

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

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U.S. DISTRICT COURT  
DISTRICT OF MASS

\_\_\_\_\_  
TRANSKARYOTIC THERAPIES, INC., )

Plaintiff )

v. )

GENZYME CORPORATION )  
and MOUNT SINAI SCHOOL OF )  
MEDICINE OF NEW YORK UNIVERSITY, )

Defendants. )  
\_\_\_\_\_

00 CV 11922 MLW

Civil Action No.

RECEIVED \$ 25395  
AMOUNT \$ 150.00  
RECEIVED IN. yes  
LOCAL RULE 41 yes  
WAIVER OF SERV. /  
MCF ISSUED  
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DATE 9-19-00

**COMPLAINT FOR DECLARATORY JUDGMENT  
OF NON-INFRINGEMENT AND PATENT INVALIDITY**

This is a declaratory judgment action. Plaintiff Transkaryotic Therapies, Inc., ("TKT") requests a declaration that it does not infringe United States Patent No. 5,356,804 (the "804 Patent") and that the '804 Patent is invalid.

**The Parties**

1. Plaintiff TKT is a Delaware corporation with a principal place of business at 195 Albany Street, Cambridge, Massachusetts.

2. Defendant Genzyme Corporation ("Genzyme") is a Massachusetts corporation with a principal place of business at One Kendall Square, Cambridge, Massachusetts.

3. Defendant Mount Sinai School of Medicine of New York University ("Mount Sinai") is a not-for-profit New York corporation with a principal place of business at One Gustave L. Levy

Place, New York, New York. Upon information and belief, Mount Sinai does and transacts business in the Commonwealth of Massachusetts, including, without limitation, by licensing certain rights in the '804 Patent to Genzyme.

**Jurisdiction and Venue**

4. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202 because this action arises under the patent laws of the United States, and the Federal Declaratory Judgment Act.

5. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400 because both TKT and Genzyme maintain their principal places of business in Massachusetts.

**Factual Allegations**

6. TKT is a biopharmaceutical company engaged in the business of developing and commercializing human therapeutic products. Among those products are proteins that are administered to persons who suffer from rare genetic diseases for which no effective treatment had been developed prior to TKT's work.

7. Fabry disease is an inherited rare genetic disorder caused by deficient activity of the lysosomal enzyme alpha-galactosidase A (" $\alpha$ -Gal A"). An  $\alpha$ -Gal A deficiency causes deposits of a fatty substance, known as ceramidetrihexoside, to build up in various tissues in the body. Those deposits ultimately result in extreme pain, serious renal, cardiac and vascular disease, and, premature death. Prior to TKT's work, there had been no effective treatment available to persons who suffer from Fabry disease.

8. TKT has developed a biologically active human  $\alpha$ -Gal A protein which may be administered to persons suffering from Fabry disease, called Replagal<sup>TM</sup>. On or about June 16, 2000,

TKT filed a Biologics License Application ("BLA") with the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell Replagal™ in the United States.

9. The '804 Patent, entitled "Cloning and Expression of Biologically Active Human Alpha-Galactosidase A," issued on October 18, 1994. A copy of the '804 Patent is attached as Exhibit A to this Complaint. Defendant Mount Sinai asserts that it is the assignee of the '804 Patent. Defendant Genzyme asserts that it is the exclusive licensee of the '804 Patent.

10. On July 25, 2000, without first ascertaining the method used by TKT to produce Replagal™, defendants Genzyme and Mount Sinai filed a Complaint in the United States District Court for the District of Delaware in an action entitled Genzyme Corporation and Mount Sinai School of Medicine of New York University v. Transkaryotic Therapies, Inc., Civil Action No. 00-677-GMS ("the Delaware Action"), in which Genzyme and Mount Sinai allege that the manufacture of Replagal™ by TKT infringes at least two of the claims of the '804 Patent.

11. On the same day, Genzyme issued, and widely disseminated, a press release announcing that it had commenced the Delaware Action. In that press release, Genzyme's Senior Vice President and Chief Patent Counsel stated on behalf of Genzyme that: "We are confident that the Mount Sinai patent is valid and enforceable against TKT's alpha-galactosidase A product." The following day, stories describing Genzyme's contentions in the Delaware Action were carried in major newspapers throughout the United States.

12. Notwithstanding the foregoing, in the eight weeks since the commencement of the Delaware Action, Genzyme and Mount Sinai have intentionally refrained from serving on TKT the Summons and Complaint in the Delaware Action, and Genzyme and Mount Sinai have not otherwise prosecuted the Delaware Action.

13. The commencement of the Delaware Action, and the publicity intentionally generated by Genzyme with respect to the Delaware Action, have created doubt among physicians, patients and firms involved in the distribution of biopharmaceuticals, as to the permissibility of the manufacture, use and sale of Replagal™. That uncertainty has caused, and is causing, injury to TKT.

14. The manufacture and use of Replagal™ does not, and the manufacture, use, offer for sale and sale of Replagal™ in the future will not, infringe, literally or under the doctrine of equivalents, any claim of the '804 Patent. Moreover, the claims of the '804 Patent are invalid by reason of their failure to comply with the legal standards for patentability set forth, *inter alia*, in 35 U.S.C. §§ 102, 103 and 112.

15. An actual controversy exists between TKT, on the one hand, and Genzyme and Mount Sinai, on the other, as to non-infringement and invalidity of the '804 Patent.

**COUNT ONE**  
**(Non-infringement)**

16. TKT repeats and realleges paragraphs 1 through 15 of this Complaint as if fully set forth herein.

17. Replagal™, and the process for manufacturing Replagal™, do not infringe any claim of the '804 Patent.

**COUNT TWO**  
**(Invalidity)**

18. TKT repeats and realleges paragraphs 1 through 17 of this Complaint as if fully set forth herein.

19. Each of the claims of the '804 Patent is invalid for failure to comply with the legal standards for patentability set forth, *inter alia*, in 35 U.S.C. §§ 102, 103, and 112.

**PRAYER FOR RELIEF**

WHEREFORE, TKT respectfully requests that this Court:

1. Determine and declare (a) that the manufacture, use, offer for sale, and sale, of Replagal™ does not, and will not, infringe, literally or under the doctrine of equivalents, any claim of the '804 Patent; and (b) that TKT's conduct relating to the manufacture, use, offer for sale, and sale, of Replagal™ has not constituted, and will not constitute, contributory infringement or the inducement of others to infringe the '804 Patent.

2. Determine and declare that the claims of the '804 Patent are invalid;

3. Determine that this is an exceptional case, and award to TKT its reasonable attorneys fees;

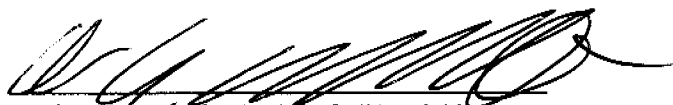
4. Award to TKT the costs of this action; and

5. Grant such other and further relief as the Court deems appropriate in the circumstances.

TRANSKARYOTIC THERAPIES, INC.,

By its attorneys,

September 19, 2000



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