IN THE CIRCUIT COURT OF THE NINTH JUDICIAL CIRCUIT
IN AND FOR ORANGE COUNTY, FLORIDA
GENERAL JURISDICTION DIVISION

SYNOGEN MANAGEMENT
GROUP, INC.,

and

CASE NO.: 2019-CA-012605-O

NEXTGEN BIOLOGICS, INC.,

Movants,

v.

ISE PROFESSIONAL TESTING &
CONSULTING SERVICES, INC.,

Respondent.
_____/

EMERGENCY MOTION TO CONFIRM ARBITRATION FINAL AWARD

Movants Synogen Management Group, Inc. ("Synogen") and NeXtGen Biologics, Inc. ("Nextgen") respectfully move this Court for an Order confirming the Final Award issued in the Arbitration between Synogen and Nextgen, as claimants, and ISE Professional Testing & Consulting Services, Inc. ("ISE"), as respondent, Case No.: AAA 01-19-0002-3786 (the "Arbitration"), and the entry of judgment in favor of Synogen and Nextgen and against ISE.

NATURE OF THE ACTION

1. This is a motion to confirm the Final Award ("Award") issued in an arbitration conducted in Orlando, Florida under the rules of the American

Arbitration Association ("AAA"), between Synogen and Nextgen, as claimants, and ISE, as respondent. The Final Award in the Arbitration was issued on December 3, 2019 by empaneled Arbitrator Catharine Biggs Arrowood. The twenty-eight page Final Award is reasoned, and finds in favor of Synogen and Nextgen and against ISE on all claims. The Award is final and enforceable under Section 9 of the Federal Arbitration Act ("FAA").[1] A true and correct copy of the Final Award is attached as Exhibit "A".

THE PARTIES

2. Movant Synogen Management Group, Inc. is a Florida corporation, with a focus in the tech, med-tech and biotech industries. Synogen's principal place of business is 101 SE 2 Place, Suite 201-B, Gainesville, FL 32601. Synogen is a party to a License Agreement with Respondent ISE, made effective September 23, 2014 ("License Agreement"). A true and correct copy of the Synogen-ISE License Agreement is attached as Exhibit "B".

3. Respondent ISE Professional Testing & Consulting Services, Inc. is a Florida corporation controlled by its principal and President, Ryanne Early. ISE holds a number of patent applications relating to bio-regenerative growth technology, specific to non-mammalian tissue. These patent rights are at center of

[1] In the alternative, the Award is also final and enforceable under the Florida Arbitration Code. See below Section B of Memorandum of Law.

the Synogen-ISE License Agreement. See generally Ex. B. ISE's principal place of business is 2785 S Bay Street, Suite G, Eustis, FL 32726.

4. Movant NeXtGen Biologics, Inc. is a Delaware corporation with principal place of business at 13709 Progress Blvd., Box 11, Alachua, FL 32615. Nextgen is a party to a Sublicense Agreement with Synogen, made effective October 14, 2014, under which Nextgen is granted certain rights under the prime Synogen-ISE License Agreement. A true and correct copy of the Synogen-Nextgen Sublicense Agreement is attached as Exhibit "C".

JURISDICTION AND VENUE

5. This Court has jurisdiction over these proceedings under the Federal Arbitration Act (9 U.S.C. § 9), and to the extent the FAA is not applicable, the Florida Arbitration Code (Fla. Stat. § 682.181), as the Arbitration was venued in this state and the Final Award was issued in the Ninth Judicial Circuit.

6. This Court has personal jurisdiction over Respondent under Fla. Stat. §§ 48.193 (1)(a) and (7), and because Respondent consented to arbitration in Florida, which Arbitration is at center of this motion to confirm an award.

7. Venue is proper in this Court under 9 U.S.C. § 9, and Fla. Stat. § 682.19, as the Arbitration was venued, and the Final Award was issued, in this judicial district.

STATEMENT OF OPERATIVE FACTS

A. The Parties' Agreements

8. The Arbitration arises from the License Agreement between Synogen and ISE, executed October 16, 2014 and made effective September 23, to which Nextgen is a third party beneficiary. See Ex. A at ¶¶ 12-13, 22; see generally Exs. "B" and "C".

9. Under the Synogen-ISE License Agreement, Synogen contracted for: (i) an exclusive license to certain patent rights (i.e., Licensed Patents); and (ii) a non-exclusive license to a trade secret process technology or decellularization process (i.e., Licensed Know-How). See Ex. A at ¶ 14; Ex. B at §§ 1.7, 2.1.

10. Further, under the License Agreement, Synogen maintains the right to prosecute the Licensed Patents, and ISE must cooperate in Synogen's patent prosecution efforts. See Ex. A at ¶ 18; Ex. B at § 9.

11. In accordance with the License Agreement, Synogen executed a Sublicense Agreement with Nextgen, made effective October 14, 2014, under which Synogen granted to Nextgen certain rights under prime licenses. See Ex. A at ¶ 22-25; see generally Ex. C.

12. Nextgen is a third-party beneficiary to the Synogen-ISE License Agreement. Id.

13. Section 13 of the License Agreement requires arbitration of disputes arising out of the agreement, in relevant part:

> 13.2 All controversies, claims, demands or disputes arising out of or relating to this Agreement will be resolved by arbitration by a neutral arbitrator. To initiate this process, the Party requesting arbitration must send the other Party written notice demanding arbitration (the "Demand").
>
> 13.3 The arbitration will be governed by the rules of the American Arbitration Association ("AAA") . . . The arbitrator will be selected by mutual agreement of the parties within fifteen (15) days of the Demand being sent. The arbitrator must be an attorney with a background in intellectual property and human biologics. In the event that the Parties are unable to agree to the name of an arbitrator within fifteen (15) days of the Demand being sent, then the case will be transferred to the AAA and selection of the single arbitrator will proceed according to the AAA's rules . . .

Ex. B at §§ 13.2 and 13.3.

B. The Dispute & Arbitration

14. Following execution of the License and Sublicense Agreements, Synogen, with Nextgen, developed a bio-regenerative growth product (NeoMatriX®), and moved the product towards market. Synogen and Nextgen carried all costs associated with the development and commercialization of the product, more than $7.5 million. More than $1.7 million of those costs were paid to Seed Biotech, Inc. ("Seed")—a company closely related to ISE at which Ryanne Early, the principal and President at ISE, is a principal and the CEO. See Ex. A at

¶¶ 28-31.

15. Despite Synogen and Nextgen's efforts and full compliance with the Parties' agreements, Respondent ISE wrongfully breached the License Agreement in repeatedly refusing to transfer the Licensed Know-How to Synogen, then unilaterally and improperly attempting to terminate the agreement without basis. See Ex. A at ¶¶ 35-43.

16. As a result, on July 31, 2019, Movants were forced to demand arbitration before the AAA, which Demand was amended on September 16, 2019 ("Amended Demand"). See generally a true and correct copy of the Amended Demand as Exhibit "D". In the Amended Demand, Movants' assert claims for, *inter alia*, breach of contract stemming from Respondent's (i) refusal to transfer the Licensed Know-How and (ii) failure to cooperate in, and interference with, Synogen's patent prosecution efforts. Id.

17. In response, Respondent ISE submitted an Answering Statement including ten counterclaims against Movants. See generally a true and correct copy of ISE's Amended Answering Statement as Exhibit "E".

18. On September 11, 2019, the Arbitrator and Parties conducted a preliminary hearing, following which Arbitration Order No. 2 (Corrected Scheduling Order) was issued. See generally a true and correct copy of Arbitration Order No. 2 as Exhibit "F". Arbitration Order No. 2 details the schedule of

deadlines in the Arbitration, and confirms the Parties' agreements to apply the FAA and Florida substantive law, and to conduct the final hearing in Orlando, Florida. See Ex. F at ¶¶ 1, 5 and Table of Deadlines.

19. However, rather than participate in the Arbitration in good faith, Respondent ISE employed a lengthy pattern of bad faith tactics, which included delay tactics and willful defiance of orders on the part of ISE, as well as ISE's counsel making intentional misrepresentations and taking furtive steps to undermine the arbitration. See e.g., Ex. A at ¶ 102 ("Regrettably, ISE has made clear throughout this proceeding that its schedule and convenience is the only one that matters and that it will ignore the rules and rulings of this process."); ¶ 103 (noting Respondent's prior counsel lied to a mediator and AAA concerning settlement); ¶ 106 (explaining in response to the Arbitrator reaching out to confirm Respondent was aware of deadlines, Respondent refused to reply and instead revoked consent to direct communication); ¶ 108 (noting despite issuing 14 document requests and receiving more than nineteen thousand pages of materials, including confidential and sensitive documents, Respondent refused to produce a single document despite repeated opportunities and warnings); fn. 2 (explaining Respondent's former counsel contacted the venue provider for the final hearing and "without notice to the AAA, the arbitrator, counsel for Claimants or Claimants, cancelled the arrangements for the hearing.").

20. Then, on October 4, 2019, Ryanne Early—principal and President at ISE—apparently as a settlement tactic, threatened to take actions against (i.e., undermine, abandon or invalidate) the patents at center of the Arbitration, if Movants continued to litigate their claims before the Arbitrator. Id. at ¶ 112. As a result, Synogen and Nextgen were forced to move for immediate injunctive relief in the Arbitration, which relief was granted. See id.; see also a true and correct copy of the Arbitrator's Injunctive Award as Exhibit "G". Without explanation, Respondent refused to comply with the Arbitrator's Injunctive Award. As a result, Movants were forced to confirm the Injunctive Award before this Court, then move for civil contempt as a result of continued noncompliance. See November 15, 2019 and November 26, 2019 Orders of this Court as Exhibits "H" and "I", respectively. It was not until this Court **held Respondent ISE in civil contempt** and ordered a hearing on sanctions, that Respondent ISE finally complied with the injunction **at the hearing on civil contempt sanctions**.

21. The final hearing in the Arbitration was held on October 23, 2019 in Orlando, Florida. In attendance for Synogen and Nextgen were: (i) Jamie Grooms, Chairman at Synogen; (ii) Jonelle Toothman, CEO at Nextgen; and (iii) attorneys John Huh, Scott Vernick and Janelly Crespo of DLA Piper. See Ex. A at ¶ 3. Movants submitted into evidence more than eighty (80) exhibits, including witness statements of Mr. Grooms and Ms. Toothman. Mr. Grooms and Ms. Toothman

presented under oath for questioning by Arbitrator Arrowood. Respondent ISE refused to attend. True and correct copies of the transcript of the Arbitration Final Hearing and Arbitration Exhibits are attached as Exhibits "J" and composite Exhibit "K", respectively.[2]

22. In all, Synogen and Nextgen submitted more than one hundred (100) pages of arguments and briefing to the Arbitrator. See e.g., true and correct copies of Synogen and Nextgen's Pre- and Post-Hearing Briefs, and Motion to Bar Respondent's Counterclaims as Exhibits "L", "M" and "N", all without exhibits, respectively.

C. The Arbitration Award

23. On December 3, 2019, the Arbitrator executed the Final Award, and the AAA issued the Award to the Parties. See Ex. A at p. 28 and cover letter; see also December 3, 2019 Email from AAA, a true and correct copy of which is attached as Exhibit "O".

24. The Final Award finds in favor of Synogen and Nextgen and against ISE on all claims and counterclaims, dismissing all counterclaims with prejudice.

25. The Award holds, in relevant part:

a. The Arbitrator finds in favor of Claimants Synogen Management Group, Inc. and Nextgen Biologics, Inc., and against Respondent ISE Professional Testing & Consulting Services, Inc. on all claims and counterclaims in this matter;

[2] For convenience of the Court and due to size, composite Exhibit K will be provided to the Court on a USB drive with a courtesy hard copy of the motion and exhibits.

b. The Synogen-ISE License Agreement . . . [is an] enforceable contract[] and remain[s] in full force and effect. Claimants hold the exclusive license to the Licensed Patents, and are permitted to practice the Licensed Patents;

c. Nextgen has the right at its sole option to survive the termination of the License Agreement by ISE and to enter a direct license with ISE on substantially the same terms contained in the License Agreement;

d. ISE is enjoined from breaching Section 5 of the License Agreement. Specifically, in accordance with § 5.2.1 of the License Agreement, ISE shall transfer promptly to Synogen, and not later than 10 business days from the entry of this Final Award, the Licensed Know-How and all information owned, controlled or otherwise in ISE's possession that may be relevant to the development of a commercially viable manufacturing process contemplated by the License Agreement; ISE is directed to otherwise cooperate with Synogen and Nextgen in the development of this process;

e. ISE is further prohibited from breaching the provisions of the License Agreement relating to the prosecution of the patents. Specifically, ISE is prohibited from directly or indirectly interfering with or impeding Synogen's prosecution and preparation of the Licensed Patents through counsel of Synogen's choice, and is directed to cooperate with Synogen and its counsel, including executing any documents deemed necessary by Synogen to enable its continued work on the patent prosecution and preparation;

f. Claimants are entitled to and ISE shall pay damages and interest as follows:

    i. Compensatory damages to be paid to Nextgen in the total amount of $867,683.95 (consisting of $653,683.95 for Claimants' costs to date in their attempt to create a manufacturing decellularization process without the Licensed Know-How and $214,000 for Claimants' costs to

date relating to marketing and sales efforts in anticipation of the product's launch);

ii. Interest at a rate of 6.33 percent per annum to accrue on this amount from the date of this Final Award till payment.

g. ISE's continued misconduct in this proceeding was in bad faith and warrants a full award of Claimants' attorneys' fees and costs to Claimants. This conduct appears to be an extension of ISE's effort to avoid the consequents of its contractual obligations without just cause after the Claimants here performed theirs;

h. Claimants are entitled to and ISE shall pay Claimants their reasonable attorneys' fees and costs relating to this Arbitration in the amount of $903,116.93. . . . ISE shall pay Claimant[s] for the AAA Fees and Arbitrator's compensation the amount of $74,598.67.

See Ex. A at ¶ 114 and pp. 27-28.

26. The Award requires payment of all amounts due to Synogen and Nextgen—totaling $1,845,399.55—"[w]ithin thirty days of the date of this Final Award", and transfer of the Licensed Know-How and related information to Synogen within ten business days. See Ex. A at 28.

27. Thirty days, and ten business days, have passed from execution and issuance of the Award. Still, Respondent ISE has not made any payment or any attempts to transfer the Licensed Know-How and comply with the Final Award of Arbitration.

28. The License Agreement providing for private arbitration among the Parties allows for direct appeal of the Award to the AAA only if "filed within

thirty (30) days of receipt of the award." See Ex B at § 13.6. On day thirty-one the Award is final and not appealable. Similarly, the AAA Optional Appellate Rules require any appeal be submitted within thirty days from the date of the underlying award. See AAA Optional Appellate Rules A-3(a)(i).

29. Respondent ISE did not notice its appeal of the December 3, 2019 Award within thirty days—i.e., on or before January 2, 2019.[3]

30. Accordingly, the Award is final and enforceable.

31. As a result of issuance of the Arbitrator's Final Award, the interim Injunctive Award issued by the Arbitrator and confirmed by this Court on November 15, 2019 is no longer effective and enforceable. See Ex. G at 5 ("This interim award remains effective until the Final Award is issued in this matter . . ."); see generally Ex. H.

32. The Final Award contains substantially similar injunctive relief, enjoining ISE "from directly or indirectly[] interfering with or impeding Synogen's prosecution and preparation of the Licensed Patents . . . ." See Ex. A at 27-28. However, this injunctive relief cannot be enforced by the Court until confirmed as a judgment. Meaning, the injunction does not yet have the power of the Court behind it.

[3] Consistent with its practices throughout these proceedings, Respondent ISE disregarded the thirty day deadline. Instead, Respondent submitted its Notice of Appeal on day thirty-one. However, this is insufficient to, and as a matter of law cannot, trigger the appeals process. The Award is now final and enforceable, as explained in Section C below.

33. Unfortunately, ISE has previously levied threats against the Licensed Patents, and taken steps to interfere with Synogen's patent prosecution rights, including by revoking a Power of Attorney issued to Synogen, without notice and during the pendency of the Arbitration centering on the very patent rights. See Ex. A at 48; see generally Ex. G.

34. And, as noted above, ISE has repeatedly willfully disregarded Arbitration Orders, and the Arbitrator's interim Injunctive Award and Orders of this Court.

35. Indeed, it required this Court holding ISE and its principal, Ryanne Early, in civil contempt for ISE and Early to comply with the interim injunction.

36. As a result, Movants have serious concerns Respondent will act in accord with its previous threats and take actions to harm and/or invalidate the patent rights awarded to Movants in the Final Award.

MEMORANDUM OF LAW

A. The Federal Arbitration Act Applies to this Motion

37. This Court has jurisdiction to confirm the Final Award under the Federal Arbitration Act and, to the extent the FAA is not applicable, the Florida Arbitration Code. "Federal courts and state courts have concurrent jurisdiction to enforce the [FAA]." Baltin v. Alaron Trading Corp., 128 F.3d 1466, 1469 (11th Cir. 1997).

38. "[T]he FAA does not confer subject matter jurisdiction on federal courts," which must "have an independent jurisdictional basis to entertain cases arising under the FAA." Id. In cases where there is no independent basis for federal jurisdiction (e.g., diversity or federal question), a state court may be called upon to apply the FAA, including in a motion to enforce an arbitration agreement or award. *See e.g.,* Visiting Nurse Ass'n of Fla., Inc. v. Jupiter Med. Center, 154 So.3d 1115, 1124-25 (Fla. 2014); Terminix Intern. Co., LP v. Ponzio, 693 So. 2d 104, 106 (Fla. 5th DCA 1997).

39. As between the FAA and Florida Arbitration Code, the Florida Supreme Court has held on no fewer than two occasions that the FAA takes precedence. See Visiting Nurse Ass'n of Fla., Inc., 154 So.3d at 1124–25 (Fla. 2014); Kong v. Allied Professional Ins. Co., 750 F. 3d 1295, 1303-04 (11th Cir. 2014) (holding that the FAA preempts the Florida Arbitration Code in a motion to compel arbitration).

40. Here, the Parties agreed, and the Arbitrator confirmed by Order, the Federal Arbitration Act applies to the Arbitration. See Ex. F at ¶ 1 ("The Federal Arbitration Act will apply in the Arbitration . . . .").

B. Under the Federal Arbitration Act, this Court Must Confirm the Award

41. The FAA instructs that "at any time within one year after [an arbitral] award is made any party to the arbitration may apply to the court . . . for an order

confirming the award, and thereupon the court must grant such an order unless the award is vacated, modified, or corrected as prescribed in sections 10 and 11 of this title." 9 U.S.C. § 9 (emphasis added).

42. The Award has not been vacated under 9 U.S.C. § 10, or modified or corrected under 9 U.S.C. § 11, and cannot be.

43. The grounds for vacating and modifying an arbitral award are incredibly limited, and the standards for doing so are exceptionally lofty. See AIG Baker Sterling Heights, LLC v. Am. Multi-Cinema, Inc., 508 F.3d 995, 1001 (11th Cir. 2007) ("[J]udicial review of arbitration decisions is among the narrowest known to the law.").

44. In fact, a court considering confirmation must presume an arbitration award will be confirmed as drafted. See B.L. Harbert Int'l, LLC v. Hercules Steel Co., 441 F.3d 905, 909 (11th Cir. 2006). And, notably, "[a]rbitrators have no obligation to the court to give their reasons for an award." United Steelworkers of Am. v. Enter. Wheel & Car Corp., 363 U.S. 593, 598 (1960); Wiregrass Metal Trades Council AFL-CIO v. Shaw Envtl. & Infrastructure, Inc., 837 F.3d 1083, 1090 (11th Cir. 2016) ("Arbitrators usually are not required to include explanations, much less detailed ones, and they often do not."); Cat Charter, LLC v. Schurtenberger, 646 F.3d 836, 844 (11th Cir. 2011) ("Generally, an arbitrator need not explain her decision.").

45. As a corollary to this point, when the court can identify any plausible reason for an arbitrator's award, whether or not stated, the court must resolve any ambiguity by finding the award is proper. See Wiregrass Metal, 837 F.3d at 1091-92 ("[W]hen it is not apparent from the arbitrator's stated reasoning (or lack thereof) whether she permissibly interpreted [the] agreement or impermissibly modified it, and one can plausibly read the award either way, the court must resolve the ambiguity by finding that the award is an interpretation of the contract and enforcing it.").

46. Here, the Arbitrator's twenty-eight page Final Award is detailed and reasoned. There can be no reasonable argument the Award should be vacated and/or modified.

47. Accordingly, as this Motion is filed before this Court within one year of the date of the issuance of the Final Award dated December 3, 2019, respectfully, the Final Award must be confirmed.[4]

[4] The same is true under the Florida Arbitration Code. Like the FAA, under the Florida Arbitration Code, short of vacating or modifying an arbitral award, the award **must** be confirmed on motion by a party. See Fla. Stat. § 682.12. And, like the FAA, under Florida Arbitration Code, the grounds for vacating and modifying an arbitral award are incredibly limited, and the standards for doing so are exceptionally lofty. See e.g., Della Penna v. Zabawa, 931 So. 2d 155, 160 (5th DCA 2006) (confirming arbitral award and finding Florida Arbitration Code recognizes essentially identical grounds for vacating an award as the FAA, and if a statutory ground is not proven, the award must be confirmed); District School Bd. Of St. Johns Cty. V. Timoney, 524 So. 2d 1129, 1130-31 (5th DCA 1988) (holding that a "high degree of conclusiveness" attaches to an arbitration award and that the standard of review applied to arbitration awards is very limited); Wells v. Castro, 117 So. 3d 1233, 1238 (Fla. 3d DCA 2013) (noting judicial review of arbitral awards is incredibly limited and cannot be reversed for application of incorrect standards or errors of law).

C. The Award is Final and Enforceable

48. Under the License Agreement, the Parties agreed the decision of the Arbitrator shall become final and binding "after the time for filing the notice of appeal pursuant to the Appellate Rules has expired." See Ex B at § 13.6.

49. Under the Agreement, the time for filing the notice of appeal of the Award to the AAA is "within thirty (30) days of receipt of the award." See Ex B at § 13.6. Similarly, the AAA Optional Appellate Rules require any appeal be submitted within thirty days from the date of the underlying award. See AAA Optional Appellate Rules A-3(a)(i).

50. Accordingly, on day thirty-one the Award is final and binding, and not appealable.

51. Respondent ISE did not notice its appeal of the December 3, 2019 Award within thirty days—i.e., on or before January 2, 2019.

52. Consistent with its practices and delay tactics throughout these proceedings,[5] Respondent ISE willfully disregarded the thirty day deadline. Instead, Respondent submitted an untimely Notice of Appeal to AAA.

53. Movants have requested AAA dismiss or strike ISE's untimely Notice of Appeal for lack of jurisdiction, waiver, and under the mandatory claim-processing rule. A true and correct copy of Synogen and Nextgen's Motion to

[5] See e.g., Ex. A at ¶ 102 ("Regrettably, ISE has made clear throughout this proceeding that its schedule and convenience is the only one that matters and that it will ignore the rules and rulings of this process.").

Dismiss Respondent's Untimely Notice of Appeal is attached as Exhibit "P".

54. Accordingly, the Award is final and enforceable. See AT&T Techs., Inc. v. Communications Workers of Am., 475 U.S. 643, 648-49 ("[A]rbitrators derive their authority to resolve disputes only because the parties have agreed in advance to submit such grievances to arbitration."); Della Penna v. Zabawa, 931 So. 2d 155, 164 (Fla. 5th DCA 2006) ("An arbitrator's jurisdiction derives from the parties' agreement . . . ."); Seaboard Sur. Co. v. Cates, 604 So. 2d 570, 571 (3rd DCA 1992) (explaining that a "defendant had no right to arbitrate contractual disputes where its contract specifically provided that demand within 30 days was a precondition for arbitration and defendant failed to file any such demand"); cf. Hamer v. Neighborhod Housing Servs., 138 S. Ct. 13, 18 (2017) (finding that the Fed. R. Civ. P. timeline to file a Notice of Appeal was a mandatory claim-processing rule and "unalterable"); Peltz v. Dist. Ct. of Appeal, 605 So. 2d 865, 866 (Fla. 1992) (noting that an "untimely filing of a notice of appeal precludes the appellate court from" entertaining that appeal).

55. This Court has jurisdiction over this straightforward issue, as "[r]equiring an arbitrator to acknowledge this undisputed fact[—i.e., the untimeliness of the Notice of Appeal—] would be an exercise in futility." See Fluor Enterprises, Inc. v. Tri-City Elec. Contractors, Inc., 784 So. 2d 1260 (5th DCA 2001); Hubbard Const. Co. v. Jacobs Civil, Inc., 969 So. 2d 1069, 1072 (5th

DCA 2007) (holding the trial court properly denied sending the matter to arbitration where the demanding party failed to meet the contract requirement to submit to arbitration within 20 days) (majority); id. at 1075 (noting a trial court's decision to determine timeliness of a submission to arbitration is proper because "requiring an arbitrator to acknowledge an undisputed fact "would be an exercise in futility.") (dissent) (citing Fluor Enterprises, 784 So. 2d at 1260; Seaboard Sur. Co., 604 So. 2d at 571; Lyons v. Krathen, 368 So.2d 906, 908 (3d DCA 1979).

WHEREFORE, Movants now seeks this Court's confirmation of the Final Award, and the entry of judgment in favor of Synogen Management Group, Inc. and NeXtGen Biologics, Inc. and against ISE as a result of the Award and Order.

CONCLUSION

56. For the foregoing reasons, Movants Synogen Management Group, Inc. and NeXtGen Biologics, Inc. respectfully request the Court grant this Motion, and:

(i) issue an Order confirming the Final Award;

(ii) direct that judgment be entered as set out in the Award; and

(iii) grant such other and further relief as the Court deems just and proper, including interest accruing through the date of the payment of the Award.

January 6, 2020

Respectfully submitted,

DLA PIPER LLP (US)

s/ John D. Huh

John D. Huh (admitted *pro hac vice*)
Scott M. Vernick (admitted *pro hac vice*)
One Liberty Place
1650 Market Street, Suite 5000
Philadelphia, PA 19103
t: 215.656.3300 / f: 215.656.3301
john.huh@dlapiper.com
scott.vernick@dlapiper.com

Harout J. Samra (Florida Bar. No. 70523)
Janelly Crespo (Florida Bar. No. 124073)
200 South Biscayne Boulevard, Suite 2500
Miami, FL 33131
t: 305.423.8500 / f: 305.437.8131
harout.samra@dlapiper.com
janelly.crespo@dlapiper.com

Attorneys for Movants Synogen Management Group, Inc. and NeXtGen Biologics, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been electronically filed and served through Florida Courts e-filing portal on January 6, 2020.

s/ Harout Jack Samra
Harout Jack Samra

Amber N. Davis, Esq.
adavis@bwsmiplaw.com
Kevin W. Wimberly, Esq.
kwimberly@bwsmiplaw.com
BEUSSE WOLTER SANKS & MAIRE PLLC
390 North Orange Avenue, Suite 2500
Orlando, FL 32801
Telephone: (407) 926-7700
Facsimile: (407) 926-7720

Counsel for Respondent

Exhibit A

AMERICAN ARBITRATION ASSOCIATION®
INTERNATIONAL CENTRE FOR DISPUTE RESOLUTION®

Rebecca Storrow
Vice President
Miami Tower, 100 SE 2nd Street, Suite 2300
Miami, FL 33131
Telephone: (305)358-7777
Fax: (305)358-4931

December 3, 2019

John D. Huh, Esq.
DLA Piper, LLP
1650 Market Street
Suite 4900
Philadelphia, PA 19103
Via Email to: john.huh@dlapiper.com

Amber Davis, Esq.
Beusse Wolter Sanks Mora & Maire, PA
390 North Orange Avenue
Suite 2500
Orlando, FL 32801
Via Email to: adavis@bwsmiplaw.com

Case Number: 01-19-0002-3786

Synogen Management Group, Inc.
and NeXt Gen Biologics, Inc.
-vs-
ISE Professional Testing &
Consulting Services, Inc.

Dear Parties:

By direction of the arbitrator(s) attached please find the duly executed Award in the above matter. Please remember there is to be no direct communication with the arbitrator(s). All communication shall be directed to the AAA.

A financial reconciliation has been conducted and each party will receive a separate financial accounting for this matter. Any refunds will be processed as soon as possible and any party with an outstanding balance will continue to receive monthly invoices until the balance is paid in full.

Note that the financial reconciliation reflects costs as they were incurred during the course of the proceeding. Any apportionment of these costs by the arbitrator, pursuant to the Rules, will be addressed in the award and will be stated as one party's obligation to reimburse the other party for costs incurred. Any outstanding balances the parties may have with the American Arbitration Association (the AAA) for the costs incurred during the arbitration proceedings remain due and payable to the AAA even after the final award is issued, and regardless of the arbitrator's apportionment of these costs between the parties in the award.

Pursuant to the AAA's current policy, in the normal course of our administration, the AAA may maintain certain electronic case documents in our electronic records system. Such electronic documents may not constitute a complete case file. Other than certain types of electronic case documents that the AAA maintains indefinitely, electronic case documents will be destroyed 18 months after the date of this letter.

We appreciate the opportunity to assist you in resolving your dispute. As always, please do not hesitate to contact me if you have any questions.

Sincerely,

Angela Romero Valedon
Director of ADR Services
Direct Dial: (786)406-6642
Email: AngelaValedon@adr.org
Fax: (305)358-4931

cc:
Scott Vernick, Esq.
Ryanne Early
Kevin W. Wimberly, Esq.
Catharine B. Arrowood, Esq.

AMERICAN ARBITRATION ASSOCIATION

SYNOGEN MANAGEMENT GROUP, INC., and NEXTGEN BIOLOGICS, INC., Claimants, v. ISE PROFESSIONAL TESTING & CONSULTING SERVICES, INC., Respondent.	**Case No. 01-19-0002-3786**

FINAL AWARD

1. The undersigned Arbitrator was designated by Claimant Synogen Management Group, Inc. (**Synogen**) and Respondent ISE Professional Testing & Consulting Services Inc. (**ISE**) in accordance with their arbitration agreement contained in Section 13 of the License Agreement between ISE and Synogen executed October 16, 2014 and effective September 23, 2014 (**License Agreement**) (Ex.1[1]). Subsequently, Claimant NextGen Biologics, Inc (**NextGen**) was added as a Claimant in light of ISE's acknowledgement of NextGen as a sublicensee to Synogen (See Ex.1 at App. A), the agreement that sublicensees survive termination of the License Agreement (Ex.1 at §2.2.1) and the agreement to arbitrate contained in Section 13 of the License Agreement between Synogen and NextGen effective October 15, 2014 (**Sublicense Agreement**) (Ex.2). See Order No. 6 in this matter.

2. Both the License Agreement and the Sublicense Agreement (the **Agreements**) are governed by the laws of the State of Florida (Ex. 1 at §16.1; Ex.2

[1] "Ex." refers to the exhibits submitted at the hearing.

at §16.1). The Federal Arbitration Act applies and the arbitration was conducted pursuant to the Commercial Arbitration Rules (**Rules**) of the American Arbitration Association (**AAA**). Synogen, NextGen and ISE are referred to herein as the **Parties**.

3. Having been duly sworn, the undersigned Arbitrator heard the proofs and allegations of the Parties by, among other things, taking evidence at a hearing conducted on October 23, 2019 at the offices of Veritext-Orange Legal at 633 East Colonial Drive, Orlando, Florida 32803[2]. Claimants were represented by Janelly Crespo, John Huh, and Scott Vernick of DLA Piper. Jamie Grooms, Chairman of Synogen, and Jonelle Toothman, CEO of Nextgen, appeared on behalf of the Claimant companies. Respondent did not appear at the hearing venue either through counsel or through a corporate representative. Respondent was initially represented by Nelson Mullins, which filed a Notice of Change of Representation on September 25, 2019 in which it withdrew from this matter and designated Ryanne Early (**Early**), CEO of Respondent as ISE's contact. Ex. 17. Post-hearing, the firm of Beusse Wolter Sanks & Maire PLLC appeared for Respondent and filed ISE's Post-Hearing Brief on November 15, 2019.

4. The evidence received at the hearing is reflected in the hearing transcript. Claimants moved the following exhibits into the record: Exs. 1-86; and Exs. A (Decl. Michael Lodato), B (Decl. Statement of Jamie Grooms), C (Decl. of Jonelle Toothman) and D (Decl. of John Huh). On October 29, 2019, Claimants submitted a supplement to the Huh Decl. as Ex. E. Claimants' exhibits were accepted into evidence. ISE did not propound evidentiary objections to any of Claimants' exhibits as part of the pre-hearing process (See Order No. 2 ¶10) or at the hearing.

---

[2] By agreement, this matter was to be heard at the offices of Veritext located at 37 North Orange Avenue, Suite 500, Orlando, Florida. On October 21, 2019, it was learned that a representative of Erika Birg of Nelson Mullins, former counsel to ISE, contacted Veritext, and, without notice to the AAA, the arbitrator, counsel for Claimants or Claimants, cancelled the arrangements for the hearing. See Hearing Exhibit A, Declaration of Michael Lodato. Veritext provided a nearby location and timely notice was provided by AAA to the Parties via email and Federal Express. Respondent received both notices and in fact communicated with the AAA via that same email address the day of the hearing. See Post-Hearing Brief of Claimants at Ex. 2 and 4.

5. After Claimants presented the Witness Statements of Jamie Grooms and Jonelle Toothman as the direct examinations of these witnesses as permitted under Order No. 2 ¶9(a), the Arbitrator asked questions of Claimants' witnesses. Respondent ISE waived its opportunity to examine Claimants' witnesses and proffered no evidence at the hearing. Claimants noted their intent to question Respondent's representative and principal, Ryanne Early, who did not appear. It is acknowledged that Ms. Early submitted material to the AAA (and the same was transmitted to the arbitrator) via email the day of the hearing.

6. The Parties were permitted to submit post-hearing briefing, proposed awards and updated fee and costs petitions by Friday, November 15, 2019, as provided in Order No. 2 (Ex.22). Claimants did so. Respondent, through counsel, submitted a post-hearing brief. The undersigned held the record open over the weekend until Monday, November 18, 2019 to permit Respondent to supply copies of cases and the hearing transcript cited in Respondent's brief. Following receipt of these materials on November 18, 2019 the record was formally closed.

7. The undersigned is cognizant of the provisions of AAA Rule 31. Rule 31 does not permit an award to be made solely on the default of a party. The undersigned, in making this decision on the merits, has reviewed and considered the entire record, including everything submitted by the Parties whether or not timely supplied and regardless of whether it was supplied in accordance with the orders entered in this matter or other procedures applicable to this matter. In addition, in the interest of fairness, the undersigned deferred consideration of sanctions until the Parties' positions were fully presented and the record was closed. See, e.g. AAA Rule 23 and 28.

8. Based on the evidence, proofs and materials submitted by the Parties, the Arbitrator makes the following findings and conclusions and enters the following FINAL AWARD.

The Parties

9. Claimant Synogen is a Florida corporation, with a focus in the tech, med-tech and biotech industries.

10. Respondent ISE is a Florida corporation controlled by its principal and President, Ryanne Early. ISE holds a number of patent applications relating to bio-regenerative growth technology, specific to non-mammalian tissue.

11. Claimant Nextgen is a Delaware corporation, with its principal place of business in Florida. As described below, Nextgen was created with the agreement of ISE for the purpose of holding the rights to certain of ISE's bio-regenerative growth technologies and to develop and bring to market derivative products for human healthcare applications.

The Dispute

12. This dispute relates to allegations of breaches of the Agreements in connection with Synogen's and Nextgen's efforts to utilize ISE's patents and know-how.

Synogen-ISE License Agreement

13. Following months of negotiations (See, e.g. Ex. 61, 43 and 75), on October 16, 2014, Synogen and ISE executed a License Agreement, made effective September 23, 2014 (**License Agreement**) (Ex. 1).

14. Under the License Agreement, ISE provided Synogen an exclusive license to certain patent rights defined therein (**Licensed Patents**) and a non-exclusive license to certain trade secrets defined as "unpatented trade secret process technology, know-how and related proprietary information solely as applied to or used for decellurization of urodele derived tissue." (**Licensed Know-How**). See Ex.1 at §§ 1.7, 1.9, 2.1, 5.2.1, 5.2.2. The Licensed Know-How was also described as "Controlled by ISE." Id. at §1.7. **Control** was defined as intellectual property "that a Party...owns ... and has the ability to grant access, license or sublicense in or to ...." Id. at § 1.3.

15. In exchange for these rights, Synogen agreed, among other things, to: (a) use "commercially reasonable efforts to pursue the development of the technology

embodied in the Licensed Patents"; (b) cover "past, present, and future costs, fees, and expenses . . . related to the preparation, filing, prosecution, issuance and maintenance of" the licensed technology; (c) pay to ISE fifty percent (50%) "of all consideration received for [any] Sublicense of the Licensed Patents;" and, (d) "prosecute and maintain the Licensed Patents using counsel of [Synogen's] choice. Ex. 1 at §§ 3.1,4.1, 4.2 and 9.1.

16. ISE agreed, and the License Agreement specifically contemplated, that Synogen would form Nextgen and sublicense Synogen's rights to it[3].

17. The License Agreement provided for ISE to provide consulting services when reasonably requested to do so. Ex. 1 at § 5.1. The License Agreement further contemplated that ISE would promptly transfer Licensed Know-How upon the request of Synogen (Ex.1 at §5.2.1) and Synogen and ISE would "promptly establish a commercially viable manufacturing procedure which utilizes the Licensed Know-How." Ex.1 at § 5.2.2.

18. Further, Licensor ISE agreed that it "shall...cooperate in all respects with Licensee's efforts in preparing and prosecuting the Licensed Patents," including submitting declarations when requested and making available needed information and specimens, among other things. Ex. 1 §9.3.

19. The License Agreement could be terminated unilaterally without cause by Claimant Synogen on 45 days written notice to ISE. Ex. 1 at §11.2. On the other hand, Respondent ISE's right to terminate was limited to providing thirty days' notice of termination following Synogen's failure to cure after 45 days' notice past due reports or payments or material breach of the Agreement. Ex. 1 at § 11.3. Section 11.3.2 dealing with material breach further provided that ISE's right to terminate

---

[3] See Ex. 1 at § 1.12 (defining Sublicense); § 2.2 ("[Synogen] may grant, in its sole discretion, written Sublicenses to third parties which are not Excluded Sublicensees"); § 2.2.1 (Sublicensees granted the right "at the Sublicensee's option" to survive termination of the prime Synogen-ISE licenses in the event of a dispute between Synogen and ISE); § 3.1 ("[Synogen] agrees and warrants to... pursue the development of the technology . . . principally through sublicensing the Licensed Patents"); §§ 5.2.1, 5.2.2 (contemplating that the Licensed Know-How will be shared with Synogen's Sublicensees); and, Appendix A (Synogen to "form[] Sublicensee . . . Nextgen" and "enter into a sublicense with Nextgen.").

would be automatically stayed in the event that, during the cure period, Synogen initiated the License Agreement's dispute resolution process.

20. Synogen and ISE agreed to arbitrate all disputes exclusively pursuant to the Rules of the AAA (Ex. 1 §13) and to require each sublicensee to do the same. Ex. 1 §13.1. The License Agreement also required that any compulsory counterclaim as defined by Fed. R. Civ. Proc. 13 be submitted in the arbitration proceeding or be "forever barred." Ex. 1 § 13.1.

Synogen-Nextgen Sublicense Agreement

21. In accordance with the License Agreement, Synogen entered a Sublicense Agreement with Nextgen, executed January 26, 2015 and made effective October 14, 2014 (**Sublicense Agreement**). Ex. 2.

22. The terms of the License and Sublicense Agreements make clear that Nextgen is a third party beneficiary of the License Agreement, as discussed in more detail below.

23. The License Agreement explicitly provided that sublicensees are provided a right to survive termination of the prime license between Synogen and ISE, "at the Sublicensee's option." Ex. 1 § 2.2.1. Thus, even if the Synogen-ISE License Agreement was properly terminated as to the primary licensee (i.e. Synogen), Nextgen's rights under the licenses "remain valid." Ex. 3.

24. Nextgen became the primary financial beneficiary of the Agreements, retaining 97 to 98.5 percent of Net Sales obtained from any product developed from the Licensed Patents. Ex. 2 § 4.4. Synogen and ISE were to receive only 0.75 to 1.5 percent of Net Sales related to the commercialization of the licensed technologies. Id.; Ex. 1 § 4.2.

25. Synogen and ISE, in drafting and executing the prime License Agreement, intended the sublicensee, specifically identified as Nextgen, to act as the primary point in development and commercialization efforts on any product. In other words, ISE and Synogen clearly intended that Nextgen, as a company, would use the Licensed Patent and Know-How to develop, advance the bio-regenerative growth technology, and ultimately manufacture the resulting products.

The Parties' Claims

26. Synogen and Nextgen Claims. Claimant Synogen asserted four claims in the Amended Demand (9/16/2019). It alleged that ISE breached the License Agreement by failing to transfer the Know-How (Claim 1) and refusing to cooperate in the patent prosecution (Claim 2); it also alleged that ISE breached the covenant of good faith and fair dealing (Claim 3) and violated Florida's Unfair Trade Practices Act (Claim 4). Claimant Nextgen alleged one claim, that ISE breached the License Agreement by failing to recognize that Nextgen's rights of termination survival under the License and Sublicense Agreements (Claim 5).

27. ISE's Counterclaims. In its Amended Answer and Counterclaim (9/16/2019), ISE asserted ten counterclaims against Synogen. ISE requested a declaratory judgment that it properly terminated the License Agreement (Claim 1), that Section 5.2 of the License Agreement (regarding the transfer of Licensed Know-How) was unenforceable (Claim 2) and that ISE is not obligated to enter into a direct license with Nextgen (Claim 3). ISE also asserted claims for breach of contract against Synogen as to Section 9.1 of the License Agreement (regarding patent prosecution) (Claim 4) and failure to pay ISE for hours of consulting time (Claim 5). Further, ISE alleged that Synogen breached its NDA with ISE (Claim 6); and, sought specific performance by Synogen in the form of an accounting (Claim 7), as well as injunctive relief and damages arising from the failure to allow an accounting (Claim 8). Finally, ISE sought recovery of its attorneys' fees (Claim 9) and the disqualification of DLA Piper (Claim 10). No counterclaims were asserted against Nextgen.

Summary of Events

28. Synogen Develops the Product. Following execution of the License and Sublicense Agreements, Synogen, with Nextgen, over a period of some years, developed the intended bio-regenerative growth product, now referred to as NeoMatriX®.

29. Synogen and Nextgen funded the project, carrying the more than $7.5 million in costs associated with the development and commercialization of the product. Grooms Decl. ¶ 26; Toothman Decl. ¶ 17.

30. During this period, Synogen paid ISE 50 percent of all consideration received from Sublicensees. Grooms Decl. ¶ 29.

31. More than $1.7 million of Claimants' costs were paid to Seed Biotech Inc. (**Seed**), a company closely related to ISE. Ryanne Early, the principal and President at ISE, is also a principal and the CEO of Seed. Ex. 31; Toothman Decl. ¶ 18.; Ex. 61 (Early described as CSO (Chief Science Officer) and Founder of Seed).

32. ISE Consulting Work. Although Ms. Early did not make always it clear when she was operating on behalf of SEED as opposed to ISE[4], the record contains no invoices issued by ISE to Synogen or NextGen that purport to relate to the performance of any consulting work by ISE as described in Section 5.1 of the License Agreement.

33. FDA approval. By October 2018, NeoMatriX received 510(k) clearance from the U.S. Food and Drug Administration ("FDA"), the certification required to take a medical device to market. Ex. 4.

34. Patent Prosecution. In addition to developing the product, Synogen continued to pursue the patent rights and, in January 2019, received notice from the USPTO of impending issuance of U.S. patent rights. Ex. 5.

35. ISE fails to transfer the Know-How or to cooperate in developing a manufacturing process. However, ISE failed to transfer the Know-How, even though it was obligated to do so "promptly" after the execution of the License Agreement (See Ex. 1 § 5.2.1) and even though Synogen and Nextgen repeatedly requested that the Licensed Know-How that ISE claimed to own and control, be transferred. See e.g., Exs. 6, 7, 51 (at Exhibit 22) and 62; Grooms Decl ¶ 38. 34.

---

[4] Ms. Early conducted ISE business from a Seed ("@seedbiotech.com") account and her signature block for her personal email account refers to her positions at both entities. See Ex. 41. Ms. Early also made payments for ISE and Seed from her personal bank account and directed payments owed to ISE under the License Agreement be instead made to Seed. See Ex. 42.

36. For example, on October 22, 2018, Mr. Grooms communicated directly with ISE President, Ryanne Early, to remind her that the Know-How had yet to be provided to Synogen and Nextgen:

> I decided to send this note to keep us on track. As mutually agreed we have a compliance issue as it relates to the manufacturing black box requirement in our agreement. We have agreed to sit down to discuss a solution to this issue. My goal is to use our timeline within the agreement (45 days) to resolve so we have an agreement that works for all parties.

Ex. 8.

37. ISE did not meaningfully respond to this request, sent over four years after the effective date of the License Agreement, September 23, 2014. Ex. 1 §5.2.1.

38. ISE now contends that it should be excused from performing this obligation because there was no meeting of the minds as to the meaning of Licensed Know-How. See, e.g., Respondent's Post-Hearing Brief at p.7. This, however, was not cited by ISE as one of its "excuses" during the four plus years Synogen was developing the product. See Grooms Decl. ¶¶35-37.

39. ISE fails to assist in developing the manufacturing process. The License Agreement also obligated ISE to work with Synogen to "promptly establish a commercially viable manufacturing procedure which utilizes the Licensed Know-How for making decellularized Uroldele extracellular matrix tissue, which manufacturing procedure will include a black box aspect....." Ex. 1 at § 5.2.2. Like the obligation to transfer the Know-How, there was no evidence that ISE performed this obligation. Grooms Decl. ¶ 33; Toothman Decl. ¶ 22.

40. ISE attempts to terminate Synogen. Instead, on November 7, 2018, Erika Birg of Nelson Mullins[5], counsel for ISE, sent a letter to Synogen, suggesting, for the first time in the over four years the License Agreement had been in place, that Synogen was in breach of the License Agreement. Ex. 9. Grooms Decl. ¶ 43.

---

[5] Nelson Mullins and Ms. Birg appear to have represented ISE for many years, even prior to the execution of the License Agreement. See Ex. 43 (5-8-2014 email exchange with Ms. Birg regarding negotiations of the License Agreement.)

41. There followed correspondence between Gerard Bencen, counsel for Synogen, and Ms. Birg, counsel for ISE, including a letter from Mr. Bencen dated December 22, 2018, responding in detail to ISE's allegations of Synogen's breach. Ex. 59.

42. Over three months later, by letter dated April 5, 2019 (Ex. 10), ISE, through counsel, purported to terminate the License Agreement, claiming that the "period to cure these breaches expired on December 22, 2018." Ex. 10. Exhibit 10, however, made no reference to Mr. Bencen's detailed December 22, 2018 letter of cure (Ex .59). Further, the record does not reflect that ISE ever provided Synogen with the additional thirty-day notice required by the License Agreement. Ex. 1 at ¶ 11.3.

43. Synogen disputed the purported April 5 termination (Ex.10) by letter dated May 2, 2019 (Ex.11) and pointed out, among other things, that ISE had no right to unilaterally terminate and that the April 5 termination was not effective because ISE failed to provide the additional thirty day notice required under the License Agreement.

44. Continued performance by Synogen and Nextgen. Following the exchange of letters regarding the purported termination, Synogen and Nextgen continued to perform their obligations under the Agreements. In May 2019, Synogen retained additional counsel at DLA Piper to assist in the prosecution of the Licensed Patents, as permitted and required by § 9.1 of the License Agreement. Grooms Decl. ¶ 56.

45. Patent Prosecution Continues. In conflict with its April 5, 2019 letter purporting to terminate Synogen, ISE, in June 2019, cooperated with Synogen and supplied Synogen's attorneys at DLA Piper with a Limited Power of Attorney to continue the patent work. See Exs. 37-38. However, by July 10, 2019, the relationship between Synogen and ISE deteriorated; ISE attempted to revoke the Limited Power of Attorney (Ex. 39) and continued to refuse to transfer the Licensed Know-How, preventing Synogen and Nextgen from moving forward with the manufacturing, marketing and sale of NeoMatrix.

46. Synogen initiates this arbitration. By letter dated July 15, 2019 and in

accordance with the License Agreement, Synogen notified ISE of its intent to initiated this arbitration. Ex. 57. The demand was filed by ISE and received by AAA on July 31, 2019. As noted, Nextgen was later added as a Claimant and ISE asserted ten counterclaims against Synogen.

47. Post-arbitration notice conduct. Immediately after receipt of notice of intent to initiate this arbitration, on July 16, 2019, Ms. Birg, writing on behalf of ISE, stated ISE's intent to revoke the Limited Power of Attorney provided to DLA Piper and demanded that Synogen cease prosecution of the patents, citing ISE's purported termination of the License Agreement. See Ex. 40.

48. Later, on Friday, October 4, 2019, ISE's CEO, Ryanne Early threatened to take actions against the patents at issue if Claimants continued to arbitrate this matter. See Grooms Decl. ¶¶ 57-60; the materials submitted by Claimants in support of the October 7 Motion for Interim Relief; and, Order No. 11 (Ex. 49). Thereafter, consistent with ISE's threat, DLA Piper received notice from the USPTO that ISE had formally revoked DLA Piper's power of attorney, and shifted power of attorney at the USPTO to Ms. Birg's firm[6], Nelson Mullins. *Id.*

49. Following the issuance of interim relief (Order No. 11, Ex. 49), on October 11, 2019, Synogen requested ISE cooperate in amending the power of attorney at the USPTO back to Synogen's chosen counsel, DLA Piper. *See* Ex. 80. ISE did not respond.

ISE Materially Breached the Agreements and Damaged Claimants

50. ISE breached the License Agreement in several material respects: it breached Section 5.2.1 of the License Agreement by failing to promptly transfer to Synogen the trade secret process, i.e. the Licensed Know-How; it breached Section 5.2.2 of the License Agreement by failing to cooperate in the prompt development of a manufacturing process; and, it breached Section 9.3 of the License Agreement by failing to cooperate with Synogen in the pursuit of the patents. This conduct also breached the licenses ISE granted in Section 2 and, by affirmatively interfering with

[6] Ms. Birg and Nelson Mullins withdrew from this arbitration by notice on September 25, 2019. Ex.17.

Synogen's patent prosecution and ability to develop a manufacturing process, violated Sections 5 and 9 of the License Agreement. ISE also breached Section 2.2.1 of the License Agreement when it refused to acknowledge that Synogen's sublicensee, Nextgen, has an option to survive the termination of the License Agreement.

51. To establish a breach of contract, a party must establish three elements: "(1) a valid contract, (2) a material breach, and (3) damages." *Havens v. Coast Florida, P.A.*, 117 So.3d 1179, 1181 (Fla. Dist. Ct. App. 2013). Here, the evidence clearly establishes all three elements as to ISE.

52. The License Agreement is a valid, enforceable contract that controls the Synogen-ISE relationship, ISE's arguments about Licensed Know-How, notwithstanding.

53. Meeting of the Minds. The evidence does not support ISE's argument that there was no meeting of the minds as to what the Know-How entailed. ISE's decellularization process, its Know-How, was its trade secret, which it represented it "controlled." Following the execution of the Agreement, ISE described its secret process as an algorithm (Transcript pp. 23-26) and confirmed that it would work with Synogen on the development of a manufacturing process based on this algorithm.

54. In his letter of December 22, 2018, Mr. Bencen, counsel for Synogen discussed ISE's proposal for the disclosure under License Agreement §5.2.2 so that the work on the manufacturing process could proceed. See Ex. 59 pp. 1-2. Mr. Bencen confirmed that the process was a known one when he stated: "Ms. Early/ISE/SEED is and has been already for some time decellularizing axolotl tissue to provide tissue according to Synogen's/Nextgen's specifications/ requirements." Id.

55. Every word used in a contract does not have to appear in the definitions section of an agreement to permit a meeting of the minds to occur, particularly where, as here, it is clear that the parties understood what was being discussed. *See Corp. Fin. Inc. v. Principal Life Ins. Co.*, 461 F. Supp. 1274, 2006 US Dist. Lexis 84542 (SD Fla 2006) at p. 17 (headnote 18) (use of language "willing to offer" and "contingent on premium requirements being satisfied" not fatal to finding meeting of minds as to agreement to pay bonus), cited by Respondent in its Post-Hearing Brief.

56. Here, ISE represented that it owned a method for decellularization of urodele derived tissue (Ex.1 §1.3) and agreed it would disclose it to Synogen, after the License Agreement was executed and effective. Ex. 1 § 5.2. ISE/SEED purported to use the Licensed Know-How to generate the very tissue that was provided to Synogen/Nextgen for submission to the FDA, leading to FDA approval. Ex. 59 (12/22/2018 Bencen letter at CLMTS006801 (p.4, footnote 1)). The Know-How is real and known. ISE has simply chosen not to provide it to Claimants as it is required to do.

57. It is undisputed that ISE never transferred the Know-How and never cooperated in connection with the development of a commercially viable manufacturing process and in so doing breached the Agreement.

58. ISE also breached the License Agreement by interfering with and refusing to cooperate in the patent prosecution efforts. Ex. 1 § 9.3 permits Synogen to utilize "counsel of its choice to prosecute the Licensed Patents" and requires that ISE "cooperate in all respects with [Synogen]'s efforts in preparing and prosecuting the Licensed Patents, and . . . have its employees appear before patent offices and submit declarations when requested." ISE is in breach of this obligation having revoked the limited power of attorney for DLA Piper and otherwise refusing to support Synogen's patent prosecution work.

59. ISE also breached Section 2.2.1 of the Synogen-ISE License Agreement which (Ex. 1) accords sublicensees, including Nextgen, the option to survive the termination of the prime Synogen-ISE License Agreement "at the Sublicensee's option."

60. Synogen and ISE expressly and unambiguously intended § 2.2.1 as a protection to sublicensees against disputes under the prime Synogen-ISE license. Grooms Decl. ¶¶ 19-20; See Ex. 3.

61. Following ISE's attempt to terminate the License Agreement, on June 27, 2019, Nextgen sent ISE written notice that if "the License Agreement between Synogen and ISE [is] deemed terminated, now or in the future, Nextgen intends, and reserves its right, to exercise its option under Section 2.2.1 of the License Agreement

and survive such termination." Ex. 12. ISE responded on July 16, 2019, refusing to acknowledge Nextgen's right of survival. Ex. 13.

62. Nextgen is a Third Party Beneficiary. Nextgen, in addition to Synogen, has standing to complain about ISE's breaches of the License Agreement, including ISE's refusal to acknowledge Nextgen's rights of survival, because Nextgen is plainly an intended third party beneficiary under the License Agreement.

63. "[T]o establish an action for breach of a third party beneficiary contract, [a party] must allege and prove the following four elements (1) existence of a contract; (2) the clear or manifest intent of the contracting parties that the contract primarily and directly benefit the third party; (3) breach of the contract by a contracting party; and (4) damages to the third party resulting from the breach." *Foundation Health v. Westside EKG Assoc.*, 944 So.2d 188, 194-95 (Fla. 2006) (internal quotation marks omitted).

64. A party is an intended beneficiary if the parties to the contract express, or the contract itself expresses, an intent to primarily and directly benefit the third party. *See Dingle v. Dellinger*, 134 So. 3d 484, 488 (Fla. Dist. Ct. App. 2014).

65. The License Agreement instructs Synogen to sublicense the Licensed Patents and Know-How to a third party and contains multiple provisions confirming that Nextgen is an intended beneficiary. Ex. 1 §§ 2.2 ("[Synogen] may grant, in its sole discretion, written Sublicenses to third parties which are not Excluded Sublicensees"); § 2.2.1 (gives Sublicensees the right, "at the Sublicensee's option," to survive termination of the prime Synogen-ISE licenses in the event of a dispute between Synogen and ISE); § 5.2.1 (contemplates that the Licensed Know-How will be shared with Synogen's Sublicensees).

66. Significantly here, the License Agreement specifically contemplated that Nextgen would be that third party Sublicensee. Ex.1 at Appendix A (providing explicitly for the formation and licensing of Nextgen).

67. Moreover, from the start, ISE, through Ms. Early, was well aware of Nextgen's intended central role in the development and commercialization of the technology and that Nextgen was relying on the Licensed Patents and Know-How to

perform that role. ISE was informed prior to the execution of the License Agreement, in May 2014, that Nextgen, not Synogen, would be responsible for covering "all past debt and all past and future fees that exist in association with preparation of the [Licensed Patents'] applications." Ex. 43. As a result, at the time of contracting, ISE was aware that Nextgen would be responsible for much of the financial consideration owed to ISE under the License Agreement. Id.; Ex. 1 § 4.1.

68. Consistent with this, under the License Agreement and Sublicense Agreement, Nextgen was a financial beneficiary retaining 97 to 98.5 percent of Net Sales from any product developed from the Licensed Patents. Ex. 2 ¶ 12. By contrast, under the agreements, Synogen and ISE each receive only 0.75 to 1.5 percent of Net Sales related to the commercialization of the licensed technologies. Id.; Ex. 1 § 4.2.

69. In sum, Nextgen was to be formed with the specific purpose of holding the rights under the License Agreement and acting as the key point in the development and commercialization of the technologies. Grooms Decl. ¶ 8, 23, 65. As contemplated, Nextgen took the lead relating to development and commercialization of the product efforts, with no complaint from ISE, while Synogen took the lead on patent prosecution with Nextgen covering the costs. Grooms Decl. ¶ 25.

70. ISE was fully aware Nextgen would bear significant costs payable to ISE under the License Agreement and, through Ms. Early, was intimately involved in the development and commercialization efforts surrounding NeoMatriX. Toothman Decl. ¶¶ 10-17.

71. For these reasons, Nextgen is a third party beneficiary of the License Agreement and, in refusing to acknowledge Nextgen's option to survive the termination of the License Agreement, ISE breached its obligations to both Synogen and Nextgen under both Agreements.

72. Materiality. ISE's breaches are plainly material as they go to the heart of the Agreements. *MDS (Canada) Inc. v. Rad Source Techs., Inc.*, 720 F.3d 833, 849 (11th Cir. 2013) (a material breach of contract under Florida law is material where that party's nonperformance "go[es] to the essence of the contract."); *Faro Techs., Inc. v. Brainlab, U.S.A, Inc.*, 12-177, 2013 WL 12361030, at *2 (M.D. Fla. Jan. 16, 2013)

(material breach has occurred when "an injured party has sustained a substantial injury due to [that] breach.").

73. Synogen's and Nexgen's rights to exercise the license rights granted with respect to the Licensed Patents and Licensed Know-How are at the center of the Agreements (*See Rad Source Techs., Inc.,* 720 F.3d at 849) as is ISE's obligation to cooperate in the patent prosecution efforts and to meaningfully participate in the development of a manufacturing process for product developed by Synogen and Nextgen. ISE's refusal to participate in these efforts and its effort to terminate Synogen and eliminate its Sublicensee Nextgen after both spent over four years and millions of dollars developing a product, which could be commercialized, frustrates the very purpose of the Agreements.

74. Harm and Damages. As a result of ISE's refusal to deliver the promised decellularization process, NeoMatriX has yet to be taken to market, and the significant effort, time and capital expended to produce an FDA-approved product, is now at risk. Grooms Decl. ¶ 49; Toothman Decl. ¶ 28.

75. ISE's breaches delayed the launch of NeoMatriX by at least fourteen months, causing significant harm to Synogen and Nextgen. For calendar year 2019, NeoMatrix sales were reasonably expected to be upwards of $1 million. Ex. 32; Toothman Decl. ¶¶ 28-30.

76. Further, because the decellularization process must substantially conform to the process promised by ISE in order to comply with the already FDA cleared 510(k) Claimants may be required to amend and resubmit substantial regulatory materials to again gain clearance by the FDA. The reasonable forecast for costs of resubmission is $549,000. Ex. 14; Toothman Decl. ¶¶ 33-35.

77. Claimants began to take steps to mitigate their damages and to develop an alternative manufacturing process, when ISE would not provide the Licensed Know-How or participate in the development of the process. To date, Nextgen has expended $653,683.95 towards the creation of an efficient and commercially viable manufacturing process to replace the one promised by ISE to Synogen. Toothman Decl. ¶ 32-34. These steps by Nextgen were reasonable and appropriate to attempt

to mitigate the harm caused by ISE's decision to essentially walk away from its obligations under the License Agreement. In addition, Nextgen has spent $214,000.00 in marketing costs that were wasted due to the delays arising from ISE's breaches. Toothman Decl. ¶ 31.

78. Synogen also alleges that ISE's breaches placed it in breach of its obligations to Nextgen, such that it is required to forfeit 7.9 percent of its shares in Nextgen, valued at $3.1 million. Grooms Decl. ¶ 52. However, Synogen has pointed to no provision of the Sublicense Agreement between Synogen and Nextgen (Ex. 2) that mandates this financial consequence and has provided no documentation of its actual occurrence. Accordingly, I do not address these damages here.

79. ISE's conduct continues to damage Claimants, meaning that Synogen and Nextgen may be entitled to additional damages, including recovery of the stock forfeit described above, if ISE fails to cure its breaches and comply with its contractual obligations going forward.

Respondent ISE's Defenses Have No Basis

80. ISE's defense is essentially that Synogen breached their Agreement, ISE properly terminated it and, therefore, ISE cannot itself have breached the License Agreement. ISE's defenses appear to be based on the same arguments as its Counterclaims.

81. Although Respondent's Counterclaims fail for failure to pay the AAA fees and are barred due to ISE's sanctionable conduct, as discussed below, Respondent, citing Rule 57, quite correctly notes in its Post-Hearing Brief that dismissal of a counterclaim for failure to pay fees does not preclude that party from providing a defense to the claims asserted by the party initiating the arbitration.

82. Effect of Agreement's Bar to Claims Not Asserted. Although I address the defenses on the merits, I note that Respondent, in its Post-Hearing Brief did not discuss the term of the Licensing Agreement which imposes a preclusive effect where a party fails to file and submit compulsory claims as defined in the Federal Rules of Civil Procedure. Ex. 1 at § 13.4 ("Any claim not submitted or filed as required is forever barred"). This language is of importance because Respondent's

Counterclaims are compulsory and the facts underlying those Counterclaims are essentially the same facts cited by Respondent to defend itself against Claimants' claims, i.e., that Respondent was excused from performing because Claimants allegedly breached their agreements and the Agreements were properly terminated. ISE's failure to pursue the Counterclaims, whether for failure to pay fees or otherwise, results in a bar to its arguments and the facts it alleges underlie those claims due to this term of the License Agreement; and, there is a consequential preclusive effect on ISE's use of those arguments and facts as defenses to the Claims asserted here.

83. Nonetheless, I examined the merits of the defenses and, even though I considered everything submitted by Respondent in this matter, even if submitted in violation of the rules applicable to this matter or the orders entered during this proceeding, Respondent's arguments and proofs as to its defenses fail as a matter of law and fact.

84. ISE's attempt to terminate the License Agreement over four years into its term, after Synogen and its sublicensees invested upwards of $7.5 million into the development of the technology, was not well-founded and was clearly a bad faith effort to avoid the bargain it struck years before.

85. ISE's November 7, 2018 letter of "breach" came only after Synogen's repeated and formal requests for the transfer of the Know-How and was the first time, four years into the term of the License Agreement, that ISE raised any of these supposed breaches. Grooms Decl. ¶ 43. Each of the items listed by ISE were curable and, separately or collectively, were not sufficiently material to warrant the termination of the License Agreement.

86. Cure. Mr. Bencen's December 22, 2018 letter (Ex. 59) makes clear that Synogen cured any deficiencies. Only uncured delinquencies in reporting or payment obligations and material breaches trigger ISE's ability to terminate. Ex. 1 §11. It is notable that Ms. Birg's April 5, 2019 letter (Ex. 10) purporting to terminate the License Agreement, merely lists the same sections recited in the initial notice of breach letter (Ex. 9) dated November 7, 2018 and broadly declares that no cure has

been effected, omitting any explanation of how that can be in light of Mr. Bencen's detailed letter of December 22, 2018. Ex. 59.

87. A close examination of ISE's contentions, including its more refined version of those contentions contained in its September 16, 2019 Amended Answer and Counterclaim (Ex. 29), eliminates any doubt about the lack of any genuine basis for ISE's termination efforts.

88. Payment Reports. ISE claimed that Synogen breached Section 2.2.3 of the License Agreement because Synogen failed to produce reports documenting payments it had received from its Sublicensees. Ex. 29. But, in making this argument, ISE misstated the License Agreement. It provides:

> [Synogen] . . . agrees to forward to [ISE] annually a copy of all reports **received** by [Synogen] from its Sublicensees pertinent to payments received under said Sublicense.

License Agrmt. (Ex. 1), § 2.2.3 (emphasis added).

89. Synogen was only required to provide ISE the reports that it received from its sublicensees related to payments it obtained under a sublicense. Synogen never received such reports from Nextgen and the License Agreement provides no obligation on Synogen to manufacture, or demand, such reports. Toothman Decl. ¶ 41. Accordingly, Section 2.2.3 was not breached by Synogen.

90. Insurance. ISE also claimed that Synogen breached Section 14.2 of the License Agreement. Section 14.2 of the License Agreement provides:

> Prior to the first use of a Product in a human and thereafter annually between January 1 and January 31 of each year, [Synogen] will present evidence to [ISE] that [insurance] coverage is being maintained with [ISE] listed as an additional insured.

License Agrmt. (Ex. 1), § 14.2(ii) (emphasis added).

91. At this point, NeoMatriX has not yet been taken to market and it is unclear that any obligation to list ISE as an additional insured or submit proof of insurance has been triggered. Consequently, Section 14.2 has not been breached. Toothman Decl. ¶ 42. In addition, breach of the provision, under the circumstances

here, with no indication of harm or damage, would not be material.

92. Development Reports. ISE also claimed Synogen breached § 3.2 regarding Development Reports documenting the efforts taken to develop the Licensed Patents. Mr. Bencen's letter addresses this and a cure was effected to the extent there was any breach. Ex. 59. Nowhere does ISE explain how this remained uncured.

93. In sum, ISE's defenses fail. ISE's supposed termination is ineffective and the License Agreement remains in full force and effect both as to Synogen and Nextgen.

ISE's Counterclaims are Barred

94. Failure to pay AAA filing fees. ISE's ten Counterclaims are subject to dismissal for failure to pay the required AAA filing fees. Rule 57(b) (where one party refuses to comply with payment obligations, the Arbitrator has authority to "limit[that] party's ability to assert or pursue their claim[s]."). By letter dated October 8, 2019, the AAA notified ISE that its Counterclaims would "be returned [and] not presented to the arbitrator" if ISE continued to refuse to pay its fees by October 15. Ex. 68. ISE did not respond to this notice and failed to pay the required fees. Accordingly, ISE's Counterclaims are dismissed for failure to pay fees.

Relief Granted to Synogen and Nextgen

95. Injunctive Relief. Synogen and Nextgen are entitled to permanent injunctive relief as to ISE in the following respects: (a) ISE is to be enjoined from violating Section 5 of the License Agreement by, in accordance with § 5.2.1 of the License Agreement, transferring to Synogen within 10 business days from the entry of this Final Award, the Licensed Know-How and all information owned, controlled or otherwise in ISE's possession that may be relevant to the development of a commercially viable manufacturing process contemplated by the License Agreement; ISE is directed to otherwise cooperate with Synogen and Nextgen in the development of this process; and, (b) ISE is prohibited from violating the patent prosecution provisions of the License Agreement by being prohibited from directly or indirectly, interfering with or impeding Synogen's prosecution and preparation of the Licensed

Patents through counsel of Synogen's choice, and is directed to cooperate with Synogen and its counsel, including executing any documents deemed necessary by Synogen to enable its continued work on the patent prosecution and preparation.

96. Declaratory Relief. Synogen and Nextgen are further entitled to declaratory relief as to Nextgen's rights should ISE attempt to terminate the License Agreement in future. To be entitled to declaratory relief, a party must show [it] is in doubt as to some right or status and that [it] is entitled to have such doubt removed." *Palumbo v. Moore*, 777 So.2d 1177, 1178 (Fla. Dist. Ct. App. 2001); *Orange Cnty. v. Expedia, Inc.*, 985 So.2d 622, 627 (Fla. Dist. Ct. App. 2008); *Orange Cnty. v. Expedia, Inc.*, 985 So.2d 622, 627 (Fla. Dist. Ct. App. 2008). Here, Nextgen clearly has the right at its sole option to survive the termination of the License Agreement and to enter a direct license with ISE substantially the same terms contained in the License Agreement. Ex. 1 § 2.2.1.

97. Damages. ISE has the opportunity to avoid exposure to additional damages which Claimants will incur should ISE continue to breach the Agreements and ignore the injunctive relief granted here. At present, Nextgen is entitled to recover the total of $867,683.95 from ISE, representing the costs incurred to date in the attempt to develop a manufacturing process and the marketing expenses that were wasted because ISE breached, leaving the Claimants with no product to market.

98. Attorneys' Fees and Costs and Sanctions. The undersigned has the ability to award costs and fees to the prevailing party in this matter under AAA Rules. Under Rule 47(d), "[t]he award of the arbitrator[] may include: . . . (ii) an award of attorneys' fees if all parties have requested such an award or it is authorized by law or their arbitration agreement." R47(d) (emphasis added). Here, all parties including ISE (Ex. 29 at p. 15) expressly requested attorneys' fees. In recognition of this fact, Order No. 2 acknowledges that a Final Award "may include an award of attorneys' fees and costs." Ex. 18 at ¶ 14. See also Ex. 78 (the Parties' jointly proposed scheduling order submitted September 10, 2019).

99. The undersigned is also authorized to award fees and costs as a sanction. See Rule 58 (a) ("the arbitrator may, upon a party's request, order appropriate

sanctions where a party fails to comply with its obligations under these rules or with an order of the arbitrator."); *Marshall & Co. v. Duke*, 114 F.3d 188, 190 (11th Cir. 1997) ("[A]rbitrators have the power to award attorney's fees pursuant to the "bad faith" exception to the American Rule."); *id* ("[E]very judicial and quasi-judicial body has the right to award attorneys' fees under the common law bad faith exception to the American Rule."); *First Auto. Serv. Corp. v. First Colonial Ins. Co.*, No. 07-682, 2010 WL 2431889, at *5 (M.D. Fla. Jul. 16, 2010) (applying *Marshall* to an arbitration governed by the Federal Arbitration Act); Rule 23 ("[I]n the case of willful non-compliance with any order issued by the arbitrator, [the arbitrator has authority to] draw[] adverse inferences, exclud[e] evidence and other submissions," among other sanctions. Here, Claimants have requested sanctions repeatedly, including the bar of ISE's counterclaims. Ex. 24.

100. To date, the undersigned, in deferring ruling on those requests until the record was fully closed, has taken to the extreme the requirement of Rule 58(b) that the party that may be subject to a sanction be given the opportunity to respond prior to any determination regarding the sanctions application. While frustrating for Claimants, it has been only fair to provide ISE with repeated and explicit opportunities to explain itself and to defer a decision on sanctions until the record is closed.

101. Unfortunately, ISE ignored the multiple requests to provide its position and instead disengaged from much of this Arbitration. The following summarizes the facts and circumstances warranting sanctions.

102. Breach of the agreement to arbitrate. ISE breached its agreement to arbitrate and ignored the AAA Rules applicable thereto. After insisting on a schedule even more abbreviated than the Parties' agreement required, ISE, both before and after the withdrawal of its counsel, ignored the expedited schedule established in part to work around Ms. Early's alleged unavailability. Regrettably, ISE has made clear throughout this proceeding that its schedule and convenience is the only one that matters and that it will ignore the rules and rulings of this process.

103. Failure to participate in scheduled mediation. This matter was set for

mediation September 23, 2019. That morning, ISE, through counsel, postponed the mediation on the grounds that Ms. Early was "too ill to travel". Ex. 16. Later that day, ISE's counsel informed the mediator and the AAA, but not opposing counsel or the undersigned, that the "clients reached a settlement agreement" by phone. Ex. 16. After the AAA contacted opposing counsel, it was learned that the matter was not in fact settled. Ex. 16.

104. Failure to meet deadlines. That same day, September 23, 2019, ISE failed to file any response to the Amended Demand filed by Claimants. The undersigned communicated with ISE's counsel over the next few days in an effort to determine the reasons for the lack of a responsive document without success. See, e.g, Ex. 64.

105. Failure to Engage Following Withdrawal of ISE Counsel. On September 25, 2019, ISE's counsel filed a Notice of Change of Representation, effectively withdrawing from representing ISE in this proceeding. Ex. 17. At that time, Ms. Early was designated as the contact for ISE. But, Ms. Early never meaningfully engaged in this proceeding and essentially withdrew ISE from it.

106. Revocation of participation in direct exchange. Given the approaching deadlines in this matter, including production of documents on September 26 (pursuant to expedited rulings on objections), a status call on September 27 and the hearing itself set to begin October 23, the undersigned reached out to Ms. Early to be sure she had been informed of all deadlines as well as the consequences of not meeting them. See Ex. 21. ISE did not respond to this inquiry; instead, on September 27, 2019, ISE revoked its earlier agreement to the direct exchange program, cutting off direct communication between the arbitrator and the Parties. This meant that, in this fast moving case, all communications required an additional step and had to be directed through the AAA. See Order No. 8 (Ex. 22) at ¶4.

107. No request for postponement. Since late September, Ms. Early has occasionally and selectively communicated with the AAA on behalf of ISE making it clear that ISE received and understood communications from AAA and the undersigned, including that the hearing would be convened consistent with the

schedule ISE agreed to in this matter. ISE at no time requested postponement of the hearing or explained its failure to meet deadlines, despite receiving multiple communications about the consequences of ignoring them. See Order No. 11 (Ex. 49) ¶ 4 ("the AAA has reached out to Ms. Early . . . requesting a response as to Respondent's intent with regard to this Arbitration. Respondent has ignored these requests."), ¶ 5 ("Respondent has ignored deadlines in this matter and refused to engage with Claimants in the exchanges required to make this arbitration process work."), *id.* (outlining Respondent's disregard for the Orders and deadlines in this Arbitration).

108. ISE's Failure to Produce Documents. ISE submitted 14 document requests to Claimants in this Arbitration. The undersigned ruled on the objections by Claimants and directed Claimants to produce documents. See Order No. 7 (Ex. 47). During a very short time frame, Claimants reviewed roughly 25,000 documents, and produced nearly 19,000 pages of responsive, non-privileged materials. In contrast, ISE chose to ignore its similar deadline and produced nothing.

109. ISE ignores opportunities to cure. Although ISE never requested an extension to produce, it was provided essentially with three deadlines: the original deadline in Order No. 2 (Ex. 18); a second deadline to cure the failure to produce, established following Claimants' motion to compel ISE's production (with the note that ISE's continued failure to adhere to deadlines may lead to sanctions) in Order No. 8 (Ex. 22) ¶6; and, a final deadline to produce established in Order No. 9 (Ex.25) in connection with Claimants' attempt to use subpoenas and additional requests to obtain documents. Ms. Early actively avoided service of the subpoenas issued from this Arbitration. See Ex. 72. ISE, SEED and Ms. Early produced nothing.

110. Knowledge of Sanctions. ISE was repeatedly notified that it could not ignore deadlines without risking sanctions. See, e.g., Order No. 8 (Ex. 22) at ¶ 7; Order No. 9 (Ex. 25) ¶¶ 3-4; Order No. 10 (Ex. 48) ¶8 ("Respondent's conduct at this point appears to be willful non-compliance with the spirit and letter of this proceeding in violation of Respondent's obligations. I reserve the right to impose sanctions based on this conduct.").

111. Yet, ISE refused to participate in telephonic status conferences, never requested any extension to permit it to engage new counsel, never offered any explanation for its repeated missed deadlines, and never explained its abrupt shift from aggressively pursuing its position to almost complete disengagement overnight.

112. Then, on October 4, 2019, prior to the hearing set in this matter, Respondent threatened to take actions against the patents at issue and demanded that Claimants cease and disengage from the arbitration of this matter, requiring the issuance of an order granting interim relief to Claimants. Order No. 11 (Ex. 49).[7]

113. In sum, ISE essentially disregarded all deadlines after September 23, 2019, repeatedly ignored the content of Orders as well as messages from the Arbitrator, many of which were intended to ensure that ISE was treated fairly. ISE was aware of the need to respond as well as its responsibilities in this proceeding.

114. Now that the record in this matter is closed, I conclude that ISE's continued misconduct in this proceeding was in bad faith and warrants a full award of Claimants' attorneys' fees and costs to Claimants. This conduct appears to be an extension of ISE's effort to avoid the consequences of its contractual obligations without just cause after the Claimants here performed theirs.

115. Claimants have filed documentation demonstrating that their fees and costs amount to $903,116.93, consisting of $844,051.25 in attorneys' fees and non-AAA costs and fees of $ 59,065.73. Exs. D and E. ISE has offered no evidence to dispute the reasonableness of these amounts and I therefore conclude that the amounts are reasonable, particularly given the accelerated nature of this matter and the conduct of ISE requiring Claimants to file multiple protective motions as well as to defend its counsel from a motion to disqualify.

116. In addition, based on the egregious nature of ISE's conduct in this proceeding, and, in the alternative, I further conclude that ISE's Counterclaims should be barred and otherwise dismissed with prejudice, as a sanction. See also Ex. 1 at § 13.4 which bars compulsory counterclaims regardless of whether they are

[7] According to Respondent's Post-Hearing Brief, the court confirmed this Interim Award (Order no. 11 (Ex.49)) on November 15, 2019.

asserted. To hold otherwise would condone ISE's unabashed disrespect for its contract obligations, this process and the rule of law.

Disposition of Claims

117. Synogen and Nextgen Claims. In summary, I conclude that ISE breached the License Agreement by failing to transfer the Know-How (Claim 1) and refusing to cooperate in the patent prosecution (Claim 2). I also conclude that ISE breached the covenant of good faith and fair dealing (Claim 3). I do not conclude that ISE violated Florida's Unfair Trade Practices Act (Claim 4) as this was not argued by Claimants in their Hearing Briefs. I further conclude that ISE breached the License Agreement by failing to recognize Nextgen's rights of termination survival under the License and Sublicense Agreements (Claim 5). Synogen and Nextgen are entitled to declaratory and permanent injunctive relief outlined above and damages as well as to be reimbursed their attorneys' fees and costs associated with this proceeding.

118. ISE's Counterclaims. ISE's Counterclaims are barred due to its failure to pay its filing fees and the preclusive effect of the License Agreement for failure to pursue those claims here. These claims are also barred as a sanction. To be clear, ISE is not entitled to the declaratory judgments it requested, i.e. that it properly terminated the License Agreement (Claim 1), that Section 5.2 of the License Agreement (regarding the transfer of Licensed Know-How) was unenforceable (Claim 2) or that ISE is not obligated to enter into a direct license with Nextgen (Claim 3). Synogen did not breach Section 9.1 of the License Agreement (regarding patent prosecution) (Claim 4) or the provision relating to payment to ISE for consulting time (Claim 5). Further, I do not find that Synogen breached its NDA with ISE (Claim 6). Next, ISE is not entitled to specific performance by Synogen in the form of an accounting (Claim 7) or injunctive relief and is not entitled to recover damages from Synogen relating to the alleged failure to allow an accounting (Claim 8). ISE is not entitled to recover its attorneys' fees (Claim 9). ISE's claim regarding the disqualification of DLA Piper (Claim 10) was separately dealt with in Order No. 3,

which order is incorporated herein by reference to the extent necessary to make this Final Award complete.

For the foregoing reasons the Arbitrator finds and declares that:

1. The American Arbitration Association has jurisdiction over this dispute;

2. The Arbitrator finds in favor of Claimants Synogen Management Group, Inc. and Nextgen Biologics, Inc., and against Respondent ISE Professional Testing & Consulting Services, Inc. on all claims and counterclaims in this matter;

3. The Arbitrator issues the following declaratory judgment:

   A. The Synogen-ISE License Agreement and the Synogen-Nextgen Sublicense Agreement are enforceable contracts and remain in full force and effect. Claimants hold the exclusive license to the Licensed Patents, and are permitted to practice the Licensed Patents;

   B. Nextgen has the right at its sole option to survive the termination of the License Agreement by ISE and to enter a direct license with ISE on substantially the same terms contained in the License Agreement.

4. The Arbitrator orders the following permanent injunction against ISE :

   A. ISE is enjoined from breaching Section 5 of the License Agreement. Specifically, in accordance with § 5.2.1 of the License Agreement, ISE shall transfer promptly to Synogen, and not later than 10 business days from the entry of this Final Award, the Licensed Know-How and all information owned, controlled or otherwise in ISE's possession that may be relevant to the development of a commercially viable manufacturing process contemplated by the License Agreement; ISE is directed to otherwise cooperate with Synogen and Nextgen in the development of this process;

   B. ISE is further prohibited from breaching the provisions of the License Agreement relating to the prosecution of the patents. Specifically, ISE is prohibited from directly or indirectly, interfering with or impeding Synogen's prosecution and preparation of the Licensed Patents through counsel of Synogen's choice, and is directed to cooperate with Synogen

and its counsel, including executing any documents deemed necessary by Synogen to enable its continued work on the patent prosecution and preparation.

5. Claimants are entitled to and ISE shall pay damages and interest as follows:

A. Compensatory damages to be paid to Nextgen in the total amount of $867,683.95 (consisting of $653,683.95 for Claimants' costs to date in their attempt to create a manufacturing decellularization process without the Licensed Know-How and $214,000 for Claimants' costs to date relating to marketing and sales efforts in anticipation of the product's launch);

B. Interest at a rate of 6.33 percent per annum to accrue on this amount from the date of this Final Award till payment.[8]

6. Claimants are entitled to and ISE shall pay Claimants their reasonable attorneys' fees and costs relating to this Arbitration in the amount of $903,116.93. The Administrative Fees and Expenses of the AAA totaled $24,875.00. The Arbitrator's compensation and expenses totaled $60,037.42. Therefore, ISE shall pay Claimant for the AAA Fees and Arbitrator's compensation the amount of $74,598.67.

7. Within thirty days of the date of this Final Award, Respondent shall pay Claimant the total of the amounts due under this Award, including the fees and costs and interest; and

8. This Award is in full settlement of all claims submitted to this Arbitration by the Parties. All submitted claims not expressly granted herein are hereby denied.

Dated: December 3, 2019

Catharine Biggs Arrowood Arbitrator

[8] *See SunTrust Inv. Servs., Inc. v. Thorlton*, No. 617CV182ORL22GJK, 2017 WL 11025662, at *3 (M.D. Fla. May 17, 2017) ("In Florida, interest from the date of the arbitral award is required where the award liquidated the amount owed.") (Internal quotations omitted); Fla. Stat. Ann. § 55.03 (West).

Exhibit B

LICENSE AGREEMENT BETWEEN ISE AND SYNOGEN

TABLE OF CONTENTS

Section 1	Definitions
Section 2	Grant
Section 3	Due Diligence
Section 4	Payments
Section 5	Consulting services and technology transfer
Section 6	Confidentiality
Section 7	Certain Warranties and Disclaimers of Licensor
Section 8	Record Keeping
Section 9	Patent Prosecution
Section 10	Infringement and Invalidity
Section 11	Term and Termination
Section 12	Assignability
Section 13	Dispute Resolution Procedures
Section 14	Product Liability; Conduct of Business
Section 15	Use of Names
Section 16	Miscellaneous
Section 17	Notices
Section 18	Contract Formation and Authority

Initials: RT

License Agreement between ISE and Synogen

This Agreement is made effective the 23rd day of September, 2014 (the "Effective Date") by and between ISE Professional Testing & Consulting Services, Inc. ("LICENSOR"), a Florida corporation having a principal address at 2007 NW 5th St., Gainsville, FL, 32603, and Synogen Management Group, Inc. (hereinafter called "LICENSEE") a Florida corporation having a principal address at 6565 NW 81st Blvd., Gainesville, FL 32653 (each of LICENSOR AND LICENSEE a "Party" and collectively the "Parties").

WHEREAS, LICENSOR owns certain inventions that are described in the "Licensed Patents" and "Licensed Know-How" defined below, and LICENSOR is willing to grant a license to LICENSEE under the Licensed Patents and Licensed Know-How and LICENSEE desires a license under all of them;

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth below, the Parties covenant and agree as follows:

Section 1: Definitions

1.1 "Affiliate" means: (a) any person or entity which controls at least fifty percent (50%) of the equity or voting stock of the LICENSEE or (b) any person or entity fifty percent (50%) of whose equity or voting stock is owned or controlled by the LICENSEE or (c) any person or entity of which at least fifty percent (50%) of the equity or voting stock is owned or controlled by the same person or entity owning or controlling at least fifty percent (50 %) of LICENSEE.

1.2 "Change of Control" shall mean

(a) any consolidation, merger, combination, reorganization or other transaction in which LICENSEE is not the surviving entity other than a transaction, the principal purpose of which is to effect a change in domicile or the form of entity of LICENSEE

(b) the shares of stock of LICENSEE constituting in excess of fifty percent (50%) of the voting power of LICENSEE are exchanged for or changed into other stock or securities, cash, and/or other property other than in the context of a financial transaction

(c) a sale or other disposition of all or substantially all of the assets of the LICENSEE, or the assignment of this Agreement to a Third Party or Affiliate pursuant to Section 12.

1.3 "Control" and its correlative terms, "Controlled" or "Controls" shall mean, with respect to any intellectual property right or other intangible property, that a Party or one of its Affiliates owns or has a license or sublicense to such item or right, and has the ability to grant access, license or sublicense in or to such right without violating the terms of any agreement or other arrangement with any Third Party

1.4 "Development Plan" means a written report summarizing the development activities that are to be undertaken by the LICENSEE to bring Licensed Products and/or Licensed Processes to the market. The Development Plan is attached as Appendix A.

1.5 "Development Report" means a written account of LICENSEE's progress under the Development Plan having at least the information specified on Appendix B to this Agreement, and shall be sent to the address specified on Appendix B

1.6 "Improvements" means any improvement, enhancement or modification arising from the research and development under Section 2.3 and which relate to Urodeles. Improvements will be included as Licensed Patents to the extent such Improvements are patentable and will be included as Licensed Know-How to the extent such Improvements are not patentable.

1.7 "Licensed Know-How" means unpatented trade secret process technology, know how, and related proprietary information solely as applied to or used for decellurization of urodele derived tissue Controlled by ISE.

Initials: _____

1.8 "Licensed Field" means all fields permitted by law. For the avoidance of doubt, LICENSOR is not providing and cannot provide a license to intellectual property of third parties not controlled by LICENSOR which now or in the future overlaps with the scope of the claims in Licensed Patents.

1.9 "Licensed Patents" means all of the following LICENSOR intellectual property.

1.9.1 PCT application Serial Number PCT/US2014/010890 entitled "Decellularized Biomaterial from Non-Mammalian Tissue, filed January 9, 2014, inventor Ryanne Early and United States Patent application Serial Number 61/750,555, entitled "Decellularized Biomaterial from Non-Mammalian Tissue", filed January 9, 2013, inventor Ryanne Early; and all United States and foreign patents and patent applications based on this PCT and this U.S. application;

1.9.2 any and all United States and foreign patent applications based on or claiming priority to any of the patent applications identified in section 1.9.1; and

1.9.3 any and all patents issuing from the patent applications identified in Section 1.9.1 and 1.9.2, including, but not limited to, letters patents, patents of addition, divisionals, reissues, re-examinations, term extensions, term restorations, term adjustments and supplementary protection certificates.

1.10 "Licensed Product" means any product or method, or part thereof, developed by LICENSEE or its Sublicensee that utilizes Urodele extracellular matrix tissue, in any form, or utilizes material isolated or extracted from Urodele extracellular matrix tissue.

1.11 "Licensed Territory" means the world.

1.12 "Sublicense" means, directly or indirectly, to sublicense or grant any other right with respect to any right licensed to LICENSEE under this Agreement.

1.13 "Sublicensee" means any entity to which LICENSEE grants a sublicense.

1.14 "Third Party" means any entity that is not a Party or an Affiliate of a Party.

1.15 "Valid Claim" means a claim of any issued, unexpired patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental authority of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise.

Section 2: <u>Grant</u>

2.1 License

2.1.1 License under Licensed Patents

Subject to the terms of this agreement, LICENSOR hereby grants to LICENSEE an exclusive license, in the Licensed Field and in the Licensed Territory, under the Licensed Patents and the patentable Improvements to make, have made, develop, use, lease, import, export, offer to sell, sell and have sold Licensed Products

2.1.2 License under Licensed Know-How

Subject to the terms of this agreement, LICENSOR hereby grants to LICENSEE a non-exclusive license, in the Licensed Field and in the Licensed Territory, to use the Licensed Know-How and the Improvements that are not patentable in the making, development, use, lease, import, export, offer to sell, and sale of Licensed Products.

Initials: 

2.2 Sublicense

2.2.1 "LICENSOR and LICENSEE will agree upon an initial list of companies to which a Sublicense may not be granted, which list shall be attached hereto as Appendix C (the "Excluded Sublicensees"). LICENSOR and LICENSEE will meet annually to review and update the list of Excluded Sublicenses and as deemed appropriate by each Party. LICENSOR and LICENSEE agree that they will act in good faith in the review and updating of the list and will not unreasonably prohibit the removal or addition of a company from or to the list of Excluded Sublicensees. In the event of a dispute with regard to the list of the Excluded Sublicensees, or in the event that one party believes that the other party is acting unreasonably or not in good faith then the parties shall proceed through mediation as required under Section 13. LICENSEE may grant, in its sole discretion, written Sublicenses to third parties which are not Excluded Sublicensees through one or more tiers. For the avoidance of doubt, LICENSEE may not and will not sublicense the Licensed Patents, whether in or out of the Licensed Field and Licensed Territory, to any individual, entity or party not explicitly permitted under this Agreement without the express written consent of LICENSOR. Any agreement granting a Sublicense shall be consistent with the terms and conditions of this Agreement. In the event of termination of this Agreement by LICENSOR, any Sublicense shall, at the Sublicensee's option, survive such termination, provided that the Sublicensee is not in material breach of any of its obligations under such Sublicense and provided that the Sublicensee and LICENSOR enter into a direct license on substantially the same terms as the sublicense. Licensor shall not be required to undertake obligations in addition to those required by this Agreement, and LICENSOR's rights under such direct license shall be consistent with its rights under this Agreement, taking into account the scope of the license granted under such direct license.

2.2.2 In respect to Sublicenses granted by LICENSEE, LICENSEE shall not receive from Sublicensees anything of value in lieu of cash payments in consideration for any Sublicense under this Agreement without the express prior written permission of LICENSOR.

2.2.3 LICENSEE shall provide LICENSOR with a copy of each sublicense agreement within ten (10) days after the execution of any Sublicense and further agrees to forward to LICENSOR annually a copy of all reports received by LICENSEE from its Sublicensees pertinent to payments received under said Sublicense.

2.3 Grant Back

Subject to the terms and conditions of this Agreement, LICENSOR hereby retains the rights under the Licensed Patents and patentable Improvements, to make and use Licensed Products solely for the purpose of conducting internal research at LICENSOR's or LICENSEE's premises.

Section 3: <u>Due Diligence</u>

3.1 Development

LICENSEE agrees and warrants to use commercially reasonable efforts to pursue the development of the technology embodied in the Licensed Patents, principally through sublicensing the Licensed Patents to Third Parties, not including the Excluded Sublicensees;

3.2 Reports

LICENSEE agrees to provide LICENSOR with an annual Development Report fifteen (15) days after the end of the calendar year, respecting efforts taken by LICENSEE and any Sublicensee to develop Licensed Patents. Failure to provide the required reports constitutes a material breach of this Agreement and grounds for termination of the Agreement and the license if not cured according to Section 11 herein.

Initials: 

Section 4: Payments

4.1 Payment of past Intellectual Property Costs

LICENSEE is responsible for settlement and/or payment of all outstanding debt owed by LICENSOR to Foley and Lardner through the Effective Date of this Agreement, including but not limited to, settling and/or paying any and all past, present and future costs, fees and expenses (including without limitation any and all legal fees) related to or associated with the preparation, filing, prosecution, issuance and maintenance of any and all patent or intellectual property protection in the Licensed Territory for the Licensed Patents and the Licensed Products, and the licensing and/or sale of the Licensed Patents and Licensed Products. LICENSOR agrees the amount owed by LICENSEE shall not be materially in excess of that already identified by ISE to LICENSEE as outstanding, which is $47,154.45. All payments for outstanding debt and past and present fees and expenses (including without limitation any and all legal fees) shall be paid by LICENSEE to Foley and Lardner , provided that LICENSEE and Foley and Lardner may negotiate and agree upon a lower payment in full settlement of the debt or a structured payment arrangement as deemed appropriate.

4.2 Payments respecting amounts received for Sublicenses

LICENSEE shall pay LICENSOR fifty percent (50%) of all consideration received for the Sublicense of the Licensed Patents, including fifty percent (50%) consideration received based on running royalties and fifty percent (50%) of any non-royalty consideration received such as minimum royalties, milestone payments or other payments for a Sublicense of the Licensed Patents. For the avoidance of doubt, for consideration to qualify, the consideration must be consideration for the Sublicense of the Licensed Patents, and not consideration for items like advance payment or reimbursement for product development, payment for equity sold at fair market value, payment for reimbursement of patent costs, payment for a sublicense of other rights, and the like.

4.3 Payments for sales by LICENSEE

In the event that LICENSEE itself develops a Licensed Product, the Parties shall negotiate in good faith commercially reasonable terms for a running royalty or licensee fee to be paid by LICENSEE. In the event that the Parties are unable to agree upon commercially reasonable terms within sixty (60) days of initiating such negotiations, then, at LICENSEE's request, the Parties must submit the determination of commercially reasonable terms to an independent referee agreed upon by Parties who has significant relevant experience in the licensing of medical products. If hired, the referee will work with the parties to resolve the dispute without further action. If the Parties do not agree on a referee within fifteen (15) days after the termination of the sixty (60)-day period immediately following such election, or the parties are unable to resolve the dispute with the referee within thirty (30) days after selection, then either Party may request that an independent accounting or consulting firm ("consultant") be hired to review and decide either the royalty amount or license fee based on current market factors and research that it decides in its sole discretion. The consultant must deliver to the Parties as promptly as practicable (but in any case no later than thirty (30) days from the date of engagement), a report setting forth its determination of the royalty or license fee. The decision of the consultant will be final and non-appealable. The referee's and/or consultant's fees and expenses will be shared equally by the Parties. Each Party shall otherwise bear its own costs. The parties further agree (1) to require the referee or the consultant to execute a non-disclosure agreement and (2) to cooperate fully in the resolution of any dispute hereunder.

4.4 Accounting for Payments

4.4.1 Any amounts that remain unpaid after the date they are due to LICENSOR under this Section 4, Section 7, or any other section of this Agreement will begin to accrue interest at the rate of one and one-half percent

Initials:

(1.5%) per month commencing the day after the payment is due. However, in no event shall this interest provision be construed as a grant of permission for any payment delays. LICENSEE is responsible for repayment to LICENSOR of any attorney, collection agency, or other out-of-pocket LICENSOR expenses required to collect overdue payments due from this Section 4, Section 7, or any other applicable section of this Agreement

4.4.2 Except as otherwise directed, all amounts owing to LICENSOR under this Agreement shall be paid in U.S. dollars to LICENSOR at the following address:

ISE Professional Testing & Consulting Services, Inc,
2007 NW 5th St.
Gainsville, FL, 32603
Attention: Ryanne Early

All monies owing stated in currencies other than U.S. dollars shall be converted at the rate shown in the Federal Reserve Noon Valuation - Value of Foreign Currencies on the day preceding the payment due date.

4.4.3 An accounting statement showing how any amounts payable to LICENSOR under Section 4.2 or 4.3 have been calculated shall be submitted to LICENSOR on the date of each such payment. The accounting statements must contain a written representation signed by an executive officer of LICENSEE that states that the statements are true, accurate, and fairly represent all amounts payable to LICENSOR pursuant to this Agreement.

Section 5: Consulting services and technology transfer

5.1 Consulting services

LICENSOR will provide consulting services to LICENSEE including but not limited to technical assistance and training, as is necessary, up to fifteen (15) hours per month at a rate equal to the lowest rate charged by LICENSOR in any of its contracts for similar services, and shall use its best efforts to provide services in excess of such amount when reasonably requested by LICENSEE. LICENSEE will notify LICENSOR at least one (1) month in advance of the date services are to be rendered and reimburse LICENSOR for reasonable business and travel costs associated in providing such services.

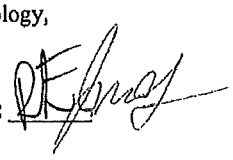
5.2 Technology Transfer

5.2.1 Following the Effective Date, LICENSOR will transfer promptly at the request and expense of LICENSEE the Licensed Know-How. LICENSEE understands and agrees that the Licensed Know-How is the confidential and proprietary information of LICENSOR and LICENSEE agrees to (i) hold and protect the Licensed Know-How as LICENSEE's confidential information, (ii) use the Licensed Know-How only for the purposes of this Agreement, and (iii) disclose the Licensed Know-How only to Sublicensees who have executed an agreement protecting LICENSOR's confidentiality, proprietary and intellectual property rights in the Licensed Know-How with terms at least as restrictive as the provisions of this Agreement.

5.2.2 LICENSOR and LICENSEE will promptly establish a commercially viable manufacturing procedure which utilizes the Licensed Know-How for making decellularized Uroldele extracellular matrix tissue, which manufacturing procedure will include a black box aspect, LICENSEE may disclose this manufacturing procedure to Sublicensees under the confidentiality provisions as set forth in 5.2.1, EXCEPT THAT, LICENSEE may NOT disclose to Sublicnesees the black box aspects of the manufacture procedure.

Section 6: Confidentiality

6.1 For the purposes of this Agreement, the term "Confidential Information" shall mean without limitation, ideas, concepts, plans, designs, marketing techniques, sales techniques, forecasts, products, technology,

Initials: 

methods, procedures, pricing, costs, cost reports, customer prospects, designs, computer systems, passwords, computer software, procedures, methods, formulae, financial statements, assets, liabilities, revenues, business methods, marketing information, marketing methods, acquisition plans, contract terms, contract negotiations, compensation information, structures and plans, employee responsibilities and duties, copyright, trademark and patent applications, all business and technical information, data, know-how, costs, projections, samples, revenue projections, business plans, clinical protocols, formulae or other information which are owned or are in the possession of one or more of the parties to this Agreement, disclosed by one Party to the other, directly or indirectly, in writing or orally. Confidential Information does not include information that:(a) is or subsequently becomes part of the public domain through no fault of the Recipient (defined below); (b) is received from a Third Party under no obligation of confidentiality to the Disclosing Party and who has a lawful right to disclose the information; (c) was known by the Recipient prior to the time of first disclosure by the Disclosing Party, as demonstrated by written documentation; or (d) is independently developed by the Recipient without the aid, application or use of such Confidential Information, as demonstrated by written documentation.

6.2 This Agreement applies to all Confidential Information disclosed from one party (the "Disclosing Party") to the other (the "Recipient"), as of the Effective Date of this Agreement and does not affect or supersede or novate any prior Agreement, which applies only to information up until the Effective Date of this Agreement.

6.3 Each Party agrees not to use the Confidential Information received for any purpose other than in connection with the Licenses granted herein. The Recipient agrees to limit disclosure of the Confidential Information to its employees, officers, directors, Affiliates and consultants with a bona fide need to know, but only to the extent necessary in connection with the Licenses. All individuals receiving access to the Confidential Information must previously have entered into a confidentiality agreement with the Recipient or otherwise be bound under terms at least as restrictive as those contained herein.

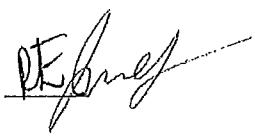
6.4 Recipient shall hold Confidential Information in strict confidence and agrees to take all reasonable efforts to prevent disclosure of any Confidential Information to persons outside of its own organization and unauthorized use for a period of seven (7) years or in the event that the Confidential Information also constitutes a trade secret, then as long as it remains a trade secret under applicable law.

6.5 Any materials or documents of one Party that are furnished to the other Party will be promptly returned to the Disclosing Party, accompanied by all copies of the documentation made by the Recipient, at the Disclosing Party's request, except that one copy of any written information may be retained by the Receiving Party in legal archives.

6.6 This Agreement is binding upon and for the benefit of the parties, and the right to the Confidential Information granted to the Recipient may not be assigned; (ii) This Agreement shall not be construed to grant any license or other rights except as specified herein; (iii) Each Disclosing Party warrants that it believes that (a) it is the owner or licensee of its Confidential Information or otherwise has the right to disclose such Confidential Information in its possession and (b) it has the right to enter into the Agreement without any breach of its obligations to others; (iv) Each Disclosing Party makes no other warranty relating to the Confidential Information and the use to be made thereof by the Recipient and disclaims all implied warranties.

6.7 The parties agree that the disclosure of Confidential Information by recipient without the Disclosing Party's written permission may cause the Disclosing Party irreparable harm and that any breach of this Agreement may entitle a party injunctive relief, in addition to any other legal remedies available to it, in any court of competent jurisdiction.

6.8 In the event that any Confidential Information is requested from a Recipient by legal process, such as a subpoena or a request for production, is required to be disclosed by law, or pursuant to the direction of a court or government agency ("Request"), the Recipient must provide the Disclosing Party with prior written notice of the Request within two (2) business days and shall not disclose the Confidential Information absent consent of the Disclosing Party. The Recipient and the Disclosing Party agree to take

Initials: 

all reasonable efforts, collectively and independently, to limit disclosure of the Confidential information in accordance with the law.

Section 7: Certain Warranties and Disclaimers of LICENSOR

7.1 LICENSOR represents that it is the owner of the Licensed Patents or otherwise has the right to grant the licenses granted to LICENSEE in this Agreement. However, nothing in this Agreement shall be construed as:

7.1.1 a warranty or representation by LICENSOR as to the validity or scope of any right included in the Licensed Patents;

7.1.2 a warranty or representation that anything made, used, sold or otherwise disposed of under the license granted in this Agreement will or will not infringe patents of Third Parties;

7.1.3 an obligation to bring or prosecute actions or suits against Third Parties for infringement of Licensed Patents; or

7.1.4 an obligation to furnish any services other than those specified in this Agreement.

7.2 EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, LICENSOR MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT AND VALIDITY OF PATENT RIGHTS CLAIMS, ISSUED OR PENDING. LICENSOR ASSUMES NO RESPONSIBILITIES WHATSOEVER WITH RESPECT TO USE, SALE, OR OTHER DISPOSITION BY LICENSEE, ITS SUBLICENSEE(S), OR THEIR VENDEES OR OTHER TRANSFEREES OF PRODUCT INCORPORATING OR MADE BY USE OF INVENTIONS LICENSED UNDER THIS AGREEMENT.

Section 8: Record Keeping

8.1 LICENSEE and its Sublicensee(s) shall keep books and records sufficiently to verify the accuracy and completeness of LICENSEE's and its Sublicensee(s)'s accounting referred to above, including without limitation inventory, purchase, and invoice records, manufacturing records, sales analysis, general ledgers, financial statements, and tax returns relating to the Licensed Products. All books and records must be preserved for a period not less than three years after they are created or as required by federal law, both during and after the term of this Agreement.

8.2 LICENSEE and its Sublicensee(s) agree to take all steps necessary so that LICENSOR may, within thirty (30) days of its written request, audit, review and/or copy all the books and records at a single U.S. location to verify the accuracy of LICENSEE's and its Sublicensee(s)'s accounting. The review may be performed by any authorized employees or contractors of LICENSOR as well as by any attorneys and/or accountants designated by LICENSOR, upon reasonable notice and during regular business hours. If a deficiency, as determined by LICENSOR, with regard to any payment hereunder is determined, LICENSEE and/or its Sublicensee(s) agree to pay the deficiency within thirty (30) days of receiving notice thereof along with applicable interest as described in Section 4. If a payment deficiency for a calendar year exceeds six percent (6%) of the royalties paid for that year, then LICENSEE and its Sublicensee(s) are be responsible for paying LICENSOR's out-of-pocket expenses incurred with respect to such review.

Section 9: Patent Prosecution

9.1 LICENSEE shall prosecute and maintain the Licensed Patents using counsel of its choice. LICENSEE shall not be able to delegate this responsibility to a Third Party or an Affiliate. LICENSEE shall provide LICENSOR with advance copies of all patent applications, amendments, and other filings with the United States Patent and Trademark Office and foreign patent offices and all related correspondence. LICENSEE will also provide LICENSOR with copies of office actions and other communications and correspondence

Initials: _____

relating to Licensed Patents and received by LICENSEE from the United States Patent and Trademark Office and foreign patent offices. LICENSOR agrees not to disclose any information received to a Third Party. LICENSOR retains the right to comment on prosecution, and LICENSEE shall take into account the reasonable comments made by LICENSOR.

9.2 LICENSEE is responsible for and must pay all costs and expenses incurred by LICENSEE and related to the preparation, filing, prosecution (including interferences), issuance, maintenance, defense (including oppositions) and reporting of the Licensed Patents during the term of the Agreement.

9.3 LICENSOR shall, at the request and expense of LICENSEE, cooperate in all respects with LICENSEE's efforts in preparing and prosecuting the Licensed Patents, and, to the extent possible and necessary, have its employees appear before patent offices and submit declarations when requested and make available relevant records, papers, information, samples, specimens, and the like.

9.4 Unless the Parties mutually agree to abandon a Licensed Patent, if LICENSEE declines to pay for patent expenses for any Licensed Patent or gives sixty (60) days notice that it intends to decline to pay for patent expenses for any Licensed Patent, then the license granted hereunder respecting such Licensed Patent automatically terminates after the expiration of such sixty (60) days in the involved country and/or jurisdiction.

Section 10: Infringement and Invalidity

10.1 LICENSEE agrees to inform LICENSOR promptly in writing of any alleged infringement of the Licensed Patents by a Third Party and of any available evidence thereof.

10.2 During the term of this Agreement, LICENSEE shall have the right, but shall not be obligated, to prosecute at its own expense any infringements of the Licensed Patents. If LICENSEE prosecutes any infringement, LICENSOR agrees that LICENSEE may include LICENSOR as a co-plaintiff in any suit, without expense to LICENSOR. No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the written consent of LICENSOR, which consent shall not be unreasonably withheld. LICENSEE shall indemnify LICENSOR against any order for costs, fees and damages that may be made against LICENSOR in such proceedings.

10.3 If within six (6) months after having been notified of any alleged infringement, LICENSEE has been unsuccessful in persuading the alleged infringer to desist but has not brought an infringement action against the alleged infringer, or if LICENSEE shall notify LICENSOR at any time prior thereto of its intention not to bring suit against the alleged infringer, then, and in those events only, LICENSOR may, but is not obligated, to prosecute at its own expense any infringement of the Licensed Patents, and LICENSOR may, for those purposes, include LICENSEE as a co-plaintiff in any suit, without expense to LICENSEE. No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the consent of LICENSEE, which consent may not be unreasonably withheld. LICENSOR will indemnify LICENSEE against any order for costs that may be made against LICENSEE in such proceedings.

10.4 In the event that a declaratory judgment action is brought against LICENSOR or LICENSEE by a Third Party alleging invalidity, unpatentability, unenforceability, or non-infringement of the Licensed Patents, LICENSEE, at its option, within twenty (20) days after commencement of such action, may take over the sole defense of the action at its own expense.

10.5 In the event that a Party shall undertake the enforcement by litigation and/or defense of the Licensed Patents by litigation, then the other Party shall have the right, but not the obligation, to voluntarily join that litigation, represented by its own counsel at its own expense. In the event that LICENSEE shall undertake the enforcement by litigation and/or defense of the Licensed Patents by litigation, any recovery of damages by LICENSEE for any such suit shall be applied first in satisfaction of any unreimbursed expenses and legal fees of LICENSEE relating to the suit, and next toward reimbursement of LICENSOR for any legal fees, and unreimbursed expenses. The balance remaining from any recovery will be divided equally between LICENSEE and LICENSOR. In the event that LICENSOR undertakes the enforcement by

Initials: 

litigation and/or defense of the Licensed Patents by litigation, any recovery of damages by LICENSOR for any such suit shall be applied first in satisfaction of any unreimbursed expenses and legal fees of LICENSOR relating to the suit, and next toward reimbursement of LICENSEE for any legal fees, and unreimbursed expenses. The balance remaining from any recovery will be divided, with twenty five percent (25%) going to LICENSEE and seventy five percent (75%) going to LICENSOR.

10.6 In any suit in which either Party is involved to enforce or defend the Licensed Patents pursuant to this Agreement, the other Party hereto shall, at the request and expense of the Party initiating such suit, cooperate in all respects and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, samples, specimens, and the like.

Section 11: Term and Termination

11.1 The term of this license begins on the Effective Date of this Agreement and continues until the date that no Licensed Patent remains an enforceable patent. For the avoidance of doubt, upon expiration of the obligation to pay royalties in any country for a Licensed Product, the licenses granted herein as to such Licensed Product in such country shall be fully-paid, royalty free, irrevocable and shall continue in perpetuity in such country.

11.2 LICENSEE may terminate this Agreement at any time by giving at least forty five (45) days written notice of such termination to LICENSOR. Upon termination, all licenses granted under this Agreement immediately cease and each Party shall immediately return all of the other Party's confidential and proprietary information to LICENSOR.

11.3 LICENSOR may terminate this Agreement by giving LICENSEE at least thirty (30) days written notice of termination if LICENSEE:

11.3.1 is delinquent on any report or payment as specified in any section of this Agreement and the delinquency, after written notice, remains uncured for forty five (45) days;

11.3.2 is in material breach of this Agreement, and the breach, after written notice, remains uncured for forty five (45) days; provided, that any right to terminate under this Section 11.3.2 shall be stayed in the event that, during such cure period, the LICENSEE shall have initiated dispute resolution in good faith in accordance with this Agreement with respect to the alleged default, which stay shall last so long as LICENSEE diligently and in good faith cooperates in the prompt resolution of such dispute resolution proceedings; or

11.3.3 goes into bankruptcy, liquidation or proposes having a receiver control any assets.

11.4 LICENSOR must give LICENSEE notice within one (1) day of a Change of Control, which shall be in writing and may be delivered in any method to ensure receipt within the time period. Upon receiving notice of a Change of Control, LICENSOR may terminate this Agreement by giving LICENSEE at least fifteen (15) days written notice. For the avoidance of doubt, if LICENSOR agrees in writing in advance to a particular Change in Control, then LICENSOR shall have waived its right to terminate this Agreement under this Section 11.4 as to that particular Change in Control.

11.5 Upon the termination of this Agreement for any reason, nothing herein shall be construed to release either Party from any obligation that matured prior to the effective date of such termination. LICENSEE shall remain obligated to provide an accounting for and to pay royalties earned to the date of termination. LICENSEE may, however, after the effective date of such termination, sell all Licensed Products, and complete Licensed Products in the process of manufacture at the time of such termination and sell the same, provided that LICENSEE shall remain obligated to provide an accounting for and to pay running royalties thereon.

Section 12: Assignability

Initials: 

12.1 LICENSEE shall have the right to assign the License Agreement, upon prior written consent from LICENSOR, not to be unreasonably withheld, to an Affiliate or to a Third Party in conjunction with the transfer or sale of substantially all of the assets or stock of the business entity to which the License Agreement relates.

Section 13: Dispute Resolution Procedures

13.1 In the event of a dispute between the Parties, they agree and each Sublicensee which enters into a direct license must agree, that all disputes will be resolved through mediation or arbitration exclusively and not in court. If any Party is forced to bring a motion to compel arbitration in court and that motion is granted, then the moving Party is entitled to recover all attorneys' fees and costs related to the court action, and the Parties agree that either the court or arbitrator is authorized to grant those fees as part of a sanction or award against the non-moving Party.

13.2 All controversies, claims, demands or disputes arising out of or relating to this Agreement will be resolved by arbitration by a neutral arbitrator. To initiate this process, the Party requesting arbitration must send the other Party written notice demanding arbitration (the "Demand").

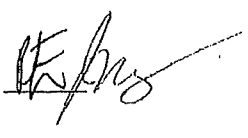
13.3 The arbitration will be governed by the rules of the American Arbitration Association ("AAA"), but the Parties agree to try to select an arbitrator themselves without requiring the AAA to administer the arbitration. The arbitrator will be selected by mutual agreement of the parties within fifteen (15) days of the Demand being sent. The arbitrator must be an attorney with a background in intellectual property and human biologics. In the event that the Parties are unable to agree to the name of an arbitrator within fifteen (15) days of the Demand being sent, then the case will be transferred to the AAA and selection of the single arbitrator will proceed according to the AAA's rules. To effectuate the transfer, either Party may submit the written demand for arbitration in accordance with the AAA's rules within five (5) days following the expiration of the time to agree to the name of the arbitrator.

13.4 In any arbitration proceeding, each Party must submit or file any claim that would constitute a compulsory counterclaim (as defined by the then current rule 13 of the Federal Rules of Civil Procedure) within the same proceeding as the demand to which it relates. Any claim not submitted or filed as required is forever barred. The arbitrator may not consider any settlement discussions or offers that might have been made by either Party subject to the arbitration. The Parties agree that in the arbitration proceeding there will be no depositions and no exchange of information by way of interrogatory.

13.5 The arbitration hearing will be held in the City of Gainesville, Florida. A hearing must be scheduled within sixty (60) days of the date of Demand, or in the event that the matter is transferred to the AAA, then within sixty (60) days of the date of the appointment of the arbitrator, who must agree to this time frame prior to appointment. The arbitrator must render his or her decision within thirty (30) days of the close of the arbitration hearing record. The hearing record must close within ninety (90) days of the presentation of the Demand.

13.6 The Parties further agree that the award may be appealed pursuant to the AAA's Optional Appellate Arbitration Rules ("Appellate Rules") or submitted directly to the AAA for appeal following an independent determination; that the award rendered by the arbitrator must, at a minimum, be a reasoned award; and that the award will not be considered final until after the time for filing the notice of appeal pursuant to the Appellate Rules has expired. Appeals must be filed within thirty (30) days of receipt of the award, as defined by Rule A-3 of the Appellate Rules, by filing a Notice of Appeal with the AAA. Following the appeal process, the decision rendered by the appeal tribunal may be entered in any court having jurisdiction thereof. If either party takes an appeal, then the award will be final only in accordance with the AAA rules.

13.7 At any point in time prior to or after a Demand has been made, either Party may request the other Party to agree to mediation of the dispute through a mutually agreed upon mediator. The request shall be in writing. If the parties cannot agree upon a mediator, then the Party requesting mediation will submit the request to

Initials: 

the AAA to select a mediator for the parties and then mediation will proceed according to the AAA's mediation rules then in effect. In the event a request for mediation is made, then mediation is mandatory. Although mediation is not binding, both Parties recognize that mediation may resolve the disputes without incurring substantial costs and agree to participate in mediation in good faith within thirty (30) days of the request for mediation being made, or as soon as possible thereafter if there is a delay caused solely by the selected mediator's schedule.

Section 14: Product Liability

14.1 LICENSEE and Sublicensee(s) shall, at all times during the term of this Agreement and thereafter, indemnify, defend and hold LICENSOR, and each of its directors, officers, employees, and agents, and the inventors of the Licensed Patents, regardless of whether such inventors are employed by LICENSOR at the time of the claim, harmless against all claims and expenses, including legal expenses and reasonable attorneys' fees, whether arising from a Third Party claim or resulting from LICENSOR's enforcing this indemnification clause against LICENSEE, arising out of the death or injury to any person or persons or out of any damage to property and against any other claim, proceeding, demand, expense and liability of any kind whatsoever resulting from the development, production, manufacture, sale, use, lease, consumption, marketing, or advertisement of Licensed Products or arising from any right or obligation of LICENSEE hereunder. Notwithstanding the above, LICENSOR at all times reserves the right to retain counsel of its own to defend LICENSOR's, and the inventor's interests.

14.2 LICENSEE covenants that (i) LICENSEE or its Sublicensee will maintain liability insurance coverage appropriate to the risk involved in the development, producing, manufacturing, clinical trials, selling, marketing, using, leasing, consuming, or advertising the products subject to this Agreement and (ii) prior to the first use of a Product in a human, LICENSEE's or its Sublicensee's insurance coverage will list LICENSOR as an additional insured. Prior to the first use of a Product in a human and thereafter annually between January 1 and January 31 of each year, LICENSEE will present evidence to LICENSOR that coverage is being maintained with LICENSOR listed as an additional insured. In addition, LICENSEE shall provide LICENSOR with at least thirty (30) days prior written notice of any change in or cancellation of the insurance coverage.

Section 15: Use of Names

Neither Party shall use the names of the other Party, nor of any of either entity's employees, agents, or Affiliates, nor the name of any inventor of Licensed Patents, nor any adaptation of such names, in any promotional, advertising or marketing materials or any other similar form of publicity, or to suggest any endorsement by such entities or individuals, without the prior written approval of other Party, or the individual involved.

Section 16: Miscellaneous

16.1 This Agreement is governed by the laws of the State of Florida.

16.2 The Parties hereto are independent and not joint venturers or partners.

ENTIRE AGREEMENT

16.3 This Agreement constitutes the full understanding between the Parties with reference to the subject matter hereof, and no statements or agreements by or between the Parties, whether orally or in writing, may vary or modify the written terms of this Agreement. This Agreement may not be amended or modified except in writing as mutually agreed upon by the Parties.

16.4 Survival

The provisions of this Section shall survive the termination of this Agreement. Upon termination of the Agreement for any reason, the following sections of the License Agreement will remain in force as non-cancelable obligations:

Initials: 

- Section 6 Confidentiality
- Section 8 Record Keeping
- Section 11.4 Requirement to pay royalties after Agreement termination
- Section 13 Dispute Resolution
- Section 14 Product Liability
- Section 15 Use of Names

Section 17: Notices

Any notice required to be given pursuant to the provisions of this Agreement shall be in writing and shall be deemed to have been given:

- if sent by facsimile transmission, when receipt thereof is acknowledged at the facsimile number of the recipient as set forth below, **or**
- the second day following the day on which the notice has been delivered prepaid to a courier service, **or**
- five (5) business days following deposit in the U.S. mail if sent certified mail, **(return receipt acknowledgement is not required to certify delivery).**

17.1 If to LICENSOR:

President
ISE Professional Testing & Consulting Services, Inc.
1909 Hickory Trace Dr.
Fleming Island, FL 32003
Facsimile Number:

With a copy to:
Geoffrey Vickers
Nelson Mullins Riley & Scarborough, LLP
150 4th Ave. N., Suite 1100
Nashville, TN 37219
Facsimile Number: 615-664-5341

17.2 If to LICENSEE:

President
Synogen Management Group, Inc.
6565 NW 81st Blvd
Gainesville, Fl 32653
Facsimile Number:

With a copy to:
Edward R. Gates
WolfGreenfield
600 Atlantic Avenue
Boston, Ma 02210
Fax: 617-646-8646

Initials:

Section 18: Contract Authority

18.1 LICENSOR and LICENSEE hereby warrant and represent that the persons signing this Agreement have authority to execute this Agreement on behalf of the Party for whom they have signed.

18.2 Force Majeure

No default, delay, or failure to perform on the part of LICENSEE or LICENSOR shall be considered a default, delay or failure to perform otherwise chargeable hereunder, if such default, delay or failure to perform is due to causes beyond either Party's reasonable control including, but not limited to: strikes, lockouts, or inactions of governmental authorities, epidemics, war, embargoes, fire, earthquake, hurricane, flood, acts of God, or default of common carrier. In the event of such default, delay or failure to perform, any date or times by which either Party is otherwise scheduled to perform shall be extended automatically for a period of time equal in duration to the time lost by reason of the excused default, delay or failure to perform.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Agreement on the dates indicated below.

ISE Professional Testing & Consulting Services, Inc.

_____ Date: October 16, 2014
Ryanne Early
President

Synogen Management Group, Inc.

By: _____ Date: 10/16/_____, 2014
Jamie Grooms
President

Initials: _____

Appendix A

1. Formation of Sublicensee companies
   a. Last quarter 2014, form NextGen
   b. 2015 recruit management for Next Gen
   c. 2015 raise funds with NextGen
   d. 2015 enter into a sublicense with NextGen
2. Last quarter 2014, establish Black Box manufacture procedure with ISE
3. Sublicensee development program
   a. 2015 NextGen to establish a development plan for a lead product.
4. LICENSEE development program (only applicable if agreement reached under Section 4.3)

a. None planned

Narrative: Synogen will approach the market in two ways. The first is like NeXtGen; where Synogen will form a company, support the hiring of a team, and support fundraising to get specific technology field housed and licensed. The second is straight licensing. Work will be serial, to an extent. The primary focus at the start is the formation and funding and support of NextGen. Upon establishing NextGen to a point of stability, Synogen will start pursuing the next field opportunity, and so on.

Appendix B

1. Efforts made in connection with formation of Sublicensee companies
   a. Company formation
   b. Funds raised
   c. Management recruited
2. Sublicensee development program
   a. Development activities accomplished, specifying the activity and the date of the accomplishment.
3. LICENSEE development program (only applicable if agreement reached under Section 4.3)

Initials: 

Exhibit C

LICENSE AGREEMENT BETWEEN NEXTGEN AND SYNOGEN

TABLE OF CONTENTS

Section 1	Definitions
Section 2	Grant
Section 3	Due Diligence
Section 4	Payments
Section 5	Technology transfer
Section 6	Confidentiality
Section 7	Certain Warranties and Disclaimers of Licensor
Section 8	Record Keeping
Section 9	Patent Prosecution
Section 10	Infringement and Invalidity
Section 11	Term and Termination
Section 12	Assignability
Section 13	Dispute Resolution Procedures
Section 14	Product Liability; Conduct of Business
Section 15	Use of Names
Section 16	Miscellaneous
Section 17	Notices
Section 18	Contract Formation and Authority

Initials:

RegenX Science Exhibit 1071
Page 70

License Agreement between NeXtGen and Synogen

This Agreement (the "Agreement") is made effective the 15th day of October, 2014 (the "Effective Date") by and between Synogen Management Group, Inc., a Florida corporation having a principal address at 6565 NW 81st Blvd., Gainesville, FL 32653 ("LICENSOR"), and NeXtGen , a Florida corporation having a principal address at 747 SW 2nd Avenue, IMB #5, Gainesville, FL, 32601 ("LICENSEE") (each of LICENSOR AND LICENSEE a "Party" and collectively the "Parties").

WHEREAS, LICENSOR entered into an agreement on the 23rd day of September, 2014 with ISE Professional Testing & Consulting Services, Inc., entitled " License Agreement between ISE and Synogen"; ("The ISE Agreement");

WHEREAS, LICENSOR Controls, through The ISE Agreement, certain inventions that are described in the "Licensed Patents" and "Licensed Know-How" defined below, and LICENSOR is willing to grant a field limited sublicense to LICENSEE under the Licensed Patents and Licensed Know-How and LICENSEE desires a license under them;

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth below, the Parties covenant and agree as follows:

Section 1: Definitions

1.1 "Affiliate" means: (a) any person or entity which controls at least fifty percent (50%) of the equity or voting stock of the LICENSEE, or (b) any person or entity fifty percent (50%) of whose equity or voting stock is owned or controlled by the LICENSEE or (c) any person or entity of which at least fifty percent (50%) of the equity or voting stock is owned or controlled by the same person or entity owning or controlling at least fifty percent (50 %) of LICENSEE.

1.2 "Control" and its correlative terms, "Controlled" or "Controls" shall mean, with respect to any intellectual property right or other intangible property, that a Party or one of its Affiliates owns or has a license or sublicense to such item or right, and has the ability to grant access, license or sublicense in or to such right without violating the terms of any agreement or other arrangement with any Third Party. Notwithstanding anything to the contrary in this Agreement, in the event that a Third Party merges or consolidates with or acquires LICENSEE or LICENSEE transfers to a Third Party all or substantially all of its assets to which this Agreement relates (such Third Party and its Affiliates immediately prior to such merger, consolidation or transfer (the "Subject Transaction"), collectively, the "Acquiring Entities"), the following shall not be deemed to be Controlled by LICENSEE for purposes of this Agreement: (i) any subject matter not acquired from LICENSEE that is owned or controlled by any Acquiring Entity immediately prior to the effective date of such Subject Transaction, and (ii) any subject matter developed or acquired by or on behalf of any Acquiring Entity after a Subject Transaction without use of non-public proprietary Licensed Know-How.

1.3 "Covered by a Licensed Patent" means that absent the license granted herein, the manufacture, use, sale, offer for sale or importation of a product or practice of a method would otherwise infringe a Valid Claim under the Licensed Patents.

1.4 "Development Plan" means a written report summarizing the development activities that are to be undertaken by the LICENSEE to bring Licensed Products and/or Licensed Processes to the market. The Development Plan will be provided to LICENSOR no later than March 15, 2015.

1.5 "Development Report" means a written account of LICENSEE's progress under the Development Plan containing the information reasonably agreed to by LICENSEE and LICENSOR, and shall be sent to the notice address specified for LICENSOR.

Initials:

1.6 "Licensed Know-How" means unpatented trade secret process technology, know how, and related proprietary information Controlled by Synogen pursuant to the ISE Agreement solely as applied to or used for decellurization of Urodele derived tissue as of the Effective Date.

1.7 "Licensed Field" means all diagnostic and therapeutic applications of medical devices, EXCEPT THAT, the Licensed Field does not include a medical device combined with a second product that is not a medical device if the second product (x) utilizes Urodele extracellular matrix tissue, in any form, or utilizes material isolated or extracted from Urodele extracellular matrix tissue and (y) is Covered by a Licensed Patent, unless, in which case, LICENSEE obtains a license under the Licensed Patents to utilize such second product.

1.8 "Licensed Patents" means all of the following LICENSOR intellectual property.

1.8.1 PCT application Serial Number PCT/US2014/010890 entitled "Decellularized Biomaterial from Non-Mammalian Tissue, filed January 9, 2014, inventor Ryanne Early and United States Patent application Serial Number 61/750,555, entitled "Decellularized Biomaterial from Non-Mammalian Tissue", filed January 9, 2013, inventor Ryanne Early; and all United States and foreign patents and patent applications based on this PCT and this U.S. application;

1.8.2 any and all United States and foreign patent applications based on or claiming priority to any of the patent applications identified in section 1.9.1; and

1.8.3 any and all patents issuing from the patent applications identified in Section 1.9.1 and 1.9.2, including, but not limited to, letters patents, patents of addition, divisionals, reissues, re-examinations, term extensions, term restorations, term adjustments and supplementary protection certificates.

1.9 "Licensed Product" means medical devices as defined by section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act or methods utilizing such medical devices, or part thereof, developed by LICENSEE or its Sublicensee that utilizes Licensed Know-How or is Covered by a Licensed Patent in the Licensed Field.

1.10 "Licensed Territory" means the world.

1.11 "Patent Challenge" means a challenge to the validity, patentability, enforceability and/or non-infringement of any of the Licensed Patents or otherwise opposing any of the Licensed Patents.

1.12 "Patented Royalty Product" means any product, or part thereof, on a country-by-country basis, that (i) is Covered by a Licensed Patent, in the country in which such product is made, used, imported or sold, or (ii) that is used in a method which is Covered by a Licensed Patent in the country in which such method is practiced.

1.13 "Sublicense" means, directly or indirectly, to sublicense or grant any other right with respect to any right licensed to LICENSEE under this Agreement.

1.14 "Sublicensee" means any entity to which LICENSEE grants a sublicense.

1.15 "Third Party" means any entity that is not a Party or an Affiliate of a Party.

1.16 "Valid Claim" means a claim (i) of any issued, unexpired patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental authority of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise or (ii) of any patent application that has not been cancelled, withdrawn or abandoned, that is being prosecuted in good faith, and that has not been pending (including via claims of priority) for more than 7 years.

Initials:

RegenX Science Exhibit 1071
Page 72

Section 2: Grant

2.1 License

2.1.1 License under Licensed Patents

Subject to the terms of this agreement and the ISE Agreement, LICENSOR hereby grants to LICENSEE an exclusive license, solely in the Licensed Field and in the Licensed Territory, under the Licensed Patents to make, have made, develop, use, lease, import, export, offer to sell, sell and have sold Licensed Products.

2.1.2 License under Licensed Know-How

Subject to the terms of this agreement and the ISE Agreement, LICENSOR hereby grants to LICENSEE a non- exclusive license, solely in the Licensed Field and in the Licensed Territory, to use the Licensed Know-How that are not patentable in the making, development, use, lease, import, export, offer to sell, and sale of Licensed Products.

2.1.3 Certain Prohibited Activities.

During the Term, LICENSEE shall not develop or commercialize any product that utilizes the Licensed Know-How or that is Covered by a Licensed Patent, other than Licensed Products in the Licensed Field. Notwithstanding the foregoing, an Acquiring Entity (as defined in Section 1.3 above) shall be free to continue engaging in any activities in which such Acquiring Entity was engaged prior to the Acquiring Entity becoming an Acquiring Entity, so long as no Licensed Patent or non-public proprietary Licensed Know-How are used by the Acquiring Entity in such activities.

2.1.4 Compliance with terms of ISE Agreement

The Parties acknowledge that the Licensed Patents and Licensed Know How include patents and know-how Controlled by LICENSOR under the ISE Agreement. Accordingly it is expressly acknowledged and agreed by the Parties that LICENSEE'S right and license to such patents and know-how is subject to the terms and conditions of the ISE Agreement and is subject to LICENSEE'S compliance (and its respective Sublicensees' compliance) with the terms and conditions of the ISE Agreement applicable to LICENSEE and its Sublicensees.

2.2 Sublicense

2.2.1 A list of companies to which a Sublicense may not be granted is attached hereto as Appendix A (the "Excluded Sublicensees"). If ISE Professional Testing & Consulting Services, Inc requests LICENSOR under the ISE Agreement to include one or more additional companies on Appendix A, then each such additional company shall be deemed an Excluded Sublicensees only if (x) LICENSEE has not already entered into an agreement with such company prior to notifying LICENSEE of such addition. LICENSOR will use commercially reasonable efforts to prevent ISE Professional Testing & Consulting Services, Inc from requiring additional companies to be listed on Appendix A. Additionally, LICENSOR will engage with ISE Professional Testing & Consulting Services, Inc. in an effort to reduce or eliminate the right of ISE Professional Testing & Consulting Services, Inc to add to the list of Excluded Sublicensees. Subject to the terms of this agreement, LICENSEE may grant written Sublicenses to Third Parties (other than Excluded Sublicensees) with the prior written consent of LICENSOR not to be unreasonably withheld, conditioned or delayed. Any agreement granting a Sublicense shall be consistent with the terms and conditions of this Agreement. Without limiting the foregoing, LICENSEE shall at all times: (a) ensure that any Sublicense agreement in respect of a Licensed Product shall include due diligence obligations with respect to such Sublicensee's development and commercialization of

Initials: _____

RegenX Science Exhibit 1071
Page 73

the Licensed Product that are at least as stringent as those contained in this Agreement (b) use its reasonable commercial efforts to ensure that Sublicensees perform such diligence obligations and (c) remain responsible for any payments due hereunder with respect to activities of the Sublicensee. In the event of termination of this Agreement by LICENSOR, any Sublicense shall, at the Sublicensee's option, survive such termination, provided that the Sublicensee is not in material breach of any of its obligations under such Sublicense and provided that the Sublicensee and LICENSOR enter into a direct license on substantially the same terms as the sublicense. LICENSOR shall not be required to undertake obligations in addition to those required by this Agreement, and LICENSOR's rights under such direct license shall be consistent with its rights under this Agreement, taking into account the scope of the license granted under such direct license.

2.2.2 In respect of Sublicenses granted by LICENSEE, LICENSEE shall not receive from Sublicensees anything of value in lieu of cash payments as consideration for any Sublicense under this Agreement without the express prior written consent LICENSOR. LICENSOR will engage with ISE Professional Testing & Consulting Services, Inc to amend the provisions of the ISE Agreement to provide that the consent of ISE Professional Testing & Consulting Services, Inc. to receipt of such non-cash payment shall not be unreasonably withheld, conditioned or delayed. To the extent the ISE Agreement is so amended, this Agreement shall also reflect such standard of consent.

2.2.3 LICENSEE shall provide LICENSOR with a copy of each Sublicense agreement within ten (10) days after the execution of any Sublicense and further shall promptly forward to LICENSOR annually a copy of all reports received by LICENSEE from its Sublicensees pertinent to payments received under said Sublicense.

2.3 Retained Rights

Subject to the terms and conditions of this Agreement, LICENSOR hereby retains for itself and for ISE Professional Testing & Consulting Services, Inc. the rights under the Licensed Patents and Licensed Know-How, to make and use Licensed Products solely for the purpose of conducting internal research by ISE Professional Testing & Consulting Services, Inc. and by LICENSOR.

Section 3: <u>Due Diligence</u>

3.1 Development

3.1.1 LICENSEE agrees to use commercially reasonable efforts to pursue the development of the technology embodied in the Licensed Patents. Reasonable commercial efforts shall include, with respect to the efforts to be expended to accomplish a given assigned objective, the efforts and resources a reasonably prudent and diligent medical device company would normally use to diligently accomplish a similar objective under similar circumstances. Without limiting the foregoing, such efforts shall require LICENSEE (or its Sublicensee) to promptly assign responsibilities for development and commercialization activities to specific employee(s) who are held accountable for the progress, monitoring and completion of such activities.

3.1.2 LICENSEE agrees to use commercially reasonable efforts to carry out the activities set forth in the Development Plan.

3.1.3 LICENSEE agrees to meet the following milestones:
sell a first commercial product in the U.S. market no later than June 30, 2017;
-sell a second commercial product in the U.S. market no later than December 31, 2019;
-sell a first commercial product in the European market no later than June 30, 2018;
-sell a second commercial product in the European market no later than December 31, 2020.

3.2 Reports

Initials: _____

RegenX Science Exhibit 1071
Page 74

LICENSEE agrees to provide LICENSOR with an annual Development Report fifteen (15) days after the end of each calendar year, respecting efforts taken by LICENSEE and any Sublicensee to develop Licensed Patents. Failure to provide the required reports constitutes a material breach of this Agreement and grounds for termination of the Agreement and the license if not cured according to Section 11 herein.

Section 4: Payments

4.1 License Issue Fee. LICENSEE shall pay to LICENSOR a non-refundable non-creditable license issue fee of $10,000.00 no later than February 16, 2015.

4.2 Annual License Maintenance Fee. LICENSEE shall pay to LICENSOR a non-creditable, non-refundable annual license maintenance fee of $5,000.00 each year on the anniversary of the Effective Date of this Agreement. The annual license maintenance fee is payable until the first commercial sale of a Licensed Product, after which time royalties instead of the annual license maintenance fee are due.

4.3 Past Patent Costs. LICENSEE is responsible for settlement and/or payment of $47,154.45 to Foley and Lardner, which relates to the preparation, filing, prosecution, issuance and licensing of the Licensed Patents. LICENSEE will, no later than March 16, 2015, either (i) negotiate an agreement with Foley and Lardner for a settlement amount and payment plan in full satisfaction of the $47,154.45 owed to Foley and Lardner (and supply a copy of that agreement to LICENSOR), the terms of which shall form an obligation of LICENSEE under this Agreement, or (ii) pay $47,154.45 to LICENSOR.

4.4 Royalty on Licensed Products.

4.4.1 LICENSEE shall pay to LICENSOR earned royalties on a product by product and country by country basis calculated as a percentage of Net Sales, as follows:

(a) three percent (3 %) of Net Sales of Licensed Products that are Patented Royalty Products.

(b) Two and one quarter percent (2.25%) of Net Sales of Licensed Products sold during a period of regulatory exclusivity pertaining to such Licensed Products.

(c) One and one half percent (1.5%) of Net Sales of Licensed Products that are Licensed Products solely because they meet the definition of Subsection 1.8 above but do not fall within Section 4.4.1(a) or 4.4.1(b) above, for a period of ten (10) years, on a product by product and country by country basis, from the first commercial sale of each such different Licensed Product in each such country.

(d) For purposes of this Agreement, the term "Net Sales" shall mean sales revenue actually received for a Licensed Product, less any discounts, rebates, and returns.

4.4.2 Earned royalties are as of the date the Licensed Product is accounted for as sold. If a Licensed Product falls into more than one category 4.3(a), 4.3(b) and 4.3(c) above, then the highest applicable earned royalty percentage shall apply, but in no event shall two percentages be aggregated.

4.5 Payments respecting amounts received for Sublicenses

4.5.1 Earned royalties. With respect to Sublicenses granted by LICENSEE under Section 2.2, LICENSEE shall pay to LICENSOR an amount equal to what LICENSEE would have been required to pay under Section 4.3 had LICENSEE sold the Licensed Products that are sold by a Sublicensee.

Initials:

4.5.2 Non-royalty Consideration. If LICENSEE receives any fees, milestone payments or other payment under a Sublicense of the rights granted herein that are not based directly on the amount or value of Licensed Products sold by the Sublicensee (i.e., any payments other than earned royalty payments, hereinafter "Non-royalty consideration"), LICENSEE shall pay LICENSOR a percentage of such Non-royalty Consideration, as follows:

-fifty percent (50%) if the Sublicense is entered into before April 15, 2015;
-thirty percent (30%) if the Sublicense respecting a particular Licensed Product is entered into prior to the first commercial sale of such Licensed Product but after April 15, 2015; and
-ten percent (10%) if the Sublicense respecting a particular Licensed Product is entered into after the first commercial sale of such Licensed Product.

4.6 Accounting for Payments

4.6.1 LICENSEE shall, on and from the date of the first commercial sale anywhere in the Territory, deliver to LICENSOR, within sixty (60) days after the end of each calendar quarter, a report setting forth for such calendar quarter the following information on a Licensed Product-by-Licensed Product basis: (a) Net Sales, (b) the royalties due to LICENSOR on account of Net Sales and (c) the exchange rates used in calculating any of the foregoing. If no royalties were payable for any calendar quarter, LICENSEE'S report shall so state. LICENSEE shall pay all royalty payments for such calendar quarter along with each such report.

4.6.2 Any amounts that remain unpaid more than thirty days after the date they are due to LICENSOR under this Section 4 or any other section of this Agreement will begin to accrue interest at the rate of one and one-half percent (1.5%) per month commencing on the thirty-first day after the payment is due. However, in no event shall this interest provision be construed as a grant of permission for any payment delays. LICENSEE is responsible for repayment to LICENSOR of reasonable attorney, collection agency, or other out-of-pocket LICENSOR expenses required to collect overdue payments due from this Section 4 or any other applicable section of this Agreement

4.6.3 Except as otherwise directed, all amounts owing to LICENSOR under this Agreement shall be paid in U.S. dollars to LICENSOR at the following address:

Synogen Management Group, Inc.
6565 NW 81st Blvd
Gainesville, Fl 32653

All monies owing stated in currencies other than U.S. dollars shall be converted at the rate shown in the Federal Reserve Noon Valuation - Value of Foreign Currencies on the day preceding the payment due date.

4.7 An accounting statement showing how any amounts payable to LICENSOR under Section 4.4 or 4.5 have been calculated shall be submitted to LICENSOR on the date of each such payment. The accounting statements must contain a written representation signed by an executive officer of LICENSEE that states that the statements are true, accurate, and fairly represent all amounts payable to LICENSOR pursuant to this Agreement.

Section 5: Technology transfer

5.1 Following the Effective Date, LICENSOR will transfer whenever made available to LICENSOR by ISE Professional Testing & Consulting Services, Inc., and at the expense of LICENSEE, the Licensed Know-How. LICENSEE understands and agrees that the Licensed Know-How is Controlled by LICENSOR and is the Confidential Information of ISE Professional Testing & Consulting Services, Inc., and LICENSEE agrees to (i) hold and protect the Licensed Know-How as LICENSEE's confidential information, (ii) use the Licensed Know-How only as permitted by the terms of this Agreement, and (iii)

Initials:

disclose the Licensed Know-How only to Sublicensees who have executed an agreement protecting LICENSOR's and ISE Professional Testing & Consulting Services, Inc.'s, confidential, proprietary and intellectual property rights in the Licensed Know-How with terms at least as restrictive as the provisions of this Agreement. Such agreement shall name LICENSOR and ISE Professional Testing & Consulting Services, Inc. as third party beneficiaries.

5.2 LICENSEE acknowledges that LICENSOR and ISE Professional Testing & Consulting Services, Inc., plan to establish a commercially viable manufacturing procedure which utilizes and will become part of the Licensed Know-How for making decellularized Uroldele extracellular matrix tissue, which manufacturing procedure will include a black box aspect, LICENSEE may disclose this manufacturing procedure to Sublicensees under the confidentiality provisions as set forth in 5.2.1, EXCEPT THAT, LICENSEE may NOT disclose to Sublicensees the black box aspects of the manufacture procedure.

Section 6: Confidentiality

6.1 For the purposes of this Agreement, the term "Confidential Information" shall mean without limitation, ideas, concepts, plans, designs, marketing techniques, sales techniques, forecasts, products, technology, methods, procedures, pricing, costs, cost reports, customer prospects, designs, computer systems, passwords, computer software, procedures, methods, formulae, financial statements, assets, liabilities, revenues, business methods, marketing information, marketing methods, acquisition plans, contract terms, contract negotiations, compensation information, structures and plans, employee responsibilities and duties, copyright, trademark and patent applications, all business and technical information, data, know-how, costs, projections, samples, revenue projections, business plans, clinical protocols, formulae or other information which are owned or are in the possession of one or more of the parties to this Agreement, disclosed by one Party to the other, directly or indirectly, in writing or orally. Confidential Information does not include information that:(a) is or subsequently becomes part of the public domain through no fault of the Recipient (defined below); (b) is received from a Third Party under no obligation of confidentiality to the Disclosing Party and who has a lawful right to disclose the information (provided that if such information or materials are lawfully disclosed to the Recipient by a Third Party under conditions of confidentiality, such information shall continue to be considered Confidential Information for purposes of this Agreement, provided that the restrictions in the Section 6.1 shall not limit any permitted use or disclosure of such information allowed under the Recipient's agreement with such Third Party; (c) was known by the Recipient prior to the time of first disclosure by the Disclosing Party, as demonstrated by written documentation; or (d) is independently developed by the Recipient without the aid, application or use of such Confidential Information, as demonstrated by written documentation.

6.2 This Agreement applies to all Confidential Information disclosed from one party (the "Disclosing Party") to the other (the "Recipient"), as of the Effective Date of this Agreement and does not affect, supersede or novate any prior agreement regarding confidentiality, which shall be deemed amended to apply only to confidential information up until the Effective Date of this Agreement.

6.3 Each Party agrees not to use the Confidential Information received except in connection with the Licenses granted herein. The Recipient agrees to limit disclosure of the Confidential Information to its employees, officers, directors, Affiliates and consultants with a bona fide need to know, and to Sublicensees, but in each case only to the extent necessary in connection with the Licenses and as limited by the terms of this Agreement. All individuals receiving access to the Confidential Information must previously have entered into a confidentiality agreement with the Recipient or otherwise be bound under terms at least as restrictive as those contained herein.

6.4 Recipient shall hold Confidential Information in strict confidence and agrees to take all reasonable efforts to prevent disclosure of any Confidential Information to persons outside of its own organization and unauthorized use for a period of seven (7) years or in the event that the Confidential Information also constitutes a trade secret, then as long as it remains a trade secret under applicable law.

6.5 Any materials or documents of the Disclosing Party that are furnished to a Recipient will be promptly returned to the Disclosing Party, accompanied by all copies of the documentation made by the Recipient,

Initials:

at the Disclosing Party's request, except that one copy of any written information may be retained by the Recipient in legal archives.

6.6 This Agreement is binding upon and for the benefit of the parties, and the right to the Confidential Information granted to the Recipient may not be assigned; (ii) This Agreement shall not be construed to grant any license or other rights except as specified herein; (iii) Each Disclosing Party warrants that it believes that (a) it is the owner or licensee of its Confidential Information or otherwise has the right to disclose such Confidential Information in its possession and (b) it has the right to enter into the Agreement without any breach of its obligations to others; (iv) Each Disclosing Party makes no other warranty relating to the Confidential Information and the use to be made thereof by the Recipient and disclaims all implied warranties.

6.7 The parties agree that the disclosure of Confidential Information by recipient without the Disclosing Party's written permission may cause the Disclosing Party irreparable harm and that any breach of this Agreement may entitle a party injunctive relief, in addition to any other legal remedies available to it, in any court of competent jurisdiction.

6.8 In the event that any Confidential Information is requested from a Recipient by legal process, such as a subpoena or a request for production, is required to be disclosed by law, or pursuant to the direction of a court or government agency ("Request"), the Recipient must provide the Disclosing Party with prior written notice of the Request within two (2) business days of receipt thereof. The Recipient and the Disclosing Party agree to take all reasonable efforts, collectively and independently, to limit disclosure of the Confidential Information in accordance with the law.

Section 7: Certain Warranties and Disclaimers of LICENSOR

7.1 LICENSOR represents that it has the right to grant the licenses granted to LICENSEE in this Agreement. However, nothing in this Agreement shall be construed as:

7.1.1 warranty or representation by LICENSOR as to the validity or scope of any right included in the Licensed Patents;

7.1.2 a warranty or representation that anything made, used, sold or otherwise disposed of under the license granted in this Agreement will or will not infringe patents of Third Parties;

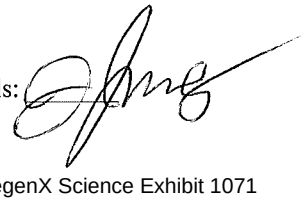
7.1.3 an obligation to bring or prosecute actions or suits against Third Parties for infringement of Licensed Patents; or

7.1.4 an obligation to furnish any services other than those specified in this Agreement.

7.2 EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, LICENSOR MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT AND VALIDITY OF PATENT RIGHTS CLAIMS, ISSUED OR PENDING. LICENSOR ASSUMES NO RESPONSIBILITIES WHATSOEVER WITH RESPECT TO USE, SALE, OR OTHER DISPOSITION BY LICENSEE, ITS SUBLICENSEE(S), OR THEIR VENDEES OR OTHER TRANSFEREES OF PRODUCT INCORPORATING OR MADE BY USE OF INVENTIONS LICENSED UNDER THIS AGREEMENT.

Section 8: Record Keeping

8.1 LICENSEE and its Sublicensee(s) shall keep books and records sufficiently to verify the accuracy and completeness of LICENSEE's and its Sublicensee(s)'s accounting referred to above, including without limitation inventory, purchase, and invoice records, manufacturing records, sales analysis, general

Initials: 

ledgers, financial statements, and tax returns relating to the Licensed Products. All books and records must be preserved for a period not less than three years after they are created or as required by federal law, both during and for the three-year period after the term of this Agreement.

8.2 LICENSEE and its Sublicensee(s) shall allow LICENSOR and ISE Professional Testing & Consulting Services, Inc., within thirty (30) days of a written request, to audit, review and/or copy the books and records at a single U.S. location to verify the accuracy of LICENSEE's and its Sublicensee(s)'s accounting. The review may be performed by any authorized employees or contractors of LICENSOR or of ISE Professional Testing & Consulting Services, Inc., as well as by any attorneys and/or accountants designated by LICENSOR or by ISE Professional Testing & Consulting Services, Inc., upon reasonable notice and during regular business hours. If a deficiency, as determined by LICENSOR or by ISE Professional Testing & Consulting Services, Inc., with regard to any payment hereunder is determined, LICENSEE and/or its Sublicensee(s) agree to pay the deficiency within thirty (30) days of receiving notice thereof along with applicable interest as described in Section 4. If a payment deficiency for a calendar year exceeds six percent (6%) of the royalties paid for that year, then LICENSEE and its Sublicensee(s) are be responsible for paying LICENSOR's (or ISE Professional Testing & Consulting Services, Inc.'s, as applicable) out-of-pocket expenses incurred with respect to such review. All information obtained by LICENSOR or ISE Professional Testing & Consulting Services, Inc. pursuant to this Section 8 shall be deemed Confidential Information. For the avoidance of doubt, if LICENSEE disputes the existence or amount of the purported deficiency, LICENSEE may invoke the dispute resolution provisions of this Agreement to resolve the dispute. LICENSOR will work to amend the ISE Agreement such that ISE Professional Testing & Consulting Services, Inc. does not have a direct right to audit LICENSEE'S books and records. If such amendment is entered into, then this Agreement will be deemed to have been amended to eliminate the rights granted to ISE Professional Testing & Consulting Services, Inc. under this Section 8.2. If LICENSOR disputes an audit of its books and records under the ISE Agreement, LICENSEE shall, at the expense of LICENSOR, cooperate with LICENSOR to provide the relevant information of LICENSEE to LICENSOR in connection with such dispute, subject in all cases to the confidentiality provisions hereof.

Section 9: Patent Prosecution

9.1 LICENSOR shall prosecute and maintain the Licensed Patents using counsel of its choice. LICENSOR shall provide LICENSEE with advance copies of all patent applications, amendments, and other filings with the United States Patent and Trademark Office and foreign patent offices and all related correspondence. LICENSOR will also provide LICENSEE with copies of office actions and other communications and correspondence relating to Licensed Patents and received by LICENSOR from the United States Patent and Trademark Office and foreign patent offices. LICENSEE agrees not to disclose any information received pursuant to this Section 9.1 to a Third Party. LICENSEE shall have the right to comment on prosecution, and LICENSOR shall take into account the reasonable comments made by LICENSEE.

9.2 LICENSEE is responsible for and must pay all reasonable costs and expenses incurred by LICENSOR and related to the preparation, filing, prosecution (including interferences), issuance, maintenance, defense (including oppositions) and reporting of the Licensed Patents, but exclusive of expenses to be paid by LICENSOR under Section 9.3 ("Patent Costs") during the term of the Agreement so long as they relate to Licensed Products in the Licensed Field. If LICENSOR licenses its patents or know-how outside of the Licensed Field, it shall use commercially reasonable efforts to require reimbursement of a proportional amount of the Patent Costs from such licensees. To the extent another licensee is obligation to reimburse Patent Costs, LICENSEE'S obligation to pay for Patent Costs shall be reduced.

9.3 LICENSEE shall, at the request and expense of LICENSOR, cooperate in all respects with LICENSOR's efforts in preparing and prosecuting the Licensed Patents, and, to the extent possible and necessary, have its employees appear before patent offices and submit declarations when requested and make available relevant records, papers, information, samples, specimens, and the like.

Initials: _____

RegenX Science Exhibit 1071
Page 79

9.4 Unless the Parties mutually agree to abandon a Licensed Patent, if LICENSEE declines to pay Patent Costs it is required to pay under Section 9.2 for any Licensed Patent or gives sixty (60) days' notice that it intends to decline to pay such required Patent Costs, then the license granted hereunder respecting such Licensed Patent shall automatically terminate after the expiration of such sixty (60) days in the involved country and/or jurisdiction.

Section 10: Infringement and Invalidity

10.1 LICENSEE agrees to inform LICENSOR promptly in writing of any alleged infringement of the Licensed Patents by a Third Party and of any available evidence thereof.

10.2 During the term of this Agreement, LICENSEE shall have the right, but shall not be obligated, to prosecute at its own expense any infringements of the Licensed Patents. If LICENSEE prosecutes any infringement, LICENSOR agrees that LICENSEE may include LICENSOR and ISE Professional Testing & Consulting Services, Inc. as a co-plaintiff in any suit (and LICENSOR shall exercise its rights under the ISE Agreement to procure that ISE Professional Testing & Consulting Services, Inc. be joined as a co-plaintiff, without expense to LICENSOR or to ISE Professional Testing & Consulting Services, Inc. No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the written consent of LICENSOR, which consent shall not be unreasonably withheld. LICENSEE shall indemnify LICENSOR and ISE Professional Testing & Consulting Services, Inc. against any order for costs, fees and damages that may be made against such Party in such proceedings.

10.3 If within six (6) months after having been notified of any alleged infringement, LICENSEE has been unsuccessful in persuading the alleged infringer to desist but has not brought an infringement action against the alleged infringer, or if LICENSEE shall notify LICENSOR at any time prior thereto of its intention not to bring suit against the alleged infringer, then LICENSOR (or ISE Professional Testing & Consulting Services, Inc.) may, but is not obligated, to prosecute at its own expense any infringement of the Licensed Patents, and LICENSOR (or ISE Professional Testing & Consulting Services, Inc., as applicable) may, for those purposes, include LICENSEE as a co-plaintiff in any suit, without expense to LICENSEE. No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the consent of LICENSEE, which consent may not be unreasonably withheld. LICENSOR (or ISE Professional Testing & Consulting Services, Inc., as applicable) shall indemnify LICENSEE against any order for costs that may be made against LICENSEE in such proceedings.

10.4 In the event that a declaratory judgment action is brought against LICENSOR or LICENSEE by a Third Party alleging invalidity, unpatentability, unenforceability, or non-infringement of the Licensed Patents, LICENSEE, at its option, within twenty (20) days after commencement of such action, may take over the sole defense of the action at its own expense.

10.5 In the event that a Party shall undertake the enforcement by litigation and/or defense of the Licensed Patents by litigation, then the other Party shall have the right, but not the obligation, to voluntarily join that litigation, represented by its own counsel at its own expense. In the event that LICENSEE shall undertake the enforcement by litigation and/or defense of the Licensed Patents by litigation, any recovery of damages by LICENSEE for any such suit shall be applied first in satisfaction of any unreimbursed expenses and legal fees of LICENSEE relating to the suit, and next toward reimbursement of ISE Professional Testing & Consulting Services, Inc. for any legal fees, and unreimbursed expenses, and next toward reimbursement of LICENSOR for any legal fees, and unreimbursed expenses. The balance remaining from any recovery will be divided between ISE Professional Testing & Consulting Services, Inc. (25%), LICENSEE (50%) and LICENSOR (25%). In the event that LICENSOR or ISE Professional Testing & Consulting Services, Inc. undertakes the enforcement by litigation and/or defense of the Licensed Patents by litigation, any recovery of damages by LICENSOR (or ISE Professional Testing & Consulting Services, Inc., as applicable) for any such suit shall be applied first in satisfaction of any unreimbursed expenses and legal fees of ISE Professional Testing & Consulting Services, Inc. , next in satisfaction of any unreimbursed expenses and legal fees of LICENSOR relating to the suit, and next toward reimbursement of LICENSEE for any legal fees, and unreimbursed expenses. The balance

Initials:

remaining from any recovery will be retained by LICENSOR or ISE Professional Testing & Consulting Services, Inc., as applicable.

10.6 In any suit in which either Party is involved to enforce or defend the Licensed Patents pursuant to this Agreement, the other Party hereto shall, at the request and expense of the Party initiating such suit, cooperate in all respects and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, samples, specimens, and the like.

Section 11: Term and Termination

11.1 The term of this license begins on the Effective Date of this Agreement and continues until the date that no Licensed Patent remains an enforceable patent or no royalty is due, whichever is later. For the avoidance of doubt, upon expiration of the obligation to pay royalties in any country for a Licensed Product, the licenses granted herein as to such Licensed Product in such country shall be fully-paid, royalty free, irrevocable and shall continue in perpetuity in such country.

11.2 LICENSEE may terminate this Agreement at any time by giving at least forty five (45) days written notice of such termination to LICENSOR. Upon termination, all licenses granted under this Agreement immediately cease and each Party shall immediately return all of the Disclosing Party's Confidential Information to the Disclosing Party.

11.3 LICENSOR may terminate this Agreement by giving LICENSEE at least thirty (30) days written notice of termination if LICENSEE:

11.3.1 is delinquent on any report or payment as specified in any section of this Agreement and the delinquency, after written notice, remains uncured for forty five (45) days;

11.3.2 is in material breach of this Agreement, and the breach, after written notice, remains uncured for sixty (60) days; provided, that any right to terminate under this Section 11.3.2 shall be stayed in the event that, during such cure period, the LICENSEE shall have initiated dispute resolution in good faith in accordance with this Agreement with respect to the alleged default, which stay shall last so long as LICENSEE diligently and in good faith cooperates in the prompt resolution of such dispute resolution proceedings;

11.3.3 brings or assists another in bringing, or permits a Sublicensee to bring or assist another in bringing, a Patent Challenge against the Licensed Patents; or

11.3.4 goes into bankruptcy, liquidation or proposes having a receiver control any assets.

11.4 Upon the termination of this Agreement for any reason, nothing herein shall be construed to release either Party from any obligation that matured prior to the effective date of such termination. LICENSEE shall remain obligated to provide an accounting for and to pay royalties earned to the date of termination. LICENSEE may, however, after the effective date of such termination, sell all Licensed Products, and complete Licensed Products in the process of manufacture at the time of such termination and sell the same, provided that LICENSEE shall remain obligated to provide an accounting for and to pay running royalties thereon.

Section 12: Assignability

LICENSEE shall have the right to assign the License Agreement, upon prior written consent from LICENSOR, not to be unreasonably withheld, conditioned or delayed, to an Affiliate or to a Third Party in conjunction with the transfer or sale of substantially all of the assets or stock of the business entity to which the License Agreement relates.

Section 13: Dispute Resolution Procedures

Initials:

RegenX Science Exhibit 1071
Page 81

13.1 Any dispute, controversy or claim that may arise relating to the terms of this Agreement or the activities of the Parties shall be referred to the Chief Executive Officers of the Parties, who shall use good faith efforts to mutually agree upon the proper course of action to resolve the dispute. If any dispute is not resolved by these individuals (or their designees) within thirty (30) days after such dispute is referred to them, then either Party may request within fifteen (15) days of the end of the thirty (30) day period the other Party to agree to mediation of the dispute through a mutually agreed upon mediator. The request shall be in writing. If the parties cannot agree upon a mediator, then the Party requesting mediation will submit the request to the AAA to select a mediator for the parties and then mediation will proceed according to the AAA's mediation rules then in effect. In the event a request for mediation is made, then mediation is mandatory. Although mediation is not binding, both Parties recognize that mediation may resolve the disputes without incurring substantial costs and agree to participate in mediation in good faith within thirty (30) days of the request for mediation being made, or as soon as possible thereafter if there is a delay caused solely by the selected mediator's schedule. At any time after the mediation is complete or in the event mediation is not requested, either Party may resort to the Florida courts for resolution of the dispute. Notwithstanding anything to the contrary in this Agreement, if either Party in its sole judgment believes in good faith that any such dispute could cause it irreparable harm, such Party (i) will be entitled to seek equitable relief in order to avoid such irreparable harm and (ii) will not be required to follow the procedures set forth in this Section 13.

Section 14: Product Liability

14.1 LICENSEE and Sublicensee(s) shall, at all times during the term of this Agreement and thereafter, indemnify, defend and hold LICENSOR, and each of its directors, officers, employees, and agents, and the inventors of the Licensed Patents, regardless of whether such inventors are employed by LICENSOR at the time of the claim, harmless against all claims and expenses, including legal expenses and reasonable attorneys' fees, whether arising from a Third Party claim or resulting from LICENSOR's enforcing this indemnification clause against LICENSEE, arising out of the death or injury to any person or persons or out of any damage to property and against any other claim, proceeding, demand, expense and liability of any kind whatsoever resulting from the development, production, manufacture, sale, use, lease, consumption, marketing, or advertisement of Licensed Products or arising from any right or obligation of LICENSEE hereunder. Notwithstanding the above, LICENSOR at all times reserves the right to retain counsel of its own to defend LICENSOR's, and the inventor's interests.

14.2 LICENSEE covenants that (i) LICENSEE or its Sublicensee will maintain liability insurance coverage appropriate to the risk involved in the development, production, manufacture, clinical trials, sale, marketing, use, leasing, consumption, or advertisement of the products subject to this Agreement and (ii) prior to the first use of a Product in a human, LICENSEE's or its Sublicensee's insurance coverage will list LICENSOR as an additional insured. Prior to the first use of a Product in a human and thereafter annually between January 1 and January 31 of each year, LICENSEE will present evidence to LICENSOR that coverage is being maintained with LICENSOR listed as an additional insured. In addition, LICENSEE shall provide LICENSOR with at least thirty (30) days prior written notice of any change in or cancellation of the insurance coverage.

Section 15: Use of Names

No Party shall use the names of any other Party, nor of any of their respective entity's employees, agents, or Affiliates, nor the name of any inventor of Licensed Patents, nor any adaptation of such names, in any promotional, advertising or marketing materials or any other similar form of publicity, or to suggest any endorsement by such entities or individuals, without the prior written approval of other Party, or the individual involved.

Section 16: Miscellaneous

16.1 This Agreement is governed by the laws of the State of Florida without respect to the conflicts of laws provisions thereof. The parties consent to the jurisdiction of the state and federal courts in Florida and waive any defense of *forum non conveniens* for such courts.

Initials:

16.2 The Parties hereto are independent and not joint venturers or partners.

16.3 This Agreement constitutes the full understanding between the Parties with reference to the subject matter hereof, and no statements or agreements by or between the Parties, whether orally or in writing, may vary or modify the written terms of this Agreement. This Agreement may not be amended or modified except in writing as mutually agreed upon by the Parties.

16.4 Survival

The provisions of this Section shall survive the termination of this Agreement. Upon termination of the Agreement for any reason, the following sections of the License Agreement will remain in force as non-cancelable obligations:

- Section 6 Confidentiality
- Section 8 Record Keeping
- Section 11.4 Requirement to pay royalties after Agreement termination
- Section 13 Dispute Resolution
- Section 14 Product Liability
- Section 15 Use of Names

Section 17: Notices

17.1 Any notice required to be given pursuant to the provisions of this Agreement shall be in writing and shall be deemed to have been given:

- if sent by electronic mail, 24 hours after sending, **or**
- the day following the day on which the notice has been delivered prepaid to an overnight courier service, **or**
- five (5) business days following deposit in the U.S. mail if sent certified mail, **(return receipt acknowledgement is not required to certify delivery).**

17.2 If to LICENSOR:

President
Synogen Management Group, Inc.
6565 NW 81st Blvd
Gainesville, Fl 32653
email: Jamie M. Grooms <jmg.jmgrooms@gmail.com>

With a copy to:
Edward R. Gates
WolfGreenfield
600 Atlantic Avenue
Boston, Ma 02210
email: edward.gates@wolfgreenfield.com

17.3 If to LICENSEE:

President
NeXtGen Biologics, Inc.
747 SW 2nd Avenue, IMB #5
Gainesville, Fl 32601
jltoothman@nextgenbiologics.com

Initials: 

With a copy to:

Keli Whitlock
Duane Morris LLP
1330 Post Oak Blvd, Suite 800
Houston, TX 77056
Kwhitlock@duanemorris.com

Section 18: Contract Authority

18.1 LICENSOR and LICENSEE hereby warrant and represent that the persons signing this Agreement have authority to execute this Agreement on behalf of the Party for whom they have signed.

18.2 Force Majeure

No default, delay, or failure to perform on the part of LICENSEE or LICENSOR shall be considered a default, delay or failure to perform otherwise chargeable hereunder, if such default, delay or failure to perform is due to causes beyond either Party's reasonable control including, but not limited to: strikes, lockouts, or inactions of governmental authorities, epidemics, war, embargoes, fire, earthquake, hurricane, flood, acts of God, or default of common carrier. In the event of such default, delay or failure to perform, any date or times by which either Party is otherwise scheduled to perform shall be extended automatically for a period of time equal in duration to the time lost by reason of the excused default, delay or failure to perform.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Agreement on the dates indicated below.

NEXTGEN

By: _____ Date: January 26, 2015
Jonelle Toothman
President

Synogen Management Group, Inc.

By: _____ Date: January 26, 2015
Jamie Grooms
President

Initials: _____

Appendix A

MIMEDx Group, Inc.
1775 West Oak Commons Ct. NE
Marietta, GA 30062
Toll Free: 888.543.1917
Local: 678.384.6720

Initials:

Attachment 1:

First Amendment to License Agreement Between NeXtGen and Synogen:

Section 3.1.3. is hereby amended to read:

"3.1.3 LICENSEE agrees to meet the following milestones:
-sell a first commercial product in the U.S. market no later than Feb. 28, 2020;
-sell a second commercial product in the U.S. market no later than December 31, 2021;
-sell a first commercial product in the European market no later than Feb. 28, 2021;
-sell a second commercial product in the European market no later than December 31, 2022."

Agreed to on 9/13/2017 by Mr. Jamie Grooms on behalf of Synogen Management Group, Inc. _____.

Jamie Grooms

Exhibit D

AMERICAN ARBITRATION ASSOCIATION

SYNOGEN MANAGEMENT GROUP, INC., and NEXTGEN BIOLOGICS, INC., Claimants, v. ISE PROFESSIONAL TESTING & CONSULTING SERVICES, INC., Respondent.	**Case No. 01-19-0002-3786** **AMENDED DEMAND FOR ARBITRATION UNDER COMMERCIAL ARBITRATION RULES**

Claimants Synogen Management Group, Inc. ("Synogen") and NeXtGen Biologics, Inc. ("Nextgen") demand arbitration against respondent ISE Professional Testing & Consulting Services, Inc. ("ISE"), as follows:

I. PARTIES

1. Claimant Synogen is a Florida corporation. Synogen is represented in this Arbitration by DLA Piper LLP (US), 1650 Market St., Suite 5000, Philadelphia, PA 19103.

2. Claimant Nextgen is a Florida corporation. Nextgen is represented in this Arbitration by DLA Piper LLP (US), at the same address.

3. Respondent ISE is a Florida corporation. ISE is represented by Nelson Mullins Riley & Scarborough LLP, 201 17th St., Suite 1700, Atlanta, GA 30363.

4. Synogen and ISE are parties to a License Agreement, made effective September 23, 2014 ("License Agreement"). The Synogen-ISE License Agreement is attached as Exhibit 1. Under the Synogen-ISE License Agreement, Synogen contracted for an exclusive license to certain

Licensed Patents[1] and a non-exclusive license to certain Licensed Know-How. *See id*. §§ 1.7, 1.9, 2.

5. Synogen and Nextgen are parties to a Sublicense Agreement, made effective October 15, 2014 ("Sublicense Agreement"). The Synogen-Nextgen Sublicense Agreement is attached as Exhibit 2. Under the Synogen-Nextgen Sublicense Agreement, Synogen granted to Nextgen certain rights under the Licensed Patents and Licensed Know-How. *See id*. §§ 1.7, 1.9, 2.

II. ARBITRATION

6. The American Arbitration Association ("AAA") has authority to arbitrate the disputes among the parties under § 13 of the Synogen-ISE License Agreement.

7. Sections 13.2 and 13.3 of the License Agreement provide, in relevant part:

> 13.2 All controversies, claims, demands or disputes arising out of or relating to this Agreement will be resolved by arbitration by a neutral arbitrator. To initiate this process, the Party requesting arbitration must send the other Party written notice demanding arbitration (the "Demand").
>
> 13.3 The arbitration will be governed by the rules of the American Arbitration Association ("AAA") . . . The arbitrator will be selected by mutual agreement of the parties within fifteen (15) days of the Demand being sent. The arbitrator must be an attorney with a background in intellectual property and human biologics. In the event that the Parties are unable to agree to the name of an arbitrator within fifteen (15) days of the Demand being sent, then the case will be transferred to the AAA and selection of the single arbitrator will proceed according to the AAA's rules . . .

8. Nextgen is a third-party beneficiary to the License Agreement, including, without limitation, §§ 2.2.1 and 13.

[1] Capitalized terms are defined identically in the ISE-Synogen License Agreement and Synogen-Nextgen Sublicense Agreement.

9. On this point, § 13.1 provides, "[i]n the event of a dispute between the Parties, they agree and each Sublicensee which enters into a direct license must agree, that all disputes will be resolved through mediation or arbitration exclusively and not in court."

10. The Synogen-ISE License Agreement specifically contemplates that Synogen will sublicense the rights under the agreement:

i. § 1.12 defines "Sublicense" as "to grant any other right with respect to any right licensed to [Synogen] under this Agreement";

ii. § 2.2, titled Sublicense, states "[Synogen] may grant, in its sole discretion, written Sublicenses to third parties which are not Excluded Sublicensees";

iii. § 2.2.1 gives Sublicensees the right, "at the Sublicensee's option," to survive termination of the prime Synogen-ISE licenses in the event of a dispute between Synogen and ISE;

iv. § 3.1 provides, "[Synogen] agrees and warrants to use commercially reasonable efforts to pursue the development of the technology . . . principally through sublicensing the Licensed Patents"; and

v. § 5.2.1 contemplates that the Licensed Know-How will be shared with Synogen's Sublicensees.

See License Agrmt. (Ex. 1) §§ 1.12, 2.2, 2.2.1, 3.1, 5.2.1.

11. And, the Synogen-ISE License Agreement specifically contemplates that Synogen will sublicense the rights under the agreement *to Nextgen*. *See* License Agrmt. (Ex. 1), Appendix A (the License Agreement directs Synogen to "form[] Sublicensee . . . NextGen" and "enter into a sublicense with NextGen.").

12. Further, Appendix A to the License Agreement directs, "[t]he primary focus at the start is the formation and funding and support of NextGen." *See* License Agrmt. (Ex. 1), Appendix A.

13. Under the Synogen-ISE License Agreement and Synogen-Nextgen Sublicense Agreement, Nextgen retains 97 to 98.5 percent of Net Sales from any product developed from the

Licensed Patents, and Synogen and ISE share the remainder evenly—i.e., Synogen and ISE each receive 0.75 to 1.5 percent of Net Sales. *See* License Agrmt. (Ex. 1) § 4.2; Sublicense Agrmnt. (Ex. 2) § 4.4.

14. ISE was provided with a true and accurate copy of the Synogen-Nextgen Sublicense Agreement.

15. Synogen sent written notice to ISE demanding arbitration on July 15, 2019. Synogen's July 15, 2019 letter to ISE is attached as Exhibit 3.

16. The parties were not able to agree to the single arbitrator, and fifteen days lapsed since the Demand. Accordingly, Synogen effectuated the transfer of the dispute to the AAA under § 13.3 of the License Agreement July 31, 2019.

17. Section 13 of the License Agreement outlines additional parameters for the Arbitration:

i. [t]he arbitration hearing will be held in the City of Gainesville, Florida;

ii. [the] hearing must be scheduled . . . within sixty (60) days of the date of the appointment of the arbitrator, who must agree to this time frame prior to appointment; and

iii. [t]he hearing record must close within ninety (90) days of the presentation of the Demand.

See License Agrmt. (Ex. 1) § 13.5.

III. OPERATIVE FACTS

A. The Synogen-ISE License Agreement and the Product

18. As stated, Synogen and ISE are parties to a License Agreement, made effective September 23, 2014. *See* License Agrmt. (Ex. 1).

19. Under the License Agreement, Synogen contracted for:

RegenX Science Exhibit 1071
Page 91

i. an exclusive license to develop and commercialize the Licensed Patents—i.e., effectively, technology covering broad rights relating to "decellularized biomaterial from non-mammalian tissue"; and

ii. a non-exclusive license to use the Licensed Know-How—i.e., the process for decellularizing the product, "which [] procedure will include a black box aspect."

See License Agrmt. (Ex. 1) §§ 1.7, 1.9, 2, 5.2.2.

20. From the Licensed Patents, Synogen, with sublicensee Nextgen, developed a human skin graft product derived from the tissue of an amphibian species.

21. The skin graft product is branded NeoMatriX®.

22. To manufacture and commercialize the NeoMatriX product, Synogen requires the contracted-for Licensed Know-How and black box aspect. On information and belief, the Know-How and black box aspect, in combination, are the process to decellularize the amphibian tissue, and thus, manufacture the product.

23. As stated, Synogen has contracted-for rights to this manufacturing procedure under the License Agreement. Section 2.1 of the License Agreement sets forth: "[ISE] hereby grants to [Synogen] a non-exclusive license . . . to the Licensed Know-How . . . in the making, development, use . . . and sale of [the product]."

24. More specifically, § 5.2.1 of the License Agreement unequivocally and unambiguously requires ISE to "transfer promptly at the request and expense of Synogen the Licensed Know-How."

25. And, § 5.2.2 of the License Agreement requires ISE, with Synogen, to "promptly establish a commercially viable manufacturing procedure which utilizes the Licensed Know-How for making decellularized [product], which manufacturing procedure will include a black box aspect."

RegenX Science Exhibit 1071
Page 92

26. In exchange for these rights to the technology and manufacturing procedure, Synogen agreed to: (i) be responsible for the settlement and/or payment of ISE's outstanding intellectual property costs (§ 4.1); (ii) prosecute the Licensed Patents at Synogen's own expense (§§ 4.1, 9.1); and pay to ISE fifty percent (50%) of all consideration received under the sublicenses by royalties, milestone payments or otherwise (§ 4.2).

27. Synogen performed all obligations under the License Agreement.

B. Synogen and Nextgen's Efforts to Commercialize the Technology

28. To date, Synogen has paid to ISE 50% of all consideration received through its sublicensees.

29. And, in accordance with §§ 4.1 and 9.1 of the License Agreement, Synogen has aggressively pursued the prosecution of the Licensed Patents to protect the technology, and, with sublicensee Nextgen, has covered all related expenses of the prosecution.

30. Synogen has aggressively pursued the patent rights since September 2014—now almost five years—and continues to pursue patent rights in the following jurisdictions at significant expense: the United States; Canada; China; Europe; Hong Kong; Israel; Japan; and Korea.

31. As a result of Synogen and Nextgen's efforts, on January 10, 2019, Synogen received a Non-Final Office Action from the United States Patent and Trademark Office ("USPTO") indicating the impending issuance of U.S. patent rights. *See* the January 10, 2019 Office Action as Exhibit 4.

32. Further, in accordance with § 4.1 of the License Agreement, Synogen, through sublicensee Nextgen, resolved ISE's outstanding intellectual property costs.

33. And, as stated above, Synogen, with Nextgen, developed the licensed technology into the product NeoMatriX—a novel human skin graft product.

RegenX Science Exhibit 1071
Page 93

34. On October 11, 2018, Synogen and Nextgen received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") to market the product.

35. In reliance on the exclusive rights to the technology and license to the manufacturing process, Synogen and Nextgen have expended incredible efforts, time and money over the past five years in development of the product, pursuit of clearance by the FDA, and in prosecution of the patents in the various jurisdictions, for the product NeoMatriX.

36. In all, Synogen and Nextgen have spent more than $7.5 million in developing and bringing the product towards market. Taking the product to market continues to be delayed by ISE's misconduct. As a result of that delay, Synogen and Nextgen continue to incur damages.

C. ISE's Breach: Refusal to Transfer the Manufacturing Process

37. Synogen and Nextgen are at the precipice of commercializing NeoMatriX, and taking the product to market.

38. However, Synogen cannot manufacture the NeoMatriX product without the Licensed Know-How and black box aspect. On information and belief, in combination, the Know-How and black box aspect outline the process for decellularizing the derivative tissue materials.

39. As detailed, Synogen has contracted-for rights to the Licensed Know-How, and to "a commercially viable manufacturing procedure . . . for making decellularized [product], which manufacturing procedure will include a black box aspect." See License Agrmt. (Ex. 1) § 5.2.2.

40. Synogen has repeatedly requested transfer of the Licensed Know-How, black box aspect and the commercially viable manufacturing procedure under the License Agreement.

41. Understanding that Synogen and Nextgen are at a critical juncture with respect to NeoMatriX, and that Synogen and Nextgen have expended considerable money and resources to

RegenX Science Exhibit 1071
Page 94

reach this juncture, ISE is holding the requested information hostage, and breaching its express and unambiguous obligations under the License Agreement.

42. To date, ISE has refused the requests in direct contravention of the License Agreement, and without providing any support for its breach of contract.

43. In a November 5, 2017 email from Jamie Grooms, Chairman of the Board at Synogen, to Geof Vickers, counsel for ISE, Jamie requested the parties "turn [their] intention to escrowing the process." *See* the November 5, 2017 email from Jamie Grooms as Exhibit 5.

44. In an October 22, 2018 email from Mr. Grooms to Ryanne Early, President of ISE, Mr. Groom's explained:

> So, I decided to send this note to keep us on track. **As mutually agreed we have a compliance issue as it relates to the manufacturing blackbox requirement in our agreement.** We have agreed to sit down to discuss a solution to this issue. My goal is to use our timeline within the agreement (45 days) to resolve so we have an agreement that works for all parties.

See the October 22, 2018 email from Jamie Grooms as Exhibit 6 (emphasis added).

45. In response to Synogen's requests for transfer of its contracted-for rights, counsel for ISE sent a letter to Synogen on November 7, 2018 outlining a number of purported breaches of the License Agreement by Synogen. *See* ISE's November 7, 2018 letter to Synogen as Exhibit 7. The letter was nothing more than a transparent attempt by ISE to manufacture a breach in the hope of escaping its obligations under the agreement to provide the information requested by Synogen.

46. By its November 7, 2018 letter, ISE again refused to transfer the Licensed Know-How and black box aspect in direct contravention of its clear contract obligations. *See id*.

RegenX Science Exhibit 1071
Page 95

47. On April 5, 2019, ISE improperly attempted to terminate the License Agreement, citing the manufactured and technical breaches. *See* ISE's April 5, 2019 letter to Synogen as Exhibit 8.

48. However, as outlined in Synogen's May 2, 2019 letter to ISE, Synogen was not in breach of the License Agreement at any relevant time, and ISE has no right to unilaterally, and without support, terminate the agreement. *See* Synogen's May 2, 2019 letter to ISE as Exhibit 9.

49. ISE's attempts to manufacture technical breaches and terminate Synogen's license is a transparent effort to avoid its obligations under the agreement.

50. ISE and its President, Ryanne Early, appear to be willing to take all measures to avoid disclosure of the Licensed Know-How and black box aspect.

51. ISE's actions are in bad faith.

52. Synogen and its sublicensees, in reliance on the exclusive license to the technology and rights to the manufacturing process, expended significant efforts, time and money in development of the product NeoMatriX, clearance of the product to market by the FDA, and prosecution of patent rights in eight different jurisdictions.

53. And now that the branded product NeoMatriX is developed, approved to be marketed in the U.S., and has been given an indication of forthcoming patent rights in the U.S., all based on Synogen's and its sublicensees' efforts and money, ISE is attempting to revoke the licenses to avoid its obligations under the agreement.

54. Ryanne Early is also a principal and the CEO at Seed Biotech, Inc. ("Seed")—a Texas corporation with a focus on the biotech industry.

RegenX Science Exhibit 1071
Page 96

55. On information and belief, Ryanne Early uses each company interchangeably, and personally, and the corporate formalities one would expect from two different companies are severely lacking.

56. For example, Ms. Early conducts ISE business from a seedbiotech.com email address, and her Gmail address signature refers to positions at both ISE and Seed.

57. The principal place of business, mailing address and registered business address for ISE is the law office of Michael A. Croak—Ryanne Early's father.

58. Ryanne Early is the sole owner, president and employee of ISE.

59. And, on information and belief, ISE is underfunded.

D. ISE's Breach: Refusal to Cooperate in Patent Prosecution Efforts

60. Section 9.3 of the License Agreement requires ISE to "cooperate in all respects with [Synogen]'s efforts in preparing and prosecuting the Licensed Patents, and . . . have its employees appear before patent offices and submit declarations when requested."

61. On July 10, 2019, Synogen submitted to the USPTO two formality documents—a Patent Assignment and a Declaration.

62. Both documents were reviewed and signed by Ryanne Early, President of ISE. The Patent Assignment was signed by Ms. Early on May 30, 2014, and the Declaration on May 7, 2019. The Patent Assignment and Declaration are attached as Exhibits 10 and 11, respectively.

63. Synogen forwarded the Patent Assignment to ISE by email for review on March 18, 2019.

64. And, ISE, through counsel at Nelson Mullins, forwarded to Synogen the reviewed and signed Declaration on May 7, 2019.

65. Notwithstanding these facts, on July 16, 2019, ISE sent a letter to Synogen purporting to notify Synogen that its July 10th submissions to the USPTO constituted a "material breach" and "[in]curable [breach]" of the License Agreement. ISE's July 16, 2019 letter is attached as Exhibit 12.

66. As its bases, ISE alleged Synogen failed to provide "advance copies" of the two documents, and that Synogen violated § 15 of the License Agreement—a provision barring use of another company's name in promotional and marketing materials. See *id*.

67. ISE's July 16, 2019 letter is another transparent effort by ISE to manufacture a breach of the agreement in the hope of escaping its obligations.

68. As a result of ISE's continued bad faith efforts, on July 18, 2019, Synogen was forced to respond to ISE's July 16, 2019 letter on the manufactured patent issues. Synogen's July 18, 2019 letter is attached as Exhibit 13.

69. As stated, Synogen continues to pursue patent rights in the following jurisdictions at significant expense: the United States; Canada; China; Europe; Hong Kong; Israel; Japan; and Korea.

70. As a result of Synogen's and its sublicensees' efforts, on January 10, 2019, Synogen received a Non-Final Office Action from the USPTO indicating the impending issuance of U.S. patent rights. *See* Ex. 4.

71. The continued patent prosecution efforts across the open jurisdictions are necessary to protect the licensed technology.

72. Notwithstanding this, on July 26, 2019, ISE, through email by counsel at Nelson Mullins, demanded "no further patent documents should be filed" in the open patent prosecution actions. ISE's July 26, 2019 email is attached as Exhibit 14.

RegenX Science Exhibit 1071
Page 98

E. Nextgen's Survival of the Synogen-ISE License

73. Section 2.2.1 of the Synogen-ISE License Agreement accords sublicensees the option to survive the termination of the prime Synogen-ISE license "at the Sublicensee's option."

74. Synogen and ISE expressly and unambiguously intended § 2.2.1 as a protection to sublicensees against disputes under the prime Synogen-ISE license.

75. Geof Vicker's, counsel to ISE, August 14, 2014 email to Edward Gates, counsel to Synogen, makes this clear. In memorializing discussions between representatives of Synogen and ISE relating to the terms of the draft License Agreement, Mr. Vickers wrote:

> If company does a license with a sub license and the primary companies have made a dispute/default, that sub license needs to remain valid. *the contract does not currently reflect that but it needs to in this context "licensor survives any dispute between the two primaries so the sub license survives."

See Geof Vicker's August 14, 2014 email as Exhibit 15.

76. On June 27, 2019, Nextgen sent written notice to ISE advising ISE that as a result of ISE's purported repudiation of the Synogen-ISE License Agreement, Nextgen intends, and reserves its right, to exercise its option under § 2.2.1 of the License Agreement to survive any termination of the prime license. Nextgen's June 27, 2019 letter to ISE is attached as Exhibit 16.

77. On July 16, 2019, ISE sent a response letter to Nextgen refusing to recognize Nextgen's right to survive the Synogen-ISE license under § 2.2.1 of the License Agreement.

78. And, in its Answering Statement in this Arbitration submitted August 19, 2019, ISE asserted a claim (Claim 3) requesting a declaratory judgment that Nextgen has no right to enter into a direct license agreement with ISE under § 2.2.1 of the License Agreement.

79. Accordingly, by its Answering Statement ISE placed Nextgen's rights at issue in this Arbitration, and waived any objection to Nextgen joining this Arbitration.

RegenX Science Exhibit 1071
Page 99

IV. NATURE OF THE CLAIMS

80. Claimants repeat and incorporate the preceding paragraphs of this Demand as if set forth herein at length.

A. Claim I: Breach of Contract for Failure to Transfer the Manufacturing Process – Synogen Against ISE

81. Synogen and ISE are parties to the License Agreement, made effective September 23, 2014. *See* License Agreement (Ex. 1).

82. The License Agreement is an enforceable contract.

83. Under the License Agreement, Synogen contracted for, among other things, a non-exclusive license to the Licensed Know-How. *See* License Agreement (Ex. 1) §§ 1.7, 2 ("[ISE] hereby grants to [Synogen] a non-exclusive license . . . to the Licensed Know-How . . . in the making, development, use . . . and sale of [the product].")

84. Under § 5.2.1 of the License Agreement, ISE is required to "transfer promptly at the request and expense of Synogen the Licensed Know-How."

85. And, under § 5.2.2 of the License Agreement, ISE is required to "promptly establish a commercially viable manufacturing procedure which utilizes the Licensed Know-How for making decellularized [product], which manufacturing procedure will include a black box aspect."

86. Synogen performed all obligations under the License Agreement.

87. ISE is in breach of the License Agreement, by among other things, (i) refusing to transfer the Licensed Know-How and (ii) refusing to establish and transfer a commercially viable manufacturing procedure.

88. As a result of ISE's breaches of contract, Synogen has been deprived the benefit of its bargain under the License Agreement and suffered harm including monetary damages.

Wherefore, Synogen requests entry of judgment on Claim I against ISE, and that the Arbitrator award relief to Synogen as outlined in Section V of this Demand.

B. Claim II: Breach of Contract for Refusal to Cooperate in the Patent Prosecution – Synogen Against ISE

89. Synogen and ISE are parties to the License Agreement, made effective September 23, 2014. *See* License Agreement (Ex. 1).

90. The License Agreement is an enforceable contract.

91. Under the License Agreement, ISE is required to "cooperate in all respects with [Synogen]'s efforts in preparing and prosecuting the Licensed Patents, and . . . have its employees appear before patent offices and submit declarations when requested." License Agrmt. (Ex. 1) § 9.3.

92. Synogen performed all obligations under the License Agreement.

93. ISE is in breach of the License Agreement, by among other things, (i) refusing to cooperate in good faith in the submission of the Patent Assignment and Declaration documents to the USPTO, and (ii) its demand that "no further patent documents [are] filed."

94. As a result of ISE's breaches of contract, Synogen has been deprived the benefit of its bargain under the License Agreement and suffered harm including monetary damages.

Wherefore, Synogen requests entry of judgment on Claim II against ISE, and that the Arbitrator award relief to Synogen as outlined in Section V of this Demand.

C. Claim III: Breach of the Covenant of Good Faith and Fair Dealing – Synogen Against ISE

95. Florida recognizes the implied covenant of good faith and fair dealing in contractual relationships.

96. The Synogen-ISE License Agreement is an enforceable contract.

RegenX Science Exhibit 1071
Page 101

97. ISE has breached the implied covenant of good faith and fair dealing by its arbitrary and unreasonable conduct, including, without limitation, (i) its refusal to transfer the Licensed Know-How, and (ii) refusal to establish and transfer a commercially viable manufacturing procedure.

98. ISE's obligation to transfer the Know-How and commercially viable manufacturing procedure under the License Agreement is clear and unambiguous. *See* License Agreement (Ex. 1) §§ 1.7, 2, 5.2.1, 5.2.2.

99. And, ISE's refusals are in direct contravention to the unambiguous terms of the License Agreement.

100. As a result of ISE's breach of the implied covenant of good faith and fair dealing, Synogen has been deprived the benefit of its bargain under the License Agreement and suffered harm including monetary damages.

Wherefore, Synogen requests entry of judgment on Claim II against ISE, and that the Arbitrator award relief to Synogen as outlined in Section V of this Demand.

D. Claim IV: Violation of Florida's Deceptive and Unfair Trade Practices Act – Synogen Against ISE

101. Synogen contracted with ISE for the transfer of the exclusive rights to the Licensed Patents and the non-exclusive rights to the Licensed Know-How.

102. At the time of the agreement, ISE promised to provide the Licensed Know-How, black box aspect and a "commercially viable manufacturing procedure" to Synogen.

103. In exchange for these rights, Synogen paid fair market consideration.

104. In direct contravention to the clear terms of the agreement, ISE has refused to transfer the Licensed Know-How.

RegenX Science Exhibit 1071
Page 102

105. Instead, to avoid its clear obligations under the agreement to transfer the Know-How, black box aspect and manufacturing process, ISE has taken unreasonable positions and improperly attempted to terminate the License Agreement and Synogen's rights to the Licensed Patents and Licensed Know-How.

106. ISE has provided no explanation for its unreasonable breach position, and its actions are unethical, deceptive and are in bad faith.

107. As a result of ISE's deceptive practices, Synogen's contracted-for rights to the technology have no market value.

108. As a result of ISE's violation of Florida's Deceptive and Unfair Trade Practices Act, Synogen has been deprived the benefit of its bargain under the License Agreement and suffered harm including the diminution in value of its received rights and monetary damages.

Wherefore, Synogen requests entry of judgment on Claim III against ISE, and that the Arbitrator award relief to Synogen as outlined in Section V of this Demand.

E. Claim V: Breach of Contract for Failure to Transfer the Manufacturing Process – Nextgen Against ISE

109. The Synogen-ISE License Agreement is an enforceable agreement.

110. Nextgen is a third-party beneficiary to the License Agreement, including, without limitation, §§ 2.2.1 and 13.

111. Section 2.2.1 of the License Agreement accords sublicensees the option to survive the termination of the prime license at the sublicensee's option, and to enter into a direct license agreement with ISE on substantially the same terms as the sublicense agreement. *See* License Agreement (Ex. 1) § 2.2.1.

112. On June 27, 2019, Nextgen sent written notice to ISE advising ISE that as a result of ISE's purported repudiation of the Synogen-ISE License Agreement, Nextgen intends, and

RegenX Science Exhibit 1071
Page 103

reserves its right, to exercise its option under § 2.2.1 of the License Agreement to survive any termination of the prime license.

113. Despite purportedly terminating the Synogen-ISE License Agreement, ISE has refused to recognize Nextgen's contractual rights under § 2.2.1 of the License Agreement.

Wherefore, in the alternative, should the License Agreement be deemed terminated, Nextgen requests entry of judgment on Claim V against ISE, and that the Arbitrator award relief to Nextgen as outlined in Section V of this Demand.

V. REQUEST FOR RELIEF

Wherefore, claimants Synogen Management Group, Inc. and NeXtGen Biologics, Inc. request damages, and declaratory and injunctive relief, as follows:

A. Injunctive Relief – Synogen Against ISE

1. In accordance with § 5.2.1 of the License Agreement, ISE shall transfer promptly to Synogen, and not later than 3 business days from the entry of this Arbitrator's Award, the Licensed Know-How;

2. And, in accordance with § 5.2.2 of the License Agreement, ISE shall promptly, and not later than 3 business days from the entry of this Arbitrator's Award, establish, and transfer to Synogen, a commercially viable manufacturing procedure which utilizes the Licensed Know-How for making decellularized [product], which manufacturing procedure will include a black box aspect;

B. Monetary Damages – Synogen and Nextgen Against ISE

3. Monetary damages to compensate Synogen and Nextgen for all losses, including but not limited to, lost revenues, expenses incurred in pursuit of development of the technology,

RegenX Science Exhibit 1071
Page 104

and regulatory and patent approvals, and expenses incurred in pursuit of alternative manufacturing processes, and the value of Nextgen's business should it be destroyed by ISE's breaches;

4. Reasonable attorneys' fees, expenses, and related litigation and arbitration costs under AAA Rule R-47(d), as a sanction for bad faith litigation conduct, and generally at law and in equity;

5. All other relief that the Arbitrator finds just;

C. Declaratory Relief – Nextgen Against ISE

6. In the alternative, should the License Agreement between Synogen and ISE be deemed terminated, Nextgen has the right, at its sole option, under § 2.2.1 of the License Agreement to survive the termination of the prime license, and to enter into a direct license with ISE on substantially the same terms as the Synogen-Nextgen Sublicense Agreement.

Synogen and Nextgen reserve the right to modify and supplement their claims, including their requests for relief, as more facts become available and to submit all documents, exhibits, witness statements and other evidence as necessary to prove their claims and damages.

RegenX Science Exhibit 1071
Page 105

Date: September 16, 2019

DLA PIPER LLP (US)

s/ Janelly Crespo
Janelly Crespo

200 South Biscayne Boulevard, Suite 2500
Miami, FL 33131
T: 305.423.8500 / F: 305.437.8131
janelly.crespo@dlapiper.com

John D. Huh (*R 1-3.11 statement pending*)
Scott M. Vernick (*R 1-3.11 statement pending*)

One Liberty Place
1650 Market Street, Suite 5000
Philadelphia, PA 19103
T: 215.656.3300 / F: 215.656.3301
john.huh@dlapiper.com
scott.vernick@dlapiper.com

Attorneys for Synogen Management Group, Inc. and NeXtGen Biologics, Inc.

Exhibit E

IN THE AMERICAN ARBITRATION ASSOCIATION

SYNOGEN MANAGEMENT GROUP, INC.,

Claimant,

Arbitration Case No. 01-19-0002-3786

v.

ISE PROFESSIONAL TESTING & CONSULTING SERVICES, INC.,

Respondent.
_____/

RESPONDENT ISE PROFESSIONAL TESTING & CONSULTING SERVICES, INC.'S AMENDED ANSWER AND COUNTERCLAIMS

Respondent and Counterclaim Claimant ISE Professional Testing & Consulting Services, Inc. ("ISE") amends its answer and counterclaims against Synogen Management Group, Inc. ("Synogen") on the grounds below as required by the American Arbitration Association ("AAA") Commercial Arbitration Rule ("Rules") § R-5(b) and the parties' September 23, 2014 License Agreement ("License Agreement").

I. PRELIMINARY STATEMENT

This case is about Synogen's abuse of the license ISE granted it to prosecute a patent application (14/759895) for Decellularized Biomaterial from Non-Mammalian Tissue. Since ISE entered into the License Agreement in September 2014, Synogen repeatedly failed to keep up its end of the bargain.[1] Synogen's breaches of the License Agreement began almost immediately (although unknown to ISE) and persisted throughout the life of the License Agreement and beyond.

[1] A copy of the License Agreement is attached as Exhibit 1.

ISE put Synogen on notice of its breaches of the License Agreement multiple times[2] and ultimately terminated.

Synogen through its then-counsel, Gerard Bencen,[3] tried to cure several of the identified breaches. But Synogen failed to do so. ISE wrote back to Synogen, insisting that several breaches were incurable or were not cured, and preserved its right to terminate the License Agreement .[4] And Synogen's counsel responded, seeking even more forbearance of Synogen's and its Sublicensees several breaches of that contract.[5] Synogen refused to deal with ISE in good faith, and ISE was left with no choice but to terminate the License Agreement.

Synogen, in the proverbial race to the courthouse, asserts four claims against ISE, all of which fail. Count I is for breach of contract for alleged failure to transfer the manufacturing procedure or "know-how." This claim fails because Synogen misinterprets the License Agreement, reading Section 5 as those they were disparate obligations rather than as part of an entire process together. The Licensed Know-How was to be transferred only as part of the "black box." There

---

[2] A copy of ISE's November 7, 2018 Notice is attached as Exhibit 2. Copies of the emails to Synogen and its counsel about Synogen's refusal to pay are attached collectively as Exhibit 3.

[3] Synogen is on its third law firm since the Effective Date of the License Agreement. First there was Ed Gates at Wolf Greenfield, then Gerard Bencen at the Patent Arts law firm, and now DLA Piper.

ISE continues to maintain that it is ethically impossible for a law firm to represent adverse parties. DLA Piper should not be allowed to represent Synogen in arbitration as it also represented ISE before the United States Patent and Trademark Office ("USPTO") in matters substantially related to the issues here and must be disqualified.

[4] A copy of ISE's December 21 letter is attached as Exhibit 4.

[5] A copy of Synogen's December 22, 2018 letter is attached as Exhibit 5. December 22, 2018 was the last day to cure any material breaches that could be cured. Some of the remaining breaches, as Synogen's counsel recognized, were both material breaches and incurable, giving a right to ISE to terminate the License Agreement. Instead of curing the breaches, Synogen asked for more time.

CONFIDENTIAL – FOR ARBITRATION PURPOSES ONLY

RegenX Science Exhibit 1071
Page 109

was never any agreement to transfer technology to Synogen that it could transfer to others except in connection with a black box, and the License Agreement contemplates that.

Synogen never properly prepared for this to happen. Although Synogen suggests that ISE thwarted development through a third party, the truth is actually that Synogen wanted ISE to turn over its process to a third party without Synogen's involvement. ISE attempted to interact with the person several times, and when the parties finally started trying to understand the process for developing the black box (which is a mutual obligation), Synogen turned tail and decided it wanted to amend the agreement instead. And, in blatant violation of the License Agreement, Synogen effectively washed its hands of the entire matter and put NeXtGen, its Sublicensee in charge. But because there was never a true meeting of the minds, as will be clear throughout the multiple years' exchange of communications; any requirement to "black box" ISE's proprietary and trade secret technology is ambiguous, and no party agrees to its meaning. Thus, this entire section of the License Agreement is unenforceable.

Count II is for breach of contract for refusing to cooperate with the patent prosecution. That is blatantly false: ISE could not cooperate with a patent prosecution when it was not being given copies of filings and an opportunity to comment as required by the License Agreement. There are no facts before the termination of the License Agreement that support such a claim. Moreover, Synogen's prior material breaches (particularly its failure to give ISE advance copies and opportunity to comment on filings at the USPTO) and delegating this function to its Sublicensee excuse ISE from any further performance under the License Agreement.

Count III is a mere restatement of Counts I and II and fails for the same reasons. And as ISE will show at the hearing, ISE always cooperated and acted in good faith. It was instead Synogen and its Sublicensees who made unreasonable demands and acted improperly.

Count IV for violating the Florida Deceptive and Unfair Trade Practices Act fails because Synogen is not a consumer, and even so, no facts support the claim; this is just a twisted claim meant to expand the arbitration unnecessarily.

ISE asserts counterclaims against Synogen for (1) a declaratory judgment that ISE properly terminated the License Agreement; (2) a declaratory judgment, if needed, that Section 5 of the License Agreement is unenforceable because there is no meeting of the minds; (3) a declaratory judgment that ISE need not enter into licenses with Synogen's Sublicensees because of their material breaches and because it is discretionary; (4) breach of contract for failing to provide ISE with advance copies and opportunity to comment on the patent prosecution and for delegating the patent prosecution to a Sublicensee; (5) for breach of contract over ISE's uncompensated time and effort in connection with the patent and bringing a product to market; (6) for breach of a direct Synogen-ISE NDA that supercedes the confidentiality provisions in the License Agreement; (7) for specific performance of an accounting of all fees, royalties, and investments as allowed by the License Agreement; (8) for injunctive relief and damages for Synogen's failure to turn over records reflecting consideration it received from the sublicenses; (9) for attorneys' fees; and (10) for disqualification of DLA Piper from representing Synogen here because it also represented ISE before the USPTO (Synogen and ISE were to joint clients and thus DLA Piper cannot be adverse to ISE now under Florida law). As ISE will show at the hearing, it is ISE who complied with the parties' agreement, not Synogen. Thus, Synogen should recover nothing, and ISE should be granted all of the relief it requests.

II. BACKGROUND

Jamie Grooms, Synogen's Chief Executive Officer, and Ryanne Early, ISE's President, have known each other a long time. Indeed, Mr. Grooms became intrigued with Ms. Early's ideas,

research, and concepts about using regenerative amphibians (urodele/axolotls) to aid in human medical and cosmetic needs. To that end, the parties signed an informal, back–of–the–napkin deal by which Mr. Grooms and Ms. Early would go in 50-50 on development of this brave new area of biologics.

ISE first filed a patent application in 2013 in pursuit of this idea to protect its intellectual property. Thereafter, Mr. Grooms approached Ms. Early to formalize their agreement with a license for the pending patent application. In specific consideration of paying outstanding legal fees to the law firm that filed the patent application for fees for consulting, and for a 50% share of the fees and revenue, Ms. Early, through ISE, gave Synogen an exclusive license to pursue the patent application. (License Agreement § 2.1.)

ISE also gave Synogen a non-exclusive license to certain general but undefined "Know-How" relating to the method to decellularize tissue, but in a "black box." That "black box" concept was integral to the plan but undefined. Synogen's own counsel confessed that Synogen does not know "what the black box is." (Jan. 17, 2019 Email from G. Bencen attached as Ex. 6.) There was no real meeting of the minds on that license or its scope.

Following the License Agreement, Synogen signed two Sublicenses to which ISE is not a party—one to NeXtGen Biologics, Inc.[6] ("NeXtGen") and one to RegenX Science, Inc.[7] ("RegenX"). Synogen then abandoned its direct work on the patent prosecution, turning it over to NeXtGen's attorneys, and, upon information and belief, NeXtGen and RegenX.[8] For example,

[6] Mr. Grooms is the Chairman of NeXtGen.

[7] Mr. Grooms is the Chairman of RegenX as well.

[8] RegenX has had different counsel than NeXtGen at times. But earlier this year, RegenX's counsel made a child patent application with the USPTO without ISE's knowledge and consent, something RegenX (not Synogen) disclosed after Synogen demanded arbitration.

CONFIDENTIAL – FOR ARBITRATION PURPOSES ONLY

RegenX Science Exhibit 1071
Page 112

Synogen turned over responsibility to pay the attorneys who filed the patent application to NeXtGen, and NeXtGen failed to pay the fees in a timely manner (the first breach of the License Agreement).[9] Synogen's shift to NeXtGen caused many disruptions in ISE's business as NeXtGen's personnel failed to respect the License Agreement requirements for notice on consulting and payment for ISE's time. ISE ended up spending many hours (hundreds is a reasonable estimate), assisting NeXtGen in its business—all uncompensated.

Things came to a head in the Fall of 2018, when it became clear that Synogen was not going to abide by the terms of the License Agreement, including paying revenue, keeping ISE informed on the patent prosecution, requiring its Sublicensees to maintain insurance, and the like. As a result, in early November 2018, ISE sent Synogen a default notice. (Ex. 2.) Synogen had 45 days to "cure" those defects it could cure, but as Synogen's counsel recognized, Synogen could never cure some breaches. (*See* Ex. 5 at 3.)

To attempt to get things back on track, while reserving its rights to terminate, ISE requested Synogen to make a proposal as to how to fulfill the "black box" aspect of the "Know-How" license, which included some prerequisites like hiring a project manager. Synogen and NeXtGen's patent counsel responded, offering himself up as the project manager and specifically providing NeXtGen with access to ISE's trade secrets when it was clear that no Sublicensee was to have access. So once again the parties stopped in their tracks because of Synogen's disregard for the contract and its delegating its patent functions to NeXtGen.

As this was going on, it also became clear that in violation of the License Agreement, Synogen was not giving ISE notice of any patent filings. Instead, Synogen made and was making

[9] This breach was not cured within forty-five days, giving ISE the right to terminate the License Agreement.

CONFIDENTIAL – FOR ARBITRATION PURPOSES ONLY

filings at the USPTO and in multiple foreign countries (as stated in the Demand) without giving ISE any opportunity to review and comment. And because ISE has not been able to be involved, since her provisional application, Synogen has moved the entire patent application away from focusing on the product (the amphibian tissue) to the process, which ISE keeps as a trade secret. ISE made this comment to patent counsel, objecting, but Synogen refused to consider ISE's comments (when it was provided a copy). And in rare instances when Synogen gave ISE an advance copy of any filing, it did so with insufficient time for ISE to review and consider. For example, on July 10, 2019, Synogen's DLA Piper counsel gave ISE less than eight hours to review and comment before filing with the patent office under ISE's name by emailing it to counsel with no indication of when DLA Piper planned to file. This violated the License Agreement Section 9.1.

Synogen also allowed a Sublicensee (RegenX) to state *falsely* to the USPTO that it represented ISE, filing a "child" patent application without ever notifying ISE or providing a copy of the application in advance. This, like delegating the patent prosecution to NeXtGen, otherwise violates License Agreement Section 9.1 and is a material breach of the License Agreement.

III. ISE'S ANSWER AND AFFIRMATIVE DEFENSES TO SYNOGEN'S CLAIMS

ISE denies that Synogen is entitled to any relief at all for the reasons stated herein. None of Synogen's claims are supported by facts or law. Although Synogen may have filed first, it is

Synogen, not ISE, who breached the License Agreement.[10] Because of Synogen's prior material breaches, ISE is released, and Synogen cannot succeed on its claims.[11]

Synogen also cannot recover for speculative damages in the form of lost revenues for a product that has never been sold, for investments made by others (not Synogen), or for expenses to develop a manufacturing process when ISE never agreed to manufacture this product and when Section 5 is unenforceable. Synogen also failed to mitigate its damages.

Synogen also has no right to any form of injunctive or equitable relief and has unclean hands as a result of its conduct. Synogen's own actions have put the parties in the position in which they find themselves, and thus Synogen is not entitled to any equitable relief. In sum, all of Synogen's claims fail and ISE is entitled to an award in its favor.

IV. ISE'S CLAIMS AGAINST SYNOGEN[12]

Incorporating the facts above and as ISE will prove at the hearing, ISE asserts these claims against Synogen.

Claim 1. **Declaratory Judgment that ISE Properly Terminated the License Agreement.**

There is an actual dispute between the parties about whether ISE's termination of the License Agreement was effective. A declaration that ISE properly terminated the License Agreement will resolve this issue.

---

[10] ISE admits that the exhibits attached to the original Demand are correct copies of documents but denies Synogen's characterization of them or that they represent all of the relevant communications.

[11] In Claim II, Synogen argues that ISE improperly halted patent prosecution after ISE's termination of the License Agreement. One problem with that argument is timing; ISE already terminated the License Agreement so Synogen has no live rights to prosecute the patent.

[12] ISE does not waive any additional claim it may learn of before or during the hearing and intends to submit additional facts in support of its claims through witness statements, the prehearing brief, and testimony at the hearing. Because of the limited insight ISE has had to Synogen, and because of the limited prehearing exchange, ISE may learn of other breaches during this arbitration.

As detailed above, Synogen breached the License Agreement at its very outset, trying to avoid having to pay for the initial patent work; Indeed, Synogen foisted this responsibility onto NeXtGen, who then for *years* refused to pay.

Other breaches, all of which were not cured or were incurable included:

- Synogen did not require the Sublicensees to prepare development reports
- Synogen and its Sublicensees failed to get and maintain insurance even when testing it on human subjects;
- Synogen did not provide ISE with notice and opportunity to comment on the patent filings. In violation of the Agreement, Jamie Grooms, on behalf of Synogen, specifically authorized RegenX to file patent filings in April 2019 not provided to ISE until ISE itself discovered them;
- Synogen improperly shifted the patent work to NeXtGen and RegenX, which is very clear from the attached letter from NeXtGen's counsel, Gerard Bencen (Ex. 8.) These are all material breaches of the License Agreement. As a result, ISE justifiably terminated the Agreement and ISE is released from all obligations under the License Agreement.
- Synogen failed to work with ISE in a reasonable and professional manner to transfer the technology, including by suggesting that NeXtGen's counsel be the project manager, when NeXtGen was never to have access to the trade secrets.

In sum, Synogen ignored, flouted, and outright breached the contract giving ISE the right to terminate, which ISE properly did.

Claim 2. **Declaratory Judgment Action Under Section 5.2 of the License Agreement.**

There is a bona fide dispute between the parties over the scope and meaning of Section 5.2 of the License Agreement. Even Synogen's counsel has said Synogen does not know what the parties intended when they agreed to transfer the "Know How" through a "black box." In multiple conversations over the years, no one determined how to satisfy Section 5.2. For years, the parties have gone back and forth. Only one thing is clear, ISE and Synogen never had a meeting of the minds on how this would work, and thus there is no contractual obligation. Moreover, if there is any breach of Section 5.2.2, as it is an obligation of both parties and thus a breach of Synogen for which ISE cannot be held solely liable. Thus, the License of Know-How is unenforceable, and ISE requests a declaratory judgment to the effect, which will resolve the issue.

The License to the "Know-How" is not enforceable because it is too vague, and there is no agreement on what it means. And there was no meeting of the minds on how to accomplish it. And Synogen did not give ISE any consideration worth turning over its trade secrets[13] without the ability to turn it into a manufacturing device incorporating those secrets, but hidden from others. Everyone acknowledged that ISE never planned to turn over its trade secrets except in the black-box where the secrets would be protected. But, because even Synogen cannot say "what the black box is," there was no meeting of the minds about how to transfer the licensed Know-How and thus that license is unenforceable. (Ex. 6.)

Because NeXtGen and Synogen insist on being represented by the same counsel, despite it being clear that the Sublicensees may never receive "the black box aspects of the manufacture procedure" there has been considerable confusion (even by Synogen's counsel) over who could access to the information. Synogen must protect the black box. But because Synogen has turned

[13] ISE licenses its trade secrets to others for payment.

everything and responsibility over to NeXtGen, the contract cannot be completed as originally anticipated. Hence, ISE is entitled to a declaratory judgment that Section 5.2 is unenforceable.

Claim 3. Declaratory Judgment that ISE Does Not Need to Enter into Direct Licenses With Synogen's Sublicensees.

As noted above, Synogen breached the License Agreement. Because of those breaches, ISE properly terminated the contract. Yet, both NeXtGen and RegenX are contending that under the License Agreement, because ISE has terminated, ISE must enter into direct licenses with them independently. Notably, ISE is not a party to any contracts with Synogen's Sublicensees, and the Sublicensees, are not parties to the License Agreement.

License Agreement Section 2.2.1 provides that Sublicenses will survive, "provided that the Sublicensee is not in material breach of any of its obligations under such Sublicense and provided that the Sublicensee and LICENSOR enter into a direct license on substantially the same terms as the Sublicense." (License Agreement § 2.2.1 (emphasis added).) Survival thus hinges on the happening of two events, neither of which has occurred. First, the Sublicensees materially breached their obligations, including but not limited RegenX's undisclosed and unauthorized patent filings and failing to maintain insurance. These are material breaches. Second, ISE does not have to enter into Sublicenses under the License Agreement; the "provided that" language shows that it is conditional. At this juncture, ISE has all of the rights to the patent and to its trade secret process. It is not obliged to enter into any agreement in advance as it is nothing more than an agreement to agree and is unenforceable. As a result, ISE should be released from Section 2.2.1.

Claim 4. Breach of Contract for Synogen's Failing to Follow Section 9.1 of the License Agreement.

ISE has complied with all terms of the License Agreement. Synogen breached Section 9.1 of the License Agreement by not providing advance copies of patent filings to ISE and by not

incorporating ISE's reasonable comments when ISE did get a chance to comment. Synogen also breached the contract by delegating the patent prosecution and development to its Sublicensee, NextGen, which is specifically prohibited by the License Agreement. (Ex. 1 § 9.1 ("LICENSEE shall prosecute and maintain the Licensed Patents using counsel of its choice. ***LICENSEE shall not be able to delegate this responsibility to a Third Party or an Affiliate.***").)[14] Synogen turned over patent responsibility to NeXtGen and later authorized RegenX to make additional filings.

Thus, as ISE will show at the hearing, Synogen wholly abandoned its responsibilities to prosecute the patent in favor of a Sublicensee, who then abused ISE's good graces, made unreasonable demands, and frustrated pursuit of the purpose of the License Agreement. Synogen's conduct also breaches the implied covenant of good faith and fair dealing. ISE is entitled to compensatory and equitable relief.

Claim 5. Breach of Contract—Synogen Refused To Pay ISE For Hundreds of Hours of Consulting Time.

ISE has complied with all terms of the License Agreement. But Synogen never considered Section 5.1 of the License Agreement, which set forth how ISE would support Synogen, through paid consulting. Synogen never followed Section 5.1. Instead, Synogen gave its Sublicensees permission to contact and harass ISE directly, hounding ISE for information and assistance. ISE expected to be paid for that work but Synogen has never offered to pay ISE for this time. Synogen's conduct also breaches the implied covenant of good faith and fair dealing. ISE is entitled to compensatory and equitable relief.

[14] Upon information and belief, NeXtGen and RegenX are either Third Parties or Affiliates or both. This will be the subject of discovery and evidence at the hearing. A copy of NeXtGen's attorney's correspondence demonstrating the improper delegation is attached as Exhibit 7.

Claim 6. **Breach of Contract – Synogen Breached its NDA with ISE.**

On April 13, 2015, after the License Agreement was entered into, Synogen executed a separate non-disclosure agreement in favor of ISE ("NDA") that superceded Synogen's confidentiality obligations to ISE as stated in the License Agreement.[15]

In the NDA, Synogen agrees that ISE has Confidential Information, which is defined as:

> 1. ***Definition.*** **For the purposes of this Agreement, the term "Confidential Information" shall mean any and all information, know-how and data, technical or non-technical, disclosed or provided by the Company, whether disclosed or provided in oral, written, graphic, photographic, electronic or any other form. By way of illustration but not limitation, "Confidential Information" includes inventions, mask works, trade secrets, ideas, processes, formulas, source and object codes, data, programs, other works of authorship, know-how, improvements,discoveries, developments, designs and techniques; information regarding plans for research, development, new products, regulatory matters, marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, suppliers and customers; and information regarding the skills and compensation of other employees of the Company. but not limited to, all technical data, engineering information, product specifications, data, know-how, formulae, compositions, processes, improvements, devices, designs, methods, sketches, photographs, graphs, drawings, samples, inventions, discoveries, concepts, ideas, past, current and planned research and development, current and planned manufacturing or distribution methods and processes, computer software and programs, financial and any other information.**

Upon information and belief, Synogen has breached the NDA by sharing ISE confidential information with prohibited persons. The NDA provides that:

> b. **All Confidential Information will be kept secret and confidential and shall not be disclosed to anyone except to a limited group consisting of employees, directors, officers, and partners who are actually engaged in the evaluation or collaboration referred to above. The Confidential Information will not be disclosed to outside professional advisors, agents, attorneys, accountants and/or other representatives similarly engaged, without the prior written consent of the Company. Each person to whom such Confidential Information is disclosed must be advised of its confidential nature and of the terms of this Agreement and must agree to abide by such terms.**

(NDA § 3.b.) It is believed, based on the information available to ISE (and subject to discovery and testimony at the hearing), that Synogen has shared ISE's Confidential Information with Sublicensees, attorneys, investors, and perhaps others in violation of the Agreement. ISE should

[15] The NDA is attached as Exhibit 8.

be awarded injunctive relief, return of its Confidential Information, and damages, as proven at the hearing.

Claim 7. Specific Performance of the Contract—ISE is Entitled to an Accounting Before a Hearing.

ISE has complied with all terms of the License Agreement. Under License Agreement Sections 8.1, 8.2, and 11.5, ISE is entitled to and demands an accounting from Synogen and an inspection of all books and records within thirty (30) days. Along with documents to be exchanged prior to the hearing, Synogen must allow ISE to come inspect the records. This accounting will assess whether Synogen has also breached Section 4.2 of the License Agreement relating to the acceptance of consideration. Upon information and believe, Synogen has accepted consideration from NeXtGen and Regenx not shared with ISE and to which ISE may have payment as part of an award.

Claim 8. Injunctive Relief and Damages Arising from Synogen's Refusal to Allow a Contractually Allowed Accounting.

In its Answer to ISE's Counterclaims, Synogen refuses to provide an accounting, a right that survives the contract termination. ISE may have an immediate order directing Synogen to comply with the right to an accounting as there is no legitimate dispute. In addition, ISE should be awarded any damages in connection with any information revealed from the accounting, such as failure to share all funds received as consideration for any Sublicense or as may otherwise be shown. For example, ISE should be awareded its share of monies paid by Sublicensees on Synogen's behalf for the patent prosecution, which is consideration for the Sublicense. This amount is unknown to ISE and ISE will need information from Synogen and perhaps its Sublicensee to prove that.

Claim 9. **ISE is Entitled to Recover its Attorney's Fees.**

Because of Synogen's misconduct, ISE has incurred attorney's fees and expenses unnecessarily in dealing with Synogen's breaches. This caused a loss for ISE for which Synogen is responsible. Thus, under the AAA Rules, ISE asks the arbitrator to award it all of its attorney's fees, expenses, and costs, including the fees of the AAA and the arbitrator as may be determined through the hearing.

Claim 10. **DLA Piper Should Be Disqualified.**

Florida law provides that counsel may not represent the owner of a patent in the patent application/prosecution process and then represent the party's adversary in litigation about the scope of the party's right to use the patents. DLA Piper demanded ISE provide it with a power of attorney to allow DLA Piper to represent ISE at the USPTO. Hoping to avoid this arbitration process, and during the parties' prior attempts to resolve the suit, ISE, without prejudice to revoke the power of attorney, gave DLA Piper that power of attorney, which DLA Piper then filed with the USPTO and used in prosecution of the patents.

ISE later revoked the power of attorney—a move Synogen suggested in a July 18, 2019 letter that ISE could not do.[16] Synogen also refused to give ISE a copy of all patent filings and communications with the USPTO. Indeed, with this counterclaim on the horizon, DLA Piper did so only on August 16, 2019, a month after ISE's request.[17] Its and Synogen's failure to do so earlier is a breach of the License Agreement.

[16] A true and correct of the letter and the power of attorney are attached as a composite Exhibit 9.

[17] Because Synogen just provided this, ISE reserves and does not waive all claims it may have in this regard.

Synogen can choose counsel to represent it at the USPTO under the License Agreement (while it was in effect), but it cannot then turn that same counsel against ISE in an adversarial position. Synogen needs to choose new counsel to represent it here, and should not be allowed to proceed with counsel who once represented ISE on a substantially related matter—prosecution of the patents.

V. PRAYER FOR RELIEF

ISE thus asks the Arbitrator to deny Synogen's claims in their entirety and to:

1. enter a declaratory judgment that ISE's termination of the License Agreement was effective;

2. enter a declaratory judgment that Section 5.2 of the License Agreement is unenforceable;

3. enter a declaratory judgment that ISE need not enter into licenses with Synogen's Sublicensees;

4. find Synogen in breach of Section 9.1 of the License Agreement and award damages to ISE in an amount to be proven at the hearing;

5. award damages against Synogen for breach of contract for uncompensated consulting time, as proven at the hearing;

6. award injunctive relief and damages against Synogen for breach of the NDA;

7. order specific performance in the form of an accounting from Synogen as provided in the License Agreement (if Synogen fails to cooperate);

8. order injunctive relief and damages against Synogen for refusing to provide the accounting required by the License Agreement;

9. award ISE its attorney's fees and expenses in connection with Synogen's breaches of contract and this arbitration (including all fees of arbitration);

10. disqualify DLA Piper from this matter and require Synogen to obtain new counsel; and

11. to award all further relief that the arbitrator determines to be appropriate and just under the parties agreement to arbitrate.

Respectfully submitted, this 16th of September, 2019.

/s/ Erika C. Birg
Erika C. Birg
Florida Bar No. 55435
NELSON MULLINS RILEY & SCARBOROUGH LLP
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000
(404) 322-6050 (fax)
erika.birg@nelsonmullins.com

Attorney for ISE Professional Testing & Consulting Services, Inc.

Exhibit F

AMERICAN ARBITRATION ASSOCIATION® | INTERNATIONAL CENTRE FOR DISPUTE RESOLUTION®

American Arbitration Association

Order#2 CORRECTED SCHEDULING ORDER

Case Number: 01-19-0002-3786

Synogen Management Group, Inc.
-vs-
ISE Professional Testing &
Consulting Services, Inc.

Pursuant to the Commercial Arbitration Rules of the American Arbitration Association (AAA) effective October 1, 2013, a preliminary hearing was held on September 11, 2019 before Arbitrator Catharine Biggs Arrowood. Participating for Claimant were John Huh and Scott Vernick of DLA Piper LLP (US), for Respondent Erika Birg of Nelson Mullins Riley & Scarborough LLP and for AAA Angela Romero. A court reporter engaged by Respondent also attended. Following the hearing, correspondence was exchanged on certain issues raised during the hearing. Following further correspondence from counsel, this Order #2 which replaces Order #1 was issued.

By agreement of the Parties and Order of the Arbitrator, the following is now in effect:

1. **Applicable Law**: The Federal Arbitration Act will apply in the Arbitration and Florida law will be applied substantively to the arbitration.

2. **Parties and Amendments to Claims:** All the necessary or appropriate parties are included in the arbitration. The Parties may request to amend their claims

and/or counterclaims and/or request to add any additional necessary parties on or before September 16, 2019; responses, if any, are due by September 23, 2019. The responses shall include the answer, including defenses, to the amendment as well as any substantive opposition to the amendment or addition of parties.

3. Motions:

(a) Respondent previously indicated its intent to submit a motion to disqualify Claimant's counsel and did so on September 10, 2019. Claimant will file its response by September 18, 2019. Any reply, which shall not exceed five pages, will be filed by September 20, 2019.

(b) In light of the expedited requirements in the Parties' arbitration agreement, motions, particularly dispositive motions, are discouraged. Parties may raise any matter by email to the Arbitrator. The Party raising the matter shall certify that the Parties have conferred and been unable to resolve the matter and shall succinctly state the issue at hand. The other Party shall respond succinctly by email within 48 hours of the initiating email to the Arbitrator. The Arbitrator will determine if further briefing, argument or discussion is needed; if the matter appears ripe for decision, the Arbitrator will rule.

4. Filings. In general, copies of all cited authorities shall be furnished to the Arbitrator in electronic form. If a filing exceeds ten pages, a hard copy is to be sent to the Arbitrator.

5. Hearing: The Parties now estimate that this case will require 5 days of hearing time, inclusive of arguments. The Parties have agreed that the hearing in this

matter will commence before the Arbitrator in Orlando Florida on October 23 to October 29, 2019. The hearing will run each day from approximately 9am to 5pm with a lunch break. The approximately thirty hours of hearing time (five days times six hours per day) will be split evenly between the Parties and the court reporter will track the time used by each Party, including opening, closing, objections, cross examination, etc. The Parties may present any part of their case by written witness declaration. As to experts, Parties may choose to rely on their written expert reports. The Arbitrator reserves the right to request that witnesses, including experts, appear for cross examination. This is a firm setting, and will not be changed or continued absent exceptional circumstances, upon a showing of good cause.

6. **Additional Conferences**: Additional telephonic conferences with the Arbitrator have been scheduled for the following times: September 27 at 11 EDT; October 8 at 2 pm EDT and October 21 at 2pm EDT (this call will serve as the prehearing conference). The Parties shall confer at least two business days prior to the time set for the call and either submit a proposed agenda or notify the AAA and the Arbitrator that there is no need for the call.

7. **Exchange of Information/Discovery**:

(a) The Parties' agreement does not permit depositions or interrogatories. The Parties do not believe an initial exchange of witnesses and documents is appropriate for this case.

(b) The Parties agree that each Party may serve no more than 15 requests for

production of documents by September 18, 2019. The Parties are asked to use a Redfern/spreadsheet format in WORD with four columns, one each for the request, objections, if any, by the responding Party, reply by the requesting Party and a ruling, if any is needed, by the Arbitrator. Objections and responses are due September 20, 2019; any reply by September 23, 2019. The Parties will exchange documents no later than September 26, 2019.

(c) Discovery Protocols and Confidentiality. The Parties are to confer regarding a Protective Order which shall include, among other things, their agreement on electronic discovery protocols, a clawback agreement for inadvertently disclosed privileged documents and any cost shifting agreements, if appropriate. The Parties are to submit their agreed on or proposed Protective Order to the Arbitrator by September 18, 2019.

(d) Privilege. It is anticipated that documents responsive to the discovery requests will include attorney client privileged matter. The Parties are to segregate and retain any documents being withheld due to privilege which reflect third party recipients. On September 26, 2019, each Party is to notify the other of the total number of privileged documents which reflect third party recipients and provide the other Party with the identity of those third parties as well as the number of such communications involving that third party.

8. Subpoenas: Subpoenas to secure the appearance of non-party witnesses or documents will be issued by the Arbitrator. The Party requesting the subpoena shall

disclose the subpoena to and shall confer with all other Parties prior to requesting its issuance and shall indicate if any Party opposes the issuance. If a Party objects to issuance of the subpoena or the content of any subpoena, such objection shall be presented to the Arbitrator no more than 2 business days after issuance is requested, unless a shorter time is ordered by the Arbitrator. Subpoenas for the attendance of witnesses at the hearing may be submitted at any time but shall be submitted no later than October 14, 2019.

9. Witness and Expert Disclosures:

(a) The Parties shall each file a disclosure of all witnesses, including experts, reasonably expected to be called by them by October 14, 2019. Should any Party choose to submit its witness testimony in writing, it shall provide a copy of that witness statement by October 18, 2019.

(b) Expert witness reports relevant to a Parties' claims shall be exchanged on October 14, 2019. Any rebuttal expert reports shall be exchanged on October 17, 2019. Expert reports shall set forth each expert's qualifications, opinions and the reasons for them. The substance of each expert's direct testimony must fairly and reasonably reflect the expert's report. There shall be no additional discovery of experts.

10. Hearing Exhibits: The following procedure is intended to resolve documentary objections and to eliminate evidentiary objections at the hearing to the extent reasonably possible. On October 14, 2019, the Parties shall exchange a list of all

exhibits (including document numbers) to be offered. By October 17, 2019, the Parties shall attempt to agree upon and submit a single set of joint exhibits numbered sequentially (and in chronological order to the extent possible) and labeled as Hearing or Joint Exhibits. Each exhibit so labeled will be deemed authentic and otherwise admissible. The Parties are to prepare an index to the Hearing or Joint Exhibits that is electronically searchable by date and exhibit number. To the extent a Party identifies exhibits that the other Party objects to including in the Hearing or Joint Exhibit group, those exhibits shall be separately numbered as Claimant's Exhibit or Respondent's Exhibit as the case may be and their use will be ruled on at the hearing. The Parties shall bring to the hearing sufficient copies of any exhibit to be used at the hearing for use by the other Party, the witness, the Arbitrator, and/or the court reporter, so that the hearing is not delayed while exhibits are being located.

11. Arbitration Hold: Counsel are to inform the Parties that the Arbitrator has ordered an arbitration hold which applies to any and all documents, materials, communications, data or other similar items relating to the disputes among Synogen and ISE and related entities, concerning the Synogen-ISE September 24, 2014 Agreement. The Parties should take steps to prevent the destruction of all documents, both paper and electronic. If any party has an automatic document deletion/destruction program in place that system should be overridden until the case is completed.

12. Hearing Briefs, Award Drafts and Fee Submissions: On October 18, 2019, the Parties will file Hearing Briefs which shall be no longer than forty pages.

November 15, 2019 is tentatively set as the date for the submission of Post-Hearing Briefs, which will be no longer than ten pages in length, Award Drafts and fees and costs submissions.

13. Stenographic Record: The Parties desire a stenographic record of the hearing as well as all proceedings in this matter and have arranged for a court reporter and agreed as to the costs. The Parties will arrange to furnish a copy of any transcript to the Arbitrator on the same timing and basis as the Parties and will bear any related costs evenly, subject to a possibly different ruling in the final award in this matter.

14. Award: The award in this matter will be a reasoned award and, pursuant to Rule R 47(d) of the Commercial Rules and the agreement of the Parties, may include an award of attorneys' fees and costs.

15. Mediation/Judicial Settlement Conference Services: The Parties have indicated their intent to mediate their dispute and shall notify the AAA and the Arbitrator immediately if this matter is resolved.

16. Direct Exchange. The Parties agree to participate in Direct Exchange. Provided there is *no ex parte* communication with the Arbitrator, the Parties may communicate directly with the Arbitrator by submitting documents to the Arbitrator so long as copies are simultaneously sent to the other Party and the AAA (except for hearing exhibits and discovery documents) by the same means. As noted above, a hard copy of any filing that exceeds ten pages should be sent to the Arbitrator by mail in addition to any electronic transmission. The following are the addresses to be used:

i. For Claimant: john.huh@dlapiper.com and scott.vernick@dlapiper.com

ii. For Respondent: erika.birg@nelsonmullins.com and tinicia.thornton@nelsonmullins.com

iii. For Arbitrator: cbarrowood@parkerpoe.com;301 Fayetteville Street, Suite 1400; Raleigh, NC 27601; Office: (919) 890-4142; Mobile: (919) 274-8022.

iv. For AAA: angelavaledon@adr.org

17. Disclosures: Each counsel and Party has a continuing obligation to protect the integrity of the arbitration proceeding by promptly providing the Arbitrator the information necessary to allow her to comply with her ongoing duties of disclosure pursuant to the Code of Ethics for Arbitrators in Commercial Disputes and the American Arbitration Association. Counsel, for themselves and for each of their clients, acknowledge the continuing obligation to supplement the identification of potential fact and expert witnesses, consulting experts, counsel participation and representation in any capacity, and any other individual or entity interested in the outcome of the arbitration. Any issues concerning disqualification of the Arbitrator shall be raised promptly with the AAA.

18. File Destruction: The Arbitrator will destroy her files related to this matter 365 days after the filing of the Award unless otherwise notified by the parties.

19. Deadlines and Enforcement: Section 13.5 of the Parties' September 24,

2014 Agreement provides that a hearing in this matter must be "scheduled" (as opposed to held or completed) within sixty days of the date of the appointment of the arbitrator. Further, it provides that the hearing record must be closed within ninety days of the "presentation" (as opposed to filing or service) of the Demand. In setting this schedule, the Arbitrator has carefully weighed the Parties' views on scheduling as expressed during the scheduling call and multiple emails thereafter with due regard to the language of their agreement. A table of deadlines is attached for convenience. The language of this Order shall prevail should there be any conflict between the table and this Order. The Parties consent to the deadlines stated herein and understand that these deadlines will be strictly enforced to avoid unnecessary delay and to ensure an expedient and fair resolution of this matter. This order shall continue in effect unless and until amended by subsequent order of the Arbitrator.

Dated: September 16, 2019

Arbitrator: Catherine B Mueller

Table of Deadlines

#	Deadline	Action
2	9/16/19	Amendments; additional parties
3a	9/18/19	Responses to DQ motion
7b, 7c	9/18/19	Submit protective order and 15 requests
2,7b	9/20/19	Submit objections to requests; reply to DQ (5 pages)
7b	9/23/19	Replies to objections
2	9/23/19	Response to amendments
7b, 7d	9/26/19	Exchange documents and identify privilege per order
6	9/27/19	Status call at 11:00 am
6	10/8/19	Status call at 2:00 pm
8, 9a, 9b, 10	10/14/19	Submit hearing subpoenas; witness lists, expert reports and exchange lists of documents you anticipate using
9b, 10	10/17/19	Submit any rebuttal expert reports; finalize joint exhibits
9a,12	10/18/19	Submit hearing briefs; exchange witness statements
6	10/21/19	Status call for final hearing at 2:00 pm
5	10/23/19 to 10/29/19	Hearing
12	11/15/19	Tentative date to submit draft awards; post hearing briefs and fees and costs requests

Exhibit G

AMERICAN ARBITRATION ASSOCIATION

SYNOGEN MANAGEMENT GROUP, INC., and NEXTGEN BIOLOGICS, INC., Claimants, v. ISE PROFESSIONAL TESTING & CONSULTING SERVICES, INC., Respondent.	**Case No. 01-19-0002-3786**

Order #11 Interim Award re Injunctive Relief

Claimants filed their Rule 37 request for interim relief including temporary injunctive relief in this Arbitration on Monday, October 7, 2019. The motion was supported by a declaration of Jamie Grooms, co-founder and the Chairman at Synogen. Claimants also relied on their submissions in support of their earlier Motion to Bar Counterclaim and Motion for Summary Judgment. All of these filings have been furnished to Respondent by AAA at or shortly after they were received by the AAA. A scheduled telephonic conference was conducted in this matter on October 8, 2019 at 2 PM EDT. The agenda for the status conference included Claimants' motion for interim relief. All parties had notice of the agenda for the hearing.

ISE chose not to participate in the scheduling conference but sent via email during the conference a document entitled "Declaration of Ryanne Early in Response to Declaration of Jamie Grooms and in Objection to Motion for Temporary Restraining Order[1]." Ms. Early is the "founder and CEO of Respondent[] ISE" and the designated representative of ISE following the

[1] Ms. Birg's "declaration"was not made under oath or penalty of perjury.

Notice of Withdrawal of Erika Birg, of Nelson Mullins, counsel for ISE in this matter. This matter is now ripe for ruling[2].

1. This matter involves a dispute between Claimant Synogen and its sublicensee NeXtGen, and Respondent ISE, the owner of the intellectual property licensed to Synogen. The Synogen-ISE License Agreement (the Agreement) was entered into October 16, 2014, made effective September 23, 2014. Exhibit 1[3]. Essentially, ISE provided Synogen (i) an exclusive license to certain patent rights; and (ii) a non-exclusive license to trade secret process technology or the decellularization process defined as "Licensed Know-How." See Ex. 1 at §§ 1.7, 1.9, 2, 5.2.2.

2. In short form, Synogen was to take ISE's technology and commercialize it and pursue related patent prosecution. Synogen entered into a sublicense with NeXtGen, as it was permitted to do, to assist it in this process. See Exh. 1, Appendix A which authorizes the formation of and sublicensing to NeXtGen. The Agreement provides that ISE "cooperate in all respects with [Synogen]'s efforts in preparing and prosecuting the Licensed Patents, and . . . [must] have its employees appear before patent offices and submit declarations when requested."

3. The contracted for patent technology is described in the patent application as "decellularized biomaterial from non-mammalian tissue." See Exh. 2. To practice the patent technology, the decellularization process is needed. Without the process to decellularize the tissue, Claimants contend that they cannot take the intellectual property from paper to real world application. Respondents' failure to supply information related to the decellularization process, the "Licensed Know-How," is one of the focuses of this dispute.

---

[2] In making this ruling, I have reviewed and relied on the materials submitted with Claimants' Motion to Bar Counterclaim and Motion for Summary Judgment as well as the additional materials submitted with Claimants' October 7, 2019 email seeking interim relief in addition to consideration of Respondent's .October 8, 2019 filing.

[3] Unless otherwise noted, all references to exhibits are to those exhibits attached to Claimants' September 30, 2019 Motion to Bar.

4. During the five years following the execution of the Agreement in October 2014, Synogen, with sublicensee NeXtGen, developed from the licensed technology a human skin graft product (NeoMatriX®), and moved the product towards market. 10/4/2019 Declaration of Jamie Grooms ¶15.[4] In October 2018, NeoMatriX received 510(k) clearance from the FDA. See Exh. 3. In January 2019, Synogen received notice from the USPTO of impending issuance of U.S. patent rights. See Exh. 4.

5. Synogen and NeXtGen carried all costs associated with the development and commercialization of the product—more than $7.5 million. See Grooms Decl. ¶14-16. Approximately $1.7 million of that amount was paid to Seed Biotech, Inc., a company alleged to be related to ISE through shared principals, Ryanne Early and her husband. Ryanne Early is a principal and the CEO at Seed, and the principal and President at ISE. 10/4/2019 Declaration of Jonelle Toothman ¶11-12[5].

6. Claimants contend that Ryanne Early uses each company interchangeably, and personally, and that corporate formalities one would expect are lacking. See Exh 5 and 6.

7. In addition to its allegations that Respondent has failed to provide the Licensed Know-How pursuant to the Agreement, Claimants allege that Respondent has not cooperated consistently and appropriately in connection with Claimants' efforts to prosecute the patent right, as it is obligated to do under the Agreement. Respondent contends (See Amended Answer and Counterclaim (9/16/19) at page 8 and footnote 11) that it has properly terminated the Agreement and is thus excused from cooperating and supporting the patent prosecution. Claimants dispute this.

[4] Mr. Grooms' 10/4/2019 Declaration was submitted in support of Claimants' Motion for Summary Judgment.
[5] Ms. Toothman's Declaration was submitted in sport of Claimants' Motion for Summary Judgment.

8. Claimants assert that "ISE has refused to allow Synogen to engage with the U.S. Patent and Trademark Office, which will likely result in the abandonment of applications necessary to secure Synogen's exclusive right to use those technologies." 10/4/19 Grooms Decl. ¶23. The record contains evidence of this refusal, including but not limited to Exhibit 44 to Claimants' Motion for Summary Judgment. In that document, an email dated October 3, 2019, from Respondent's counsel, Ms. Birg[6] to DLA Piper demands that Synogen and DLA Piper cease taking steps to prosecute the patent. Notably, ISE has not seriously contended much less proven that the patent prosecution work being pursued by Synogen and its counsel, DLA Piper, is substantively defective or improper.

9. Further, Respondent, directly through its CEO Ms. Early, recently threatened to actively interfere with the patent prosecution. Prior to Monday, October 7, 2019, a telephone call occurred between Ms. Early and Mr. Grooms. According to Mr. Grooms, Ms. Early made a threat to take action against (i.e., undermine, abandon or invalidate) the Licensed Patents if Synogen and NeXtGen Biologics, Inc. ("NeXtGen") continue to arbitrate and/or litigate the disputes among the Parties in this Arbitration. See 10/7/19 Declaration of Jamie Grooms.

10. Finally, as the arbitrator was about to execute this order, we were informed that on September 27, 2019, ISE through its counsel Nelson Mullins, revoked the limited power of attorney required for Synogen's counsel DLA Piper to continue the prosecution of patents for Synogen. See 10/9/19 email from John Huh attached here as Exhibit A. None of this was disclosed by Ms. Early in the document she filed yesterday. This action confirms Claimants' fears that ISE intends to thwart Claimants' ability to continue to prosecute the patents prior to

[6] On September 25, 2019, Ms. Birg filed with the AAA a notice of change of representation stating : … that Nelson Mullins Riley & Scarborough LLP, Erika Birg, and Lindsay Builder are no longer representing ISE Professional Testing & Consulting Services, Inc. with respect to the above-captioned arbitration."

adjudication of the issues in this dispute, damaging the prospects of successful prosecution of the patents and leading to harm that cannot be corrected or remediated by damages.

11. This matter goes to full hearing on October 23, 2019.

12. Based on the above, Claimants have sufficiently shown:

i. a substantial likelihood of success on the merits on their breach of contract claims;

ii. irreparable harm if this temporary injunction is not granted; and

iii. that the balance of harms among the parties, and the public interest, weighs in favor of granting the preliminary injunctive relief.

13. Minimal bond is required as ISE has made no showing that it will suffer harm resulting from this temporary injunction. Accordingly, I direct that Synogen deposit $500.00 with the AAA for this purpose.

NOW THEREFORE, Respondent ISE Professional Testing & Consulting Services, Inc. ("ISE"), and any of its attorneys, representatives or agents, are hereby **ENJOINED** from, directly or indirectly, interfering with or impeding Synogen Management Group, Inc.'s ("Synogen") prosecution and preparation of the Licensed Patents through counsel of Synogen's choice and are directed to cooperate with Synogen and its counsel, including executing any documents deemed necessary by Synogen to enable its continued work on the patent prosecution and preparation. This interim award remains effective until the Final Award is issued in this matter or until otherwise amended by the Arbitrator.

Dated: October 9, 2019

Catharine Biggs Arrowood Arbitrator

EXHIBIT A

Arrowood, Catharine B.

From:	Huh, John <john.huh@dlapiper.com>
Sent:	Wednesday, October 09, 2019 11:21 AM
To:	AngelaValedon@adr.org; REarlyISE@gmail.com; Vernick, Scott
Cc:	Arrowood, Catharine B.
Subject:	RE: Synogen Management Group, Inc. v. ISE Professional Testing & - Case 01-19-0002-3786
Attachments:	ISE POA to Nelson Mullins.pdf
Importance:	High

Caution: External email

Angela,
Please forward the below to Arbitrator Arrowood as soon as possible:

Dear Arbitrator Arrowood,
We write to address a very urgent and disturbing development, which relates to Claimants' motion for interim injunctive relief pursuant to AAA Rule 37. As you noted in Order # 10, this motion is ripe for ruling. We recently discovered that ISE made a filing with the United States Patent Office last week that revoked the Limited Power of Attorney required for DLA Piper to prosecute the Licensed Patents for Synogen. ISE's filing replaced DLA Piper (and Synogen) with Nelson Mullins, which continues to represent ISE despite tactically withdrawing from this Arbitration. ISE's filing effectively precludes Synogen's rights to prosecute the License Patents. The filing, which was filed by Nelson Mullins, is attached.

Notably, this filing was just a couple of days prior to ISE's threat to undermine Synogen's rights with respect to the Licensed Patents and the patent prosecution process. Moreover, it contradicts the declaration submitted by ISE yesterday in opposition to the motion for interim injunctive relief. Tellingly, ISE chose to conceal this filing as it is not mentioned in ISE's declaration. We now know that ISE already executed its threat prior to the submission of that declaration. This also confirms that ISE and its counsel, Nelson Mullins, are engaged in bad faith tactics and will continue to undermine the Licensed Patents by interfering with Synogen's rights to prosecute the License Patents.

In light of ISE's filing, nothing stands in the way of Nelson Mullins and ISE from invalidating or undermining the patent. Therefore, we respectfully request the motion for interim injunctive relief be granted, and that the proposed order be entered as soon as possible.
Respectfully,
John

John D. Huh
Partner
215.656.2450 **T**
215.606.2150 **F**
john.huh@dlapiper.com
LinkedIn

DLA PIPER

DLA Piper LLP (US)
One Liberty Place
1650 Market Street, Suite 5000
Philadelphia, Pennsylvania 19103-7300

United States
www.dlapiper.com

From: AngelaValedon@adr.org <AngelaValedon@adr.org>
Sent: Wednesday, October 09, 2019 8:20 AM
To: REarlyISE@gmail.com; Vernick, Scott <Scott.Vernick@us.dlapiper.com>; Huh, John <John.Huh@us.dlapiper.com>
Cc: cbarrowood@parkerpoe.com
Subject: Synogen Management Group, Inc. v. ISE Professional Testing & - Case 01-19-0002-3786

[EXTERNAL]

Hello,

Please review the attached correspondence regarding the above-referenced case.

Feel free to contact me with any questions, comments or concerns you have related to this matter.

Thank you.

AAA Angela Romero Valedon, Esq.
Director of ADR Services

American Arbitration Association

T: 786 406 6642 E: AngelaValedon@adr.org
100 SE 2nd St., Ste. 2300, Miami, Fl 33131
adr.org | icdr.org | aaamediation.org



The information in this transmittal (including attachments, if any) is privileged and/or confidential and is intended only for the recipient(s) listed above. Any review, use, disclosure, distribution or copying of this transmittal is prohibited except by or on behalf of the intended recipient. If you have received this transmittal in error, please notify me immediately by reply email and destroy all copies of the transmittal. Thank you.

The information contained in this email may be confidential and/or legally privileged. It has been sent for the sole use of the intended recipient(s). If the reader of this message is not an intended recipient, you are hereby notified that any unauthorized review, use, disclosure, dissemination, distribution, or copying of this communication, or any of its contents, is strictly prohibited. If you have received this communication in error, please reply to the sender and destroy all copies of the message. To contact us directly, send to postmaster@dlapiper.com. Thank you.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/759,895	07/08/2015	Ryanne Early	040035/09002

CONFIRMATION NO. 3358

POA ACCEPTANCE LETTER

27530
Nelson Mullins Riley & Scarborough LLP
IP Department
One Wells Fargo Center
301 South College Street, 23rd Floor
Charlotte, NC 28202

OC000000111578809

Date Mailed: 10/02/2019

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 09/27/2019.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/hsarwari/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
14/759,895	07/08/2015	Ryanne Early	SYG-19-1252US/426329-002

CONFIRMATION NO. 3358

POWER OF ATTORNEY NOTICE

35811
IP GROUP OF DLA PIPER LLP (US)
ONE LIBERTY PLACE
1650 MARKET ST, SUITE 5000
PHILADELPHIA, PA 19103

OC0000011157879

Date Mailed: 10/02/2019

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 09/27/2019.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/hsarwari/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
14/759,895	07/08/2015	1651	4590	040035/09002	33	11

CONFIRMATION NO. 3358

CORRECTED FILING RECEIPT

27530
Nelson Mullins Riley & Scarborough LLP
IP Department
One Wells Fargo Center
301 South College Street, 23rd Floor
Charlotte, NC 28202

Date Mailed: 10/02/2019

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Ryanne Early, Fleming Island, FL;

Applicant(s)

ISE Professional Testing & Consulting Services, Inc., Eustis, FL;

Assignment For Published Patent Application

ISE Professional Testing & Consulting Services, Inc., Eustis, FL

Power of Attorney: The patent practitioners associated with Customer Number 27530

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/US2014/010890 01/09/2014
which claims benefit of 61/750,555 01/09/2013

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: No

Permission to Access Search Results: No

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 08/27/2015

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 14/759,895**

Projected Publication Date: Not Applicable

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

DECELLULARIZED BIOMATERIAL FROM NON-MAMMALIAN TISSUE

Preliminary Class

424

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: Yes

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific

countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

PTO/AIA/80 (07-17)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:

[X] Practitioners associated with Customer Number: 27530

OR

[ ] Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:

[X] The address associated with Customer Number: 27530

OR

[ ]

Firm or individual name		
Address		
City	State	Zip
Country		
Telephone	Email	

Assignee name and address: ISE Professional Testing & Consulting Services, Inc.
2785 S. Bay St. Suite G
Eustis, FL 32726

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/AIA/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of the practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee.

Signature	Date September 13, 2019
Name Ryanne Early	Telephone 352-474-0823
Title President, ISE Professional Testing & Consulting Services, Inc.	

This collection of information is required by 37 CFR 1.31, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public, which is to update (and by the USPTO to process) the file of a patent or reexamination proceeding. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 18 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: ISE Professional Testing & Consulting Services, Inc.

Application No./Patent No.: 14/759,895 Filed/Issue Date: July 8, 2015

Titled: DECELLULARIZED BIOMATERIAL FROM NON-MAMMALIAN TISSUE

ISE Professional Testing & Consulting Services, Inc., a corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

   ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

   ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

A. ☑ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 049715, Frame 0325, or for which a copy thereof is attached.

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

   1. From: _____ To: _____

      The document was recorded in the United States Patent and Trademark Office at

      Reel _____, Frame _____, or for which a copy thereof is attached.

   2. From: _____ To: _____

      The document was recorded in the United States Patent and Trademark Office at

      Reel _____, Frame _____, or for which a copy thereof is attached.

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

4. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☑ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Lloyd G. Farr/	September 27, 2019
Signature	Date
Lloyd G. Farr	38,446
Printed or Typed Name	Title or Registration Number

Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Corrected Application Data Sheet

Application Information

Application Number::	14/759,895
Filing Date::	07/08/2015
Application Type::	Nonprovisional
Subject Matter::	Utility
Title::	DECELLULARIZED BIOMATERIAL FROM NON-MAMMALIAN TISSUE
Attorney Docket Number::	~~S1860.70000US01~~ 040035/09002

Correspondence Information

Customer Number	~~035811~~ 27530
Email Address	ip@nelsonmullins.com

Representative Information

Representative Customer Number	~~23628~~ 27530

Applicant Information

Applicant Number::	1
Applicant Type::	Assignee
Organization Name::	ISE Professional Testing & Consulting Services, Inc.
Street of mailing address::	~~2007 NW 6th Street~~ 2785 S. Bay St. Suite G

City of mailing address::	~~Gainesville~~ Eustis
State or Province of mailing address::	FL
Country of mailing address::	US
Postal or Zip Code of mailing address::	~~32603~~ 32726

Assignee Information Including Non-Applicant Assignee Information

Applicant Number::	1
Applicant Type::	Assignee
Organization Name::	ISE Professional Testing & Consulting Services, Inc.
Street of mailing address::	~~2007 NW 5th Street~~ 2785 S. Bay St. Suite G
City of mailing address::	~~Gainesville~~ Eustis
State or Province of mailing address::	FL
Country of mailing address::	US
Postal or Zip Code of mailing address::	~~32603~~ 32726

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).** This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants. See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Lloyd G. Farr/	Date (YYYY-MM-DD)	2019-09-27
Name	Lloyd G. Farr	Registration Number	38,446

Electronic Acknowledgement Receipt

EFS ID:	37301912
Application Number:	14759895
International Application Number:	
Confirmation Number:	3358
Title of Invention:	DECELLULARIZED BIOMATERIAL FROM NON-MAMMALIAN TISSUE
First Named Inventor/Applicant Name:	Ryanne Early
Customer Number:	35811
Filer:	Lloyd G. Farr/Jennifer Falcone
Filer Authorized By:	Lloyd G. Farr
Attorney Docket Number:	SYG-19-1252US/426329-002
Receipt Date:	27-SEP-2019
Filing Date:	08-JUL-2015
Time Stamp:	14:48:07
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Power of Attorney	0430035_09002_POA.pdf	278161 04f1cf4b8da32a79e1dbbc35d3771cc346e8a1ce	no	2

Warnings:

Information:					
2	Assignee showing of ownership per 37 CFR 3.73	0430035_09002_373C.pdf	134984 fd7682b43daa8a45db0ac83d1be34a83ce7e8cf0	no	3
Warnings:					
Information:					
3	Application Data Sheet	040035_09002_FSADS.pdf	71780 66a948fd711096410370cebf47074f133cae30a4	no	3
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
		Total Files Size (in bytes):	484925		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Exhibit H

IN THE CIRCUIT COURT OF THE NINTH JUDICIAL CIRCUIT
IN AND FOR ORANGE COUNTY, FLORIDA

SYNOGEN MANAGEMENT GROUP, INC.,

and

NEXTGEN BIOLOGICS, INC.,

Movants,

v.

ISE PROFESSIONAL TESTING & CONSULTING SERVICES, INC.,

Respondent.
_____/

CASE NO. 2019-CA-012605-O
BUSINESS COURT

ORDER GRANTING EMERGENCY MOTION TO CONFIRM ARBITRATION AWARD FOR INJUNCTIVE RELIEF

This Cause came before the Court for an evidentiary hearing on November 12, 2019, on the Emergency Motion to Confirm Arbitration Award for Injunctive Relief filed by Petitioners, Synogen Management Group, Inc. ("Synogen") and NeXtGen Biologics, Inc. ("NeXtGen," collectively with Synogen, "Petitioners") on October 15, 2019 (the "Emergency Motion"). The Court reviewed the Response in Opposition to Emergency Motion to Confirm Arbitration Award for Injunctive Relief and, Alternatively, Motion to Modify or Vacate Interim Arbitration Award filed by Respondent, ISE Professional Testing & Consulting Services, Inc. ("Respondent") on November 12, 2019, heard testimony from Jamie Grooms, the co-founder of Synogen, listened to argument of counsel, and reviewed supplemental briefs filed by the parties on November 13, 2019. The Court is fully advised on the premises. For the following reasons, the Emergency Motion is **GRANTED**:

I. Background

Petitioners and Respondents have been embroiled in an arbitration dispute arising out of a License Agreement entered into between Synogen and ISE in 2014. Pursuant to that Agreement, ISE gave Synogen an exclusive license in certain "Licensed Patents," and a non-exclusive license in trade secrets referenced as "Licensed Know-How." *See* Emergency Motion, Ex. B at § 2.1. The Agreement also allowed Synogen to "prosecute and maintain the Licensed Patents using counsel of its choice." *Id.* at § 9.1. One of Petitioners' breach of contract claims involves Respondent's failure to comply with this section of the Agreement. *See* Ex. C at ¶¶ 89-94.

On October 7, 2019, Petitioners requested interim relief in the arbitration proceeding. *Id.* at Ex. E-2. On October 8, 2019, the Arbitrator convened a hearing which neither Respondent nor its lawyers attended.[1] In her Order #11 Interim Award re: Injunctive Relief dated October 9, 2019 ("Interim Arbitration Award"), the Arbitrator found that Respondent had refused to allow Synogen's lawyers to continue to engage with the United States Patent and Trademark Office regarding the Licensed Patents. *Id.* at Ex. A, ¶ 8. Specifically, she noted that Respondent had revoked the limited power of attorney necessary for Synogen's lawyers to prosecute the Licensed Patents. *Id.* at ¶ 10. The Arbitrator concluded "[Respondent] intends to thwart [Petitioners'] ability to continue to prosecute the [Licensed Patents] prior to adjudication of issues in this dispute, damaging the prospects of successful prosecution of the patents and leading to harm that cannot be corrected or remediated by damages." *Id.* In making these conclusions, the Arbitrator relied on a sworn declaration from Mr. Grooms, an unsworn declaration by Respondent's president, Ryenne Early, and hundreds of pages of submissions in support of Petitioners' previously-filed

[1] Respondent's current lawyers did not represent Respondent until November 10, 2019.

RegenX Science Exhibit 1071
Page 162

Motion to Bar Counterclaim and Motion for Summary Judgment. *Id.* at 1 (citing Ex. D and Ex E-1).

Accordingly, the Arbitrator enjoined Respondent "and any of its attorneys, representatives or agents" from "directly or indirectly, interfering with [Synogen's] prosecution and preparation of the Licensed Patents through counsel of Synogen's choice and are directed to cooperate with Synogen and its counsel, including executing any documents deemed necessary by Synogen to enable its continued work on the patent prosecution and preparation." *Id.* at 5.

Since then, the parties proceeded to a final arbitration hearing. Post-hearing briefs are due today, and the Arbitrator will theoretically enter a final ruling sometime thereafter.

Petitioners seek confirmation of the Interim Arbitration Award. Respondents contend that the Court should either vacate or modify the Interim Arbitration Award because it does not comply with Florida substantive law, and it is facially overbroad.

II. Analysis

The Court has jurisdiction to resolve this issue under the Federal Arbitration Act ("FAA"), and where applicable, the Florida Arbitration Code ("FAC"). *See Visiting Nurse Ass'n of Fla., Inc. v. Jupiter Med. Center*, 154 So. 3d 1115, 1124-25 (Fla. 2014). Here, the parties agreed, and the Arbitrator ordered, that the FAA applied to these proceedings. *See* Emergency Motion, Ex. D at ¶ 1. Respondent nevertheless argues that the operative portion of the FAC relating to interim awards does not conflict with, and is therefore not preempted by, the FAA. *See* Respondent's Supplemental Brief at 3; *see also Powertel, Inc. v. Bexley*, 743 So. 2d 570, 573 (Fla. 1st DCA 1999) (noting that FAC applies to FAA-governed contracts "only to the extent that it is not in conflict with [the] federal law.").

The FAC has a specific pre-award provision; the FAA does not. The FAC directs trial courts to confirm interim awards unless it "vacates, modifies, or corrects the award under § 682.13 or § 682.14." § 682.081(1), Fla. Stat. The FAC requires the Court to vacate a pre-award arbitration ruling if it "fails to satisfy the legal standards for awarding a party injunctive or equitable relief." *Id.* at § 682.081(2)(b). The FAC lacks similar language relating to post-award confirmations. *Id.* at § 682.13. Respondents contend that the Arbitrator did not satisfy legal standards because the Interim Arbitration Award lacked specific factual findings for all four elements of a temporary injunction. *See, e.g., XIP Techs., LLC v. Ascend Glob. Servs., LLC*, 253 So. 3d 1183, 1187-88 (Fla. 2d DCA 2018). The FAA does not distinguish between pre-award and post-award confirmations. *See* 9 U.S.C. § 9. Respondents nonetheless argue that confirming the Interim Arbitration Award would still be inappropriate because the Arbitrator exceeded her powers by failing to follow the same Florida law. No reported decisions analyze the intersection of these statutory provisions.

Regardless of which statute applies, the Court concludes it should not vacate the Interim Arbitration Award. If the FAA applies, then the Interim Arbitration Award is significantly more detailed than what the law requires. *See, e.g., United Steelworkers of Am. v. Enterprise Wheel & Car Corp.*, 363 U.S. 593, 598 (1960) (stating that "[a]rbitrators have no obligation to the court to give their reasons for an award."). If the FAC applies, the Arbitrator did not exceed her powers because she made appropriate factual findings to support the Interim Arbitration Award. This ruling outlined specific bases for the Arbitrator's ruling and described the enjoined acts with reasonable detail. *See* Fla. R. Civ. P. 1.610(c). The Arbitrator recited the four elements of a temporary injunction, but she did not just "parrot" the list. *Compare City of Jacksonville v. Naegele Outdoor Advert. Co.*, 634 So. 2d 750, 754 (Fla. 1st DCA 1994). Rather, the Arbitrator's

ruling outlined facts that supported all four elements. Despite Respondent's contrary assertions, this included facts supporting irreparable harm and the public interest. Specifically, the Arbitrator found that irreparable harm would occur if Respondent undermined, abandoned or invalidated the Licensed Patents before she could enter a final arbitration award. The public interest is certainly not disserved by allowing contracting parties to reach a final resolution of a dispute over intellectual property instead of allowing the abandonment and potential destruction of that property's value.

Finally, the Court declines to exercise any discretion that it might have to modify the Interim Arbitration Award.[2] Regardless of whether the FAA or FAC applies, the Court has no applicable statutory power to modify the Arbitrator's ruling. *See* 9 U.S.C. § 11 (outlining permissible bases to modify an arbitration award); § 682.14(1), Fla. Stat. (same). The Court respectfully declines to adopt the expansive reading of the FAC provision urged by the Respondent because it does not fit the statute's plain language. The Interim Arbitration Award affects the merits of the parties' controversy. *See* § 682.14(1)(c), Fla. Stat.

III. Conclusion

For the foregoing reasons, Petitioners' Emergency Motion is **GRANTED**. The Interim Arbitration Award is **CONFIRMED**.

DONE AND ORDERED in Chambers in Orange County, Florida this 15th day of November, 2019.

HONORABLE DAN TRAVER
CIRCUIT COURT JUDGE

[2] The Court acknowledges and respects, however, the Petitioners' expressed agreement to construe the Interim Arbitration Award in a limited manner that addresses many – although not all – of the Respondent's concerns about its breadth. *See* Petitioner's Supplemental Brief at 5.

Copies furnished to:

Harout J. Samra, DLA Piper LLP (US), harout.samra@us.dlapiper.com, ariana.amar@us.dlapiper.com, and raymond.zamora@us.dlapiper.com, *Counsel for Movants*

Janelly Crespo, DLA Piper LLP (US), janelly.crespo@us.dlapiper.com, *Counsel for Movants*

John Huh, DLA Piper LLP (US), john.huh@us.dlapiper.com, *Counsel for Movants*

Scott Vernick, DLA Piper LLP (US), scott.vernick@us.dlapiper.com, *Counsel for Movants*

Amber N. Davis, Beusse Wolter Sanks & Maire, PPLC, adavis@bwsmiplaw.com, *Counsel for Respondent.*

Kevin W. Wimberly, Beusse Wolter Sanks & Maire, PPLC, adavis@bwsmiplaw.com, *Counsel for Respondent.*

Exhibit I

IN THE CIRCUIT COURT OF THE
NINTH JUDICIAL CIRCUIT, IN AND
FOR ORANGE COUNTY, FLORIDA

CASE NUMBER: 2019-CA-012605-O

SYNOGEN MANAGEMENT GROUP
AND NEXTGEN BIOLOGICS
Plaintiff(s),
vs.

ISE PROFESSIONAL TESTING
AND CONSULTING SERVICES
Defendant(s).
_____/

ORDER SETTING HEARING

THIS MATTER came on before the Court, and the Court, after reviewing the file, and being otherwise informed in the premises, it is hereby **ORDERED AND ADJUDGED** as follows:

This case is scheduled for a hearing on **Emergency Motion for Civil Contempt** on **November 26, 2019, at 10:30 am** in Court Room 1, Orange County Courthouse, 2000 E Michigan Street, Orlando, Florida 32806.

DONE AND ORDERED in Orlando, Orange County, Florida on this 25 day of November 2019.

_____
John E Jordan
Circuit Judge

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that the foregoing was filed with the Clerk of the Court this ____ day of November 2019 by using the Florida Courts E-Filing Portal System. Accordingly, a copy of the foregoing is being served on this day to all attorney(s)/interested parties identified on the ePortal Electronic Service List, via transmission of Notices of Electronic Filing generated by the ePortal System.

Cathy Stephens, Judicial Assistant to Judge John E Jordan

If you are a person with a disability who needs any accommodation in order to participate in this proceeding, you are entitled, at no cost to you, to the provision of certain assistance. Please contact the ADA Coordinator, Human Resources, Orange County Courthouse, 425 N. Orange Avenue, Suite 510, Orlando, Florida, (407) 836-2303, at least 7 days before your scheduled court appearance, or immediately upon receiving this notification if the time before the scheduled appearance is less than 7 days; if you are hearing or voice impaired, call 711.

RegenX Science Exhibit 1071
Page 169

Exhibit J



Deposition of:

Arbitration

October 23, 2019

In the Matter of:

Synogen Management Group vs. ISE Professional Testing

Veritext Legal Solutions
888.777.6690 | cs-midatlantic@veritext.com | 215-241-1000

AMERICAN ARBITRATION ASSOCIATION
CASE NO.: 01-19-0002-3786

SYNOGEN MANAGEMENT GROUP, INC.,
And
NEXTGEN BIOLOGICS, INC.,
Claimants,
vs.
ISE PROFESSIONAL TESTING &
CONSULTING SERVICES, INC.,

Respondent.

_____/

PROCEEDINGS:	ARBITRATION
BEFORE:	HONORABLE CATHARINE BIGGS ARROWOOD
DATE:	WEDNESDAY, OCTOBER 23, 2019
TIME:	9:00 A.M. - 9:36 A.M.
PLACE:	ORANGE LEGAL 633 E. COLONIAL DRIVE ORLANDO, FLORIDA 32803
STENOGRAPHICALLY REPORTED BY:	SANDRA NARUP REGISTERED PROFESSIONAL REPORTER, REALTIME SYSTEMS ADMINISTRATOR & FLORIDA PROFESSIONAL REPORTER

A P P E A R A N C E S:

JOHN D. HUH, ESQUIRE
SCOTT M. VERNICK, ESQUIRE
OF: DLA Piper, LLP
1650 Market Street
Suite 5000
Philadelphia, PA 19103
215-656-2450
John.huh@dlapiper.com
Scott.vernick@dlapiper.com
APPEARING ON BEHALF OF CLAIMANT

JANELLY CRESPO, ESQUIRE
OF: DLA Piper, LLP
200 S. Biscayne Boulevard
Suite 2500
Miami, Florida 33131
305-423-8502, FAX-305-675-0702
Janelly.crespo@dlapiper.com
APPEARING ON BEHALF OF THE CLAIMANT

ALSO PRESENT:
JONELLE TOOTHMAN, CEO OF NEXTGEN
JAMIE GROOMS
JODI HUDSON

Exhibit Index

Exhibit	Description
84	TimeKeeper Sheets
85	Detail Invoice/Statement
86	Transperfect Legal Solutions Invoices
A	Declaration of Michael Lodato
B	Witness Statement of Jamie Grooms
C	Witness Statement of Jonelle Toothman
D	Declaration of John D. Huh

P R O C E E D I N G S

****

THE COURT: Okay. Good morning, everyone. I'd like to start by going around the table and just have everybody introduce themselves for the purposes of the record.

MR. HUH: John Huh from DLA Piper on behalf of claimants.

MR. VERNICK: Scott Vernick, also DLA Piper, on behalf of claimants.

MS. CRESPO: Janelly Crespo, DLA Piper on behalf of claimant.

MS. TOOTHMAN: Jonelle Toothman, CEO, NeXtGen.

MR. GROOMS: Jamie Grooms, board member of NeXtGen, and director of Synogen.

MS. HUDSON: Jodi Hudson, DLA Piper, on behalf of claimants.

THE COURT: Very good. Thank you.

So I'm opening now the hearing into the matter of Synogen and NeXtGen v. ISE. This hearing is being convened pursuant to proper notice, having been given some time ago, and pursuant to the agreement of the parties to hold this arbitration in Orlando on October 23rd.

I note for the record that we have no

representative of the respondent here, either by way of a party representative or counsel.

It is my understanding that counsel for the respondent withdrew a few weeks ago, that no new counsel has been suggested or identified in the interim.

We have had communications from Ryanne Early, whom I believe is the CEO of the respondent, about a variety of things. But, in general, ISE has not responded to the various deadlines contained in the scheduling order and is not here today. So we are going to proceed with this hearing nonetheless.

And, obviously, if anyone from respondent comes, we will admit them to the hearing and let them participate, but they are not here as of nine o'clock, which was the noticed time.

So with that, Mr. Huh, I'll let you begin.

MR. HUH: Thank you.

First and foremost, thank you for your time throughout this arbitration, as well as your time today. I know we dealt with some unusual and unfortunate circumstance, and we really appreciate your guidance throughout that process.

I just want to take care of some preliminary issues. We just filed verified statements for Scott

Vernick and myself to practice in Florida for this arbitration. And Ms. Janelly Crespo is a member of the Florida Bar.

These documents have been filed, two verified statements. I don't think I need to mark them as exhibits, but I brought you courtesy copies --

THE COURT: Thank you very much.

MR. HUH: -- just in case.

THE COURT: I appreciate that. And I just got notification from the AAA that they have them, and they have uploaded them to the case file.

MR. HUH: Okay. Great.

The other preliminary matter that I want to address is the change of location for the hearing, which the respondent has had adequate notice of -- I believe over five days or so -- and explained the circumstances for the change of location.

We're currently at 633 East Colonial Drive, which was not the original location, but it's about eight minutes away from the original location.

Just for the record, we were contacted by Veritext that the original location -- the reservation for the original location was cancelled after the respondent's former counsel and counsel at the time, Erika Birg at Nelson, Mullins, or someone

at Nelson & Mullins, contacted Veritext and instructed them that they would not be moving forward with this arbitration.

THE COURT: And may I interrupt you just one moment?

My recollection is that during the original scheduling conference that we had in this matter, Nelson, Mullins and the respondent engaged Veritext to have a court reporter participate in that telephone conference.

MR. HUH: Yes, that is correct.

THE COURT: And am I not correct that that's how it came to be that we were going to have the hearing at a different Veritext location in Orlando?

MR. HUH: Yes. The original location for the -- under the contract for the hearing is Gainesville. The parties and counsel agreed to other locations for convince, and Nelson, Mullins, on behalf of respondent, proposed Veritext's office in Orlando. And it was through Nelson, Mullins' relationship contact at Veritext that those reservations were made.

THE COURT: The initial reservations.

MR. HUH: Yeah, the initial reservations.

And then at some point shortly after

withdrawing from this arbitration, someone at Nelson & Mullins reached out or contacted Veritext and said that they would no longer be moving forward without this -- they would no longer be moving forward in this arbitration.

THE COURT: And if I may interrupt you there.

I did not receive any notification of that, and I do not believe that AAA did either.

MR. HUH: I believe that is correct, that the reservation was cancelled and that Nelson, Mullins had contacted Veritext.

DLA Piper also, on behalf of claimants, did not receive any notification from Ms. Birg or her firm or from respondent that they had contacted Veritext and notified them of the change of counsel in this arbitration.

As a result, when we later talked to Veritext to confirm the location, they advised us of what had happened between them and Nelson & Mullins and were able to provide us the space we're currently holding this hearing today.

Veritext has kindly agreed to instruct anyone who shows up at the original location for this arbitration, to provide them with directions here and to contact us if anyone does show up.

I have with me that I'd like to move into evidence eventually is a declaration of our contact, who is a case manager at DLA Piper who is our contact for Veritext. He is -- he has submitted a declaration reiterating the description I gave today that he's the one who had conversations with Veritext.

And in support of his declaration, he's also attached an E-mail from Veritext stating that the reason why the original location's reservation was let go was because Nelson, Mullins contacted them and told them we would not be moving forward with this arbitration.

And they also confirmed in the E-mail that they would notify any individual or party that arrives at the original location for today's hearing that the location has been changed.

THE COURT: Why don't we -- I think you've already got prenumbered exhibits elsewhere, so why don't we just mark that Exhibit A.

MR. HUH: Exhibit A. Sure.

(Exhibit A was marked for identification.)

THE COURT: And I'd like to have that in the record, because I want there to be no doubt, at least from the point of view of the arbitrator,

respondent has had more than sufficient notice of both time and the date and the place of the hearing, and they are not here, which is really unfortunate.

MR. HUH: That's correct.

I believe, as at least by last Friday, Ms. Early did receive notification from us when we contacted AAA to confirm the location of the hearing. And I assume that her counsel for -- her former counsel, Ms. Birg at Nelson & Mullins, must have had communication with her, because Nelson & Mullins continues to represent her or her other entities in various capacities, including for an arbitration before the American Arbitration Association involving Ms. Early's entity Seed, and that arbitration involves one of the claimants that is present today.

THE COURT: So, in other words, you and others at DLA Piper have had direct contact with Nelson, Mullins and Ms. Birg in other proceedings where Nelson, Mullins continues to represent a related -- a company that is related to the respondent, ISE, here?

MR. HUH: That is correct. And even this morning, we received an E-mail from the American Arbitration Association that went to myself and

Ms. Birg at Nelson & Mullins, and that is -- and that was in connection with the arbitration involving one of Ms. Early's entities and claimant, NeXtGen.

THE COURT: Do you happen to have the AAA case number for that other proceeding? It might be useful, just for the record, to make that clear.

MR. HUH: Yes, I do. That is AAA Case Number 01-19-002-7261.

THE COURT: Okay. Thank you. All right.

MR. HUH: So if it's okay with you, I would respectfully move to admit this into the record and evidence. That is the declaration of Michael Lodato that's been marked as Exhibit A.

In addition to that, I would like to move into evidence the witness statements of Jamie Grooms, as well as Jonelle Toothman. And I respectfully request that this serve as their testimony in lieu of any live testimony today.

THE COURT: And I will just note for the record that as part of the scheduling conference that we had a couple months ago, it was agreed among counsel for both sides that in -- due to the time constraints imposed by the parties' contract, and just the physical issues surrounding needing to get

the arbitration done, and in particular to accommodate Ms. Early's schedule, we agreed on the submission of initial position statements by both the claimant and the respondent, as opposed to live testimony.

And this was, in part, due, as I recall, to Ms. Ryanne's inability to be available for a five- or six-day stretch consecutively. At least as I recall, I think we all said it would take eight or nine days to arbitrate this mater and by the use of the written witness statements to present your cases in chief.

We were able to get the time arbitration narrowed down to five or six days instead. So I will therefore accept these witness statements presented on behalf of the claimants, and we'll put those into the record.

Should we mark these Exhibits B and C? Again, I don't want to --

MR. HUH: Sure.

THE COURT: -- disrupt the numbering.

We'll make Mr. Grooms' Exhibit B and Ms. Toothman Exhibit C.

(Exhibit B & C were marked for identification.)

MR. HUH: I would also like to respectfully

move in evidence what I have pre-marked as Exhibit D. It's a declaration of -- that I've submitted that supports our requests for attorneys' fees and costs.

Attached to my declaration as Exhibit D are Exhibits 84, 85 and 86. And these are essentially time entries of timekeepers on this matter, as well as invoices from the American Arbitration Association and vendors.

(Exhibits D, 84, 85, & 86 were marked for identification.)

THE COURT: Okay. I will accept those into the record. Do you have a clip? If you don't, we'll get one later. I just want to be sure the exhibits don't get separated from the declaration.

MR. HUH: And then, finally, I would like to submit into the record and evidence our -- an exhibit binder that contains Exhibits 1 through 83. The majority of these exhibits were identified on the exhibit list that we produced and served to the other side in compliance with the schedule and order in this case.

The respondent did not provide us with an exhibit list and also declined to make any objections to the exhibits identified on our exhibit

list. In light of that, I believe they have either consented or waived any objection to admitting these exhibits into the record and as evidence.

The only additional document in this binder is Exhibit 83, which is -- I believe it's also attached to the declaration of Michael Lodato, which has been marked as Exhibit A. It's the supporting E-mail from Veritext confirming why the change in location was necessary.

THE COURT: I will accept those exhibits, and I would like to note for the record that the scheduling order did include a specific period of time for both parties, both sides to lodge objections to the exhibits that were being identified that might be used at the hearing. And I received no objections from the respondent to the claimant's exhibits. Accordingly, I will accept these into evidence.

MR. HUH: Thank you.

And mainly for the reasons set forth in our prehearing brief, and based on the evidence in record, which I believe completes the evidentiary record, at least as to the merits of the arbitration, I know we still have to potentially supplement the record for any award of fees and

costs, to the extent we need documentation.

I would like to point out that the time sheets and time entries that are attached to my declaration in support of our request for fees and costs are through -- are current through September 30th and doesn't capture the time and costs associated with this arbitration through whenever we submit any proposed award. And so we would respectfully request to supplement that documentation, to the extent any fees or costs are awarded.

THE COURT: Right. We will -- the record in this case will be kept open certainly at least through November 15th, which is the date in the scheduling order, by which the parties are to submit -- as I recall. I hope I've got that right -- are to submit the proposed award documentation, final briefing and any additional fees and costs. So there will be plenty of time to supplement that as appropriate.

MR. HUH: Okay.

THE COURT: If you don't mind right now, I just had a couple of questions I wanted to ask your two witnesses.

MR. HUH: Sure.

THE COURT: Unless you've got something else

you want to --

MR. HUH: There is.

THE COURT: -- present right now.

Okay. Sure.

MR. HUH: Because I'll be very brief.

THE COURT: Okay.

MR. HUH: But I do believe, based on the evidence that's in the record to date, that claimants are entitled to a full award and all of the relief they requested.

I do want to touch on a couple of points --

THE COURT: Sure.

MR. HUH: -- especially with respect to the award of fees and costs and just clarify our position on that request.

THE COURT: Sure.

MR. HUH: The record is clear that both parties agreed, both at the preliminary hearing, as well as in their filings with the American Arbitration Association, that the arbitrator would be authorized to award reasonable attorneys' fees and costs to the prevailing party.

Also by demanding reasonable attorneys' fees and costs in their -- through their claims and counterclaims and demands filed with the American

Arbitration Association, the arbitrator is authorized, under the commercial rules, to award fees or costs to -- fees and costs to the prevailing party. And for the same reasons, the parties have waived any objection to the award of fees and costs.

And then, finally, in the alternative, we again believe that our motion for -- our motion to preclude counterclaims and for sanctions, again, it provides another reason for the award of reasonable attorneys' fees and costs.

The last point that I just want to touch on for the record has to do with respondent's counterclaims. Based on the evidence in the record, it's at least clear to us that respondents have failed to meet their burden of proof, and those counterclaims fail on their merits, and that an award should be entered in favor of claimants with respect to the counterclaims.

Alternatively, I believe that the counterclaim should be precluded as an administrative matter, because respondents have affirmatively notified AAA and then executed on their plans and intentions not to meet their financial obligations to the American Arbitration Association.

So under the American Arbitration commercial

rules, those claims could also be administratively precluded. The counterclaims could be administratively precluded.

Alternatively, again, for the reasons articulated in our motion to preclude counterclaims and for sanctions, we believe that provides another ground -- or we believe that motion provides other grounds for precluding the counterclaims, or at least any evidence or arguments in support of those counterclaims.

THE COURT: And with regard to the counterclaims, as you know, I have held open the -- your claimant's motion to bar and claimant's motion for summary judgment with regard to the counterclaim. And we have also held open the dismissal of the counterclaim for administrative reasons, in part because I wanted to be sure that the respondent had every opportunity to challenge those motions and to present any evidence in opposition.

And by their absence here today, it is clear to me they do not have any basis for responding or they intend to present no opposition to those motions. So it is my plan to deal with those motions in the final award, as opposed to separately. So just so

you'll know.

Okay?

MR. HUH: Thank you.

THE COURT: Anything else?

MR. HUH: No. That's it for now.

THE COURT: Okay. If you don't mind, I just have a couple of -- a few questions for my own clarification. And if we could put Mr. Grooms under oath first, I just want to ask him a couple of questions about the agreement.

COURT REPORTER: Would you raise your right hand, please?

Do you solemnly swear or affirm that the testimony you're about to give in this cause is the truth, the whole truth and nothing but the truth?

THE WITNESS: Yes.

THEREUPON

JAMIE GROOMS

Was called as a witness and, having first been duly sworn, testified as follows:

THE COURT: Okay. Mr. Grooms, I just had a couple of questions about the agreement just for my own edification.

One, I noted, in Section 9 of the agreement -- I don't know if you've got a copy of it there.

THE WITNESS: I don't have a copy. I don't have my glasses with me.

THE COURT: Mine is marked up, so if you maybe could -- or give him the notebook will be fine.

And is it Exhibit 1?

MR. VERNICK: It's Exhibit 1.

THE COURT: So I'm referring to Hearing Exhibit 1, which is the -- correct title -- license agreement between ISE and Synogen.

Do you have that there?

THE WITNESS: I have it. I'm getting a pair of glasses.

THE COURT: Yeah.

If you would go to Page 8 of the agreement. And I think, if the pagination is the same, at the bottom, it's Section 9, Patent Prosecution.

THE WITNESS: I'm going to have to have someone read it, because I don't have my glasses.

THE COURT: Oh, dear. I'm sorry. Okay.

THE WITNESS: I left them in my car.

THE COURT: And it is very small print.

THE WITNESS: It is.

MS. TOOTHMAN: Where are we referring to? Section 9.1?

THE COURT: Section 9 -- Section 9.1, Patent

Prosecution.

MR. HUH: Can we pop it up?

THE WITNESS: These work.

THE COURT: And I wanted to ask you about that first sentence that reads, licensee shall prosecute and obtain the Licensed Patents using counsel of its choice.

THE WITNESS: Uh-huh.

THE COURT: I noted, in reviewing the exhibits in preparation for the hearing today, that there were several different patent counsel, and you're now using DLA Piper.

THE WITNESS: Correct.

THE COURT: Has ISE revoked their limited power of attorney with regard to DLA Piper during the pendency of this hearing?

THE WITNESS: The power of attorney has been an issue all along, and right now, we don't have an active P of A.

THE COURT: From ISE?

THE WITNESS: Correct. And we need it desperately.

THE COURT: And has ISE indicated to you any substantive reason why it objects to DLA Piper?

THE WITNESS: No, ma'am.

THE COURT: They just simply revoked the limited power of attorney?

THE WITNESS: That's correct.

THE COURT: And I will elsewhere in this agreement, the licensor -- in fact, I think it's Section 9.3 -- is obligated to cooperate in all respects with regard to patent prosecution. Is that right?

THE WITNESS: That's correct, ma'am.

THE COURT: Do you believe that ISE is currently cooperating?

THE WITNESS: No, ma'am.

THE COURT: Okay. And could you explain for me -- I know a little bit about FDA approvals and patent prosecution and the like. But I gather that you obtained an approval from the FDA on some sort of preliminary basis.

Would you talk just a little bit about that?

THE WITNESS: Well, it's not preliminary. We have FDA clearance as NeXtGen to sell this product --

THE COURT: I see.

THE WITNESS: -- according to two things. The patent is a side issue. But the process they were supposed to give us and we've tested this whole

material to, they've chosen not to give us that. So it's held up our actual commercialization. If she complied with the agreement, we could be selling that product for patients today.

THE COURT: Okay. And I gather from reading your declaration that -- and maybe some of these questions should be directed to Ms. Toothman. I'm not quite sure. But I'm going to direct it to you first. If you want to defer to her, that's fine, because --

THE WITNESS: Thank you.

THE COURT: -- I want to ask her some questions as well.

With regard to the FDA approval, I understand that the process that ISE committed they would provide to you under the license agreement did not get provided.

THE WITNESS: Correct.

THE COURT: And is it correct, from your -- my reading of your declaration that you-all have undertaken steps to essentially mitigate that failure and attempt to develop a process of your own?

THE WITNESS: I'm going to defer half of it to her. We've attempted to, you know, extract that

information from her all along this whole way, but because it wasn't happening, then I'll turn the question over to the CEO of the company that will answer the part of what we've done on our own.

THE COURT: Okay. And with regard to the process that ISE was to provide under this license agreement, did you have -- did Ms. Early or others on behalf of ISE represent to you that they had such a process?

THE WITNESS: Yes. And they defined what it is. They mischaracterize it and define what it is all in the same day. So it's an algorithm. That's all it is.

THE COURT: All right. And I saw in some of the documents filed by respondent, prior to their stopping their participation in this matter, if you will, some reference that the -- this Licensed Know-How, this procedure could not be defined and was very mysterious and unknown.

At the same time, I saw in the agreement their -- the agreement that that process would be kept confidential up until this point.

Do you have any comment on that argument by them?

THE WITNESS: Yeah. What you said is correct.

And that's why I used the word mischaracterization and defining what it is in the same sentence. At the end of the day, it is an algorithm on how the process -- a chemical algorithm.

What they said in one of the mediations was, it's a machine. So they were not honest with us on what it actually was and tried to distract us. But Ryanne's told me before this --

THE COURT: That would be Ms. Early.

THE WITNESS: Ms. Early.

She's told me many times, all it is is an algorithm, a chemical process algorithm. And all that I was trying to do was put that in escrow so I could have that to protect the companies that did the hard work of getting these things FDA approved, available to them, and that's never happened.

THE COURT: Okay. Thank you. That's all I had for you, so --

MR. HUH: Could I ask just one quick question?

THE COURT: Oh, sure. Please feel free to interrupt anything I may have muddied here.

MR. HUH: You stated that Ms. Early notified you or asserted that the process was an algorithm, a chemical algorithm. Correct?

THE WITNESS: Yes.

MR. HUH: And she made that representation multiple times?

THE WITNESS: Yes.

MR. HUH: And she made the -- did she make those representations outside of the context of any settlement discussions as well?

THE WITNESS: Yes. This was before we had any contest at all going on. This was just my education with her in the beginning phase.

MR. HUH: Okay. Thank you.

THE COURT: Okay. All right. Any other questions for Mr. Grooms?

Okay. Then we'll go on to Ms. Toothman.

If we may put her under oath, please.

COURT REPORTER: Would you raise your right hand, please?

Do you solemnly swear or affirm that the testimony you're about to give in this cause is the truth, the whole truth and nothing but the truth?

THE WITNESS: I do.

THEREUPON

JONELLE TOOTHMAN

Was called as a witness and, having first been duly sworn, testified as follows:

THE COURT: Ms. Toothman, now, you are with

NeXtGen.

THE WITNESS: Correct.

THE COURT: Right?

Which is the sublicensee.

THE WITNESS: Yes, ma'am.

THE COURT: And would you just take one minute, just for the record, and, in your own words, tell me what your company's role has been in the development of this product.

THE WITNESS: Our company's role has been to take it from infancy through the FDA process in regards to all data required for safety and efficacy to get product approved by the FDA.

THE COURT: Okay. And would you explain a little bit about the steps that have been taken to attempt to deal with the lack of the Licensed Know-How that ISE was to provide?

THE WITNESS: So the FDA approval for the product that we have approval on, it requires certain tests, biocompatibility type of tests, safety tests. And it identifies that specific process to allow that material to get approved by the FDA.

So not having that process, we've had to hire somebody internally. We've had to rent space.

We've had to build a manufacturing facility in-house all within the timeframe of -- starting in January, after this whole thing kind of happened, and try to invent a process that could have some of the same end points that we can go back to the FDA and said -- and say, instead of repeating every single test, here are a few tests we'll repeat to show you that the end points are the same.

However, I can't look the FDA in the eye and say, this is exactly the same process, because I've never been given the process. Therefore, we're going to the assumption that the FDA is going to ask us to repeat all of the tests in order to get a FDA approval of the same product with our own process.

So we started initiating those steps in January, and it will take us probably until this time next year, to have a finished good product to starting selling again.

THE COURT: And is there some risk, you might not have that finished process by that time?

THE WITNESS: Absolutely. Every day is a risk. And every day, going back to the FDA again is also a risk.

THE COURT: So, again, just so I understand, when you realized that ISE was not going to perform

the contract and provide you with the algorithm and the process that it had committed to do, you began trying to take steps, reverse engineer, essentially, and create a work-around for that problem.

THE WITNESS: Absolutely.

THE COURT: Okay. And, thus far, have not succeeded in doing that, but you're earnestly attempting to do that.

THE WITNESS: That is correct.

THE COURT: Okay. That's all I have.

MR. HUH: I just have a couple quick questions.

THE COURT: Go ahead.

MR. HUH: The reverse engineering, there's no guarantee that that's going to be successful.

THE WITNESS: It's hard to call it reverse engineering, because you would have to know some of the steps along with it, which we received none from Ms. Early. But yes, it's a process. It's going to take time.

MR. HUH: It's a process that's not fully developed today.

THE WITNESS: That is correct.

MR. HUH: And it might never be fully developed.

THE WITNESS: That is absolutely -- I mean,

that's correct.

MR. HUH: Thank you.

THE COURT: Thank you.

And I appreciate you clarifying that. I used the term, reverse engineering, out of ignorance here, so don't read anything into that. I'm just trying to get a shorthand for the efforts you're -- description of the efforts that you're trying to undertake to duplicate or solve the problem of not having the process.

Oh, let me ask her one other question, if you don't mind.

I know this is in your declaration, but you all have spent a lot of money over a long period of time, in the belief that this additional process would be furnished to you on a timely basis. What -- what -- about how much money, and this is just in round terms, has been spent to date, attempting to develop this product?

THE WITNESS: So, we have spent -- we've spent $9.1 million in total, since the beginning of 2016, end of 2015, actually. And, yes, we have -- this has put us in a position to possibly lose a company.

Luckily, we have supporters, and we're going to get through this, hopefully. But it's something

that we never would have foreseen and has caused huge damages to the company, in both timing, as well as financially.

THE COURT: Okay. And one other question.

I know there's a related company called Seed. Could you just briefly tell me what relationship that has, in sort of your day-to-day work on this project that's at issue here?

THE WITNESS: Ryanne Early has several different companies that she uses differently in some ways. I have yet to understand how she uses them and who does what within her corporations.

But, the way I see it is, Seed is a separate company that also provides products, and has done testing on our behalf. We have paid Seed over $1.7 million directly to initiate some of the studies required to go through the FDA.

So, more of a testing agency, consulting, but also has a company that produces similar type of products and patents that produce similar type of exercise and matrix products.

THE COURT: What -- Ms. Early has represented that ISE owns the process, that is the process that you're attempting -- you need to get, under this agreement to complete your product development.

THE WITNESS: She had represented that ISE owns that process. However, Seed uses that process to produce their current products. And Seed used that process to consult with us and make the products that we used in the FDA filings. So those are very interchangeable.

THE COURT: The companies.

THE WITNESS: Yes.

THE COURT: Yes.

All right. That's all I've got.

MR. HUH: Okay. I just have a couple of questions on that, just to clarify for the record, because I think it gets confusing with Seed, Ms. Early's company, Seed, and her other company, the respondent in this case, ISE.

So, ISE, under the license agreement with Synogen, agreed to provide the Know-How to Synogen. Is that correct?

THE WITNESS: Correct.

MR. HUH: And Ms. Early is the chief executive officer of ISE.

THE WITNESS: Correct.

MR. HUH: And, at the same time, Ms. Early, through her other company, Seed, entered into a contract with NeXtGen, to assist NeXtGen through the

FDA clearance process. Is that correct?

THE WITNESS: Correct.

MR. HUH: And through that -- under that contract, Ms. Early used ISE's Know-How, right, which would be the process to -- that was directly relied upon, for her to assist the company, or assist NeXtGen, in getting FDA approval. Is that correct?

THE WITNESS: Correct.

MR. HUH: Okay. Thank you.

THE COURT: Okay. Very good. That's all I have.

Is there any other presentation? There's obviously no one here for the respondent, to conduct any cross-examination. So, let me ask if the claimant has any other evidence it wishes to present at this time.

MR. HUH: The only other additional evidence that we were hoping to provide were -- would be through hostile witnesses that we were planning to call, including Ms. Early. But, obviously, she is in willful defiance of these proceedings and the orders, and her absence here demonstrates that.

So we're unable to do that, and I think that is just another indication of how the claimants have

been prejudiced throughout this arbitration by some of the bad faith tactics and gamesmanship we've seen by respondents -- by the respondent, respondent's officers, and respondent's former counsel.

THE COURT: So, is your case complete now?

MR. HUH: Yes.

THE COURT: Okay.

So I will now, for the record, call on the respondent to provide something. Obviously, they're not here. But, again, I want it to be very clear in the record that they have not shown up. They have not taken this opportunity to present any evidence to me, one way or the other, with regard to either their defense of the claims that the two claimants have made, or with regard to supporting the counterclaim that they have asserted.

So I will -- I'm going to close this record very shortly. It's now about 9:35 in the morning, and we've not had a phone call or any other indication that anyone for respondent has shown up in any way, phone in or otherwise, to present any opposing evidence.

So I will adjourn this hearing shortly and, then, be making my decision based on what is in the record as of today.

I do intend to keep the record open until November 15th, for the submission of proposed awards. Early in this case, I had asked for -- if the parties would do this, because they were both seeking declaratory relief and injunctive relief, and it would be very helpful to me to see precisely what each party articulates as the declarations and injunction that they seek. And so, the record in this matter will remain open through November 15th to receive those documents.

Similarly, if there is any petition for -- additional petition for fees and costs, the record will remain open until then.

Both parties are certainly free to submit their proposed awards and fee updates earlier, should they choose to do so, but I will not be issuing an award until after that November 15th date passes.

Are there any questions about that?

MR. HUH: Not at this time.

THE COURT: Okay.

So, nothing further coming before us, I will -- we will simply end the hearing today, and it -- the record, however, will remain open, as stated.

MR. HUH: Okay. Thank you very much.

THE COURT: Thank you.

(Thereupon, the proceedings were recessed for the day at 9:36 a.m.)

CERTIFICATE OF OATH

STATE OF FLORIDA:
COUNTY OF ORANGE:

I, Sandra Narup, Registered Professional Reporter, Realtime Systems Administrator and Florida Professional Reporter, Notary Public, State of Florida, do hereby certify that JAMIE GROOMS AND JONELLE TOOTHMAN personally appeared before me on October 23, 2019 and was duly sworn and produced Florida driver's license as identification.

Signed this 23rd day of October, 2019.



_____
Sandra Narup
Registered Professional Reporter,
Realtime Systems Administrator
and Florida Professional Reporter
Notary Public, State of Florida
My Commission No.: GG 143504
Expires: January 15, 2022

CERTIFICATE OF REPORTER

STATE OF FLORIDA)
)
COUNTY OF ORANGE)

I, Sandra Narup, Registered Professional Reporter, Realtime Systems Administrator and Florida Professional Reporter, Notary Public, State of Florida, I was authorized to and did stenographically report the foregoing proceedings; and that the transcript, pages 3 through 35, is a true and accurate record of my stenographic notes.

I FURTHER CERTIFY that I am not a relative, or employee, or attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

Dated this 23rd day of October, 2019.



_____

SANDRA NARUP
Registered Professional Reporter,
Realtime Systems Administrator &
Florida Professional Reporter

&

& 1:8,19 6:1 7:2 7:19 9:9,10 10:1 11:24 12:10 37:24

0

01-19-0002-3786 1:2
01-19-002-7261 10:9

1

1 12:18 19:5,6,8
1.7 30:16
143504 36:21
15 36:22
15th 14:13 34:2,9 34:17
1650 2:3
19103 2:4

2

200 2:8
2015 29:22
2016 29:21
2019 1:13 36:10,13 37:19
2022 36:22
215-656-2450 2:5
23 1:13 36:10
23rd 3:24 36:13 37:19
2500 2:9
2999 36:17 37:22

3

3 37:10
305-423-8502 2:10
305-675-0702 2:10
30th 14:5
32803 1:16
33131 2:9
35 37:11

5

5000 2:4

6

633 1:16 5:18

8

8 19:14
83 12:18 13:5
84 2:17 12:6,10
85 2:17 12:6,10
86 2:18 12:6,10

9

9 18:24 19:16,25
9.1 19:24,25 29:21
9.3 21:6
9:00 1:14
9:35 33:18
9:36 1:14 35:2

a

a.m. 1:14,14 35:2
aaa 5:10 7:8 9:7 10:5,8 16:21
able 7:20 11:13
absence 17:21 32:23
absolutely 27:21 28:5,25
accept 11:15 12:12 13:10,17
accommodate 11:2
accurate 37:11
action 37:17,18
active 20:19
actual 22:2
addition 10:15
additional 13:4 14:17 29:15 32:18 34:12
address 5:14
adequate 5:15
adjourn 33:23
administrative 16:20 17:16
administratively 17:1,3
administrator 1:19 36:7,19 37:7 37:24
admit 4:14 10:12
admitting 13:2
advised 7:18
affirm 18:13 25:17
affirmatively 16:21
agency 30:18
ago 3:22 4:4 10:22
agreed 6:17 7:22 10:22 11:2 15:18 31:17
agreement 3:23 18:10,22,24 19:9 19:14 21:5 22:3 22:16 23:7,20,21 30:25 31:16
ahead 28:12
algorithm 23:12 24:3,4,12,12,23,24 28:1
allow 26:22
alternative 16:6
alternatively 16:19 17:4
american 1:1 9:13 9:24 12:8 15:19 15:25 16:23,25
answer 23:4
appeared 36:10
appearing 2:6,11
appreciate 4:22 5:9 29:4
appropriate 14:19
approval 21:16 22:14 26:18,19 27:14 32:7
approvals 21:14
approved 24:15 26:13,22
arbitrate 11:10
arbitration 1:1,11 3:23 4:20 5:2 6:3 7:1,5,16,24 8:13 9:13,13,15,25 10:2 11:1,13 12:8 13:24 14:7 15:19 16:1,24,25 33:1
arbitrator 8:25 15:20 16:1
argument 23:23
arguments 17:9
arrives 8:15
arrowood 1:12
articulated 17:5
articulates 34:7
asked 34:3
asserted 24:23 33:16
assist 31:25 32:6,7
associated 14:6
association 1:1 9:14,25 12:9 15:20 16:1,24
assume 9:8
assumption 27:12
attached 8:9 12:5 13:5 14:3
attempt 22:22 26:16
attempted 22:25

attempting 28:8 29:19 30:24
attorney 20:15,17 21:2 37:15,17
attorneys 12:3 15:21,23 16:10
authorized 15:20 16:2 37:9
available 11:7 24:16
award 13:25 14:8 14:16 15:9,14,21 16:2,5,9,17 17:25 34:16
awarded 14:10
awards 34:3,15
b
b 2:19 11:18,22,24
back 27:5,22
bad 33:2
bar 5:3 17:13
based 13:21 15:7 16:13 33:24
basis 17:22 21:17 29:16
began 28:2
beginning 25:9 29:21
behalf 2:6,11 3:7 3:10,12,16 6:19 7:12 11:16 23:8 30:15
belief 29:15
believe 4:8 5:16 7:8,9 9:5 13:1,5 13:22 15:7 16:7 16:19 17:6,7 21:10
biggs 1:12
binder 12:18 13:4
biocompatibility 26:20
biologics 1:5
birg 5:25 7:13 9:9 9:19 10:1
biscayne 2:8
bit 21:14,18 26:15
board 3:14
bottom 19:16
boulevard 2:8
brief 13:21 15:5
briefing 14:17
briefly 30:6
brought 5:6
build 27:1
burden 16:15
c
c 2:1,19 3:1 11:18 11:23,24
call 28:15 32:21 33:8,19
called 18:19 25:23 30:5
cancelled 5:23 7:10
capacities 9:12
capture 14:6
car 19:20
care 4:24
case 1:2 5:8,11 8:3 10:5,8 12:22 14:12 31:15 33:5 34:3
cases 11:11
catharine 1:12
cause 18:14 25:18
caused 30:1
ceo 2:13 3:13 4:8 23:3
certain 26:20
certainly 14:12 34:14
certificate 36:1 37:1
certify 36:9 37:14
challenge 17:18
change 5:14,17 7:15 13:8
changed 8:17
chemical 24:4,12 24:24
chief 11:12 31:20
choice 20:7
choose 34:16
chosen 22:1
circumstance 4:22
circumstances 5:17
claimant 2:6,11 3:12 10:3 11:4 32:16
claimant's 13:17 17:13,13
claimants 1:6 3:8 3:10,17 7:12 9:15 11:16 15:9 16:17 32:25 33:14
claims 15:24 17:1 33:14
clarification 18:8
clarify 15:14 31:12
clarifying 29:4
clear 10:7 15:17 16:14 17:21 33:10
clearance 21:20 32:1
clip 12:13
close 33:17
colonial 1:16 5:18
comes 4:14
coming 34:21
comment 23:23
commercial 16:2 16:25
commercialization 22:2
commission 36:21
committed 22:15 28:2
communication 9:10
communications 4:7
companies 24:14 30:10 31:7
company 9:21 23:3 29:23 30:2,5 30:14,19 31:14,14 31:24 32:6
company's 26:8 26:10
complete 30:25 33:5
completes 13:22
compliance 12:21
complied 22:3
conduct 32:14
conference 6:7,10 10:21
confidential 23:22
confirm 7:18 9:7
confirmed 8:14
confirming 13:8
confusing 31:13
connected 37:17
connection 10:2
consecutively 11:8
consented 13:2
constraints 10:24

consult 31:4
consulting 1:8 30:18
contact 6:21 7:25 8:2,4 9:18
contacted 5:21 6:1 7:2,11,14 8:11 9:7
contained 4:10
contains 12:18
contest 25:8
context 25:5
continues 9:11,20
contract 6:16 10:24 28:1 31:25 32:4
convened 3:21
conversations 8:6
convince 6:18
cooperate 21:6
cooperating 21:11
copies 5:6
copy 18:25 19:1
corporations 30:12
correct 6:11,12 7:9 9:4,23 19:8 20:13,21 21:3,9 22:18,19 23:25 24:24 26:2 28:9 28:22 29:1 31:18 31:19,22 32:1,2,8 32:9
costs 12:4 14:1,4,6 14:10,18 15:14,21 15:24 16:3,3,5,10 34:12
counsel 4:2,3,5 5:24,24 6:17 7:15 9:8,9 10:22 20:6 20:11 33:4 37:15 37:17
counterclaim 16:19 17:15,16 33:16
counterclaims 15:25 16:8,13,16 16:18 17:2,5,8,10 17:12
county 36:4 37:3
couple 10:22 14:22 15:11 18:7 18:9,22 28:11 31:11
court 3:3,18 5:7,9 6:4,9,12,23 7:6 8:18,23 9:17 10:5 10:10,20 11:21 12:12 13:10 14:11 14:21,25 15:3,6,12 15:16 17:11 18:4 18:6,11,21 19:3,7 19:13,19,21,25 20:4,9,14,20,23 21:1,4,10,13,22 22:5,12,19 23:5,14 24:9,17,20 25:11 25:15,25 26:3,6,14 27:19,24 28:6,10 28:12 29:3 30:4 30:22 31:7,9 32:11 33:5,7 34:20,25
courtesy 5:6
create 28:4
crespo 2:7 3:11,11 5:2
cross 32:15
current 14:5 31:3
currently 5:18 7:20 21:11

d

d 2:2,20,20 3:1 12:2,5,10
damages 30:2
data 26:12
date 1:13 9:2 14:13 15:8 29:18 34:17
dated 37:19
day 11:8 23:12 24:3 27:21,22 30:7,7 35:1 36:13 37:19
days 5:16 11:10,14
deadlines 4:10
deal 17:24 26:16
dealt 4:21
dear 19:19
decision 33:24
declaration 2:18 2:20 8:2,5,8 10:13 12:2,5,15 13:6 14:3 22:6,20 29:13
declarations 34:7
declaratory 34:5
declined 12:24
defense 33:14
defer 22:9,24
defiance 32:22
define 23:11
defined 23:10,18
defining 24:2
demanding 15:23
demands 15:25
demonstrates 32:23
description 2:16 8:5 29:8
desperately 20:22
detail 2:17
develop 22:22 29:19
developed 28:21 28:24
development 26:8 30:25
different 6:14 20:11 30:10
differently 30:10
direct 9:18 22:8
directed 22:7
directions 7:24
directly 30:16 32:5
director 3:15
discussions 25:6
dismissal 17:16
disrupt 11:21
distract 24:7
dla 2:3,8 3:7,9,11 3:16 7:12 8:3 9:18 20:12,15,24
dlapiper.com 2:5 2:6,10
document 13:4
documentation 14:1,9,17
documents 5:4 23:15 34:10
doing 28:7
doubt 8:24
drive 1:16 5:18
driver's 36:11
due 10:23 11:6
duly 18:19 25:23 36:11
duplicate 29:9

e

e 1:16 2:1,1 3:1,1 8:9,14 9:24 13:7
earlier 34:15
early 4:7 9:6 23:7 24:9,10,22 28:18 30:9,22 31:20,23 32:4,21 34:3
early's 9:14 10:3 11:2 31:14
earnestly 28:7
east 5:18
edification 18:23
education 25:8
efficacy 26:12
efforts 29:7,8
eight 5:20 11:9
either 4:1 7:8 13:1 33:13
employee 37:15,16
engaged 6:8
engineer 28:3
engineering 28:13 28:16 29:5
entered 16:17 31:24
entities 9:12 10:3
entitled 15:9
entity 9:14
entries 12:7 14:3
erika 5:25
escrow 24:13
especially 15:13
esquire 2:2,2,7
essentially 12:6 22:21 28:3
eventually 8:2
everybody 3:5
evidence 8:2 10:13 10:16 12:1,17 13:3,18,21 15:8 16:13 17:9,19 32:16,18 33:12,22
evidentiary 13:22
exactly 27:10
examination 32:15
executed 16:22
executive 31:20
exercise 30:21
exhibit 2:16,16 8:20,21,22 10:14 11:22,23,24 12:1,5 12:18,20,24,25 13:5,7 19:5,6,8
exhibits 5:6 8:19 11:18 12:6,10,14 12:18,19,25 13:3 13:10,14,17 20:9
expires 36:22
explain 21:13 26:14
explained 5:16
extent 14:1,10
extract 22:25
eye 27:9

f

facility 27:1
fact 21:5
fail 16:16
failed 16:15
failure 22:22
faith 33:2
far 28:6
favor 16:17
fax 2:10
fda 21:14,16,20 22:14 24:15 26:11 26:13,18,23 27:5,9 27:12,13,22 30:17 31:5 32:1,7
fee 34:15
feel 24:20
fees 12:3 13:25 14:4,10,18 15:14 15:21,23 16:3,3,5 16:10 34:12
file 5:11
filed 4:25 5:4 15:25 23:15
filings 15:19 31:5
final 14:17 17:25
finally 12:16 16:6
financial 16:23
financially 30:3 37:18
fine 19:4 22:9
finished 27:17,20
firm 7:13
first 4:19 18:9,19 20:5 22:9 25:23
five 5:16 11:7,14
florida 1:16,19 2:9 5:1,3 36:3,7,8,11 36:20,21 37:2,7,8 37:24
follows 18:20 25:24
foregoing 37:10
foremost 4:19
foreseen 30:1
former 5:24 9:9 33:4
forth 13:20
forward 6:3 7:3,4 8:12
free 24:20 34:14
friday 9:5
full 15:9
fully 28:20,23
furnished 29:16
further 34:21 37:14

g

g 3:1
gainesville 6:17
gamesmanship 33:2
gather 21:15 22:5
general 4:9
getting 19:11 24:15 32:7
gg 36:21
give 18:14 19:4 21:25 22:1 25:18
given 3:22 27:11
glasses 19:2,12,18
go 8:11 19:14 25:13 27:5 28:12 30:17
going 3:4 4:12 6:13 19:17 22:8 22:24 25:8 27:12 27:12,22,25 28:14 28:18 29:24 33:17
good 3:3,18 27:17 32:11
great 5:12
grooms 2:13,19 3:14,14 10:16 11:22 18:8,18,21 25:12 36:9
ground 17:7
grounds 17:8
group 1:3
guarantee 28:14
guidance 4:23

h

half 22:24
hand 18:12 25:16
happen 10:5
happened 7:19 24:16 27:3

happening 23:2
hard 24:15 28:15
hearing 3:19,20 4:12,14 5:14 6:14 6:16 7:21 8:16 9:2 9:8 13:15 15:18 19:7 20:10,16 33:23 34:22
held 17:12,15 22:2
helpful 34:6
hire 26:24
hold 3:23
holding 7:20
honest 24:6
honorable 1:12
hope 14:15
hopefully 29:25
hoping 32:19
hostile 32:20
house 27:1
hudson 2:14 3:16 3:16
huge 30:2
huh 2:2,20 3:7,7 4:17,18 5:8,12 6:11,15,24 7:9 8:21 9:4,23 10:8 10:11 11:20,25 12:16 13:19 14:20 14:24 15:2,5,7,13 15:17 18:3,5 20:2 20:8 24:19,22 25:1,4,10 28:11,13 28:20,23 29:2 31:11,20,23 32:3 32:10,18 33:6 34:19,24

i

identification 8:22 11:24 12:11 36:12
identified 4:5 12:19,25 13:15
identifies 26:21
ignorance 29:5
imposed 10:24
inability 11:7
include 13:12
including 9:12 32:21
index 2:16
indicated 20:23
indication 32:25 33:20
individual 8:15
infancy 26:11
information 23:1
initial 6:23,24 11:3
initiate 30:16
initiating 27:15
injunction 34:8
injunctive 34:5
instruct 7:22
instructed 6:2
intend 17:23 34:1
intentions 16:22
interchangeable 31:6
interested 37:18
interim 4:6
internally 26:25
interrupt 6:4 7:6 24:21
introduce 3:5
invent 27:4
invoice 2:17
invoices 2:18 12:8
involves 9:15
involving 9:14 10:3
ise 1:8 3:20 4:9 9:21 19:9 20:14 20:20,23 21:10 22:15 23:6,8 26:17 27:25 30:23 31:1,15,16,21
ise's 32:4
issue 20:18 21:24 30:8
issues 4:25 10:25
issuing 34:16

j

jamie 2:13,19 3:14 10:16 18:18 36:9
janelly 2:7 3:11 5:2
janelly.crespo 2:10
january 27:2,16 36:22
jodi 2:14 3:16
john 2:2,20 3:7
john.huh 2:5
jonelle 2:13,19 3:13 10:17 25:22 36:9
judgment 17:14

k

keep 34:1
kept 14:12 23:22
kind 27:3
kindly 7:22
know 4:21 13:24 17:12 18:1,25 21:14 22:25 23:18 26:17 28:16 29:13 30:5 31:17 32:4

l

lack 26:16
left 19:20
legal 1:15 2:18
license 19:8 22:16 23:6 31:16 36:11
licensed 20:6 23:17 26:16
licensee 20:5
licensor 21:5
lieu 10:18
light 13:1
limited 20:14 21:2
list 12:20,24 13:1
little 21:14,18 26:15
live 10:19 11:4
llp 2:3,8
location 5:14,17 5:19,20,22,23 6:14 6:15 7:18,23 8:16 8:17 9:7 13:8
location's 8:10
locations 6:18
lodato 2:18 10:13 13:6
lodge 13:13
long 29:14
longer 7:3,4
look 27:9
lose 29:23
lot 29:14
luckily 29:24

m

m 2:2
ma'am 20:25 21:9 21:12 26:5
machine 24:6
mail 8:9,14 9:24 13:7
majority 12:19
making 33:24
management 1:3
manager 8:3

manufacturing 27:1
mark 5:5 8:20 11:18
marked 8:22 10:14 11:24 12:1 12:10 13:7 19:3
market 2:3
mater 11:10
material 22:1 26:22
matrix 30:21
matter 3:19 5:13 6:7 12:7 16:20 23:16 34:9
mean 28:25
mediations 24:5
meet 16:15,23
member 3:14 5:2
merits 13:23 16:16
miami 2:9
michael 2:18 10:13 13:6
million 29:21 30:16
mind 14:21 18:6 29:12
mine 19:3
minute 26:6
minutes 5:20
mischaracterizat... 24:1
mischaracterize 23:11
mitigate 22:21
moment 6:5
money 29:14,17
months 10:22
morning 3:3 9:24 33:18
motion 16:7,7 17:5 17:7,13,13
motions 17:19,23 17:24
move 8:1 10:12,15 12:1
moving 6:2 7:3,4 8:12
muddied 24:21
mullins 5:25 6:1,8 6:18,20 7:2,10,19 8:11 9:9,11,19,20 10:1
multiple 25:2
mysterious 23:19

n

n 2:1 3:1
narrowed 11:14
narup 1:18 36:6 36:18 37:6,23
necessary 13:9
need 5:5 14:1 20:21 30:24
needing 10:25
nelson 5:25 6:1,8 6:18,20 7:1,10,19 8:11 9:9,10,18,20 10:1
never 24:16 27:11 28:23 30:1
new 4:4
nextgen 1:5 2:13 3:13,15,20 10:4 21:20 26:1 31:25 31:25 32:7
nine 4:16 11:10
notary 36:8,21 37:8
note 3:25 10:20 13:11
notebook 19:4
noted 18:24 20:9
notes 37:12
notice 3:21 5:15 9:1
noticed 4:16
notification 5:10 7:7,13 9:6
notified 7:15 16:21 24:22
notify 8:15
november 14:13 34:2,9,17
number 10:6,8
numbering 11:21

o

o 3:1
o'clock 4:16
oath 18:9 25:14 36:1
objection 13:2 16:5
objections 12:25 13:14,16
objects 20:24
obligated 21:6
obligations 16:23
obtain 20:6
obtained 21:16
obviously 4:13 32:14,21 33:9
october 1:13 3:24 36:10,13 37:19
office 6:19
officer 31:21
officers 33:4
oh 19:19 24:20 29:11
okay 3:3 5:12 10:10,11 12:12 14:20 15:4,6 18:2 18:6,21 19:19 21:13 22:5 23:5 24:17 25:10,11,13 26:14 28:6,10 30:4 31:11 32:10 32:11 33:7 34:20 34:24
open 14:12 17:12 17:15 34:1,9,13,23
opening 3:19
opportunity 17:18 33:12
opposed 11:4 17:25
opposing 33:22
opposition 17:20 17:23
orange 1:15 36:4 37:3
order 4:11 12:21 13:12 14:14 27:13
orders 32:23
original 5:19,20 5:22,23 6:6,15 7:23 8:10,16
orlando 1:16 3:24 6:14,20
outside 25:5
owns 30:23 31:1

p

p 2:1,1 3:1 20:19
pa 2:4
page 19:14
pages 37:10
pagination 19:15
paid 30:15
pair 19:11
part 10:21 11:6 17:17 23:4
participate 4:15 6:9

participation 23:16
particular 11:1
parties 3:23 6:17 10:24 13:13 14:14 15:17 16:4 34:4 34:14 37:15,16
party 4:2 8:15 15:22 16:4 34:7
passes 34:17
patent 19:16,25 20:11 21:7,15,24
patents 20:6 30:20
patients 22:4
pendency 20:16
perform 27:25
period 13:12 29:14
personally 36:10
petition 34:11,12
phase 25:9
philadelphia 2:4
phone 33:19,21
physical 10:25
piper 2:3,8 3:7,9 3:11,16 7:12 8:3 9:18 20:12,15,24
place 1:15 9:2
plan 17:24
planning 32:20
plans 16:22
please 18:12 24:20 25:14,16
plenty 14:18
point 6:25 8:25 14:2 16:11 23:22
points 15:11 27:5 27:8
pop 20:2
position 11:3 15:15 29:23
possibly 29:23
potentially 13:24
power 20:14,17 21:2
practice 5:1
pre 12:1
precisely 34:6
preclude 16:8 17:5
precluded 16:20 17:2,3
precluding 17:8
prehearing 13:21
prejudiced 33:1
preliminary 4:24 5:13 15:18 21:17 21:19
prenumbered 8:19
preparation 20:10
present 2:12 9:16 11:11 15:3 17:19 17:23 32:16 33:12 33:21
presentation 32:13
presented 11:16
prevailing 15:22 16:3
print 19:21
prior 23:15
probably 27:16
problem 28:4 29:9
procedure 23:18
proceed 4:12
proceeding 10:6
proceedings 1:11 9:19 32:22 35:1 37:10
process 4:23 21:24 22:15,22 23:6,9,21 24:4,12,23 26:11 26:22,24 27:4,10 27:11,14,20 28:2 28:18,20 29:10,15 30:23,23 31:2,2,4 32:1,5
produce 30:20 31:3
produced 12:20 36:11
produces 30:19
product 21:21 22:4 26:9,13,19 27:14,17 29:19 30:25
products 30:14,20 30:21 31:3,4
professional 1:8 1:18,19 36:6,7,19 36:20 37:6,8,23,24
project 30:8
proof 16:15
proper 3:21
proposed 6:19 14:8,16 34:2,15
prosecute 20:5
prosecution 19:16 20:1 21:7,15
protect 24:14
provide 7:20,24 12:23 22:16 23:6 26:17 28:1 31:17 32:19 33:9
provided 22:17
provides 16:9 17:6 17:7 30:14
public 36:8,21 37:8
purposes 3:5
pursuant 3:21,22
put 11:16 18:8 24:13 25:14 29:23

q

question 23:3 24:19 29:11 30:4
questions 14:22 18:7,10,22 22:7,12 25:12 28:11 31:12 34:18
quick 24:19 28:11
quite 22:8

r

r 2:1 3:1
raise 18:11 25:15
reached 7:2
read 19:18 29:6
reading 22:5,20
reads 20:5
realized 27:25
really 4:22 9:3
realtime 1:19 36:7 36:19 37:7,24
reason 8:10 16:9 20:24
reasonable 15:21 15:23 16:9
reasons 13:20 16:4 17:4,17
recall 11:6,9 14:15
receive 7:7,13 9:6 34:10
received 9:24 13:16 28:17
recessed 35:1
recollection 6:6
record 3:6,25 5:21 8:24 10:7,12,20 11:17 12:13,17 13:3,11,22,23,25 14:11 15:8,17 16:12,13 26:7 31:12 33:8,11,17

33:25 34:1,8,12,23 37:11
reference 23:17
referring 19:7,23
regard 17:11,14 20:15 21:7 22:14 23:5 33:13,15
regards 26:12
registered 1:18 36:6,19 37:6,23
reiterating 8:5
related 9:20,21 30:5
relationship 6:21 30:6
relative 37:14,16
relied 32:6
relief 15:10 34:5,5
remain 34:9,13,23
rent 26:25
repeat 27:7,13
repeating 27:6
report 37:9
reported 1:18
reporter 1:18,19 6:9 18:11 25:15 36:6,8,19,20 37:1 37:7,8,23,24
represent 9:11,20 23:8
representation 25:1
representations 25:5
representative 4:1 4:2
represented 30:22 31:1
request 10:18 14:4 14:9 15:15
requested 15:10
requests 12:3
required 26:12 30:17
requires 26:19
reservation 5:23 7:10 8:10
reservations 6:22 6:23,24
respect 15:13 16:18
respectfully 10:12 10:17 11:25 14:8
respects 21:7
responded 4:10
respondent 1:9 4:1,4,8,13 5:15 6:8,19 7:14 9:1,21 11:4 12:23 13:16 17:18 23:15 31:15 32:14 33:3,9,20
respondent's 5:24 16:12 33:3,4
respondents 16:14 16:21 33:3
responding 17:22
result 7:17
reverse 28:3,13,15 29:5
reviewing 20:9
revoked 20:14 21:1
right 10:10 14:11 14:16,21 15:3 18:11 20:18 21:8 23:14 25:11,15 26:3 31:10 32:4
risk 27:19,21,23
role 26:8,10
round 29:18
rules 16:2 17:1
ryanne 4:7 30:9
ryanne's 11:7 24:8

s

s 2:1,8 3:1
safety 26:12,21
sanctions 16:8 17:6
sandra 1:18 36:6 36:18 37:6,23
saw 23:14,20
schedule 11:2 12:21
scheduling 4:11 6:7 10:21 13:12 14:14
scott 2:2 3:9 4:25
scott.vernick 2:6
section 18:24 19:16,24,25,25 21:6
see 21:22 30:13 34:6
seed 9:14 30:5,13 30:15 31:2,3,13,14 31:24
seek 34:8
seeking 34:5
seen 33:2
sell 21:20
selling 22:3 27:18
sentence 20:5 24:2
separate 30:13
separated 12:15
separately 17:25
september 14:5
serve 10:18
served 12:20
services 1:8
set 13:20
settlement 25:6
sheets 2:17 14:2
shorthand 29:7
shortly 6:25 33:18 33:23
show 7:25 27:7
shown 33:11,20
shows 7:23
side 12:21 21:24
sides 10:23 13:13
signature 36:17 37:22
signed 36:13
similar 30:19,20
similarly 34:11
simply 21:1 34:22
single 27:6
six 11:8,14
small 19:21
solemnly 18:13 25:17
solutions 2:18
solve 29:9
somebody 26:25
sorry 19:19
sort 21:16 30:7
space 7:20 26:25
specific 13:12 26:21
spent 29:14,18,20 29:20
start 3:4
started 27:15
starting 27:2,18
state 36:3,8,21 37:2,8
stated 24:22 34:23
statement 2:17,19 2:19
statements 4:25 5:5 10:16 11:3,11

11:15
stating 8:9
stenographic 37:12
stenographically 1:17 37:9
steps 22:21 26:15 27:15 28:3,17
stopping 23:16
street 2:3
stretch 11:8
studies 30:17
sublicensee 26:4
submission 11:3 34:2
submit 12:17 14:7 14:15,16 34:14
submitted 8:4 12:2
substantive 20:24
succeeded 28:7
successful 28:14
sufficient 9:1
suggested 4:5
suite 2:4,9
summary 17:14
supplement 13:25 14:9,19
support 8:8 14:4 17:9
supporters 29:24
supporting 13:7 33:15
supports 12:3
supposed 21:25
sure 8:21 11:20 12:14 14:24 15:4 15:12,16 17:17 22:8 24:20
surrounding 10:25
swear 18:13 25:17
sworn 18:20 25:24 36:11
synogen 1:3 3:15 3:20 19:9 31:17 31:17
systems 1:19 36:7 36:19 37:7,24

t

table 3:4
tactics 33:2
take 4:24 11:9 26:6,11 27:16 28:3,19
taken 26:15 33:12
talk 21:18
talked 7:17
telephone 6:10
tell 26:7 30:6
term 29:5
terms 29:18
test 27:7
tested 21:25
testified 18:20 25:24
testimony 10:18 10:19 11:5 18:14 25:18
testing 1:8 30:15 30:18
tests 26:20,20,21 27:7,13
thank 3:18 4:18,19 5:7 10:10 13:19 18:3 22:11 24:17 25:10 29:2,3 32:10 34:24,25
thing 27:3
things 4:9 21:23 24:15
think 5:5 8:18 11:9 19:15 21:5 31:13 32:24
time 1:14 3:22 4:16,19,20 5:25 9:2 10:23 11:13 12:7 13:13 14:2,3 14:6,18 23:20 27:17,20 28:19 29:15 31:23 32:17 34:19
timeframe 27:2
timekeeper 2:17
timekeepers 12:7
timely 29:16
times 24:11 25:2
timing 30:2
title 19:8
today 4:11,21 7:21 8:5 9:16 10:19 17:21 20:10 22:4 28:21 33:25 34:22
today's 8:16
told 8:12 24:8,11
toothman 2:13,19 3:13,13 10:17 11:23 19:23 22:7 25:13,22,25 36:9
total 29:21
touch 15:11 16:11
transcript 37:10
transperfect 2:18
tried 24:7
true 37:11
truth 18:15,15,15 25:19,19,19
try 27:3
trying 24:13 28:3 29:7,8
turn 23:2
two 5:4 14:22 21:23 33:14
type 26:20 30:19 30:20

u

uh 20:8
unable 32:24
understand 22:14 27:24 30:11
understanding 4:3
undertake 29:9
undertaken 22:21
unfortunate 4:22 9:3
unknown 23:19
unusual 4:21
updates 34:15
uploaded 5:11
use 11:10
useful 10:7
uses 30:10,11 31:2

v

v 3:20
variety 4:9
various 4:10 9:12
vendors 12:9
verified 4:25 5:4
veritext 5:22 6:1,8 6:14,21 7:2,11,14 7:17,22 8:4,7,9 13:8
veritext's 6:19
vernick 2:2 3:9,9 5:1 19:6
view 8:25
vs 1:7

w

waived 13:2 16:5
want 4:24 5:13 8:24 11:19 12:14

15:1,11 16:11
18:9 22:9,12
33:10
wanted 14:22
17:17 20:4
way 4:1 23:1
30:13 33:13,21
ways 30:11
we've 21:25 22:25
23:4 26:24,25
27:1 29:20 33:2
33:19
wednesday 1:13
weeks 4:4
went 9:25
willful 32:22
wishes 32:16
withdrawing 7:1
withdrew 4:4
witness 2:19,19
10:16 11:11,15
18:16,19 19:1,11
19:17,20,22 20:3,8
20:13,17,21,25
21:3,9,12,19,23
22:11,18,24 23:10
23:25 24:10,25
25:3,7,20,23 26:2
26:5,10,18 27:21
28:5,9,15,22,25
29:20 30:9 31:1,8
31:19,22 32:2,9
witnesses 14:23
32:20
word 24:1
words 9:17 26:7
work 20:3 24:15
28:4 30:7
written 11:11

y

yeah 6:24 19:13
23:25
year 27:17

Exhibit L

AMERICAN ARBITRATION ASSOCIATION

SYNOGEN MANAGEMENT GROUP, INC., and NEXTGEN BIOLOGICS, INC., Claimants, v. ISE PROFESSIONAL TESTING & CONSULTING SERVICES, INC., Respondent.	**Case No. 01-19-0002-3786**

PRE-HEARING BRIEF OF CLAIMANTS SYNOGEN MANAGEMENT GROUP, INC. & NEXTGEN BIOLOGICS, INC.

Date: October 18, 2019

DLA PIPER LLP (US)

Janelly Crespo (Fla. Bar ID 124073)

200 South Biscayne Boulevard, Suite 2500
Miami, FL 33131
T: 305.423.8500 / F: 305.437.8131
Janelly.Crespo@dlapiper.com

John D. Huh (*R 1-3.11 statement submitted*)
Scott M. Vernick (*R 1-3.11 statement submitted*)

One Liberty Place
1650 Market Street, Suite 4900
Philadelphia, PA 19103
T: 215.656.3300 / F: 215.656.3301
John.Huh@dlapiper.com
Scott.Vernick@dlapiper.com

Attorneys for Synogen Management Group, Inc. and NeXtGen Biologics, Inc.

TABLE OF CONTENTS

Page

I. INTRODUCTION 1

II. STATEMENT OF UNCONTESTED FACTS 4

A. The Parties 4

B. The Synogen-ISE License Agreement 4

1. The Synogen-Nextgen Sublicense Agreement 5

C. Synogen and Nextgen's Efforts to Commercialize the Technology 6

D. ISE's Refusal to Transfer the Manufacturing Process 7

E. Nextgen's Survival of the Synogen-ISE License Agreement 10

III. PROCEDURAL HISTORY 11

A. ISE's Bad Faith Litigation Tactics 11

1. Mediation: ISE's Erratic Practices & Intentional Misstatements 11

2. ISE's Disengagement From the Arbitration Proceedings 12

a. The Tactical Withdrawal of Counsel at Nelson Mullins 12

b. The September 27, 2019 Status Hearing Call 14

c. The Parties' Document Productions 15

3. ISE's Threats Against the Patents and the Preliminary Injunction 17

IV. ARGUMENT 18

A. Breach of Contract (Synogen Against ISE) 18

1. A valid contract governs the Synogen-ISE relationship 19

2. ISE materially breached the terms of the License Agreement 20

a. Failure to Transfer the Licensed Know-How 20

b. Refusal to Cooperate in the Preparation and Prosecution of the Licensed Patents 22

3. ISE's material breaches have and will continue to cause harm 24

a. Failure to Transfer the Licensed Know-How 25

b. Refusal to Cooperate in the Preparation and Prosecution of the Licensed Patents 25

B. Breach of Contract (Nextgen Against ISE) 26

1. Nextgen is a Third-Party Beneficiary of the License Agreement 27

2. Nextgen sustained monetary damages as a result of ISE's material breach of the License Agreement 30

C. The Arbitrator Should Not Give Weight to ISE's Counterclaim that the License Agreement has been Terminated 32

RegenX Science Exhibit 1071
Page 221

D. Declaratory Relief: Nextgen's Right of Survival 35
E. Claimant's Award of Attorneys' Fees and Costs 37
1. The parties placed attorneys' fees and costs at issue in this Arbitration 37
2. The Arbitrator may award attorneys' fees and costs as a sanction for ISE's bad faith tactics in this Arbitration 37
F. Request for Relief 39
V. CONCLUSION 40

RegenX Science Exhibit 1071
Page 222

TABLE OF AUTHORITIES

Page(s)

Cases

Am. Sur. Co. of N.Y. v. Smith,
100 Fla. 1012, 130 So. 440, 441 (Fla. 1930) 28

Beefy Trail, Inc. v. Beefy King Int'l, Inc.,
267 So. 2d 853 (Fla. 4th DCA 1972) 21

Caretta Trucking v. Cheoy Lee Shipyards,
647 So. 2d 1028 (Fla. 4th DCA 1994) 27

Dingle v. Dellinger,
134 So. 3d 484 (Fla. Dist. Ct. App. 2014) 27

Excess Risk Underwriters, Inc. v. Lafayette Life Ins. Co.,
328 F. Supp. 2d 1319 (S.D. Fla. 2004) 27

Faro Techs., Inc. v. Brainlab, U.S.A, Inc.,
12-177, 2013 WL 12361030 (M.D. Fla. Jan. 16, 2013) 22

First Auto. Serv. Corp. v. First Colonial Ins. Co.,
No. 07-682, 2010 WL 2431889 (M.D. Fla. Jul. 16, 2010) 39

Florida Power & Light Co. v. Road Rock, Inc.,
920 So. 2d 201 (Fla. 4th DCA 2006) 28

Foundation Health v. Westside EKG Assoc.,
944 So.2d 188 (Fla. 2006) 27

Havens v. Coast Florida, P.A.,
117 So.3d 1179 (Fla. Dist. Ct. App. 2013) 18

Heller v. Carnival Corp.,
191 F. Supp. 3d 1352 (S.D. Fla. 2016) 27

Jenne v. Church & Tower, Inc.,
814 So. 2d 522 (Fla. 4th DCA 2002) 28

Lapidus v. NCL Am. LLC,
No. 12-21183, 2012 WL 2193055, at *6 (S.D. Fla. Jun. 14, 2012) 27

Marshall & Co. v. Duke,
114 F.3d 188 (11th Cir. 1997) 39

MDS (Canada) Inc. v. Rad Source Techs., Inc.,
720 F.3d 833 (11th Cir. 2013) 21, 24, 25

RegenX Science Exhibit 1071
Page 223

Nestler-Poletto Realty, Inc. v. Kassin,
730 So. 2d 324 (Fla. 4th DCA 1999) 28

Orange Cnty. v. Expedia, Inc.,
985 So.2d 622 (Fla. Dist. Ct. App. 2008) 36

Palumbo v. Moore,
777 So.2d 1177 (Fla. Dist. Ct. App. 2001) 35, 36

Smith v. Beverley Hills Club Apts., LLC,
No. 15-23450, 2016 WL 344975 (S.D. Fla. Jan. 28, 2016) 28

Other Authorities

AAA Commercial Rule 47(a) 26

AAA Commercial Rule 47(d) 37

AAA Commercial Rule R-37(a) 26

AAA Commercial Rule R-57(b) 32

RegenX Science Exhibit 1071
Page 224

Claimants Synogen Management Group, Inc. ("Synogen") and NeXtGen Biologics, Inc. ("Nextgen") respectfully submit this Pre-Hearing Brief in this Arbitration against Respondent ISE Professional Testing & Consulting Services, Inc. ("ISE").

I. INTRODUCTION

The claims in this Arbitration are straightforward. At center, under the Synogen-ISE License Agreement ("License Agreement"), made effective September 23, 2014, ISE granted to Synogen certain rights:

(i) an exclusive license to certain patent rights; and

(ii) a non-exclusive license to a trade secret process technology or decellularization process—i.e., the Licensed Know-How.

See Synogen-ISE License Agreement as **Exhibit 1**, §§ 1.7, 1.9, 2, 5.2.1, 5.2.2; *see also* Arbitration Order No. 11 as **Exhibit 49**, ¶ 1. This much is clear, and undisputed. Despite this, ISE has repeatedly refused, and continues to refuse, to comply with its clear obligation to deliver to Synogen the decellularization process. ISE has provided no explanation for this refusal.

Instead, ISE has engaged in a strategy to undermine and disengage from this Arbitration. Since September 23, 2019, ISE has intentionally missed **all** mandatory deadlines in this Arbitration. ISE has not produced a **single** document. ISE has not responded to a single meet and confer request. ISE has not attended any telephonic status hearing with the Arbitrator. ISE decided not to even respond to any of Claimants' multiple motions (including motions to compel discovery, and for sanctions and judgment on all claims). ISE has not submitted any witness or exhibits lists. And, compounding ISE's complete disregard for the Orders in this Arbitration, ISE has decided to ignore the direct messages of the Arbitrator, despite repeated warnings on ISE's bad faith tactics, and despite the fact ISE has selectively messaged the AAA—for e.g., to revoke its consent to Direct Exchange communication, and convey its refusal to pay required AAA fees. As a final point

RegenX Science Exhibit 1071
Page 225

on ISE's complete disregard in this Arbitration, ISE never requested any extension or offered any explanation for its total disregard of the mandatory deadlines and Orders. ISE has offered **no** explanation for its 180 degree shift in this litigation—from effectively driving this dispute and contentiously papering the record, to complete disengagement overnight.

That said, ISE's strategy is now clear: avoid disclosure of the decellularization process at all costs, even if this means intentionally breaching the License Agreement (including by interfering with Synogen's patent prosecution efforts), and refusing to participate, or comply with Orders, in this Arbitration. It is deeply concerning and disappointing that ISE and its former counsel chose to engage in bad faith litigation tactics to achieve ISE's goal.

In support of this strategy, on September 18, 2019, ISE's counsel—Erika Birg and Lindsay Builder at Nelson Mullins Riley & Scarborough LLP ("Nelson Mullins")—abruptly withdrew from this Arbitration, with a simple form withdrawal. No reason was provided. DLA Piper did not receive a call or note to explain the circumstances. And, for some reason, Ms. Birg, in emailing the notice of withdrawal, did not include the Arbitrator on the message. Notably, after the withdrawal, Ms. Birg and Nelson Mullins continued to represent ISE in settlement discussions relating to this very matter, and still continues to represent the closely-related company Seed Biotech, Inc. ("Seed") in parallel arbitration. ISE's counsel's withdrawal was clearly tactical.

To cap all of this off, on October 4, 2019, Ryanne Early—principal and President at ISE—threatened to take actions against (i.e., undermine, abandon or invalidate) the patents at issue in this Arbitration, if Claimants continued to participate in this proceeding before the Arbitrator. As a result, Claimants were forced to move for temporary and immediate injunctive relief. In issuing the injunction, the Arbitrator found Claimants have sufficiently shown:

(i) a substantial likelihood of success on the merits on their breach of contract claims;

(ii) irreparable harm if this temporary injunction is not granted; and

(iii) that the balance of harms among the parties, and the public interest, weighs in favor of granting the preliminary injunctive relief.

See Order No. 11 (Ex. 49), ¶ 12. Notwithstanding the Arbitrator's injunction, ISE continues to refuse to cooperate in Synogen's patent efforts, and continues to make threats against the patents. On October 15, 2019, Claimants were forced to move before a Florida Circuit Court for emergency confirmation of the Arbitrator's preliminary injunction. This action is still pending. No hearing has yet been scheduled. ISE's bad faith conduct has risen to incredible heights.

As a result of ISE's misconduct, Claimants have suffered, and continue to suffer, significant and irreparable harm. In reliance on ISE's promises under the License Agreement, Synogen and Nextgen carried **all** costs associated with the development and commercialization of the patent technology—more than $7.5 million.[1] More recently, Claimants spent in excess of $650,000 on efforts to recreate the promised, but not delivered, decellularization process. And, in this Arbitration, Claimants have incurred costs and fees resulting from ISE's continued breaches, threats and general bad faith tactics.[2]

Against this backdrop, and for the reasons outlined below, Claimants respectfully request the Arbitrator enter an award in favor of Claimants and against Respondent on all claims, and award Claimants the relief outlined in Section IV.F of this brief.

[1] Notably, upwards of $1.7 million of these costs were paid to Seed—a company closely related to ISE at which Ryanne Early, the principal and President of ISE, is a principal and the CEO. Ms. Early uses these companies interchangeably, and the companies appear to be alter egos of Ms. Early.

[2] Notably, these are only examples of some of the harms suffered by Claimants. The full and significant harms inflicted on Claimants by ISE's breaches is detailed throughout this brief, and in the Witness Statements of Jamie Grooms, Chairman at Synogen, and Jonelle Toothman, CEO at Nextgen.

RegenX Science Exhibit 1071
Page 227

II. STATEMENT OF UNCONTESTED FACTS

A. The Parties

Synogen is a Florida corporation, with a focus in the tech, med-tech and biotech industries. Grooms Stmnt, ¶ 4. Relevant to this action, Synogen determined to develop a novel bio-regenerative growth technology for broad application in human healthcare. *Id*. at ¶ 5.

ISE is a Florida corporation controlled by its principal and President, Ryanne Early. ISE holds a number of patent applications relating to bio-regenerative growth technology, specific to non-mammalian tissue.

Nextgen is a Delaware corporation, with principal place of business in Florida. Nextgen was organized for a singular purpose: to hold the rights to ISE's bio-regenerative growth technologies, and develop and bring to market derivative products for human healthcare applications. Toothman Stmnt, ¶¶ 4-5.

B. The Synogen-ISE License Agreement

Synogen and ISE are parties to a License Agreement, executed October 16, 2014 and made effective September 23, 2014 ("License Agreement"). *See generally* License Agrmt. (Ex. 1). Under the agreement, Synogen contracted for:

(i) an exclusive license to certain patent rights (i.e., Licensed Patents); and

(ii) a non-exclusive license to a trade secret process technology or decellularization process (i.e., Licensed Know-How).

Id. at §§ 1.7, 2.1; Order No. 11 (Ex. 49), ¶ 1. In exchange for these rights, Synogen agreed to: (i) cover "past, present, and future costs, fees, and expenses . . . related to the preparation, filing, prosecution, issuance and maintenance of" the licensed technology; and (ii) pay to ISE fifty percent (50%) "of all consideration received for [any] Sublicense of the Licensed Patents." *Id.* at §§ 4.1, 4.2. These are the material terms of the Synogen-ISE License Agreement.

RegenX Science Exhibit 1071
Page 228

As stated, Synogen entered the License Agreement for the specific purpose of developing a bio-regenerative growth technology for application in human patients in the healthcare industry. Grooms Stmnt, at ¶ 5. To this end, Synogen acquired both the Licensed Patents and Licensed Know-How. Importantly, Synogen requires **both** the patent technology and Know-How (i.e., decellularization process) to develop and bring to market the intended product (now NeoMatriX®). *Id.* at ¶¶ 13-14. Without ISE's process to decellularize tissue, Synogen cannot take its developed product from paper to real world application. Grooms Stmnt, at ¶¶ 13-14. Meaning, without the decellularization process, Claimants cannot manufacture NeoMatriX. *See* Order No. 11 (Ex. 49), ¶ 3.

1. The Synogen-Nextgen Sublicense Agreement

The Synogen-ISE License Agreement specifically contemplates that Synogen will sublicense the rights under the prime license agreement. *See, e.g.*, License Agrmt. (Ex. 1), §§ 1.12 (defining Sublicense); § 2.2 (directing "[Synogen] may grant, in its sole discretion, written Sublicenses to third parties which are not Excluded Sublicensees"); § 2.2.1 (giving Sublicensees the right, "at the Sublicensee's option," to survive termination of the prime Synogen-ISE licenses in the event of a dispute between Synogen and ISE); § 3.1 (stating "[Synogen] agrees and warrants to use commercially reasonable efforts to pursue the development of the technology . . . principally through sublicensing the Licensed Patents"); §§ 5.2.1, 5.2.2 (contemplating that the Licensed Know-How will be shared with Synogen's Sublicensees). And, notably, the License Agreement specifically contemplates that this principal Sublicensee will be Nextgen. *Id*. at Appendix A (the License Agreement directs Synogen to "form[] Sublicensee . . . NextGen" and "enter into a sublicense with NextGen."). In accordance with the License Agreement, Synogen entered the Sublicense Agreement with Nextgen, executed January 26, 2015 and made effective October 14,

RegenX Science Exhibit 1071
Page 229

2014. *See* the Synogen-Nextgen Sublicense Agreement as **Exhibit 2**.

The terms of the License and Sublicense Agreements highlight the fact that Nextgen is a primary beneficiary of the License Agreement. First, under the License Agreement, Sublicensees are provided a right to survive termination of the prime license between Synogen and ISE, "at the Sublicensee's option." License Agrmt. (Ex. 1), § 2.2.1. Meaning, that even if the Synogen-ISE License Agreement is terminated as to the primary licensee (i.e. Synogen), Nextgen's rights under the licenses "remain valid." *See* Geof Vicker's August 14, 2014 Email as **Exhibit 3**. Second, under the agreements, Nextgen retains 97 to 98.5 percent of Net Sales obtained from any product developed from the Licensed Patents. *See* Sublicense Agrmt. (Ex.2), § 4.4. Stated differently, under the agreements, Synogen and ISE each receive only 0.75 to 1.5 percent of Net Sales related to the commercialization of the licensed technologies. *Id*.; *see also* License Agrmt. (Ex. 1), § 4.2. And, third, as outlined directly above, Synogen and ISE, in drafting and executing the prime License Agreement, clearly intended the sublicensee—identified as Nextgen—to act as the primary point in development and commercialization efforts on any product. Grooms Stmnt, at ¶ 22. Synogen and ISE contemplated that Nextgen would be built around the patent technology, with the singular purpose of developing and advancing the bio-regenerative growth technology, and related products. Grooms Stmnt, at ¶ 23. And, this design was executed in the formation and development of Nextgen. Grooms Stmnt, at ¶¶ 18-24; Toothman Stmnt., ¶¶ 12-16.

C. Synogen and Nextgen's Efforts to Commercialize the Technology

Following execution of the License and Sublicense Agreements, Synogen, with Nextgen, developed a bio-regenerative growth product (NeoMatriX), and moved the product towards market. Synogen and Nextgen carried **all** costs associated with the development and commercialization of the product, more than $7.5 million. Grooms Stmnt, at ¶ 26; Toothman

RegenX Science Exhibit 1071
Page 230

Stmnt, at ¶ 17; Order No. 11 (Ex. 49), ¶ 5. More than $1.7 million of those costs were paid to Seed—a company closely related to ISE at which Ryanne Early, the principal and President at ISE, is a principal and the CEO. *See* Nextgen Product Development Costs, Seed Biotech, Inc. as **Exhibit 31**; *see also* Toothman Stmnt, at ¶ 18; Order No. 11 (Ex. 49), ¶ 5.

Synogen and Nextgen had tremendous success developing NeoMatriX. In October 2018, NeoMatriX received 510(k) clearance from the U.S. Food and Drug Administration ("FDA")—a certification required to take a medical device to market. *See* Nextgen's Notice of FDA 510(k) Clearance as **Exhibit 4**. And, in January 2019, Synogen received notice from the United States Patent and Trademark Office ("USPTO") of impending issuance of U.S. patent rights. *See* the January 10, 2019 Patent Office Action as **Exhibit 5**. In other words, Synogen and Nextgen's efforts and significant expenditures paid off. Towards the close of 2018, Synogen and Nextgen were primed to take NeoMatriX to market, and begin receiving revenues.

All that was left for Synogen and Nextgen to take NeoMatriX to market—and realize their goal of a commercialized, novel bio-regenerative growth product—was transfer of the decellularization process to Synogen to permit the manufacture of product. Grooms Stmnt, ¶ 33; Toothman Stmnt, ¶ 22.

D. ISE's Refusal to Transfer the Manufacturing Process

As Synogen and Nextgen expended tremendous resources and progressed with the development of NeoMatriX, Synogen requested that ISE transfer the Licensed Know-How. Grooms Stmnt, ¶ 34. For example, on November 5, 2017, Jamie Grooms, Chairman at Synogen, sent an email to ISE's counsel, Geof Vickers. There, Mr. Grooms explained that he "would like to turn [the parties'] attention to escrowing the process"—i.e., Licensed Know-How. *See* the November 5, 2017 email from J. Grooms to G. Vickers as **Exhibit 6**. Mr. Vickers, on behalf of

ISE, responded that Mr. Grooms, Ms. Early, and he would "need to have a call to discuss the process issue." *Id*. Mr. Vickers did not assert that Synogen was in breach of the License Agreement, or that Synogen was not owed the Licensed Know-How. He simply noted a discussion needed to occur to effect the transfer. *Id*. Despite efforts by Mr. Grooms to schedule this call to discuss the transfer of the Licensed Know-How, the call never occurred. Grooms Stmnt, ¶ 38; *see, e.g*., December 4, 2017 text message from J. Grooms to R. Early as **Exhibit 7** ("Can we set up a call about documenting the process here soon?"). Instead, ISE and its counsel began engaging in the bad faith tactics and misconduct that continues in this Arbitration.

On October 22, 2018, Mr. Grooms again communicated with ISE—this time with its President, Ryanne Early—to relay that the "manufacturing black box," also known as the decellularization process or Licensed Know-How, had yet to be produced:

> I decided to send this note to keep us on track. **As mutually agreed we have a compliance issue as it relates to the manufacturing black box requirement in our agreement**. We have agreed to sit down to discuss a solution to this issue. My goal is to use our timeline within the agreement (45 days) to resolve so we have an agreement that works for all parties.

See October 22, 2018 email from J. Grooms to R. Early as **Exhibit 8**. Again, ISE refused to meaningfully respond. Grooms Stmnt, ¶ 40.

Instead, on November 7, counsel for ISE sent a letter to Synogen, conveniently suggesting Synogen was in breach of the License Agreement. *See* November 7, 2018 Letter from ISE to Synogen as **Exhibit 9**. The letter pointed to false and manufactured technical breaches of the Agreement—*i.e*., supposed failures to provide proof of adequate insurance, and deficiencies in reporting obligations. *Id*. This is the first instance—four years into the term of the agreement—ISE raised any of these supposed breaches. Grooms Stmnt, ¶ 43. Then, on April 5, 2019, ISE improperly attempted to terminate the License Agreement, citing these false and manufactured

technical breaches. *See* April 5, 2019 Letter from ISE to Synogen as **Exhibit 10**. However, as outlined in Synogen's response dated May 2, 2019, Synogen was not in breach of the License Agreement, and ISE had no right to unilaterally, and without support, terminate the Agreement. *See* May 2, 2019 Letter from Synogen to ISE as **Exhibit 11**.

ISE's actions are transparent. ISE's actions are designed to avoid its clear obligations under the agreement to deliver the decellularization process. At bottom, § 5.2.1 of the License Agreement unambiguously requires ISE to "transfer promptly at the request and expense of [Synogen] the Licensed Know-How." But, for some still unknown reason, ISE has repeatedly refused, and continues to refuse, to provide this information. As a result, NeoMatriX has yet to be taken to market, and the significant effort, time and capital expended to produce an FDA-approved product, is now at risk. Grooms Stmnt, ¶ 49; Toothman Stmnt, ¶ 28.

ISE's breaches have delayed the launch of NeoMatriX by at least fourteen months, causing significant harm to Synogen and Nextgen. Nextgen's economic team forecasts upwards of $1 million in sales of NeoMatriX in 2019. *See* Budgeted Sales for Nextgen in 2019 as **Exhibit 32**; Toothman Stmnt, ¶¶ 28-30. And, as a result of ISE's breaches, Nextgen has been forced to expend considerable funds in an attempt to recreate—or rather reverse engineer—an efficient and commercially viable manufacturing process to replace the one promised by ISE. Toothman Stmnt, ¶ 32. Nextgen has budgeted $1.2 million for these efforts, and to date, spent more than $650,000. Toothman Stmnt, ¶ 33. The efforts have not yet revealed a workable process. Toothman Stmnt, ¶¶ 33-34. And, notably, the recreated decellularization process will need to substantially conform to the process promised by ISE, to comply with the already FDA cleared 510(k). Otherwise, Nextgen will need to amend and resubmit substantial regulatory materials to again gain clearance by the FDA. Nextgen's regulatory team forecasts this will cost $549,000. *See* New 510(k) Testing Plan

RegenX Science Exhibit 1071
Page 233

as **Exhibit 14**; Toothman Stmnt, ¶¶ 33-35. But for ISE's breach, these costs would not be incurred.

E. Nextgen's Survival of the Synogen-ISE License Agreement

Section 2.2.1 of the Synogen-ISE License Agreement accords sublicensees the option to survive the termination of the prime Synogen-ISE license "at the Sublicensee's option." Synogen and ISE expressly and unambiguously intended § 2.2.1 as a protection to sublicensees against disputes under the prime Synogen-ISE license. Grooms Stmnt, ¶¶ 19-20. Geof Vicker's, counsel to ISE, August 14, 2014 email to Edward Gates, counsel to Synogen, makes this clear. In memorializing discussions between Ryanne Early and Jamie Grooms relating to negotiations on the terms of a draft License Agreement, Mr. Vickers wrote:

> If company does a license with a sub license and the primary companies have made a dispute/default, that sub license needs to remain valid. *the contract does not currently reflect that but it needs to in this context "licensor survives any dispute between the two primaries so the sub license survives."

See Ex. 3.

Accordingly, following ISE's attempt to improperly terminate the License Agreement, on June 27, 2019, Nextgen sent ISE written notice advising that if "the License Agreement between Synogen and ISE [is] deemed terminated, now or in the future, Nextgen intends, and reserves its right, to exercise its option under Section 2.2.1 of the License Agreement and survive such termination." *See* June 27, 2019 Letter from Nextgen to ISE as **Exhibit 12**. ISE responded, ignoring Section 2.2.1 of the License Agreement—a provision it explicitly requested—and refused to acknowledge Nextgen's right to survival, without citing any reasonable explanation. *See* July 16, 2019 Letter from ISE to Nextgen as **Exhibit 13**.

RegenX Science Exhibit 1071
Page 234

III. PROCEDURAL HISTORY

A. ISE's Bad Faith Litigation Tactics

The same bad faith tactics which forced claimants to bring this action, are now playing out in the Arbitration. ISE's strategy is now clear: avoid disclosure of the decellularization process at all costs, even if this means intentionally breaching the License Agreement, engaging in bad faith litigation tactics, and intentionally refusing to comply with Orders in this Arbitration. And, unfortunately, there is no reason to expect this will change.

1. Mediation: ISE's Erratic Practices & Intentional Misstatements

On September 6, 2019, ISE triggered the compulsory mediation provision under the License Agreement. The parties scheduled mediation for September 24 in Tampa, Florida, before the Honorable Melvia B. Green. *See* documents on scheduling mediation as **Exhibit 15**.

On September 23—the day prior to the scheduled mediation, at 7:47 AM ET—counsel for ISE notified Claimants and Judge Green, "[m]y client [i.e., Ryanne Early] is too ill to travel for mediation. *See* September 23, 2019 emails on cancelling mediation as **Exhibit 16**.[3] Accordingly, Judge Green cancelled the mediation. *Id*.

Just two minutes after Judge Green's cancellation email, Ms. Birg, removed counsel for Claimants (John Huh and Scott Vernick) from the email traffic, and falsely stated to the AAA and mediator, "[t]he clients reached a settlement agreement this morning by phone, so all is good!" *Id*. at 2. No such settlement had occurred. *Id.* at 1. Ms. Birg's statement to Judge Green and the AAA was knowingly false. The only reason Claimants' counsel received this message, and were able to correct the record, is that the AAA copied Claimants' counsel back into the email traffic in a

[3] Notably, shortly after Ms. Birg's initial email cancelling mediation, Jamie Grooms received a call from Ryanne Early, stating ISE was ready to settle this matter. Ms. Early did not mention any illness. *Id.* Rather, as the reason for cancelling the in-person mediation, Ms. Early cited the accruing legal fees and that she did not feel travel for mediation was necessary in light of her proposed settlement.

subsequent message. After Claimants' counsel highlighted Ms. Birg's misrepresentation to Judge Green and the AAA, Ms. Birg went radio silent. To date, Ms. Birg has offered no explanation as to why she knowingly made misrepresentations to a former judge serving as a mediator.

2. ISE's Disengagement From the Arbitration Proceedings

Since September 23, 2019, ISE has chosen to defy **all** deadlines in this Arbitration. ISE has not produced a **single** document. ISE has not responded to a single meet and confer request. ISE has not attended any telephonic status hearing with the Arbitrator. ISE has not responded to any of Claimants' motions (including motions to compel discovery, and for sanctions and judgment on all claims). ISE has not submitted any witness or exhibits lists. And, compounding ISE's complete disregard for the Orders in this Arbitration, ISE has ignored the direct messages of the Arbitrator, despite repeated warnings on ISE's bad faith tactics, and despite the fact ISE has selectively messaged the AAA—e.g., to revoke its consent to Direct Exchange communications, and to convey its refusal to pay required AAA fees.

As a final point on ISE's complete disregard in this Arbitration, ISE never requested any extension or offered any explanation on the repeated missed deadlines. *See generally* Order No. 11 (Ex. 49), ¶ 4 (noting that dating to September 26, the Arbitrator has received just two communications from Respondent); *id*. ("the AAA has reached out to Ms. Early . . . requesting a response as to Respondent's intent with regard to this Arbitration. Respondent has ignored these requests."); ¶ 5 ("Respondent has ignored deadlines in this matter and refused to engage with Claimants in the exchanges required to make this arbitration process work."); *id*. (outlining Respondent's disregard for the Orders and deadlines in this Arbitration).

a. *The Tactical Withdrawal of Counsel at Nelson Mullins*

ISE's first missed deadline came on September 23, shortly after denial of its baseless and transparently tactical motion to disqualify counsel at DLA Piper. On September 23, ISE failed to

submit replies in support of its Requests for Production, or any response to claimants' Amended Demand. *See* September 24-25, 2019 emails on respondent's missed deadlines as **Exhibit 64**.

As a result, on the morning of September 24, the Arbitrator noted by email she had not received respondent's submissions, and requested clarity on the issue. *Id*. ISE (and ISE's counsel) did not respond to the Arbitrator's email. *Id*. On September 25, the Arbitrator again requested clarity from ISE and its counsel on the missed deadlines:

> Ms. Birg: please advise whether your client did or did not respond to the amended demand as described in Order #2.
>
> Settlement is certainly encouraged. But until it is accomplished we move forward keeping to the deadlines, unless good cause is shown to do otherwise.

Id. And, again, ISE (and ISE's counsel) did not respond to the Arbitrator's email. *Id*. Instead, counsel for ISE—Erika Birg and Lindsay Builder at Nelson Mullins—submitted to the AAA a form withdrawal from the Arbitration, without copying the Arbitrator, and without explanation. *See* September 25, 2019 form attorney-withdrawal as **Exhibit 17**. The form withdrawal directed all future communications to:

> ISE Professional Testing & Consulting Services, Inc.
> Attention: Ryanne Early
> 2785 S. Bay St. G
> Eustis, FL 32726
>
> *REarlyISE@gmail.com*

Id. No reason was provided for counsel's withdrawal. DLA Piper did not receive a call or note to explain the circumstances. And, notably, Ms. Birg and Nelson Mullins continued to represent ISE in settlement discussions relating to this matter, and before the USPTO. And Ms. Birg and Nelson Mullins still continue to represent ISE's closely-related company, Seed, in a separate arbitration. This withdrawal was nothing more than a veiled attempt to avoid this Arbitration and the

Arbitrator's Orders. *See* Arbitration Order No. 10 as **Exhibit 48**, ¶ 6 (noting counsel's withdraw "left the appearance that such withdrawal is tactical in nature, intended to disrupt this proceeding."). Nelson Mullins continued to represent ISE, just not here. Indeed, Ms. Birg emailed DLA Piper on October 3, 2019 on behalf of ISE on proposed settlement to this dispute. *See* October 3, 2019 Email from ISE to Synogen as **Exhibit 44**.[4]

b. *The September 27, 2019 Status Hearing Call*

In accordance with the operative Scheduling Order No. 2, a status hearing was scheduled in this matter for September 27, 2019. *See* Arbitration Order No. 2 as **Exhibit 18**, at Table of Deadlines. Ahead of the status call, the parties were required to meet and confer and submit a proposed agenda for the hearing. *Id*. at ¶ 6. Claimants complied and circulated a proposed agenda for the meeting to Ms. Early on September 25. *See* September 25, 2019 Email from DLA Piper to R. Early as **Exhibit 19**. On theme, Ms. Early did not respond to the meet and confer request. *See* September 25, 2019 email from DLA Piper as **Exhibit 20**.

On September 26, the day prior to the scheduled status hearing, Ms. Early emailed the Arbitrator directly, removing DLA Piper counsel from the email, and noting she was not available for the next day's status hearing. *See* September 26, 2019 emails on the status hearing as **Exhibit 21**, at 2. The Arbitrator promptly responded to ISE's email, explaining the scheduled status hearing under the operative Scheduling Order would need to proceed. *Id.*at 1. Ms. Early ignored this message from the Arbitrator.

The parties' status hearing call went forward on September 27. *See* Arbitration Order No. 8 as **Exhibit 22**. Ms. Early and ISE again defied the Orders in the Arbitration by not participating

[4] It is unclear if ISE is unrepresented in this dispute. For example, Nelson Mullins continues to represent Ms. Early's other company, Seed, in a parellel arbitration before the AAA. Also, Ms. Early's husband is an attorney barred in Texas. *See* Christian Early's State Bar of Texas page as **Exhibit 79**. Notably, Ms. Early's husband is a director or officer of Seed.

in the hearing. *Id*. However, on that call, the AAA notified the Arbitrator and Claimants that ISE had revoked its consent to Direct Exchange communications with the Arbitrator, and was now refusing to continue to make required AAA payments. *Id.* These actions are clearly intended to disrupt and delay the Arbitration proceeding, and prejudice Claimants. There is no other explanation. These actions forced Claimants to pay the required AAA fees owed by ISE.

And, notably, in blatant defiance of the Orders in this Arbitration, ISE has decided not to participate in a single mandatory status hearing in this Arbitration since September 11—the initial hearing with the Arbitrator. *See id*.; Order No. 10 (Ex. 48).

c. *The Parties' Document Productions*

ISE has also failed to make any efforts to meet its discovery obligations in this Arbitration. For example, ISE has refused to produce a **single** document in this Arbitration. In accordance with Order No. 2, the deadline for final production of documents in this Arbitration was September 26, 2019. *See* Order No. 2 (Ex. 18), ¶ 7. Claimants expended significant efforts to produce final documents by that deadline, and in a good-faith response to ISE's requests. Claimants reviewed roughly 25,000 documents, and produced nearly 19,000 pages of responsive, non-privileged materials. On the other hand, ISE has not produced a single document in this Arbitration, despite the passing of not one, but three deadlines set by the Arbitrator—including the deadline set in Order No. 8 compelling ISE's production, and noticing that ISE's continued failure to adhere to deadlines in this matter may lead to sanctions. *See* Order No. 8 (Ex. 22), ¶¶ 6-7; Order No. 2 (Ex. 18), ¶ 7; Arbitration Order No. 9 as **Exhibit 25**. Incredibly, despite these warnings on the seriousness of its continued dilatory conduct and failures to comply with Orders in this Arbitration, ISE still has not made **any** efforts to comply with deadlines.[5]

[5] The time constraints imposed on this production, and the expedited hearing date of October 23, 2019, was, in large part, at the insistence of ISE. *See* Order No. 8 (Ex. 22). And, the Arbitrator has made clear that extensions to

RegenX Science Exhibit 1071
Page 239

Based on ISE's continued bad faith conduct, Claimants have placed ISE on notice, at least three times, that they intend to seek sanctions. *See, e.g.*, September 27, 2019 email from DLA Piper as **Exhibit 23**; September 30, 2019 Motion to Bar Respondents Counterclaims and Proceed with Direct Communications, and for Sanctions as **Exhibit 24**; Opposition to ISE's Motion for Disqualification as **Exhibit 35**. In addition, the Arbitrator has similarly placed ISE on notice that its continued bad faith and dilatory conduct may result in sanctions. *See, e.g.*, Order No. 8 (Ex. 22), at ¶ 7; Order No. 10 (Ex. 48), ¶ ("Respondent's conduct at this point appears to be willful non-compliance with the spirit and letter of this proceeding in violation of Respondent's obligations. I reserve the right to impose sanctions based on this conduct."). Incredibly, ISE continues to violate the Arbitrator's Orders and disregard all mandatory deadlines in this Arbitration.

On September 30, Claimants submitted a motion requesting the Arbitrator issue third party subpoenas to Ryanne Early, personally, and Seed, the closely-related company to ISE. *See* September 30, 2019 Claimants' motion on third party discovery as **Exhibit 26**. The subpoenas are needed only as a result of ISE's refusals to produce documents. The subpoenas request the identical materials that were requested from ISE, or a subset of those materials.[6] *See id*. The Arbitrator issued the subpoenas on October 3, *see* Arbitration Order No. 12 as **Exhibit 50**, and Claimants immediately made efforts to serve the subpoenas, including at Ms. Early's home address in Tennessee and Seed's registered address in Texas. *See* Claimants' request for substitute service as

this expedited timeline would be rare, following only a showing of good cause. *See* Order No. 2 (Ex. 18). In hindsight, it is clear that the time constraints were part of ISE's larger strategy of bad faith gamesmanship in this Arbitration and to prejudice Claimants. Indeed, despite several Orders and multiple warnings by the Arbitrator and Claimants, ISE has failed to produce a single document in this Arbitration.

[6] The corporate formalities one would expect from both ISE and Seed appear to be seriously lacking. For example, Ms. Early conducts ISE business from a Seed ("@seedbiotech.com") account, and her signature block for her personal email account—from which she regularly conducts business for ISE and Seed—refers to her positions at both entities. *See* email compilation from R. Early Accounts as **Exhibit 41**. Further, Ms. Early has made payments for ISE and Seed from her personal bank account, and directed payments owed to ISE under the License Agreement be instead made to Seed. *See* proofs of bank account transactions as **Exhibit 42**.

RegenX Science Exhibit 1071
Page 240

Exhibit 72. It quickly became apparent that Ms. Early was actively avoiding service, and seemingly went as far as to abandon her home. *Id*. The measures taken by Ms. Early and ISE to avoid producing any documents in this Arbitration are incredible. On October 10, the Arbitrator granted Claimants request for substitute service. *See* Ex. 50. Claimants executed substitute service the same day, however, with just thirteen days to the Arbitration, there is not meaningful time to compel and collect documents, let alone conduct a meaningful review.

Accordingly, ISE and its principal's actions have severely prejudiced Claimants' positions in this litigation, and ability to present complete evidentiary proofs.

3. ISE's Threats Against the Patents and the Preliminary Injunction

To cap all of this off, on Friday, October 4, 2019, Ryanne Early threatened to take actions against (i.e., undermine, abandon or invalidate) the patents at issue in this Arbitration, if Claimants continue to litigate this matter before this Arbitrator and do not disengage. *See* Claimants' Motion for Preliminary Injunctive Relief submitted October 7, 2019 as **Exhibit 55**. Consistent with Ms. Early's threat, DLA Piper received notice from the USPTO that ISE revoked DLA Piper's power of attorney, and instead shifted power of attorney at the USPTO to Ms. Birg's firm, Nelson Mullins. *See* Order No. 11 (Ex. 49), at 8-9. As a result, Claimants were forced to move for temporary and immediate injunctive relief in this Arbitration the next Monday, October 7. *See* Ex. 55.

In issuing the injunction, the Arbitrator found Claimants have sufficiently shown:

(i) a substantial likelihood of success on the merits on their breach of contract claims;

(ii) irreparable harm if this temporary injunction is not granted; and

(iii) that the balance of harms among the parties, and the public interest, weighs in favor of granting the preliminary injunctive relief.

See Order No. 11 (Ex. 49), ¶ 12. Notwithstanding the Arbitrator's injunction, ISE continues to

RegenX Science Exhibit 1071
Page 241

refuse to cooperate in Synogen's patent efforts, and continues to make threats against the patents. On October 11, Synogen requested ISE cooperate in amending the power of attorney at the USPTO back to Synogen's chosen counsel, DLA Piper. *See* October 11, 2019 email from DLA Piper to R. Early as **Exhibit 80**. ISE did not respond to this message. Accordingly, on October 15, 2019, Claimants were forced to move before a Florida Circuit Court for emergency confirmation of the Arbitrator's preliminary injunction. This action is still pending, and no hearing has yet been scheduled.

IV. ARGUMENT

Based on the undisputed facts in this Arbitration, Synogen and Nextgen are owed an award in their favor and against ISE. Simply, there is no dispute: ISE contracted, but refused, to provide Synogen with the Licensed Know-How. Accordingly, ISE is in breach of the License Agreement. Claimants are entitled to continue to practice the Licensed Patents, and, respectfully, must be provided the Licensed Know-How. In addition, Claimants are entitled to compensatory relief, and attorneys' fees and costs.

And, in this litigation, apparently as a tactic to exert pressure on Claimants, ISE has refused to cooperate in, and now has even impeded and levied threats against, Synogen's patent prosecution efforts. As a result, the Arbitrator was forced to issue a preliminary injunction against ISE. *See* Order No. 11 (Ex. 49). From these breaches, Claimants are entitled to compensatory and injunctive relief, including a permanent injunction against ISE, and attorneys' fees and costs.

As a final point, Claimants are also alternatively entitled to attorneys' fees and costs as a result of ISE's incredible bad faith actions in this Arbitration.

A. Breach of Contract (Synogen Against ISE)

In order to establish a breach of contract, a party must establish three elements: "(1) a valid

RegenX Science Exhibit 1071
Page 242

contract, (2) a material breach, and (3) damages." *Havens v. Coast Florida, P.A.*, 117 So.3d 1179, 1181 (Fla. Dist. Ct. App. 2013). Here, as discussed below and above, the undisputed facts clearly establish all three elements. The undisputed facts of record clearly establish ISE materially breached the License Agreement, a valid contract, and as a result Claimants suffered significant harm and are owed the relief requested.

1. A valid contract governs the Synogen-ISE relationship

First, the uncontested facts compel the conclusion that a valid, enforceable contract exists and controls the Synogen-ISE relationship. This is clear. ISE cannot reasonably argue the contrary.

On October 16, 2014, Synogen and ISE—sophisticated parties represented by outside counsel—entered into the License Agreement, made effective September 23, 2014. *See generally* License Agrmt., (Ex. 1). Under the agreement, ISE unambiguously and expressly contracted to provide Synogen: (i) an exclusive license to the Licensed Patents; and (ii) a non-exclusive license to the Licensed Know-How. *Id.* at §§ 1.7, 1.9, 2.1. In exchange, Synogen agreed to: (i) cover "any and all past, present, and future costs, fees, and expenses . . . related to the preparation, filing, prosecution, issuance and maintenance of" the licensed technology; and (2) pay to ISE 50 percent "of all consideration received for [any] Sublicense of the Licensed Patents." *Id.* at §§ 4.1, 4.2.

Synogen has performed all obligations under the License Agreement. *See* Ex. 11; Grooms Stmnt, ¶ 29. Claimants have covered all "costs, fees, and expenses . . . related to the preparation, filing, prosecution, issuance and maintenance of" the licensed technology, and Synogen has paid ISE 50% percent "of all consideration received" from Sublicensees. License Agrmt. (Ex. 1), §§ 4.1, 4.2; Grooms Stmnt, ¶ 29. Stated differently, Synogen has performed, and continues to perform, in good faith the material terms of the License Agreement. Thus, the undisputed facts support a finding that a valid, enforceable contract exists and governs the Synogen-ISE relationship.

RegenX Science Exhibit 1071
Page 243

2. ISE materially breached the terms of the License Agreement

Second, the undisputed facts establish ISE's failures to perform resulted in at least two material breaches of the License Agreement.

a. *Failure to Transfer the Licensed Know-How*

Under the License Agreement, "ISE provided Synogen . . . (ii) a non-exclusive license to trade secret process technology or the decellularization process defined as Licensed Know-How." Order No. 11 (Ex. 49), ¶ 1 (internal quotations omitted). This is a finding of fact in this Arbitration. And, it is a clear term of the agreement, and cannot be disputed. *See* License Agrmt. (Ex. 1), §§ 5.2.1 ("[ISE] will transfer promptly at the request and expense of [Synogen] the Licensed Know-How."); § 2.1 ("[ISE] hereby grants to [Synogen] a non-exclusive license . . . to the Licensed Know-How . . . in the making, development, use . . . and sale of [the product]."); § 5.2.2 (requiring ISE, with Synogen, to "promptly establish a commercially viable manufacturing procedure which utilizes the Licensed Know-How for making decellularized [product]). The License Agreement defines Licensed Know-How as the "trade secret process technology, know how, and related proprietary information [] used for decellularization of urodele derived tissue"—i.e., the product. *Id.* at § 1.7. These provisions, read separately and/or together, specifically and unambiguously require ISE to produce the trade secret process needed to manufacture NeoMatriX, at Synogen's request.

Synogen, through Jamie Grooms, repeatedly requested ISE provide the decellularization process. Grooms Stmnt, ¶¶ 34-40; *see e.g.*, Ex. 6 (on November 5, 2017, Mr. Grooms requested ISE's counsel, Geof Vickers, "turn [the parties] attention to escrowing the process," or Licensed Know-How); Ex. 7 (on December 4, 2017, Mr. Grooms asked Ms. Early, "Can we set up a call about documenting the process here soon?"). More formally, in Mr. Grooms' October 2018

RegenX Science Exhibit 1071
Page 244

communication to Ms. Early, he made clear that ISE was in breach of its obligation under the License Agreement to provide the "manufacturing back box"—i.e., decellularization process or Licensed Know-How. *See* Ex. 8. Mr. Grooms, acknowledging that without the process Synogen and Nextgen would be forced to delay production of NeoMatriX, wrote:

> I decided to send this note to keep us on track. As mutually agreed **we have a compliance issue as it relates to the manufacturing black box requirement in our agreement.** We have agreed to sit down to discuss a solution to this issue. My goal is to use our timeline within the agreement (45 days) to resolve so we have an agreement that works for all parties.

See id. (emphasis added). Yet, even after being placed on notice of this breach, ISE refused to transfer the decellularization process to Synogen. Grooms Stmnt, ¶ 41. It has now become clear, through this Arbitration, ISE has no intention of disclosing the decellularization process. In fact, it is now clear ISE is willing to violate Orders in this Arbitration to avoid its contractual obligations. And, unfortunately, there is no reason to expect this will change.

ISE's failure to provide the Licensed Know-How to Synogen constitutes a material breach of the License Agreement for, at least, two reasons. First, ISE's failure to perform in accordance with the License Agreement corrupted the "essence of the contract." To constitute a vital or material breach of contract under Florida law, a party's nonperformance must "go to the essence of the contract." *MDS (Canada) Inc. v. Rad Source Techs., Inc.,* 720 F.3d 833, 849 (11th Cir. 2013). Stated differently, a "failure to perform some minor part of [a] contractual duty cannot be classified as a material or vital breach." *See Beefy Trail, Inc. v. Beefy King Int'l, Inc.*, 267 So. 2d 853, 857 (Fla. 4th DCA 1972). The breach at issue here, however, is material, not minor.

Synogen entered the License Agreement and incurred obligations to pay ISE significant remuneration in exchange for (i) the Licensed Patents, and (ii) Licensed Know-How. Synogen did so because it knew that without both the Licensed Patents **and** Know-How, the product it intended

RegenX Science Exhibit 1071
Page 245

to develop would remain theoretical—i.e., the product could not be efficiently manufactured or scaled to meet market demands. Grooms Stmnt, ¶¶ 13-14. Meaning, without ISE's decellularization process, Claimants cannot commercialize NeoMatriX. This needed, and promised, decellularization process is contained in the Licensed Know-How. License Agrmt. (Ex. 1), at §§ 1.7, 5.2.1, 5.2.2. Therefore, it is beyond doubt that the provision of the Licensed Know-How—i.e., the decellularization process—is at the very core of the License Agreement, as without it Synogen cannot bring NeoMatriX to market. Meaning, the specific purpose at center of the contract is frustrated.

Additionally, a court may find that a material breach has occurred when "an injured party has sustained a substantial injury due to [that] breach." *Faro Techs., Inc. v. Brainlab, U.S.A, Inc.*, 12-177, 2013 WL 12361030, at *2 (M.D. Fla. Jan. 16, 2013) (quotation omitted). Of course, as discussed in more detail below, Synogen has suffered such substantial damage as a result of ISE's failure to transfer the decellularization process. *See infra* Section III(A)(3). Based on its expectation that the Licensed Know-How would be "transferred promptly" on request, Claimants incurred tremendous expense—exceeding $7.5 million—developing NeoMatriX. Grooms Stmnt, ¶ 26. ISE failed to deliver on its obligation under the agreement. Accordingly, Synogen has incurred financial harm sufficient to document the material nature of ISE's breach of §§ 2.1, 5.2.1, and 5.2.2 of the License Agreement, among others.

b. *Refusal to Cooperate in the Preparation and Prosecution of the Licensed Patents*

Under the License Agreement, ISE is required to "cooperate in all respects with [Synogen]'s efforts in preparing and prosecuting the Licensed Patents, and . . . [must] have its employees appear before patent offices and submit declarations when requested." License Agrmt. (Ex. 1), § 9.3. ISE is in breach this obligation.

RegenX Science Exhibit 1071
Page 246

In May 2019, Synogen retained counsel at DLA Piper to assist in the prosecution of the Licensed Patents as required by § 9.1 of the License Agreement. Grooms Stmnt, ¶ 56. To support its efforts to prosecute the Licensed Patents, DLA Piper, on Synogen's behalf, requested a limited power of attorney ("LPA") from ISE—the named applicant on the patent prosecutions—to conduct a brief interview with the examiner at the USPTO. *See* June 6, 2019 email from DLA Piper requesting LPA as **Exhibit 37**. The LPA was executed on June 11. *See* June 11, 2019 executed LPA as **Exhibit 38**. However, in a brazen effort to manufacture yet another false breach in this action, ISE revoked the LPA on July 10, 2019, *see* July 10, 2019 email from Ms. Birg to Synogen as **Exhibit 39**, and then incredibly instructed, "under no circumstances is Synogen allowed to file anything with the USPTO . . . ." *See* July 16, 2019 Letter from Erika Birg as **Exhibit 40**, at 1. Then, again, on October 3, 2019, ISE alleged "Synogen has no authority to proceed in any respect on that patent." *See* Ex. 44. In other words, ISE admitted, through counsel, that it would no longer be cooperating with Synogen's efforts in preparing or prosecuting the Licensed Patents. Thus, ISE has breached the License Agreement.

Then, on October 4, 2019, ISE took its breaches of its patent obligations to an incredible level. On a call with Jamie Grooms, Ryanne Early **threatened** to take actions against (i.e., undermine, abandon or invalidate) the patents at issue in this Arbitration, if Claimants continue to litigate this matter and do not disengage. *See* Ex. 55; Grooms Stmnt, ¶ 58. And, consistent with Ms. Early's threat, DLA Piper received notice from the USPTO that ISE revoked DLA Piper's power of attorney, and instead shifted power of attorney at the USPTO to Nelson Mullins. *See* Order No. 11 (Ex. 49), at 8-9. As a result, Claimants were forced to move for temporary and immediate injunctive relief in this Arbitration on October 7. *See* Ex. 55.

In issuing the injunction, the Arbitrator found Claimants have sufficiently shown:

RegenX Science Exhibit 1071
Page 247

(i) a substantial likelihood of success on the merits on their breach of contract claims;

(ii) irreparable harm if this temporary injunction is not granted; and

(iii) that the balance of harms among the parties, and the public interest, weighs in favor of granting the preliminary injunctive relief.

See Order No. 11 (Ex. 49), ¶ 12. Notwithstanding the Arbitrator's injunction, ISE continues to refuse to cooperate in Synogen's patent efforts, and continues to make threats against the patents.

This breach is material. The provision and prosecution of the Licensed Patents cut to the very essence of the contract: the protections offered by the exclusive right to practice the Licensed Patents. *Rad Source Techs., Inc.,* 720 F.3d at 849. Without intervention by the Arbitrator, the Licensed Patents will be left unprotected, rendering the technologies non-exclusive to Synogen.[7] Stated differently, ISE's bad faith gamesmanship has already seeped into the USPTO. Synogen's ability to prosecute the Licensed Patents is at risk. This bad faith conduct could take the form of invalidation or abandonment of the Licensed Patents, such that any third-party could begin developing products to compete with NeoMatriX, the exact outcome exclusivity of the Licensed Patents was intended to prevent. Clearly, such misconduct would irreparably harm Claimants.

For these reasons, the undisputed facts establish that ISE's failure to provide the Licensed Know-How and cooperate in the prosecution of the Licensed Patents constitute material breaches of the License Agreement.

3. ISE's material breaches have and will continue to cause harm

Finally, the undisputed facts illuminate the grave and irreparable damage Synogen has and will continue to suffer as a result of ISE's breaches of the License Agreement, including its failure to provide the promised decellularization process and its interference with the patent prosecution.

[7] Notably, Synogen continues to pursue patent rights in the following jurisdictions necessary to protect the Licensed Patents: the United States; Canada; China; Europe; Hong Kong; Israel; Japan; and Korea.

RegenX Science Exhibit 1071
Page 248

a. *Failure to Transfer the Licensed Know-How*

As summarized above, ISE's material breach has caused, and will continue to cause, substantial and irreparable injury to Synogen. As an initial consideration, Claimants invested significant time, money, and resources to develop and commercialize NeoMatriX, and take the product to market. Grooms Stmnt, ¶ 26. As stated, in reliance on the prime Synogen-ISE licenses, Claimants have spent in excess of $7.5 million in these efforts. *Id.* As a result of ISE's breaches of its contractual obligations, Synogen's investment is at risk of being lost, and Synogen may be liable for part, or the entirety of the $7.5 million investment. As a further result of ISE's breaches, and ISE's refusal to deliver the decellularization process to date, Synogen is required to forfeit 7.9 percent of its shares in Nextgen, valued at $3.1 million. Grooms Stmnt, ¶ 52.

In addition, Synogen is harmed by the significant delays ISE's breaches have caused in launching of the product NeoMatriX, now in excess of 14 months. *Id*. at 48. At this point, Synogen expected NeoMatriX to be generating significant revenues, and that Synogen would be receiving related profits. *Id*. at 31. Unfortunately, as a result of ISE's breaches, Synogen and Nextgen are still months, at least, from taking NeoMatriX to market, and realizing revenues. *Id*. at 48. Accordingly, Synogen has suffered, and will continue to suffer, significant financial harm in the form of lost investment and lost profits, and the final element of a breach of contract claim has been established.

b. *Refusal to Cooperate in the Preparation and Prosecution of the Licensed Patents*

The damage caused by ISE's refusal to comply with § 9.3 of the License Agreement is more than sufficient to establish a breach of contract—it is irreparable such as to support the grant of injunctive relief under AAA Commercial Rules R-37(a) and 47(a). Of course, ISE's failure to cooperate in the prosecution of the patent since July 2019 has delayed the issuance of an

RegenX Science Exhibit 1071
Page 249

enforceable patent, which has caused associated financial damage to Synogen related to the necessary postponement of NeoMatriX's release. Grooms Stmnt, ¶ 50. But, more importantly, ISE's failure to cooperate has jeopardized Claimants' entire investment in the Licensed Patents, in Nextgen, and threatens Nextgen's very existence.

Absent intervention by the Arbitrator to permanently enjoin ISE from further interfering with Synogen's preparation and prosecution of the Licensed Patents, Synogen will be unable to ensure it receives exclusive use of the technology underlying the Licensed Patents. This is because ISE's interference in the prosecution of the patents could result in the invalidation or abandonment of applications currently pending before the USPTO (and foreign patent offices). And, once these applications are abandoned, whether expressly or by inaction, Synogen will be unable to protect the technology used to develop NeoMatriX. Notably, this means that Synogen and Nextgen will be unable to raise additional funds to support the development and commercialization of NeoMatriX, and Claimants' $7.5 million investment in NeoMatriX will be lost. Grooms Stmnt, ¶ 64. Simply put, allowing ISE to disregard its commitment to cooperate with the prosecution of the Licensed patents will devastate and irreparably harm both Synogen and Nextgen.

In sum, the undisputed facts establish that ISE breached the License Agreement under Florida law, and Synogen is owed an award in its favor to include monetary damages and injunctive relief.

B. Breach of Contract (Nextgen Against ISE)

Nextgen is a third party beneficiary to the License Agreement. Accordingly, Nextgen is entitled to recover for ISE's material breaches of the agreement. Florida law makes this clear. "[T]o establish an action for breach of a third party beneficiary contract, [a party] must allege and prove the following four elements (1) existence of a contract; (2) the clear or manifest intent of the

RegenX Science Exhibit 1071
Page 250

contracting parties that the contract primarily and directly benefit the third party; (3) breach of the contract by a contracting party; and (4) damages to the third party resulting from the breach." *Foundation Health v. Westside EKG Assoc.*, 944 So.2d 188, 194-95 (Fla. 2006) (internal quotation marks omitted). "A party is an intended beneficiary only if the parties to the contract clearly express, or the contract itself expresses, an intent to primarily and directly benefit the third party or a class of persons to which that party claims to belong." *Dingle v. Dellinger*, 134 So. 3d 484, 488 (Fla. Dist. Ct. App. 2014). As addressed above, the License Agreement constitutes a valid contract, which ISE has and continues to materially breach. Thus, Nextgen must only demonstrate that it is a third-party beneficiary of the License Agreement, and sustained damage. It can establish both.

1. Nextgen is a Third-Party Beneficiary of the License Agreement

Again, to establish that Nextgen is a third-party beneficiary to the License Agreement, it must establish that the "parties expressed an intent for the contract to benefit [it] or [it] must plead the specific contractual provisions that [the parties] intended to benefit [it]." *Heller v. Carnival Corp.*, 191 F. Supp. 3d 1352, 1364 (S.D. Fla. 2016) (citing *Lapidus v. NCL Am. LLC*, No. 12-21183, 2012 WL 2193055, at *6 (S.D. Fla. Jun. 14, 2012); *see also Excess Risk Underwriters, Inc. v. Lafayette Life Ins. Co.*, 328 F. Supp. 2d 1319, 1343-1344 (S.D. Fla. 2004); *Caretta Trucking v. Cheoy Lee Shipyards*, 647 So. 2d 1028, 1031 (Fla. 4th DCA 1994). And for at least two, independently sufficient reasons, the Arbitrator should find that Nextgen is a third party beneficiary to the License Agreement.

First, ISE has conceded that Nextgen is a third-party beneficiary. On September 16, 2019, Synogen submitted its Amended Demand for Arbitration to include Nextgen as a claimant. *See* Am. Demand for Arbitration as **Exhibit 27**. ISE failed to respond to that amendment. And, the Arbitrator confirmed Nextgen's inclusion as a claimant in this Arbitration. *See* Order No. 6 as

RegenX Science Exhibit 1071
Page 251

Exhibit 28. Necessary to the Arbitrator's decision to permit Nextgen to be joined as a claimant was a finding that Nextgen was, in fact, a third party beneficiary to the License Agreement. This is because Florida law is clear: non-parties to a contract cannot compel parties to a contract to arbitrate, *Florida Power & Light Co. v. Road Rock, Inc.*, 920 So. 2d 201, 203 (Fla. 4th DCA 2006), unless it is determined that the party is a third party beneficiary to the contract. *See Smith v. Beverley Hills Club Apts., LLC*, No. 15-23450, 2016 WL 344975, at *6 (S.D. Fla. Jan. 28, 2016) (*Nestler-Poletto Realty, Inc. v. Kassin*, 730 So. 2d 324, 326 (Fla. 4th DCA 1999)). Thus, by failing to object to Nextgen's inclusion in this action, and in turn Nextgen's status as a third party beneficiary to the License Agreement, ISE has waived its ability to now argue the opposite (i.e. that Nextgen is not a third party beneficiary to the License Agreement). Nextgen's third party beneficiary status is now established by the law of the case. *See* Order No. 6 (Ex. 28).

Second, notwithstanding the above dispositive analysis, the terms of the License Agreement also make clear that Nextgen is an intended third party beneficiary. To assess whether a non-signatory is an intended or third party beneficiary of an agreement, courts in "Florida look[] to the 'nature or terms of a contract' to find the parties' clear or manifest intent that it 'be for the benefit of a third party.'" *Jenne v. Church & Tower, Inc.*, 814 So. 2d 522, 524 (Fla. 4th DCA 2002) (quoting *Am. Sur. Co. of N.Y. v. Smith*, 100 Fla. 1012, 130 So. 440, 441 (Fla. 1930)). Here, the express terms of the License Agreement illustrate that the parties intended Nextgen to be a primary and direct beneficiary of the License Agreement. The License Agreement instructs Synogen to sublicense the Licensed Patents and Know-How. *See, e.g.*, License Agrmt. (Ex. 1), §§ 2.2 ("[Synogen] may grant, in its sole discretion, written Sublicenses to third parties which are not Excluded Sublicensees"); § 2.2.1 (gives Sublicensees the right, "at the Sublicensee's option," to survive termination of the prime Synogen-ISE licenses in the event of a dispute between Synogen

RegenX Science Exhibit 1071
Page 252

and ISE); § 5.2.1 (contemplates that the Licensed Know-How will be shared with Synogen's Sublicensees). And, notably, the License Agreement specifically contemplates that **Nextgen** will be that Sublicensee. *See* License Agrmt. (Ex. 1), Appendix A (providing, explicitly, for the formation and licensing of rights of Nextgen).

Further, the agreements of the parties make clear Nextgen retains **97 to 98.5 percent** of Net Sales from any product developed from the Licensed Patents. *See* Sublicense Agrmt. (Ex. 2), ¶ 12. By contrast, under the agreements, Synogen and ISE each receive only 0.75 to 1.5 percent of Net Sales related to the commercialization of the licensed technologies. *See id*.; License Agrmt. (Ex. 1), § 4.2. For ISE to argue that Nextgen, the entity receiving the lion's share of revenue from the technology at issue, is not a direct beneficiary of the License Agreement strains the bounds of credulity. To drive this point home, by design under the License Agreement, Nextgen was formed with the specific purpose of holding the rights under the prime license agreement, and acting as point in development and commercialization of the technologies. Grooms Stmnt, ¶ 8, 23, 65. And, this is in fact reality. Nextgen has taken the lead on **all** efforts (other than patent prosecution, for which Nextgen has covered costs) relating to development and commercialization of the product. Grooms Stmnt, ¶ 25. Clearly, Nextgen is the exemplar of the definition of third party beneficiary.

Moreover, under the License Agreement, Sublicensees are provided an option to survive the termination of the prime license, "at the Sublicensee's option." License Agrmt. (Ex. 1), § 2.2.1. This means that even if the prime License Agreement was terminated as to Synogen, Nextgen's rights effectively "remain valid." *See* Ex. 3. Notably, this provision of the License Agreement was added at the request of ISE, and clearly documents ISE's intent to allow a Sublicensee to benefit from the licensed technologies in the event the prime license with Synogen is terminated. *Id.*; *see also* July 16, 2014 draft License Agreement with Nelson Mullins' Commentary as **Exhibit 33**

RegenX Science Exhibit 1071
Page 253

(commenting on a draft agreement, ISE's counsel noted that permitting it to retain the right to choose when a Sublicense would survive would "create an unworkable obstacle to licensing to a credible partner."). Or, in other words, ISE believed the Sublicensees, not Synogen, were the primary beneficiaries of the License Agreement.

As a final point, ISE was aware that Nextgen would bare significant costs payable to ISE under the License Agreement. Ms. Early has been intimately involved over the course of the last five years in the development and commercialization efforts surrounding NeoMatriX. Toothman Stmnt, ¶¶ 10-17. From that experience, Ms. Early is well aware of Nextgen's central role in the development and commercialization efforts of the technology, and Nextgen's reliance on the Licensed Patents and Know-How. More importantly, Ms. Early and ISE were informed prior to the execution of the License Agreement, in May 2014, that Nextgen, not Synogen, would be responsible for covering "all past debt and all past and future fees that exist in association with preparation of the [Licensed Patents'] applications." *See* May 8, 2014 email from R. Early as **Exhibit 43**. Stated differently, at the time of contracting ISE was aware Nextgen was responsible for much of the consideration owed to ISE under the License Agreement. *See id.*; *see also* License Agrmt. (Ex. 1), § 4.1.

For these reasons, the undisputed facts establish that Nextgen is a third party beneficiary of the License Agreement.

2. Nextgen sustained monetary damages as a result of ISE's material breach of the License Agreement

The undisputed facts also support finding that Nextgen has suffered four concrete, and cognizable harms as a direct result of ISE's material breaches of the License Agreement. First, in an attempt to find a way to salvage NeoMatriX, Nextgen budgeted $1.2 million to identify an alternate process for decellularizing and manufacturing the product. Toothman Stmnt, ¶ 33.

RegenX Science Exhibit 1071
Page 254

Nextgen has already spent more than $650,000 in these efforts. *Id*. Meaning, as a result of ISE's breaches, Nextgen has been forced to expend considerable funds in an attempt to recreate—or rather reverse engineer—an efficient and commercially viable manufacturing process to replace the one promised by ISE. Toothman Stmnt, ¶ 32. The efforts have not yet revealed a workable process. Toothman Stmnt, ¶¶ 32-34. But for ISE's breach, these costs would not have been incurred.

Second, Nextgen spent considerable funds to obtain 510(k) clearance for NeoMatriX from the FDA. *Id*. at ¶ 28. That clearance, however, was predicated on the manufacturing process contained within the Licensed Know-How. *Id*. at ¶ 34. Thus, even if Nextgen is able to reinvent a manufacturing process for NeoMatriX, the FDA would require Nextgen to resubmit for clearance based on the new decellularization process, and, yet again, obtain 510(k) clearance to go to market. *Id*. Nextgen's regulatory team estimates the cost to obtain the revised FDA 510(k) clearance is $549,000, excluding legal and regulatory fees. *See* New 510(k) Testing Plan (Ex. 14). Again, this cost would not have been incurred but for ISE's breach. *Id*. at 35.

Third, Nextgen has hired staff and incurred significant costs related to marketing and selling a product that has yet to be manufactured because of ISE's material breach of the License Agreement. These costs, as of October 2, 2019, exceed $214,000. *See* Consolidated Profit and Loss Statement related to Nextgen Sales Department as **Exhibit 30**. Without the decellularization process, Nextgen's expenses incurred related to these employees have no value, as the employees have no commercialized product to market and sell.

And, fourth, after years of development, Nextgen anticipated manufacturing and selling NeoMatriX by the close of 2018. Toothman Stmnt, ¶ 22. In light of ISE's breach, the manufacture and sale of NeoMatriX has been postponed. *Id*. at ¶ 29. As such, Nextgen has lost revenue—

RegenX Science Exhibit 1071
Page 255

upwards of $1 million—it could have collected from the sale of NeoMatriX but for ISE's refusal to provide Synogen the decellularization process. *Id*. at ¶ 29-30.

As a final point on damages, beyond monetary harm, should ISE's breaches of the License Agreement continue, Nextgen will be irreparably harmed, and likely destroyed. As designed by the License Agreement, Nextgen is a start-up company built around the Licensed Patent technology. Grooms Stmnt, ¶ 23. Based on the patent rights, Nextgen raised significant funds. Nextgen has a single product—NeoMatriX. Nextgen exclusively focused its time, money and resources on the development and commercialization of the patent technology, and the NeoMatriX product, over the past five years. Grooms Stmnt, ¶¶ 26, 64-65. Without the patent rights and ability to manufacture the product, Nextgen will be destroyed. Nextgen will not be able to raise additional funds. The sole purpose for which Nextgen was formed will be frustrated. *Id*.

For each of these reasons, standing alone and certainly in tandem, Nextgen has satisfied the final element to establish a breach of contract claim against ISE. Therefore, the Arbitrator should enter an award in favor of Nextgen and against ISE.

C. The Arbitrator Should Not Give Weight to ISE's Counterclaim that the License Agreement has been Terminated

As a threshold issue, ISE's counterclaims should be barred because ISE refuses to pay its required AAA fees. *See* AAA Commercial Rule R-57(b) (where one party refuses to comply with payment obligations, the Arbitrator has authority to "limit[that] party's ability to assert or pursue their claim[s]."). By letter dated October 8, 2019, the AAA notified ISE its counterclaims will "be returned [and] not presented to the arbitrator" if ISE continues to refuse to pay its fees on its counterclaims by October 15. *See* October 8, 2019 Letter from the AAA as **Exhibit 68**. ISE failed to respond to this notice, and failed to pay the required fees. Accordingly, ISE's counterclaims should be barred from this Arbitration.

RegenX Science Exhibit 1071
Page 256

In addition, ISE's counterclaims should be barred as a result of ISE's bad faith conduct and refusal to comply with **all** discovery orders in this Arbitration. ISE has the burden to prove its counterclaims. As a result of its bad faith conduct and improper disengagement from this Arbitration, ISE has intentionally failed to meet this burden. For example, ISE has not produced a **single** document in support of its claims. Accordingly, ISE's counterclaims should be barred as a sanction for ISE's bad faith conduct, and for failure of record support.

Even if, however, the Arbitrator elects not to bar ISE's counterclaims in response to Claimants' motion, the Arbitrator should still find that the License Agreement remains in full force and effect. First, ISE's attempt to terminate the License Agreement five years into its term—after Synogen and its sublicensees invested upwards of $7.5 million into development of the technology, much of which was paid to ISE's principal, Ryanne Early—and only after taking a position that it will not comply with its clear obligations to share the Licensed Know-How, based on manufactured and false technical breaches, is clear bad faith. This cannot be allowed. It is noteworthy that ISE's November 7, 2018 letter, in response to Synogen's formal request for the decellularization process, is the first instance—four years into the term of the agreement—ISE raised any of these supposed breaches. Grooms Stmnt, ¶ 43.

Second, Synogen has not breached the License Agreement so as to permit ISE's purported termination. Synogen made this clear to ISE in a May 2, 2019 letter. *See* May 2, 2019 Letter to ISE from Synogen (Ex. 11). For example, ISE claims that Synogen breached Section 2.2.3 of the License Agreement because Synogen failed to produce reports documenting payments it had received from its Sublicensees. *See* ISE's Am. Answer and Counterclaims as **Exhibit 29**. But, in making that argument, ISE misstates the License Agreement. The language contained in the cited provision is clear:

RegenX Science Exhibit 1071
Page 257

> [Synogen] . . . agrees to forward to [ISE] annually a copy of all reports **received** by [Synogen] from its Sublicensees pertinent to payments received under said Sublicense.

See License Agrmt. (Ex. 1), § 2.2.3 (emphasis added). Synogen was only required to produce documents to ISE it had received from its sublicensees related to payments it obtained under a sublicense. The fact is, Synogen never received such reports from its Sublicensees, and the License Agreement provides no obligation on Synogen to manufacture, or demand, such reports. Toothman Stmnt, ¶ 41. Accordingly, there was never a breach of Section 2.2.3.

Further, ISE claims that Synogen breached Section 14.2 of the License Agreement. Again, even a cursory review of this provision makes clear that ISE's claim falls flat. Section 14.2 of the License Agreement provides:

> **Prior to the first use of a Product in a human** and thereafter annually between January 1 and January 31 of each year, [Synogen] will present evidence to [ISE] that [insurance] coverage is being maintained with [ISE] listed as an additional insured.

License Agrmt. (Ex. 1), § 14.2(ii) (emphasis added). As the product has not yet been taken to market or applied to human use, no obligation to list ISE as an additional insured or submit proof of insurance has been triggered. Toothman Stmnt, ¶ 42. Accordingly, there was never a breach of Section 14.2. Moreover, even assuming some obligation did exist under § 14.2 and that Synogen remains in default (which it is not), a breach under § 14.2, even when uncured, is not sufficient to trigger the termination provisions of the License Agreement. Under the License Agreement, only uncured delinquencies in **reporting or payment** obligations and **material** breaches are sufficient to trigger termination. *See* License Agrmt. (Ex. 1), § 11. Failure to submit proof of insurance is plainly insufficient.

Finally, ISE claims Synogen breached § 3.2 of the License Agreement. Again, this is false. ISE alleges that Synogen failed to provide Development Reports documenting the efforts taken to

RegenX Science Exhibit 1071
Page 258

develop the Licensed Patents. *See* November 7, 2018 Letter from ISE to Synogen (Ex. 9). However, even if that is true (and it is not), any purported default under Section 3.2 was cured within 45 days, pursuant to § 11, with service of Synogen's December 22, 2018 letter detailing the efforts taken by Synogen's sublicensees to develop the Licensed Patents. *See* May 2, 2019 Letter from Synogen to ISE (Ex. 11); *see* December 22, 2018 Letter from Synogen to ISE as **Exhibit 59**. This alleged breach is yet another smokescreen orchestrated by ISE to avoid its obligations under the License Agreement.

Accordingly, as a threshold issue, ISE's counterclaims should be precluded as ISE refuses to meet its financial obligations relating to this Arbitration. In addition, ISE's counterclaims should be barred as a result of ISE's incredible and repeated bad faith conduct in this Arbitration. And, finally, even if ISE's counterclaims are considered, they still fail because ISE has not, and cannot, identify a single breach sufficient to terminate the License Agreement. ISE's supposed termination is ineffective, and the License Agreement remains in full force and effect.

D. Declaratory Relief: Nextgen's Right of Survival

Nextgen respectfully requests a declaration that it currently possesses, as a Sublicensee of the License Agreement, a right to survive that Agreement's termination. "To be entitled to declaratory relief, a party must show [it] is in doubt as to some right or status and that [it] is entitled to have such doubt removed." *Palumbo v. Moore*, 777 So.2d 1177, 1178 (Fla. Dist. Ct. App. 2001). In order to obtain declaratory relief, a party must show: (i) a *bona fide*, actual, present practical need for the declaration; (ii) that the declaration deals with a present, ascertained, or ascertainable state of facts; (iii) that some right is dependent on fact or law applicable to facts; (iv) that some person have or reasonably may have actual, present, adverse, and antagonistic interest in the subject matter in either fact or law; (v) that the case is before the court by proper process; and (vi)

RegenX Science Exhibit 1071
Page 259

that the relief sought is not merely the giving of legal advice by the court. *Id.*; *Orange Cnty. v. Expedia, Inc.*, 985 So.2d 622, 627 (Fla. Dist. Ct. App. 2008). "Declaratory judgments are not unusual in contract cases." *Palumbo*, 777 So.2d at 1179.

Here, both parties have requested declaratory relief, waiving any objections to such relief. And, the undisputed facts of record support the issuance of the requested declaration. Section 2.2.1 of the License Agreement is unambiguous: Nextgen, as a sublicensee, has the sole and unequivocal right to survive the termination of the prime license, and to enter into a direct license with ISE on substantially the same terms as its Sublicense Agreement with Synogen. *See* License Agrmt. (Ex. 1), § 2.2.1. It is disingenuous for ISE to suggest otherwise. Section 2.2.1 was added to the License Agreement at ISE's Request. *See* G. Vicker's August 14, 2014 email (Ex. 3). In fact, the original version of the License Agreement provided that "[i]n the event of termination . . . any sublicense will, **at the LICENSOR's** [i.e. ISE's] option, survive such termination." *See* July 16, 2014 draft License Agreement with ISE's Commentary (Ex. 33). Only following ISE's comment that permitting ISE to retain the right to choose when a sublicense would survive would "create an unworkable obstacle to licensing to a credible partner," was the provision amended. *Id.* at Comment on § 2.2.3. The amended, final provision instructs: "[A]ny Sublicense shall, **at the Sublicensee's option**, survive such termination." License Agrmt. (Ex. 1), § 2.2.1. This evidences the parties' clear intent to allow a Sublicensee, like Nextgen, to survive the termination of the prime License Agreement.

Nextgen has a reasonable, actual and present belief that ISE will refuse (as has become its practice) to comply with its contractual obligations. Specifically, this belief is founded on ISE's Amended Answer and Counterclaims. There, ISE explicitly requests that the Arbitrator find that "ISE does not need to enter into direct licenses with Synogen's Sublicensees." ISE's Am. Answer

RegenX Science Exhibit 1071
Page 260

and Counterclaims (Ex. 29). Therefore, the Arbitrator should enter a declaration reaffirming what the License Agreement already makes clear: "any Sublicensee shall, at the Sublicensee's option, survive [] termination" of the prime license. *See* License Agrmt. (Ex. 1), § 2.2.1.

E. Claimant's Award of Attorneys' Fees and Costs.

Claimants are entitled to attorneys' fees and costs under AAA Commercial Rules, and as a sanction for ISE's bad faith tactics in this Arbitration.

1. The parties placed attorneys' fees and costs at issue in this Arbitration

As a preliminary matter, ISE waived its right to object to the imposition of attorneys' fees and costs under AAA Commercial Rules. Under AAA Commercial Rule 47(d), "[t]he award of the arbitrator[] may include: . . . (ii) an award of attorneys' fees **if all parties have requested such an award** or it is authorized by law or their arbitration agreement." AAA R-47(d) (emphasis added). Here, it is undisputed that all parties—including ISE through its Amended Answer and Counterclaims—expressly requested attorneys' fees. *See* ISE's Am. Answer and Counterclaims (Ex. 29), at 15. In recognition of this fact, the Arbitrator's Order No. 2 acknowledges that a Final Award "may include an award of attorneys' fees and costs." *See* Order No. 2 (Ex. 18), at ¶ 14. The parties specifically agreed to, and jointly proposed, this provision in Order No. 2. *See* the parties' jointly proposed scheduling order submitted September 10, 2019 as **Exhibit 78**. Accordingly, the Arbitrator is endowed with the authority to enter an award for attorneys' fees in this Arbitration, and ISE has expressly waived any objection to such an award.

2. The Arbitrator may award attorneys' fees and costs as a sanction for ISE's bad faith tactics in this Arbitration

ISE's conduct in this Arbitration is sanctionable. ISE's actions demonstrate a complete lack of respect for this Arbitration process, and the law. This sort of bad faith practice cannot and should not be tolerated.

RegenX Science Exhibit 1071
Page 261

ISE has completely disengaged from this Arbitration. Since September 23, 2019, ISE has disregarded **all** deadlines. ISE and its counsel repeatedly ignored the Arbitrator's Orders and deadlines, and even direct messages from the Arbitrator. *See e.g.*, Order No. 10 (Ex. 48); Exs. 20, 64. And, to date—now just five days ahead of the final hearing—ISE still has not produced a **single** document in this Arbitration, despite the passing of not one, but three deadlines set by the Arbitrator—including the deadline set in Order No. 8 compelling ISE's production, and noticing that ISE's continued failure to adhere to deadlines in this matter may lead to sanctions. *See* Order No. 8 (Ex. 22), ¶¶ 6-7. Incredibly, despite these warnings on the seriousness of its continued dilatory conduct, ISE still has not made **any** efforts to comply with deadlines. *See* Order No. 10 (Ex. 48), ¶ 4 (noting that dating to September 26, the Arbitrator has received just two communications from Respondent); *id*. ("the AAA has reached out to Ms. Early . . . requesting a response as to Respondent's intent with regard to this Arbitration. Respondent has ignored these requests."); ¶ 5 ("Respondent has ignored deadlines in this matter and refused to engage with Claimants in the exchanges required to make this arbitration process work."); *id*. (outlining Respondent's disregard for the Orders and deadlines in this Arbitration); *see generally* September 30, 2019 Motion to Bar Respondents Counterclaims (Ex. 24). And, notably, ISE never requested any extension or offered any explanation on the repeated missed deadlines, or for ISE's 180 degree shift in this litigation—from effectively driving this dispute and contentiously papering the record, to complete disengagement overnight.

To cap all of this off, as detailed above, on October 4, 2019, ISE's principal Ryanne Early threatened to take actions against (i.e., undermine, abandon or invalidate) the patents at issue in this Arbitration, if Claimants continue to litigate this matter and do not disengage. *See* Order No. 11 (Ex. 49), ¶ 9. As a result, the Arbitrator was forced to issue a preliminary injunctive award

RegenX Science Exhibit 1071
Page 262

against ISE. *See* Order No. 11 (Ex. 49). Notwithstanding the Arbitrator's injunction, ISE continues to refuse to cooperate in Synogen's patent efforts, and continues to make threats against the patents. ISE's conduct, of which this Section can only briefly cover, has reached a level well beyond bad faith.

ISE's continued misconduct is precisely the type of bad faith tactics that run contrary to the purposes of arbitration and warrant the award of attorneys' fees and costs. The Arbitrator has, and, respectfully, should exercise, the inherent power to award the requested relief. *See Marshall & Co. v. Duke*, 114 F.3d 188, 190 (11th Cir. 1997) ("[A]rbitrators have the power to award attorney's fees pursuant to the "bad faith" exception to the American Rule."); *id* ("[E]very judicial and quasi-judicial body has the right to award attorneys' fees under the common law bad faith exception to the American Rule."); *see also First Auto. Serv. Corp. v. First Colonial Ins. Co*., No. 07-682, 2010 WL 2431889, at *5 (M.D. Fla. Jul. 16, 2010) (applying *Marshall* to an arbitration governed by the Federal Arbitration Act); R-23 ("[I]n the case of willful non-compliance with any order issued by the arbitrator, [the arbitrator has authority to] draw[] adverse inferences, exclud[e] evidence and other submissions," among other sanctions.). To hold otherwise would condone the unabashed disrespect for this process, and the rule of law.

Accordingly, Claimants respectfully request the Arbitrator enter an award in favor of Claimants to include reasonable attorneys' fees and costs incurred in this Arbitration.

F. Request for Relief

Claimants Synogen Management Group, Inc. and NeXtGen Biologics, Inc. respectfully request the Arbitrator issue an award in their favor and against ISE, as follows:

1. Declaratory relief, in the form of:
    i. The Synogen-ISE License Agreement remains in full force and effect. Accordingly, Claimants hold the exclusive license to the Licensed Patents, and are permitted to practice the Licensed Patents;

RegenX Science Exhibit 1071
Page 263

ii. In accordance with § 5.2.1 of the License Agreement, ISE shall transfer promptly to Synogen, and not later than 3 business days from the entry of this Final Award, the Licensed Know-How, trade secret process technology and/or decellularization process, and all information required to properly effectuate the transfer and use of the process;

2. Compensatory relief of:
   a. $3.1 million to Synogen for the value of its forfeited shares;

   b. $867,683.95 to Nextgen
      i. $653,683.95 for the amount equal to Claimants' costs in the attempts to recreate the promised, but undelivered, decellularization process; and

      ii. $214,000 for the amount equal to Claimants' costs relating to marketing and sales efforts in anticipation of the product's launch;

3. Reasonable attorneys' fees and costs relating to this Arbitration;[8] and

4. Injunctive relief, in the form of an injunction ENJOINING ISE, and any of its attorneys, representatives or agents, from, directly or indirectly, interfering with or impeding Synogen's prosecution and preparation of the Licensed Patents through counsel of Synogen's choice and are directed to cooperate with Synogen and its counsel, including executing any documents deemed necessary by Synogen to enable its continued work on the patent prosecution and preparation.

In the alternative, should the License Agreement between Synogen and ISE be deemed terminated, Nextgen has the right, at its sole option, under § 2.2.1 of the License Agreement to survive the termination of the prime license, and to enter into a direct license with ISE on substantially the same terms as the Synogen-Nextgen Sublicense Agreement.

V. CONCLUSION

For the above stated reasons, Claimants respectfully request the Arbitrator enter an award in favor of Claimants and against Respondent on all claims, and award Claimants the relief outlined in Section IV.F of this brief.

[8] Claimants will submit documentation in support of the reasonable attorneys' fees and costs incurred relating to this Arbitration by October 29, 2019, and likely sooner.

RegenX Science Exhibit 1071
Page 264

Date: October 18, 2019

DLA PIPER LLP (US)

s/ Janelly Crespo
Janelly Crespo

200 South Biscayne Boulevard, Suite 2500
Miami, FL 33131
T: 305.423.8500 / F: 305.437.8131
janelly.crespo@dlapiper.com

John D. Huh (*R 1-3.11 statement submitted*)
Scott M. Vernick (*R 1-3.11 statement submitted*)

One Liberty Place
1650 Market Street, Suite 5000
Philadelphia, PA 19103
T: 215.656.3300 / F: 215.656.3301
john.huh@dlapiper.com
scott.vernick@dlapiper.com

Attorneys for Synogen Management Group, Inc. and NeXtGen Biologics, Inc.

Exhibit M

AMERICAN ARBITRATION ASSOCIATION

SYNOGEN MANAGEMENT GROUP, INC., and NEXTGEN BIOLOGICS, INC., Claimants, v. ISE PROFESSIONAL TESTING & CONSULTING SERVICES, INC., Respondent.	**Case No. 01-19-0002-3786**

POST-HEARING BRIEF OF CLAIMANTS SYNOGEN MANAGEMENT GROUP, INC. & NEXTGEN BIOLOGICS, INC.

Date: November 4, 2019

DLA PIPER LLP (US)

Janelly Crespo (Fla. Bar ID 124073)

200 South Biscayne Boulevard, Suite 2500
Miami, FL 33131
T: 305.423.8500 / F: 305.437.8131
janelly.crespo@dlapiper.com

John D. Huh (*admitted under R 1-3.11*)
Scott M. Vernick (*admitted under R 1-3.11*)

One Liberty Place
1650 Market Street, Suite 4900
Philadelphia, PA 19103
T: 215.656.3300 / F: 215.656.3301
John.Huh@dlapiper.com
Scott.Vernick@dlapiper.com

Attorneys for Synogen Management Group, Inc. and NeXtGen Biologics, Inc.

Claimants Synogen Management Group, Inc. ("Synogen") and NeXtGen Biologics, Inc. ("Nextgen") respectfully submit this Post-Hearing Brief, which supplements Claimants' Pre-Hearing Brief, in this Arbitration against Respondent ISE Professional Testing & Consulting Services, Inc. ("ISE").

I. INTRODUCTION

As Claimants have repeatedly explained: this is not a complex case, it is a straightforward breach of contract action. This case is about ISE's attempt to escape its unambiguous obligations under an indisputably valid agreement at all costs, including by intentionally disregarding this Arbitration, and engaging in bad faith tactics to avoid and undermine the authority of the Arbitrator. Claimants submit this Post-Hearing Brief not to repeat undisputed facts and legal argument presented in previous filings and at the Final Hearing, but to detail ISE's continued bad faith conduct. Unsurprisingly, since the filing of Claimants' Pre-Hearing Brief, ISE's bad faith arbitration tactics have not abated. ISE continues to intentionally disregard this Arbitration, and its contractual obligations, by willfully defying orders and an interim award entered by the Arbitrator.

Therefore, in light of the undisputed facts and legal argument presented by Claimants in their Pre-Hearing Brief and at the Final Hearing, respectfully, the Arbitrator should enter an award in Claimants' favor on all claims as outlined in Claimants' proposed Final Award.

II. FACTUAL & PROCEDURAL UPDATE SINCE THE SUBMISSION OF CLAIMANTS PRE-HEARING BRIEF

A. ISE Continues to Intentionally Defy All Orders in this Arbitration

Claimants have made every effort to conduct this Arbitration in good faith. To that end, Claimants have met every deadline and complied with all Orders in this Arbitration. With the filing of this brief and accompanying proposed Final Award, Claimants have met each of its obligations

RegenX Science Exhibit 1071
Page 268

under the operative Scheduling Order. Claimants took serious their obligations in this Arbitration because the outcome is critical to their rights and business interests. Without the relief requested herein, additional substantial and irreparable harm will follow.

Unfortunately, the same cannot be said for ISE. ISE has taken every opportunity to subvert and undermine this Arbitration. It has refused to produce documents required to defend or litigate the claims and counterclaims, expended significant effort to avoid disclosure of the trade secret process (the same process promised under the License Agreement), and willfully violated numerous Orders entered by the Arbitrator in an attempt to avoid litigating this matter on the merits, all of which has severely prejudiced Claimants.

Claimants' Pre-Hearing Brief outlines ISE's bad faith conduct through October 18, 2019. Since the filing of that submission, ISE has not changed course. ISE did not file a pre-hearing brief. Nor did ISE provide witness statements or exhibits to either Claimants or the Arbitrator. ISE also failed to participate in a pre-scheduled meet and confer with Claimants and a pre-scheduled status conference with the Arbitrator. Incredibly, ISE has not satisfied a single deadline contained in the operative Scheduling Order since September 18, 2019. Perhaps most egregious is ISE's intentional decision to not appear at the Final Hearing (without any explanation). Put simply, ISE has continued to blatantly disregard and defy all mandatory deadlines and Orders in this Arbitration, despite adequate notice of its obligations.

B. ISE's Disregard of the Injunctive Relief Granted by the Arbitrator

Due to ISE's continued bad faith conduct—specifically ISE's threat to undermine, abandon, or invalidate the Licensed Patents at the core of this Arbitration—Claimants filed a Motion for Preliminary Injunctive Relief on October 7, 2019. *See* Hr'g Ex. 55. The Arbitrator issued an interim award enjoining ISE from interfering with the prosecution of the Licensed

RegenX Science Exhibit 1071
Page 269

Patents after concluding that Claimants had sufficiently documented (1) a substantial likelihood of success on the merits on their breach of contract claims; (2) irreparable harm if the temporary injunction was not granted; and (3) that the balance of harms among the parties, and the public interest weighed in favor of preliminary injunctive relief. *See* Order No. 11 (Hr'g Ex. 49), ¶ 12. Of course, on theme, ISE ignored this Interim Award and has continued to interfere with the prosecution of the Licensed Patents.

Due to ISE's refusal to comply with the Interim Award, Claimants were forced to move before a Florida Circuit Court for emergency confirmation of the Arbitrator's preliminary injunction. That action, however, has yet to meaningfully progress because ISE and its principal Ryanne Early have taken great pains to evade service of summons. As of October 30, Claimants have attempted to serve Michael A. Croak, ISE's registered agent and Ms. Early's father, on at least four separate occasions to no avail. Despite the fact that Florida law requires a registered agent be open and able to accept service between 10:00 am and 12:00 pm, Mr. Croak's office has been closed during each service attempt made during that time. Service has also been attempted numerous times on Ryanne Early as President of ISE. Those attempts have been futile as well. In fact, during one of those attempts, the police were contacted to remove the process server from Ms. Early's neighborhood.

C. The Hearing

The Final Hearing took place on October 23, 2019 in Orlando, Florida. The time and location of this hearing were determined by agreement of the parties, and reflected in the operative Scheduling Order. *See* Hr'g Trans., Ex. 1, at 3:20-24; *see also* Order No. 2, Hr'g Ex. 18.[1]

[1] The original location for the Arbitration, set by the License Agreement was Gainesville, Florida. *See* License Agmt. (Hr'g Ex. 1), § 13.5. The parties and counsel, however, agreed to other locations for convenience. *See* Hr'g Trans., at 3:20-24. Nelson Mullins Riley & Scarborough, on behalf of Respondent, proposed to host the Final Hearing at Veritext's office in Orlando. *See* Decl. of Michael Lodato (Hr'g Ex.

RegenX Science Exhibit 1071
Page 270

The Arbitrator, Claimants and Claimants' counsel traveled to Orlando for the hearing. Claimants timely appeared on October 23 prepared to present evidence, examine witnesses, and establish that ISE was in breach of the License Agreement. *See* Hr'g Trans., at 4:7-17. ISE was not similarly prepared. ISE did not even attend the Final Hearing, and did not provide any notice or explanation to the Arbitrator or Claimants.[2] Rather, ISE remained willfully mute, which required Claimants, Claimants' counsel, and the Arbitrator to make costly arrangements (*i.e.*, airfare and hotels) and postpone other commitments to get to Orlando for the in-person Final Hearing. Stated differently, ISE did not even extend the common courtesy of notifying the AAA, the Arbitrator, or Claimants' counsel that it would not be attending the Final Hearing. This is unacceptable and disrespectful to the Arbitrator and Claimants.

Despite ISE's attempt to obstruct this Arbitration, the Final Hearing proceeded on October 23. At the hearing, Claimants submitted: (1) the Declaration of Michael Lodato[3]; (2) the

---

A), at ¶ 5. Claimants agreed, and Nelson Mullins contacted Veritext to make the necessary reservations. *See id.* Shortly thereafter, Nelson Mullins abruptly withdrew from this Arbitration, and notified Veritext that it was no longer moving forward with this Arbitration. As a result, the reservation with Veritext was canceled. *See id.* at ¶¶ 6-7. Neither Claimants nor the AAA were notified of this cancellation. *See* Hr'g Trans., at 7:6-21. Fortunately, Claimants, through counsel, contacted Veritext and were able to reserve another Veritext location for the Final Hearing. *See* Hr'g Ex. A, at ¶ 8; *see also* Hr'g Trans., at 7:17-21. Respondent, the AAA and the Arbitrator were informed of the change of location, and Veritext acknowledged that if anyone appeared at the original location, they would be directed to the proper office. *See* Hr'g Trans., at 7:22-25.

[2] *See, e.g.*, *id* at 3:25, 4:1-11 ("I note for the record that we have no representative of the respondent here, wither by way of a party representative or counsel. It is my understanding that counsel for the respondent withdrew a few weeks ago, that no new counsel has been suggested or identified in the interim. We have had communications from Ryanne Early, whom I believe is the CEO of respondent, about a variety of things. But, in general, ISE has not responded to the various deadlines contained in the scheduling order and is not here today."); 9:1-4 ("[R]espondent has had more than sufficient notice of both time and the date and the place of the hearing, and they are not here, which is really unfortunate."); 33:10-16 ("I want to be very clear in the record that they have not shown up. They have not taken this opportunity to present any evidence to me, one way or the other, with regard to wither their defense of the claims that the two claimants have made, or with regard to supporting the counterclaim that they have asserted.").

[3] Decl. of Michael Lodato, Hr'g Ex. A.

Declaration of John Huh[4]; (3) the Witness Statement of Jamie Grooms[5]; (4) the Witness Statement of Jonelle Toothman[6]; and (5) Final Hearing Exhibits 1 through 86[7]. These submissions were made without objection, and accepted into evidence. *See* Hr'g. Trans., at 13:10-17 ("I would like to note for the record that the scheduling order did include a specific period of time for both parties, both sides to lodge objections to the exhibits that were being identified that might be used at the hearing. And I received no objections from the respondent to the claimant's exhibits.").

The Arbitrator also solicited testimony from Claimants' two witnesses: Mr. Grooms and Ms. Toothman. Mr. Grooms testified that despite being obliged by the License Agreement to cooperate with the prosecution of the Licensed Patents, ISE revoked the power of attorney Synogen "desperately" needed to prosecute the contracted-for patents. *See id*. at 20:14-22; 21:1-12. He also testified that Ryanne Early confirmed that ISE possessed, but has refused to disclose, the process defined in the License Agreement as the Licensed Know-How. *See generally*, *id.* at 22-24. Ms. Toothman then articulated that Nextgen was tasked with commercializing the technologies licensed by Synogen from ISE, and explained how Nextgen's commercialization efforts were hampered as a direct result of ISE's refusal to transfer the Licensed Know-How. *See generally, id.* at 25-32. Ms. Toothman further stressed that without the Licensed Know-How, Nextgen would incur great expense as the "FDA [wa]s going to ask [Nextgen] to repeat all of the tests in order to get . . . FDA approval . . . ." *Id.* at 27:11-14. Notably, ISE presented no cross examination of Mr. Grooms or Ms. Toothman. *Id.* at 32:13-15 ("There's obviously no one here for the respondent, to conduct any cross-examination.").

---

4 Decl. of John Huh, Hr'g Ex. D.
5 Stmt. of Jamie Grooms, Hr'g Ex. B.
6 Stmt. of Jonelle Toothman, Hr'g Ex. C.
7 *See* Hr'g, Trans., at 12:5-6; 12:16-22.

RegenX Science Exhibit 1071
Page 272

Following the testimony of Mr. Grooms and Ms. Toothman, the Arbitrator called for ISE to "provide something" for the record. *Id.* at 33:8-9. Of course, ISE was not present and no evidence was offered "with regard to either [its] defense of the claims that the two claimants have made, or with regard to supporting the counterclaim[s] that [it] ha[s] asserted." *See id.* at 33:10-16; *see also id*. at 17:21-23 (making clear that ISE's absence at the hearing confirmed that it had no basis to oppose the exclusion of its counterclaims from the arbitration). So, the Arbitrator adjourned the hearing. *Id.* at 34:21-22.

Notwithstanding ISE's decision to disregard this Arbitration, on October 24, ISE attempted to submit (*ex parte*) never-before-seen evidence to the AAA. *See* October 24, 2019 Email from Ryanne Early to AAA, Ex. 2. Specifically, ISE claimed that this evidence documented that Nextgen performed "2 human clinical studies . . . while not having insurance identifying ISE." *Id*. But the time had long passed for ISE to present evidence that should have been disclosed to Claimants months ago and presented at the Final Hearing. If anything, ISE's attempt reveals that it has willfully defied the Orders in this Arbitration despite having full notice (*i.e.*, ISE is actively using the email address that receives notices from the AAA).

II. ARGUMENT

Based on the undisputed facts before the Arbitrator, there can be no doubt that ISE has materially breached the License Agreement. And, as a result, Claimants are owed the relief requested in their Pre-Hearing brief, and outlined in the proposed Final Award.

A. ISE Breached the License Agreement

On October 16, 2014, Synogen and ISE—sophisticated parties represented by outside counsel—entered into an exclusive license agreement made effective September 23, 2014. *See generally* License Agmt. (Hr'g Ex. 1). Under that Agreement, ISE unambiguously and expressly

RegenX Science Exhibit 1071
Page 273

contracted to provide Synogen: (1) an exclusive license to the Licensed Patents; and (2) a non-exclusive license to the Licensed Know-How. *Id.* at §§ 1.7, 2.1.1, 2.1.2. In exchange, Synogen agreed to pay ISE: (1) "any and all past, present, and future costs, fees, and expenses, . . . related to the preparation, filing, prosecution, issuance and maintenance of" the licensed technology; and (2) 50% "of all consideration received for [any] Sublicense of the Licensed Patents." *Id.* at §§ 4.1-4.2. Synogen has performed all obligations under the License Agreement. *See* May 2, 2019 Letter from Synogen to ISE (Hr'g Ex. 11). But, for reasons unknown, ISE elected to breach this Agreement and has refused to provide Synogen the contracted-for Licensed Know-How.

ISE has not only refused to transfer the Licensed Know-How to Synogen, it has also taken steps to actively undermine Claimants' exclusive use of the Licensed Patents. Under the License Agreement, ISE is required to "cooperate in all respects with [Synogen]'s efforts in preparing and prosecuting the Licensed Patents, and . . . [must] have its employees appear before patent offices and submit declarations when requested." License Agmt. (Hr'g Ex. 1), § 9.3. But ISE has interfered, not cooperated, with Claimants' prosecution of the Licensed Patents. For example, ISE, through Ryanne Early, has refused to provide Claimants with a power of attorney, "desperately" needed by Synogen to prosecute the Licensed Patents, and has repeatedly threatened to take steps to invalidate the Licensed Patents due to Claimants participation in this Arbitration. Hr'g Trans., at 20:20-22; *see also, e.g.*, Hr'g Exs. 49; 56; 70; 80 (illustrating actions taken by ISE to interfere with the Licensed Patents).

ISE's failure to cooperate in the prosecution of the Licensed Patents not only amounts to a material breach of the License Agreement, but illustrates ISE's disdain for this Arbitration. In recognition of the threat posed by ISE's bad faith conduct, the Arbitrator entered an interim award for injunctive relief mandating that ISE desist from its efforts to undermine the Licensed Patents.

RegenX Science Exhibit 1071
Page 274

Specifically, the Arbitrator mandated that ISE "cooperate with Synogen and its counsel, including executing any documents deemed necessary by Synogen to enable its continued work on the patent prosecution and preparation." Hr'g Ex. 49, at 5. Yet ISE's nefarious conduct persists; ISE acknowledged yet continues to disregard a clear award entered by the Arbitrator. *See* Hr'g Exs. 49; 56; 70; 80.

B. ISE's Breaches of the License Agreement and Bad Faith Conduct Continue to Cause Harm to Claimants

As a result of ISE's refusal to honor its contractual commitments and its bad faith conduct during the course of this Arbitration, including its failure to provide the promised Licensed Know-How and its interference with the prosecution of the Licensed Patents, Claimants have and will suffer significant and irreparable harm. This harm was detailed in Claimants' Motion for Summary Judgment[8], Motion for Preliminary Injunctive Relief[9] and Pre-Hearing Brief[10], and exhibits and testimony presented by Claimants at the Final Hearing. Those filings, exhibits, and statements are incorporated herein by reference.

Claimants respectfully request the Arbitrator award the relief outlined in these submissions and exhibits, including post-award, pre-judgment interest at a rate of 6.33 percent per year. *See SunTrust Inv. Servs., Inc. v. Thorlton*, No. 617CV182ORL22GJK, 2017 WL 11025662, at *3 (M.D. Fla. May 17, 2017) ("In Florida, interest from the date of the arbitral award is required where the award liquidated the amount owed.") (Internal quotations omitted); Fla. Stat. Ann. § 55.03 (West). The requested relief is detailed in Claimants' Pre-Hearing Brief and proposed Final Award.

---

8 *See* Hr'g Ex. 54.
9 *See* Hr'g Ex. 55.
10 *See* Pre-Hearing Brief, Ex. 3.

RegenX Science Exhibit 1071
Page 275

C. ISE's Counterclaims Against Claimants Should be Dismissed

Each of ISE's ten misguided counterclaims against Claimants should be dismissed. ISE has failed to present any competent evidence or legal argument to support its contrived counterclaims, thus woefully failing to meet its burden of proof to sustain those claims. And, insofar as ISE argues that it has submitted evidence in support of its counterclaims, such evidence must not be considered by the Arbitrator. Thus, on the merits, ISE's counterclaims fail and an award must be entered in favor of Claimants.

For the first time in this Arbitration, on October 24, ISE improperly attempted to submit documents, *ex parte*, to the AAA. *See* October 24, 2019 Email from Ryanne Early to AAA, Ex. 2. Specifically, ISE claimed that this evidence documented that Nextgen performed "2 human clinical studies . . . while not having insurance identifying ISE." *Id*. These documents, however, must not be considered by the Arbitrator because they were untimely submitted. First, evidence to be used at the Final Hearing was to be produced no later than September 26, 2019. *See* Order No. 2 (Hr'g Ex. 18), at 10. ISE did not produce a single document at that time, or any time prior to the Final Hearing. *See, e.g.*, Order No. 8 (Hr'g Ex. 22). Second, the Arbitrator made clear at the Final Hearing that the hearing record remained open ***only*** for the submission of proposed awards and supplemental petitions for fees and costs, not for the submission of never-before-produced "evidence" in support of a counterclaim.[11] For those reasons, and those outlined in Mr. Huh's email dated October 24, ISE's newly submitted "evidence" cannot be considered in this Arbitration. *See* October 24, 2019 Email from John Huh to AAA, Ex. 4. However, even if ISE's

[11] *See* Hr'g. Trans., at 34:1-3 ("I do intend to keep the record open until November 15th, for the submission of proposed awards."); 34:11-15 ([I]f there is any petition for -- additional petition for fees and costs, the record will remain open until then. Both parties are certainly free to submit their proposed awards and fee updates earlier, should they choose to do so . . . ."); 34:22-23 ("[W]e will simply end the hearing today, and it -- the record, however, will remain open, ***as stated***." (emphasis added)).

RegenX Science Exhibit 1071
Page 276

improper submission of documents is considered, even a cursory review of those documents establishes that they fall woefully short of supporting any of ISE's counterclaims.

Alternatively, ISE's counterclaims should either be dismissed as a sanction for its bad faith arbitration conduct, or administratively barred due to ISE's failure to pay the AAA dues required to raise a counterclaim. *See* Claimants Motion to Bar Respondent's Counterclaims (Hr'g Ex. 24); October 8, 2019 Letter from AAA to ISE concerning fees due on Counterclaims (Hr'g Ex. 68).

III. CONCLUSION

For these reasons, in addition to those set forth in Claimants' October 18, 2019 Pre-Hearing Brief, and the arguments and evidence presented at the Final Hearing on October 23, 2019, Claimants respectfully request the Arbitrator enter an award in their favor on all claims presented in the Amended Arbitration Demand. A proposed award, detailing the relief requested and now owed, will be filed.

RegenX Science Exhibit 1071
Page 277

Date: November 4, 2019

DLA PIPER LLP (US)

s/ Janelly Crespo
Janelly Crespo

200 South Biscayne Boulevard, Suite 2500
Miami, FL 33131
T: 305.423.8500 / F: 305.437.8131
janelly.crespo@dlapiper.com

John D. Huh (*admitted under R 1-3.11*)
Scott M. Vernick (*admitted under R 1-3.11*)

One Liberty Place
1650 Market Street, Suite 5000
Philadelphia, PA 19103
T: 215.656.3300 / F: 215.656.3301
john.huh@dlapiper.com
scott.vernick@dlapiper.com

Attorneys for Synogen Management Group, Inc. and NeXtGen Biologics, Inc.

Exhibit N

AMERICAN ARBITRATION ASSOCIATION

SYNOGEN MANAGEMENT GROUP, INC., and NEXTGEN BIOLOGICS, INC., Claimants, v. ISE PROFESSIONAL TESTING & CONSULTING SERVICES, INC., Respondent.	**Case No. 01-19-0002-3786**

CLAIMANTS' MOTION TO BAR RESPONDENT'S COUNTERCLAIMS AND PROCEED WITH DIRECT COMMUNICATION, AND FOR SANCTIONS

Date: September 30, 2019

DLA PIPER LLP (US)

Janelly Crespo (Fla. Bar ID 124073)

200 South Biscayne Boulevard, Suite 2500
Miami, FL 33131
T: 305.423.8500 / F: 305.437.8131
janelly.crespo@dlapiper.com

John D. Huh (*R 1-3.11 statement pending*)
Scott M. Vernick (*R 1-3.11 statement pending*)

One Liberty Place
1650 Market Street, Suite 4900
Philadelphia, PA 19103
T: 215.656.3300 / F: 215.656.3301
John.Huh@dlapiper.com
Scott.Vernick@dlapiper.com

Attorneys for Synogen Management Group, Inc. and NeXtGen Biologics, Inc.

TABLE OF CONTENTS

I. INTRODUCTION 1

II. OPERATIVE FACTS 4

A. The Dispute 4

1. ISE's Breach: Refusal to Transfer the Decellularization Process 5

B. The Arbitration: ISE's Continued Bad Faith 7

1. Mediation: ISE's Erratic Practices & Intentional Misstatements 7

2. ISE's Disengagement From the Arbitration Proceedings 8

a. The September 27, 2019 Status Hearing Call 10

b. The Parties' Document Productions 11

III. ARGUMENT 12

A. Respondent Must be Barred From Pursuing Its Counterclaims 12

1. ISE's Continued Bad Faith Conduct Dictates in Favor of Barring Its Claims 13

B. This Arbitration Should Continue to Proceed Under Direct Exchange Communication Procedures 15

C. Claimants Should Be Awarded Attorneys' Fees and Costs, and Evidentiary Inferences in Their Favor 16

IV. CONCLUSION 18

RegenX Science Exhibit 1071
Page 281

TABLE OF AUTHORITIES

Page(s)

Cases

First Auto. Serv. Corp. v. First Colonial Ins. Co.,
No. 07-682, 2010 WL 2431889 (M.D. Fla. Jul. 16, 2010) 17

Marshall & Co. v. Duke,
114 F.3d 188 (11th Cir. 1997) 17

Meyrowitz v. Brendel,
No. 16-81793-CIV, 2018 WL 6308709 (S.D. Fla. Aug. 28, 2018) 13

Sanderson Farms, Inc. v. Gatlin,
848 So. 2d 828 (Miss. 2003) 13

TIC Park Ctr., 9 LLC v. Cabot,
No. 16-CIV-24569, 2018 WL 3744394 (S.D. Fla. June 7, 2018) 13

Other Authorities

Mitchell L. Marinello & Alison T. Schwartz, *What to Do When a Party Refuses to Pay its Share of Arbitration Costs* 13

AAA Commercial Rule L-3(a) 16

AAA Commercial Rule R-57 ..... 3, 12, 13

AAA Commercial Rule R-58 15

RegenX Science Exhibit 1071
Page 282

Claimants Synogen Management Group, Inc. ("Synogen") and NeXtGen Biologics, Inc. ("Nextgen") respectfully submit this motion to address respondent ISE Professional Testing & Consulting Services, Inc.'s ("ISE") continued bad faith litigation tactics. As a result of respondent's refusal to participate in this action, claimants are now forced to move:

(i) to bar respondent's counterclaims;

(ii) to proceed with direct communication in this Arbitration; and

(iii) for sanctions in the form of fees, costs and evidentiary inferences.

I. INTRODUCTION

The same bad faith tactics which forced claimants to bring this action, are now playing out in the Arbitration. ISE is determined not to produce the decellularization process (the same process Synogen is clearly entitled to under the Synogen-ISE License Agreement), and determined to avoid litigating this matter on the merits. To accomplish this, ISE is willing to disregard Arbitration deadlines, and direct messages and Orders from the Arbitrator. Simply, ISE's actions demonstrate a complete lack of respect for this Arbitration process, and law. At this point, ISE's misconduct has materially prejudiced and irreparably harmed claimants, particularly as the hearing is nearly three weeks away.

Synogen's contract right to the Licensed Know-How (i.e., decellularization process) could not be more clear.[1] And ISE knows this—which is precisely why ISE's strategy, since losing on its baseless and transparently tactical motion to disqualify counsel, has become to disengage from

[1] *See* License Agrmnt. (Ex. 1), § 2.1 ("[ISE] hereby grants to [Synogen] a non-exclusive license . . . to the Licensed Know-How . . . in the making, development, use . . . and sale of [the product]."); § 5.2.1 (requiring ISE to "transfer promptly at the request and expense of Synogen the Licensed Know-How."); § 5.2.2 (requiring ISE, with Synogen, to "promptly establish a commercially viable manufacturing procedure which utilizes the Licensed Know-How for making decellularized [product], which manufacturing procedure will include a black box aspect.").

RegenX Science Exhibit 1071
Page 283

the Arbitration. Over the past week, ISE missed **all** deadlines under operative Scheduling Order No. 2.

DATE	EVENT/DEADLINE	NOTES
9.23	PARTIES SUBMIT REPLIES TO RESPONSES & OBJECTIONS TO RFPS	
	PARTIES SUBMIT RESPONSES TO AMENDED PLEADINGS	
9.25	PARTIES SUBMIT PROPOSED AGENDA FOR HEARING CALL	Parties must first meet and confer
9.26	PARTIES EXCHANGE FINAL DOCUMENTS, AND NOTE BUCKETS OF PRIVILEGED DOCUMENTS DISCLOSED TO THIRD PARTIES (NO. OF DOCUMENTS AND PERSONS)	
9.27	HEARING CALL @ 11 AM	
9.30	ISE'S PRODUCTION OF FULL & FINAL DOCUMENTS	Per Arbitrator's Order No. 8, compelling ISE's production

Compounding ISE's violation of the Orders in this Arbitration, ISE ignored direct messages from the Arbitrator. ISE failed to attend Friday's (September 27) status hearing, despite multiple reminders and messages from the Arbitrator on the importance of the hearing and need to attend. ISE did not request any extension or relief from the Scheduling Order. ISE simply decided to not comply with deadlines, and not participate in the hearing, without explanation. Contrastingly, claimants have met every single deadline and fully complied with all Orders.

ISE's strategy is now clear: avoid disclosure of the decellularization process at all costs, even if this means refusing to comply with Orders of this Arbitration, and participation in this Arbitration. As such, it seems highly likely ISE will not comply with any Final Award.

In support of this strategy, on September 18, 2019, ISE's counsel—Erika Birg and Lindsay Builder at Nelson Mullins Riley & Scarborough LLP ("Nelson Mullins")—abruptly withdrew from this Arbitration, with a simple form withdrawal. No reason was provided. But, notably, ISE had received a number of adverse rulings in this Arbitration leading up to the withdrawal. DLA Piper did not receive a call or note to explain the circumstances. And, for some reason, Ms. Birg,

RegenX Science Exhibit 1071
Page 284

in emailing the notice of withdrawal, did not include the Arbitrator on the message. Notably, **Ms. Birg continues to represent ISE in settlement discussions relating to this very matter**, and continues to represent the closely-related company Seed Biotech, Inc. ("Seed") in a parallel arbitration.

To cap all of this off, without explanation, ISE has now revoked its consent to the Direct Exchange process for communications with the Arbitrator, and refuses to continue to make required payments to the AAA, despite having asserted ten counterclaims in this Arbitration. ISE's actions are clearly intended to disrupt and delay the proceedings. There is no other explanation. This sort of bad faith practice cannot be permitted. ISE's refusal to participate in good faith in these proceedings now severely prejudices claimants. ISE did not produce a **single** document at the deadline for productions, or at the later deadline imposed by the Arbitrator's Order No. 8 compelling ISE's compliance. And, it must be expected this noncompliance will continue.

In situations such as this, the AAA Commercial Rules allow the Arbitrator to fashion the procedures to minimize the harm to the good faith party. *See e.g.,* AAA Rules R-57(b) (where one party refuses to comply with payment obligations, the Arbitrator has authority to "limit[that] party's ability to assert or pursue their claim[s]"); R-58 ("The arbitrator may, upon a party's request, order appropriate sanctions where a party fails to comply with its obligations under these rules or with an order of the arbitrator"); L-3(a) ("The arbitrator shall take such steps as deemed necessary or desirable to avoid delay and to achieve a fair, speedy and cost-effective resolution of a Large, Complex Commercial Dispute."); R-43 ("The AAA may direct that any oral or written communications that are sent by a party or their representative shall be sent in a particular manner.").

RegenX Science Exhibit 1071
Page 285

Against this backdrop, and for the reasons outlined below, claimants respectfully request the Arbitrator: (i) bar respondent's counterclaims; (ii) Order the Arbitration continue under the Direct Exchange procedure; and (iii) award claimants attorneys' fees and costs, as well as evidentiary inferences in their favor.

II. OPERATIVE FACTS

A. The Dispute

To fully appreciate the bad faith tactics playing out in this Arbitration, it is important to understand the history of the dispute.

At center of this action is the Synogen-ISE License Agreement, made effective September 23, 2014. *See* License Agrmnt. as Exhibit 1. At the most basic level, under the agreement Synogen contracted for:

(i) an exclusive license to certain patent rights; and

(ii) a non-exclusive license to a trade secret process technology—i.e., the decelluarization process or "Licensed Know-How."

See License Agrmt. (Ex. 1) §§ 1.7, 1.9, 2, 5.2.2.

To practice the patent technology, the decellularization process is needed. The contracted-for patent technology is "**decellularized** biomaterial from non-mammalian tissue." *See* U.S. Patent Application, Pub. No. US 2015/0352257 A1 as Exhibit 2 (emphasis added). Without the process to decellularize the tissue, claimants cannot take the intellectual property from paper to real world application. Meaning, without the process, claimants cannot manufacture any product.

RegenX Science Exhibit 1071
Page 286

1. ISE's Breach: Refusal to Transfer the Decellularization Process

Synogen, with sublicensee Nextgen,[2] developed from the licensed technology a human skin graft product (NeoMatriX®), and moved the product towards market. In October 2018, NeoMatriX received 510(k) clearance from the FDA. *See* Nextgen's Notice of FDA 510(k) Clearance as Exhibit 3. And, in January 2019, Synogen received notice from the USPTO of impending issuance of U.S. patent rights. *See* the January 10, 2019 Office Action as Exhibit 4.

Synogen and Nextgen carried **all** costs associated with the development and commercialization of the product—more than $7.5 million. And, upwards of $1.7 million of these costs were paid to Seed Biotech, Inc.—a closely related company to ISE with shared principals (Ryanne Early and her husband).[3] Synogen performed all obligations under the License Agreement. And, Synogen, with Nextgen, expended incredible efforts, time and money over the past five years to develop the licensed technology into the product NeoMatriX, and bring the product towards market.

Towards the close of 2018, Synogen and Nextgen were primed to take the product to market. However, the companies' efforts stalled as a result of ISE's refusal to transfer the

---

[2] Under the Synogen-Nextgen Sublicense Agreement, made effective October 15, 2014, Nextgen has certain rights to the patent technology and Know-How under the prime license. *See* Synogen-Nextgen Sublicense Agreement as Exhibit 2, §§ 1.7, 1.9, 2. Notably, the Synogen-ISE License Agreement specifically contemplates that Synogen will sublicense the rights under the prime agreement *to Nextgen*. *See* License Agrmt. (Ex. 1), Appendix A (the License Agreement directs Synogen to "form[] Sublicensee . . . NextGen" and "enter into a sublicense with NextGen.").

[3] Ryanne Early is a principal and the CEO at Seed, and the principal and President at ISE. On information and belief, Ryanne Early uses each company interchangeably, and personally, and the corporate formalities one would expect from two different companies are severely lacking. For example, Ryanne Early conducts ISE business from a seedbiotech.com email address, and her Gmail address signature refers to positions at both ISE and Seed. *See* Ryanne Early emails as Exhibit 5. The principal place of business, mailing address and registered business address for ISE is the law office of Michael A. Croak—Ryanne Early's father. Based on opposing counsel's representations, ISE is underfunded, and Ryanne Early is the sole owner, president and employee at ISE. And, Ryanne Early moves money among her business and personal bank accounts freely, without regard to corporate formality. *See* proofs of bank account transfers as Exhibit 6.

RegenX Science Exhibit 1071
Page 287

contracted-for[4] decellularization process. Synogen has repeatedly requested transfer of the process, including more formally on October 22, 2018:

> So, I decided to send this note to keep us on track. **As mutually agreed we have a compliance issue as it relates to the manufacturing blackbox requirement in our agreement.** We have agreed to sit down to discuss a solution to this issue.

See the October 22, 2018 email from Jamie Grooms, Chairman at Synogen, to Ryanne Early as Exhibit 7 (emphasis added).

Without explanation, ISE has refused the requests. Instead, on November 7, 2018, ISE sent a letter to Synogen outlining a number of supposed breaches of the License Agreement—i.e., supposed failures to provide proof of adequate insurance, and deficiencies in reporting obligations. *See* ISE's November 7, 2018 letter as Exhibit 8. This is the first instance—four years into the term of the agreement—ISE raised any of these supposed breaches. Then, on April 5, 2019, ISE improperly attempted to terminate the License Agreement, citing these false and manufactured technical breaches. *See* ISE's April 5, 2019 letter as Exhibit 9.

Now, ISE seeks to terminate Synogen's (and by extension, Nextgen's) license to the technology on these bases, to avoid disclosure of its trade secret decellularization process—the same process ISE promised to transfer under the License Agreement. This is clear bad faith, and cannot stand.

---

[4] As stated, Synogen's contract right to the License Know-How (i.e., decellularization process) could not be more clear. *See* License Agrmnt. (Ex. 1), § 2.1 ("[ISE] hereby grants to [Synogen] a non-exclusive license . . . to the Licensed Know-How . . . in the making, development, use . . . and sale of [the product]."); § 5.2.1 (requiring ISE to "transfer promptly at the request and expense of Synogen the Licensed Know-How."); § 5.2.2 (requiring ISE, with Synogen, to "promptly establish a commercially viable manufacturing procedure which utilizes the Licensed Know-How for making decellularized [product], which manufacturing procedure will include a black box aspect.").

RegenX Science Exhibit 1071
Page 288

B. The Arbitration: ISE's Continued Bad Faith

As outlined above, ISE's bad faith tactics continued into this Arbitration. ISE's strategy here is to avoid disclosure of the decellularization process, even if that means refusing to comply with deadlines or the Arbitrator's Orders. It seems highly likely ISE will continue this noncompliant pattern, and fail to comply with even the Final Award in this Arbitration.

1. Mediation: ISE's Erratic Practices & Intentional Misstatements

On September 6, 2019, ISE triggered the compulsory mediation provision under the License Agreement. The parties scheduled mediation for September 24 in Tampa, FL, before the Honorable Melvia B. Green. *See* mediation schedule documents as Exhibit 10.

On September 23, the day prior to the scheduled mediation, at 7:47 AM ET, counsel for ISE notified claimants and Judge Green, "[m]y client [i.e., Ryanne Early] is too ill to travel for mediation.[5] We unfortunately have to cancel." *See* September 23, 2019 emails on cancelling mediation as Exhibit 11. Shortly after this initial email cancelling mediation, at 8:15 AM ET, Ms. Birg informed everyone to "hold for tomorrow," and that she would "be back" with an update. *Id.* No update followed. Accordingly, Judge Green cancelled the mediation at 9:33 AM ET to account for mounting difficulties in participants' travel as a result of the last minute uncertainty. *Id.*

Just two minutes after Judge Green's cancellation email, **Ms. Birg removed counsel at DLA Piper (John Huh and Scott Vernick) from the email traffic**, and falsely stated to the AAA and mediator, "[t]he clients reached a settlement agreement this morning by phone, so all is good!"

---

[5] Notably, shortly after Ms. Birg's initial email cancelling mediation, Jamie Grooms, Chairman at Synogen and Board Member at Nextgen, received a call from Ryanne Early, stating ISE was ready to settle this matter. Ryanne Early did not mention any illness. Instead, as the reason for cancelling the in-person mediation, Ryanne Early cited the fees she already owed Ms. Birg's law firm, and lack of need to travel in light of her decision to offer a settlement proposal.

The parties continue to discuss settlement terms. However, claimants have made clear: "until a settlement is reached, the arbitration should continue to move forward, particularly given that the hearing date is less than a month away." *See* September 24, 2019 email from John Huh as Exhibit 12.

RegenX Science Exhibit 1071
Page 289

Id. The only reason DLA Piper counsel received this message, and were able to correct the record, is that the AAA copied DLA Piper counsel back into the email traffic in a subsequent message. *Id.* Ms. Birg's statement to Judge Green and the AAA was knowingly false. Counsel for DLA Piper corrected the email record. *Id.*

2. ISE's Disengagement From the Arbitration Proceedings

ISE has now completely disengaged from this Arbitration. Since September 23, 2019, ISE has missed **all** deadlines under operative Scheduling Order No. 2, and the deadline imposed by Order No. 8 compelling ISE's late production of documents, despite multiple warnings from claimants and the Arbitrator. ISE knowingly ignored or violated the following deadlines and Orders:

DATE	EVENT/DEADLINE	NOTES
9.23	PARTIES SUBMIT REPLIES TO RESPONSES & OBJECTIONS TO RFPS	
	PARTIES SUBMIT RESPONSES TO AMENDED PLEADINGS	
9.25	PARTIES SUBMIT PROPOSED AGENDA FOR HEARING CALL	Parties must first meet and confer
9.26	PARTIES EXCHANGE FINAL DOCUMENTS, AND NOTE BUCKETS OF PRIVILEGED DOCUMENTS DISCLOSED TO THIRD PARTIES (NO. OF DOCUMENTS AND PERSONS)	
9.27	HEARING CALL @ 11 AM	
9.30	ISE'S PRODUCTION OF FULL & FINAL DOCUMENTS	Per Arbitrator's Order No. 8, compelling ISE's production

See Arbitration Order Nos. 2 and 8 as Exhibits 13 and 14, respectively,

ISE's first missed deadline came on September 23, shortly after denial of its baseless and transparently tactical motion to disqualify counsel at DLA Piper. On September 23, ISE failed to submit replies in support of its Requests for Production, or any response to claimants' Amended Demand. *See* September 24-25, 2019 emails on respondent's missed deadlines as Exhibit 15.

As a result, on the morning of September 24, Arbitrator Arrowood noted by email she had not received respondent's submissions, and requested clarity on the issue. *Id.* ISE (and ISE's counsel) did not respond to Arbitrator Aroowood's email. *Id.* On September 25, Arbitrator Arrowood again requested clarity from ISE and its counsel on the missed deadlines:

> Ms. Birg: please advise whether your client did or did not respond to the amended demand as described in Order #2.
>
> Settlement is certainly encouraged. But until it is accomplished we move forward keeping to the deadlines, unless good cause is shown to do otherwise.

Id. And, again, ISE (and ISE's counsel) did not respond to the Arbitrator's email. *Id.* Instead, counsel for ISE—Erika Birg and Lindsay Builder at Nelson Mullins—submitted to the AAA a form withdrawal from the Arbitration, without copying Arbitrator Arrowood, and without explanation. *See* September 25, 2019 form attorney-withdrawal as Exhibit 16. The form withdrawal directed all future communications to:

> ISE Professional Testing & Consulting Services, Inc.
> Attention: Ryanne Early
> 2785 S. Bay St. G
> Eustis, FL 32726
>
> *REarlyISE@gmail.com*

Id. No reason was provided for counsel's withdrawal. Decl. of S. Vernick, ¶ 7. DLA Piper did not receive a call or note to explain the circumstances. Decl. of S. Vernick, ¶ 8. And, notably, **Ms. Birg and Nelson Mullins continue to represent ISE in settlement discussions relating to this matter**, and continues to represent the closely-related company Seed in a parallel arbitration. Decl. of S. Vernick, ¶ 9. This withdrawal was nothing more than a veiled attempt to avoid this Arbitration and the Arbitrator's Orders. Ms. Birg and Nelson Mullins still represent ISE, just not here. Indeed,

Ms. Birg emailed DLA Piper on Friday, September 27 on behalf of ISE offering a proposed settlement to this dispute. Decl. of S. Vernick, ¶ 10.

a. The September 27, 2019 Status Hearing Call

In accordance with the operative Scheduling Order No. 2, a status hearing call was scheduled in this matter for September 27, 2019. *See* Order No. 2 (Ex. 13), Table of Deadlines. Ahead of the status call, the parties were required to meet and confer and submit a proposed agenda for the hearing. *Id.* at ¶ 6.

Accordingly, after ISE's counsel's abrupt withdrawal, on September 25, counsel for claimants emailed Ryanne Early (at the provided address), outlining the parties' obligations to confer and submit a proposed agenda, attaching Order No. 2, and proposing an agenda:

> It is nice to meet you via email. In accordance with Order No. 2 in the Arbitration (attached), there is a status call this Friday, September 27 at 11 AM. The parties must confer at least two business days prior to the call to submit a proposed agenda. See Order No. 2, ¶ 6. We propose the following agenda:
>
> . . .
>
> Please let us know if you have any comments on these proposed items, and whether you have additional proposed items for the call. We are happy to get on a call if that is easier. We are free from 4-5 PM ET, and can make ourselves available later as well if necessary.

See September 25, 2019 email from John Huh as Exhibit 17. On theme, Ryanne Early did not respond to the meet and confer request. *See* September 25, 2019 email from Scott Vernick as Exhibit 18.

On September 26, the day prior to the scheduled status hearing, Ryanne Early emailed Arbitrator Arrowood directly, removing DLA Piper counsel from the email, and noting she was

RegenX Science Exhibit 1071
Page 292

not available for the next day's status hearing.[6] *See* September 26, 2019 emails on the status hearing as Exhibit 19. Arbitrator Arrowood promptly responded to ISE's email, noting the scheduled status hearing under the operative Scheduling Order No. 2 would need to proceed, and again attaching Order No. 2. *See* Ex. 19. Ryanne Early did not respond to this message from the Arbitrator. Decl. of S. Vernick, ¶ 13.

Accordingly, the parties' scheduled status hearing call went forward on September 27. *See* Order No. 8 (Ex. 14). Ryanne Early and ISE did not participate in the hearing. *Id.* And, notably, on the status call, AAA Case Manager Angela Valedon notified Arbitrator Arrowood and claimants that ISE had revoked its consent to the direct exchange process for communications with the Arbitrator, and was now refusing to continue to make required payments to the AAA. Decl. of S. Vernick, ¶ 14.[7]

b. The Parties' Document Productions

In accordance with Order No. 2, the deadline for final production of documents in this Arbitration was September 26, 2019. *See* Order No. 2 (Ex. 13), ¶ 7. Claimants expended significant efforts in producing final documents by the deadline, and in a good-faith response to ISE's requests. Decl. of S. Vernick, ¶ 17. Claimants reviewed roughly 25,000 documents, and produced nearly 19,000 pages of responsive, non-privileged materials. Decl. of S. Vernick, ¶ 18. ISE now has the benefit of claimants' documents.

On the other hand, ISE has not produced a **single** document in this Arbitration. Decl. of S. Vernick, ¶ 19. And, notably, ISE has not requested any extension, or provided any explanation for

---

[6] Notably, this is the **sole** communication received in this Arbitration from ISE or ISE's counsel from September 23 to date, outside of Erika Birg email enclosing the form withdrawal.

[7] Claimants have agreed to pay respondent's share of the required payments to AAA. Claimants respectfully reserve the right to collect those payments from respondent.

RegenX Science Exhibit 1071
Page 293

the lack of a production. Decl. of S. Vernick, ¶ 20. It seems ISE simply decided not to produce documents, but allowed claimants to move forward with their good-faith production.

On September 27, after the deadline for the productions passed, claimants placed ISE on notice that they would seek to compel ISE's production, and sanctions for ISE's continued bad faith tactics. *See* September 27, 2019 email from John Huh on ISE's deficient production as Exhibit 20. ISE did not respond to claimants' notice. Decl. of S. Vernick, ¶ 20. Accordingly, ahead of the September 27 status hearing, claimants moved to compel ISE's document production, and requested sanctions. *See* September 27, 2019 email from Scott Vernick as Exhibit 21. Still, ISE did not respond. Decl. of S. Vernick, ¶ 20. Order No. 8 was issued in this Arbitration on September 27, granting, among other things, claimants' motion to compel ISE's document production. *See* Order No. 8 (Ex. 14), ¶ 6. In accordance with Order No. 8, ISE's full and final production of documents in response to claimants' requests was due September 30 at 12 PM ET. *See* Order No. 8 (Ex. 14), ¶ 6. ISE failed to produce a single document at this deadline, despite repeated opportunities to make the production. Decl. of S. Vernick, ¶ 19.

III. ARGUMENT

A. Respondent Must be Barred From Pursuing Its Counterclaims

Respondent ISE has completely disengaged from this Arbitration. Beyond its complete disregard for the deadlines in this matter and the Arbitrator's Orders, ISE now also "refuses to meet its financial obligations related to this matter," specifically including AAA required deposits and fees. *See* Order No. 8 (Ex 15), ¶ 4. Accordingly, ISE should be barred from continuing to pursue its affirmative claims—i.e., ISE's ten counterclaims. AAA Commercial Rule R-57 is clear on this point:

> If arbitrator compensation or administrative charges have not been paid in full, the AAA may so inform the parties in order that one of them may advance the required payment.

RegenX Science Exhibit 1071
Page 294

(a) Upon receipt of information from the AAA that payment for administrative charges or deposits for arbitrator compensation have not been paid in full, to the extent the law allows, **a party may request that the arbitrator take specific measures relating to a party's non-payment**.

(b) **Such measures may include, but are not limited to, limiting a party's ability to assert or pursue their claim**. In no event, however, shall a party be precluded from defending a claim or counterclaim.

AAA Commercial Rule R-57 (emphasis added). The relief under Rule R-57 makes sense. Where, as here, a party to an arbitration refuses to pay required AAA fees and deposits, that defaulting party should not be able to benefit from the very administrative services that it refuses to pay, for its own financial gain. For these reasons, ISE's counterclaims should be barred. *See Meyrowitz v. Brendel*, No. 16-81793-CIV, 2018 WL 6308709, at *3 (S.D. Fla. Aug. 28, 2018) (stating a party's intentional failure to pay deposits required by the AAA amounted to waiver of the defaulting party's affirmative claims for relief under AAA Rule 57); *TIC Park Ctr., 9 LLC v. Cabot*, No. 16-CIV-24569, 2018 WL 3744394, at *4 (S.D. Fla. June 7, 2018) ("[p]ayment of fees is a procedural condition precedent that the trial court should not review."); *Sanderson Farms, Inc. v. Gatlin*, 848 So. 2d 828, 838 (Miss. 2003) (finding a party "waived its right to arbitration by refusing to pay its one-half of the costs associated with filing and administrative fees"); see also, Mitchell L. Marinello & Alison T. Schwartz, *What to Do When a Party Refuses to Pay its Share of Arbitration Costs*, 18 DISP. RESOL. MAG. 29, 30 (Winter 2012) (stating that "if the claimant does not pay its share of the expenses, then it is eminently fair . . . to dismiss the claimant's case.").

1. ISE's Continued Bad Faith Conduct Dictates in Favor of Barring Its Claims

Moreover, ISE's continued bad faith conduct, and the severe prejudice claimants suffer as a result, militates in favor of barring ISE's claims. As detailed above, over the past week, ISE

RegenX Science Exhibit 1071
Page 295

missed **all** deadlines under operative Scheduling Order No. 2. ISE has repeatedly ignored messages from claimants, and even direct messages from the Arbitrator. *See e.g.*, Exs. 15, 17-18. ISE failed to attend Friday's (September 27) status hearing, despite multiple reminders and messages from the Arbitrator on the importance of the hearing and need to attend. *See* Ex. 19. And, ISE has made zero efforts to comply with its obligations to produce documents. ISE has not produced a **single** document in this Arbitration, despite the passing of not one, but two deadlines set by the Arbitrator—including the deadline set in Order No. 8 compelling ISE's production, and noticing that ISE's continued failure to adhere to deadlines in this matter may lead to sanctions. *See* Order No. 8 (Ex. 14), ¶¶ 6-7. Incredibly, despite these warnings on the seriousness of its continued dilatory conduct and failures to comply with Orders in this Arbitration, ISE still has not made **any** efforts to comply with deadlines.

This sort of bad faith practice cannot be permitted. ISE's refusal to participate in good faith in these proceedings now severely prejudices claimants. As stated, ISE has not produced a **single** document in this Arbitration.

The final hearing in this Arbitration is just three weeks away. Claimants' business positions—caused by ISE's breach of the License Agreement and refusal to provide the key piece to the manufacturing process—preclude the possibility of a material extension. Claimants need an efficient result in this matter. It goes without saying: time is of the essence. ISE cannot be permitted to drag its feet and produce documents this week, or later. Claimants expended significant efforts in producing final documents by the deadline, and in a good-faith response to ISE's requests. Claimants reviewed roughly 25,000 documents, and produced nearly 19,000 pages of responsive, non-privileged materials. Decl. of S. Vernick, ¶ 18.

RegenX Science Exhibit 1071
Page 296

ISE now has the benefit of claimants documents. In the coming weeks, the parties must prepare pre-hearing briefs, expert reports, witness statements and prepare for the final hearing. Claimants need ISE's production to litigate this matter, and prepare their claims and defenses. And, respectfully, claimants needed the productions last week, so the review could be under way. There was already very little time. Every day, and every hour of ISE's violation of the Orders materially prejudices and irreparably harms claimants.

Accordingly, claimants respectfully request the Arbitrator preclude ISE's counterclaims, or in the alternative, preclude ISE from submitting any evidence in this Arbitration and draw adverse inferences against ISE on all factual proofs, including at the final hearing. The Arbitrator has authority to order this relief under AAA's Commercial Rules, and the inherent power of the position. *See* AAA Commercial Rule R-58 ("The arbitrator may, upon a party's request, order appropriate sanctions where a party fails to comply with its obligations under these rules or with an order of the arbitrator."); R-23 ("[I]n the case of willful non-compliance with any order issued by the arbitrator, [the arbitrator has authority to] draw[] adverse inferences, exclud[e] evidence and other submissions," among other sanctions.).

B. This Arbitration Should Continue to Proceed Under Direct Exchange Communication Procedures

At the outset of this matter, the parties agreed to the Direct Exchange method of communication with the Arbitrator. This is reflected in the operative Scheduling Order No. 2. *See* Order No. 2 (Ex. 13), ¶ 16. The parties selected Direct Exchange for its efficiencies. Direct Exchange expedites communications, as the Arbitrator, the parties and AAA are on each communication. Direct Exchange removes the added and unneeded steps of forwarding emails along the chain, with the AAA as the middle-man. And, here, where the parties are under incredibly tight deadlines, each hour in the day is important.

RegenX Science Exhibit 1071
Page 297

That said, for some unstated reason, ISE revoked its consent to the Direct Exchange process for communications with the Arbitrator. This is clearly intended to disrupt and delay the proceedings. There is no other explanation. And, as made clear in this brief, ISE has completely disengaged from this Arbitration. ISE is not even participating in communications, so it is curious as to why ISE has a strong stance on the exchange of information in this Arbitration. To force Direct Exchange on claimants can only be designed to cause issues and delays. This is in line with ISE's broader bad faith tactics in this action, and continued violations of this Arbitration's Orders, which is now at least at **four** violations. This sort of bad faith practice cannot be permitted.

In situations such as this, the AAA Commercial Rules allow the Arbitrator to fashion the procedures to minimize the harm to the good faith party. *See e.g.,* AAA Commercial Rule L-3(a) ("The arbitrator shall take such steps as deemed necessary or desirable to avoid delay and to achieve a fair, speedy and cost-effective resolution of a Large, Complex Commercial Dispute."); R-43 ("The AAA may direct that any oral or written communications that are sent by a party or their representative shall be sent in a particular manner."). Accordingly, claimants respectfully request the Arbitrator Order communications continue under the Direct Exchange method.

C. Claimants Should Be Awarded Attorneys' Fees and Costs, and Evidentiary Inferences in Their Favor

ISE's conduct in this Arbitration is sanctionable. It exemplifies improper gamesmanship and bad faith. ISE's actions demonstrate a complete lack of respect for this Arbitration process, and law. This sort of bad faith practice cannot be tolerated. ISE's refusal to participate in good faith in these proceedings now severely prejudices claimants.

As made clear in this brief, ISE has completely disengaged from this Arbitration. ISE and its counsel have repeatedly ignored deadlines, Orders in this Arbitration and direct messages from the Arbitrator. *See e.g.*, Exs. 15, 17-18. ISE failed to attend Friday's (September 27) status hearing,

RegenX Science Exhibit 1071
Page 298

without explanation. *See* Ex. 19. And, ISE has made zero efforts to comply with its obligations to produce documents. ISE has not produced a **single** document in this Arbitration, despite the passing of not one, but two deadlines set by the Arbitrator—including the deadline set in Order No. 8 compelling ISE's production, and noticing that ISE's continued failure to adhere to deadlines in this matter may lead to sanctions. *See* Order No. 8 (Ex. 14), ¶¶ 6-7. Incredibly, despite these warnings on the seriousness of its continued dilatory conduct and failures to comply with Orders in this Arbitration, ISE still has not made **any** efforts to comply with deadlines. Not surprisingly, it seem ISE's counsel at Nelson Mullins continues to represent ISE in this dispute, and withdrew from this Arbitration for some tactical reason relating to ISE's noncompliance with Orders. Such improper gamesmanship cannot be tolerated.

ISE's continued conduct is precisely the type of bad faith tactics that run contrary to the purposes of arbitration and warrant the award of reasonable attorneys' fees and costs, and evidentiary sanctions. The Arbitrator has the inherent power to award this relief. *See Marshall & Co. v. Duke*, 114 F.3d 188, 190 (11th Cir. 1997) ("[A]rbitrators have the power to award attorney's fees pursuant to the "bad faith" exception to the American Rule that each party bears its own attorney's fees."); *id* ("[E]very judicial and quasi-judicial body has the right to award attorneys' fees under the common law bad faith exception to the American Rule."); *see also First Auto. Serv. Corp. v. First Colonial Ins. Co.*, No. 07-682, 2010 WL 2431889, at *5 (M.D. Fla. Jul. 16, 2010) (applying *Marshall* to an arbitration governed by the Federal Arbitration Act); R-23 ("[I]n the case of willful non-compliance with any order issued by the arbitrator, [the arbitrator has authority to] draw[] adverse inferences, exclud[e] evidence and other submissions," among other sanctions.).

RegenX Science Exhibit 1071
Page 299

Accordingly, claimants respectfully request the Arbitrator award reasonable attorneys' fees and costs incurred in this Arbitration to date, including fees and costs relating to document collection, review and production.

In addition, claimants respectfully request the Arbitrator issue sanctions against ISE in the form of adverse evidentiary inferences, and as a bar against submission of all documents and information ISE failed to produce in direct violation of the Orders issued to date.

IV. CONCLUSION

For the foregoing reasons, claimants' respectfully request the Arbitrator: (i) bar respondent's counterclaims; (ii) Order the Arbitration continue under the Direct Exchange procedure; and (iii) award claimants attorneys' fees and costs, as well as evidentiary inferences in climants' favor and against respondent.

Date: September 30, 2019

DLA PIPER LLP (US)

s/ Janelly Crespo
Janelly Crespo

200 South Biscayne Boulevard, Suite 2500
Miami, FL 33131
T: 305.423.8500 / F: 305.437.8131
janelly.crespo@dlapiper.com

John D. Huh (*R 1-3.11 statement pending*)
Scott M. Vernick (*R 1-3.11 statement pending*)

One Liberty Place
1650 Market Street, Suite 5000
Philadelphia, PA 19103
T: 215.656.3300 / F: 215.656.3301
john.huh@dlapiper.com
scott.vernick@dlapiper.com

Attorneys for Synogen Management Group, Inc. and NeXtGen Biologics, Inc.

Exhibit O

Vernick, Scott

From: AngelaValedon@adr.org
Sent: Tuesday, December 03, 2019 3:05 PM
To: REarlyISE@gmail.com; adavis@bwsmiplaw.com; Vernick, Scott; Huh, John; kwimberly@bwsmiplaw.com
Cc: cbarrowood@parkerpoe.com
Subject: Synogen Management Group, Inc. v. ISE Professional Testing & - Case 01-19-0002-3786
Attachments: CM118.pdf; Final Award .pdf

[EXTERNAL]

Hello,

Please review the attached correspondence regarding the above-referenced case.

Feel free to contact me with any questions, comments or concerns you have related to this matter.

Thank you.

AAA Angela Romero Valedon, Esq.
Director of ADR Services

American Arbitration Association

T: 786 406 6642 E: AngelaValedon@adr.org
100 SE 2nd St., Ste. 2300, Miami, Fl 33131
adr.org | icdr.org | aaamediation.org

The information in this transmittal (including attachments, if any) is privileged and/or confidential and is intended only for the recipient(s) listed above. Any review, use, disclosure, distribution or copying of this transmittal is prohibited except by or on behalf of the intended recipient. If you have received this transmittal in error, please notify me immediately by reply email and destroy all copies of the transmittal. Thank you.

AMERICAN ARBITRATION ASSOCIATION

SYNOGEN MANAGEMENT GROUP, INC., and NEXTGEN BIOLOGICS, INC., Claimants, v. ISE PROFESSIONAL TESTING & CONSULTING SERVICES, INC., Respondent.	**Case No. 01-19-0002-3786**

ARBITRATION CLAIMANTS' MOTION TO DISMISS RESPONDENT'S UNTIMELY NOTICE OF APPEAL

Arbitration Claimants Synogen Management Group, Inc. ("Synogen") and NeXtGen Biologics, Inc. ("Nextgen") move to dismiss ISE Professional Testing and Consulting Services, Inc.'s ("ISE") untimely appeal for lack of jurisdiction, waiver and under the mandatory claim-processing rule. Synogen and Nextgen reserve all rights and do not waive any jurisdictional objection.

I. INTRODUCTION

Respectfully, the American Arbitration Association ("AAA") cannot entertain Respondent ISE's untimely appeal. ISE's Notice of Appeal must be stricken and its appeal dismissed. The Parties' agreement providing for private arbitration instructs, "[a]ppeals must be filed within thirty (30) days of receipt of the award." On day thirty-one the award is final and not appealable. ISE admits this fact in its Notice of Appeal. *See* Notice of Appeal at 1 ("This appeal is being brought

pursuant to Section 13.6 of the License Agreement, which directs that all appeals must be submitted directly to the AAA within thirty (30) days of the Final Award.").

The Arbitrator's Final Award was executed and issued December 3, 2019. *See* Notice of Appeal at 1; *see also* Final Award as Exhibit 1 at 28; December 3, 2019 Email from AAA as Exhibit 2. By its own admission, under the clear terms of the arbitration agreement ISE was required to submit its Notice of Appeal no later than January 2, 2019. ISE failed to meet this mandatory deadline. As a result, ISE is barred from asserting this appeal.

II. OPERATIVE PROCEDURAL HISTORY

Synogen and ISE entered into a License Agreement, executed October 16, 2014 and made effective September 23, 2014. Under that Agreement, Synogen contracted for: (i) an exclusive license to certain patent rights (*i.e.*, Licensed Patents); and (ii) a non-exclusive license to a trade secret process technology or decellularization process (*i.e.*, the Licensed Know-How). As directed by the Agreement, Synogen also executed a Sublicense Agreement with Nextgen (together with Synogen, "Claimants"), which granted Nextgen certain rights under the Synogen-ISE License Agreement. Despite Claimants' compliance with their contractual commitments, ISE willfully breached the License Agreement by, among other things, refusing to transfer the Licensed Know-How.

Claimants initiated this Arbitration on July 31, 2019. While ISE engaged in a lengthy pattern of bad faith tactics in an attempt to stall this action, the Arbitration proceeded on schedule.[1]

[1] *See e.g.,* Exhibit 1, at ¶ 102 ("Regrettably, ISE has made clear throughout this proceeding that its schedule and convenience is the only one that matters and that it will ignore the rules and rulings of this process."); ¶ 103 (noting Respondent's counsel lied to a mediator and AAA concerning settlement); ¶ 106 (explaining in response to the Arbitrator reaching out to confirm Respondent was aware of deadlines, Respondent refused to reply and instead revoked consent to direct communication); ¶ 108 (noting despite issuing 14 document requests and receiving thousands of pages of materials, including confidential and sensitive documents, Respondent refused to produce a single document despite repeated opportunities and warnings).

RegenX Science Exhibit 1071
Page 304

A final hearing was held on October 23, 2019, at which Claimants submitted more than eighty (80) exhibits, witness statements, and live testimony. Respondent ISE refused to attend. The Final Award was executed and issued on December 3, 2019. *Id.* The same day (December 3, 2019), the AAA sent a copy of the Final Award by email to: (i) Ryanne Early, President and principal of ISE; (ii) ISE's counsel; and (iii) Claimant's counsel. *See* Exhibit 2.

ISE filed its Notice of Appeal on January 3, 2019. Therein, ISE acknowledges that its appeal was "brought pursuant to Section 13.6 of the License Agreement, which directs that all appeals **must** be submitted directly to the AAA within thirty (30) days of the Final Award," and that the Final Award was entered on December 3, 2019. *See* Notice of Appeal at 1 (emphasis added); Exhibit 1, at 28; Exhibit 2. Stated differently, ISE concedes that it was required to file its notice by January 2, 2019, and that its Notice is untimely.

Now, in light of ISE's refusal to withdraw its untimely Notice of Appeal, Claimants must respectfully request the AAA strike ISE's Notice and dismiss the untimely appeal.[2]

III. ARGUMENT

A. ISE's Notice of Appeal is Untimely.

ISE's Notice of Appeal is untimely. ISE acknowledges the License Agreement requires that all "[a]ppeals must be filed within (30) days of receipt of the award . . . by filing a Notice of Appeal with the AAA." Notice of Appeal, Ex. 2 ("License Agreement"), at § 13.6; *accord* Rule A-3 ("Filing Requirements"). ISE received the Award at issue on December 3, 2019 and filed its Notice of Appeal thirty-one days later on January 3. *See* Exhibit 1 at 28; *see also* Exhibit 2. The

[2] Claimants informed ISE of its procedural blunder and requested ISE withdraw its Notice prior to the filing of this Motion. ISE did not respond to Claimants' request. Instead, as Claimants were preparing to submit this Motion, ISE filed a Motion for One-Day Extension of Time with the AAA. Claimants will file a response to ISE's arguments and motion in a separate opposition filing.

RegenX Science Exhibit 1071
Page 305

Notice of Appeal was due on January 2.[3] Thus, there can be no dispute that ISE's Notice is untimely. Accordingly, as set forth below, the Notice of Appeal must be stricken and this appeal dismissed for lack of jurisdiction, waiver and under the mandatory claim-processing rule.

B. ISE's Untimely Notice of Appeal Must be Dismissed for Lack of Jurisdiction.

ISE's Notice of Appeal must be dismissed because jurisdiction is lacking. Arbitration is a creature of contract and consent. Indeed, "arbitrators derive their authority to resolve disputes only because the parties have agreed in advance to submit such grievances to arbitration." *AT&T Techs., Inc. v. Communications Workers of Am*., 475 U.S. 643, 648–49 (1986); *see also Della Penna v. Zabawa*, 931 So. 2d 155, 164 (Fla. 5th DCA 2006) ("An arbitrator's jurisdiction derives from the parties' agreement . . . ."). As such, an arbitrator's jurisdiction is limited by the terms of the parties' agreement. Therefore, "courts may not require arbitration beyond the scope of [a] contractual agreement, because 'a party cannot be required to submit to arbitration any dispute which he has not agreed so to submit.'" *JPay, Inc. v. Kobel*, 904 F.3d 923, 929 (11th Cir. 2018) (citing *United Steelworkers of Am. v. Warrior & Gulf Navigation Co.*, 363 U.S. 574, 582 (1960)); *cf. Seaboard Sur. Co. v. Cates*, 604 So. 2d 570, 571 (Fla. Dist. Ct. App. 1992) (explaining that a "defendant had no right to arbitrate contractual disputes where its contract specifically provided that demand within 30 days was a precondition for arbitration and defendant failed to file any such demand"). Put simply, the AAA lacks the jurisdiction to arbitrate controversies in a manner contrary to the express terms of the parties' arbitration agreement.

Here, as detailed above, ISE acknowledges that the operative License Agreement provides that an appeal in this Arbitration "must be filed within (30) days of receipt of the award." Notice

[3] AAA Appellate Rule A-18(b) provides: "all deadlines under these Rules shall be determined by calendar days. If the last day of the time period is a legal holiday or weekend day, the period shall be extended until the first business day which follows."

of Appeal, Ex. 2, at § 13.6. Indeed, Claimants' consent to the AAA's jurisdiction is contingent upon the filing of a timely notice of appeal. *Id.* In other words, the AAA lacks jurisdiction under the License Agreement to entertain an appeal following an untimely notice of appeal. Therefore, because ISE's Notice of Appeal was untimely, the Panel lacks the jurisdiction necessary to hear the instant appeal.

C. ISE's Untimely Notice of Appeal Must be Stricken and Dismissed Under the Mandatory Claim-Processing Rule.

ISE's untimely Notice of Appeal must be dismissed because it was filed contrary to a mandatory claim-processing rule, which "if properly invoked, . . . **must** be enforced." *Hamer v. Neighborhod Housing Servs.*, 138 S. Ct. 13, 18 (2017) (emphasis added). A mandatory claim-processing rule is an "unalterable" procedural rule placing a time limitation on a specified event. *See Nutraceutical Corp. v. Lambert*, 139 S. Ct. 710, 714 (2019) (noting that mandatory claim-processing rules are "unalterable"); *Hamer,* 138 S. Ct. at 17 (finding that the Fed. R. Civ. P. timeline to file a Notice of Appeal was a mandatory claim-processing rule). If such a rule is violated, dismissal is warranted. *See, e.g.*, *Hamer,* 138 S. Ct. 13 at 17; *Peltz v. Dist. Ct. of Appeal*, 605 So. 2d 865, 866 (Fla. 1992) (noting that an "untimely filing of a notice of appeal precludes the appellate court from" entertaining that appeal); *Elmouki v. DOT*, 251 So. 3d 290, 291 (Fla. DCA 1st 2018) (same); *Griffis v. Dep't of Bus. & Prof. Reg.*, 90 So. 3d 320, 321 (Fla. DCA 1st 2012) (same); *State Farm Mut. Auto Ins. Co. v. Open MRI of Orlando, Inc.*, 780 So. 2d 339, 341 (Fla. 5th DCA 2001) (same).

Here, the deadline imposed on ISE to file a Notice of Appeal is a mandatory claim-processing rule. The procedural rules governing this action stem from the License Agreement and AAA Optional Appellate Arbitration Rules. Each of these procedural fonts demands that a Notice of Appeal be filed within 30 days of receiving notice of an award. And neither provides for an

extension of that deadline. Stated differently, the procedural rules governing ISE's Notice of Appeal must be construed as mandatory claim-processing rules barring this appeal. ISE ignored this rule and instead elected to file an untimely appeal at its own risk. As Claimants now properly invoke the License Agreement's 30-day deadline for the filing of a Notice of Appeal, ISE's Notice must be stricken and this appeal dismissed as untimely.

IV. CONCLUSION

Based on the foregoing, Claimants respectfully request the AAA grant this Motion to Dismiss ISE's Notice of Appeal.[4]

Date: January 6, 2020

DLA PIPER LLP (US)

s/ John D. Huh
John D. Huh (*R 1-3.11 statement submitted*)
Scott M. Vernick (*R 1-3.11 statement submitted*)

One Liberty Place
1650 Market Street, Suite 5000
Philadelphia, PA 19103
T: 215.656.3300 / F: 215.656.3301
john.huh@dlapiper.com
scott.vernick@dlapiper.comJanelly Crespo

Janelly Crespo
200 South Biscayne Boulevard, Suite 2500
Miami, FL 33131
T: 305.423.8500 / F: 305.437.8131
janelly.crespo@dlapiper.com

Attorneys for Synogen Management Group, Inc. and NeXtGen Biologics, Inc.

[4] In light of the frivolous nature of ISE's Notice of Appeal and ISE's refusal to withdraw the Notice despite Claimants' notices, Claimants reserve the right to seek reasonable attorneys' fees and costs, as well as the right to seek other sanctions.

EXHIBIT 1

AMERICAN ARBITRATION ASSOCIATION®
INTERNATIONAL CENTRE FOR DISPUTE RESOLUTION®

Rebecca Storrow
Vice President
Miami Tower, 100 SE 2nd Street, Suite 2300
Miami, FL 33131
Telephone: (305)358-7777
Fax: (305)358-4931

December 3, 2019

John D. Huh, Esq.
DLA Piper, LLP
1650 Market Street
Suite 4900
Philadelphia, PA 19103
Via Email to: john.huh@dlapiper.com

Amber Davis, Esq.
Beusse Wolter Sanks Mora & Maire, PA
390 North Orange Avenue
Suite 2500
Orlando, FL 32801
Via Email to: adavis@bwsmiplaw.com

Case Number: 01-19-0002-3786

Synogen Management Group, Inc.
and NeXt Gen Biologics, Inc.
-vs-
ISE Professional Testing &
Consulting Services, Inc.

Dear Parties:

By direction of the arbitrator(s) attached please find the duly executed Award in the above matter. Please remember there is to be no direct communication with the arbitrator(s). All communication shall be directed to the AAA.

A financial reconciliation has been conducted and each party will receive a separate financial accounting for this matter. Any refunds will be processed as soon as possible and any party with an outstanding balance will continue to receive monthly invoices until the balance is paid in full.

Note that the financial reconciliation reflects costs as they were incurred during the course of the proceeding. Any apportionment of these costs by the arbitrator, pursuant to the Rules, will be addressed in the award and will be stated as one party's obligation to reimburse the other party for costs incurred. Any outstanding balances the parties may have with the American Arbitration Association (the AAA) for the costs incurred during the arbitration proceedings remain due and payable to the AAA even after the final award is issued, and regardless of the arbitrator's apportionment of these costs between the parties in the award.

Pursuant to the AAA's current policy, in the normal course of our administration, the AAA may maintain certain electronic case documents in our electronic records system. Such electronic documents may not constitute a complete case file. Other than certain types of electronic case documents that the AAA maintains indefinitely, electronic case documents will be destroyed 18 months after the date of this letter.

We appreciate the opportunity to assist you in resolving your dispute. As always, please do not hesitate to contact me if you have any questions.

Sincerely,

Angela Romero Valedon
Director of ADR Services
Direct Dial: (786)406-6642
Email: AngelaValedon@adr.org
Fax: (305)358-4931

cc:
Scott Vernick, Esq.
Ryanne Early
Kevin W. Wimberly, Esq.
Catharine B. Arrowood, Esq.

AMERICAN ARBITRATION ASSOCIATION

SYNOGEN MANAGEMENT GROUP, INC., and NEXTGEN BIOLOGICS, INC., Claimants, v. ISE PROFESSIONAL TESTING & CONSULTING SERVICES, INC., Respondent.	**Case No. 01-19-0002-3786**

FINAL AWARD

1. The undersigned Arbitrator was designated by Claimant Synogen Management Group, Inc. (**Synogen**) and Respondent ISE Professional Testing & Consulting Services Inc. (**ISE**) in accordance with their arbitration agreement contained in Section 13 of the License Agreement between ISE and Synogen executed October 16, 2014 and effective September 23, 2014 (**License Agreement**) (Ex.1[1]). Subsequently, Claimant NextGen Biologics, Inc (**NextGen**) was added as a Claimant in light of ISE's acknowledgement of NextGen as a sublicensee to Synogen (See Ex.1 at App. A), the agreement that sublicensees survive termination of the License Agreement (Ex.1 at §2.2.1) and the agreement to arbitrate contained in Section 13 of the License Agreement between Synogen and NextGen effective October 15, 2014 (**Sublicense Agreement**) (Ex.2). See Order No. 6 in this matter.

2. Both the License Agreement and the Sublicense Agreement (the **Agreements**) are governed by the laws of the State of Florida (Ex. 1 at §16.1; Ex.2

[1] "Ex." refers to the exhibits submitted at the hearing.

at §16.1). The Federal Arbitration Act applies and the arbitration was conducted pursuant to the Commercial Arbitration Rules (**Rules**) of the American Arbitration Association (**AAA**). Synogen, NextGen and ISE are referred to herein as the **Parties**.

3. Having been duly sworn, the undersigned Arbitrator heard the proofs and allegations of the Parties by, among other things, taking evidence at a hearing conducted on October 23, 2019 at the offices of Veritext-Orange Legal at 633 East Colonial Drive, Orlando, Florida 32803[2]. Claimants were represented by Janelly Crespo, John Huh, and Scott Vernick of DLA Piper. Jamie Grooms, Chairman of Synogen, and Jonelle Toothman, CEO of Nextgen, appeared on behalf of the Claimant companies. Respondent did not appear at the hearing venue either through counsel or through a corporate representative. Respondent was initially represented by Nelson Mullins, which filed a Notice of Change of Representation on September 25, 2019 in which it withdrew from this matter and designated Ryanne Early (**Early**), CEO of Respondent as ISE's contact. Ex. 17. Post-hearing, the firm of Beusse Wolter Sanks & Maire PLLC appeared for Respondent and filed ISE's Post-Hearing Brief on November 15, 2019.

4. The evidence received at the hearing is reflected in the hearing transcript. Claimants moved the following exhibits into the record: Exs. 1-86; and Exs. A (Decl. Michael Lodato), B (Decl. Statement of Jamie Grooms), C (Decl. of Jonelle Toothman) and D (Decl. of John Huh). On October 29, 2019, Claimants submitted a supplement to the Huh Decl. as Ex. E. Claimants' exhibits were accepted into evidence. ISE did not propound evidentiary objections to any of Claimants' exhibits as part of the pre-hearing process (See Order No. 2 ¶10) or at the hearing.

---

[2] By agreement, this matter was to be heard at the offices of Veritext located at 37 North Orange Avenue, Suite 500, Orlando, Florida. On October 21, 2019, it was learned that a representative of Erika Birg of Nelson Mullins, former counsel to ISE, contacted Veritext, and, without notice to the AAA, the arbitrator, counsel for Claimants or Claimants, cancelled the arrangements for the hearing. See Hearing Exhibit A, Declaration of Michael Lodato. Veritext provided a nearby location and timely notice was provided by AAA to the Parties via email and Federal Express. Respondent received both notices and in fact communicated with the AAA via that same email address the day of the hearing. See Post-Hearing Brief of Claimants at Ex. 2 and 4.

5. After Claimants presented the Witness Statements of Jamie Grooms and Jonelle Toothman as the direct examinations of these witnesses as permitted under Order No. 2 ¶9(a), the Arbitrator asked questions of Claimants' witnesses. Respondent ISE waived its opportunity to examine Claimants' witnesses and proffered no evidence at the hearing. Claimants noted their intent to question Respondent's representative and principal, Ryanne Early, who did not appear. It is acknowledged that Ms. Early submitted material to the AAA (and the same was transmitted to the arbitrator) via email the day of the hearing.

6. The Parties were permitted to submit post-hearing briefing, proposed awards and updated fee and costs petitions by Friday, November 15, 2019, as provided in Order No. 2 (Ex.22). Claimants did so. Respondent, through counsel, submitted a post-hearing brief. The undersigned held the record open over the weekend until Monday, November 18, 2019 to permit Respondent to supply copies of cases and the hearing transcript cited in Respondent's brief. Following receipt of these materials on November 18, 2019 the record was formally closed.

7. The undersigned is cognizant of the provisions of AAA Rule 31. Rule 31 does not permit an award to be made solely on the default of a party. The undersigned, in making this decision on the merits, has reviewed and considered the entire record, including everything submitted by the Parties whether or not timely supplied and regardless of whether it was supplied in accordance with the orders entered in this matter or other procedures applicable to this matter. In addition, in the interest of fairness, the undersigned deferred consideration of sanctions until the Parties' positions were fully presented and the record was closed. See, e.g. AAA Rule 23 and 28.

8. Based on the evidence, proofs and materials submitted by the Parties, the Arbitrator makes the following findings and conclusions and enters the following FINAL AWARD.

The Parties

9. Claimant Synogen is a Florida corporation, with a focus in the tech, med-tech and biotech industries.

10. Respondent ISE is a Florida corporation controlled by its principal and President, Ryanne Early. ISE holds a number of patent applications relating to bio-regenerative growth technology, specific to non-mammalian tissue.

11. Claimant Nextgen is a Delaware corporation, with its principal place of business in Florida. As described below, Nextgen was created with the agreement of ISE for the purpose of holding the rights to certain of ISE's bio-regenerative growth technologies and to develop and bring to market derivative products for human healthcare applications.

The Dispute

12. This dispute relates to allegations of breaches of the Agreements in connection with Synogen's and Nextgen's efforts to utilize ISE's patents and know-how.

Synogen-ISE License Agreement

13. Following months of negotiations (See, e.g. Ex. 61, 43 and 75), on October 16, 2014, Synogen and ISE executed a License Agreement, made effective September 23, 2014 (**License Agreement**) (Ex. 1).

14. Under the License Agreement, ISE provided Synogen an exclusive license to certain patent rights defined therein (**Licensed Patents**) and a non-exclusive license to certain trade secrets defined as "unpatented trade secret process technology, know-how and related proprietary information solely as applied to or used for decellurization of urodele derived tissue." (**Licensed Know-How**). See Ex.1 at §§ 1.7, 1.9, 2.1, 5.2.1, 5.2.2. The Licensed Know-How was also described as "Controlled by ISE." Id. at §1.7. **Control** was defined as intellectual property "that a Party...owns ... and has the ability to grant access, license or sublicense in or to ...." Id. at § 1.3.

15. In exchange for these rights, Synogen agreed, among other things, to: (a) use "commercially reasonable efforts to pursue the development of the technology

embodied in the Licensed Patents"; (b) cover "past, present, and future costs, fees, and expenses . . . related to the preparation, filing, prosecution, issuance and maintenance of" the licensed technology; (c) pay to ISE fifty percent (50%) "of all consideration received for [any] Sublicense of the Licensed Patents;" and, (d) "prosecute and maintain the Licensed Patents using counsel of [Synogen's] choice. Ex. 1 at §§ 3.1,4.1, 4.2 and 9.1.

16. ISE agreed, and the License Agreement specifically contemplated, that Synogen would form Nextgen and sublicense Synogen's rights to it[3].

17. The License Agreement provided for ISE to provide consulting services when reasonably requested to do so. Ex. 1 at § 5.1. The License Agreement further contemplated that ISE would promptly transfer Licensed Know-How upon the request of Synogen (Ex.1 at §5.2.1) and Synogen and ISE would "promptly establish a commercially viable manufacturing procedure which utilizes the Licensed Know-How." Ex.1 at § 5.2.2.

18. Further, Licensor ISE agreed that it "shall...cooperate in all respects with Licensee's efforts in preparing and prosecuting the Licensed Patents," including submitting declarations when requested and making available needed information and specimens, among other things. Ex. 1 §9.3.

19. The License Agreement could be terminated unilaterally without cause by Claimant Synogen on 45 days written notice to ISE. Ex. 1 at §11.2. On the other hand, Respondent ISE's right to terminate was limited to providing thirty days' notice of termination following Synogen's failure to cure after 45 days' notice past due reports or payments or material breach of the Agreement. Ex. 1 at § 11.3. Section 11.3.2 dealing with material breach further provided that ISE's right to terminate

---

[3] See Ex. 1 at § 1.12 (defining Sublicense); § 2.2 ("[Synogen] may grant, in its sole discretion, written Sublicenses to third parties which are not Excluded Sublicensees"); § 2.2.1 (Sublicensees granted the right "at the Sublicensee's option" to survive termination of the prime Synogen-ISE licenses in the event of a dispute between Synogen and ISE); § 3.1 ("[Synogen] agrees and warrants to... pursue the development of the technology . . . principally through sublicensing the Licensed Patents"); §§ 5.2.1, 5.2.2 (contemplating that the Licensed Know-How will be shared with Synogen's Sublicensees); and, Appendix A (Synogen to "form[] Sublicensee . . . Nextgen" and "enter into a sublicense with Nextgen.").

would be automatically stayed in the event that, during the cure period, Synogen initiated the License Agreement's dispute resolution process.

20. Synogen and ISE agreed to arbitrate all disputes exclusively pursuant to the Rules of the AAA (Ex. 1 §13) and to require each sublicensee to do the same. Ex. 1 §13.1. The License Agreement also required that any compulsory counterclaim as defined by Fed. R. Civ. Proc. 13 be submitted in the arbitration proceeding or be "forever barred." Ex. 1 § 13.1.

Synogen-Nextgen Sublicense Agreement

21. In accordance with the License Agreement, Synogen entered a Sublicense Agreement with Nextgen, executed January 26, 2015 and made effective October 14, 2014 (**Sublicense Agreement**). Ex. 2.

22. The terms of the License and Sublicense Agreements make clear that Nextgen is a third party beneficiary of the License Agreement, as discussed in more detail below.

23. The License Agreement explicitly provided that sublicensees are provided a right to survive termination of the prime license between Synogen and ISE, "at the Sublicensee's option." Ex. 1 § 2.2.1. Thus, even if the Synogen-ISE License Agreement was properly terminated as to the primary licensee (i.e. Synogen), Nextgen's rights under the licenses "remain valid." Ex. 3.

24. Nextgen became the primary financial beneficiary of the Agreements, retaining 97 to 98.5 percent of Net Sales obtained from any product developed from the Licensed Patents. Ex. 2 § 4.4. Synogen and ISE were to receive only 0.75 to 1.5 percent of Net Sales related to the commercialization of the licensed technologies. Id.; Ex. 1 § 4.2.

25. Synogen and ISE, in drafting and executing the prime License Agreement, intended the sublicensee, specifically identified as Nextgen, to act as the primary point in development and commercialization efforts on any product. In other words, ISE and Synogen clearly intended that Nextgen, as a company, would use the Licensed Patent and Know-How to develop, advance the bio-regenerative growth technology, and ultimately manufacture the resulting products.

The Parties' Claims

26. Synogen and Nextgen Claims. Claimant Synogen asserted four claims in the Amended Demand (9/16/2019). It alleged that ISE breached the License Agreement by failing to transfer the Know-How (Claim 1) and refusing to cooperate in the patent prosecution (Claim 2); it also alleged that ISE breached the covenant of good faith and fair dealing (Claim 3) and violated Florida's Unfair Trade Practices Act (Claim 4). Claimant Nextgen alleged one claim, that ISE breached the License Agreement by failing to recognize that Nextgen's rights of termination survival under the License and Sublicense Agreements (Claim 5).

27. ISE's Counterclaims. In its Amended Answer and Counterclaim (9/16/2019), ISE asserted ten counterclaims against Synogen. ISE requested a declaratory judgment that it properly terminated the License Agreement (Claim 1), that Section 5.2 of the License Agreement (regarding the transfer of Licensed Know-How) was unenforceable (Claim 2) and that ISE is not obligated to enter into a direct license with Nextgen (Claim 3). ISE also asserted claims for breach of contract against Synogen as to Section 9.1 of the License Agreement (regarding patent prosecution) (Claim 4) and failure to pay ISE for hours of consulting time (Claim 5). Further, ISE alleged that Synogen breached its NDA with ISE (Claim 6); and, sought specific performance by Synogen in the form of an accounting (Claim 7), as well as injunctive relief and damages arising from the failure to allow an accounting (Claim 8). Finally, ISE sought recovery of its attorneys' fees (Claim 9) and the disqualification of DLA Piper (Claim 10). No counterclaims were asserted against Nextgen.

Summary of Events

28. Synogen Develops the Product. Following execution of the License and Sublicense Agreements, Synogen, with Nextgen, over a period of some years, developed the intended bio-regenerative growth product, now referred to as NeoMatriX®.

29. Synogen and Nextgen funded the project, carrying the more than $7.5 million in costs associated with the development and commercialization of the product. Grooms Decl. ¶ 26; Toothman Decl. ¶ 17.

30. During this period, Synogen paid ISE 50 percent of all consideration received from Sublicensees. Grooms Decl. ¶ 29.

31. More than $1.7 million of Claimants' costs were paid to Seed Biotech Inc. (**Seed**), a company closely related to ISE. Ryanne Early, the principal and President at ISE, is also a principal and the CEO of Seed. Ex. 31; Toothman Decl. ¶ 18.; Ex. 61 (Early described as CSO (Chief Science Officer) and Founder of Seed).

32. ISE Consulting Work. Although Ms. Early did not make always it clear when she was operating on behalf of SEED as opposed to ISE[4], the record contains no invoices issued by ISE to Synogen or NextGen that purport to relate to the performance of any consulting work by ISE as described in Section 5.1 of the License Agreement.

33. FDA approval. By October 2018, NeoMatriX received 510(k) clearance from the U.S. Food and Drug Administration ("FDA"), the certification required to take a medical device to market. Ex. 4.

34. Patent Prosecution. In addition to developing the product, Synogen continued to pursue the patent rights and, in January 2019, received notice from the USPTO of impending issuance of U.S. patent rights. Ex. 5.

35. ISE fails to transfer the Know-How or to cooperate in developing a manufacturing process. However, ISE failed to transfer the Know-How, even though it was obligated to do so "promptly" after the execution of the License Agreement (See Ex. 1 § 5.2.1) and even though Synogen and Nextgen repeatedly requested that the Licensed Know-How that ISE claimed to own and control, be transferred. See e.g., Exs. 6, 7, 51 (at Exhibit 22) and 62; Grooms Decl ¶ 38. 34.

---

[4] Ms. Early conducted ISE business from a Seed ("@seedbiotech.com") account and her signature block for her personal email account refers to her positions at both entities. See Ex. 41. Ms. Early also made payments for ISE and Seed from her personal bank account and directed payments owed to ISE under the License Agreement be instead made to Seed. See Ex. 42.

36. For example, on October 22, 2018, Mr. Grooms communicated directly with ISE President, Ryanne Early, to remind her that the Know-How had yet to be provided to Synogen and Nextgen:

> I decided to send this note to keep us on track. As mutually agreed we have a compliance issue as it relates to the manufacturing black box requirement in our agreement. We have agreed to sit down to discuss a solution to this issue. My goal is to use our timeline within the agreement (45 days) to resolve so we have an agreement that works for all parties.

Ex. 8.

37. ISE did not meaningfully respond to this request, sent over four years after the effective date of the License Agreement, September 23, 2014. Ex. 1 §5.2.1.

38. ISE now contends that it should be excused from performing this obligation because there was no meeting of the minds as to the meaning of Licensed Know-How. See, e.g., Respondent's Post-Hearing Brief at p.7. This, however, was not cited by ISE as one of its "excuses" during the four plus years Synogen was developing the product. See Grooms Decl. ¶¶35-37.

39. ISE fails to assist in developing the manufacturing process. The License Agreement also obligated ISE to work with Synogen to "promptly establish a commercially viable manufacturing procedure which utilizes the Licensed Know-How for making decellularized Uroldele extracellular matrix tissue, which manufacturing procedure will include a black box aspect....." Ex. 1 at § 5.2.2. Like the obligation to transfer the Know-How, there was no evidence that ISE performed this obligation. Grooms Decl. ¶ 33; Toothman Decl. ¶ 22.

40. ISE attempts to terminate Synogen. Instead, on November 7, 2018, Erika Birg of Nelson Mullins[5], counsel for ISE, sent a letter to Synogen, suggesting, for the first time in the over four years the License Agreement had been in place, that Synogen was in breach of the License Agreement. Ex. 9. Grooms Decl. ¶ 43.

---

[5] Nelson Mullins and Ms. Birg appear to have represented ISE for many years, even prior to the execution of the License Agreement. See Ex. 43 (5-8-2014 email exchange with Ms. Birg regarding negotiations of the License Agreement.)

41. There followed correspondence between Gerard Bencen, counsel for Synogen, and Ms. Birg, counsel for ISE, including a letter from Mr. Bencen dated December 22, 2018, responding in detail to ISE's allegations of Synogen's breach. Ex. 59.

42. Over three months later, by letter dated April 5, 2019 (Ex. 10), ISE, through counsel, purported to terminate the License Agreement, claiming that the "period to cure these breaches expired on December 22, 2018." Ex. 10. Exhibit 10, however, made no reference to Mr. Bencen's detailed December 22, 2018 letter of cure (Ex .59). Further, the record does not reflect that ISE ever provided Synogen with the additional thirty-day notice required by the License Agreement. Ex. 1 at ¶ 11.3.

43. Synogen disputed the purported April 5 termination (Ex.10) by letter dated May 2, 2019 (Ex.11) and pointed out, among other things, that ISE had no right to unilaterally terminate and that the April 5 termination was not effective because ISE failed to provide the additional thirty day notice required under the License Agreement.

44. Continued performance by Synogen and Nextgen. Following the exchange of letters regarding the purported termination, Synogen and Nextgen continued to perform their obligations under the Agreements. In May 2019, Synogen retained additional counsel at DLA Piper to assist in the prosecution of the Licensed Patents, as permitted and required by § 9.1 of the License Agreement. Grooms Decl. ¶ 56.

45. Patent Prosecution Continues. In conflict with its April 5, 2019 letter purporting to terminate Synogen, ISE, in June 2019, cooperated with Synogen and supplied Synogen's attorneys at DLA Piper with a Limited Power of Attorney to continue the patent work. See Exs. 37-38. However, by July 10, 2019, the relationship between Synogen and ISE deteriorated; ISE attempted to revoke the Limited Power of Attorney (Ex. 39) and continued to refuse to transfer the Licensed Know-How, preventing Synogen and Nextgen from moving forward with the manufacturing, marketing and sale of NeoMatrix.

46. Synogen initiates this arbitration. By letter dated July 15, 2019 and in

accordance with the License Agreement, Synogen notified ISE of its intent to initiated this arbitration. Ex. 57. The demand was filed by ISE and received by AAA on July 31, 2019. As noted, Nextgen was later added as a Claimant and ISE asserted ten counterclaims against Synogen.

47. Post-arbitration notice conduct. Immediately after receipt of notice of intent to initiate this arbitration, on July 16, 2019, Ms. Birg, writing on behalf of ISE, stated ISE's intent to revoke the Limited Power of Attorney provided to DLA Piper and demanded that Synogen cease prosecution of the patents, citing ISE's purported termination of the License Agreement. See Ex. 40.

48. Later, on Friday, October 4, 2019, ISE's CEO, Ryanne Early threatened to take actions against the patents at issue if Claimants continued to arbitrate this matter. See Grooms Decl. ¶¶ 57-60; the materials submitted by Claimants in support of the October 7 Motion for Interim Relief; and, Order No. 11 (Ex. 49). Thereafter, consistent with ISE's threat, DLA Piper received notice from the USPTO that ISE had formally revoked DLA Piper's power of attorney, and shifted power of attorney at the USPTO to Ms. Birg's firm[6], Nelson Mullins. *Id.*

49. Following the issuance of interim relief (Order No. 11, Ex. 49), on October 11, 2019, Synogen requested ISE cooperate in amending the power of attorney at the USPTO back to Synogen's chosen counsel, DLA Piper. *See* Ex. 80. ISE did not respond.

ISE Materially Breached the Agreements and Damaged Claimants

50. ISE breached the License Agreement in several material respects: it breached Section 5.2.1 of the License Agreement by failing to promptly transfer to Synogen the trade secret process, i.e. the Licensed Know-How; it breached Section 5.2.2 of the License Agreement by failing to cooperate in the prompt development of a manufacturing process; and, it breached Section 9.3 of the License Agreement by failing to cooperate with Synogen in the pursuit of the patents. This conduct also breached the licenses ISE granted in Section 2 and, by affirmatively interfering with

[6] Ms. Birg and Nelson Mullins withdrew from this arbitration by notice on September 25, 2019. Ex.17.

Synogen's patent prosecution and ability to develop a manufacturing process, violated Sections 5 and 9 of the License Agreement. ISE also breached Section 2.2.1 of the License Agreement when it refused to acknowledge that Synogen's sublicensee, Nextgen, has an option to survive the termination of the License Agreement.

51. To establish a breach of contract, a party must establish three elements: "(1) a valid contract, (2) a material breach, and (3) damages." *Havens v. Coast Florida, P.A.*, 117 So.3d 1179, 1181 (Fla. Dist. Ct. App. 2013). Here, the evidence clearly establishes all three elements as to ISE.

52. The License Agreement is a valid, enforceable contract that controls the Synogen-ISE relationship, ISE's arguments about Licensed Know-How, notwithstanding.

53. Meeting of the Minds. The evidence does not support ISE's argument that there was no meeting of the minds as to what the Know-How entailed. ISE's decellularization process, its Know-How, was its trade secret, which it represented it "controlled." Following the execution of the Agreement, ISE described its secret process as an algorithm (Transcript pp. 23-26) and confirmed that it would work with Synogen on the development of a manufacturing process based on this algorithm.

54. In his letter of December 22, 2018, Mr. Bencen, counsel for Synogen discussed ISE's proposal for the disclosure under License Agreement §5.2.2 so that the work on the manufacturing process could proceed. See Ex. 59 pp. 1-2. Mr. Bencen confirmed that the process was a known one when he stated: "Ms. Early/ISE/SEED is and has been already for some time decellularizing axolotl tissue to provide tissue according to Synogen's/Nextgen's specifications/ requirements." Id.

55. Every word used in a contract does not have to appear in the definitions section of an agreement to permit a meeting of the minds to occur, particularly where, as here, it is clear that the parties understood what was being discussed. *See Corp. Fin. Inc. v. Principal Life Ins. Co.*, 461 F. Supp. 1274, 2006 US Dist. Lexis 84542 (SD Fla 2006) at p. 17 (headnote 18) (use of language "willing to offer" and "contingent on premium requirements being satisfied" not fatal to finding meeting of minds as to agreement to pay bonus), cited by Respondent in its Post-Hearing Brief.

56. Here, ISE represented that it owned a method for decellularization of urodele derived tissue (Ex.1 §1.3) and agreed it would disclose it to Synogen, after the License Agreement was executed and effective. Ex. 1 § 5.2. ISE/SEED purported to use the Licensed Know-How to generate the very tissue that was provided to Synogen/Nextgen for submission to the FDA, leading to FDA approval. Ex. 59 (12/22/2018 Bencen letter at CLMTS006801 (p.4, footnote 1)). The Know-How is real and known. ISE has simply chosen not to provide it to Claimants as it is required to do.

57. It is undisputed that ISE never transferred the Know-How and never cooperated in connection with the development of a commercially viable manufacturing process and in so doing breached the Agreement.

58. ISE also breached the License Agreement by interfering with and refusing to cooperate in the patent prosecution efforts. Ex. 1 § 9.3 permits Synogen to utilize "counsel of its choice to prosecute the Licensed Patents" and requires that ISE "cooperate in all respects with [Synogen]'s efforts in preparing and prosecuting the Licensed Patents, and . . . have its employees appear before patent offices and submit declarations when requested." ISE is in breach of this obligation having revoked the limited power of attorney for DLA Piper and otherwise refusing to support Synogen's patent prosecution work.

59. ISE also breached Section 2.2.1 of the Synogen-ISE License Agreement which (Ex. 1) accords sublicensees, including Nextgen, the option to survive the termination of the prime Synogen-ISE License Agreement "at the Sublicensee's option."

60. Synogen and ISE expressly and unambiguously intended § 2.2.1 as a protection to sublicensees against disputes under the prime Synogen-ISE license. Grooms Decl. ¶¶ 19-20; See Ex. 3.

61. Following ISE's attempt to terminate the License Agreement, on June 27, 2019, Nextgen sent ISE written notice that if "the License Agreement between Synogen and ISE [is] deemed terminated, now or in the future, Nextgen intends, and reserves its right, to exercise its option under Section 2.2.1 of the License Agreement

and survive such termination." Ex. 12. ISE responded on July 16, 2019, refusing to acknowledge Nextgen's right of survival. Ex. 13.

62. Nextgen is a Third Party Beneficiary. Nextgen, in addition to Synogen, has standing to complain about ISE's breaches of the License Agreement, including ISE's refusal to acknowledge Nextgen's rights of survival, because Nextgen is plainly an intended third party beneficiary under the License Agreement.

63. "[T]o establish an action for breach of a third party beneficiary contract, [a party] must allege and prove the following four elements (1) existence of a contract; (2) the clear or manifest intent of the contracting parties that the contract primarily and directly benefit the third party; (3) breach of the contract by a contracting party; and (4) damages to the third party resulting from the breach." *Foundation Health v. Westside EKG Assoc.*, 944 So.2d 188, 194-95 (Fla. 2006) (internal quotation marks omitted).

64. A party is an intended beneficiary if the parties to the contract express, or the contract itself expresses, an intent to primarily and directly benefit the third party. *See Dingle v. Dellinger*, 134 So. 3d 484, 488 (Fla. Dist. Ct. App. 2014).

65. The License Agreement instructs Synogen to sublicense the Licensed Patents and Know-How to a third party and contains multiple provisions confirming that Nextgen is an intended beneficiary. Ex. 1 §§ 2.2 ("[Synogen] may grant, in its sole discretion, written Sublicenses to third parties which are not Excluded Sublicensees"); § 2.2.1 (gives Sublicensees the right, "at the Sublicensee's option," to survive termination of the prime Synogen-ISE licenses in the event of a dispute between Synogen and ISE); § 5.2.1 (contemplates that the Licensed Know-How will be shared with Synogen's Sublicensees).

66. Significantly here, the License Agreement specifically contemplated that Nextgen would be that third party Sublicensee. Ex.1 at Appendix A (providing explicitly for the formation and licensing of Nextgen).

67. Moreover, from the start, ISE, through Ms. Early, was well aware of Nextgen's intended central role in the development and commercialization of the technology and that Nextgen was relying on the Licensed Patents and Know-How to

perform that role. ISE was informed prior to the execution of the License Agreement, in May 2014, that Nextgen, not Synogen, would be responsible for covering "all past debt and all past and future fees that exist in association with preparation of the [Licensed Patents'] applications." Ex. 43. As a result, at the time of contracting, ISE was aware that Nextgen would be responsible for much of the financial consideration owed to ISE under the License Agreement. Id.; Ex. 1 § 4.1.

68. Consistent with this, under the License Agreement and Sublicense Agreement, Nextgen was a financial beneficiary retaining 97 to 98.5 percent of Net Sales from any product developed from the Licensed Patents. Ex. 2 ¶ 12. By contrast, under the agreements, Synogen and ISE each receive only 0.75 to 1.5 percent of Net Sales related to the commercialization of the licensed technologies. Id.; Ex. 1 § 4.2.

69. In sum, Nextgen was to be formed with the specific purpose of holding the rights under the License Agreement and acting as the key point in the development and commercialization of the technologies. Grooms Decl. ¶ 8, 23, 65. As contemplated, Nextgen took the lead relating to development and commercialization of the product efforts, with no complaint from ISE, while Synogen took the lead on patent prosecution with Nextgen covering the costs. Grooms Decl. ¶ 25.

70. ISE was fully aware Nextgen would bear significant costs payable to ISE under the License Agreement and, through Ms. Early, was intimately involved in the development and commercialization efforts surrounding NeoMatriX. Toothman Decl. ¶¶ 10-17.

71. For these reasons, Nextgen is a third party beneficiary of the License Agreement and, in refusing to acknowledge Nextgen's option to survive the termination of the License Agreement, ISE breached its obligations to both Synogen and Nextgen under both Agreements.

72. Materiality. ISE's breaches are plainly material as they go to the heart of the Agreements. *MDS (Canada) Inc. v. Rad Source Techs., Inc.*, 720 F.3d 833, 849 (11th Cir. 2013) (a material breach of contract under Florida law is material where that party's nonperformance "go[es] to the essence of the contract."); *Faro Techs., Inc. v. Brainlab, U.S.A, Inc.*, 12-177, 2013 WL 12361030, at *2 (M.D. Fla. Jan. 16, 2013)

(material breach has occurred when "an injured party has sustained a substantial injury due to [that] breach.").

73. Synogen's and Nexgen's rights to exercise the license rights granted with respect to the Licensed Patents and Licensed Know-How are at the center of the Agreements (*See Rad Source Techs., Inc.,* 720 F.3d at 849) as is ISE's obligation to cooperate in the patent prosecution efforts and to meaningfully participate in the development of a manufacturing process for product developed by Synogen and Nextgen. ISE's refusal to participate in these efforts and its effort to terminate Synogen and eliminate its Sublicensee Nextgen after both spent over four years and millions of dollars developing a product, which could be commercialized, frustrates the very purpose of the Agreements.

74. Harm and Damages. As a result of ISE's refusal to deliver the promised decellularization process, NeoMatriX has yet to be taken to market, and the significant effort, time and capital expended to produce an FDA-approved product, is now at risk. Grooms Decl. ¶ 49; Toothman Decl. ¶ 28.

75. ISE's breaches delayed the launch of NeoMatriX by at least fourteen months, causing significant harm to Synogen and Nextgen. For calendar year 2019, NeoMatrix sales were reasonably expected to be upwards of $1 million. Ex. 32; Toothman Decl. ¶¶ 28-30.

76. Further, because the decellularization process must substantially conform to the process promised by ISE in order to comply with the already FDA cleared 510(k) Claimants may be required to amend and resubmit substantial regulatory materials to again gain clearance by the FDA. The reasonable forecast for costs of resubmission is $549,000. Ex. 14; Toothman Decl. ¶¶ 33-35.

77. Claimants began to take steps to mitigate their damages and to develop an alternative manufacturing process, when ISE would not provide the Licensed Know-How or participate in the development of the process. To date, Nextgen has expended $653,683.95 towards the creation of an efficient and commercially viable manufacturing process to replace the one promised by ISE to Synogen. Toothman Decl. ¶ 32-34. These steps by Nextgen were reasonable and appropriate to attempt

to mitigate the harm caused by ISE's decision to essentially walk away from its obligations under the License Agreement. In addition, Nextgen has spent $214,000.00 in marketing costs that were wasted due to the delays arising from ISE's breaches. Toothman Decl. ¶ 31.

78. Synogen also alleges that ISE's breaches placed it in breach of its obligations to Nextgen, such that it is required to forfeit 7.9 percent of its shares in Nextgen, valued at $3.1 million. Grooms Decl. ¶ 52. However, Synogen has pointed to no provision of the Sublicense Agreement between Synogen and Nextgen (Ex. 2) that mandates this financial consequence and has provided no documentation of its actual occurrence. Accordingly, I do not address these damages here.

79. ISE's conduct continues to damage Claimants, meaning that Synogen and Nextgen may be entitled to additional damages, including recovery of the stock forfeit described above, if ISE fails to cure its breaches and comply with its contractual obligations going forward.

Respondent ISE's Defenses Have No Basis

80. ISE's defense is essentially that Synogen breached their Agreement, ISE properly terminated it and, therefore, ISE cannot itself have breached the License Agreement. ISE's defenses appear to be based on the same arguments as its Counterclaims.

81. Although Respondent's Counterclaims fail for failure to pay the AAA fees and are barred due to ISE's sanctionable conduct, as discussed below, Respondent, citing Rule 57, quite correctly notes in its Post-Hearing Brief that dismissal of a counterclaim for failure to pay fees does not preclude that party from providing a defense to the claims asserted by the party initiating the arbitration.

82. Effect of Agreement's Bar to Claims Not Asserted. Although I address the defenses on the merits, I note that Respondent, in its Post-Hearing Brief did not discuss the term of the Licensing Agreement which imposes a preclusive effect where a party fails to file and submit compulsory claims as defined in the Federal Rules of Civil Procedure. Ex. 1 at § 13.4 ("Any claim not submitted or filed as required is forever barred"). This language is of importance because Respondent's

Counterclaims are compulsory and the facts underlying those Counterclaims are essentially the same facts cited by Respondent to defend itself against Claimants' claims, i.e., that Respondent was excused from performing because Claimants allegedly breached their agreements and the Agreements were properly terminated. ISE's failure to pursue the Counterclaims, whether for failure to pay fees or otherwise, results in a bar to its arguments and the facts it alleges underlie those claims due to this term of the License Agreement; and, there is a consequential preclusive effect on ISE's use of those arguments and facts as defenses to the Claims asserted here.

83. Nonetheless, I examined the merits of the defenses and, even though I considered everything submitted by Respondent in this matter, even if submitted in violation of the rules applicable to this matter or the orders entered during this proceeding, Respondent's arguments and proofs as to its defenses fail as a matter of law and fact.

84. ISE's attempt to terminate the License Agreement over four years into its term, after Synogen and its sublicensees invested upwards of $7.5 million into the development of the technology, was not well-founded and was clearly a bad faith effort to avoid the bargain it struck years before.

85. ISE's November 7, 2018 letter of "breach" came only after Synogen's repeated and formal requests for the transfer of the Know-How and was the first time, four years into the term of the License Agreement, that ISE raised any of these supposed breaches. Grooms Decl. ¶ 43. Each of the items listed by ISE were curable and, separately or collectively, were not sufficiently material to warrant the termination of the License Agreement.

86. Cure. Mr. Bencen's December 22, 2018 letter (Ex. 59) makes clear that Synogen cured any deficiencies. Only uncured delinquencies in reporting or payment obligations and material breaches trigger ISE's ability to terminate. Ex. 1 §11. It is notable that Ms. Birg's April 5, 2019 letter (Ex. 10) purporting to terminate the License Agreement, merely lists the same sections recited in the initial notice of breach letter (Ex. 9) dated November 7, 2018 and broadly declares that no cure has

been effected, omitting any explanation of how that can be in light of Mr. Bencen's detailed letter of December 22, 2018. Ex. 59.

87. A close examination of ISE's contentions, including its more refined version of those contentions contained in its September 16, 2019 Amended Answer and Counterclaim (Ex. 29), eliminates any doubt about the lack of any genuine basis for ISE's termination efforts.

88. Payment Reports. ISE claimed that Synogen breached Section 2.2.3 of the License Agreement because Synogen failed to produce reports documenting payments it had received from its Sublicensees. Ex. 29. But, in making this argument, ISE misstated the License Agreement. It provides:

> [Synogen] . . . agrees to forward to [ISE] annually a copy of all reports **received** by [Synogen] from its Sublicensees pertinent to payments received under said Sublicense.

License Agrmt. (Ex. 1), § 2.2.3 (emphasis added).

89. Synogen was only required to provide ISE the reports that it received from its sublicensees related to payments it obtained under a sublicense. Synogen never received such reports from Nextgen and the License Agreement provides no obligation on Synogen to manufacture, or demand, such reports. Toothman Decl. ¶ 41. Accordingly, Section 2.2.3 was not breached by Synogen.

90. Insurance. ISE also claimed that Synogen breached Section 14.2 of the License Agreement. Section 14.2 of the License Agreement provides:

> Prior to the first use of a Product in a human and thereafter annually between January 1 and January 31 of each year, [Synogen] will present evidence to [ISE] that [insurance] coverage is being maintained with [ISE] listed as an additional insured.

License Agrmt. (Ex. 1), § 14.2(ii) (emphasis added).

91. At this point, NeoMatriX has not yet been taken to market and it is unclear that any obligation to list ISE as an additional insured or submit proof of insurance has been triggered. Consequently, Section 14.2 has not been breached. Toothman Decl. ¶ 42. In addition, breach of the provision, under the circumstances

here, with no indication of harm or damage, would not be material.

92. Development Reports. ISE also claimed Synogen breached § 3.2 regarding Development Reports documenting the efforts taken to develop the Licensed Patents. Mr. Bencen's letter addresses this and a cure was effected to the extent there was any breach. Ex. 59. Nowhere does ISE explain how this remained uncured.

93. In sum, ISE's defenses fail. ISE's supposed termination is ineffective and the License Agreement remains in full force and effect both as to Synogen and Nextgen.

ISE's Counterclaims are Barred

94. Failure to pay AAA filing fees. ISE's ten Counterclaims are subject to dismissal for failure to pay the required AAA filing fees. Rule 57(b) (where one party refuses to comply with payment obligations, the Arbitrator has authority to "limit[that] party's ability to assert or pursue their claim[s]."). By letter dated October 8, 2019, the AAA notified ISE that its Counterclaims would "be returned [and] not presented to the arbitrator" if ISE continued to refuse to pay its fees by October 15. Ex. 68. ISE did not respond to this notice and failed to pay the required fees. Accordingly, ISE's Counterclaims are dismissed for failure to pay fees.

Relief Granted to Synogen and Nextgen

95. Injunctive Relief. Synogen and Nextgen are entitled to permanent injunctive relief as to ISE in the following respects: (a) ISE is to be enjoined from violating Section 5 of the License Agreement by, in accordance with § 5.2.1 of the License Agreement, transferring to Synogen within 10 business days from the entry of this Final Award, the Licensed Know-How and all information owned, controlled or otherwise in ISE's possession that may be relevant to the development of a commercially viable manufacturing process contemplated by the License Agreement; ISE is directed to otherwise cooperate with Synogen and Nextgen in the development of this process; and, (b) ISE is prohibited from violating the patent prosecution provisions of the License Agreement by being prohibited from directly or indirectly, interfering with or impeding Synogen's prosecution and preparation of the Licensed

Patents through counsel of Synogen's choice, and is directed to cooperate with Synogen and its counsel, including executing any documents deemed necessary by Synogen to enable its continued work on the patent prosecution and preparation.

96. Declaratory Relief. Synogen and Nextgen are further entitled to declaratory relief as to Nextgen's rights should ISE attempt to terminate the License Agreement in future. To be entitled to declaratory relief, a party must show [it] is in doubt as to some right or status and that [it] is entitled to have such doubt removed." *Palumbo v. Moore*, 777 So.2d 1177, 1178 (Fla. Dist. Ct. App. 2001); *Orange Cnty. v. Expedia, Inc.*, 985 So.2d 622, 627 (Fla. Dist. Ct. App. 2008); *Orange Cnty. v. Expedia, Inc.*, 985 So.2d 622, 627 (Fla. Dist. Ct. App. 2008). Here, Nextgen clearly has the right at its sole option to survive the termination of the License Agreement and to enter a direct license with ISE substantially the same terms contained in the License Agreement. Ex. 1 § 2.2.1.

97. Damages. ISE has the opportunity to avoid exposure to additional damages which Claimants will incur should ISE continue to breach the Agreements and ignore the injunctive relief granted here. At present, Nextgen is entitled to recover the total of $867,683.95 from ISE, representing the costs incurred to date in the attempt to develop a manufacturing process and the marketing expenses that were wasted because ISE breached, leaving the Claimants with no product to market.

98. Attorneys' Fees and Costs and Sanctions. The undersigned has the ability to award costs and fees to the prevailing party in this matter under AAA Rules. Under Rule 47(d), "[t]he award of the arbitrator[] may include: . . . (ii) an award of attorneys' fees if all parties have requested such an award or it is authorized by law or their arbitration agreement." R47(d) (emphasis added). Here, all parties including ISE (Ex. 29 at p. 15) expressly requested attorneys' fees. In recognition of this fact, Order No. 2 acknowledges that a Final Award "may include an award of attorneys' fees and costs." Ex. 18 at ¶ 14. See also Ex. 78 (the Parties' jointly proposed scheduling order submitted September 10, 2019).

99. The undersigned is also authorized to award fees and costs as a sanction. See Rule 58 (a) ("the arbitrator may, upon a party's request, order appropriate

sanctions where a party fails to comply with its obligations under these rules or with an order of the arbitrator."); *Marshall & Co. v. Duke*, 114 F.3d 188, 190 (11th Cir. 1997) ("[A]rbitrators have the power to award attorney's fees pursuant to the "bad faith" exception to the American Rule."); *id* ("[E]very judicial and quasi-judicial body has the right to award attorneys' fees under the common law bad faith exception to the American Rule."); *First Auto. Serv. Corp. v. First Colonial Ins. Co.*, No. 07-682, 2010 WL 2431889, at *5 (M.D. Fla. Jul. 16, 2010) (applying *Marshall* to an arbitration governed by the Federal Arbitration Act); Rule 23 ("[I]n the case of willful non-compliance with any order issued by the arbitrator, [the arbitrator has authority to] draw[] adverse inferences, exclud[e] evidence and other submissions," among other sanctions. Here, Claimants have requested sanctions repeatedly, including the bar of ISE's counterclaims. Ex. 24.

100. To date, the undersigned, in deferring ruling on those requests until the record was fully closed, has taken to the extreme the requirement of Rule 58(b) that the party that may be subject to a sanction be given the opportunity to respond prior to any determination regarding the sanctions application. While frustrating for Claimants, it has been only fair to provide ISE with repeated and explicit opportunities to explain itself and to defer a decision on sanctions until the record is closed.

101. Unfortunately, ISE ignored the multiple requests to provide its position and instead disengaged from much of this Arbitration. The following summarizes the facts and circumstances warranting sanctions.

102. Breach of the agreement to arbitrate. ISE breached its agreement to arbitrate and ignored the AAA Rules applicable thereto. After insisting on a schedule even more abbreviated than the Parties' agreement required, ISE, both before and after the withdrawal of its counsel, ignored the expedited schedule established in part to work around Ms. Early's alleged unavailability. Regrettably, ISE has made clear throughout this proceeding that its schedule and convenience is the only one that matters and that it will ignore the rules and rulings of this process.

103. Failure to participate in scheduled mediation. This matter was set for

mediation September 23, 2019. That morning, ISE, through counsel, postponed the mediation on the grounds that Ms. Early was "too ill to travel". Ex. 16. Later that day, ISE's counsel informed the mediator and the AAA, but not opposing counsel or the undersigned, that the "clients reached a settlement agreement" by phone. Ex. 16. After the AAA contacted opposing counsel, it was learned that the matter was not in fact settled. Ex. 16.

104. Failure to meet deadlines. That same day, September 23, 2019, ISE failed to file any response to the Amended Demand filed by Claimants. The undersigned communicated with ISE's counsel over the next few days in an effort to determine the reasons for the lack of a responsive document without success. See, e.g, Ex. 64.

105. Failure to Engage Following Withdrawal of ISE Counsel. On September 25, 2019, ISE's counsel filed a Notice of Change of Representation, effectively withdrawing from representing ISE in this proceeding. Ex. 17. At that time, Ms. Early was designated as the contact for ISE. But, Ms. Early never meaningfully engaged in this proceeding and essentially withdrew ISE from it.

106. Revocation of participation in direct exchange. Given the approaching deadlines in this matter, including production of documents on September 26 (pursuant to expedited rulings on objections), a status call on September 27 and the hearing itself set to begin October 23, the undersigned reached out to Ms. Early to be sure she had been informed of all deadlines as well as the consequences of not meeting them. See Ex. 21. ISE did not respond to this inquiry; instead, on September 27, 2019, ISE revoked its earlier agreement to the direct exchange program, cutting off direct communication between the arbitrator and the Parties. This meant that, in this fast moving case, all communications required an additional step and had to be directed through the AAA. See Order No. 8 (Ex. 22) at ¶4.

107. No request for postponement. Since late September, Ms. Early has occasionally and selectively communicated with the AAA on behalf of ISE making it clear that ISE received and understood communications from AAA and the undersigned, including that the hearing would be convened consistent with the

schedule ISE agreed to in this matter. ISE at no time requested postponement of the hearing or explained its failure to meet deadlines, despite receiving multiple communications about the consequences of ignoring them. See Order No. 11 (Ex. 49) ¶ 4 ("the AAA has reached out to Ms. Early . . . requesting a response as to Respondent's intent with regard to this Arbitration. Respondent has ignored these requests."), ¶ 5 ("Respondent has ignored deadlines in this matter and refused to engage with Claimants in the exchanges required to make this arbitration process work."), *id.* (outlining Respondent's disregard for the Orders and deadlines in this Arbitration).

108. ISE's Failure to Produce Documents. ISE submitted 14 document requests to Claimants in this Arbitration. The undersigned ruled on the objections by Claimants and directed Claimants to produce documents. See Order No. 7 (Ex. 47). During a very short time frame, Claimants reviewed roughly 25,000 documents, and produced nearly 19,000 pages of responsive, non-privileged materials. In contrast, ISE chose to ignore its similar deadline and produced nothing.

109. ISE ignores opportunities to cure. Although ISE never requested an extension to produce, it was provided essentially with three deadlines: the original deadline in Order No. 2 (Ex. 18); a second deadline to cure the failure to produce, established following Claimants' motion to compel ISE's production (with the note that ISE's continued failure to adhere to deadlines may lead to sanctions) in Order No. 8 (Ex. 22) ¶6; and, a final deadline to produce established in Order No. 9 (Ex.25) in connection with Claimants' attempt to use subpoenas and additional requests to obtain documents. Ms. Early actively avoided service of the subpoenas issued from this Arbitration. See Ex. 72. ISE, SEED and Ms. Early produced nothing.

110. Knowledge of Sanctions. ISE was repeatedly notified that it could not ignore deadlines without risking sanctions. See, e.g., Order No. 8 (Ex. 22) at ¶ 7; Order No. 9 (Ex. 25) ¶¶ 3-4; Order No. 10 (Ex. 48) ¶8 ("Respondent's conduct at this point appears to be willful non-compliance with the spirit and letter of this proceeding in violation of Respondent's obligations. I reserve the right to impose sanctions based on this conduct.").

111. Yet, ISE refused to participate in telephonic status conferences, never requested any extension to permit it to engage new counsel, never offered any explanation for its repeated missed deadlines, and never explained its abrupt shift from aggressively pursuing its position to almost complete disengagement overnight.

112. Then, on October 4, 2019, prior to the hearing set in this matter, Respondent threatened to take actions against the patents at issue and demanded that Claimants cease and disengage from the arbitration of this matter, requiring the issuance of an order granting interim relief to Claimants. Order No. 11 (Ex. 49).[7]

113. In sum, ISE essentially disregarded all deadlines after September 23, 2019, repeatedly ignored the content of Orders as well as messages from the Arbitrator, many of which were intended to ensure that ISE was treated fairly. ISE was aware of the need to respond as well as its responsibilities in this proceeding.

114. Now that the record in this matter is closed, I conclude that ISE's continued misconduct in this proceeding was in bad faith and warrants a full award of Claimants' attorneys' fees and costs to Claimants. This conduct appears to be an extension of ISE's effort to avoid the consequences of its contractual obligations without just cause after the Claimants here performed theirs.

115. Claimants have filed documentation demonstrating that their fees and costs amount to $903,116.93, consisting of $844,051.25 in attorneys' fees and non-AAA costs and fees of $ 59,065.73. Exs. D and E. ISE has offered no evidence to dispute the reasonableness of these amounts and I therefore conclude that the amounts are reasonable, particularly given the accelerated nature of this matter and the conduct of ISE requiring Claimants to file multiple protective motions as well as to defend its counsel from a motion to disqualify.

116. In addition, based on the egregious nature of ISE's conduct in this proceeding, and, in the alternative, I further conclude that ISE's Counterclaims should be barred and otherwise dismissed with prejudice, as a sanction. See also Ex. 1 at § 13.4 which bars compulsory counterclaims regardless of whether they are

[7] According to Respondent's Post-Hearing Brief, the court confirmed this Interim Award (Order no. 11 (Ex.49)) on November 15, 2019.

asserted. To hold otherwise would condone ISE's unabashed disrespect for its contract obligations, this process and the rule of law.

Disposition of Claims

117. Synogen and Nextgen Claims. In summary, I conclude that ISE breached the License Agreement by failing to transfer the Know-How (Claim 1) and refusing to cooperate in the patent prosecution (Claim 2). I also conclude that ISE breached the covenant of good faith and fair dealing (Claim 3). I do not conclude that ISE violated Florida's Unfair Trade Practices Act (Claim 4) as this was not argued by Claimants in their Hearing Briefs. I further conclude that ISE breached the License Agreement by failing to recognize Nextgen's rights of termination survival under the License and Sublicense Agreements (Claim 5). Synogen and Nextgen are entitled to declaratory and permanent injunctive relief outlined above and damages as well as to be reimbursed their attorneys' fees and costs associated with this proceeding.

118. ISE's Counterclaims. ISE's Counterclaims are barred due to its failure to pay its filing fees and the preclusive effect of the License Agreement for failure to pursue those claims here. These claims are also barred as a sanction. To be clear, ISE is not entitled to the declaratory judgments it requested, i.e. that it properly terminated the License Agreement (Claim 1), that Section 5.2 of the License Agreement (regarding the transfer of Licensed Know-How) was unenforceable (Claim 2) or that ISE is not obligated to enter into a direct license with Nextgen (Claim 3). Synogen did not breach Section 9.1 of the License Agreement (regarding patent prosecution) (Claim 4) or the provision relating to payment to ISE for consulting time (Claim 5). Further, I do not find that Synogen breached its NDA with ISE (Claim 6). Next, ISE is not entitled to specific performance by Synogen in the form of an accounting (Claim 7) or injunctive relief and is not entitled to recover damages from Synogen relating to the alleged failure to allow an accounting (Claim 8). ISE is not entitled to recover its attorneys' fees (Claim 9). ISE's claim regarding the disqualification of DLA Piper (Claim 10) was separately dealt with in Order No. 3,

which order is incorporated herein by reference to the extent necessary to make this Final Award complete.

For the foregoing reasons the Arbitrator finds and declares that:

1. The American Arbitration Association has jurisdiction over this dispute;

2. The Arbitrator finds in favor of Claimants Synogen Management Group, Inc. and Nextgen Biologics, Inc., and against Respondent ISE Professional Testing & Consulting Services, Inc. on all claims and counterclaims in this matter;

3. The Arbitrator issues the following declaratory judgment:

   A. The Synogen-ISE License Agreement and the Synogen-Nextgen Sublicense Agreement are enforceable contracts and remain in full force and effect. Claimants hold the exclusive license to the Licensed Patents, and are permitted to practice the Licensed Patents;

   B. Nextgen has the right at its sole option to survive the termination of the License Agreement by ISE and to enter a direct license with ISE on substantially the same terms contained in the License Agreement.

4. The Arbitrator orders the following permanent injunction against ISE :

   A. ISE is enjoined from breaching Section 5 of the License Agreement. Specifically, in accordance with § 5.2.1 of the License Agreement, ISE shall transfer promptly to Synogen, and not later than 10 business days from the entry of this Final Award, the Licensed Know-How and all information owned, controlled or otherwise in ISE's possession that may be relevant to the development of a commercially viable manufacturing process contemplated by the License Agreement; ISE is directed to otherwise cooperate with Synogen and Nextgen in the development of this process;

   B. ISE is further prohibited from breaching the provisions of the License Agreement relating to the prosecution of the patents. Specifically, ISE is prohibited from directly or indirectly, interfering with or impeding Synogen's prosecution and preparation of the Licensed Patents through counsel of Synogen's choice, and is directed to cooperate with Synogen

and its counsel, including executing any documents deemed necessary by Synogen to enable its continued work on the patent prosecution and preparation.

5. Claimants are entitled to and ISE shall pay damages and interest as follows:

A. Compensatory damages to be paid to Nextgen in the total amount of $867,683.95 (consisting of $653,683.95 for Claimants' costs to date in their attempt to create a manufacturing decellularization process without the Licensed Know-How and $214,000 for Claimants' costs to date relating to marketing and sales efforts in anticipation of the product's launch);

B. Interest at a rate of 6.33 percent per annum to accrue on this amount from the date of this Final Award till payment.[8]

6. Claimants are entitled to and ISE shall pay Claimants their reasonable attorneys' fees and costs relating to this Arbitration in the amount of $903,116.93. The Administrative Fees and Expenses of the AAA totaled $24,875.00. The Arbitrator's compensation and expenses totaled $60,037.42. Therefore, ISE shall pay Claimant for the AAA Fees and Arbitrator's compensation the amount of $74,598.67.

7. Within thirty days of the date of this Final Award, Respondent shall pay Claimant the total of the amounts due under this Award, including the fees and costs and interest; and

8. This Award is in full settlement of all claims submitted to this Arbitration by the Parties. All submitted claims not expressly granted herein are hereby denied.

Dated: December 3, 2019

Catharine Biggs Arrowood Arbitrator

[8] *See SunTrust Inv. Servs., Inc. v. Thorlton*, No. 617CV182ORL22GJK, 2017 WL 11025662, at *3 (M.D. Fla. May 17, 2017) ("In Florida, interest from the date of the arbitral award is required where the award liquidated the amount owed.") (Internal quotations omitted); Fla. Stat. Ann. § 55.03 (West).

EXHIBIT 2

Vernick, Scott

From: AngelaValedon@adr.org
Sent: Tuesday, December 03, 2019 3:05 PM
To: REarlyISE@gmail.com; adavis@bwsmiplaw.com; Vernick, Scott; Huh, John; kwimberly@bwsmiplaw.com
Cc: cbarrowood@parkerpoe.com
Subject: Synogen Management Group, Inc. v. ISE Professional Testing & - Case 01-19-0002-3786
Attachments: CM118.pdf; Final Award .pdf

[EXTERNAL]

Hello,

Please review the attached correspondence regarding the above-referenced case.

Feel free to contact me with any questions, comments or concerns you have related to this matter.

Thank you.

AAA Angela Romero Valedon, Esq.
Director of ADR Services

American Arbitration Association

T: 786 406 6642 E: AngelaValedon@adr.org
100 SE 2nd St., Ste. 2300, Miami, Fl 33131
adr.org | icdr.org | aaamediation.org

The information in this transmittal (including attachments, if any) is privileged and/or confidential and is intended only for the recipient(s) listed above. Any review, use, disclosure, distribution or copying of this transmittal is prohibited except by or on behalf of the intended recipient. If you have received this transmittal in error, please notify me immediately by reply email and destroy all copies of the transmittal. Thank you.