JUDGE BRODERICK

21 CV 08206

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ERRANT GENE THERAPEUTICS, LLC

Plaintiff,

-against-

MEMORIAL SLOAN-KETTERING CANCER CENTER and SLOAN KETTERING INSTITUTE OF CANCER RESEARCH

Defendants.

Case No. _____

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Errant Gene Therapeutics, LLC ("EGT"), for its Complaint for Declaratory Judgment against Defendants Memorial Sloan-Kettering Cancer Center ("MSKCC") and Sloan Kettering Institute for Cancer Research ("SKI") (collectively "MSK" or "Defendants"), hereby alleges as follows:

INTRODUCTION

1. EGT is a biopharmaceutical company, established in 1993 by its founder and CEO, Mr. Patrick Girondi, after his son was diagnosed with Beta Thalassemia, a rare inherited blood disorder. Since that time, and for the greater part of nearly two decades, EGT has dedicated itself to developing treatments for life-threatening diseases, with a special focus on rare diseases, (commonly referred to as orphan diseases) through the use of gene therapy — a scientific technique that treats genetic disorders by modifying, replacing, and/or inactivating mutated genes responsible for causing the disease.

2. As a result of its tireless efforts, EGT has successfully developed recombinant vectors that can be used in gene therapy treatment of rare genetic diseases, such as Sickle Cell

Disease and Beta Thalassemia (also referred to as β-thalassemia). Indeed, EGT became the first company to obtain Orphan Drug Designation for Beta Thalassemia in the United States and Europe, and the first to produce a commercial batch (8-10 patients) of gene therapy for Beta Thalassemia.

3. MSK granted EGT an exclusive, royalty-free commercial license to U.S. Patent Nos. 7,541,179 ("the '179 Patent") and 8,058,061 ("the '061 Patent"), titled "Vector Encoding Human Globin Gene And Use Thereof In Treatment of Hemoglobinopathies," which claim recombinant vectors that are used in the treatment of hemoglobinpathies, such as Sickle Cell Disease and Beta Thalassemia.

4. In this action, EGT seeks a declaration that recombinant vectors SNS23.B87.A1 and SNS23.2.B87.A1 (collectively, the "SNS23 Vectors") are covered by a valid claim of the '179 Patent and/or '061 Patent.

5. A real, immediate, substantial, and justiciable controversy exists between EGT and MSK as to whether the SNS23 Vectors are within the scope of, at least, claims 1 and 23 of the '179 Patent, and claims 1 and 11 of the '061 Patent, either literally or under the doctrine of equivalents.

THE PARTIES

6. EGT is a Delaware limited liability company with its principal place of business at 308 East Emily Street, Tampa, Florida 33603.

7. Upon information and belief, MSKCC is a New York corporation with its principal place of business at 1275 York Avenue, New York, New York 10065.

8. Upon information and belief, SKI is (i) a research affiliate of MSKCC and (ii) a New York membership corporation, with principal offices at 1275 York Avenue, New York, New York 10065.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this case pursuant to federal question jurisdiction, 28 U.S.C. §§ 1331, 1338, the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and the Patent Laws of the United States, 35 U.S.C. § 1 *et. seq*.

10. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338, and 2201 based on a definite and concrete, real and substantial justiciable controversy between, EGT and MSK for a declaratory judgment that the SNS23 Vectors are covered by a valid claim of the '179 Patent and/or '061 Patent.

11. This Court has subject matter jurisdiction over this action based on a real and immediate controversy between EGT and MSK regarding whether the manufacture, use, importation, and sale of the SNS23 Vectors are covered by a valid claim of the '179 Patent and/or '061 Patent.

12. This Court has personal jurisdiction over MSKCC because MSKCC is a New York corporation with its principal place of business at 1275 York Avenue, New York, New York 10065.

13. This Court has personal jurisdiction over SKI because SKI is a New York membership corporation with principal offices at 1275 York Avenue, New York, New York 10065.

14. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(a), 1391(c), and 1400(b) because all Defendants reside or are located in this District, a substantial part of the events or omissions giving rise to EGT's claims occurred in this District, Defendants regularly conduct business in this District, and Defendants are subject to personal jurisdiction in this District.

THE PATENTS-AT-ISSUE

15. On June 2, 2009, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '179 Patent entitled, "Vector Encoding Human Globin Gene and Use Thereof in Treatment of Hemoglobinopathies," to Michel Sadelain, Stefano Rivella, Chad May, and Joseph Bertino, and the '179 Patent was assigned to MSKCC. A true and correct copy of the '179 Patent is attached as Exhibit A.

16. Upon information and belief, MSKCC assigned the '179 Patent to SKI.

17. The '179 Patent issued from U.S. Patent Application No. 10/188,221, which claims priority to provisional application nos. 60/301,861 filed on June 29, 2001, and 60/302,852 filed on July 2, 2001.

18. On November 15, 2011, the USPTO issued the '061 Patent entitled, "Vector Encoding Human Globin Gene and Use Thereof in Treatment of Hemoglobinopathies," to Michel Sadelain, Stefano Rivella, Chad May, and Joseph Bertino and, the '061 Patent was assigned to MSKCC. A true and correct copy of the '061 Patent is attached as Exhibit B.

19. Upon information and belief, MSKCC assigned the '061 Patent to SKI.

20. The '061 Patent issued from U.S. patent application No. 12/433,412, which is a division of application No. 10/188,221 filed on July 1, 2002, now the '179 Patent. The '061 Patent claims priority to provisional application nos. 60/301,861 filed on June 29, 2001, and 60/302,852 filed on July 2, 2001.

EGT Has an Exclusive, Royalty-Free, Commercial License to the '179 and '061 Patents

21. [redacted]

[redacted]

22. The intellectual property licensed in the 2005 Agreement is set forth under Exhibit A thereto, and includes: U.S. Patent Application No. 10/188,221, filed on July 1, 2002, Vector Encoding Human Globin Gene and Use thereof in Treatment of Hemoglobinopathies; U.S. Provisional Applications Nos. 60/301,861, filed on June 29, 2001 and 60,302,852 filed on July 2, 2001; and International Application No. PCT/US2002/020988. *See* Exhibit D, 2005 Agreement, at Exhibit A ("Patent Rights").

23. The 2005 Agreement further provides that the "Patent Rights shall mean all of the following [MSK] intellectual property: (a) the United States and foreign patents and patent applications listed in Exhibit A; (b) the United States and foreign patents issued from the applications listed in Exhibit A and from divisionals and continuations of these applications; (c) claims of U.S. and foreign continuation-in-part applications, and of the resulting patents, which are directed to the subject matter specifically described in the U.S. and foreign patent applications listed in Exhibit A; and (d) any reissues or re-examinations of patents described in (a), (b), or (c), above." *See* Exhibit D, at Art. 1 § 1.10.

24. The '179 Patent issued from U.S. Patent Application No. 10/188,221, which is listed in Exhibit A to the 2005 Agreement. The '061 Patent is a Division of Application No. 10/188,221 filed on July 1, 2002, now the '179 Patent. The '179 and '061 Patents claim priority to Provisional Application Nos. 60/301,861 and 60/302,852, which are listed in Exhibit A to the 2005 Agreement.

25. EGT has an exclusive, royalty-free commercial license to any process, service, or any product or part thereof made, used or sold that is covered by a valid claim of the '179 Patent and/or the '061 Patent.

26. EGT has an exclusive, royalty-free commercial license to any process, service, or any product or part thereof made, used, or sold that is manufactured by using a process covered by a valid claim of the '179 and/or the '061 Patent.

FACTUAL BACKGROUND

EGT is on the Verge of Finding a Cure for Sickle Cell Disease and Beta Thalassemia

27. Sickle Cell Disease is a genetic disease that affects millions of people throughout the world and is particularly common amongst those with ancestors from sub-Saharan Africa; Spanish-speaking regions in the Western hemisphere (South America, the Caribbean, and Central America), Saudi Arabia, India, and Mediterranean countries such as Turkey, Greece, and Italy.

28. Beta Thalassemia (a cousin to Sickle Cell Disease) is a rare, inherited blood disorder (passed on from one or both parents) caused by mutations in the hemoglobin beta ("HBB") gene, which prevents the body from properly producing hemoglobin, the protein in red blood cells that transports oxygen to organs and tissues. While Beta Thalassemia affects a large population of children worldwide – most often people who are of Mediterranean (Greek, Italian, and Middle Eastern), Asian or African descent – it is rare in the United States and the disease is overlooked.

29. People with Beta Thalassemia often develop severe anemia, which can cause damage to the heart, liver, and hormone producing glands, and they may suffer from bone deformities, enlarged spleens, delayed growth rates, and congenital heart failure.

30. The only established cure for Beta Thalassemia is a bone marrow or stem cell

transplant, yet fewer than 25% of patients have compatible donors. Short of such a transplant, people with Beta Thalassemia require blood transfusions (every 14 to 28 days), which in turn, require them to undergo painful iron chelation medications to reduce iron build-up in the blood from the transfusions themselves. Even with frequent blood transfusions, Beta Thalassemia most often results in death by the time a person reaches their late 20s. Indeed, the average age of mortality is twenty-eight years.

31. The clinical trial using the EGT-produced vector has the longest track record of treating patients with Beta Thalassemia in the United States, and is the only clinical trial with experience in both harsh and mild chemotherapeutic prep-regimens.

32. In 2000, EGT began financially supporting the research of Drs. Michel Sadelain and Stefano Rivella, both of whom were researchers at MSK, and had published a paper on their experiments with gene therapy for treating Beta Thalassemia in mice.

33. EGT's tireless efforts, and work with Dr. Sadelain and others, resulted in the development of the TNS9.3.55 vector (the "TNS9 Vector") for the treatment of Beta Thalassemia.

34. In 2003, however, MSK informed EGT that it would no longer continue to support the Beta Thalassemia and Sickle Cell Disease gene therapy project, as its primary focus was on cancer research and treatment.

35. EGT committed every available resource at its disposal to produce the TNS9 Vector — what became trademarked by EGT as Thalagen — in accordance with the U.S. Federal Drug Administration's ("FDA") stringent approval process for investigational new drugs ("IND").

36. In addition, EGT diligently, through various industrial research agreements with MSK and other top medical centers, continued testing and refining the TNS9 Vector to ensure patient safety, and to ensure conformance with the highest manufacturing and testing standards,

designated by the FDA as chemical Good Manufacturing Practice ("cGMP").

37. In 2007, EGT became the first entity to pass the FDA Recombinant DNA Committee for gene therapy in Beta Thalassemia (and future applications in Sickle Cell Disease).

38. In 2008, EGT successfully requested a pre-IND meeting with the FDA to advance to clinical (*i.e.*, human) trials, the next stage necessary to develop the TNS9 Vector.

39. On September 1, 2010, EGT completed the manufacture and production of a batch of the TNS9 Vector in an amount sufficient to treat 8-10 patients in a Phase I clinical trial. The physical production of the TNS9 Vector alone cost $1,300,000.

MSK Delays Clinical Trials and Litigation Ensues

40. Armed with the first commercial batch of the TNS9 Vector, EGT was eager to begin the clinical trial. MSK requested that EGT deliver the TNS9 Vector to MSK for use in a mobilization study. EGT, completely trusting of their partner, complied pursuant to the 2005 Agreement.

41. In October 2010, MSK demanded a $4 million cash advance from EGT before it would allow any clinical trial involving the TNS9 Vector to take place at MSK.

42. Given that part of EGT's mission was to make gene therapy treatment not only safe, but affordable to patients, EGT refused to agree to such a demand. Moreover, Dr. John Tisdale, the then-EGT Principal Investigator on the Beta Thalassemia gene therapy project at the National Institutes of Health ("NIH") was willing to hold the clinical trial and treat patients for less than $50,000 each. Using the NIH would save over $3 million in funding that could be used for further Beta Thalassemia research. Thus, it would have been fiscally irresponsible for EGT to pay MSK 8 times more for a comparable service.

43. EGT also refused MSK's $4 million cash demand because MSK could not

guarantee that the clinical trial would be completed, and meanwhile, the FDA wanted a patient to be treated every 3 months. Indeed, as of the filing of this action, MSK has treated only 4 patients with the TNS9 vector.

44. Desperate to begin clinical trials and to work towards finding a cure for his son, Mr. Girondi and EGT sent a living organism courier to pick up the TNS9 Vector from MSK in March 2011. MSK refused to return the TNS9 Vector to EGT.

45. Given that many months had passed without treating a single patient with the TNS9 Vector, EGT met with MSK on June 16, 2011. At the June 16, 2011 meeting, MSK proposed a new agreement: MSK would take control over from EGT the clinical trial and commercial exploitation of the TNS9 Vector. In addition, MSK and its representatives repeatedly stated that MSK had already spent significant funds to draft the IND application, that the IND application was complete and ready to be filed immediately, and that MSK would treat patients with EGT's TNS9 Vector by October 2011.

46. Due to EGT's strong desire to move forward with the clinical trial and the IND application process with the FDA, MSK's representations induced EGT to execute an agreement dated June 17, 2011 (the "2011 Agreement"), whereby MSK assumed the right to commercially develop the TNS9 Vector, and EGT maintained 50% of the upside of the gene therapy project.

47. With the 2011 Agreement, EGT believed that the potential to commercialize and realize profits from EGT's TNS9 Vector wsould motivate MSK to aggressively proceed to the market with it. But that was not the case. In fact, MSK did not file the IND application until September 2011, which the FDA rejected. And it was not until over 9 months later, and nearly a year after the June 16, 2011 meeting, that the FDA accepted the IND.

48. From November 2011 through June 2013, an additional two years later, MSK

treated the first 3 out of 7-10 (intended) patients with the TNS9 Vector. By 2015, MSK acknowledged that they had no funding to proceed with the clinical trial and were no longer actively pursuing the exploitation of EGT's TNS9 Vector. Yet MSK still refused to return the TNS9 Vector to EGT.

49. Thus, beginning in 2015, EGT commenced a lawsuit against MSK, seeking the return of the TNS9 Vector, including any and all information (laboratory, clinical or otherwise) related thereto. When MSK (again) refused to return the TNS9 Vector, EGT commenced two additional lawsuits – one in New York state court entitled, *Errant Gene Therapeutics, LLC v. Sloan Kettering Institute for Cancer Research, et al.*, Index. No. 150856/2017 (N.Y. Cty. Sup. Ct.) (the "New York Litigation"), and one in Massachusetts state court entitled, *Errant Gene Therapeutics, LLC v. Third Rock Ventures, LLC, et al.*, Civil Action No. 19-1832 (Mass. Sup. Ct.) (the "Massachusetts Litigation") – seeking, among other things, damages for fraud, unfair competition, and breach of contract.

50. [redacted]

51. [redacted]

which includes the '179 and '061 Patents. Ex. C, ¶ 2a.

ACTS GIVING RISE TO THIS ACTION

52. Dr. Sadelain slightly modified the TNS9 Vector to create very similar vectors, identified as the SNS23 Vectors.

53. Upon information and belief, Dr. Sadelain affirmatively stated that the "SNS23 Vector is *very very very very very very* similar to the TNS9 Vector."

54. Upon information and belief, Dr. Sadelain stated that the development of the SNS23 Vectors was a "real straight arrow" from the TNS9 Vector.

55. In 2015, the New York Stem Cell organization awarded teams led by Dr. Sadelain of MSK and Dr. Shahin Rafii of Cornell University $15,700,000 to improve the TNS9 Vector and to begin clinical trials. According to https://news.weill.cornell.edu/news/2015/05/scientists-receive-157m-to-develop-stem-cell-therapies-to-treat-blood-disorders, "[t]he team led by Drs. Sadelain and Riviere brings significant expertise with stem-cell engineering and clinical translation of innovative cell therapies. Drs. Juliet Barker, Sergio Giralt and Farid Boulad will lead the phase I clinical trials at MSK that are expected to start within the next two to three years." But by February 2021, Dr. Sadelain stated that he did not have sufficient funding to begin clinical trials.

56. On May 12, 2021, after receiving the Outstanding Achievement Award from the American Society of Gene & Cell Therapy's ("ASGCT"), Dr. Sadelain presented to the world data on the TNS9 and SNS23 Vectors during his delivery of the George Stamatoyannopoulos Memorial Lecture entitled, "Gene Therapy Through the Lens of the Beta Globin Gene" at the 24th annual ASGCT conference. In his lecture, Dr. Sadelain said: "Without the addition of any transducing enhancer we can attain levels of gene transfer that we could not with the earlier version of TNS9," explicitly indicating that the SNS23 Vector is a later version of the TNS9 Vector.

57. Upon information and belief, MSK is aware that the TNS9 Vector is within the scope of the claims of the '179 and '061 Patents.

58. However, MSK disputes that the SNS23 Vectors are within the scope of a valid claim of the '179 Patent and/or '061 Patent.

59. MSK agrees that EGT has an exclusive, royalty-free, commercial license to the patents listed in the 2005 Agreement (*i.e.*, the '179 and '061 Patents).

60. However, MSK refuses to acknowledge that the SNS23 Vectors are covered by any valid claim of the '179 Patent and/or '061 Patent.

61. Despite the SNS23 Vectors being covered by the '179 and '061 Patents, MSK has refused to provide to EGT the SNS23 Vectors or any data concerning the SNS23 Vectors.

62. MSK disputes that EGT's exclusive, royalty-free, commercial license to the '179 and '061 Patents allows EGT to engage in developing, making, having made, using, importing, selling or offering to sell the SNS23 Vectors because such Vectors are covered by the claims of the '179 and '061 Patents, either directly or under the doctrine of equivalents.

63. On June 2, 2020, MSK filed a U.S. patent application No. 16/890,436 ("the '436 Patent Application"), titled "Globin Gene Therapy For Treating Hemoglobinopathies," which was published on September 17, 2020 as U.S. Patent Publication No. US2020/0291433 ("the '433 Publication").

64. MSK has submitted claims in the '436 Patent Application that cover recombinant vectors, including the SNS23.B87.A1 and SNS23.2.B87.A1 vectors.

65. MSK's '436 Patent Application includes pending claims that cover the SNS23.B87.A1 and SNS23.2.B87.A1 vectors.

66. MSK's '436 Patent Application includes descriptions about the TNS9 Vector, and other SNS vectors, including the SNS23.B87.A1 and SNS23.2.B87.A1 vectors.

67. In an August 4, 2021 correspondence, MSK's counsel stated that "MSK has no ownership rights in the [SNS23] vector." Upon information and belief, MSK transferred all rights, title, and interest, including any commercialization rights, in the SNS23 Vectors to someone other than EGT.

68. Even though MSK purports to have no ownership rights in the SNS23 Vectors, MSK's '436 Patent Application has one or more pending claims that cover the SNS23 Vectors. There is no recorded patent assignment for the '436 Patent Application in the USPTO's Patent Assignment Database.

69. Upon information and belief, MSK transferred all rights, title, and interest in the SNS23 Vectors to someone other than EGT, with knowledge (or reasonable belief) that such SNS23 Vectors are within the scope of the claims of the '179 and '061 Patents, and with knowledge that EGT has an exclusive royalty-free commercial license to the '179 and '061 Patents.

70. Upon information and belief, MSK filed the '436 Patent Application with claims covering the SNS23 Vectors with knowledge (or reasonable belief) that the SNS23 Vectors are within the scope of the claims of the '179 and '061 Patents and with knowledge that EGT has an exclusive royalty-free commercial license to the '179 and '061 Patents.

71. Upon information and belief, MSK has misappropriated EGT's patent / license rights as well as the fruit of EGT's work and expenditures by, among other things, filing the '436 Patent Application with claims that cover the SNS23 Vectors.

72. Upon information and belief, MSK has misappropriated EGT's patent / license rights as well as the fruit of EGT's work and expenditures, by among other things, transferring all rights, title, and interest in the SNS23 Vectors to someone other than EGT.

73. Upon information and belief, if EGT were to engage in any research and development, business and/or commercialization activities for the SNS23 Vectors, EGT will be sued for infringing the patent when it subsequently issues from MSK's '436 Patent Application.

74. An actual and justiciable controversy exists between EGT and MSK as to the coverage and scope of the claims of the '179 and '061 Patents with respect to the SNS23 Vectors.

75. MSK's actions have placed a cloud over EGT's current business activities and research and development, and efforts to commercialize its treatment for Sickle Cell Disease and Beta Thalassemia.

76. The ongoing controversy created by MSK's assertions — that EGT does not have an exclusive, royalty-free commercial license to the SNS23 Vectors since such Vectors are not covered by the claims of the '179 and '061 Patents — has adversely affected EGT's ability to operate and pursue its business dedicated to developing treatments for Sickle Cell Disease and Beta Thalassemia, and will continue to do so unless the controversy between MSK and EGT is resolved by this Court.

FIRST CAUSE OF ACTION
The '179 Patent

77. EGT repeats and incorporates by reference the allegations in paragraphs 1 through 76.

78. EGT seeks a judicial declaration that the SNS23 Vectors are within the scope of claims 1 and 23 of the '179 Patent so that EGT may engage in developing, making, having made, using, importing, selling or offering to sell the SNS23 Vectors that are covered by the '179 Patent, either directly or under the doctrine of equivalents.

79. The '179 Patent covers recombinant lentiviral vectors having a region encoding a functional β-globin gene; and large portion of the β-globin locus control regions ("LCR") which

include DNase I hypersensitive sites HS2, HS3 and HS4 provides expression of β-globin when introduced into a mammal, for example a human, in vivo.

80. "In accordance with the invention, a recombinant lentiviral vector is provided comprising:

(a) a region comprising a functional globin gene; and

(b) large portions of the β-globin locus control regions which include large portions of DNase I hypersensitive sites HS2, HS3 and HS4. The regions may be the complete site or some lesser site which provides the same functionality as the specific sequences set forth below. This vector provides expression of β-globin when introduced into a mammal, for example a human, in vivo. Optionally, the vector further comprises a region encoding a dihydrofolate reductase.

By incorporation of different globin genes, the vector of the invention may be used in treatment of hemoglobinopathies, including α- and β-thalassemia and sickle-cell disease." '179 Patent, at col. 1:47-62 (Ex. A at 6).

81. At least, the SNS23.B87.A1 and SNS23.2.B87.A1 vectors are in accordance with the invention claimed in the '179 Patent. *See* '179 Patent Claim Chart, Ex. E.

82. EGT has an exclusive, royalty-free commercial license to the vectors that are within the scope of the claims of the '179 Patent.

83. Claim 1 of the '179 Patent is directed to a recombinant vector comprising a nucleic acid encoding a functional globin operably linked to a 3.2-kb nucleotide fragment which consists essentially of three contiguous nucleotide fragments obtainable from a human β-globin locus control region (LCR), the three fragments being a BstXI and SnaBI HS2-spanning nucleotide fragment of said LCR, a BamHI and HindIII HS3-spanning nucleotide fragment of said LCR and

a BamHI and BanII HS4-spanning nucleotide fragment of said LCR, said vector providing expression of the globin in a mammal in vivo.

84. Claim 23 of the '179 Patent is directed to a recombinant vector comprising a nucleic acid encoding a functional globin operably linked to a 3.2-kb nucleotide fragment which consists essentially of three nucleotide fragments obtainable from a human β-globin LCR, the three fragments being a BstXI and SnaBI, HS2-spanning nucleotide fragment of said LCR, a BamHI and HindIII, HS3-spanning nucleotide fragment of said LCR, and a BamHI and BanII, HS4-spanning nucleotide fragment of said LCR, wherein the HS3-spanning nucleotide fragment and the HS4-spanning nucleotide fragment are adjacent to each other and the vector further comprises 2 GATA-1 binding sites at the junction between the HS3-spanning and HS4-spanning nucleotide fragments, said vector providing expression of the globin in a mammal in vivo.

85. As demonstrated in the '179 Patent claim chart (*see* Ex. E), the SNS23.B87.A1 and SNS23.2.B87.A1 vectors are within the scope of claims 1 and 23 of the '179 Patent, either literally or under the doctrine of equivalents.

86. A judicial declaration that the SNS23 Vectors are within the scope of claims 1 and 23 of the '179 Patent is necessary and appropriate at this time so that EGT can exercise its exclusive licensing rights to the '179 Patent.

SECOND CAUSE OF ACTION
The '061 Patent

87. EGT repeats and incorporates by reference the allegations in paragraphs 1 through 86.

88. EGT seeks a judicial declaration that the SNS23 Vectors are within the scope of claims 1 and 11 of the '061 Patent so that EGT may engage in developing, making, having made,

using, importing, selling or offering to sell the SNS23 Vectors that are covered by the '061 Patent, either directly or under the doctrine of equivalents.

89. The '061 Patent covers recombinant lentiviral vectors having a region encoding a functional β-globin gene; and large portion of the β-globin locus control regions ("LCR") which include DNase I hypersensitive sites HS2, HS3 and HS4 provides expression of β-globin when introduced into a mammal, for example a human, in vivo.

90. "In accordance with the invention, a recombinant lentiviral vector is provided comprising:

(a) a region comprising a functional globin gene; and

(b) large portions of the β-globin locus control regions which include large portions of DNase I hypersensitive sites HS2, HS3 and HS4. The regions may be the complete site or some lesser site which provides the same functionality as the specific sequences set forth below. This vector provides expression of β-globin when introduced into a mammal, for example a human, in vivo. Optionally, the vector further comprises a region encoding a dihydrofolate reductase.

By incorporation of different globin genes, the vector of the invention may be used in treatment of hemoglobinopathies, including α- and β-thalassemia and sickle-cell disease." '061 Patent, at col. 1:50-64 (Ex. B at 5).

91. At least, the SNS23.B87.A1 and SNS23.2.B87.A1 vectors are in accordance with the invention claimed in the '061 Patent. *See* '061 Patent Claim Chart, Ex. F.

92. EGT has an exclusive, royalty-free commercial license to the vectors that are within the scope of the claims of the '061 Patent.

93. Claim 1 of the '061 Patent is directed to an isolated mammalian hematopoietic progenitor cell or an isolated mammalian stem cell comprising a recombinant lentiviral vector.

94. Claim 11 of the '061 Patent is directed to a method of making a mammalian hematopoietic progenitor cell or a mammalian stem cell.

95. As demonstrated in the '061 Patent claim chart (*see* Ex. F) the SNS23.B87.A1 and SNS23.2.B87.A1 vectors are within the scope of claims 1 and 11 of the '061 Patent, either literally or under the doctrine of equivalents.

96. A judicial declaration that the SNS23 Vectors are within the scope of claims 1 and 11 of the '061 Patent is necessary and appropriate at this time so that EGT can exercise its exclusive licensing rights to the '061 Patent.

PRAYER FOR RELIEF

WHEREFORE, EGT respectfully requests that the Court enter judgement in its favor granting the following relief:

A. A declaration that the SNS23.B87.A1 and SNS23.2.B87.A1 vectors are within the scope of claims 1 and 23 of the '179 Patent, such that developing, making, having made, using, importing, selling or offering to sell these vectors would infringe claims 1 and 23 of the '179 Patent, either directly or under the doctrine of equivalents;

B. A declaration that the SNS23.B87.A1 and SNS23.2.B87.A1 vectors are within the scope of claims 1 and 11 of the '061 Patent, such that developing, making, having made, using, importing, selling or offering to sell these vectors would infringe claims 1 and 11 of the '061 Patent, either directly or under the doctrine of equivalents;

C. A declaration that EGT has the legal right to make, use, import, sell, or offer for sale the SNS23.B87.A1 and SNS23.2.B87.A1 vectors under EGT's exclusive, royalty-free,

commercial license to the '179 Patent because such vectors are covered by a valid claim of the '179 Patent;

D. A declaration that EGT has the legal right to make, use, import, sell, or offer for sale the SNS23.B87.A1 and SNS23.2.B87.A1 vectors under EGT's exclusive, royalty-free, commercial license to the '061 Patent because such vectors are covered by a valid claim of the '061 Patent;

E. An order declaring that this is an exceptional case and awarding EGT its costs, expenses, and attorneys' fees under 35 U.S.C. § 285;

F. An award of prejudgment and post-judgment interest; and

G. Such other and further relief as the Court may deem just and proper under the circumstances.

DEMAND FOR JURY TRIAL

Plaintiff EGT hereby demands a trial by jury as to all issues so triable in this case.

Dated: September 30, 2021
New York, New York

Respectfully Submitted,

LOEB & LOEB LLP

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