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 GERARD H. BENCEN IN SUPPORT OF PATENT OWNER'S RESPONSE IN SUPPORT OF DISCRETIONARY DENIAL UNDER 37 C.F.R. § 42.107(a)

I, Gerard H. Bencen, declare as follows:

1. I respectfully submit this Declaration in support of Patent Owner's Response in Support of Discretionary Denial Under 37 C.F.R. 42.107(a) in connection with Case No: IPR2025-00621 concerning U.S. Patent No. 11,660,376 ("the '376 Patent"), which issued from U.S. application Serial No. 16/801,956, which was filed as a child of U.S. application Serial No. 14/759,895 ("the '895 Application"), which matured into U.S. Patent No. 10,617,790 ("the '790 Patent), which is the subject matter of Case No: IPR2025-00620, also filed by Petitioner.

2. I am over the age of eighteen (18) and otherwise competent to make this Declaration. I am a Registered U.S. Patent Attorney, in good standing before the bar of the State of Florida and the U.S. Patent & Trademark Office (Reg. No. 35,746), and my place of business is Patent-Arts PLLC, 10 E. University Ave., Gainesville, FL 32601.

3. I am being compensated at my rate of $ 400.00 per hour for my services. No part of my compensation is dependent on my opinions or on the outcome of this proceeding. I have no financial interest in any of the parties to this proceeding. I have personal knowledge of, and could testify competently to, the facts discussed below. This Declaration is not a waiver of the attorney-client privilege or the work product immunity; no waiver of the attorney-client privilege or the work product immunity is intended by this Declaration.

EX-2020
RegenX Science, Inc. v. NeXtGen Biologics, Inc.
002

4. I have worked as a Registered U.S. Patent Attorney with Patent Owner, NeXtGen Biologics, since 2017. I am personally familiar with, and able to speak to, Patent Owner's out-licensing of the '790 Patent (which includes out-licensing of the '376 Patent), and the out-licensing of the technology of the '790 patent (including with respect to the out-licensing of the patent application(s) in the lineage of the '790 Patent, which includes out-licensing of the application that matured into the '376 Patent). I am also personally familiar with, and able to speak to the out-licensing of the '790 patent, and the out-licensing of the technology of the '790 patent (which includes out-licensing of the '376 Patent, and out-licensing of the patent application(s) in the lineage of the '790 Patent, including out-licensing of the application that matured into the '376 Patent), by the previous owners of the '790 Patent (and the '376 Patent), and the technology of the '790 Patent (including with respect to the out-licensing of the patent application(s) in the lineage of the '790 patent, including out-licensing of the application that matured into the '376 Patent). Discussion herein is based on this out-licensing experience. I am also familiar with, have reviewed, and can speak to documents cited herein, such as EX-1017, U.S. Patent Publication 2025/0134801, and discussion herein is also based on this knowledge. In addition, I am familiar with Patent Owner's business and products and discussion herein is additionally based on this knowledge. Any matters of opinion stated herein are based on my

EX-2020
RegenX Science, Inc. v. NeXtGen Biologics, Inc.
003

education, training and experience, including my experience as to Patent Owner and previous owners of the patent-at-issue, and my experience as to Petitioner.

5. It is my view that Petitioner is a sophisticated entity that entered into arms-length license agreements involving the ’790 Patent and the ’376 Patent and has profited from those arrangements over many years.

6. Petitioner has had a field-of-use license to the ’790 Patent and the ’376 Patent dating back to as early as 2017. Prior to the issuance of the ’790 Patent, the rights to the then-pending patent application (*i.e.*, the ’895 Application) were recognized by many in the field, including Petitioner, and that were subject to numerous license agreements.

7. For example, the rights to the ’895 Application were first assigned from the inventor (Dr. Ryanne Early) to her predecessor company, ISE Professional Testing & Consulting Services, Inc., and later exclusively licensed to a second company, Synogen Management, Inc., in 2014 (Synogen).

8. Synogen, in turn, subsequently sublicensed certain rights under the ’895 Application, in separate fields of use, to each of Petitioner RegenX and Patent Owner, NeXtGen Biologics. In particular, Petitioner received a field-of-use license covering the field of “cosmeceutical” products, while all “other” fields of use were licensed to Patent Owner.

9. In 2019, ISE sought to terminate the original license it had accorded to Synogen and, as a result, the two sublicenses that Synogen had entered into with Petitioner and Patent Owner. As a result, there was an Arbitration between NeXtGen and Synogen, on the one hand, and ISE and Ryanne Early, on the other hand, which precipitated *Synogen Management Group, Inc., and NeXtGen Biologics, Inc. v. ISE Professional Testing & Consulting Services, Inc.*, Case No, 2019-CA-012605-O (Circuit Court, 9th Judicial Circuit, Orange County, Florida), which concluded in 2020 with the execution of a Settlement Agreement. While Petitioner did not participate in this litigation, either actively or financially (even though it had a license under the patent rights at issue), Petitioner did, however, retain counsel and (a) participated in prosecution before the USPTO of the '895 Application, (b) participated in the prosecution of child U.S. application Serial No. 16/801,956 that matured into the '376 Patent, (c) participated in the prosecution of foreign equivalents of the '790 Patent, and (d) filed on its own, without permission, an application descended from the '895 Application, namely U.S. application Serial No. 16/399,068 with a main claim of, "A composition comprising decellularized Urodele extracellular matrix (ECM) having functional activity", and no citation of any of the documents cited in the present IPR petition (as I have also looked at the prosecution of U.S. application Serial No. 16/399,068 via the USPTO's Patent Center).

EX-2020
RegenX Science, Inc. v. NeXtGen Biologics, Inc.
005

10. Consistent with the terms of the Settlement Agreement, ownership of the ’790 Patent and the ’376 Patent was ultimately transferred to Patent Owner, on the condition that Petitioner be allowed to enter into a sublicense to certain fields of use. Thereafter followed several years of negotiations between Petitioner and Patent Owner, which concluded with Petitioner accepting a second, direct and revised, license to the ’790 Patent on August 15, 2022. In accordance with the second license, Petitioner was again accorded an exclusive field-of-use license to develop a “cosmetic” product utilizing the claimed inventions of the ‘790 Patent and the ’376 Patent, with extended milestone deadlines as milestones under the license from Synogen to Petitioner expired during the litigation..

11. That license agreement remained in effect until shortly prior to the filing of the instant Petition. Having been given a milestone for first commercial sale of a licensed product in the U.S. by August, 2024, Petitioner failed to perform under its license Agreement with Patent Owner, albeit after having been a long time (at least about seven (7) years) licensee of the ‘790 Patent (and a licensee of patent application(s) in the lineage of the ’790 Patent, including the application that matured into the ’376 Patent and hence a licensee of the ’376 Patent), and long after having been aware of the grant of the ‘790 Patent and the ’376 Patent. Petitioner now attempts to challenge, via the subject petition, the very patent rights that: (a) Petitioner had willingly in-licensed (from first Synogen and then Patent

EX-2020
RegenX Science, Inc. v. NeXtGen Biologics, Inc.
006

Owner) for so many years, (b) Petitioner had participated in the prosecution of before the USPTO prior to grant, and (c) Petitioner had filed for on its own via a child application of the '895 Application (namely U.S. application Serial No. 16/399,068).

12. The parties' extensive course of performance reasonably gave rise to legitimate expectations on the part of Patent Owner that Petitioner would not suddenly reverse course and challenge the patent's validity, or to operate outside of its licensed field, while having had the option of continuing to benefit from the license's protections. Petitioner's attempt to now attack the very patent rights it has long enjoyed through a belated IPR petition disrupts this reliance and undermines the integrity of negotiated licensing arrangements, and is wholly inconsistent with Petitioner having actively participated in the prosecution before the USPTO and Petitioner having sought similar patent claims in a child application of the '895 Application (namely U.S. application Serial No. 16/399,068). The petition in this case is quite contrary to settled expectations.

13. For almost seven years, Petitioner was licensed to operate under the '790 Patent and the '376 Patent, it did or could have derived substantial commercial benefit from the use of the patented technology. They were given the opportunity to develop and market products incorporating the patented technology, and they made royalty payments, showing that RegenX respected and appreciated

EX-2020
RegenX Science, Inc. v. NeXtGen Biologics, Inc.
007

the validity of the ’790 Patent and the ’376 Patent. During that same period of time, Patent Owner respected the license accorded to Petitioner and has forborne from developing a “cosmeceutical” or cosmetic product. Indeed, settled expectations included that the cosmetic products market is a multi-billion dollar market, that there are far less regulatory hurdles to bring a cosmetic product to market than there are to bring a medical device to market, and that RegenX would commercialize a cosmetic product that would have provided royalty revenue back to the Patent Owner.

14. Petitioner has relied on the license to develop its core technologies, raise revenue and research financing, and position itself in the marketplace as a “leader” in bio-sourced tissue engineered products, all while enjoying the shield of a license that avoided litigation risk.

15. Outside of this IPR, Petitioner actively touts its axolotl-based tissue ECM product as “a proprietary regenerative biomaterial inspired by one of nature’s most remarkable healing organisms.” Petitioner asserts that the technology in these materials “harnesses cutting-edge molecular biology and regenerative medicine techniques to create products that transform patient care.” EX-2008.

16. Petitioner has itself filed for several patents directed at accelerating tissue regeneration and optimizing cellular repair for injuries and wounds using engineered Axolotl-tissue based ECMs, while Patent Owner’s ’790 Patent and ’376

EX-2020
RegenX Science, Inc. v. NeXtGen Biologics, Inc.
008

Patent are at the heart of that "cutting-edge" technology. *See e.g.*, EX-2017 ("The present disclosure describes a novel method for decellularizing amphibian extracellular matrix to obtain an isolated ECM that is substantially free of cellular and nuclear debris…. [and] also describes various methods of using the isolated ECM.").

17. EX-2017 is a patent publication of Petitioner's U.S. application No. 18/837,137, the national phase of PCT/US2023/062398, with a claim of priority to an application filed February 11, 2022. The first reference cited in the text of EX-2017 (at page 12) is the '790 Patent (which is the subject of Petitioner's IPR Petition in IPR2025-00620). EX-2018 is the Written Opinion that issued in the International Phase prosecution of PCT/US2023/062398. As can be seen at pages 5-7 of EX-2018, the International Phase Searching Authority cited US2020/0188557 ("the '557 App.") to deny both novelty and inventive step as to the claims of Petitioner' PCT/US2023/062398. US2020/0188557 is the patent application publication of the '376 Patent, which is the subject of the IPR Petition in this case and issued from a child application to the '895 Application. EX-1017 and EX-2018 further show that Petitioner was aware of both the '790 Patent and the '376 Patent for a long time prior to Petitioner filing its IPR Petitions.

18. In addition, in my view, Petitioner's activities prior to the grant of the '790 Patent and the '376 Patent and EX-2017 show that Petitioner is "talking out

EX-2020
RegenX Science, Inc. v. NeXtGen Biologics, Inc.
009

of both sides of its mouth" – namely taking different, contradictory positions as to the patentability of the claimed subject matter of the '790 Patent and the '376 Patent in petitions before the PTAB as compared with (a) having actively participated in the prosecution that resulted in that claimed subject matter, (b) having actively filed a descendent application from the '895 Application (namely U.S. application Serial No. 16/399,068) and pursued claims aligning with the claimed subject matter of the '790 Patent and the '376 Patent, and (c) having pursued claims to similar subject matter before the USPTO in the preparation, filing and prosecution of EX-2017.

19. In this regard, I have also looked at the prosecution of EX-2017 via the USPTO's Patent Center. I note that just as in Petitioner's prosecution of Petitioner-filed U.S. application Serial No. 16/399,068 (as a descendent of the '895 Application), none of the documents cited in Petitioner's IPR petitions IPR2025-00620 and IPR2025-00621 are discussed in EX-2017, or cited for the Examiner to consider and make of record in the prosecution of EX-2017. To me, this illustrates that contrary to the assertions in its IPR Petitions, Petitioner actually does not consider the documents it cites in its IPR Petitions to be particularly pertinent to the claimed subject matter of the '790 Patent and the '376 Patent.

20. Patent Owner currently markets and sells regenerative ECM bioscaffolds derived from axolotls for use in surgical reconstruction, chronic

EX-2020
RegenX Science, Inc. v. NeXtGen Biologics, Inc.
010

wound treatment, and tissue regeneration under the brand name "NEOMATRIX®". Patent Owner's NEOMATRIX ® product has been deployed in clinical settings, including in hospitals, military health systems, and trauma centers, where it has already demonstrated significant therapeutic benefit.

21. Patent Owner's NEOMATRIX® product is uniquely positioned to help address these urgent medical needs, while full-scale commercial adoption is still underway and will require additional financial support by future investors. Institution of IPR under these circumstances could introduce substantial uncertainty and risks, chilling future investment, and disrupting patient access, all contrary to settled expectations. This disruption also may result in reduced patient access to this technology and introduce hesitation among providers causing real and immediate consequences for patients, providers, and health systems, also all contrary to settled expectations.

22. In contrast, denying institution is consistent with settled expectations. Denying institution protects investment-driven innovation in a nascent field. The development of new ECM bioscaffold technologies requires substantial investment in R&D, regulatory approval, clinical trials, and manufacturing scale-up. The commercial viability of these products is often predicated on enforceable patent rights that protect years of research and substantial capital. The market uncertainty that would result from subjecting the '790 Patent and the '376 Patent to IPR

challenge at this pivotal commercialization stage could discourage further investment in regenerative medicines—a field that still faces major technical and clinical hurdles.

23. The timing and context of the Petition appears to be a strategic, bad-faith attempt by the Petitioner to avoid the restrictions in the license it had freely accepted, as well as avoid paying royalties and/or meeting milestones, and disrupt the Patent Owner's market position, rather than a genuine challenge to patent validity.

24. After failing to commercialize a product under its prior field-of-use license, rather than seeking to extend its field of use license under the '790 Patent and the '376 Patent, it has chosen to develop competing ECM products and to file this Petition. The timing of this Petition—aligned with the Petitioner's own commercial expansion into its former licensor's (Patent Owner's) field of operations, namely wound healing as shown on Petitioner's website—reflects Petitioner's attempt to litigate before the PTAB contract issues between Patent Owner and Petitioner, sidestep licensing obligations, and an intent to inflict commercial harm on Patent Owner by ignoring the Patent Owner's patent rights. The settled expectations call for denial of institution, and having Petitioner and Patent Owner address their contract and other issues in more appropriate venues than before the PTAB.

EX-2020
RegenX Science, Inc. v. NeXtGen Biologics, Inc.
012

25. Patent Owner has forborne opportunities to advance its own cosmetic product based upon its patented technology in respect of the license Patent Owner had provided to Petitioner. The missed opportunity costs to Patent Owner having not developed that commercial segment under its own patent is enormous.

26. The claimed Urodele-derived ECM bioscaffolds address substantial unmet medical needs, reduce costs to the healthcare system, and offer alternatives for soft tissue repair surgeries. The claimed bioscaffolds represent more than simply a new proprietary product—they support life-changing therapies with a clear and compelling public value, including improved wound care outcomes and reduced long-term healthcare costs. The settled expectations warrant that institution of proceedings be denied, including so that the technology of the patent-at-issue can be advanced to address substantial unmet medical needs, reduce costs to the healthcare system, and offer alternatives for soft tissue repair surgeries.

I declare under the penalty of perjury that the foregoing is true and correct, and that any willful false statement made in this declaration is punishable under 18 U.S.C. § 1001 by fine or imprisonment of not more than five (5) years, or both.

Executed June 13, 2025 in Gainesville, Florida.



Gerard H. Bencen