

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

VGXI, INC,	:	
	:	
Plaintiff,	:	
	:	Civil Action No.: 4:19-cv-4761
v.	:	
	:	JURY TRIAL DEMANDED
ALDEVRON LLC,	:	
	:	
Defendant.	:	

VERIFIED COMPLAINT

Plaintiff VGXI, Inc. (“VGXI”), by its counsel, files this Verified Complaint against Defendant Aldevron LLC (“Aldevron”), and in support thereof avers as follows:

PRELIMINARY STATEMENT

1. VGXI, based in Houston, is the largest GMP-compliant DNA plasmid manufacturer in the world. DNA plasmids are used to produce various gene therapies, including DNA vaccines for viruses like Middle East Respiratory Syndrome (MERS), Zika, and Ebola. To be administrable to humans, DNA plasmids must be manufactured according to the Food and Drug Administration’s regulations containing the current good manufacturing practices (“GMP”) for preparation of drug products. The demand for GMP-compliant DNA plasmids has greatly increased in recent years alongside the demand for DNA vaccines and gene therapies.

2. GMP-compliant DNA plasmids for human use are difficult to manufacture at a large scale while maintaining the necessary high standards of isolation and purification required under the GMP regulations. VGXI and its predecessors have spent more than two decades developing secret and patented proprietary techniques that permit VGXI to produce high quality GMP-compliant DNA plasmids at high yields and at lower costs than its competitors. As part of

its proprietary manufacturing process, VGXI also uses a patented system that isolates and purifies the plasmid DNA from cells, helping VGXI prepare large quantities of substantially purified plasmids (which are suitable for many uses, including DNA vaccines and gene therapy). Through this combination of patented systems and trade secret methodologies, VGXI has become the world leader in GMP-compliant DNA plasmid manufacturing.

3. To VGXI's surprise, Aldevron—a North Dakota company that previously operated for years manufacturing non-GMP DNA plasmids useful in the pre-clinical stages (animal testing only, no human testing) only—has suddenly emerged as a competing manufacturer of GMP-compliant DNA plasmids. Aldevron could not, and did not, develop these manufacturing processes overnight. Instead, Aldevron has achieved this abrupt breakthrough in its ability to compete with VGXI by underhanded means: theft of VGXI's trade secrets and illicit use of VGXI's patented system.

4. Aldevron had access to VGXI's trade secrets and patented technology, and appears to be using both to achieve the GMP-compliant DNA plasmid manufacturing process they are now advertising. Specifically, under a License Agreement beginning in 2005, VGXI licensed its patented system and trade secret DNA plasmid manufacturing processes to Aldevron, for the manufacturing of non-GMP compliant DNA plasmids. When the License Agreement terminated, in 2007, Aldevron agreed to return or destroy all confidential information and return the proprietary equipment to VGXI. Although Aldevron returned the equipment, it appears to have illegally retained the confidential information and patented system in order to achieve a GMP-compliant DNA plasmid manufacturing business. VGXI did not learn of this breach of contract, due to Aldevron's deception, until recently when Aldevron began advertising its new GMP-compliant DNA plasmid manufacturing process.

5. In addition, in May 2017, Aldevron hired an individual named Henry Hebel to lead its DNA plasmids manufacturing business. Hebel was a longtime employee of VGXI, where he helped invent the patented system and process that VGXI licensed to Aldevron, which enables the production of high-quality and high-yield plasmids. Hebel is listed as one of the inventors on the VGXI-owned patent (US 7,238,522: “An apparatus and a method for isolating a biologic product, such as plasmid DNA, from cells”). VGXI, not Hebel or Aldevron, is the assignee of all rights to that patent, yet Hebel appears to have helped Aldevron rapidly recreate VGXI’s DNA plasmid system and trade secret manufacturing processes.

6. Armed with VGXI’s trade secret manufacturing processes, coupled with the patented technology, Aldevron is now using VGXI’s intellectual property to compete unfairly in this competitive marketplace. Aldevron’s unlawful conduct threatens the loss of a significant portion of VGXI’s revenue, along with its goodwill, reputation, and market share. VGXI comes before this Court seeking equitable injunctive relief and damages, to put a stop to Aldevron’s theft of trade secrets, patent infringement, and breach of contract.

PARTIES

7. Plaintiff VGXI is a Delaware corporation with headquarters located at 2700 Research Forest Drive, Suite 180, The Woodlands, Texas 77381.

8. Defendant Aldevron is a North Dakota limited liability company with a headquarters located at 4055 41st Avenue South, Fargo, North Dakota 58104. Upon information and belief, no member of Aldevron is a citizen of Delaware or Texas.

JURISDICTION AND VENUE

9. Subject matter jurisdiction exists pursuant to 28 U.S.C. § 1332(a)(1). The amount in controversy exceeds the sum or value of \$75,000.00, exclusive of interest and costs, and is

between citizens of different states. Subject matter jurisdiction also exists under 28 U.S.C. § 1331 because this is a dispute arising under the laws of the United States, including the Defend Trade Secrets Act (“DTSA”), 18 U.S.C. § 1836 *et seq.*, and the United States Patent Act, 35 U.S.C. § 1 *et seq.* And subject matter exists under 28 U.S.C. § 1338(a) because this action arises under an Act of Congress relating to patents.

10. Venue is proper in this Court under 28 U.S.C. § 1391(b)(2) because a substantial portion of the events giving rise to the causes of action described herein occurred in the Southern District of Texas, and under 28 U.S.C. § 1391(b)(3) because Aldevron is subject to this Court’s personal jurisdiction with respect to this action.

11. Furthermore, under the terms of the License Agreement, VGXI’s predecessor ADViSYS, Inc. (“ADViSYS”) and Aldevron agreed that the exclusive venue for proceedings arising under that agreement shall be a court of competent jurisdiction in Harris County, Texas—this District. (A true and correct copy of the License Agreement is attached hereto as **Exhibit A**; *see* Ex. A at Art. 13, § 13.1.) As described more fully below, Aldevron has breached the License Agreement and misappropriated trade secrets disclosed under that License Agreement.

BACKGROUND

A. 1997 – 2004: VGXI Becomes a World-Leading Manufacturer of GMP-Compliant DNA Plasmids.

12. Over the last two decades, VGXI has emerged as a leading manufacturer of GMP-compliant DNA plasmids.

13. A predecessor to VGXI, ADViSYS, was founded in 1997 as a gene therapy company to develop technology for optimized, large scale plasmid DNA production and purification.

14. In 2001, ADViSYS opened their offices in The Woodlands, Texas as a spin-off from Baylor College of Medicine. VGXI's headquarters remains there today.

15. Eventually, ADViSYS sold substantially all of its assets to a company called VGX Pharmaceuticals, Inc., which in turn eventually sold substantially all of its assets to VGXI. All manufacturing activities were aligned into VGXI, and VGXI has since owned all rights, title, and interest to the confidential information, trade secrets, and patents discussed below. For clarity, ADViSYS may be referred to herein as VGXI.

1. VGXI's Trade Secret Manufacturing Processes and Equipment.

16. VGXI's trade secrets allow VGXI to manufacture high quality plasmid DNA in high yield batches at lower costs than its competitors. VGXI derives an economic benefit from these trade secrets, and it licenses them with strict protections to companies around the world.

17. VGXI's confidential trade secrets include its proprietary manufacturing techniques and manufacturing equipment. For example, its confidential trade secrets include optimal parameters for its continuous cell disruption technology (known as AIRMIX™) and purification procedures such as the specific sizes used for chambers in the AIRMIX and purification equipment and operating conditions for the same). It also includes other types of scientific, technical, and engineering information that VGXI uses for its proprietary processes.

18. VGXI owns its trade secrets and has always taken measures to ensure their secrecy.

19. VGXI's trade secrets are not known to the public. In fact, no other company is able to manufacture GMP-compliant DNA plasmids to the quality, yield, and standards of VGXI at similar cost. Other companies around the world have tried and failed. VGXI licenses its trade secrets and patented system and process to other companies with strict protections.

20. VGXI has continuously used its trade secrets, including in interstate commerce across the United States.

2. VGXI's Patented System and Methods Used In The Manufacturing Process.

21. As part of its proprietary manufacturing process, VGXI uses a patented system and method that isolates the plasmid DNA from cells. VGXI's patented system allows for a higher level of quality of plasmids needed for human use, the scale required for human clinical trials, and increased cost efficiency in the manufacturing process.

22. In 2004, VGXI (through ADViSYS at the time) filed U.S. Application No. 10/857,439 for this system and method. VGXI's novel system uses a high-shear mixer, a holding coil, and a bubble mixer that can more efficiently isolate cellular components, such as plasmids, than prior devices.

23. VGXI's device and process help it prepare large quantities of substantially purified plasmids, which are suitable for many uses, including DNA vaccines and gene therapy.

24. Specifically, the GMP plasmid DNA manufacturing system implemented a process that reduced cost by sixty percent while increasing purity and yield when compared to traditional methods.

25. From that 2004 application, the United States Patent & Trademark Office issued U.S. Patent No. 7,238,522 (the "'522 Patent") on July 3, 2007, entitled "Devices and Methods for Biomaterial Production." A true and correct copy of the '522 Patent is attached hereto as **Exhibit B**.

26. The named inventors of the patented device and process were Henry Hebel, Jeff Darnell, Sriram Ramakrishnan, and Hugo Gonzalez—all of whom worked at VGXI. These

individuals co-developed and implemented this patented technology, but to this day, VGXI is the sole assignee of all right, title, and interest to the '522 Patent.

27. Hebel served as the Vice President of Operations for ADViSYS beginning in 2001. He continued in a similar role with VGX Pharmaceuticals after its acquisition of ADViSYS.

28. After VGXI acquired the ADViSYS assets from VGX Pharmaceuticals, Hebel was named the Chief Operating Officer for VGXI, where he led VGXI's GMP plasmid DNA production in support of FDA and USDA clinical submissions. While Hebel was working for VGXI (formerly, ADViSYS), the company successfully obtained regulatory approval for the world's first commercial DNA plasmid-based therapy.

B. 2005 – 2007: Aldevron Has Access to VGXI's Trade Secrets and Patented Systems and Processes.

29. For the past two decades, Aldevron has been manufacturing non-GMP-compliant plasmids, for pre-clinical stages (animal testing), only.

30. On December 20, 2005, VGXI (through its predecessor ADViSYS) entered into a License Agreement with Aldevron.

31. Under the License Agreement, VGXI granted Aldevron a nonexclusive, royalty-bearing license to use VGXI's trade secrets and patents in Aldevron's North Dakota facility.

32. Specifically, the parties agreed that VGXI:

owns intellectual property and proprietary information regarding the production of plasmids; and . . . Aldevron desires to obtain a license to such existing intellectual property and to obtain certain services from [VGXI] and [VGXI] is willing to grant a license and provide such services, all on the terms and conditions herein.

(Id. at Whereas clauses (emphasis added).)

33. Under the License Agreement, the VGXI "Intellectual Property" was defined as "Patents and trade secrets and know-how owned or controlled by [VGXI] on the Effective Date

which is used in the production and purification of plasmids.” (*Id.* at Art. 1, Definitions.) This included all of VGXI’s trade secrets, and the manufacturing system and process covered by U.S. Application No. 10/857,439, filed on May 27, 2004, now U.S. Patent No. 7,238,522 (“the ’522 Patent”). (Ex. A at Ex. A-1.)

34. The License Agreement was clear by its terms that the license was solely for the purpose of producing batches of plasmids of less than 5.0 kg **in non-GMP conditions**. (*Id.* at Art. 2 (emphasis added).) That is, Aldevron was not permitted to use VGXI’s trade secrets or patent to manufacture GMP-compliant DNA plasmids, suitable for human use, like VGXI does.

35. Likewise, the parties agreed that: “[VGXI] did not grant, and Aldevron shall have no rights, to any patents, trade secrets or other intellectual property owned or controlled by [VGXI] now or in the future, except as explicitly granted herein.” (*Id.*)

36. Pursuant to the License Agreement, VGXI agreed to “order, assemble and test run, at [VGXI] and again at Aldevron’s facility, the equipment and materials necessary to produce small batches of plasmids using the [VGXI] Intellectual Property.” (*Id.* at Art. 3.)

37. And VGXI did in fact send employees—including Darnell (a co-inventor of the patented system)—to Aldevron’s facility in North Dakota in September 2006.

38. Those VGXI employees set up and tested the equipment and instructed Aldevron’s employees on the use of the equipment.

39. In this process, Aldevron learned VGXI’s trade secret manufacturing processes, and how to best utilize the VGXI equipment and patented technology to manufacture plasmid DNA, although only for non-GMP use.

40. The License Agreement also required that Aldevron immediately disclose to VGXI any Aldevron Improvements, defined as “all enhancements, developments, or modifications, that

improve the production and purification of plasmids in connection with the use of the [VGXI] Intellectual Property, discovered or invented by the employees of Aldevron.” (*Id.* at Art. 1, Art. 6, § 6.2.)

41. The License Agreement terminated in April 2007, and once it did, Aldevron no longer had a right to possess, access, and/or use VGXI’s intellectual property, including its trade secrets and patents.

42. Likewise, upon the request of VGXI, Aldevron was required to return “all drawings, documents, biological samples and other tangible manifestations of Confidential Information received pursuant to this Agreement (and all copies and reproductions thereof),” which it was legally obligated to do in any event. (*Id.* at Art. 5, § 5.3.)

43. To protect its confidential information and intellectual property, VGXI requested that Aldevron return all of the VGXI Confidential Information once the License Agreement terminated.

44. VGXI also exercised its option to repurchase all equipment it provided to Aldevron. Aldevron had no right to be in possession of, or to use, the equipment (or any copy of it) after their relationship terminated.

45. Aldevron misrepresented that it returned all of the VGXI Confidential Information; however, in reality, Aldevron deceptively retained VGXI’s highly-proprietary information—unbeknownst to VGXI—even after VGXI requested that it be returned, in violation of the License Agreement.

46. Also upon information and belief, Aldevron made and is making improvements to VGXI’s Confidential Information received under the License Agreement. Aldevron has failed to

“immediately disclose” those Aldevron Improvements as required under the License Agreement, which belong to VGXI.

C. 2007 – 2017: Hebel Has Access to VGXI Trade Secrets and Patents, While Aldevron Continues its Non-GMP Work.

47. Hebel continued working for VGXI until 2011.

48. During all of his time with VGXI, Hebel had continual access to VGXI’s trade secrets. In fact, Hebel was keenly aware of the trade secret processes that gave VGXI its market advantage, and knew how to manufacture first class, GMP-compliant DNA plasmids using VGXI’s intellectual property.

49. During the same timeframe, VGXI continued to grow while utilizing its trade secret processes and patented technologies, becoming a world leader in the field of GMP-compliant DNA plasmid production. In 2010, VGXI completed an expansion of its GMP manufacturing facility in the Woodlands. In 2012, one year after Hebel separated from VGXI, VGXI launched its Highly Documented plasmid manufacturing service to supply plasmid DNA as a raw material for GMP virus and cell therapy production. And in 2016, VGXI celebrated the grand opening of its Small Scale production plant. No other company in the world could match the quality, yield, and cost of VGXI’s plasmids.

50. All the while, Aldevron operated only in the non-GMP, small scale DNA plasmid market.

D. 2017 – Present: Aldevron Hires Hebel, and Begins Using VGXI’s Trade Secrets and Patented Products to Compete Unfairly with VGXI.

51. Aldevron hired Hebel as its Chief Operating Officer in 2017.

52. The following year, in 2018, Aldevron began competing with VGXI by selling and/or offering to sell its customers GMP plasmid DNA manufacturing services.

53. Now, illegally armed with VGXI's trade secrets learned under the License Agreement, and Hebel's knowledge of the patented system and manufacturing processes, Aldevron is suddenly a major player in GMP DNA plasmid manufacturing. Aldevron recently built a 70,000 square foot facility and has been touting its manufacturing process to win customers in this highly competitive field.

54. The quantity, purity, and pricing of Aldevron's GMP DNA plasmids bear all the hallmarks of VGXI's trade secrets and patented system.

55. Aldevron is creating plasmids at a quality, yield, quantity, and cost matching VGXI, which is impossible without VGXI's intellectual property, which VGXI knows Aldevron has in its possession.

56. Upon information and belief, Aldevron is offering for sale GMP-compliant plasmids to other companies in interstate commerce using VGXI's trade secrets and patented system and methods.

57. Unless this Court acts quickly to stop Aldevron's unlawful acts, VGXI will suffer irreparable harm as well as significant monetary damages.

COUNT I—MISAPPROPRIATION OF TRADE SECRETS
VIOLATION OF DTSA, 18 U.S.C. § 1836 *et seq.*

58. VGXI incorporates by reference the foregoing paragraphs of this Complaint as through the same were set forth at length herein.

59. VGXI is the owner of its trade secrets under 18 U.S.C. § 1839. The trade secrets are related to VGXI's GMP plasmid DNA manufacturing services that are used in or intended for use in interstate or foreign commerce.

60. VGXI's trade secrets are confidential and proprietary information, and VGXI has taken reasonable measures to keep that information secret. For example, VGXI requires any

visitors to sign in and sign out of its facility, and to be escorted at all times when visiting. VGXI's facilities are kept secure from unauthorized access through the use of key cards. VGXI's computer systems on which its confidential information is stored are protected by network security and access control systems. VGXI signs non-disclosure agreements (NDAs) when disclosing any confidential or trade secret information to any third parties. And, VGXI's employees are required to sign confidentiality agreements restricting their access to and disclosure of confidential and trade secret information.

61. Likewise, after the License Agreement terminated between VGXI's predecessor, ADViSYS, and Aldevron, ADViSYS requested that Aldevron return to it all drawings, documents, biological samples and other tangible manifestations of Confidential Information received pursuant to the agreement (and all copies and reproductions thereof). ADViSYS also repurchased all of the equipment it provided to Aldevron under the License Agreement and had Aldevron return the equipment. Aldevron represented that it had done so.

62. VGXI has expended considerable time, effort, and expense to develop and protect VGXI's trade secrets and related confidential information. VGXI's trade secrets are not generally known to the public and are not readily ascertainable by proper means to persons who could derive value from their disclosure or use.

63. VGXI's trade secrets derive independent economic value, actual and/or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who could obtain economic value from their disclosure or that person's use. VGXI's trade secrets are of substantial economic value and have conferred a competitive advantage to VGXI over would-be competitors, including Aldevron. For example, VGXI's trade secrets allow it to sell and offer to sell its GMP plasmid DNA manufacturing services at a lower

rate while maintaining customer-desired quantities and purities. This advantage was and is being compromised as a result of Aldevron's unlawful activities.

64. While the License Agreement between ADViSYS and Aldevron was in effect, Aldevron accessed VGXI's (formerly, ADViSYS) trade secrets. However, after that agreement terminated in April 2007, Aldevron had no right to possess, access, and/or use VGXI's trade secrets. Further, after the License Agreement terminated, VGXI has not consented to the use of any of its trade secrets by any third party, including Aldevron.

65. Upon information and belief, Aldevron misappropriated VGXI's trade secrets because it has begun offering for sale GMP plasmid DNA manufacturing services that bear all the hallmarks of VGXI's products which cannot be created except through the use of VGXI's trade secrets.

66. As set forth above, since the termination of the License Agreement and the hiring of Hebel, Aldevron has wrongfully possessed, accessed, used, and/or disclosed VGXI's trade secrets without any color of right and without VGXI's express or implied consent. On information and belief, at the time of each such use and/or disclosure, Aldevron knew or had reason to know that it acquired the trade secrets under circumstances giving rise to a duty to maintain their secrecy, limit their use, and return them to VGXI. As a result of its improper possession, use, and/or disclosure of VGXI's trade secrets, Aldevron has violated the Defend Trade Secrets Act.

67. As set forth above, Aldevron's conduct was, is, and remains willful and wanton. On information and belief, Aldevron used and misappropriated VGXI's trade secrets with blatant disregard for VGXI's valid and enforceable rights.

68. As a direct and proximate result of Aldevron's violation of the Defend Trade Secrets Act, VGXI has sustained damages that will be established at trial of this matter and Aldevron has been unjustly enriched.

69. Unless enjoined by this Court, Aldevron's actions have caused and will continue to cause VGXI imminent and irreparable harm.

70. VGXI has no adequate remedy at law to redress the conduct complained of herein and will suffer continued imminent and irreparable harm as a result.

WHEREFORE, VGXI demands judgment in its favor and against Aldevron:

- a. For a preliminary and permanent injunction in the form of an Order enjoining Aldevron from misappropriating, disclosing, using, or otherwise causing or allowing any use or disclosure of VGXI's trade secrets;
- b. For actual damages that VGXI is entitled to recover as a result of Aldevron's misappropriation, and enhanced damages due to Aldevron's willful and malicious conduct;
- c. For exemplary damages pursuant to 18 U.S.C. § 1836(b)(3)(c);
- d. For incidental and consequential damages as permitted by law;
- e. For interest;
- f. For VGXI's attorneys' fees and costs; and
- g. For all such other relief as this Court deems appropriate.

**COUNT II—MISAPPROPRIATION OF TRADE SECRETS
VIOLATION OF TUTSA, TEX. CIV. PRAC. & REM. CODE ANN. § 134A.001 et seq.**

71. VGXI incorporates by reference the foregoing paragraphs of this Complaint as through the same were set forth at length herein.

72. VGXI is the owner of its trade secrets under Tex. Civ. Prac. & Rem. Code § 134A.002(6). The trade secrets are related to VGXI's GMP plasmid DNA manufacturing services that are used in or intended for use in interstate or foreign commerce.

73. VGXI's trade secrets are confidential and proprietary information, and VGXI has taken reasonable measures to keep that information secret, as detailed in paragraphs 60 and 61 above.

74. VGXI has expended considerable time, effort, and expense to develop and protect VGXI's trade secrets and related confidential information. VGXI's trade secrets are not generally known to the public and are not readily ascertainable by proper means to persons who could derive value from their disclosure or use.

75. VGXI's trade secrets derive independent economic value, actual and/or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who could obtain economic value from their disclosure or that person's use. VGXI's trade secrets are of substantial economic value and have conferred a competitive advantage on VGXI over would-be competitors, including Aldevron. For example, VGXI's trade secrets allow it to sell and offer to sell its GMP plasmid DNA manufacturing services at a lower rate while maintaining customer-desired quantities and purities. This advantage was and is being compromised as a result of Aldevron's unlawful activities.

76. While the License Agreement between ADViSYS and Aldevron was in effect, Aldevron accessed VGXI's (formerly, ADViSYS) trade secrets. However, after that agreement terminated in April 2007, Aldevron had no right to possess, access, and/or use VGXI's trade secrets. Further, after the License Agreement terminated, VGXI has not consented to the use of any of its trade secrets by any third party, including Aldevron.

77. Upon information and belief, Aldevron misappropriated VGXI's trade secrets because it has begun offering, and continues to offer, for sale GMP plasmid DNA manufacturing services that bear all the hallmarks of VGXI's products which cannot be created except through the use of VGXI's trade secrets.

78. As set forth above, since the termination of the License Agreement and the hiring of Hebel, Aldevron has wrongfully possessed, accessed, used, and/or disclosed VGXI's trade secrets without any color of right and without VGXI's express or implied consent. On information and belief, at the time of each such use and/or disclosure, Aldevron knew or had reason to know that it acquired the trade secrets under circumstances giving rise to a duty to maintain their secrecy, limit their use, and return them to VGXI. As a result of its improper possession, use, and/or disclosure of VGXI's trade secrets, Aldevron has violated the Texas Uniform Trade Secrets Act.

79. As set forth above, Aldevron's conduct was, is, and remains willful and wanton. On information and belief, Aldevron used and misappropriated VGXI's trade secrets with blatant disregard for VGXI's valid and enforceable rights.

80. As a direct and proximate result of Aldevron's violation of the Texas Uniform Trade Secrets Act, VGXI has sustained damages that will be established at trial of this matter and Aldevron has been unjustly enriched.

81. Unless enjoined by this Court, Aldevron's actions have caused and will continue to cause VGXI imminent and irreparable harm.

82. VGXI has no adequate remedy at law to redress the conduct complained of herein and will suffer continued imminent and irreparable harm as a result.

WHEREFORE, VGXI demands judgment in its favor and against Aldevron:

- a. For a preliminary and permanent injunction in the form of an Order enjoining Aldevron from misappropriating, disclosing, using, or otherwise causing or allowing any use or disclosure of VGXI's trade secrets;
- b. For actual damages that VGXI is entitled to recover as a result of Aldevron's misappropriation, and enhanced damages due to Aldevron's willful and malicious conduct;
- c. For incidental and consequential damages as permitted by law;
- d. For interest;
- e. For VGXI's attorneys' fees and costs; and
- f. For all such other relief as this Court deems appropriate.

COUNT III—INFRINGEMENT OF THE '522 PATENT

83. VGXI incorporates by reference the foregoing paragraphs of this Complaint as through the same were set forth at length herein.

84. VGXI owns by assignment the entire right, title, and interest in the '522 Patent, attached as Exhibit B.

85. The '522 Patent is valid and enforceable under the laws of the United States.

86. A person of skill in the art reading the '522 Patent understands the patent is directed to apparatuses and methods for preparing large quantities of high purity DNA plasmids. Claim 1 of the '522 Patent is a representative apparatus:

1. An apparatus for isolating cellular component of interest from cells comprising:
 - (a) a first tank, wherein the first tank is used for holding a suspension of cells having the cellular component of interest;
 - (b) a mixer in fluid communication with the first tank;

- (c) a second tank in fluid communication with the mixer, wherein the second tank is used for holding a lysis solution;
- (d) a holding coil in fluid communication with the mixer; and
- (e) a bubble-mixer chamber with a top and a bottom having:
 - (i) a first inlet in fluid communication with the holding coil;
 - (ii) a second inlet in fluid communication with a third tank, wherein the third tank is used for holding a precipitation solution, a neutralization solution, or a mixture thereof;
 - (iii) a third inlet in fluid communication with a gas source;
 - (iv) a vent; and
 - (v) an outlet in fluid communication with a fourth tank, wherein the fourth tank is used for separating precipitated cellular components from fluid cell lysate; wherein, the mixer is a high-shear, low-residence-time-mixing-device, wherein the residence-time is less than or equal to about one second; the suspension of cells having the plasmid DNA from the first tank is allowed to flow into the mixer; the lysis solution from the second tank is allowed to flow into the mixer; a lysate-mixture is allowed to flow from the mixer into the holding coil; the lysate-mixture from the holding coil is allowed to flow into the bubble-mixer chamber; the precipitation solution, the neutralization solution, or the mixture thereof from the third tank is allowed to flow into the bubble-mixer chamber; and a suspension containing the cellular component of interest is allowed to flow from the bubble-mixer chamber into the fourth tank.

87. On information and belief, in violation of 35 U.S.C. § 271(a), Aldevron directly infringed and continues to directly infringe (literally and/or by the doctrine of equivalents) at least claim 1 of the '522 Patent by using, selling and/or offering to sell its GMP plasmid DNA manufacturing services to its customers. On information and belief, in connection with its GMP plasmid DNA manufacturing services, Aldevron uses a system for isolating cellular component of interest from cells ("Aldevron Accused System").

88. The Aldevron Accused System meets each and every limitation of at least claim 1 of the '522 Patent. In 2005, VGXI licensed its trade secrets and the '522 Patent to Aldevron. Upon information and belief, prior to that time, Aldevron was not able to effectively manufacture GMP-compliant DNA plasmids. Under the licensing program, and working closely with VGXI personnel, Aldevron learned VGXI's proprietary system and methods for making GMP-compliant DNA plasmids, including the apparatus recited in Claim 1 of the '522 Patent. The license was

terminated in 2007. In 2017, Hebel, an inventor of the '522 Patent, left VGXI and joined Aldevron as its Chief Operating Officer. Now, illegally armed with the VGXI's proprietary information learned under the License Agreement, and Hebel's knowledge of the patented system and manufacturing processes, Aldevron is suddenly able to manufacture in large scale, and at low cost, high purity GMP-compliant DNA plasmids. Aldevron is now a major player in GMP DNA plasmid manufacturing. Aldevron recently built a 70,000 square foot facility and has been touting its manufacturing process to win customers in this highly competitive field. Aldevron does not disclose its manufacturing system and processes to the public. Upon information and belief, Aldevron could not achieve the quantity, purity, and pricing of its GMP plasmid DNA manufacturing services without employing the apparatus recited in Claim 1 of the '522 Patent and that it learned from VGXI under the License Agreement. Other competitors have been unsuccessful in offering to sell GMP plasmid DNA manufacturing services at the quantity, purity, and pricing offered by VGXI, and VGXI uses the patented system.

89. Aldevron's infringement of the '522 Patent has been and continues to be willful and deliberate. Aldevron has had knowledge of the '522 Patent at least since it licensed the underlying patent application from VGXI in 2005, and certainly upon its issuance in 2007. However, upon information and belief, Aldevron continued to use the Aldevron Accused System to manufacture GMP-compliant DNA plasmids despite an objectively high likelihood that its actions constituted infringement of the '522 Patent.

90. VGXI has been damaged and continues to be damaged by Aldevron's infringing acts.

WHEREFORE, VGXI demands judgment in its favor and against Aldevron:

- a. For an Order finding that Aldevron directly infringes and has directly infringed the '522 Patent;
- b. For an Order finding that Aldevron has willfully infringed the '522 Patent;
- c. For damages to compensate VGXI for Aldevron's infringement of the '522 Patent pursuant to 35 U.S.C §§ 284 and 289, including enhanced damages up to three times the amount of damages found or measured and supplemental damages for any continuing post-verdict infringement up until entry of final judgment, with an accounting, as needed;
- d. An Order enjoining Aldevron, its officers, agents, employees, and those persons in active concert or participation with any of them, and Aldevron's successors and assigns, from continuing to infringe the '522 Patent;
- e. For an Order that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding VGXI its costs, expenses, and reasonable attorneys' fees incurred in this action;
- f. For incidental and consequential damages as permitted by law;
- g. For pre-judgment and post-judgment interest; and
- h. For all such other relief as this Court deems appropriate.

COUNT IV—BREACH OF CONTRACT

91. VGXI incorporates by reference the foregoing paragraphs of this Complaint as through the same were set forth at length herein.

92. The License Agreement was a valid contract entered into by VGXI's predecessor ADViSYS and Aldevron. VGXI is ADViSYS's successor in interest, and all rights under the License Agreement have inured to the benefit of VGXI.

93. ADViSYS fully performed all of its obligations under the License Agreement.

94. Aldevron has breached its contractual obligations to ADViSYS and VGXI, as detailed above, by (among other things): failing to return all drawings, documents, biological samples and other tangible manifestations of VGXI's "Confidential Information" that Aldevron received pursuant to the License Agreement (and all copies and reproductions thereof); and failing to disclose the Aldevron Improvements, which belong to VGXI.

95. As a direct and proximate result of Aldevron's breaches of the License Agreement, VGXI has sustained, and will continue to sustain, actual damages.

96. Furthermore, as a direct and proximate result of Aldevron's breaches of the License Agreement, VGXI has suffered, and will continue to suffer, irreparable harm.

WHEREFORE, VGXI demands judgment in its favor and against Aldevron:

- a. For a preliminary and permanent injunction in the form of an Order requiring Aldevron to return all of VGXI's Confidential Information and the Aldevron Improvements, and further enjoining all use of such Confidential Information and any Aldevron Improvements;
- b. For actual damages that VGXI is entitled to recover as a result of Aldevron's breaches;
- c. For incidental and consequential damages as permitted by law;
- d. For interest;
- e. For VGXI's attorneys' fees and costs; and

- f. For all such other relief as this Court deems appropriate.

COUNT V—UNJUST ENRICHMENT

97. VGXI incorporates by reference the foregoing paragraphs of this Complaint as through the same were set forth at length herein.

98. Aldevron derived benefits, including commercial advantage and private financial gain, from their unauthorized use of VGXI's trade secrets, confidential information, and patented system.

99. Aldevron was on notice and/or fully aware that VGXI was the sole owner, creator, and source of VGXI's trade secrets and patented system.

100. Aldevron obtained the benefit of using VGXI's trade secrets and patented system without VGXI's notice, authorization, and/or permission.

101. Upon information and belief, Aldevron accepted and retained the benefit of accessing and using VGXI's trade secrets and patented system to develop their own competing manufacturing process, after their previous attempts had proven commercially unsuccessful.

WHEREFORE, VGXI demands judgment in its favor and against Aldevron:

- a. For actual damages that VGXI is entitled to recover as a result of Aldevron's inequitable conduct;
- b. For an Order requiring Aldevron to disgorge the profits earned as a result of its unjust enrichment;
- c. For incidental and consequential damages as permitted by law;
- d. For interest;
- e. For VGXI's attorneys' fees and costs; and
- f. For all such other relief as this Court deems appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, VGXI hereby demands a jury trial on issues so triable.

Dated: December 6, 2019

Respectfully submitted,

BLANK ROME LLP

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Attorneys for Plaintiff, VGXI, Inc.

VERIFICATION

I, Young K. Park, President/CEO of Plaintiff VGXI, Inc., do hereby verify and affirm that the facts set forth in the foregoing Verified Complaint are true and correct to the best of my knowledge, information, and belief. I am authorized to make and am making this Verification on behalf of the Plaintiff.

This Verification is made subject to the penalties of 28 U.S.C. § 1746 for unsworn falsification to authorities.


YOUNG K. PARK

Dated: December 5, 2019