

**AMERICAN ARBITRATION ASSOCIATION
COMMERCIAL ARBITRATION TRIBUNAL**

In the Matter of Arbitration Between:

Re: 18-20-1400-0163
Achelos Therapeutics, Inc., (Claimant)
Represented by John Fialcowitz of The Law Office of John A. Fialcowitz, LLC
vs.

Lucas Packaging Group, Inc. (Respondent)
Represented by Gary A. Kraemer of Daggett, Kraemer & Gleisvik

AWARD OF ARBITRATOR

I, THE UNDERSIGNED ARBITRATOR, having been designated in accordance with the Arbitration Agreements entered into by the above-named Parties, and dated 3 February 2012, and 18 June 2012, and having been duly sworn, and having duly heard the proofs and allegations of the Parties, do hereby FIND as follows:

FACTS

The Respondent, Lucas Packaging Group, Inc., (hereinafter "LPG" or "Respondent") is a New Jersey corporation with a principal place of business located at 48 Dyer Road, Wantage, New Jersey. LPG is devoted to developing packaging for pharmaceutical and personal care cosmetic products and is the assignee of U. S. Patent 7,467,908 and its foreign counterparts, which discloses and claims a single-chambered airless metered dose dispenser, (hereinafter the "Pen"). Mr. Frank Francavilla was, and is, LPG's owner and President. Mr. Francavilla started

the business in 1990, after being employed by Becton Dickinson in its packaging research group for many years.

The Claimant, Achelios Therapeutics, Inc., (hereinafter “Achelios” or “Claimant”) purports to be a pharmaceutical development company that is engaged in, among other things, developing topically-delivered pharmaceutical products for the treatment of migraines and other conditions associated with pain and inflammation. Achelios is a Delaware corporation with a principal place of business located at 6340 Quadrangle Drive, Chapel Hill, North Carolina, and is also an affiliate of Exodos Life Sciences Limited partnership (“Exodus”) a Delaware limited partnership located at the same address. Crist J. Frangakis (“Dr. Frangakis”) was, and is, Achelios’ Chief Executive Officer and President. Dr. Frangakis contends that he has been the managing partner of Exodus since 2009 and the President & CEO of Achelios since 2012. Prior to these dates, Frangakis had been employed in various roles in the pharmaceutical industry since 1981.

ARBITRATION CLAUSES OF THE AGREEMENTS

This Arbitration proceeding arises from two separate agreements, each with a different Arbitration Clause.

Article 11.2 of the License and Supply Agreement, dated 3 February 2012, (hereinafter, “the LSA”) provides, in pertinent part, that

“[t]he Parties agree that all disputes arising under this Agreement shall be determined in accordance with the laws of the State of New Jersey If the parties have not been able to reach agreement regarding any dispute under this Agreement, the matter may be finally settled by arbitration, by which each party hereto is bound. The arbitration will take place in Sparta, New Jersey and be administered by the American Arbitration Association pursuant to the Commercial Arbitration Rules, except as expressly provided below.

... Within ten (10) business days after the arbitrator is selected, each party shall submit to the arbitrator that party's proposed resolution of the dispute and justification therefor. The arbitrator shall, within ten (10) business days after receiving the proposed resolution from each party, select one of the proposals, and such selection shall be deemed to be the arbitrator's conclusive decision and shall be binding upon the parties. Unless otherwise provided for in the arbitral award, each party shall be responsible for its own attorney's fees and costs incurred in connection with the arbitration."

The second Agreement between the parties, a Clinical Supply and Quality Agreement, effective 18 June 2012 (hereinafter, "the CSQA"), provides in pertinent part, per Article 21.2, as follows:

"Any controversy or claim between the Parties ... be determined by arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA")...(a) ...such arbitration may be conducted by a single mutually agreeable arbitrator... (e) Unless otherwise mutually agreed in writing by the Parties, the venue shall be San Francisco, if initiated by LPG or San Diego, if initiated by Achelios."

The parties, at the Preliminary Hearing, as confirmed by the undersigned in writing, did mutually agree to the arbitration being heard in Sparta, New Jersey, and to both sets of claims being heard and determined by a single arbitrator, the undersigned.

Further, since the parties could not mutually agree upon a format for evidence presentation for the arbitration procedure, it was determined by the undersigned Arbitrator, and confirmed by the parties at the Preliminary Hearing, to present the evidence in support of the claims pertaining to the License and Supply Agreement in written form, and present the evidence in support of the claims under the Clinical Supply and Quality Agreement via oral testimony at the Hearing on July 16, 2014 held at Respondent's attorney office.

BACKGROUND

During the 2011 development activities for the new formulation of ketoprofen being developed by Exodos, Dr. Frangakis became aware of the Pen from an internet search, and contacted Mr. Francavilla regarding the possible use of the Pen as a dispensing device for the new formulation. On or about 13 April 2011, LPG and Exodos entered into a Confidentiality Agreement in order to enable each of their representatives to provide each other with data and information regarding a possible arrangement regarding the Pen.

LETTER OF INTENT 20 July 2011

The discussions under the Confidentiality Agreement led to LPG and Exodos, on or about 20 July 2011, entering into a Letter of Intent (hereinafter “LOI”) in connection with the Pen. The LOI proposed the use of LPG’s stock Pen as a dispenser to deliver a patented formulation of ketoprofen under development by Exodos. The LOI provided that the parties would commence diligent good faith negotiations for a final Definitive Agreement containing the terms and provisions consistent with those set forth in Exhibit A of the LOI. Both parties would use best efforts to enter into a Definitive Agreement no later than 21 January 2012 or the LOI would terminate. The LOI provided that Exodos could transfer its rights under the LOI to a controlled affiliate and that such party “may be the party that enters into the Definitive Agreement.”

Paragraph 1 of the LOI further provided that initial limited exclusivity fee of \$50,000 was in consideration of an exclusive license to use the Pen and LPG’s associated intellectual property for a period of six months for the date of the LOI. It also provided that “Exodos shall pay \$150,000 upon the delivery by LPG of all components in form satisfactory to Exodos needed to

commence IND-enabling Stability and Functional Testing for the Product.” Paragraph 2 provided for an order of an unspecified number of stock Pens to Exodos, in order for Exodos to perform preliminary stability and functional testing of the Pens, and Paragraph 3 further provided that upon receipt of stock Pens from LPG, Exodos would use “commercially reasonable efforts to commence preliminary compatibility studies, the commercial development of the Product (including necessary R&D , Quality, Manufacturing, *etc.*) and agrees to provide, subject to the Confidentiality Agreement, all necessary technical content required to allow the manufacturing process to advance for commercialization of the Pen.”

Paragraphs 1-12 of the LOI were set forth as binding provisions.

Achelios states, and LPG affirms, that the \$50,000 limited exclusivity fee was paid by Exodos. Dr. Frangakis’s Declaration provides evidence that the \$150,000 was paid, and LPG provides no evidence to the contrary. Further, Article 5.1 of the LSA (see below), signed on behalf of both Achelios and LPG by each of their respective representatives, Dr. Frangakis and Mr. Francavilla, specifically acknowledge that all LOI payments had been made. However, the LSA, in Article 5.1, characterizes the LOI payments as “\$200,000 exclusivity fee provided for in the LOI.”

THE LICENSE AND SUPPLY AGREEMENT DATED 3 February 2012

The LSA was executed between LPG (the Licensor) and Achelios (the Licensee), as an affiliate of Exodos. It provided to Achelios “an exclusive, assignable worldwide license under the Licensed Intellectual Property to develop, seek regulatory approval for, make, have made, use, market, sell, offer to sell and import Products and to use, disclose and otherwise exercise

any and all other rights with respect to the Licensed Intellectual Property in connection with the foregoing” and further specified that “LPG shall not supply airless metered dose dispensers to any third party for use with, or grant any third party rights under the Licensed Intellectual Property to use such dispensers with, any non-steroidal anti-inflammatory drug for use in the Field.”

The LSA, in Article 4.1, also specified that “[f]rom time to time, LPG may, at the request of Licensee, perform services to customize Pens for use as a component of a Product or otherwise assist Licensee with the development of a Product. Prior to performing any such services, the Parties will collaborate to develop a Statement of Work, describing the activities to be performed by the parties and the terms and condition of such efforts.”

Further, in Article 4.3, the LSA provided that “[s]ubject to the terms and conditions of this Agreement, LPG agrees to supply to Achelios ... the Pens for use in clinical development. Such Pens shall be suitable for use in ... the relevant pre-clinical or clinical trials. ... LPG shall use reasonable efforts to fulfill any order as soon as practicable, this includes primary packaging of the empty Pen Only. Not covered by this agreement are any secondary packaging, decoration or contract filling requirements.”

Article 5.1 of the LSA states that “[t]he parties acknowledge that Exodos has paid to LPG \$200,000 exclusivity fee provided for in the LOI. Additionally, LPG acknowledges that Exodos has paid to LPG in full satisfaction of Exodos’ obligation related to expenses associated with supplying Pens on or before the Effective Date.”

Article 5.2 of the LSA lists several development milestone events which trigger payments, including \$50,000 due at “signing [*sic*] of this agreement” and a further \$150,000 due

at “Initiation and delivery of Pens for Phase I for human clinical trials pursuant to an approved IND.” Still further, it provides a \$200,000 milestone, payable in two installments of \$100,000 each, for initiation and delivery of pens- For Phase IIa human clinical trials, “the first \$100,000 due upon delivery of the Pens ordered for use in the Phase IIa trial and the second \$100,000 due upon dosing the third patient in such clinical trial.”

On 20 May 2012, James Yeager of Midwest Research Laboratories sent Mr. Francavilla samples of the placebo cream and the 5% and 10% ketoprofen creams to test in the Pens. On 21 May 2012, Mr. Francavilla acknowledged receipt of the materials, and advised that the samples were adequate for LPG to conduct their initial performance studies of the Pens. On 5 June 2012, Kelly Shiau, an LPG consultant, circulated an email attaching a power point presentation entitled “Placebo, Ketoprofen 5%, Ketoprofen 10% Preliminary Test Results.” The presentation showed the test results for Pens dispensing the three formulations. [Paragraphs 26-28 (pages 4-5) of the Declaration of Crist J. Frangakis, Ph.D.]

Shortly thereafter, LPG modified the Pens to adjust the dosing for all three formulations, and on 26 June 2012, circulated a second power point presentation with test results using the modified Pens. The second power point represented that the Pens were suitable for use with all three formulations. [Paragraphs 31-33 (page 5) of the Declaration of Crist J. Frangakis, Ph.D.]

CLINICAL SUPPLY AND QUALITY AGREEMENT DATED 18 JUNE 2012

On 18 June 2012, the Parties, together with Axcentia, executed a Clinical Supply and Quality Agreement (hereinafter, “the CSQA”). Therein, the parties agreed that “Axcentia would manufacture Product for Achelios for clinical pharmaceutical purposes, as set forth

herein.” (Recitals, paragraph II). Although the heading on page 1 of the CSQA refers only to Achelios and LPG as parties to the CSQA, representatives of each of Achelios, LPG and Axcentria each signed the CSQA on page 17, and the representatives’ initials appear on each page of the CSQA.

Paragraph 2.1 of the CSQA, as well as its Appendices I, II and III provide that “LPG via Facility shall manufacture Product for Achelios.” “Facility” means an Axcentria manufacturing establishment maintaining a current FDA Establishment Registration and located at 306 Keystone Drive Telford, PA 18969.”

On 20 June 2012, LPG issued its Invoice No. LPG-1281 for provision of Ketoprofen-filled Pens and for testing the stability of the Pens. The Invoice further provided that it was for the “Initial Deposit/Payment on Clinical Supply of 3 ml Pens” and further, that “50% Deposit is due with PO. (59,500.00).”

The CSQA originally provided that the Ketoprofen cream would be manufactured by Axcentria, and filled into the Pens by Axcentria. Further, the contract originally provided that the API (ketoprofen), other ingredients, and the batch records from Midwest Research Laboratories would all be provided to Axcentria and LPG for their use in manufacturing the initial batches of Ketoprofen cream for filling the Pens. The Pens would then be used for (a) stability studies; and (b) clinical supplies.

According to the evidence presented at the 16 July 2014 Hearing, these contract terms were very quickly ignored since they were found to be impossible. Achelios did not have the properly approved IND to import the ketoprofen API into the United States, and instead the procurement of the Ketoprofen API fell to Axcentria, who had the proper certifications to import

the Ketoprofen API. As explained by Mr. Francavilla at the Hearing, he felt obliged to assist Achelios, since his supply agreement and potential milestones under the LSA were at risk if the clinical studies never took place.

SUMMARY OF ACHELIOS'S CLAIMS:

Achelios asserts that it is entitled to an award of **\$556,243.00** in the Arbitration pursuant to the LSA and/or the CSQA which consists of the following amounts:

1) \$200,000.00 Refund of the payment by Exodos/Achelios of the payment for the exclusivity Period under the LOI, 4th/last payment, paid 19 January 2011.

[Exhibit 18 of the Declaration of Crist J. Frangakis, Ph.D.]

2) \$50,000.00 Refund of the payment of the execution fee for the LSA, paid 21 February 2012 [Exhibit 20 of the Declaration of Crist J. Frangakis, Ph.D.]

3) \$58,150.00 Refund of the payment for the initiation of Pen manufacturing, paid **29 March 2012**

[Exhibit 23 of the Declaration of Crist J. Frangakis, Ph.D.]

4) \$4,033.00 Refund of the payment for the pouches, paid **2 July 2012**

[Exhibit 21 of the Declaration of Crist J. Frangakis, Ph.D.]

5) \$9,810.00 Refund for Pen modifications, paid **10 July 2012**

[Exhibit 10 of the Declaration of Crist J. Frangakis, Ph.D.]

6) \$24,750.00 Refund of the payment by Achelios for completion of the initial payment order, paid **1 August 2012**

[Exhibit 22 of the Declaration of Crist J. Frangakis, Ph.D.]

7) \$150,000.00 Refund of the payment for Phase I Milestone under the LSA, paid **16 August 2012**

[Exhibit 22 of the Declaration of Crist J. Frangakis, Ph.D.]

8) \$59,500.00 Refund of the amount paid as a deposit on the filled Pens and stability studies which were supposed to have been done by Axcentria per Invoice LPG-1251 issued under the CSQA, paid **26 June 2012**. [Claimant's Exhibit 3 presented at the Hearing 16 July 2014]

ACHELIOS' CLAIM FOR \$200,000 PAID UNDER LOI

This claim is denied.

As evidenced by Article 5.1 of the LSA, this payment was intended as payment of the option for an exclusive period of time to evaluate the Pens and to prevent LPG from granting a license under its patents to another party. The value of the option and the prevention of LPG from finding another partner for its patented Pen was clearly realized by Achelios. To refund these monies would deny LPG its compensation for withholding its patent from others who could/would have commercialized such a dispenser in the pain relief field.

It is noted that the LOI characterizes the payments somewhat differently, but the integration clause of the LSA, Article 11.3, notes that "[t]his Agreement... supersedes any and all oral and/or written communications or understanding related to the subject matter hereof, specifically including the LOI which is expressly superseded by the Agreement..."

ACHELIOS' CLAIM FOR THE \$50,000 LSA EXECUTION FEE

This claim is denied.

The contract was entered into in good faith, and there is clear language, *inter alia*, in Article 4 of the LSA, that indicates the development nature of the Product. Article 4.1 provides for development services to be rendered, and for LPG to “use commercially reasonable efforts to accommodate any such request” relating to any Statement of Work agreed upon by the parties. In the Article 6 “Representations and Warranties” section, there is no warranty/representation regarding the suitability of the Pens for the purpose to which Achelios wished to put them, and in fact, one finds only the typical disclaimer of any additional representation/warranty, “including any warranty of merchantability or fitness for a particular purpose.”

Still further, Article 5.1 of the LSA acknowledges that “Exodos has paid LPG in full satisfaction of Exodos’ obligation related to expenses associated with supplying Pens on or before the Effective Date,” confirming the language in the LOI that LPG would supply Pens to Achelios during the option period of the LOI for Achelios to test for suitability. Achelios’ representative, Dr. Frangakis, was no novice to the pharmaceutical development field and its typical licensing terms/conditions, and was represented by thoroughly competent counsel. It is simply not credible that Achelios entered into the LSA without having performed some of its own testing on the Pens for their possible suitability as a dispensing device for its Product, and having done so, voluntarily chose to proceed with the LSA. Development of pharmaceutical products fail for various reasons, and Claimant here assumed the risk that this Agreement might not result in a successful Product.

ACHELIOS CLAIM FOR \$9,810.00 PAID FOR PEN MODIFICATIONS

This claim is denied.

Claimant provided five Declarations (Beasley, Horstmann, Yeager, Toret and Gwozdz) which provide evidence that the Pens supplied to Achelios did not function properly and did not dispense uniform doses. However, none of these declarants provide any evidence as to whether the modifications by Respondent LPG were the cause of the malfunctioning Pens. Each of the declarants focus on the fact that the Pens supplied were not uniform in their weights and in the type of spring being utilized, which caused their performance to behave erratically and/or to dispense doses which were not uniform, and which were therefore unsuitable their intended purpose, *i.e.*, the Pens were not suitable for use in preclinical or Phase I Clinical Trials.

The only evidence presented dealing with the issue of the Pen modifications is that of Dr. Frangakis. This evidence simply acknowledges that the Pens were modified to adjust dosing, and that LPG retested all three formulations (placebo, 5% and 10% formulations) and “the modified Pens passed LPG’s tests for all three formulations.” [Paragraphs 32-33 (page5) of Declaration of Crist J. Frangakis, Ph.D.]

It is rather strange that Achelios made its initial order and payment for Pens under the LSA on 29 March 2012, when preliminary testing by LPG was not reported with the MRL formulations until the 5 June 2012 report was issued by Kelly Shiau. [Paragraphs 26-28 (pages 4-5) of Declaration of Crist J. Frangakis, Ph.D.]

The invoicing for the Pen modifications does not specify a date when the work was done, but Claimant’s evidence is that “LPG modified the Pens to adjust the dosing for all three formulations, from 0.15mL/click to 0.13 mL/click” sometime between 5 June and 26 June 2012. [Paragraphs 28-31 (page5) of Declaration of Crist J. Frangakis, Ph.D.] Again, I find it unusual to place an order for materials to be used in a Clinical Study when the parameters of the device are still being modified but if Claimant was not satisfied with the Pen performance when the invoice for the modifications was issued, the obvious action would have been to contest the bill by notification to LPG. This was not done; instead, Achelios paid the invoice, with the implication that it was satisfied with the work.

ACHELIOS CLAIM FOR PEN MANUFACTURING AND SUPPLY THEREOF (\$58,150.00 + \$4,033.00 + \$24,750.00 = \$86,933

This claim is granted for the full amount of \$86,933.00.

Ample evidence has been presented by the Claimant that the Pens ordered and supplied were not suitable for use in Phase 1 Clinical Studies. As pointed out in the succinct declaration of P. Douglas Kirven, Ph.D., his testing of 119 of the Pens clearly establishes that dispensing devices with such variance were in no way suitable for use in clinical trials and were not in compliance with cGMP dosing requirements. Other declarants itemized the structural and functional variations among the pens and noted that these variations rendered the Pens unsuitable for use in pre-clinical or clinical studies.

The LSA clearly contemplated a development phase of work prior to supply of the Pens for clinical studies, and the later signing of the CSQA covers further necessary preclinical development work. Notwithstanding the fact that preclinical development had not been completed – for instance, the necessary stability studies with the filled Pens, once orders were placed for Pens, LPG was obligated, in accordance with Article 4.3 of the LSA, to supply unfilled Pens “suitable for use in, and ordered in quantities appropriate for the relevant pre-clinical or clinical trials.”

Especially noteworthy was the notation by declarant Horstmann that, despite the weight and spring size differences, the “pens were all of the same manufacturer’s lot number and are mixed together somewhat randomly.” This evidences that the supplied pens would not even be utilizable for preclinical stability studies, since they obviously varied in composition despite purporting to be from the same lot number, which could impact stability. [Declaration of Ralph Horstmann, Paragraph 17, page 3]

Further, Respondent produced no evidence whatsoever that the Pens supplied to Claimant met “Specifications, cGMPs, the FD&C Act and all other material Laws” in accordance with Article 6.3(a) of the LSA, even though it sought and was granted access to some of the delivered Pens. At the minimum, one would have expected LPG to put in evidence of an agreed-upon set of Specifications when the initial Pen order was place, and no evidence in this regard was produced by either party.

ACHELIOS CLAIM FOR REFUND OF PHASE I MILESTONE OF \$150,000.

This claim is granted for the full amount of \$150,000.

For the reasons enumerated under the previous claim for supply of the Pens, this Claim is granted. Despite the fact that necessary preclinical work was yet to be done, Respondent did not supply the empty (unfilled) Pens to Claimant that could be utilized in the Phase 1 Clinical Study, irrespective of whether the formulation was the same as, similar to or completely different from that earlier provided to Claimant, in breach of its obligation to do so.

ACHELIOS CLAIM FOR REFUND OF DEPOSIT PAID FOR WORK UNDER CLINICAL SUPPLY AND QUALITY AGREEMENT OF \$59,500

This claim is granted for the full amount of \$59,500.

Respondent admitted that he did not pay Axcentria any of the monies received as a deposit for Invoice LPG-1281, dated 20 June 2012. David Singh of Axcentria testified that when he asked about payment for his work in December 2012, he was told by Mr. Francavilla that even if he submitted an invoice, LPG did not have the funds to pay it.

COUNTERCLAIM OF LPG UNDER THE LSA

COUNTERCLAIM FOR \$100,000 MILESTONE PAYMENT FOR PHASE IIA STUDY INITIATION

This counterclaim is denied.

LPG has asserted that it was due the first part of the \$200,000 milestone, payable in two installments of \$100,000 each, for initiation and delivery of pens- For Phase Iia human clinical trials, the first \$100,000 due upon delivery of the Pens ordered for use in the Phase Iia trial pursuant to Article 5.2 of the LSA.

Exhibit 15 of the Frangakis declaration is a copy of a self-serving email which purports to memorialize a 17 December 2012 conversation between Francavilla and Frangakis where they

agreed that the Phase IIa trial Milestone Pens had not yet been ordered/delivered, and therefore this milestone had not yet been triggered. Respondent did not provide any evidence that this email was refuted in writing or orally, but Paragraph 40 of the Certification of Frank Francavilla refers to Exhibit 9 [*sic*, Exhibit 10] which is purportedly an email between the parties dated 14 February 2012 wherein Mr. Francavilla is questioning the use of the 5000 Pens ordered by Mr. Frangakis, and is asking what this order will be used for. Dr. Frangakis replies that “the Pens may be used in phase 1b” and further, that “the pens will be used for ongoing stability studies, with the clinical to support the Phase 2a and subsequent phases” evidencing that Dr. Frangakis was potentially intending to use these Pens in furtherance of the Phase IIa study.

However, the language of the LSA is: “Initiation and delivery of pens – For Phase IIa human clinical trials Estimated date of 3-15-13.” While the language is somewhat unclear, it appears that intention was that the Phase IIa human clinical trial would need to be **initiated** for this milestone to be triggered. Indeed, it would not make sense for the delivery of the container to trigger a milestone which would need to be preceded by submission of an extensive list of data and reports to the FDA, including a report detailing the completion of the Phase I safety study in humans. Any other interpretation of this Milestone in the LSA is simply not credible in that an IND holder would not offer to pay a milestone based upon delivery of the containers/dispensers for its drug formulation when the results of stability studies in the containers were not available (and apparently, as of the date of the order of the Pens from LPG, had not yet been begun due to issues with filling the drug formulation into the Pen). Lastly, although neither party produced any order records specific to this initial order of Pens, the 3000 number mentioned in the 20 June 2012 email between Frangakis and Francavilla and the Invoice #LPG-11281 would seem to be

too low to have been an order for both the preclinical stability studies and the Phase I trial, and the Phase IIa trial.

COUNTERCLAIM OF LPG UNDER CSQA FOR \$83,662.50 FOR ITS CONSULTING WORK

This counterclaim is also denied.

The second part (or alternative) of Respondent's counterclaim is a claim for compensation for services expended on behalf of Claimant in the amount of \$83,662.50 for its consulting services enumerated in Exhibit 11 of the Francavilla Declaration.

It is to be noted that the listing in Exhibit 11 contains no dates for any of the services by the LPG employees and is supported by no substantive or time documentation for most of the entries.

A careful reading also indicates that the first two pages of the list include entries for work conducted prior to the signing of the CSQA. Any of this work prior to the CSQA signing would have to fall under the LSA since that was the only agreement in place between the parties. Consequently, such work should have been covered by a Statement of Work (SOW) as required under Article 4.1 of the LSA, which requires the SOW to be in writing, and the subject of "mutual written agreement." No written evidence, except for the listing, was provided by LPG, and no "mutual written agreement" was produced as to any of the work before the CSQA was signed.

With respect to the listing of work conducted after the execution of the CSQA, LPG has produced nothing in writing which evidence of the agreement of Achelios to these "services,"

and, although there are allegations that various Achelios' parties requested the work, such requests were not produced in evidence. The testimony of Mr. Francavilla indicated that these services were in excess of what had been contemplated when LPG entered into the agreements, but such circumstances, even if true, do not entitle LPG to simply prepare a listing and consider it as a contract addendum for which it is entitled to payment. Mr. Francavilla admitted during the Hearing testimony that he was "marking up" the services of Axcentria in his invoicing to Achelios, so that LPG was being compensated for its work in acting as "middleman" for Axcentria. Assuming that Axcentria completed the work that was being billed for, LPG would have been entitled to this mark-up amount for its services under the CSQA. However, no evidence was provided as to what this amount was, or should have been.

Mr. Francavilla also testified that he did not pay Axcentria from the funds provided by Achelios because Axcentria did not present him with an invoice for those services. However, he also admitted that he told Axcentria that he couldn't pay the invoice, even if it were presented, necessitating Axcentria to seek payment directly from Achelios.

CONCLUSION

A preponderance of the evidence supports the conclusion that Achelios is entitled to \$300,677.00 from LPG which consists of:

- (1) Monies paid for Pen manufacturing and supply (including payment for foil pouches) in the amount of \$ 86,933;
- (2) Refund of Phase I Milestone payment in the amount of \$150,000; and
- (3) Refund of deposit paid for work under Clinical Supply and Quality Agreement in the amount of \$59,500.

(4) Interest in the amount of \$4,244.00 which is calculated from 28 April 2013 (60 days from the 28 February 2013 Notice of Material Breaches sent by Claimant) through the date of this Award (28 July 2014).

By a preponderance of the evidence, the conclusion is also reached that LPG is not entitled any monies under either of the counterclaims asserted under the LSA and/or the CSQA.

AWARD

Claimant is awarded \$300,677.00 on its demand.

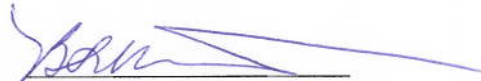
Respondent is awarded \$0.00 on its Counterclaims.

Accordingly, I Award as follows:

1. Respondent shall pay to Claimant the net sum of **\$300,677.00**
2. The administrative fees of the American Arbitration Association totaling \$13,550.00 and the compensation of the Arbitrator totaling \$9,330.00 shall be borne as incurred.
3. All the expenses of the Arbitration, including attorneys' fees, shall be borne by the party incurring them.

The undersigned, having accepted appointment of this matter and having been sworn and having agreed to fairly and honestly decide the matter in accordance with the Parties' Agreements and the Rules of the American Arbitration Association, has entered this Decision and made this Award to the best of my ability and understanding. This Award is in full settlement of all claims and counterclaims submitted to this Arbitration. All claims not expressly granted herein are hereby denied.

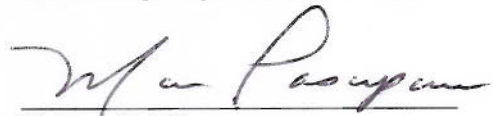
August 7, 2014


Barbara L. Renda

State of New Jersey)
 SS:
County of Morris)

On this 7 day of August, 2014, before me personally came and appeared Barbara L. Renda, to me known to be the individual described in and who executed the foregoing instrument and she acknowledged to me that she executed the same.

August 7, 2014
Date


Notary Public
My commission expires:



Maureen Pasapane
Notary Public of New Jersey
My Commission Expires 6-3-2015