

FILED

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

2016 APR -4 P 2: 28

CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

KALEO, INC.)
)
 Plaintiff,)
)
 v.)
)
 SARCOS, LC)
 Defendant.)

Civil Action No. 1:16-cv-309
(GBL/mSN)
DEMAND FOR JURY TRIAL

COMPLAINT FOR DECLARATORY RELIEF

Plaintiff, kaleo, Inc. (“kaleo”), by counsel, files the following Complaint for Declaratory Relief and, in support thereof, alleges as set forth below:

THE PARTIES

1. Plaintiff kaleo, Inc. is a corporation organized under the laws of the State of Virginia, and having a principal place of business at 111 Virginia Street, Suite 300, Richmond, Virginia 23219.

2. On information and belief, Defendant Sarcos, LC (“Sarcos”) is a corporation organized under the laws of the State of Utah and maintaining its principal place of business at 360 Wakara Way, Salt Lake City, Utah 84108.

JURISDICTION AND VENUE

3. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

4. Subject matter jurisdiction is proper in this Court under 28 U.S.C. §§ 1331 and 1338 because kaleo’s claims for declaratory relief arise under the patent laws of the United States (Title 35 of the United States Code).

5. Upon information and belief, Defendant is subject to this Court's personal jurisdiction because it does and has done substantial business in this judicial district, including in connection with various government contracts. Defendant is subject to the general jurisdiction of this Court because it has regular and systematic contacts with this forum such that the exercise of jurisdiction over it would not offend traditional notions of fair play and substantial justice.

6. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)-(c) because Sarcos is subject to personal jurisdiction in this District.

GENERAL ALLEGATIONS

7. Plaintiff kaleo is a specialty pharmaceutical company that builds innovative solutions for serious and life-threatening medical conditions. Kaleo manufactures and distributes Evzio®, which is a hand-held, single-use naloxone auto-injector for immediate administration as emergency treatment of known or suspected opioid overdose.

8. Upon information and belief, Sarcos is the alleged owner of and/or has enforcement rights to U.S. Patent No. 6,045,534 ("534 patent") titled "Disposable Fluid Injection Module" granted on April 4, 2000. A true and accurate copy of the '534 patent is attached as Exhibit A.

9. Upon information and belief, Sarcos is the alleged owner of and/or has enforcement rights to U.S. Patent No. 6,086,562 ("562 patent") titled "Disposable Automatic Injection Device" granted on July 11, 2000. A true and accurate copy of the '562 patent is attached as Exhibit B.

10. Upon information and belief, Sarcos is the alleged owner of and/or has enforcement rights to U.S. Patent No. 6,010,492 ("492 patent") titled "Apparatus for Automatic Administration of Multiple Doses of Drugs" granted on January 4, 2000. A true and accurate copy of the '492 patent is attached as Exhibit C.

11. On October 13, 2015, Mr. Vince Frantz of Global IP Law Group sent to kaleo's General Counsel, Ned Ruffin, an e-mail including a summary of the Sarcos Disposable Medical Auto-Injector Patent Portfolio. Mr. Frantz's e-mail indicates that his firm has "materials illustrating

infringement by various companies available for review.” The summary provided by Mr. Frantz highlighted, among others, the ’534 patent, the ’562 patent and the ’492 patent (collectively, “the Asserted Patents”). A true and accurate copy of the October 13, 2015 e-mail and its attachment are attached as Exhibit D.

12. On March 10, 2016, Mr. Graham Gerst of Global IP Law Group sent to Mr. Ruffin a letter again summarizing the Sarcos Drug-Injection portfolio including, among others, the ’534 patent, the ’562 patent and the ’492 patent even though Mr. Gerst clarifies that Sarcos no longer practices the alleged inventions claimed in the Asserted Patents (“Today, Sarcos focuses on developing dexterous, tele-operated robotic systems for military and other uses.”).

13. Mr. Gerst’s letter further alleged infringement by kaleo of “at least patent no. 6,045,534” along with “a claim chart documenting this fact.” Mr. Gerst indicated the “claim chart is only a sample of Kaléo’s activity that infringes the ’534 patent” and invited kaleo to “examine [its] other products and services with similar components or features.” Mr. Gerst’s March 10, 2016 letter offered a license agreement at a royalty rate of 5% if the parties “could finalize a license agreement in the next 75 days.” A true and accurate copy of the March 10, 2016 letter to kaleo is attached as Exhibit E.

14. On March 29, 2016, Mr. Gerst followed up again by leaving a voice message for Mr. Ruffin to confirm that he had received the letter and inquiring whether he had any questions regarding its content.

15. As a result of Sarcos’ detailed allegations of patent infringement by kaleo, the deadline imposed by Sarcos by which kaleo can take advantage of its licensing offer and Sarcos’ continued outreach regarding the Asserted Patents, an immediate, concrete, actual, substantial and justiciable controversy now exists between kaleo and Sarcos regarding allegations of infringement and validity of the ’534, ’562 and ’492 patents. This is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Kaleo seeks a declaration from this Court resolving the present controversy.

COUNT I
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '534 PATENT

16. Kaleo incorporates by reference the allegations set forth in paragraphs 1 through 15 of this Complaint as though set forth in full herein.

17. Sarcos has accused kaleo of infringing the '534 patent at least by making and selling the Evzio® autoinjector.

18. Kaleo has not infringed and is not infringing, directly, indirectly, contributorily, by active inducement, or otherwise, any valid and enforceable claim of the '534 patent.

19. An actual and justiciable case or controversy exists between kaleo and Sarcos concerning alleged infringement of the '534 patent, which requires a declaration of rights by this Court.

20. Based on the acts, conduct, and statements of Sarcos, kaleo has formed a reasonable apprehension and belief that Sarcos intends to and will sue kaleo for alleged infringement of the '534 patent.

21. Sarcos' incorrect allegation that kaleo infringes claims of the '534 patent has caused, and will continue to cause, damage to kaleo.

22. Kaleo is entitled to a judicial determination and declaration that it does not infringe and has not infringed, directly, indirectly, contributorily, by active inducement or otherwise, any valid and enforceable claim of the '534 patent.

COUNT II
DECLARATORY JUDGMENT OF INVALIDITY OF THE '534 PATENT

23. Kaleo incorporates by reference the allegations set forth in paragraphs 1**Error!** **Reference source not found.** through 22 of this Complaint as though set forth in full herein.

24. An actual and justiciable case or controversy exists between kaleo and Sarcos concerning the invalidity of the '534 patent, which requires a declaration of rights by this Court.

25. Kaleo contends that at least claims 11-15, 17-18, 26, 30 and 31 of the '534 patent are invalid for failing to satisfy the conditions and requirements for patentability as set forth in Title 35,

United States Code, including, but not limited to, 35 U.S.C. §§ 102, 103. A claim chart setting forth the basis for invalidity of at least independent claims 11, 26 and 31 is attached as Exhibit F.

26. Kaleo contends that at least claims 15, and 26-29 of the '534 patent are invalid for failing to satisfy the conditions and requirements for patentability as set forth in Title 35, United States Code, including, but not limited to, 35 U.S.C. § 112.

27. On information and belief, Sarcos contends that each and every claim of the '534 patent is valid.

28. Sarcos' allegation that kaleo infringes invalid claims of the '534 patent has caused, and will continue to cause, damage to kaleo.

29. Kaleo is entitled to a judicial determination and declaration that at least claims 11-15, 17-18, 26-31 of the '534 patent are invalid.

COUNT III
DECLARATORY JUDGMENT OF UNENFORCEABILITY OF THE '534 PATENT

30. Kaleo incorporates by reference the allegations set forth in paragraphs 1 through 29 of this Complaint as though set forth in full herein.

31. During prosecution of the '534 patent, in an amendment dated August 26, 1999 ("the August 26 Amendment"), counsel for Sarcos, Michael Starkweather, added a new claim 46 (which ultimately issued as claim 26) and represented to the U.S. Patent and Trademark Office that "[n]ew claim 46 was written to essentially include key limitations of claims 1 and 6." Exhibit G at 10. In reality, however, new claim 46 not only excluded key limitations of claim 1, but entirely omitted the majority of claim 6, which includes intervening claims 4 and 5. The following comparison of claims 1, 4, 5, 6 and 46 highlights the significant elements intentionally omitted from new claim 46. Key omitted elements are underlined>.

Claims 1, 4, 5 and 6	Claim 46
1. An apparatus for delivering a drug, comprising:	46. An apparatus for delivering a drug, comprising:
a housing having a distal end through which	a) a housing having a first and second

the drug is delivered and a proximal end and defining a first chamber therein;	chamber therein;
a piston disposed within said first chamber, <u>said piston defining a second chamber therein;</u>	b) a piston, positioned within the housing and between the first and second chambers, having a reservoir therein for containing the drug to be delivered;
<u>a piston core movably disposed within said second chamber of said piston and defining a reservoir between said piston and said piston core;</u>	
<u>a pressure source proximate said proximal end and in communication with said first chamber;</u> and	
an injection device <u>coupled to the piston core</u> and in communication with said reservoir for delivery of a dose of a drug contained therein.	c) an injection device, positioned to be extended into the reservoir and out of the housing, for delivering the drug out of the reservoir; and
4. The apparatus of claim 1, further including a biasing device <u>for biasing said injection device toward said proximal end.</u>	
5. The apparatus of claim 4, further including <u>an end cap attached to said distal end of said housing.</u>	
6. The apparatus of claim 5, wherein said <u>biasing device is a spring interposed between said end cap and said piston core.</u>	d) a biasing device, located proximate the piston, for retracting the injection device into the housing after the drug has been delivered.

32. Further exacerbating Sarcos' conduct is the fact that the bolded and underlined language "coupled to the piston core" was added in a previous amendment to overcome a rejection, but was omitted from newly presented claim 46. In other words, key elements added to claim 1 by amendment to overcome prior art were intentionally omitted.

33. Sarcos' counsel, Mr. Starkweather, intentionally misrepresented the scope of new claim 46 with the intent to deceive the patent Examiner to obtain allowance of the newly added claim that was broader in scope than to which Sarcos was entitled.

34. But for Mr. Starkweather's misrepresentation, the patent examiner would have had reason to further examine the claims as presented, while considering the proper scope of new claim 46.

35. The '534 patent is unenforceable due to inequitable conduct committed during the prosecution of the '534 patent.

36. On information and belief, Sarcos contends that the '534 patent is enforceable.

37. Sarcos' allegation that kaleo infringes enforceable claims of the '534 patent has caused, and will continue to cause, damage to kaleo.

38. Kaleo is entitled to a judicial determination and declaration that the '534 patent is unenforceable due to inequitable conduct.

COUNT IV
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '562 PATENT

39. Kaleo incorporates by reference the allegations set forth in paragraphs 1 through 38 of this Complaint as though set forth in full herein.

40. Sarcos has accused Kaleo of infringing the '562 at least by making and selling the Evzio® autoinjector.

41. Kaleo has not infringed and is not infringing, directly, indirectly, contributorily, by active inducement, or otherwise, any valid and enforceable claim of the '562 patent.

42. An actual and justiciable case or controversy exists between kaleo and Sarcos concerning alleged infringement of the '562 patent, which requires a declaration of rights by this Court.

43. Based on the acts, conduct, and statements of Sarcos, kaleo has formed a reasonable apprehension and belief that Sarcos intends to and will sue kaleo for alleged infringement of the '562 patent.

44. Sarcos' incorrect allegation that kaleo infringes claims of the '562 patent has caused, and will continue to cause, damage to kaleo.

45. Kaleo is entitled to a judicial determination and declaration that it does not infringe and has not infringed, directly, indirectly, contributorily, by active inducement or otherwise, any valid and enforceable claim of the '562 patent.

COUNT V
DECLARATORY JUDGMENT OF INVALIDITY OF THE '562 PATENT

46. Kaleo incorporates by reference the allegations set forth in paragraphs 1 through 45 of this Complaint as though set forth in full herein.

47. An actual and justiciable case or controversy exists between kaleo and Sarcos concerning the invalidity of the '562 patent, which requires a declaration of rights by this Court.

48. Kaleo contends that at least claims 1, 2, 5-11, 16-19, 21-26 and 28 of the '562 patent are invalid for failing to satisfy the conditions and requirements for patentability as set forth in Title 35, United States Code, including, but not limited to, 35 U.S.C. §§ 102, 103. A claim chart setting forth the basis for invalidity of at least independent claims 1, 17 and 25 is attached as Exhibit H.

49. Kaleo contends at least claim 2, 4, 6 and 9 of the '562 patent are invalid for failing to satisfy the conditions and requirements for patentability as set forth in Title 35, United States Code, including, but not limited to, 35 U.S.C. § 112.

50. On information and belief, Sarcos contends that each and every claim of the '562 patent is valid.

51. Sarcos' allegation that kaleo infringes invalid claims of the '562 patent has caused, and will continue to cause, damage to kaleo.

52. Kaleo is entitled to a judicial determination and declaration that at least claims 1, 2, 4-11, 16-19, 21-26 and 28 of the '562 patent are invalid.

COUNT VI
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '492 PATENT

53. Kaleo incorporates by reference the allegations set forth in paragraphs 1 through 52 of this Complaint as though set forth in full herein.

54. Sarcos has accused kaleo of infringing the '492 patent at least by making and selling the Evzio® autoinjector.

55. Kaleo has not infringed and is not infringing, directly, indirectly, contributorily, by active inducement, or otherwise, any valid and enforceable claim of the '492 patent.

56. An actual and justiciable case or controversy exists between kaleo and Sarcos concerning alleged infringement of the '492 patent, which requires a declaration of rights by this Court.

57. Based on the acts, conduct, and statements of Sarcos, kaleo has formed a reasonable apprehension and belief that Sarcos intends to and will sue kaleo for alleged infringement of the '492 patent.

58. Sarcos' incorrect allegation that kaleo infringes claims of the '492 patent has caused, and will continue to cause, damage to kaleo.

59. Kaleo is entitled to a judicial determination and declaration that it does not infringe and has not infringed, directly, indirectly, contributorily, by active inducement or otherwise, any valid and enforceable claim of the '492 patent.

COUNT VII
DECLARATORY JUDGMENT OF INVALIDITY OF THE '492 PATENT

60. Kaleo incorporates by reference the allegations set forth in paragraphs 1 through 59 of this Complaint as though set forth in full herein.

61. An actual and justiciable case or controversy exists between kaleo and Sarcos concerning the invalidity of the '492 patent, which requires a declaration of rights by this Court.

62. Kaleo contends that at least claims 1-21 of the '492 patent are invalid for failing to satisfy the conditions and requirements for patentability as set forth in Title 35, United States Code, including, but not limited to, 35 U.S.C. §§ 102, 103 and 112. A claim chart setting forth the basis for invalidity under 35 U.S.C. §§ 102 and 103 of at least independent claims 1 and 16 is attached as Exhibit I.

63. On information and belief, Sarcos contends that each and every claim of the '492 patent is valid.

64. Sarcos' allegation that kaleo infringes invalid claims of the '492 patent has caused, and will continue to cause, damage to kaleo.

65. Kaleo is entitled to a judicial determination and declaration that claims 1-21 of the '492 patent are invalid.

WHEREFORE, kaleo requests that the Court enter a judgment in its favor and against Sarcos as follows:

- A. Enter judgment for kaleo and against Sarcos on all counts asserted in this complaint;
- B. Declare that kaleo has not and does not infringe any valid and enforceable claim of '534 patent;
- C. Declare that kaleo has not and does not infringe any valid and enforceable claim of '562 patent;
- D. Declare that kaleo has not and does not infringe any valid and enforceable claim of '492 patent;
- E. Declare that claims 11-15, 17-18, 26-31 of the '534 patent are invalid;
- F. Declare that claims 1, 2, 5-11, 16-19, 21-26 and 28 of the '562 patent are invalid;
- G. Declare that the claims 1-21 of the '492 patent are invalid;
- H. Declare that the '534 patent is unenforceable due to inequitable conduct;
- I. Enjoin Sarcos, and its officers, directors, agents, counsel, servants, and employees and all persons in active concert or participation with any of them, from attempting to enforce the '534 patent against kaleo or any customer of kaleo by reason of such customer's use of kaleo's products;

- J. Enjoin Sarcos, and its officers, directors, agents, counsel, servants, and employees and all persons in active concert or participation with any of them, from attempting to enforce the '562 patent against kaleo or any customer of kaleo by reason of such customer's use of kaleo's products;
- K. Enjoin Sarcos, and its officers, directors, agents, counsel, servants, and employees and all persons in active concert or participation with any of them, from attempting to enforce the '492 patent against kaleo or any customer of kaleo by reason of such customer's use of kaleo's products;
- L. Find this case to be an exceptional case pursuant to 35 U.S.C. § 285 and award kaleo its attorneys' fees and expenses;
- M. Grant kaleo such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

66. Pursuant to Federal Rule of Civil Procedure 38, Plaintiff kaleo, Inc. demands a trial by jury in this action.

Respectfully submitted,

Dated: April 4, 2016

By:



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