

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

COOK IMAGING CORPORATION, d/b/a	:	
COOK PHARMACEUTICAL SOLUTIONS,	:	
	:	CIVIL ACTION
Plaintiff,	:	
	:	
v.	:	
	:	
HEMISPHERX BIOPHARMA, INC.,	:	No. 00-1211
	:	
Defendant.	:	

**FINDINGS OF FACT, CONCLUSIONS OF LAW AND JUDGMENT**

**Schiller, J.**

**May 16, 2001**

On May 9-10, 2001, this contract action was tried with the Court sitting as the fact finder. For the reasons stated below, I find in favor of plaintiff Cook Imaging Corporation on its breach of contract claim and defendant Hemispherx Biopharma, Inc. on some of its counterclaims. Specifically, defendant is entitled to compensation for damages resulting from cracked vials and adulterated product as described herein.

**I. BACKGROUND**

On March 6, 2000, plaintiff Cook Imaging Corporation, doing business as Cook Pharmaceutical Solutions, (“Cook”) filed this action for breach of contract against defendant Hemispherx Biopharma, Inc. (“HBI”). Cook alleged that it contracted with HBI to manufacture batches of a drug called Ampligen and Ampligen placebo (collectively “Ampligen”). (Compl. at ¶¶ 6-8). Cook claims that HBI failed to pay for four batches of Ampligen. (Compl. at ¶¶ 9-15).

HBI answered, generally denying the allegations set forth in the complaint and bringing

counterclaims charging that Cook breached the contract by failing to manufacture Ampligen in conformity with the standards agreed to by the parties and that Cook negligently represented that it would and did comply with these standards, breaching warranties it had made to HBI. (Counterclaim at ¶¶ 43-69). HBI seeks to recover (1) the cost and value of raw materials lost or misplaced by Cook; (2) the cost and value of product that could not be used because of a cracked vial defect in Cook's manufacturing process; (3) the cost and value of adulterated product; (4) additional administrative costs incurred by HBI as a result of Cook's quality control and quality assurance deficiencies; and (5) damages flowing from the under-enrollment of patients in HBI's United States and European cost-recovery programs. (Exhs. D-48, D-54).

Cook moved for partial summary judgment on its claims for breach of contract and unjust enrichment. On December 22, 2000, the Court denied Cook's motion. A non-jury trial followed. At trial, Cook withdrew Count III of its complaint, consisting of its claim for breach of implied covenant of good faith and fair dealing, leaving for resolution its claims for breach of contract (Count I) and unjust enrichment (Count II).

## **II. FINDINGS OF FACT AND CONCLUSIONS OF LAW<sup>1</sup>**

HBI is engaged in the business of researching, developing and testing experimental pharmaceutical compounds and drug technologies for regulatory approval and sale. (Stip. No. 1). HBI developed Ampligen to treat viral afflictions such as chronic fatigue syndrome. (Stip. No.

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<sup>1</sup>The parties agree that this case is governed by contract law covering the sale of goods. While the law of Pennsylvania and Indiana could be applicable to this case, the parties agree that there is no substantive difference in the relevant law of those states. Therefore, a conflict of laws analysis to determine which state's law applies is not required.

2). Cook provides contract pharmaceutical services to its clients, including the manufacturing and packaging of pharmaceutical products. (Stip. No. 4).

**A. The Contract**

In October of 1997, Cook agreed to make batches of Ampligen for HBI. (Stip. No. 5). HBI agreed to pay for each batch made by Cook. (Stip. No. 5). From October of 1997 through May of 1999, Cook and HBI entered into a series of Project Plans, which set forth, among other things, the size and timing of batch production. (Stip. No. 6). In total, Cook agreed to make thirteen batches. (Stip. No. 10). Prior to releasing each batch of Cook-made Ampligen for use, HBI subjected each batch to its own series of tests and reviewed the batch records. (Stip. No. 22). HBI accepted every batch made by Cook, except for the second batch (Lot No. 9711CD). (Stip. No. 29).

HBI has not paid for the last four clinical batches made by Cook in March, April, May and June of 1999 (Lot Nos. 9902CD, 9903CD, 9904CD and 9905CD) (“disputed batches”). (Stip. No. 31). Doses from all of the batches made by Cook which were released for clinical use by HBI, including the disputed batches, have been, or will be injected into patients undergoing treatment for chronic fatigue syndrome. (Stip. No. 30). Cook invoiced HBI a total of \$229,899.03 for the disputed batches. (Stip. No. 32). The invoices for those batches included an interest charge of 1.5% on all amounts 30 days past due. (Stip. No. 32). HBI never objected to the interest charge on past due invoices. (Stip. No. 32).

A contract between Cook and HBI was formed when Cook agreed to manufacture

Ampligen in exchange for payment by HBI. See Homer v. Burman, 743 N.E.2d 1144, 1146-47 (Ind. App. Ct. 2001) (observing that a contract requires an offer, acceptance, and consideration); Yarnall v. Almy, 703 A.2d 535, 538 (Pa. Super. Ct. 1997) (noting that the formation of a contract requires an offer, acceptance, and consideration or meeting of the minds) (citation omitted). It is undisputed that Cook did manufacture the requested Ampligen, which was delivered to HBI. It is also undisputed that HBI accepted four batches of Ampligen made by Cook in March, April, May, and June of 1999 (Lot Nos. 9902CD, 9903CD, 9904CD, and 9905CD) and used doses from those batches in clinical trials. Moreover, HBI does not contest the fact it has not paid Cook for these four batches of Ampligen.

Both Indiana and Pennsylvania law directs buyers to pay the contract rate for any goods accepted. See IND. CODE § 26-1-2-607(1); 13 PA. CONS. STAT. ANN. § 2607(1); McLure Oil Corp. v. Murray Equip., Inc., 515 N.E.2d 546, 552 (Ind. Ct. App. 1987) (“the buyer must pay the contract price for any goods accepted”); Industrial Molded Plastic Prods., Inc. v. J. Gross & Son, Inc., 398 A.2d 695, 699 (Pa. Super. Ct. 1979) (upon acceptance of goods, seller is “entitled to the full unpaid balance of the contract price”).

Acceptance occurs when the buyer either: (1) signifies to the seller that the goods are conforming or that he will take the goods despite their nonconformity after a reasonable opportunity to inspect the goods; (2) fails to make an effective rejection after a reasonable opportunity to inspect the goods; or (3) does any act inconsistent with the ownership of the seller. See IND. CODE § 26-1-2-606(1); 13 PA. CONS. STAT. ANN. § 2606(a). Here, it is undisputed that HBI accepted the disputed batches of Ampligen. (Stip. 29). This fact could hardly be contested

as HBI never notified Cook of any rejection of the disputed batches, in whole or in part. Instead, the disputed batches of Ampligen were released for clinical use after they satisfied HBI's release tests and batch record requirements. (Stip. Nos. 29-31).

HBI received invoices for the four unpaid batches, totaling \$229,899.03, which included an interest charge of 1.5% on all amounts 30 days past due. HBI never objected to the interest charges. (Stip. No. 32). Therefore, Cook is entitled to collect interest in accordance with the language of the invoice. See Herzog Oil Field Serv., Inc. v. Otto Torpedo Co., 570 A.2d 549, 551 (Pa. Super. Ct. 1990) (determining that 1.5% interest charge on unpaid balances past-due by more than 30 days provided for on invoice was part of contract because buyer never objected and additional term was not a material alteration of the agreement); McClure Oil, 515 N.E.2d at 555 (1.5% interest charge stated on invoice appropriate where buyer received invoices and never objected to term).

The parties agree that the total amount due under the unpaid invoices as of May 9, 2001 is \$311,656.87. (Statement of Undisputed Facts No. 12).

## **B. HBI's Counterclaims**

### **1. Raw materials lost or misplaced by Cook**

HBI provided Cook with certain of the inputs necessary to manufacture Ampligen, including polymer (Poly I and Poly C<sub>12</sub>U) raw materials. (Stip. No. 7). Cook supplied certain other raw materials. (Stip. No. 7). HBI obtained some of its polymer raw materials from Pharmacia. (Stip. No. 8). HBI did not weigh, before or after release testing, the raw materials

shipped to HBI by Pharmacia. (Stip. No. 8). Cook did not weigh the raw materials upon receipt in accordance with HBI's instructions.<sup>2</sup>

Cook's inventory card indicates that it received eight containers of polymer in April of 1999. (Exh. D-32). The testimony revealed that each container was dressed with a label indicating that the weight of the polymer inside was 66.45 grams +/- 10 grams. In theory, the total amount of polymer received by Cook was 531.6 grams. Cook's records indicate that 465.6 grams of the polymer were used in the manufacturing of Ampligen.

HBI claims that it is entitled to recover the cost of the 66.0 grams of unaccounted polymer. The label affixed to each container of polymer, however, indicates a margin of error of ten grams. As a result, the actual total weight of the polymer received by Cook could have been anywhere between 451.6 grams and 611.6 grams.

As the counterclaim plaintiff, HBI bears the burden of establishing by a preponderance of the evidence that Cook lost or misplaced the "missing" polymer. There has been no evidence presented from which the Court could reasonably conclude that the 66.0 grams of polymer at issue even existed. Because HBI failed to satisfy its burden, it cannot recover.

**2. The cost and value of product that could not be used because of a cracked vial defect in Cook's manufacturing process**

Cook makes a product called Oxilan, which is an imaging agent. (Stip. No. 4). Sometime around December of 1998, Cook was advised by a client that vials of Oxilan were cracked or scored. (Stip. No. 26). The cracking and/or scoring occurred in the process of

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<sup>2</sup>HBI asked Cook not to weigh the raw materials in order to avoid their unnecessary manipulation which could damage the raw materials.

capping the vials. Because Ampligen was filled into the same vials as Oxilan, Cook advised HBI of the issue and offered to reinspect the vials free of charge and pay for the shipping of the vials. (Stip. No. 27). Thereafter, HBI collected and returned approximately 12,300 vials to Cook for reinspection. (Stip. No. 28). Seventy-five doses of Ampligen and 30 doses of Ampligen placebo were rejected by Cook as a result of the reinspection. HBI seeks the cost of the doses of the rejected vials of Ampligen and placebo, totaling \$19,577.00, and the costs it incurred in preparing the vials for return to Cook and unloading and inventorying the vials returned from Cook, totaling \$12,181.00.

“A contract for the sale of goods may be made in any manner sufficient to show agreement, including conduct by both parties which recognizes the existence of such a contract.” IND. CODE § 26-1-2-204(1); 13 PA. CONS. STAT. ANN. § 2204. Here, the parties never executed a written embodiment of their agreement. As a result, the fact finder must determine which terms constitute the intent of the parties thereby governing their respective obligations. In doing so, the Court considered the drafts of written terms exchanged by the parties (Exh. D-1) and the conduct of the parties. See IND. CODE §§ 26-1-2-207(3), 26-1-2-208; 13 PA. CONS. STAT. ANN. §§ 2207(c), 2208. The parties clearly contemplated that the integrity of the Ampligen would not be compromised by the introduction of glass or other contaminants to the liquid drug in the process of putting the drug into vials or as a result of that process. Cook knew that the Ampligen contained in the vials at issue were needed for injection into patients in its cost-recovery programs in the United States and Europe. Moreover, no claim was or could be made that Cook, a manufacturer of pharmaceuticals, did not agree to maintain the integrity of the drug throughout

every stage of its production. If Cook had not understood this to be its obligation it would not have offered to bear the expense of testing, shipping, and inspecting the vials. (Exhs. D-8, D-9).

This undertaking did not come without cost to HBI. Thus, HBI is entitled to recover its costs. Cook shall compensate HBI for the costs it incurred in returning the vials to Cook (\$12,181.00) and upon receiving them post-reinspection and for the cost of the 75 tainted doses of Ampligen and 30 tainted doses of placebo (\$19,577.00), plus interest in the amount of \$2,782.00.

In addition, HBI is entitled to the profit it would have earned had it been able to use those doses of Ampligen in its clinical trials. At trial, it was uncontested that HBI's incremental profit per dose of Ampligen was \$31.12 in the United States and \$81.12 in Europe. The Court concludes that half of the 75 doses of Ampligen would have been used in the United States and the other half in Europe. HBI is therefore entitled to \$1167.00 plus interest in the amount of \$102.38 for losses in the United States and \$3042.00 plus interest in the amount of \$266.68 for losses in Europe.

In total, HBI is entitled to \$26,937.06 as a result of the cracked vial problem.

### **3. The cost and value of adulterated product**

The Master Batch Record, which can be likened to a recipe for the production of Ampligen, provided for three bubble point tests on a filter used in the manufacturing process. (Stip. No. 14). These tests are used to determine the integrity of the filter. Prior to the first manufacturing run of Ampligen, Cook adopted a blanket deviation to the Master Batch Record which removed the second bubble point test (performed post-autoclave, pre-fill) from the

manufacturing process without HBI's consent as required by the contract. (Stip. Nos. 15, 17; Exh. D-1).

The filter used in the manufacturing of the second batch of Ampligen manufactured by Cook (Lot No. 9711CD) failed to pass the third bubble point test (performed post-fill). (Stip. No. 18). As a result, the second batch was not usable because its sterility could not be assured. (Stip. No. 18). Cook did not release Lot No. 9711CD. (Stip. No. 19). HBI seeks the cost it incurred in supplying the polymer for that batch and in receiving and testing the batch and its lost opportunity cost because it was unable to use the batch in its cost-recovery studies.

Cook's material breach of the contract caused HBI to incur the cost of the polymer it supplied to Cook to make Lot No. 9711CD and the costs of receiving and testing Lot No. 9711CD. Therefore, HBI is entitled to recover those losses in the amount of \$22,442.00 plus interest in the amount of \$2,246.00, totaling \$24,688.00.

Cook counters by asserting that, at the outset, the parties recognized the risky nature of developmental work. Costly mistakes, Cook claims, are inherent in manufacturing a drug in its developmental stages. It is Cook's contention that the parties allocated the risks accordingly. Consequently, the agreement did not provide for the recovery of costs incurred in the manufacturing process. As evidence of this understanding, Cook emphasizes that neither party sought such costs during the course of their dealings. HBI disputes the claim that parties agreed to bear their own costs when manufacturing problems arose and that such a practice existed in the industry. It claims that it did not immediately seek the costs associated with the loss of the polymer because of its desire to repair and maintain its relationship with Cook. Cook offered

only the testimony of its executives to support its claim regarding the terms of the agreement.

The Court is unpersuaded by that testimony and finds that no such understanding was contemplated by the parties. In fact, since Cook unilaterally eliminated the second bubble point test, it must bear the consequence of not knowing whether the adulterated batch could have been avoided if it had performed the second test.

I now turn to whether HBI can recover its claimed lost opportunity costs. Of the thirteen batches of Ampligen made by Cook, some were intended for use in stability tests and others intended for use in human clinical trials. (Stip. Nos. 11, 21). Stability studies test the shelf-life of the drug by, among other things, subjecting vials of the drug to light, heat and time under controlled conditions. (Stip. No. 11). From the beginning of 1997 through today, HBI has conducted two types of clinical trials, cost recovery (Protocols AMP 509 and AMP 511) and non-cost recovery clinical trials (Protocol AMP 516). (Stip. No. 33). Cost recovery trials are permitted under certain circumstances when the Food and Drug Administration (“FDA”) allows a company without a commercial license for a particular drug to sell it to patients. The FDA permits HBI to charge patients in its United States cost recovery clinical trials (AMP 511 study) \$150 per dose of Ampligen. (Stip. No. 35). In its European cost recovery clinical studies, HBI is permitted to charge patients \$200 per dose of Ampligen. HBI decided whether doses of Ampligen would be used in stability studies or clinical trials. (Stip. No. 34).

The first three batches were originally intended for use in stability studies and the last ten batches were intended for use in human clinical trials. (Stip. No. 11). HBI asserts that while it did initially designate the second batch for stability study, it would have ultimately chosen to use

the batch in clinical trials because, inter alia, of the demand that existed for the drug. However, the testimony established that the FDA requires at least three stability batches made by one manufacturer before it will approve the drug for commercial use and permit a particular manufacturer to produce it. Moreover, in communication between the parties, HBI reiterated its intent to use the first three batches in stability testing. (Exh. P-13). HBI's only evidence to the contrary consists of the self-serving statements of HBI executives. In light of this evidence, the Court finds that the second batch would have been used in stability studies. Because the Court finds that the batch at issue (Lot No. 9711 CD) was not to be used in clinical trials, it is not necessary to determine whether the law would allow recovery of the alleged lost opportunity costs under the facts of this case.

**4. Additional administrative costs incurred at HBI as a result of Cook's quality control and quality assurance deficiencies**

The contract obligated Cook to produce Ampligen in accordance with the current Good Manufacturing Practices ("cGMP"), which are regulations governing the manufacture of drugs. (Stip. No. 9). See 21 C.F.R. §§ 210-211. HBI claims that it is entitled to compensation for costs incurred as a result of Cook's non-compliance with cGMP, primarily in the form of time spent by its manager of quality assurance in developing corrective actions and ensuring the integrity of product. Cook concedes that "mistakes" were made in the manufacturing process, but challenges the claim that those mistakes rise to the level of cGMP "violations." (Exh. P-126). All manufacturing issues, problems or discrepancies HBI raised with respect to any of the batches made by Cook were eventually resolved to HBI's satisfaction prior to the release of any batches for stability studies or clinical use. (Stip. No. 23).

HBI seeks reimbursement for the time spent by a contract employee (Steve Lieberman) hired specifically for quality assurance. The fact that he did his job well does not entitle HBI to be reimbursed for his charges. It was his responsibility to take action necessary to satisfy himself that the drug at issue was safe and effective before he authorized its release. Cook is not required to bear the costs of his time simply because HBI chose to compensate Mr. Lieberman for his services hourly instead of by paying him a salary.

#### **5. Under-enrollment in HBI's cost-recovery programs**

From 1998 through today, HBI's cost recovery clinical trials have been under-enrolled. HBI seeks to recover costs associated with its under-enrolled cost recovery clinical trial in the United States and abroad. HBI claims that it was not able to project that it would have the necessary supply of Ampligen for complete enrollment of its cost recovery trials because of Cook's failure to adhere to cGMP. HBI asks this Court to find that fifty percent (50%) of the under-enrollment was caused by an insufficient supply of Ampligen and to attribute the responsibility for any shortage of Ampligen to Cook.

The facts compel a finding to the contrary. Cook made every batch of Ampligen HBI asked Cook to make. (Stip. No. 39). The batch Cook made in June 1999 (Lot No. 9905CD) was the last batch HBI requested Cook to manufacture. (Stip. No. 39). In June and July of 1998, Cook offered to increase the production of Ampligen from 200,000 to 300,000 vials. (Stip. No. 40). HBI did not accept Cook's offer and did not ask Cook to increase production of Ampligen. (Stip. No. 40). In March and April of 1999, Cook offered to make larger batches of Ampligen (600 liter instead of 300 liter) for HBI. (Stip. No. 41). HBI did not accept Cook's offer and did

not ask Cook to produce larger batches of Ampligen. (Stip. No. 41). Moreover, HBI presented no evidence to establish that any patients were denied participation in the cost recovery program. Consequently, HBI cannot recover.

### **III. CONCLUSION**

For the reasons stated above, I find in favor of Cook on its claim for breach of contract.<sup>3</sup> Cook is entitled to recover the contract price for the disputed batches of Ampligen (Lot Nos. 9902CD, 9903CD, 9904CD and 9905CD) plus interest. HBI is entitled to recover the costs associated with the cracked vials, including: (1) costs incurred in returning the vials to Cook for reinspection and receiving the vials following reinspection; (2) cost of the doses of Ampligen deemed unusable following reinspection; and (3) the incremental profit from the use of the 75 doses of Ampligen in clinical cost recovery programs. HBI is also entitled to recover the cost of the polymer it supplied to Cook to manufacture the second batch (Lot No. 9711CD), which was unusable. Appropriate interest will be added to those awards. An order follows.

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<sup>3</sup>Since Cook is entitled to all of the relief requested on its breach of contract claim (Count I), I need not consider its claim for unjust enrichment (Count II).

IN THE UNITED STATES DISTRICT COURT FOR  
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COOK IMAGING CORP., d/b/a COOK :  
PHARMACEUTICAL SOLUTIONS, :  
Plaintiff, : CIVIL ACTION  
v. :  
HEMISPHERX BIOPHARMA, INC., : No. 00-1211  
Defendant. :

**JUDGMENT**

AND NOW, this 16th day of May, 2001, it is hereby ORDERED as followed:

1. JUDGMENT IS ENTERED in favor of plaintiff Cook Imaging Corporation and against defendant Hemispherx Biopharma, Inc. on plaintiff's breach of contract claim in the amount of \$311,656.87;
2. JUDGMENT IS ENTERED in favor of defendant Hemispherx Biopharma, Inc. and against plaintiff Cook Imaging Corporation on defendant's counterclaims as follows:
  - a. \$31,758.00 incurred in order to ship and receive the reinspected vials and as compensation for the cost of the unusable doses plus interest in the amount of \$2782.00.
  - b. \$4209.00 lost profit for 75 doses of unusable Ampligen plus interest in the amount of \$369.06

- c. \$22,442.00 incurred to supply raw materials used in the production of Lot No. 9711CD plus interest in the amount of \$2,246.00;
  - d. JUDGMENT IS ENTERED in favor of plaintiff Cook Imaging Corporation and against defendant Hemispherx Biopharma, Inc. on defendant's remaining counterclaims and requests for damages;
3. All post-trial motions, including motions for amendments to the calculations of damages, shall be filed within the time prescribed by the local rules.

BY THE COURT:

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Berle M. Schiller, J.