions that the new heater assembly unit possesses a "mounting bushing" and that, even if it does not, the new heater assembly unit is substantially equivalent to the '006 patent. (See Third Skulic Declaration, at ¶¶ 28-29) ("As described in Mr. Kolarovic's affidavit and the one drawing that he produced, and based on my inspection of the new incubator, the revised heater assembly still does the same thing, the same way, and achieves the same results as the heater assembly that is described in the 006 patent and in my patent claims.").

establish a deficiency concerning an element of plaintiff's claim). Indeed, without this evidence, the Court's initial claim construction is superfluous, as there is no description of the specific product, let alone its elements, with which to compare the claims of plaintiffs' patents. See, e.g., Techsearch, 286 F.3d at 1369 ("Summary judgment of non-infringement is also appropriate where the patent owner's proof is deficient in meeting an essential part of the legal standard for infringement, because such failure will render all other facts immaterial.").

In summary, plaintiffs have failed to make the requisite showing to defeat summary judgment. The discovery period in this litigation lasted more than 15 months, and has been closed for an additional ten months. See, e.g., Spectra Corp. v. Lutz, 839 F.2d 1579, 1581 (Fed. Cir. 1988) (thirteen months of discovery to pursue patent infringement claims constitutes reasonable discovery period). Despite this time, plaintiffs never inspected the allegedly infringing products in Hill Rom's possession, and have only identified one specific patent claim that was infringed. Moreover, with respect to this claim, plaintiffs rely upon conclusory allegations, without factual support, that each limitation in claim 1 of the '006 patent is found in the new heater assembly for the C2000 incubator. Plaintiffs provide no testimony comparing in a comprehensive manner the patented devices and the accused devices, nor does plaintiff identify with clarity the elements of the accused devices that are allegedly infringing. Finally, plaintiffs never filed a Rule 56(f) affidavit requesting a delay in the resolution of Hill-Rom's summary judgment motion and additional time to pursue discovery on its infringement claims so that it could "present by affidavit *facts* essential to justify the party's opposition." Fed. R. Civ. P. 54(f) (emphasis added). Accordingly, this Court finds that Hill-Rom is entitled to summary judgment

on plaintiffs' infringement claim as a matter of law.[25]

IV. Conclusion

For the preceding reasons, the Court GRANTS in part and DENIES in part the plaintiffs' first motion for summary judgment. The Court GRANTS the following aspects of plaintiffs' first motion for summary judgment: (i) liability for Hill Rom's failure to pay for shipped but accepted controllers in Count I of the amended complaint; (ii) dismissal of all counterclaims based on Mextel's alleged breach of ¶ 2.1(b) of the Agreement; and (iii) dismissal of damages requested in ¶ 40(a) in Hill Rom's breach of contract counterclaim. All other aspects of defendants' summary judgment motion are DENIED.

For the preceding reasons, the Court GRANTS in part and DENIES in part Hill Rom's summary judgment motion. The Court GRANTS the following aspects of Hill Rom's summary judgment motion: (i) dismissal of Counts IV-IX of the amended complaint; (ii) dismissal of plaintiffs' breach of contract claims for the recovery of damages both from ordered, but unshipped controllers and from unordered controllers; and (iii) liability for all counterclaims based on plaintiffs' breaches of ¶ 6.1(b) and ¶ 8.2 of the Agreement. All other aspects of Hill Rom's summary judgment motion are DENIED.

For the preceding reasons, the Court DISMISSES plaintiffs' second motion for summary judgment as moot.

An appropriate ORDER follows.

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[25] As a result of this holding, the Court need not address plaintiffs' motion for summary judgment as to the dismissal of Hill-Rom's patent defenses and counterclaims.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MEXTEL, INC., et al.	:	
	:	
Plaintiffs,	:	**CIVIL ACTION**
	:	
v.	:	**01-CV-7308**
	:	
AIR-SHIELDS, INC., et al.	:	
	:	
Defendants.	:	
	:	
HILL-ROM MANUFACTURING, INC., et al.	:	
	:	
Counterclaim Plaintiffs,	:	
	:	
v.	:	
	:	
MEXTEL, INC., et al.	:	
	:	
Counterclaim Defendants.	:	

ORDER

AND NOW, this ____ day of January 2005, upon consideration of Plaintiffs' Motion for Partial Summary Judgment In Favor of Plaintiffs' Contract Claims and Dismissal of Defendants' Contract Counterclaims (Doc. No. 64), filed on April 14, 2004, and all responses and supplemental briefs thereto; Plaintiffs' Second Motion for Partial Summary Judgment With Respect to the Dismissal of Patent Defenses and Counterclaims (Doc. No. 66), filed on April 14, 2004, and all responses and supplemental briefs thereto; and Defendants' Motion for Summary Judgment on Plaintiffs' Amended Complaint and Count IX of Defendants' Counterclaim (Doc.

No. 74), filed on April 14, 2004, and all responses and supplemental briefs thereto, it is hereby

ORDERED as follows:

1. Plaintiffs' First Motion For Summary Judgment (Doc. No. 64) is GRANTED in part and DENIED in part according to the following formula:

    a. Plaintiffs are entitled to summary judgment on Count I of the amended complaint with respect to Defendants' liability for failure to pay for shipped and accepted controllers;

    b. Plaintiffs are entitled to summary judgment on Defendants' breach of contract counterclaim with respect to Plaintiffs' liability for allegedly breaching ¶ 2.1(b) of the Agreement;

    c. Plaintiffs are entitled to summary judgment on damages requested pursuant to ¶ 40(a) in Defendants' breach of contract counterclaim.

    d. Plaintiffs' first motion for summary judgment motion is denied in all other respects.

2. Plaintiffs' Second Motion For Summary Judgment (Doc. No. 66) is DISMISSED as moot.

3. Defendants' Motion For Summary Judgment (Doc. No. 74) is GRANTED in part and DENIED in part according to the following formula:

    a. Defendants are entitled to summary judgment on Count I of the amended complaint with respect to Defendants' liability both for ordered, but unshipped controllers and for unordered controllers;

    b. Defendants are entitled to summary judgment as to Counts IV-IX of the amended complaint;

    c. Defendants are entitled to summary judgment on their breach of contract counterclaim with respect to Plaintiffs' liability for breaching ¶ 6.1(b) and ¶ 8.2 of the Agreement; and

    d. Defendants' summary judgment motion is denied in all other respects.

4. The Affidavit of Susan Reilly is stricken pursuant to Federal Rule of Civil Procedure 56.

BY THE COURT:

__/s/_____
Legrome D. Davis, J.