IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

ACERA SURGICAL, INC., RETECTIX, LLC, AND WASHINGTON UNIVERSITY, **Plaintiffs,** **-vs.-** **REGENISOURCE LLC,** **Defendant.**	**Case No. 5:22-cv-447** **DEMAND FOR JURY TRIAL**

ORIGINAL COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Acera Surgical, Inc. ("Acera"), Retectix, LLC ("Retectix") and Washington University ("WashU") (collectively, "Plaintiffs") file this Original Complaint for patent infringement against RegeniSource LLC ("RegeniSource"), alleging as follows:

PARTIES

1. Plaintiff Acera is corporation incorporated under the laws of Delaware with its principal place of business at 1650 Des Peres Rd., Ste 120, St. Louis, MO 63131.

2. Acera is a St. Louis based medical device company specializing in the development of innovative solutions for assisting wound healing. Much of their work is the product of the pioneering research and development of Dr. Matthew MacEwan, Acera's Chief Science Officer. In 2008, while an MD/Ph.D. student at WashU, Dr. MacEwan began investigating the use of polymer nanofibers and their potential use in the medical field, ultimately leading to the founding of Acera. Following successful product tests, Acera developed Cerafix® Dura Substitute, a nanofiber dural repair matrix and received FDA clearance

for Cerafix® in 2016. Acera also offers a product called Restrata® Wound Matrix, a fully resorbable nanofiber soft-tissue repair. Acera's products are based on the groundbreaking, patented nanofiber technology Dr. MacEwan and his colleagues developed and brought to market. Acera's technology enables the engineering of matrices closely resembling the structure and architecture of the native human extracellular matrix. The Acera nanofiber matrix technology is engineered from intricately designed fibers to create a fully resorbable regenerative scaffold. Native cells rapidly migrate into the scaffold, and then proliferate and differentiate to form new tissue. Gradual and defined resorption of the nanofiber scaffold is designed to occur at a similar rate to cellular growth and new tissue formation. As the scaffold resorbs, the porosity of the matrix gradually increases to support continued tissue integration and neovascularization, while eliciting a minimal inflammatory response.

3. Plaintiff Retectix is an LLC formed under the laws of Missouri and located in St. Louis, MO. Dr. Matthew MacEwan is the Founder and President of Retectix.

4. Plaintiff WashU is a corporation established by special act of the Missouri General Assembly approved February 22, 1853 and acts amendatory thereto, having its principal place of business at 1 Brookings Dr., St. Louis, MO 63130.

5. WashU is a world-renowned research institution located in St. Louis, Missouri. In addition to educating tens of thousands of students each year, WashU also funds nearly a billion dollars of research into numerous cutting edge and innovative fields. The developments of WashU research programs have led to breakthroughs in the areas of environmental and energy research, medical devices and agriculture. To support such endeavors, WashU maintains a robust patent portfolio.

6. Upon information and belief, Defendant RegeniSource ("Defendant") is a Texas limited liability company having its principal place of business located at 20770 U.S. Highway 281 N. Ste. 108-418, San Antonio, TX, 78258.

JURISDICTION AND VENUE

7. Plaintiffs reallege and reincorporate by reference the allegations set forth in Paragraphs 1 through 6 of this Complaint.

8. Plaintiffs assert claims for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq*, including 35 U.S.C. § 271. This Court has subject matter jurisdiction over these claims under 28 U.S.C. §§ 1331 and 1338 (federal question jurisdiction and jurisdiction over patent actions).

9. On information and belief, Defendant is subject to personal jurisdiction in this State and District as it is resident in San Antonio, Texas and is formed under the laws of the State of Texas. In particular, this Court has personal jurisdiction over Defendant because, on information and belief, Defendant is engaged in the business of selling and offering for sale the Anthem Wound Matrix and/or other nanofiber scaffold products in the United States, including within this District, and is incorporated in this District.

10. Venue is proper in this District and Division pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b) because, on information and belief, Defendant resides in this District and Division, Defendant has a regular and established place of business in this District and Division, Defendant is engaged in the business of selling and offering for sale the Anthem Wound Matrix and/or other nanofiber scaffold products within this District and Division.

THE PATENTS-IN-SUIT

11. Plaintiffs assert herein claims for infringement of United States Patent No. 11,224,677 ("the '677 Patent"), United States Patent No. 11,173,234 ("the '234 Patent"), United States Patent No. 11,253,635 ("the '635 Patent") and United States Patent No. 11,071,617 ("the '617 Patent") (collectively, the "Patents-in-Suit").

12. The '677 Patent, entitled "Tissue Substitute Materials and Methods for Tissue Repair" duly and legally issued on January 18, 2022, from U.S. Patent Application No. 17/226,384 filed on April 9, 2021, naming Matthew MacEwan as the sole inventor. Plaintiff Acera is the owner and assignee of all rights, title, and interest in and under the '677 Patent. A true and correct copy of the '677 Patent is attached hereto as **Exhibit 1** and is incorporated by reference.

13. The '234 Patent, entitled "Biomedical Patches with Spatially Arranged Fibers" duly and legally issued on November 16, 2021, from U.S. Patent Application No. 17/229,226 filed on April 13, 2021, naming Matthew MacEwan as the sole inventor. Together, Retectix and Acera are the exclusive licensee with the right of enforcement of the '234 Patent. WashU is the owner by assignment of the '234 Patent. A true and correct copy of the '234 Patent is attached hereto as **Exhibit 2** and is incorporated by reference.

14. The '635 Patent, entitled "Three Dimensional Electrospun Biomedical Patch for Facilitating Tissue Repair" duly and legally issued on February 22, 2022, from U.S. Patent Application No. 17/381,792 filed on July 21, 2021, naming Matthew MacEwan as the sole inventor. Together, Retectix and Acera are the exclusive licensee with the right of enforcement of the '635 Patent. WashU is the owner by assignment of the '635 Patent. A true and correct copy of the '635 Patent is attached hereto as **Exhibit 3** and is incorporated by reference.

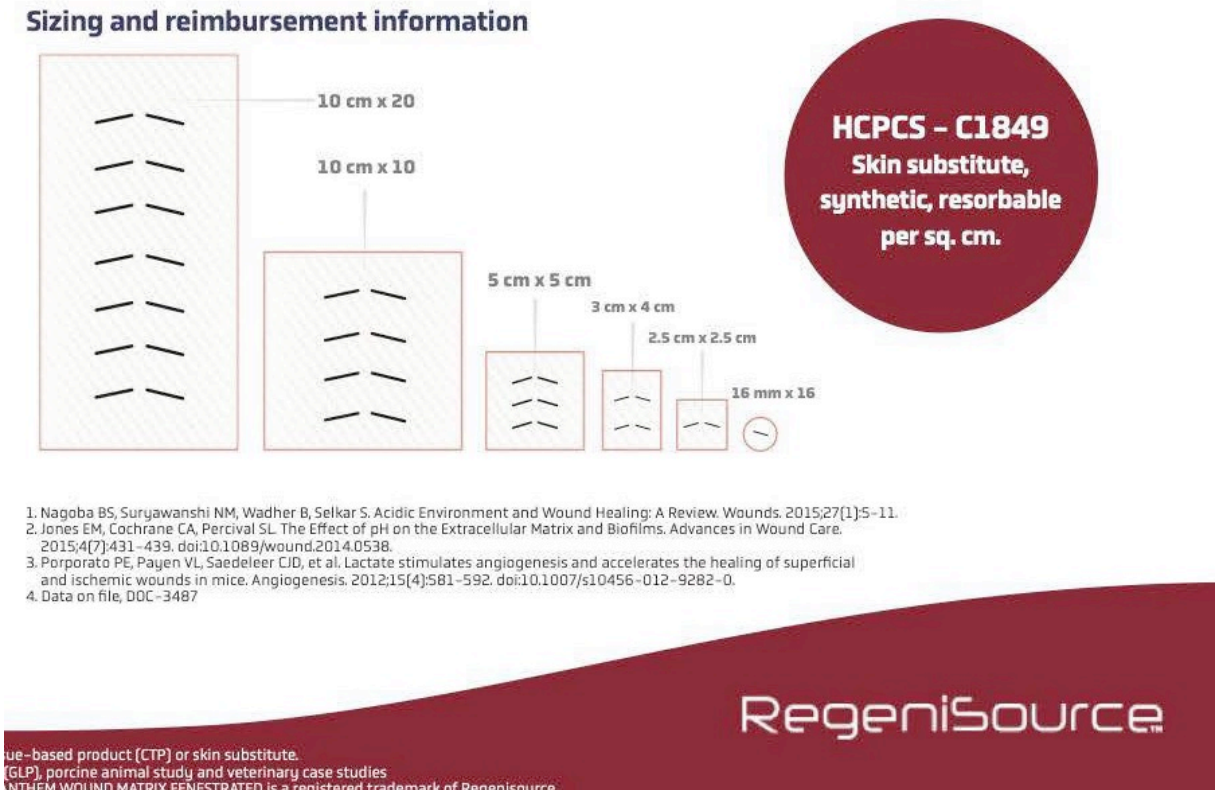
15. The ’617 Patent, entitled “Biomedical Patches with Aligned Fibers” duly and legally issued on July 27, 2021, from U.S. Patent Application No. 17/063,924 filed on October 6, 2020, naming Matthew MacEwan, Jingwei Xie, Zack Ray and Younan Xia as the inventors. Together, Retectix and Acera are the exclusive licensee with the right of enforcement of the ’617 Patent. WashU is the owner by assignment of the ’617 Patent. A true and correct copy of the ’617 Patent is attached hereto as **Exhibit 4** and is incorporated by reference.

DEFENDANT’S ACTIVITIES

16. Defendant has offered to sell and/or sold within the United States biomedical patch products made from electrospun, non-woven, matrices comprising polymeric fibers made from glycolic acid, which products are marketed by Defendant at least under the “Anthem Wound Matrix” brand (collectively “Anthem Wound Matrix”).

17. Per RegeniSource’s marketing materials, the Anthem Wound Matrix is “3D electrospun, synthetic polymer matrix designed to provide a multi-dimensional scaffold stimulus for tissue regeneration and repair of acute and chronic wounds, and burns.” Ex. 5 at 1. Further, according to RegeniSource’s marketing materials, the Anthem Wound Matrix is “[p]owered by Bioresorbable Synthetic Polymer Technology.” *Id.* The Anthem Wound Matrix is sold in a variety of sizes under the following references numbers: AN-0031 (20cm x 10cm); AN-0032 (10cm x 10cm); AN-0033 (5cm x 5cm); AN-0034 (4cm x 3cm); AN-0035 (2.5cm x 2.5cm); AN-0036 (1.6cm diameter disc). *See* Ex. 6 at 1.

18. The following image of the different sizes of the Anthem Wound Matrix (fenestrated version) appears in RegeniSource’s marketing materials.



Ex. 7 at 1.

19. On information and belief, the Anthem Wound Matrix is a private label version of the Phoenix Wound Matrix product made and sold by RenovoDerm LLC and Nanofiber Solutions, LLC. Specifically, marketing materials refer to the two products as being the same product under two different brands. *See* Ex. 8 at 1 (referring to the "Phoenix/Anthem Wound Matrix").

CLAIMS FOR PATENT INFRINGEMENT

COUNT I – INFRINGEMENT OF THE '677 PATENT

20. Plaintiffs reallege and reincorporate the allegations set forth in Paragraphs 1–19.

21. Upon information and belief, Defendant has directly infringed the '677 patent by offering for sale, and/or selling within the United States, electrospun, non-woven, wound matrices within the scope of one or more claims of the '677 patent, including the Anthem Wound

Matrix, in violation of 35 U.S.C. § 271(a). Upon information and belief, the Anthem Wound Matrix infringes at least Claim 15 of the '677 patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents.

22. Defendant's Anthem Wound Matrix includes all the limitations of Claim 15 of the '677 patent as described in, for example, Defendant's product instructions, brochures, and other marketing materials. *See* Exs. 5–10.

23. Specifically, the Anthem Wound Matrix includes a bioresorbable non-woven graft material for facilitating regeneration of tissue as indicated by RegeniSource's marketing materials which describe the Anthem Wound Matrix as an "electrospun synthetic polymer matrix . . . for tissue regeneration and repair" that is "[p]owered by Bioresorbable Synthetic Polymer Technology." Ex. 5 at 1.

Id.

24. The Anthem Wound Matrix's bioresorbable non-woven graft material includes a single non-woven electrospun polymeric scaffold. *See* Ex. 5 at 1; Ex. 6 at 1; Ex. 10 at 2–4.

25. The polymeric scaffold of the Anthem Wound Matrix is formed by a first set of non-woven electrospun polymeric fibers and a second set of non-woven electrospun polymeric fibers. *Id*. For example, the non-woven electrospun Anthem Wound Matrix "is made from two

types of polymer fibers: Poly(lactide-co-caprolactone) [and] Polyglycolic acid." Ex. 6 at 1; Ex. 10 at 4.

26. The first set of non-woven electrospun polymeric fibers and the second set of non-woven electrospun polymeric fibers of the Anthem Wound Matrix are commingled in the non-woven electrospun polymeric scaffold. *See* Ex. 5 at 1; Ex. 6 at 1.

27. The first set of non-woven electrospun polymeric fibers is formed by depositing, via electrospinning, a first polymer composition comprising glycolic acid and the second set of non-woven electrospun polymeric fibers is formed by depositing, via electrospinning, a second polymer composition which is different from the first polymer composition. *See* Ex. 5 at 1. For example, the non-woven electrospun Anthem Wound Matrix "is made from two types of polymer fibers: Poly(lactide-co-caprolactone) [and] Polyglycolic acid." Ex. 6 at 1.

28. The non-woven electrospun polymeric scaffold further comprises a plurality of pores formed by the first and second set of non-woven electrospun polymeric fibers as well as a top and bottom surface comprising one or more different physical properties including areal density. *See* Ex. 10 at 3-5; Ex. 5 at 1. The "[p]ore size and structure promotes cellular adhesion, infiltration and proliferation." *Id.*

29. Further, the Anthem Wound Matrix has sufficient flexibility for applying the graft material to human tissue and it possess sufficient mechanical strength to be trimmable. *See* Ex. 5 at 1; Ex. 6 at 1; Ex. 7 at 1. The Anthem Wound Matrix material is configured to facilitate regeneration of tissue. *See* Ex. 5 at 1; Ex. 6 at 1; Ex. 10 at 2–4.

COUNT II – INFRINGEMENT OF THE '234 PATENT

30. Plaintiffs incorporate herein the allegations made in paragraphs 1–29.

31. Upon information and belief, Defendant has directly infringed the ’234 patent by offering for sale, and/or selling within the United States, electrospun, non-woven, wound matrices within the scope of one or more claims of the ’234 patent, including the Anthem Wound Matrix, in violation of 35 U.S.C. § 271(a). Upon information and belief, the Anthem Wound Matrix infringes at least Claim 1 of the ’234 patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents.

32. Defendant’s Anthem Wound Matrix includes all the limitations of Claim 1 of the ’234 patent as described in, for example, Defendant’s product instructions, brochures, and other marketing materials. *See* Exs. 5–10.

33. Specifically, the Anthem Wound Matrix has a three-dimensional electrospun biomedical patch for facilitating tissue repair as indicated by RegeniSource’s marketing materials which describe the Anthem Wound Matrix as a “3D electrospun synthetic polymer matrix . . . for tissue regeneration and repair”. Ex. 5 at 1.

Id.

34. The Anthem Wound Matrix’s three-dimensional electrospun biomedical patch is made up of a first polymeric scaffold which comprises a first structure of deposited electrospun fibers. *See* Ex. 5 at 1; Ex. 6 at 1; Ex. 10 at 2–5.

35. The electrospun fibers of the Anthem Wound Matrix extend in a plurality of directions in three dimensions to facilitate cellular migration. *Id*.

36. The Anthem Wound Matrix facilitates cellular migration for a first period of time upon application of the patch that is less than twelve months. *Id*.

37. The Anthem Wound Matrix three-dimensional electrospun biomedical patch further comprises a second polymeric scaffold with a second structure of deposited electrospun fibers overlaid on the first polymeric scaffold. The non-woven electrospun Anthem Wound Matrix "is made from two types of polymer fibers: Poly(lactide-co-caprolactone) [and] Polyglycolic acid." Ex. 6 at 1; Ex. 10 at 4.

38. The second structure of deposited electrospun fibers of the Anthem Wound Matrix comprises portions with a higher deposition of fibers than one or more portions of the first polymeric scaffold. *Id*.

39. The second structure of deposited fibers also includes fibers which provide structural reinforcement to the patch for a second period of time upon application that is less than twelve months. *Id.*

40. Further, the plurality of deposited electrospun fibers connecting the first polymeric scaffold and second polymeric scaffold includes a first set of electrospun fibers made from a first polymer and second set of deposited electrospun fibers made from a second polymer that are interweaved. *See* Ex. 5 at 1; Ex. 6 at 1.

41. Upon information and belief, the Anthem Wound Matrix biomedical patches comprise fibers with diameters between 1 and 3000 nanometers and indicate that the biomedical patch is pliable and resistant to tearing, allowing for movement of the patch with the tissue of its user. *See* Ex. 9 at 1; Ex. 10 at 3.

COUNT III – INFRINGEMENT OF THE ’635 PATENT

42. Plaintiffs incorporate herein the allegations made in paragraphs 1–41.

43. Upon information and belief, Defendant has directly infringed the ’635 patent by offering for sale, and/or selling within the United States, electrospun, non-woven, wound matrices within the scope of one or more claims of the ’635 patent, including the Anthem Wound Matrix, in violation of 35 U.S.C. § 271(a). Upon information and belief, the Anthem Wound Matrix infringes at least Claim 1 of the ’635 patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents.

44. Defendant’s Anthem Wound Matrix includes all the limitations of Claim 1 of the ’635 patent as described in, for example, Defendant’s product instructions, brochures, and other marketing materials. *See* Exs. 5–10.

45. Specifically, the Anthem Wound Matrix includes a three-dimensional electrospun biomedical patch for facilitating tissue repair as indicated by RegeniSource’s marketing materials which describe the Anthem Wound Matrix as a “3D electrospun synthetic polymer matrix . . . for tissue regeneration and repair”. Ex. 5 at 1.

Id.

46. The Anthem Wound Matrix's three-dimensional electrospun biomedical patch is made up of a first polymeric scaffold which comprises a first structure of deposited electrospun fibers extending in a plurality of directions in three dimensions to facilitate cellular migration. *See* Ex. 5 at 1; Ex. 6 at 1; Ex. 10 at 2–5.

47. The first scaffold and electrospun fibers facilitate cellular migration for a first period of time that is less that twelve months. *Id*.

48. The Anthem Wound Matrix three-dimensional electrospun biomedical patches also have a second polymeric scaffold with a second structure of deposited electrospun fibers overlaid on the first polymeric scaffold. The non-woven electrospun Anthem Wound Matrix "is made from two types of polymer fibers: Poly(lactide-co-caprolactone) [and] Polyglycolic acid." Ex. 6 at 1; Ex. 10 at 4.

49. The second polymeric scaffold includes one or more portions with a higher deposition of fibers than one or more portions of the first polymeric scaffold. *Id.*

50. The second polymeric scaffold also includes fibers that provide structural reinforcement to the patch for a second period of time that is less than twelve months (e.g. 7–14 days). *Id*.

51. Further, the plurality of deposited electrospun fibers connecting the first polymeric scaffold and second polymeric scaffold comprise a first set of electrospun fibers generated by electrospinning a first polymer composition and second set of deposited electrospun fibers generated by electrospinning a second polymer composition, and the first and second set of fibers are entangled. *See* Ex. 5 at 1: Ex. 6 at 1.

52. The Anthem Wound Matrix biomedical patches also comprise a plurality of voids comprising one or more voids between 10 microns and 10 centimeters, and the electrospun

biomedical patch is pliable and resistant to tearing allowing for movement of the patch with the tissue when in use. *See* Ex. 7 at 1; Ex. 9 at 1; Ex. 10 at 3.

COUNT IV – INFRINGEMENT OF THE '617 PATENT

53. Plaintiffs incorporate herein the allegations made in paragraphs 1–52.

54. Upon information and belief, Defendant has directly infringed the '617 patent by offering for sale, and/or selling within the United States, electrospun, non-woven, wound matrices within the scope of one or more claims of the '617 patent, including the Anthem Wound Matrix, in violation of 35 U.S.C. § 271(a). Upon information and belief, the Anthem Wound Matrix infringes at least Claim 1 of the '617 patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents.

55. Defendant's Anthem Wound Matrix includes all the limitations of Claim 1 of the '617 patent as described in, for example, Defendant's product instructions, brochures, and other marketing materials. *See* Exs. 5–10.

56. Specifically, the Anthem Wound Matrix includes a biomedical patch device for tissue repair as indicated by RegeniSource's marketing materials which describe the Anthem Wound Matrix as a "3D electrospun synthetic polymer matrix . . . for tissue regeneration and repair". Ex. 5 at 1.

Id.

57. The Anthem Wound Matrix biomedical patch includes a first polymeric scaffold comprising a first structure of fibers with electrospun nanofibers and randomly oriented fiber sections. *See* Ex. 5 at 1; Ex. 6 at 1; Ex. 10 at 2–5.

58. The first structure of fibers is configured to promote cell growth for a first period of time that is less than three months (e.g. 7-14 days). *Id*.

59. The Anthem Wound Matrix biomedical patch also includes a second polymeric scaffold comprising a second structure of fibers with electrospun nanofibers and radially aligned fiber sections and randomly oriented fiber sections. *See* Ex. 5 at 1; Ex. 6 at 1.

60. At least some of the plurality of radially aligned fiber sections of the Anthem Wound Matrix transition into the randomly oriented fibers section, and at least some of the radially aligned fiber sections are overlaid on the randomly oriented fiber sections. *Id*.

61. The second structure of fibers of the Anthem Wound Matrix is configured to provide structural reinforcement to the first polymeric scaffold for a period of less than three months after application of the patch. *Id*.

62. The Anthem Wound Matrix biomedical patch is made from two different polymer compositions by depositing via electrospinning the first polymer composition and the second polymer composition. For example, the non-woven electrospun Anthem Wound Matrix "is made from two types of polymer fibers: Poly(lactide-co-caprolactone) [and] Polyglycolic acid." Ex. 6 at 1; Ex. 10 at 4.

63. The Anthem Wound Matrix biomedical patch also contains a surface configured to contact tissue upon application of the patch, and is sufficiently pliable to facilitate application of the patch to uneven surfaces of the tissue. *Id*.

64. The surface and scaffolds of the biomedical patch are sufficiently pliable to enable movement of the patch with the tissue and are sufficiently durable to maintain stability of the patch for a storage period prior to application. *See* Ex. 5 at 1; Ex. 6 at 1; Ex. 7 at 1; Ex. 9 at 1; Ex. 10 at 3.

DEMAND FOR A JURY TRIAL

65. Plaintiffs demand a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request judgment and seek relief as follows:

A. A judgment that Defendant and its officers, agents, servants, employees, attorneys, and all others in active concert and/or participation with Defendant have directly infringed one or more claims of each of the ’677, ’234, ’635, and/or ’617 patents;

B. A ruling that this case is exceptional under 35 U.S.C. § 285, and an award of reasonable attorneys’ fees and non-taxable costs;

C. An injunction enjoining Defendant and its officers, agents, servants, employees, attorneys, and all others in active concert and/or participation with Defendant, from infringing any and all of the ’677, ’234, ’635, and/or ’617 patents through the manufacture, use, importation, offer for sale, and/or sale of infringing products, and/or any of the other acts prohibited by 35 U.S.C. § 271;

D. An award of monetary damages compensating Plaintiffs for the infringement of the ’677, ’234, ’635, and/or ’617 patents by Defendant through payment of not less than a reasonable royalty on sales of infringing products by Defendant.

E. An assessment of prejudgment and post-judgment interest and costs against Defendant, together with an award of such interest and costs, pursuant to 35 U.S.C. § 284.

F. Any and all further necessary relief as the Court may deem just and proper.

May 6, 2022

Respectfully submitted,

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