# IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NORTH CAROLINA WESTERN DIVISION CIVIL ACTION NO. <u>08-CV-464</u>

NATIONAL GENETICS INSTITUTE, )	
and BAXTER INTERNATIONAL, INC., )	
) Plaintiffs,	COMPLAINT FOR PATENT
vs.	
	JURY TRIAL DEMANDED
TALECRIS BIOTHERAPEUTICS, INC., )	)
Defendants.	
	)

## **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs, National Genetics Institute ("NGI") and Baxter International, Inc. ("Baxter") (collectively "Plaintiffs") file this Complaint for Patent Infringement against Talecris Biotherapeutics, Inc. ("Talecris") and in support of their Complaint allege:

## **NATURE OF THE ACTION**

1. This is an action for patent infringement arising under the patent laws of the United States Patent Act, 35 U.S.C. § 1, *et seq*.

2. Plaintiffs request permanent injunctive relief and monetary damages against Defendants.

## PARTIES

3. NGI is a corporation organized and existing under the laws of the State of California. NGI is a wholly-owned subsidiary of Laboratory Corporation of America Holdings. ("LabCorp"). LabCorp's headquarters is in Burlington, North Carolina. NGI provides advanced genetic testing services for blood screening, medical testing, and clinical research.

4. Baxter is a corporation organized and existing under the laws of the State of Delaware. Baxter maintains a place of business in Deerfield, Illinois.

5. Upon information and belief, Defendant Talecris is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business in Research Triangle Park, North Carolina. Defendant Talecris, upon information and belief, does business throughout North Carolina, including in this judicial district.

#### JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338 in that it arises under an Act of Congress relating to patents. As the owner and the exclusive licensee of the patents in suit in the relevant fields, the plaintiffs have standing to bring this action.

7. This Court has personal jurisdictional over Defendant, including pursuant to N.C. Gen. Stat. §1-75.4.

8. Venue is proper in this Court, including pursuant to 28 U.S.C. §§ 1391 and 1400.

#### FACTS GIVING RISE TO THIS ACTION

9. NGI provides diagnostic and clinical services in a number of fields, including medical diagnostic testing. Among other services, NGI provides assays for human immunodeficiency virus (HIV), hepatitis A, B, and C (HAV, HBV, and HCV) viruses, and other infectious agents. NGI has pioneered robust, sensitive, and high throughput methods for pooled specimen nucleic acid testing and is licensed by both state and federal agencies to provide clinical laboratory services.

10. U.S. Patent No. 5,780,222 ("222 patent") was duly and lawfully issued by the United States Patent Office on July 14, 1998 and is entitled "Method of PCR testing of pooled blood samples." A true and correct copy of the '222 patent is attached as Exhibit A.

11. U.S. Patent No. 6,063,563 ("'563 patent") was duly and lawfully issued by the United States Patent Office on May 16, 2000 and is entitled "Method of PCR testing of pooled blood samples." A true and correct copy of the '563 patent is attached as Exhibit B.

12. U.S. Patent No. 6,566,052 ("052 patent") was duly and lawfully issued by the United States Patent Office on May 20, 2003 and is entitled "Efficient algorithm for PCR testing of blood samples." A true and correct copy of the '052 patent is attached as Exhibit C.

13. Baxter is the owner of the '222 patent, the '563 patent, and the '052 patent (collectively, "patents-in-suit") by virtue of an assignment between Alpha Therapeutic Corporation and Baxter International, Inc. dated October 16, 2003. A true and correct copy of the October 16, 2003 assignment is attached as Exhibit D.

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14. NGI is the exclusive licensee of the patents-in-suit in the relevant technology fields (diagnostic testing and screening laboratory services) in the United States and has the right to enforce the patents-in-suit against Talecris.

15. Upon information and belief, Talecris has had knowledge of the '222 patent since its formation in or about 2005.

16. Upon information and belief, Talecris has had knowledge of the '563 patent since its formation in or about 2005.

17. Upon information and belief, Talecris has had knowledge of the '052 patent since its formation in or about 2005.

#### <u>COUNT I</u>

#### INFRINGEMENT OF U.S. PATENT 5,780,222

18. Plaintiffs re-allege the allegations of Paragraphs 1 through 18 above as if fully set forth herein.

19. Generally, the '222 patent relates to methods of testing plasma donations to identify donations having a positive viral indication.

20. Defendant tests plasma donations to identify donations having a positive viral indication.

21. Upon information and belief, Defendant has infringed the '222 patent and continues to infringe. Upon information and belief, Defendant's conduct directly infringes the '222 patent by making, using, selling, offering for sale, and/or importing into the United States products and/or processes covered by the '222 patent, including processes and products Defendant employs for testing of plasma donations to identify donations having a positive viral indication.

22. Upon information and belief, Defendant's conduct indirectly infringes the '222 patent as well by inducing others to make, use, sell and/or offering for sale products and/or processes that infringe the '222 patent by, for example, providing such testing with knowledge of the '222 patent and with the intent that infringement occur.

23. Neither NGI nor Baxter has granted Defendant a license or any other right to make, use, sell, offer for sale, or import into the United States products and/or processes covered by the '222 patent.

24. Defendant's infringing actions irreparably injure NGI and Baxter and will continue to injure and damage them.

25. Upon information and belief, Defendant has infringed the '222 patent willfully, with knowledge, and with objective recklessness, for these reasons and others, making this an exceptional case and justifying the assessment of treble damages pursuant to 35 U.S.C. § 284 and the award of attorneys' fees pursuant to 35 U.S.C. § 285.

## COUNT II

## INFRINGEMENT OF U.S. PATENT 6,063,563

26. Plaintiffs re-allege the allegations of Paragraphs 1 through 18 above as if fully set forth herein

27. Generally, the '563 patent relates to methods of testing biological fluid donations to identify donations having a positive viral indication.

28. Defendant tests plasma donations to identify biological fluid donations having a positive viral indication.

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29. Defendant has infringed the '563 patent and continues to infringe. Defendant's conduct directly infringes the '563 patent by making, using, selling, offering for sale, and/or importing into the United States products and/or processes covered by the '563 patent, including processes and products Defendant employs for testing of biological fluid donations to identify donations having a positive viral indication.

30. Upon information and belief, Defendant's conduct indirectly infringes the '563 patent as well by inducing others to make, use, sell and/or offering for sale products and/or processes that infringe the '563 patent by, for example, providing such testing with knowledge of the '563 patent and with the intent that infringement occur.

31. Neither NGI nor Baxter has granted Defendant a license or any other right to make, use, sell, offer for sale, or import into the United States products and/or processes covered by the '563 patent.

32. Defendant's infringing actions irreparably injure NGI and Baxter and will continue to injure and damage them.

33. Upon information and belief, Defendant has infringed the '563 patent willfully, with knowledge, and with objective recklessness, for these reasons and others, making this an exceptional case and justifying the assessment of treble damages pursuant to 35 U.S.C. § 284 and the award of attorneys' fees pursuant to 35 U.S.C. § 285.

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#### COUNT III

#### **INFRINGEMENT OF U.S. PATENT 6,566,052**

34. Plaintiffs re-allege the allegations of Paragraphs 1 through 18 above as if fully set forth herein.

35. Generally, the '052 patent relates to methods of testing biological fluid to identify donations having a positive viral indication.

36. Defendant tests biological fluid to identify donations having a positive viral indication.

37. Defendant has infringed the '052 patent and continues to infringe. Defendant's conduct directly infringes the '052 patent by making, using, selling, offering for sale, and/or importing into the United States products and/or processes covered by the '052 patent, including processes and products Defendant employs for testing of biological fluid to identify donations having a positive viral indication.

38. Upon information and belief, Defendant's conduct indirectly infringes the '052 patent as well by inducing others to make, use, sell and/or offering for sale products and/or processes that infringe the '052 patent by, for example, providing such testing with knowledge of the '052 patent and with the intent that infringement occur.

39. Neither NGI nor Baxter has granted Defendant a license or any other right to make, use, sell, offer for sale, or import into the United States products and/or processes covered by the '052 patent.

40. Defendant's infringing actions irreparably injure NGI and Baxter and will continue to injure and damage them.

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41. Upon information and belief, Defendant has infringed the '052 patent willfully, with knowledge, and with objective recklessness, for these reasons and others, making this an exceptional case and justifying the assessment of treble damages pursuant to 35 U.S.C. § 284 and the award of attorneys' fees pursuant to 35 U.S.C. § 285.

#### PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray that judgment be entered in its favor against Defendant as follows:

1. A permanent injunction preventing Defendant Talecris, including officers, agents, servants, subcontractors, suppliers, employees, distributors, dealers and all other persons acting in concert or participation with Defendant or controlled by Defendant, from further acts of infringement, either direct, contributory or by active inducement;

2. An award of damages together with pre-judgment and post-judgment interest and costs to compensate NGI and Baxter for the infringement by Defendant, including all lost profits and/or any other damages allowed under the United States Code, including 35 U.S.C. § 284, but in no event less than a reasonable royalty;

3. A finding that this is an exceptional case and an increase of any monetary award by three times the amount found or assessed pursuant to 35 U.S.C. § 284;

4. An award of reasonable attorneys' fees incurred by NGI and Baxter as provided in 35 U.S.C. § 285; and

5. Such other and further relief that the Court may deem appropriate.

## JURY TRIAL DEMANDED

This 15<sup>th</sup> day of September 2008.

/s/\_\_\_E. Danielle T. Williams\_ Steven Gardner (NC Bar #20984) E. Danielle T. Williams (NC Bar #23283) Frank W. Leak, Jr. (NC Bar #27937) KILPATRICK STOCKTON LLP 1001 West Fourth Street Winston-Salem, NC 27101 Telephone: (336) 607-7300 Facsimile: (336) 607-7500 e-mail: sgardner@kilpatrickstockton.com e-mail: dtwilliams@kilpatrickstockton.com e-mail: fleak@kilpatrickstockton.com Hayden J. Silver, III (NC Bar #10037) KILPATRICK STOCKTON LLP 3737 Glenwood Avenue Raleigh, NC 27612 Telephone: (919) 420-1700 Facsimile: (919) 420-1880 e-mail: jaysilver@kilpatrickstockton.com Attorneys for Plaintiff National Genetics Institute /s/ William O.L. Hutchinson William O. L. Hutchinson, Esq. (NC Bar No. 32742) KING & SPALDING LLP One Morrocroft Centre 6805 Morrison Boulevard, Suite 200 Charlotte, North Carolina 28211 Telephone: (704) 503-2563 Fax: (704) 503-2622 e-mail: whutchinson@kslaw.com

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