

**IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION-CIVIL**

HEALTHCARE MANAGEMENT	:	June Term 2014
SERVICES OF BALTIMORE CNTY LLC,	:	
Plaintiff,	:	No. 4610
v.	:	
BRACCO DIAGNOSTICS, INC.,	:	COMMERCE PROGRAM
Defendant.	:	Control Number 16042387
	:	
	:	
	:	

DOCKETED
JUL 22 2016
N. ERICKSON
DAY FORWARD

OPINION

Presently pending before the court is defendant Bracco Diagnostics, Inc.'s ("Bracco") Motion for Summary Judgment. Bracco sells and distributes CardioGen-82® Generators ("Generators"), which produce Rubidium 82, a radioactive isotope used in myocardial perfusion imaging (heart imaging). Bracco also leases CardioGen-82® Infusion System (the "Infusion System Cart"), which is a processing system housed on a wheeled cart, separate from the Generator, that extracts Rubidium 82 from the Generator and injects it into the patient.

HMSBC is a limited liability company formed in 2006 or 2007 to provide management services to Dedicated Imaging, LLC, a Baltimore-area radiology facility that was owned by Dr. Irfan Shafique. Healthcare Imaging Solutions, LLC ("HIS") is the controlling member of HMSBC and Jeffrey Mandler is the managing partner of HIS, giving him control over HMSBC. HMSBC and Dedicated Imaging entered into a management contract, which called for Dedicated Imaging to pay HMSBC about \$300,000 per month for its services. Dedicated Imaging was HMSBC's only paying customer. HMSBC assisted Dedicated Imaging with cardiac imaging services, including Rubidium 82 studies, a service which Dedicated Imaging and its associated medical professionals had not performed in the past. From 2009 through 2011, HMSBC

Healthcare Management Services Of Baltimore -OPFLD



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employed about 12-14 nurses, nuclear technologists, administrative, and marketing personnel at two facilities in the Baltimore area.

Generators

On February 19, 2009, HMSBC and Cardinal Health 414, LLC (“Cardinal Health”) entered into a contract under which Cardinal Health was to provide Generators to HMSBC on a daily-use basis. Daily-use was a method of distributing Generators by which third-party distributors, like Cardinal Health, provided end users, like Dedicated Imaging, with a Generator for use one or two days a week.

Eventually, HMSBC decided to purchase Generators from Bracco. In March 2009, Bracco and HMSBC signed a sales agreement for Generators (“Sales Agreement”) under which HMSBC was to pay Bracco \$31,460 for each of the Generators, which were to be delivered approximately monthly. HMSBC was to begin accepting shipments on May 15, 2009. However, when the shipment date approached HMSBC was not prepared to begin accepting the shipments and the sales contract was delayed until November 2009. When November 2009 approached, HMSBC was still not in a position to accept shipment at its facility. HMSBC continued to utilize the daily service agreement through Cardinal Health. HMSBC never paid Bracco for the Generators under the sales agreement and Bracco never directly supplied HMSBC with Generators.

On March 31, 2010, Bracco and Cardinal Health entered into a contract with respect to Cardinal Health’s purchase of CardioGen-82® Generators. Bracco provided the following warranties to Cardinal Health:

6. Warranties and Disclaimer

- a. Bracco warrants to the Account [Cardinal Health] that the Products supplied to Account [Cardinal Health] under this Agreement (a) shall be free from defects in

material and workmanship as indicated in the package insert accompanying each unit of Product; (b) shall conform to the specifications in such package insert; (c) shall not be adulterated or misbranded within the meaning of the Federal Food Drug and Cosmetic Act, as amended; (d) shall be an article that may be introduced in interstate commerce under the provision of Sections 404 and 405 of such Act, as amended; (e) shall otherwise be produced in accordance with applicable of cGMP's to the extent such cGMP's affect salability of the Product; and (f) to Bracco's knowledge shall not infringe any patent, or trademark right of any third party. The Account [Cardinal Health] agrees and acknowledges that ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, WITH RESPECT THE PRODUCTS ARE EXPRESSLY EXCLUDED FROM THIS AGREEMENT OR ANY SALE PURSUANT HERETO.

b. The parties agree that the warranty stated herein shall ... (b) not be applicable, available, or transferable from the Account [Cardinal Health] to any third person, consumer or user of the respective unit of Product.

e. Repair and replacement of the damaged Product or any component part thereof, including actual shipping charges, is the EXCLUSIVE remedy offered by Bracco to Account [Cardinal Health] for any breach of the above – stated warranty. ¹

At some point in 2010, HMSBC stopped paying Cardinal Health for the daily-use Generators, resulting in a lawsuit brought by Cardinal Health against HMSBC for “non-payment”. HMSBC ultimately settled the lawsuit brought by Cardinal Health for \$130,000. Cardinal Health notified Bracco in January 2011 that it would not renew its contract with Bracco, for daily-use Generators.² In December 2010, HMSBC contracted with IBA Molecular North America, Inc. (“IBA”) for CardioGen-82 on a daily use basis, Infusion Cart, as well as other goods.³ The IBA agreement became effective on January 2, 2011. IBA contracted with Bracco

¹ Exhibit “P” to Plaintiff’s response to Defendant’s Motion for Summary Judgment - The Bracco/Cardinal Health Agreement. This Agreement is governed by New Jersey law.

² Exhibit “M” to Plaintiff’s response to Defendant’s Motion for Summary Judgment- Notice of Non-Renewal.

³ Exhibit “N” to Plaintiff’s response to Defendant’s Motion for Summary Judgment- IBA/HMSBC contract.

for CardioGen -82 Generators.⁴ The effective date of the contract was January 1, 2011. Bracco provided the same warranties and disclaimers to IBA as provided to Cardinal Health.⁵

Rental and Service Agreement

On June 25, 2009 and December 2009, HMSBC and Bracco entered into contracts to lease from Bracco a CardioGen-82® Infusion System Cart for \$2,000 per month.⁶ HMSBC paid a total of \$38,001.17 for the Infusion System Cart, which consisted of 15 payments of about \$2,100 per month and a larger first payment for delivery and set up of the Infusion System Cart. Paragraph 4 of this agreement provided in pertinent part as follows:

4. NO WARRANTIES BY BRACCO; MAINTENANCE, COMPLIANCE WITH LAWS AND INSURANCE.

- (a)BRACCO MAKES NO WARRANTY OR REPRESENTATION, EITHER EXPRESS OR IMPLIED, AS TO THE FITNESS, QUALITY, DESIGN, CONDITION, CAPACITY, SUITABILITY, MERCHANABILITY OR PERFORMANCE OF THE EQUIPMENT OR OF THE MATERIAL OR WORKMANSHIP THEREOF. CUSTOMER ACCORDINGLY AGREES NOT TO ASSERT ANY CLAIM WHATSOEVER AGAINST BRACCO FOR LOSS OF ANITICIPATORY PROFITS OR CONSEQUENTIAL DAMAGES.

Additionally, the contract provided in ¶ 9, items not covered by service:

- (d) LIMITATION OF LIABILITY. IN NO EVENT SHALL BRACCO BE LIABLE FOR ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING BUT NOT LIMITED TO LOSS OF PROFITS) ARISING OUT OF THE PERFORMANCE OF SERVICE BY BRACCO UNDER THIS AGREEMENT, REGARDLESS OF WHETHER SUCH DAMAGES ARE BASED ON TORT, WARRANTY, CONTRACT OR ANY OTHER LEGAL THEORY, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, BRACCO'S AGGREGATE LIABILITY UNDER THIS AGREEMENT, UNDER ANY LEGAL THEORY SHALL

⁴ Exhibit "O"- to Plaintiff's response to Defendant's Motion for Summary Judgment- Bracco/IBA contract.

⁵ Compare Bracco/Cardinal Health agreement Exhibit "P" with Bracco /IBA agreement Exhibit "O".

⁶ Exhibits "D" and "J" – to Plaintiff's response to Defendant's Motion for Summary Judgment- Rental and Service Agreement which is governed by New Jersey law.

NOT EXCEED THE AMOUNTS RECEIVED FROM CUSTROMER BY BRACCO
HEREUNDER.

The parties performed under this agreement without incident.

Recall of Generators

In 2011, two individuals, each of whom underwent cardiac PET scans using Rubidium 82 from a Generator, passed through security at U.S. airports and registered higher than normal levels of radiation. Bracco was contacted by the Federal Government. After a meeting with FDA, Bracco was informed that the Generators were adulterated and misbranded. On July 29, 2011, Bracco recalled the Generators. On February 12, 2012, with the FDA's approval, Bracco ended the recall of the Generators, and the Generators returned to market in February and March 2012. The FDA conditioned lifting the recall on the cessation of the daily-use service of the Generators. IBA and Cardinal Health no longer purchase Generators from Bracco.

Procedural History

HMSBC initiated this action by writ of summons on July 2, 2014. On December 8, 2014, HMSBC filed its complaint sounding in breach of contract, breach of express warranty and breach of implied warranty and fraud. On February 27, 2015, after preliminary objections were filed to the complaint, HMSBC filed an amended complaint. Bracco filed preliminary objections to the amended complaint. On June 15, 2016, the court sustained Bracco's preliminary objections to the amended complaint dismissing the claims for common law fraud and violations of the New Jersey Consumer Fraud Act. On December 12, 2015, the court granted HMSBC leave to file a second amended complaint to add a claim for breach of contract based on the alleged Generator Sales Agreement. HMSBC alleges as damages: 1) lost profits from its inability to conduct Rubidium 82 studies, both during and after the recall, 2) costs and attorney's fees incurred in connection with litigation filed against HMSBC and its affiliates after they defaulted

on loan payments for a PET/CT scanner and 3) the \$1,300,000 settlement HMSBC paid to resolve the litigation arising out of its default on its PET/CT scanner loan payment obligations. On February 26, 2016, Bracco filed its answer, new matter and counterclaim to the second amended complaint. On July 11, 2016, this court granted Bracco leave to file an amended answer with new matter to add the defense of statute of limitations. Presently pending before the court is Bracco's motion for summary judgment which is ripe for decision.

DISCUSSION

I. The claims for breach of contract fail.

In count I of the second amended complaint, HMSBC purports to state a claim for breach of the Sales Agreement and the Rental and Service Agreement, respectively, against Bracco. According to HMSBC, the alleged breach occurred in July, 2011, when Bracco ordered a recall of the Infusion System and suspended the supply of Generators due to safety concerns over the safe use of radioactive substance known as Rubidium. HMSBC alleges the recall caused HMSBC to cease operation of its PET/CT that employed the Infusion System and Generators supplied by Bracco. HMSBC further alleges that as a result of the recall, it suffered actual losses, lost profits and consequential damages in excess of \$1,500,000. For the reasons discussed below, HMSBC's breach of contract claims under the Sales Agreement and the Rental and Service Agreement fails.

Under New Jersey law, plaintiff has the burden to prove four elements in a claim for breach of contract: 1) that "[t]he parties entered into a contract containing certain terms"; 2) that "plaintiff[s] did what the contract required [them] to do"; 3) that "defendant[s] did not do what the contract required [them] to do[.]" defined as a "breach of the contract"; and 4) that "defendant[s'] breach, or failure to do what the contract required, caused a loss to the

plaintiff[s].”⁷ As it pertains to the Sales Agreement, there is no evidence of record that a contract between Bracco and HMSBC existed at the time of the recall wherein Bracco was obligated to sell Generators to HMSBC directly and in turn HMSBC would pay Bracco directly for the Generators. HMSBC and Bracco did enter into two Sales Agreement for Generators but the parties never performed under these agreements. The record evidence demonstrates that at the time of the recall in July 2011, HMSBC was receiving Generators from IBA on a daily use basis per a contract with IBA. As such, when the recall was implemented by Bracco in July 2011, the parties had no agreement in place under which Bracco was obligated to sell Generators to HMSBC and HMSBC was obligated to pay Bracco. Since HMSBC has failed to produce evidence of a valid contract between it and Bracco at the time of the recall, the claim for breach of contract is dismissed.⁸

In an attempt to salvage its claim for breach of contract under the Sales Agreement, HMSBC argues that the Sales Agreement and the Rental and Service Agreements merged and therefore any question regarding the existence of the Sales Agreements becomes moot. This argument is not persuasive. There is no evidence of record that supports HMSBC’s contention that the contracts merged. The Rental and Service Agreements do not contain any reference to the Sales Agreement or any language incorporating the Sales Agreement into Rental and Service Agreement. Moreover, the Rental and Service Agreement contains an integration clause

⁷*Globe Motor Co. v. Igdalev*, ---A.3d---, 2016 WL 3525351, at *6 (N.J. 2016) citing *Model Jury Charge (Civil)*, § 4.10A “The Contract Claim—Generally” (May 1998); see also *Coyle v. Englander’s*, 199 N.J. Super. 212, 223, 488 A.2d 1083 (App.Div.1985) (identifying essential elements for breach of contract claim as “a valid contract, defective performance by the defendant, and resulting damages”).

⁸ At best, HMSBC may be a third party beneficiary of the Bracco/IBA contract. However, HMSBC never asserted such a claim, and even if it did, the contract claim would fail since the damages claimed by HMSBC, lost profits and consequential damages, are barred by the contract. See Exhibit “O”- Bracco/IBA Agreement ¶ 6 (c) which states, “Neither party shall be liable to the other for any indirect, consequential or incidental damages, including without limitation, loss of profits or projected profits.”

specifically stating that it is the entire agreement between the parties supporting the fact that the agreements are separate and independent.

Notwithstanding the fact, that the two agreements are separate and independent, even if the contracts merged, the claim for breach of contract still fails. HMSBC alleges it suffered lost profits and consequential damages arising from the recall in July 2011. These damages are expressly and unambiguously barred by the limitation of liability provision in the Rental and Service Agreement. This provision provides as follows:

IN NO EVENT SHALL BRACCO BE LIABLE FOR ANY SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES (INCLUDING BUT NOT LIMITED TO LOSS OF PROFITS) ARISING OUT OF THE PERFORMANCE OF SERVICE BY BRACCO UNDER THIS AGREEMENT, REGARDLESS OF WHETHER SUCH DAMAGES ARE BASED ON TORT, WARRANTY, CONTRACT OR ANY OTHER LEGAL THEORY, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

Under the U.C.C., “parties are left free to shape their remedies to their particular requirements and reasonable agreements limiting or modifying remedies are to be given effect.”⁹ Since the parties agreed to limit their liability, HMSBC is now barred from recovering its alleged lost profits and consequential damages. Based on the forgoing, Bracco’s motion for summary judgment is granted as to the breach of contract claims.

II. The Warranty Claims fail.

In Count II and III of the second amended complaint, respectively, HMSBC purports to state claims for breach of implied warranty and breach of express warranty. Under the terms of the Rental and Service Agreement, ¶ 4 (a), HMSBC expressly agreed to waive these warranties and representations as follows:

BRACCO MAKES NO WARRANTY OR REPRESENTATION, EITHER EXPRESS OR IMPLIED, AS TO THE FITNESS, QUALITY, DESIGN, CONDITION,

⁹ N.J. Stat. Ann. § 12A:2-719, cmt. 1.

CAPACITY, SUITABILITY, MERCHANTABILITY OR PERFORMANCE OF THEIR EQUIPMENT OR THE MATERIAL OR WORKMANSHIP HEREOF. [HMSBC] ACCORDINGLY AGREES NOT TO ASSERT ANY CLAIM WHATSOEVER AGAINST BRACCO BASED THEREON. [HMSBC] FURTHER AGREES, REGARDLESS OF CAUSE, NOT TO ASSERT ANY CLAIM WHATSOEVER AGAINST BRACCO FOR LOSS OF ANTICIPATORY PROFITS OR CONSEQUENTIAL DAMAGES. ...

The complete exclusion of warranties, including warranties of merchantability and of fitness for a particular purpose, found in the Rental and Service Agreement are specifically permitted under the UCC.¹⁰ To exclude the implied warranty of merchantability, a disclaimer must mention merchantability and, when written, be conspicuous.¹¹ A clause is conspicuous when it is written such that a reasonable person against whom it is to operate ought to have noticed it. Underlying the U.C.C. is the principle that parties should be free to make contracts of their choice, including contracts disclaiming liability for breach of warranty. Once they reach such an agreement, society has an interest in seeing that the agreement is fulfilled.¹² Applying these principles to the facts at hand, it is clear that the disclaimers for express and implied warranties found in the Rental and Service Agreement are conspicuous, unambiguous and enforceable. As such, Bracco's motion for summary judgment in this regard is granted.¹³

¹⁰ See *N.J.S.A.* 12A:2-316. See also, *Gladden v. Cadillac Motor Car Div.*, 83 *N.J.* 320, 330-331, 416 *A.2d* 394 (N.J. 1980).

¹¹ *N.J.S.A.* § 12A:2-316(2).

¹² *Spring Motors Distributors, Inc. v. Ford Motor Co.*, 98 *N.J.* 555, 571, 489 *A.2d* 660, 668 (1985).

¹³ HMSBC appears to rely upon alleged oral representations and written representations made prior to execution of the agreement to support its claim for breach of warranty. HMSBC's reliance on said representations is not proper. As set forth above, the Rental and Service Agreement contains an integration clause specifically stating that the agreement constitutes the entire agreement between the parties with respect to the lease and service of the Equipment and supersedes all prior oral or written agreements, understandings and representations to the extent that they relate in any way to the subject matter hereof. See Exhibits "D" and "J" – Rental and Service Agreement ¶ 22. Additionally, ¶ 4 (a) specifically provides "No oral lease, guaranty, promise, condition, representation or warranty shall be binding upon Bracco."

As to the Generator Sales Agreement, this court has already determined that a valid and enforceable contract did not exist between HMSBC and Bracco. Consequently, any claim for breach of implied and express warranty based on the Generator Sales Agreements is nonexistent. The only other means in which HMSBC could potentially assert a claim for breach of implied and express warranty is as a third party beneficiary of the contract between Bracco and IBA. However, a review of the Agreement between Bracco and IBA unequivocally demonstrates that any warranties provided to IBA from Bracco are nontransferable.¹⁴ Accordingly, Bracco's motion for summary judgment as to the warranty claims is granted.¹⁵

CONCLUSION

For the foregoing reasons, Defendant's motion for summary judgment is granted and judgment is entered in favor of Defendant on Plaintiff's claim¹⁶ and Defendant's counterclaim is dismissed.¹⁷

BY THE COURT,


PATRICIA A. McINERNEY, SJ.

¹⁴ The letter agreement between Bracco and IBA states, "The parties agree that the warranty stated herein shall ... (b) not be applicable, available, or transferable from the Account [IBA] to any third person, consumer or user of the respective unit of Product". See Exhibit "O"- Bracco/IBA Agreement ¶ 6(b) (b).

¹⁵ Notwithstanding the limitation on transferability, damages for any breach of warranty to IBA are limited to repair and replacement. Precluded are indirect damages, consequential damages or incidental damages, including but not limited to loss of profits or projected profits. See, Exhibit "O"- Bracco/IBA agreement, ¶ 6 (c) (e).

¹⁶ Based on the foregoing reasoning set forth herein, the court finds it unnecessary to consider Bracco's other grounds for summary judgment including but not limited to the statute of limitations bar and the application of the Force Majeure provisions.

¹⁷ The court acknowledges that no party has moved for summary judgment on Bracco's counterclaim for breach of contract. However, since this court found that there were no valid contracts regarding the Generator Sales Agreement, a counterclaim for breach of the same contract does not exist and therefore the counterclaim is dismissed.