

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 Order¹." 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 ruling².

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 1³. 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 ¶11-12⁵.

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. Birg⁶ 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.

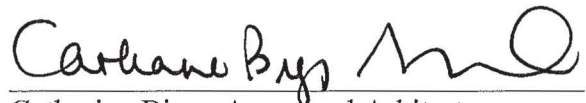
12. Based on the above, Claimants have sufficiently shown:

- 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