

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SAGE LABS, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. _____
)	
TRANSPOSAGEN)	
BIOPHARMACEUTICALS, INC.,)	
)	
Defendant.)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff SAGE, Labs. Inc. (“SAGE”), through their undersigned counsel, brings this declaratory judgment action against Defendant Transposagen Biopharmaceuticals, Inc. (“Transposagen”), and alleges as follows:

THE PARTIES

1. SAGE Labs, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 2033 Westport Center Drive, St. Louis, Missouri 63146. SAGE specializes in the development and characterization of unique, next-generation animal research models, including transgenic rats.

2. On information and belief, Defendant Transposagen Biopharmaceuticals, Inc. is a privately-held corporation organized and existing under the laws of the State of Delaware with its principal place of business located at 535 West Second Street, Lexington, Kentucky 40508. On information and belief, Transposagen is qualified to do business in Delaware and has appointed a registered agent for service of process: Capitol Services, Inc., 1675 S. State St., Ste. B, Dover, DE 19901. On information and belief, Transposagen is engaged in the business of

developing, offering to sell, and selling its products to companies and research institutions located throughout the United States, including in the State of Delaware.

JURISDICTION AND VENUE

3. This is a claim for declaratory judgment of patent invalidity and non-infringement of United States Patent Nos. 8,558,055 (“the ’055 patent”) and 8,722,964 (“the ’964 patent”) (collectively, “the patents-in-suit”), which purport to pertain to genetically modified or engineered rats (animal models of human medical conditions), and methods for the use of such animals. Copies of the patents-in-suit are attached hereto as Exhibits A and B, respectively.

4. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 for patent non-infringement and patent invalidity. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). This matter presents an actual case or controversy and serves the purpose of resolving the legal rights of the parties.

5. This Court has personal jurisdiction over Transposagen because Transposagen is a Delaware corporation and has appointed a registered agent for service of process in the State of Delaware. In addition, on information and belief, Transposagen has maintained continuous and systematic contacts with, has purposefully availed itself of the benefits and protections of the laws of, and has purposefully directed its activities at residents of, the State of Delaware. Accordingly, the exercise of personal jurisdiction over Transposagen comports with the Due Process Clause of the United States Constitution.

6. Transposagen’s contacts with the State of Delaware include, on information and belief, the business Transposagen transacts in the State of Delaware, including without limitation advertising and selling products, purported to be covered by the patents-in-suit, to customers in

the state. Additionally, Transposagen maintains a website in connection with its business (www.transposagenbio.com) that is accessible throughout the United States, including in the State of Delaware.

7. Venue is proper in this judicial district under 28 U.S.C. § 1391.

BACKGROUND

8. SAGE incorporates the preceding paragraphs as if fully set forth herein.

9. The '055 patent issued on October 15, 2013, and is entitled "Genetically Modified Rat Comprising a Cytokine Gene Disruption and Exhibiting a Greater Susceptibility to a Cytokine-Mediated Autoimmune and/or Inflammatory Disease." On its face, the '055 patent identifies Eric M. Ostertag and John Stuart Crawford as inventors and identifies Transposagen Biopharmaceuticals, Inc. as the assignee. A true and correct copy of the '055 patent as it issued, and a Certificate of Correction dated October 15, 2013, is attached to this Complaint as Exhibit A.

10. The '964 patent issued on May 13, 2014, and is entitled "Genetically Engineered or Transgenic Rats Exhibiting a Cancer Phenotype Due to a Disruption of Germline Tumor Suppression Genes." On its face, the '964 patent identifies Eric M. Ostertag and John Stuart Crawford as inventors and identifies Transposagen Biopharmaceuticals, Inc. as the assignee. A true and correct copy of the '964 patent as it issued, and a Certificate of Correction dated May 13, 2014, is attached to this Complaint as Exhibit B.

11. On or about March 18, 2015, Mr. David E. Schmit, of Frost Brown Todd LLC, counsel for Transposagen, sent a letter to Dr. Edward Weinstein, the General Manager of SAGE, regarding the '055 and '964 patents ("the March 18 Warning Letter"). A true and correct copy of that letter is attached to this Complaint as Exhibit C.

12. In the March 18 Warning Letter, counsel for Transposagen expressly communicated that “Transposagen believes that one or more of SAGE’s genetically modified rats are covered by at least one claim of one or more of [the patents-in-suit].” (Ex. C. at 1.) The March 18 Warning Letter specifically alleges infringement of the ’055 patent by making, using, selling, offering for sale, or importing modified rats having mutations in, for example, *Rag1*, *Rag2*, *Prkdc*, *Cox1*, *Cox2*, *Lgals1*, *Tbx21*, and *Ppara*. (*Id.* at 2.) The letter specifically alleges infringement of the ’964 patent by making, using, selling, offering for sale, or importing modified rats having mutations in, for example, *p53*, *Ahr*, *Met*, *Park2*, and *Pten*. (*Id.*)

13. The March 18 Warning Letter further alleges that “Transposagen values its intellectual property rights, and takes these matters very seriously” and that Transposagen believes the claims of the patents-in-suit cover any genetically modified rats having a phenotype wherein the rats have a greater susceptibility to cytokine-mediated autoimmune and/or inflammatory disease, and/or any genetically modified rat having a cancer phenotype. (*Id.* at 2-3.) Specifically, the March 18 Warning Letter alleges “the claims of the ’055 patent cover ***any genetically modified rats having a phenotype wherein the rat has a greater susceptibility to cytokine-mediated autoimmune and/or inflammatory disease***, and are not limited by any specific gene or set of genes. Likewise, the ’964 patent covers ***any genetically modified rat having a cancer phenotype***, and is not limited to a specific gene or set of genes.” (*Id.* (emphasis in original)).

14. The March 18 Warning Letter concludes by (1) demanding that SAGE “immediately stop making, using, selling, or offering for sale any and all rats or rat cells covered by the [patents-in-suit],” (2) warning SAGE that Transposagen believes SAGE may be liable for patent royalties for the patents-in-suit, (3) requesting an accounting of all rats sold with the

accused phenotypes, and (4) asking SAGE to inform its future clients of the Transposagen patents-in-suit and the “risk of patent infringement” by virtue of using SAGE’s services. (*Id.* at 4.)

15. In demanding that SAGE “stop making, using, selling, or offering for sale” the identified products, and that SAGE inform its future clients of the alleged “risk of patent infringement by virtue of manufacturing catalog or custom genetically modified rats using [SAGE’s] services,” the March 18 Warning Letter indicates that Transposagen intends to assert patent infringement claims against SAGE if Transposagen’s demands are not met. (*Id.* at 4) Transposagen’s counsel emphasizes that “Transposagen is prepared to pursue legal remedies if it becomes clear that a mutually agreeable resolution is not possible” and that to avoid such legal action, SAGE must comply with Transposagen’s demands within seven days of the letter. (*Id.*)

16. On April 1, 2015, Jeb Ledell, Chief Operating Officer of SAGE, responded directly to Eric Ostertag of Transposagen and suggested they discuss the issues presented in the March 18 Warning Letter. A true and correct copy of that email is attached to this Complaint as Exhibit D. A telephone discussion occurred between Jeb Ledell and Eric Ostertag on April 3, 2015 and an email memorializing that discussion was sent by Jeb Ledell on April 10, 2015 (“The April 10 Email”). A true and correct copy of that email is attached to this Complaint as Exhibit E.

17. The April 10 Email explained that “without prejudice to the merits of the arguments outlined in [the March 18 Warning Letter], but rather to show good faith in responding to [Transposagen’s] requests,” SAGE agreed to temporarily stop making, using, or selling the rat models outlined in the March 18 Warning Letter. (Ex. E at 1.) Further, the April 10 Email indicated that it was SAGE’s expectation that certain of the models enumerated in the

March 18 Warning Letter and/or which SAGE removed from its website do not fall within the scope of the patents-in-suit. (*Id.*) They agreed to reconvene the discussion later in the month.

18. Shortly thereafter, SAGE became aware that Transposagen began sending correspondence to third-parties in which Transposagen misrepresented the above discussions. SAGE and Transposagen exchanged emails regarding these misrepresentations on April 15, 2015, a true and correct copy of which is attached to this Complaint as Exhibit F. Specifically, Transposagen misrepresented to such third parties that (1) Transposagen has forced SAGE out of the rat model business and (2) SAGE agreed to cease selling or offering to create and sell rat models for cancer and autoimmune/inflammation. (Ex. F at 1.) SAGE raised these misrepresentations with Transposagen, and Mr. Ostertag agreed not to use SAGE's name in future communications, but indicated that Transposagen intended to continue sending cease and desist letters to end users it suspects of infringing the patents-in-suit, which likely will include customers of SAGE.

19. On Monday, August 31, 2015, SAGE reinstated sales of its *Rag1*, *Rag2*, *Prkdc*, *Cox1*, *Cox2*, *Lgals1*, *Tbx21*, *Ppara*, *p53*, *Ahr*, *Met*, *Park2*, and *Pten* rats.

20. In light of the demands in the March 18 Warning Letter, the disagreement between the parties regarding the scope of the patents-in-suit, and Transposagen's continued enforcement activity, including sending correspondence to customers and potential customers of SAGE, there is a continuing, ripe, justiciable controversy between the parties as to non-infringement and invalidity of the '055 and '964 patents. An actual case and controversy exists between the parties within the scope of this Court's jurisdiction pursuant to 28 U.S.C. § 2201 and 2202.

21. Further, based on Transposagen's threats and SAGE's reasonable apprehension of being sued by Transposagen, SAGE filed petitions at the United States Patent Trial and Appeal Board seeking *Inter Partes* Review of the '055 and '964 patents on September 8, 2015.

COUNT I:

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,558,055

22. SAGE realleges and incorporates the preceding paragraphs as if fully set forth herein.

23. There is an actual, substantial, and continuing justiciable case or controversy between Transposagen and SAGE regarding the non-infringement of the '055 patent.

24. SAGE has not directly infringed, and does not directly infringe, any claim of the '055 patent under 35 U.S.C. § 271(a). For example, SAGE does not make, use, sell, offer for sale, or import genetically modified or engineered rats, or practice methods using such rats, meeting each and every limitation, either literally or under the doctrine of equivalents, of the claims in the '055 patent.

25. SAGE has not actively induced any infringement, and does not actively induce any infringement, of the claims of the '055 patent under 35 U.S.C. § 271(b). For example, SAGE has not intentionally taken any action to induce direct infringement of the '055 patent, and SAGE lacks the knowledge and the intent that any acts would cause infringement the '055 patent.

26. SAGE has not contributorily infringed, and does not contributorily infringe, the claims of the '055 patent under 35 U.S.C. § 271(c). For example, SAGE's rats are not a component of a patented product or a material for use in a patented process, SAGE has no knowledge that its transgenic rats are especially made or especially adapted for use in infringing

the '055 patent, and there are substantial uses for SAGE's transgenic rats that would not infringe the claims of the '055 patent.

27. SAGE is entitled to a declaration pursuant to 28 U.S.C. §§ 2201 and 2202 that SAGE does not infringe any valid and enforceable claim of the '055 patent, directly or indirectly, either literally or under the doctrine of equivalents.

COUNT II
Declaratory Judgment of Invalidity of U.S. Patent No. 8,558,055

28. SAGE realleges and incorporates the preceding paragraphs as if fully set forth herein.

29. There is an actual, substantial, and continuing justiciable case or controversy between Transposagen and SAGE regarding the invalidity of the '055 patent.

30. All of the claims of the '055 patent are invalid under Title 35 of the United States Code for failing to comply with the requirements of patentability, including but not limited to at least one of §§ 101, 102, 103, and/or 112.

31. SAGE is entitled to a declaration pursuant to 28 U.S.C. §§ 2201 and 2202 that all claims of the '055 patent are invalid.

COUNT III
Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,722,964

32. SAGE realleges and incorporates the preceding paragraphs as if fully set forth herein.

33. There is an actual, substantial, and continuing justiciable case or controversy between Transposagen and SAGE regarding the non-infringement of the '964 patent.

34. SAGE has not directly infringed, and does not directly infringe, any claim of the '964 patent under 35 U.S.C. § 271(a). For example, SAGE does not make, use, sell, offer for

sale, or import genetically modified or engineered rats, or practice methods using such rats, meeting each and every limitation, either literally or under the doctrine of equivalents, of the claims in the '964 patent.

35. SAGE has not actively induced any infringement, and does not actively induce any infringement, of the claims of the '964 patent under 35 U.S.C. § 271(b). For example, SAGE has not intentionally taken any action to induce direct infringement of the '964 patent, and SAGE lacks the knowledge and intent that any acts would cause infringement the '964 patent.

36. SAGE has not contributorily infringed, and does not contributorily infringe, the claims of the '964 patent under 35 U.S.C. § 271(c). For example, SAGE's rats are not a component of a patented product or a material for use in a patented process, SAGE has no knowledge that its transgenic rats are especially made or especially adapted for use in infringing the '964 patent, and there are substantial uses for SAGE's transgenic rats that would not infringe the claims of the '964 patent.

37. SAGE is entitled to a declaration pursuant to 28 U.S.C. §§ 2201 and 2202 that SAGE does not infringe any valid and enforceable claim of the '964 patent, directly or indirectly, either literally or under the doctrine of equivalents.

COUNT IV
Declaratory Judgment of Invalidity of U.S. Patent No. 8,722,964

38. SAGE realleges and incorporates the preceding paragraphs as if fully set forth herein.

39. There is an actual, substantial, and continuing justiciable case or controversy between Transposagen and SAGE regarding the invalidity of the '964 patent.

40. All of the claims of the '964 patent are invalid under Title 35 of the United States Code for failing to comply with the requirements of patentability, including but not limited to at least one of §§ 101, 102, 103, and/or 112.

41. SAGE is entitled to a declaration pursuant to 28 U.S.C. §§ 2201 and 2202 that all claims of the '964 patent are invalid.

JURY DEMAND

42. Pursuant to Rule 38(b), Fed. R. Civ. P., SAGE requests a trial by jury.

PRAYER FOR RELIEF

WHEREFORE, SAGE respectfully requests that this Court enter judgment in its favor as follows:

(a) declare that SAGE has not directly infringed, and does not currently directly infringe, any claim of the '055 or '964 patents under 35 U.S.C. § 271(a);

(b) declare that SAGE has not induced, and does not currently induce, any infringement of any claim of the '055 or '964 patents under 35 U.S.C. § 271(b);

(c) declare that SAGE has not contributorily infringed, and does not currently contributorily infringe, any claim of the '055 or '964 patents under 35 U.S.C. § 271(c);

(d) declare that the claims of the '055 and '964 patents are invalid;

(e) declare this to be an exceptional case and award SAGE its costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 28 U.S.C. § 285;

(f) permanently enjoin Transposagen and its officers, agents, servants, employees, and attorneys, and those other persons or entities in active concert or participation with them, from asserting (either in a lawsuit or in any other manner) that SAGE infringes the '055 and '964 patents; and

(g) award SAGE any further and additional relief that this Court deems just and proper.

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