UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ERRANT GENE THERAPEUTICS, LLC, ROCCO GIRONDI and MICHAEL BUCCELLATO.	:	Civil Action No. 15 cv 02044
Plaintiffs,	:	AMENDED VERIFIED COMPLAINT
- against –	:	JURY TRIAL DEMANDED
SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH,	:	
Defendant.	:	

Plaintiffs Errant Gene Therapeutics LLC ("EGT"), Rocco Girondi, and Michael Buccellato, by their attorneys, David C. Burger P.C. and McCue Sussmane, Zapfel, Cohen & Youbi, P.C., for their Amended Verified Complaint against Sloan-Kettering Institute for Cancer Research ("SKI") herein allege as follows:

NATURE OF THE CASE

1. Thalassemia is a fatal inherited blood disorder in which mutated genes cause the production of abnormally low levels of hemoglobin and red blood cells. The average age of mortality for patients with severe forms of the disease is reported as twenty-eight years.

2. Sickle cell disease is a group of inherited blood disorders characterized by chronic anemia, painful events, and various complications due to associated tissue and organ damage. In the United States, sickle cell disease is most often seen in African Americans.

3. This action states causes of action for replevin, breach of contract, and fraud in connection with a potentially life-saving gene therapy cure for these diseases developed by

EGT which was abandoned by SKI. EGT seeks an order of replevin requiring SKI to allow EGT to continued treatment of patients in the clinical trials.

4. Plaintiffs Rocco Girondi ("Girondi") and Michael Buccellato ("Buccellato") suffer from Thalassemia and seek to advance speedy, further exploitation of the vector which may be critical in prolonging their lives.

5. In the best interests of the patients suffering from conditions that could be remedied by the subject treatment, EGT, Girondi and Buccellato pursue this action to obtain injunctive relief that would permit the further development of that treatment to expeditiously proceed.

6. Plaintiff also seeks damages for the fraud and breach of contract by SKI.

PARTIES

7. Plaintiff EGT is a biopharmaceutical company dedicated to the development of treatments for underserved, rare, life-threatening diseases, commonly referred to as "orphan diseases." EGT is a Delaware limited liability company whose place of business is located at 218 North Jefferson Street, Suite 300, Chicago, Illinois 60661, and is a citizen of the State of Illinois. Patrick Girondi is the President and Chief Executive Officer of EGT.

8. Plaintiff Rocco Girondi resides in and is a citizen of Italy. Rocco Girondi is the son of Patrick Girondi.

9. Plaintiff Michael Buccellato resides in and is a citizen of the State of California.

10. Defendant SKI is a New York membership 'not for profit' cancer research institute and hospital with annual revenues of over $2.2 billion, with principal offices at 1275 York Avenue, New York, New York 10021, and is a citizen of the State of New York.

JURISDICTION & VENUE

11. The jurisdiction of this Court is based on diversity of citizenship and is conferred by 28 U.S.C. § 1332.

12. Venue is proper under 28 U.S.C. § 1391(a) because a substantial part of the events or omissions giving rise to the claims occurred in this district.

STATEMENT OF FACTS

EGT's Development of the Technology

13. In October 1992, Patrick Girondi's eldest son, Plaintiff Rocco Girondi, was diagnosed with Thalassemia, a fatal blood disease. In 1993, Patrick Girondi left a successful trading career and founded a pharmaceutical company with hopes of curing that disease.

14. Since 1993, EGT and its predecessor have built a grass roots organization including and not limited to five Thalassemia organizations, in Asia, Europe and North America and a Sickle Cell Disease organization in the United States. Each of these organizations has supported and closely monitored all steps of the development of the EGT Vector. That represents over twenty years of work by committed executives, scientists and investments exceeding $35,000,000 from private donors, investors, and grants.

15. EGT developed the Vector as the result of relationships with world-wide research centers, including but not limited to Boston University, St. Jude Children's Research Hospital, University of Milano, Gene and Cell Therapy Center in Thessaloniki, Greece, Nasik Hospital, in Nasik India and Children's Hospital Oakland Research Institute.

16. In 2000, after seven years of personally sponsoring different research projects, including conducting a clinical trial for thirty-eight (38) patients, Patrick Girondi began supporting SKI researchers Stefano Rivella ("Rivella") and Michel Sadelain ("Sadelain") in their roles in the invention of a technology that had cured five generations of Thalassemic mice.

17. In 2003, Patrick Girondi was informed by Sadelain that SKI would no longer support their gene therapy project. SKI is expressly an Institute for Cancer Center. SKI was not interested in gene therapy for blood disorders. This was confirmed to Patrick Girondi by Sadelain and Dr. Lucio Luzzatto ("Luzzatto"), the person who was involved in hiring Sadelain and Rivella at SKI. Luzzatto was also the president of the ethics committee for gene therapy at the FDA for three years.

18. Dr. Norbert Wiech, a distinguished scientist and colleague to the then SKI President, today Director of the NIH, Harold Varmus ("Varmus"), and Patrick Girondi attempted to interest pharmaceutical companies in the project. Those companies all said the same thing, 'gene therapy' was premature and though many sympathized with the mission of a father fighting to save a son, from an investment point of view, the project was frivolous.

19. In March, 2005, with no other parties interested in saving the abandoned project, SKI sold the worldwide rights to the Vector to EGT. A copy of the agreement (the "2005 Agreement") is attached hereto as Exhibit A. SKI sold the exclusive right to exploit the Vector to EGT for use in blood disorders known as hemoglobinopathies, including Thalassemia, (also known as Cooley's Anemia), and Sickle Cell Disease. Genetically curing Thalassemic and Sickle Cell patients became the sole goal of EGT.

20. At the time of the 2005 Agreement no known human clinical data existed to support the viability of gene therapies for Thalassemia and Sickle Cell Disease based on such a

vector.

21. SKI was unwilling to fund and unable to secure outside funding for the research, and without the transfer to EGT, the research would have died.

22. Thalassemia and Sickle Cell Disease (Anemia) patients must hyper transfuse blood and receive painful iron chelation medications to reduce iron build-up that comes with the blood transfusions. The only established cure is a bone marrow or stem cell transplant. Less than 25% of patients have compatible donors. The average age of mortality is twenty-eight years.

23. EGT immediately began implementing their Vector, funding at least three separate, scientific contracts with SKI and engaging international specialists and researchers. This culminated into over four years of research and developing improvements of the Vector.

EGT Performed All Obligations Under The 2005 Agreement

24. EGT's network dedicated to developing and improving the Vector grew to include major research institutions and hospitals, such as, AMC Amsterdam, Bambino Gesu', Fairview Institute Minneapolis, Gene Center Cagliari, NIH, Notre Dame University, Policlinico Milano, Ospedale Cervello Palermo, San Matteo Pavia, University Mainz Germany and the State University of New York at Albany.

25. EGT collaborated with such companies as Sigma Tau, Voisin in Switzerland, Biomarin, Aldevron and Baxter.

26. EGT is affiliated with or has received support from Cooley's Anemia Foundation, Cooley's Anemia International, Giambrone Foundation, Italian Telethon, Jackie Robinson Foundation, Thalassemia International Federation, Thalassemia Foundation India, The Think Foundation of Mumbai, India and the World Health Organization.

27. Prior to and at all times since the date of the 2005 Agreement, EGT has used commercially reasonable efforts to develop and introduce to the markets a gene therapy treatment for Thalassemia and Sickle Cell Diseases through a thorough and diligent program consistent with sound and reasonable scientific and business judgment.

28. EGT committed every available resource to develop its technology into a gene therapy treatment known and trademarked by EGT as "Thalagen."

29. EGT welcomed SKI participation in major decisions, such as the timing of applications for regulatory approval to clinically treat patients.

30. EGT followed a comprehensive business, research and development plan and schedule, keeping SKI abreast of every detail.

31. EGT continued the grass roots effort to support the Thalassemia and Sickle Cell Disease research, involving hundreds of patients and patient groups throughout the world, many of whom are anxiously awaiting clinical trials to continue for Thalagen. EGT won awards and recognition from, among others, the Indian Thalassemia Foundation and the World Health Organization.

32. EGT diligently followed the process of obtaining U.S. governmental approval for advancing the therapy.

33. In 2007, EGT obtained Orphan Drug Designation in the United States which provides the designee with a period of market exclusivity for an approved drug.

34. In 2007, EGT obtained the unanimous approval of the NIH Recombinant DNA Advisory Committee (RAC). RAC is comprised of renowned experts and is a necessary hurdle for all gene therapies. EGT submitted a coherent file, composed of thousands of pages, based on demonstrating patient safety.

35. In 2008 EGT completed the pre-IND (Investigative New Drug) meeting with the FDA and trademarked the name "Thalagen" for its therapy for Sickle Cell Disorder and Thalassemia therapy.

36. In 2009, EGT was awarded Orphan Drug Designation in Europe. On June 2, 2009, a US Patent was awarded to the inventors of the Vector, including Sadelain and Rivella. This is the basis for Thalagen and is the intellectual property that was developed by EGT under the 2005 Agreement

Production Of Vector By EGT Using Highest Standard

37. EGT took additional time necessary to produce Vector in accordance with the highest standard of manufacturing and testing, which is designated by the FDA as chemical Good Manufacturing Practice (cGMP).

38. EGT developed the Vector designated for human use by employing a highly purifying filtration regimen and meeting U.S standards for safety, stability, purification and potency. The manufacturer must be accredited by the FDA and each cGMP production batch of Vector requires filings with the FDA. Such filing is referred to as the Drug Master File.

39. To achieve the patient safety-centric standard, four years of testing and refinement were necessary. The Vector had not been ready for Clinical Trials as SKI had initially claimed when they sold the technology to EGT in 2005.

40. On September 1, 2010, EGT completed physical production of the medicine for Phase I of the clinical trial. It took eighteen (18) months and over $1.3 million funded by EGT. Gene therapy was now at the forefront of the pharmaceutical industry and backed by billions of dollars of research. EGT had leapt over various hurdles to develop a tremendously

promising medicine, leading the competitive and lucrative race for the first successful gene therapy treatment.

41. EGT developed and produced a Vector that is closer to the endogenous (natural) gene than the unfiltered and potentially dangerous vector used by EGT's competitor Genetix, in French clinical trials outside the supervision of the FDA. Today Genetix is known as Bluebird Bio Inc. ("Bluebird").

42. The FDA was presented with a previously untested and novel method of collecting patient bone marrow stem cells. This method reduces risk to the patient and enables optimal engraftment. EGT's competitor, Bluebird, relied on a less patient-friendly procedure.

43. SKI requested that EGT delay clinical trials of Thalagen until the confirmation of the new method of collecting stem cells.

44. SKI insisted that the study was necessary to prove efficacy of the method of harvesting bone marrow stem cells. In the study, a patient's bone marrow was stimulated and then stem cells were collected from the blood.

45. An FDA pilot study of the mobilization method was conducted in the US and Greece from 2008 through October 2010.

46. EGT could not apply for FDA approval for its clinical trials until after the study had proven that the new method of collecting stem cells from blood in thalassemia patients was effective.

47. EGT assisted Italian centers to arrange for Thalassemic patients to travel to New York to participate in the mobilization study (without any immediate treatment for their disease).

48. EGT successfully spearheaded the application for a $500,000 grant from the Italian Telethon for the stem cell mobilization trial.

49. In 2009, the French government and the FDA halted all gene therapy clinical trials because of improper dominance of certain cell growth in the Bluebird thalassemic patient.

50. In 2010, new senior management was installed at SKI. With EGT poised for clinical trials of the Vector on Thalassemia patients at SKI and the National Institutes of Health ("NIH"), and with SKI unwilling to live with prior management's decision to abandon gene therapy and accept a mere royalty stream upon successful completion of the EGT clinical trials of the very promising Vector, SKI chose profits over patients. SKI ignored the needs of millions of Thalassemia and Sickle Cell Disease patients to engage in a fraudulent scheme to stop EGT's clinical trials and to take possession of EGT's technology. SKI's efforts, which included a refusal to return EGT's medicine to allow treatment at NIH, brought a halt to clinical trials of the Vector for almost one year.

51. In early 2010, Third Rock Ventures LLC. ("Third Rock") bought Genetix. Third Rock is also heavily invested in Agios Pharmaceuticals Inc. ("Agios"), a company founded by Craig B. Thompson ("Thompson"), President of SKI, in 2007. In March of 2010, Third Rock partner Dr. Philip Reilly visited SKI Head of Industrial Affairs, Andrew Maslow ("Maslow"). Third Rock wanted to purchase the EGT Vector, claiming that it was superior to the Bluebird vector which they had just purchased in a $35 million deal from Sadelain's former Harvard classmate.

52. In May, 2010, EGT President Sam Salman and Patrick Girondi visited Neil Exter, a principal of Third Rock, Mitch Finer, Chief Scientific Officer of Bluebird, and Nick

Leschley ("Leschley"), CEO of Bluebird. Leschley was formerly Business Development Officer of Agios.

53. Because of the 2009 adverse Bluebird French trials, EGT wanted a guarantee of the use of the EGT Vector as a condition to negotiations. Leschley refused and negotiations halted.

54. On June 22, 2010, Maslow sent an email to EGT confirming his belief that EGT's technology was superior to the Bluebird technology and commending EGT for years of effort to develop the Vector.

55. In September of 2010, SKI researchers urgently requested that EGT deliver the Vector to SKI to complete the mobilization study. EGT delivered to SKI the Vector, in an amount sufficient to treat 7-10 patients. The Vector was in place for the commencement of clinical trials in December 2010. The Vector was irreplaceable. No similar medicine existed anywhere in the world. EGT instructed SKI that it could use a small portion of the Vector to test in live patient cells and to complete the mobilization study.

56. The Vector was delivered to SKI based on the understanding that a part of the Vector was to be used to perform clinical trials on patients at SKI and a portion of the Vector was to be delivered to the project principal investigator Dr. John Tisdale ("Tisdale"), Senior Investigator at the NIH Molecular and Clinical Hematology Branch. Dr. Tisdale and his Branch are recognized as a center of excellence for developmental clinical activities using viral vectors for the delivery of gene therapies to treat hemoglobinopathies and specifically Sickle Cell Diseases.

57. In or around October, 2010, Maslow informed EGT that as the result of exemplary work of EGT in developing Thalagen, the SKI Board was interested in creating a

center of excellence at SKI offering boutique gene therapy with a targeted cost of up to $650,000 per patient. Maslow discussed the ability of EGT to send wealthy patients from such countries as India, Italy and Greece who could afford the treatment. This strategy represented many millions of dollars in new revenue that could be generated for SKI.

58. By October 2010, EGT had transformed the Vector from a technology with little commercial interest into an extremely valuable property.

59. As of October 2010, the final step to be completed prior to commencement of Phase I Clinical trials was an application with the FDA for an Investigative New Drug ("IND").

60. EGT orchestrated the arrival of European doctors to learn the technology for an eventual trial in Europe.

61. Through the efforts of EGT, Thalagen was developed into a drug worth at least tens of millions of dollars and possibly hundreds of millions of dollars upon commencement of a credible clinical program determining its safety in humans.

New SKI Management Launches Fraudulent Scheme To Misappropriate the Vector

62. In October 2010, Thompson arrived to head new management at SKI. On October 19, 2010, SKI attempted to halt the clinical trial process by demanding $4 million in cash in advance ($400,000 per patient for up to 10 patients) before it would allow any clinical trials at SKI. Maslow offered to treat Patrick Girondi's son, Rocco Girondi for free if EGT acceded to all of SKI's demands.

63. EGT was unwilling to pay to SKI more than eight times the cost at which patients would be treated at NIH and unwilling to pay in advance before it even knew how many patients would be tested. EGT informed SKI that the first patient would be treated at SKI for

$400,000, and that the remaining patients would be treated at NIH for less than $50,000 per patient with Principal Investigator Dr. John Tisdale.

64. Unsuccessful with its $4,000,000 extortion demand, SKI halted the clinical trial process by refusing to deliver the EGT Vector to NIH. SKI stated that it would not return the Vector and/or allow clinical trials to proceed unless EGT secured a larger pharmaceutical company as a partner for future commercial development, even though the Vector had not yet been tested in a single patient.

65. EGT turned to Sigma Tau as a tentative partner for commercial development. Sigma Tau is a pharmaceutical company that had for years supported the EGT mission. It is an orphan disease company with over $1 billion in annual sales and fifteen approved drugs for orphan indications.

66. On November 22, 2010, EGT met with Maslow and officers of Sigma Tau to confirm that Sigma Tau was a suitable partner for commercial development. Maslow stated that he had just come from a meeting with Dr. Thompson, President of SKI, to make clear to EGT and Sigma Tau that he answered directly to Dr. Thompson. Maslow then stated to the Sigma Tau officers that: "The technology does not work. If I were you, I would not invest in it."

67. On November 23, 2010, SKI claimed that EGT was in breach of the 2005 Agreement for an alleged past due license fee of $400,000 for Sickle Cell Disease. The payment had been waived by SKI in 2008 and Maslow's complimentary letter of June 22, 2010, made no mention of any arrears. EGT made the $400,000 payment on December 7, 2010.

68. In January, 2011, EGT signed a contract with Sigma Tau to act as the commercial partner demanded by SKI which would have been lucrative for SKI and EGT. The

contract provided for a $3 million down payment, the right to purchase 20% of EGT's shares at a fair market valuation of $30 million, and full funding of all development and Clinical Trial costs.

69. The Sigma Tau contract was submitted to SKI for approval, as required by the 2005 Agreement. It was immediately rejected by SKI.

SKI Fraudulently Induces EGT To Sign The 2011 Agreement

70. EGT sought every possible solution to put the trial back on track. After EGT refused SKI's offer to purchase the Vector project for a payment of $3 million, SKI commenced an arbitration on January 21, 2011, claiming that EGT had been lacking in its development duties. This is less than six months after SKI praised EGT for its fine work.

71. On March 23, 2011, EGT arranged for a special courier pick up of the Vector from SKI to have it delivered to Dr. Tisdale at NIH. SKI refused to return the Vector.

72. On June 16, 2011 EGT and SKI met at the office of SKI counsel to discuss the resumption of clinical trials. Approximately ten (10) months had passed since the Vector was delivered to SKI. Over seven months had passed since the new SKI senior management started the process of trying to take EGT's Vector and preventing the filing of an IND Application with the FDA and the treatment of patients.

73. The June 16, 2011 meeting was attended by Pat Girondi and Sam Salman on behalf of EGT and Maslow on behalf of SKI. SKI proposed a new agreement which would give SKI control of the clinical trials and commercial exploitation of the EGT Vector.

74. At the June 17, 2011, meeting Maslow made knowingly false statements to Girondi and Salman to induce EGT to enter into a new agreement with SKI. Maslow stated that SKI "had spent $1,500,000 to write the IND." Maslow stated that the "the IND is done and ready to be filed immediately." Maslow repeated this statement several times. Maslow further

stated "the first patient will be treated no later than October 2011."

75. Based on the representations of SKI, EGT entered into the agreement with SKI dated June 17, 2011 ("2011 Agreement"), a copy of which is attached hereto as Exhibit B.

76. The 2011 Agreement provided for a sale, assignment and transfer of EGT's right, title and interest in the Vector for a short term trial on three patients, evaluation of the results and gave SKI discretion to determine whether or not it would proceed further with the project which was stated to have a limited, but not specifically identified, term.

77. In return, under the 2011 Agreement, SKI would file the IND with the FDA the following day, use commercial standards to bring the project forward and fund the Clinical Trials and "use its best efforts to seek a medically reasonable determination as to the efficiency of the vector, based on the data collected for the first three patients."

78. The 2011 Agreement also provided that SKI shall pay EGT fifty percent of any consideration derived from any exploitation of the Vector.

79. The 2011 Agreement, imposed by SKI, was of limited duration. The 2011 Agreement provided, at paragraph 9, that SKI was to "keep full, true and accurate books of account containing all particulars that may be necessary for the purpose of showing the amounts payable to EGT hereunder."

80. The 2011, Agreement further states: "For the term of this agreement, upon reasonable written notice, SKI shall allow EGT or its agents to inspect such books and records for the purpose of verifying SKI's payments." (emphasis added). In 2011 EGT was years ahead of Bluebird.

81. SKI's IND was not filed until September, 2011, and then was rejected by the FDA as not ready for submission. The IND was finally accepted by the FDA in or about June

2012. The first patient was treated in November of 2012. The second and third patients were treated in February 2013 and June 2013.

82. SKI presented positive data on the clinical trial at the American Society of Hematology meeting in December of 2013. SKI further published the optimal results in 'Blood' magazine in March of 2014. Furthermore, the treated patients have significantly reduced their need for transfusions which ameliorates their medical condition and extends their life expectancy. This is proof of the efficiency of the Vector and a further indication of the value of proceeding.

83. According to the 2011 Agreement, in pursuance of diligent and commercial standards, SKI was obligated to proceed. It has been over twenty-one months since SKI treated a patient. EGT's competitor, Bluebird, has treated eight patients in the last sixteen months.

84. The 2011 Agreement incorporated the requirements of Article 3.1 of the prior 2005 License Agreement which provides as follows:

> "3.1 LICENSEE and its Sublicensees shall use commercially reasonable efforts to develop and seek registration for, and to introduce into the market, Licensed Products in Field A and in Field B through an appropriately thorough and diligent program for exploitation of the Patent Rights as detailed in the Plan referred to below, consistent with sound and reasonable scientific and business judgment, and thereafter continue active, diligent marketing efforts for one or more Licensed Products through the life of this Agreement."

(copy attached hereto as Exhibit A).

85. The fact that SKI presented positive data resulting in no adverse effects and reduced the need for transfusions obligated SKI to "use commercially reasonable efforts to develop and seek registration for, and to introduce into the market", the Vector.

86. SKI has not treated any patient for this clinical trial in twenty-one months. SKI, by its own admission, has not been able to replicate the Vector. SKI, by its own admission, lacks funding for the project.

87. SKI, by its own admission, has rejected lucrative offers of funding from others to support or acquire this project.

88. In the spring of 2013, Eric Cottington ("Cottington"), the head of Research at SKI, claimed that the fourth patient would be treated within two months. He also informed EGT that the IND for the Sickle Cell Disease Trial would be written and that the Standard Operating Procedures would be delivered to Dr. Tisdale for the commencement of the Sickle Cell Trials at NIH.

89. EGT informed Cottington that Bluebird was working on another version of their first vector and that SKI must move diligently to ensure that the best medicine eventually got to the patients.

90. In June 2013, SKI breached its agreement and removed Dr. Tisdale as Principal Investigator. Since the writing of the protocol in 2005 it was understood that Dr. Tisdale and the NIH were solely equipped to advance the gene therapy clinical trials for Sickle Cell Disease.

91. EGT continued to support the project and authorized transfer of the cell bank material (ingredients used in the production of the Vector) to SKI.

92. In October of 2013, SKI informed EGT that all of the Vector had been consumed in only three of the intended seven patients, and that SKI had analyzed and verified promising results. SKI stated that it had decided to produce more Vector.

93. In November of 2013, EGT received from the Indian Thalassemia Foundation various emails sent by SKI attempting to charge patients for the clinical trials. EGT advised SKI that charging for clinical trials without explicit written permission of the FDA damaged the project. Further EGT notified SKI that it was their responsibility to fund said clinical trials.

94. By November 2014, SKI had told EGT and the project supporter, Cooley's International, that SKI had no Vector to continue and would no longer fund the project. It had been over three years since SKI had fraudulently induced EGT to enter into the 2011 Agreement, and now SKI claimed that the project was dead.

95. As a result of SKI delays in conducting the clinical trials, the project risks losing the critical Orphan Drug Designation to Bluebird. The Orphan Drug Designation granted by the FDA guarantees market exclusivity to the designee. The risk is that an inferior product will make it to patients and the market in the place of the superior EGT Vector.

96. SKI made monthly promises since the beginning of 2014 that the fourth patient would be treated, but that never happened.

97. In late 2014, Biomarin, a pharmaceutical company which was a fitting candidate, attempted to purchase the Vector but was thwarted by SKI.

98. In December of 2014, Cottington told Patrick Girondi that he had no idea if the fourth patient had been treated but that he was confident that a deal with some major pharmaceutical company would be completed by the end of the year that would move the project forward. Also in December of 2014, Juno Pharma did an IPO. Sadelain is a scientific founder of Juno. SKI received 2,000,000 shares of stock. This further confirms SKI's priority in cancer research.

99. On January 15, 2015, Cottington told Patrick Girondi that the fourth patient had not been treated and that he had no idea when or if the fourth patient would ever be treated. Cottington also told Patrick Girondi that the project was without funding and had no Vector remaining to treat patients. He acknowledged that SKI may be forced to give the project back to EGT, but that would be his last choice.

100. Bluebird published an article in the February, 2015, 'Current Gene Therapy' journal supporting its new vector but noting that it is little changed from the old vector. The most significant difference is the removal of cHS4 insulators, which were initially put in the vector to make the product safer.

101. SKI sent a letter to EGT dated February 18, 2015, that acknowledged that SKI is not actively pursuing exploitation of the Vector. A copy of that letter is attached hereto as Exhibit C. At the same time, SKI is purporting to preclude EGT from any possible exploitation of the Vector and is summarily rejecting overtures from companies expressing strong interest in providing major funding towards the commercialization of the Vector. The project is falling further and further behind. Continuation of this path will preclude the best product from ever making it to patients who have a fatal condition.

102. SKI is forestalling any further development of the Vector of which EGT has a fifty percent interest. This would allow SKI to proceed with possible alternative treatments in which EGT has no interest. That would be a breach of the 2011 Agreement and the public interest. SKI should be ordered to immediately return the Vector to EGT so that EGT can proceed with the cure for which so many patients have been waiting.

103. After reporting positive clinical results in peer reviewed journals in three patients, SKI has not treated a patient in twenty-one (21) months. SKI has failed to produce more

Vector. This represents a breach of fiduciary duty which precludes development under the 2011 Agreement, further emphasized by the inclusion of Article 3.1 of the 2005 contract. Twenty-one (21) months is unconscionably long in the shortened lives of the thalassemia patients waiting for EGT's Vector. Twenty-one months may mean forty (40) blood transfusions (taking up to 8 hours each) and the resulting increase in harmful iron in each in the patient's bodies.

104. SKI's conduct caused EGT's counsel to send an email on February 23, 2015, noting that the License Agreement was for a limited term and that SKI was not actively pursuing exploitation of the Vector. That email concluded by stating that: "EGT hereby seeks immediate reversion of all right, title and interest in the Vector and EGT Information." ("Reversion Demand")(Copy attached hereto as Exhibit D).

105. SKI's outside legal counsel required eleven (11) days to respond to EGT's counsel. In a letter, dated March 6, 2015 (copy attached hereto as Exhibit E), SKI's outside legal counsel succinctly conceded that SKI is stonewalling any information concerning the advancement of the subject medical remedy:

> "In any event, SKI has no obligation to keep your client informed of its development plans or studies."

106. The wrongful conduct and profit motives of SKI, an institute for medical research, is preventing the individual plaintiffs and similarly situated individuals from obtaining treatment for otherwise fatal medical conditions.

107. Plaintiffs Rocco Girondi and Michael Buccellato took required tests to enroll in the project. The lost time personally affects them both as well as thousands of other similarly situated patients who will suffer irreparable harm.

FIRST CLAIM
Replevin

108. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 107 as if fully set forth herein.

109. SKI drafted and imposed upon EGT the 2011 Agreement which provided for a limited but unspecified term during which SKI would treat at least three patients under the current trial. SKI would then "use its best efforts to reach a medically reasonable determination as to the efficiency of the vector, based on the data collected from the first three patients." SKI expressly limited its obligation to further proceed with the vector: "Nothing herein shall be construed to obligate SKI to develop any therapy for thalassemia or Sickle Cell Anemia which, in its sole medical judgment is not the best potential treatment for patients."

110. SKI infused three patients, and for a period of more than twenty-one (21) months, has failed to proceed.

111. Upon information and belief, SKI utilized all of the Vector provided by EGT and has failed to generate any additional Vector to treat additional patients.

112. Plaintiffs Rocco Girondi and Buccellato and thousands of other patients in similar circumstances are suffering from life-threatening conditions which may be averted by further development of the subject Vector.

113. EGT has demanded immediate reversion of all right, title and interest in the Vector and all intellectual property and clinical trial results (the "EGT Information") and SKI has resolutely denied that demand without any lawful justification.

114. While SKI was not required by the 2011 Agreement to further develop the Vector, it did not permit SKI to preclude any further development of the Vector.

115. The March 6, 2015, letter from SKI's legal counsel concedes that SKI is stonewalling any information concerning any advancement of the Vector.

116. Plaintiffs Rocco Girondi and Buccellato are suffering from conditions that are ultimately fatal and that could be alleviated by treatment with the Vector.

117. SKI is purporting to forestall any further development of the Vector, as to which EGT has a fifty percent interest in any proceeds, in order for SKI to proceed with potential alternative treatment in which EGT has no interest and causing a delay in development of the Vector.

118. The limited duration of the 2011 Agreement does not permit such conduct. The public interest in furthering any cure to a fatal medical condition should not countenance such conduct.

119. Plaintiffs are entitled to an order of replevin directing Defendant to deliver to Plaintiff EGT the following (the "EGT Information"):

1. A letter addressed to the FDA transferring ownership of the investigational new drug application ("IND") β-Thalassemia Major With Autologous CD34+ Hematopoietic Progenitor Cells Transduced With TNS9.3.55 a Lentiviral Vector Encoding the Normal Human β-Globin to EGT;
2. All correspondence with the FDA related to the IND and each Annual Report;
3. The initial IND submission and all subsequent amendments/filings, including procedural and testing standard operating procedures ("SOP") related to transduction of the patient cells, for product continuity.

4. All laboratory and clinical data (electronic and paper) regarding the analysis/testing of the TNS9 based c-GMP lentiviral vector for clinical or non-clinical purposes, or related to the treatment of all human thalassemic patients with autologous CD 34+ transduced with the TNS9 based c-GMP lentiviral vector, including internal and external product and patient sample testing information (e.g. release testing, safety testing, stability data, etc.);
5. All correspondence with the Recombinant DNA Advisory Committee ("RAC");
6. Inventory and disposition records regarding the storage and use of the EGT provided TNS9 based c-GMP lentiviral vector used on patients;
7. All remaining TNS9 based c-GMP lentiviral vector stock, to be transferred once EGT has made appropriate shipping and storage arrangements;
8. All remaining patient products (transduced with vector but not yet transplanted, or untransduced mobilized CD34+ cells from patients waiting to be transduced and transplanted) for any patients who consent to continue in the trial pending transfer to new clinical site;
9. All patient samples being stored for possible future assessment (for clinical assessments per the protocol or for FDA required gene therapy archiving) as needed/required for patients transferring to the new trial site and/or for continued storage or archiving once EGT has made appropriate arrangements; and

10. Such other and further materials deemed necessary for continuation of this clinical trial.

SECOND CLAIM
Fraud

120. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 119 as if fully set forth herein.

121. In October 2010, new management arrived at SKI and SKI engaged in a fraudulent scheme to reverse prior management's decision to abandon gene therapy and accept a royalty stream upon successful completion of the EGT clinical trials of the very promising Vector.

122. On October 19, 2010, SKI attempted to halt the clinical trial process by demanding $4 million in cash in advance ($400,000 per patient) to which it was not entitled. Maslow offered to treat Patrick Girondi's son for free if EGT acceded to all of SKI's demands.

123. When advised that EGT was unwilling to pay to SKI more than eight times the cost at which patients would be treated at NIH, SKI halted the clinical trial process by refusing to return EGT's Vector to NIH.

124. SKI refused to return the Vector and/or allow clinical trials to proceed unless EGT secured a larger pharmaceutical company as a partner for future commercial development.

125. EGT secured Sigma Tau which was introduced to SKI to its new partner. On November 22, 2010, Maslow stated to the Sigma Tau officers that: "The technology does not work. If I were you, I would not invest in it."

126. When EGT presented SKI with a signed contract with Sigma Tau that would fully fund all trials, it was SKI rejected.

127. On November 23, 2010, SKI claimed that EGT was in breach of the 2005 Agreement for an alleged past due license fee of $400,000 that had been postponed by SKI.

128. When EGT made the $400,000 payment, SKI resorted to making knowingly false statements to induce EGT to terminate the 2005 Agreement.

129. On June 16, 2011, EGT and SKI met to discuss the resumption of the clinical trial process. Approximately ten (10) months had passed since the Vector was delivered to SKI. Over seven (7) months had passed since new SKI management had begun blocking progress. They did so by failing to return EGT's Vector, preventing the filing of an IND Application with the FDA, thereby preventing treatment of patients.

130. The June 16, 2011 meeting was held at the office of SKI counsel and was attended by Patrick Girondi and Sam Salman on behalf of EGT and Maslow on behalf of SKI.

131. SKI demanded a new agreement which would give SKI control of the clinical trials and commercial exploitation of the EGT Vector.

132. At the June 16, 2011, meeting Maslow made the following knowingly false statements to Patrick Girondi and Salman to induce EGT to enter into a new agreement with SKI. Maslow stated that SKI "had spent $1,500,000 to write the IND." Maslow stated that the "the IND is done and ready to be filed immediately." Maslow further stated "the first patient will be treated no later than October 2011."

133. Each of those statements was known by Maslow and SKI to be false. Maslow fabricated the amount spent by SKI and knew that the IND application was not prepared to be filed.

134. Maslow and SKI knew that it would be impossible to treat any patients by October, 2011. Maslow knew and failed to disclose to EGT that the required approvals of SKI's

Internal Review Boards ("IRBs") to allow the clinical trials to be performed at SKI had not yet been received. SKI had previously demanded an advance $4,000,000 payment from EGT for clinical trials that SKI was not yet approved to perform.

135. SKI knew that EGT would rely on such false statements to its detriment. SKI knew that as a result of the one year delay, which started with the entry of new SKI senior management that EGT would rely on such false statements because it would not endure further delays in the clinical trials.

136. SKI knew that there was a large group of Thalassemia patients and advocates that had supported EGT since its formation and that they were closely following the development of the Vector and awaiting the commencement of clinical trials.

137. SKI knew that the delay caused by SKI's efforts to take EGT's Vector resulted in countless blood transfusions, painful chelation medication to remove the resulting iron, and years lost in already shortened life spans.

138. SKI knew that Plaintiff Rocco Girondi, the son of Patrick Girondi who had created EGT, was then twenty-one (21) years old. The average age of mortality of Thalassemic patients is twenty-eight (28).

139. SKI knew that at that time it would take EGT eighteen (18) months to make more Vector to replace the Vector that SKI was refusing to release. Today production can be achieved in approximately 4 months.

140. SKI knew that due to SKI's actions, it would take EGT months to file an IND application.

141. SKI knew that further delay of the clinical trials would allow EGT's chief competitor to narrow the gap with EGT. At that moment, EGT was two years ahead of the Bluebird competition who had, as previously stated, abandoned their first vector in 2012.

142. Based on the exceedingly material representations that SKI had spent $1,500,000 on the IND, and that it would file the IND immediately, and treat patients by October, 2011, EGT acceded to the agreement with SKI dated June 17, 2011 ("2011 Agreement"), a copy of which is attached hereto as Exhibit B.

143. EGT would not have entered into the 2011 Agreement if SKI had not made those false statements.

144. EGT was damaged as the result of those false statements. Almost four years have passed. SKI had previously successfully infused three patients with very promising results and then abandoned the Vector.

145. SKI has done nothing during the past twenty-one (21) months, during which time EGT's competitor has treated eight (8) thalassemia patients and passed EGT in the race for Orphan Drug Designation.

146. SKI should not be permitted to preclude development of the Vector, which would likely create a situation in which a less patient safe Vector would receive exclusive Orphan Drug Designation and FDA approval.

147. SKI arbitrarily rejected a lucrative agreement with Sigma Tau which valued the project at no less than $30,000,000 in 2010.

148. EGT is entitled to damages in the amount to be proven at trial, but in no event less than $30,000,000, plus punitive damages in an amount necessary to deter future misconduct by Defendant.

THIRD CLAIM
Breach of Contract

149. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 148 as if fully set forth herein.

150. SKI breached its obligation under paragraph 4 of the 2011 Agreement to "promptly file an investigational new drug application (IND) for Vector" with the FDA. Rather than filing immediately upon signing the agreement in June 2011 as represented to EGT, SKI filed an application in September 2011, which was rejected and returned by the FDA as incomplete.

151. SKI breached its obligation under paragraph 4 of the 2011 Agreement to diligently proceed with clinical trials on three patients. Rather than commencing trial not later than October 2011 (four months later) as represented to EGT, SKI treated the first patient in November 2012, (thirteen months later). SKI did not treat the second and third patients until February 2013 and June 2013. The two years that it took SKI to perform the clinical trials on three patients was not diligent. EGT's competitor Bluebird diligently proceeded with its clinical trials of gene therapy on Thalassemia patients and treated eight (8) patients in sixteen (16) months.

152. SKI breached its obligation under paragraphs 4 and 5 of the 2011 Agreement to treat patients "in accordance with the IND protocol." SKI attempted to require Indian patients to pay for the treatment. The 2011 Agreement mandated that SKI pay for clinical trials. The FDA requires explicit approval to charge patients in a clinical trial.

153. SKI breached its obligation under paragraph 4 of the 2011 Agreement that "SKI will provide to EGT trial information, as permitted by law". SKI failed to provide trial information to EGT despite there being no legal prohibition.

154. SKI breached its obligation under paragraph 5 of the 2011 Agreement to comply with the requirements of Article 3.1 of the 2005 License Agreement which provides as follows:

> "3.1 LICENSEE and its Sublicensees shall use commercially reasonable efforts to develop and seek registration for, and to introduce into the market, Licensed Products in Field A and in Field B through an appropriately thorough and diligent program for exploitation of the Patent Rights as detailed in the Plan referred to below, consistent with sound and reasonable scientific and business judgment, and thereafter continue active, diligent marketing efforts for one or more Licensed Products through the life of this Agreement."

(copy attached hereto as Exhibit A). SKI presented positive data resulting in no adverse effects and reduced patient's need for transfusions, yet has taken no action for twenty-one (21) months, which violates such obligations. SKI has failed to "use commercially reasonable efforts to develop and seek registration for, and to introduce into the market" the Vector.

155. SKI has not treated a patient in twenty-one (21) months. SKI, by its own admission, has not been able to replicate the Vector. SKI, by its own admission, lacks funding for the project. SKI, by its own admission, has rejected lucrative offers of funding from others to support or acquire this project. There is no "appropriately thorough and diligent program for exploitation" of the very promising Vector.

156. SKI breached its obligation under paragraph 5 of the 2011 Agreement that "SKI will use its best efforts to reach a medically reasonable determination of the efficacy of the vector, based on the data collected from the first three patients." It is indisputable that the clinical trial on the first three patients achieved exactly the results that SKI and EGT desired: the Vector was proven to be safe, resulted in gene expression, and in fact markedly reduced the need for blood transfusions in patients.

157. SKI has abandoned the clinical trials of the promising Vector while Bluebird sails with its clinical trials towards exclusive orphan drug designation. SKI used all of the Vector produced by EGT and has failed to produce any more. SKI has informed EGT that it refuses to provide any more funding for the project yet SKI has rejected offers from biotech companies to fund the clinical trials or to acquire the Vector.

158. The foregoing actions are a breach of the duty of good faith and fair dealing implied in all New York contracts.

159. Abandonment of the Vector and refusal to allow EGT to continue with the clinical trials would allow Bluebird to succeed with bringing its inferior vector to market before EGT's Vector. This would be a gross violation of SKI's contractual duties to EGT and SKI's duties to the millions of Thalassemia and Sickle Cell Disease patients waiting for a cure of their deadly diseases.

160. EGT gave notice to SKI of its breaches of the 2011 Agreement.

161. SKI failed to cure its breach.

162. Plaintiff EGT is entitled to damages in the amount to be proven at trial, but in no event less than $30,000,000.

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief

On the First Cause of Action, entering an Order of Replevin directing Defendant to deliver the EGT Information to Plaintiff EGT;

On the Second Cause of Action, awarding damages to Plaintiff EGT in the amount to be proven at trial, but in no event less than $30,000,000, plus punitive damages in an amount necessary to deter future misconduct by Defendant;.

On the Third Cause of Action, awarding damages to Plaintiff EGT in the amount to be proven at trial, but in no event less than $30,000,000;

Awarding such other damages and relief as the Court deems appropriate.

Dated: April 20, 2015
New York, New York

DAVID C. BURGER P.C.

David C. Burger (DCB 8666)
140 Charles Street, #17-A
New York, New York 10022
(646) 784-7663

MCCUE SUSSMANE & ZAPFEL, P.C.

Kenneth Sussmane (SK 9301)
521 Fifth Avenue, 28th Floor
New York, New York 10175
(212) 931-5500
Attorneys for Plaintiffs

VERIFICATION

I, Pat Girondi, being duly sworn, depose and say:

I am a Chairman of Plaintiff. I have read the foregoing Amended Verified Complaint and know the contents thereof; the same is true to my own knowledge, except as to matters therein stated to be alleged on information and belief, and as to those matters, I believe it to be true.

Pat Girondi

Sworn to before me this
20th day of April, 2015

Notary Public

KENNETH S. SUSSMANE
Notary Public, State of New York
No. 02SU6057419
Qualified in New York County
Commission Expires ~~November 11, 20~~ 1/19/16