UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

REGENX SCIENCE, INC.
Petitioner,

v.

NEXTGEN BIOLOGICS, INC.
Patent Owner.

Case No: IPR2025-00621

U.S. Patent No. 11,660,376

DECLARATION OF ELISABETH CORSON

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1085	Excerpted ’376 Patent Prosecution History (February 26, 2020-January 24, 2023)
1086	July 16, 2019 Letter from ISE
1092	October 9, 2019 Interim Injunctive Relief Award

I. INTRODUCTION

1. I am the Chief Executive Officer of RegenX Science, Inc. ("RegenX" or "Petitioner"), a biotechnology company that I co-founded in 2016. RegenX is focused on developing regenerative materials derived from extracellular matrix (ECM), including ECM grafts sourced from urodeles.

2. As CEO of RegenX, I have been directly involved in RegenX's licensing, development, and commercialization efforts related to the urodele ECM technology.

3. I submit this declaration in my capacity as CEO to provide information concerning licensing relationships concerning U.S. Patent No. 11,660,376 ("'376 patent"), RegenX's involvement in related patent prosecution, and the circumstances leading to RegenX's decision to file a petition for *inter partes* review. I have personal knowledge of the facts set forth in this declaration, and if called as a witness, could and would testify competently to them.

4. I understand NeXtGen Biologics, Inc. ("NeXtgen" or "Patent Owner") has argued in its request for discretionary denial of institution of the instant *inter partes* review that RegenX had settled expectations about the validity of the '376 patent based on our prior licensing relationship. From my perspective, that claim is inconsistent with the actual licensing history, the instability that has characterized

our licensing relationship, and RegenX's role in prosecution.

II. LICENSING HISTORY

5. RegenX held a sublicense to urodele extracellular matrix (ECM) technology—including the related patent and/or patent application portfolio and associated know-how ("Licensed Technology")—during two distinct periods: from 2017 to 2020 with Synogen Management, Inc. ("Synogen"), and again from 2022 to 2024 with NeXtGen Biologics, Inc. ("NeXtGen).

6. The sublicensed patent portfolio was directed biologic materials derived from urodele amphibians, particularly axolotls, processed through decellularization to remove cellular components to reduce antigenicity. The resulting ECM material was intended to support tissue repair and regeneration, with potential applications in medical devices and cosmetic products. The Licensed Technology included the patent application which ultimately became the '376 patent, which claims decellularized ECM compositions and related materials such as grafts, implants, and coatings. RegenX's sublicenses were limited to cosmetic uses of these materials.

7. The agreements governing rights to the Licensed Technology have involved multiple parties – ISE Professional Testing & Consulting Services, Inc. ("ISE"), Synogen, NeXtGen, and RegenX – and undergone significant and repeated changes since from the first agreement was entered into.

8. ISE was the original assignee of the Licensed Technology. In 2014, ISE entered into a license agreement with Synogen (the "Synogen License") that included two parts: (i) an exclusive license to the urodele ECM patent portfolio, which included the application that matured into the '376 patent ("Licensed Patents") and (ii) a non-exclusive license to trade secret ECM decellularization technology defined as "Licensed Know-How." Ex. 1063, September 23, 2014 Synogen License, §2.1.

9. Under the Synogen License, Synogen, as the licensee, was to commercialize ISE's urodele ECM technology, and as part of that effort, was responsible for prosecution and maintenance of the Licensed Patents. Ex.1063, September 23, 2014 Synogen License, § 9.1. Synogen was not allowed to "delegate this responsibility to a Third Party or an Affiliate." *Id.* ISE, as the licensor, retained a limited right to comment. *Id.* The Synogen License stated, in relevant part:

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 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.

Id.

10. The Synogen License also addressed what would happen to downstream sublicensees if ISE terminated its agreement with Synogen. Section 2.2

stated: "in the event of termination…by [ISE], any Sublicense [e.g., RegenX and NeXtGen] shall, at the Sublicensee's option survive such termination…provided that Sublicensee and [ISE] enter into a direct license on substantially the same terms as the sublicense." Ex.1063, September 23, 2014 Synogen License, § 2.2.

11. In 2014, Synogen entered into a sublicense agreement with NeXtGen, granting NeXtGen exclusive rights to develop diagnostic and therapeutic medical device applications under the Licensed Patents (the "NeXtGen License"). Ex. 1064, October 15, 2014 NeXtGen License. Under the NeXtGen License, Synogen retained prosecution rights. *Id.*, §9.1.

12. [redacted]

13. [redacted]

[redacted]

14. Before any of the Licensed Patents had even issued,[1] the licensing arrangement began to break down, raising concerns about whether any sublicensees—including RegenX—would retain any licensing rights going forward.

15. In April 2019, ISE sent Synogen a notice of termination of the Synogen License, citing alleged breaches of contract, including deficiencies in Synogen's reporting obligations. Ex. 1067, April 5, 2019 Termination Letter.

16. In response, Synogen and NeXtGen initiated an arbitration proceeding, alleging that ISE had obstructed prosecution of the Licensed Patents, failed to provide promised manufacturing know-how, and refused to recognize NeXtGen's right to continue as a sublicensee following termination of the Synogen License. Ex. 1068, September 16, 2019 Amended Demand for Arbitration.

17. ISE responded to the arbitration by threatening to "undermine, abandon, or invalidate" the Licensed Patents if the proceeding moved forward. Ex. 1069, October 15, 2019 Emergency Motion to Confirm Arbitration Award, at 5. ISE then

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[1] U.S. Patent No. 10,617,790 (the "'790 patent") was the first to issue on April 14, 2020. The '376 patent issued on May 30, 2023.

revoked Synogen's power of attorney before the USPTO and attempted to take control over prosecution of the patents. *Id.*; Ex.1092, October 9, 2019 Interim Arbitration Award, 4-5; Ex. 1070, December 3, 2019 Final Arbitration Award, 10-11; Ex. 1086, July 16, 2019 Letter from ISE.

18. Synogen and NeXtGen ultimately obtained arbitration awards that granted injunctive relief against ISE. The arbitrator ordered that ISE was enjoined from "directly or indirectly, interfering with or impeding Synogen[]'s prosecution and preparation of the Licensed Patents." Ex. 1070, at 27–28.; Ex. 1092, 5.

19. The dispute did not end with the arbitration award. ISE continued to violate the terms of the injunction, prompting Synogen and NeXtGen to file a separate lawsuit to enforce the arbitration award in the Circuit Court of the Ninth Judicial Circuit in and for Orange County, Florida (Case No. 2019-CA-012605-O). Exs. 1069-1071.

20. Synogen and NeXtGen ultimately prevailed in that action. The court entered a final judgment in their favor in March 2020. Ex. 1072, March 31, 2020 Final Judgment. Following that decision, ISE filed for bankruptcy. Ex. 1073, May 5, 2020 Notice of Bankruptcy.

21. Following the litigation and bankruptcy, ISE, Synogen, and NeXtGen entered into a settlement agreement. Ex. 1074, August 7, 2020 Settlement Agreement; Ex. 1075, September 5, 2020 Order Approving Settlement.

22. As part of the settlement, Synogen acquired the rights to the Licensed Patents from ISE and then assigned them to NeXtGen. *Id.*; Ex. 1076, October 5, 2020 Synogen Assignment.

23. RegenX was not included in the negotiations and did not have an opportunity to participate in determining the settlement's terms, even though RegenX held a sublicense to the Licensed Patents.

24. The settlement agreement stated that "the Prior Agreements[, including the RegenX License] [were] … terminated and cancelled, in all respects with no further or surviving obligations." Ex. 1074, August 7, 2020 Settlement Agreement, at 8-9.

25. As a result, RegenX lost all rights to the Licensed Patents and was forced to renegotiate a new license on substantially different terms—a process that ultimately took nearly two years.

26. [redacted]

27. [redacted]

28. [redacted]

29. [redacted]

30. [redacted]

31. [redacted]

32. [redacted]

III. PROSECUTION OF THE LICENSED PATENTS

33. I understand that NeXtGen further argues that RegenX's actions during prosecution created a settled expectation that the claims of the Licensed Patents, including the '376 patent, were valid. In reality, RegenX had minimal involvement in the prosecution of the Licensed Patents. RegenX was not responsible for drafting or prosecuting the claims, and any role we played was limited to monitoring and occasional, optional input.

34. First, at no point between 2017 and 2024 did RegenX have the right under the applicable agreements to prosecute the Licensed Patents. [redacted]

35. In fact, when RegenX filed an application in 2019 directed to cosmetic uses of urodele ECM[2]—a field exclusively licensed to RegenX under the Synogen License—to protect its interests, ISE's counsel took over shortly thereafter, and the application was expressly abandoned by Synogen's counsel before any office action issued. Ex. 1081, U.S. Patent Application No. 16/399,068 Prosecution History (September 13, 2019 Power of Attorney); Ex. 1082, U.S. Patent Application No. 16/399,068 Prosecution History (July 31, 2020 Abandonment). That brief episode does not support a conclusion that RegenX played a substantive role in developing or affirming the validity of the patent claims.

36. Moreover, RegenX did not retain outside counsel to monitor the prosecution of the Licensed Patents until 2019. By that point, five years had passed since the '790 patent (the parent to the '376 patent) was first filed, and the patent already was approaching issuance.

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[2] As noted above, when the application was filed in 2019, Synogen had the sole responsibility to prosecute and maintain the Licensed Patents and was not allowed to "delegate this responsibility to a Third Party or an Affiliate" under the Synogen License. Ex.1063, September 23, 2014 Synogen License, § 9.1; *see also*, Ex.1065.

37. At the time our counsel became involved, the majority of the claims in the ’790 patent had already been allowed. Ex. 1083, January 10, 2019 Non-Final Rejection, 22-30, 32-39. The remaining claims were allowed shortly thereafter, following a reorganization in which certain claims were rejoined and rewritten as dependent claims to the allowed claims. Ex. 1084, Excerpted ’790 Prosecution History, 9-11, 20-23. RegenX had no meaningful involvement in drafting or submitting those claims.

38. Similarly, the ’376 patent was prosecuted by Synogen and NeXtGen. As with the ’790 patent, they were responsible for drafting and filing the claims under the terms of the agreements.

39. Based on my understanding of the file history, the only substantive office actions in the application underlying the ’376 patent—a double patenting rejection and a restriction requirement—were addressed by filing a terminal disclaimer and withdrawing certain claims. Ex. 1085, Excerpted ’376 Patent Prosecution History. There was no substantive response, and RegenX did not provide any meaningful input. Our involvement remained observational.

40. Accordingly, RegenX had only a limited role throughout this process. We were not meaningfully involved in the drafting or prosecution of the patent claims, and despite our efforts to move forward under the license, we were unable to obtain the necessary materials from NeXtGen.

41. I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

July 14, 2025	/Elisabeth Corson/
Date	Elisabeth Corson Chief Executive Officer RegenX Science, Inc.