



through its registered agent, Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

3. Upon information and belief, LabCorp America is a corporation organized and existing under the laws of the State of Delaware, with a place of business located at 358 South Main Street, Burlington, North Carolina 27215. LabCorp America can be served with process through its registered agent, Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808. Hereinafter, LabCorp Holdings and LabCorp America will collectively be referred to as "LabCorp."

4. Upon information and belief, 23andMe is a corporation organized and existing under the laws of the State of Delaware, with a place of business located at 1390 Shorebird Way, Mountain View, California 94043. 23andMe can be served with process through its registered agent, Incorporating Services, Ltd., 3500 S Dupont Hwy, Dover, Delaware 19901.

## **II. JURISDICTION AND VENUE**

5. This Court has exclusive jurisdiction of this action for patent infringement pursuant to 28 U.S.C. § 1338(a).

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400.

8. Upon information and belief, Defendants each have minimum contacts with this judicial district such that this forum is a fair and reasonable one. Defendants have also transacted and/or, at the time of the filing of this Complaint, are transacting business within the District of Delaware. Further, upon information and belief, Defendants have each committed acts of patent infringement complained of herein within the District of Delaware, including offering for sale

infringing DNA testing services. For these reasons, personal jurisdiction exists over the Defendants and venue over this action is proper in this Court under 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b).

### **III. THE PATENT-IN-SUIT**

9. On November 10, 2009, United States Patent No. 7,615,342 ("the '342 Patent") was duly and legally issued for an "ACTN3 Genotype Screen for Athletic Performance." A true and correct copy of the '342 Patent is attached as Exhibit A.

10. GTG is the owner of the '342 Patent by assignment from the University of Sydney (which was originally assigned the technology by the inventor, Kathryn Nance North) with the exclusive right to enforce and collect damages for infringement of the '342 Patent during all relevant time periods.

11. The '342 Patent generally relates to methods for analyzing the ACTN3 gene to predict athletic performance.

12. The Abstract of the '342 Patent relevantly provides:

The present invention concerns novel methods of selecting or matching a sport or sporting event to an individual (e.g. a sprint/power sport or an endurance sport) and predicting athletic performance, the methods involving assessing ACTN3 genotype. In alternative embodiments, training regimens may be optimally designed for athletes by assessing the ACTN3 genotypes. Certain embodiments concern combining the assessment of the ACTN3 genotype with other known fitness related genes to better assess the athletic potential of an individual. In addition, the genotypic analysis of the ACTN3 gene may be combined with physiological tests, physical measurements and/or psychological assessments to more optimally design a training regimen for an individual athlete.

13. Without limitation as to claims to be asserted in this action and for exemplary purposes only, Independent Claim 1 of the '342 Patent reads:

1. A method to predict potential sprinting, strength, or power performance in a human comprising:

a) analyzing a sample obtained from the human for the presence of one or more genetic variations in  $\alpha$ -actinin-3 (ACTN3) gene;

b) detecting the presence of two 577R alleles at the loci encoding amino acid number 577 of the  $\alpha$ -actinin-3 (ACTN3) protein; and

c) predicting the potential sprinting, strength, or power performance of the human, wherein the presence of two copies of the 577R allele is positively associated with potential sprinting, strength, or power performance.

14. The '342 Patent is presumed valid and enforceable pursuant to 35 U.S.C. § 282.

#### **IV. DEFENDANTS' INFRINGEMENT**

15. LabCorp is a clinical laboratory company that claims to have a national network of 54 primary laboratories, over 1,700 patient service centers, and nine specialized Centers of Excellence. LabCorp also claims to offer a range of clinical laboratory tests, new molecular tests, and esoteric tests, including advanced genomic testing. One such genomic test is ACTN3 gene testing.

16. 23andMe markets genomic testing and analysis services to the public, including ACTN3 gene testing and analysis. According to 23andMe's marketing materials, 23andMe contracts with LabCorp to perform the actual testing of a person's DNA.

17. According to 23andMe's marketing materials, LabCorp and 23andMe are working together to provide genetic testing, including  $\alpha$ -actinin-3 ("ACTN3") gene testing. Upon information and belief, Defendants, working in concert with one another, have analyzed many ACTN3 genes in humans for the presence of two 577R alleles at the loci encoding amino acid number 577 of the ACTN3 protein in order to predict the person's potential sprinting, strength, or power performance during the term of the '342 Patent.

18. If a person wishes to have ACTN3 testing performed on his or her DNA, that person may contact 23andMe to purchase a testing kit. Typically, 23andMe mails the purchaser a kit to collect a DNA specimen and instructs the purchaser to return the DNA specimen to the "Accessioning Department, NGI / 23andMe." National Genetics Institute (i.e., NGI) is one of

LabCorp's specialized Centers of Excellence. LabCorp thus performs the desired ACTN3 testing for the purchaser. Once the testing is complete, the Defendants, acting in concert, analyze the results; predict the sprinting, strength, or power performance of that purchaser; and report that prediction to the purchaser.

19. 23andMe's marketing materials describe in detail the ACTN3 gene testing that LabCorp has and is performing for 23andMe. More specifically, those marketing materials indicate that LabCorp analyzes and detects the single nucleotide polymorphism rs1815739, which is also referred to as R577X, in the ACTN3 gene. The rs1815739 polymorphism alters position 577 of the  $\alpha$ -actinin-3 protein. The marketing materials also indicate that the Defendants associate athletic performance with the ACTN3 gene, which is "turned on in a type of muscle fiber used for power-based sports." The testing method includes analyzing a sample obtained from a human for the presence of one or more genetic variations in the ACTN3 gene and detecting the presence of two 577R alleles (i.e., rs1815739(C,C)) at the loci encoding amino acid number 577 of the ACTN3 protein. Defendants then use the presence of two 577R alleles to predict the potential sprinting, strength, or power performance of the human because the presence of two copies of the 577R allele is positively associated with potential sprinting, strength, or power performance. Thus, Defendants' ACTN3 testing directly infringes upon one or more claims of the '342 Patent.

20. Defendants had actual knowledge of the '342 Patent during times relevant to this action through at least the knowledge of their employees and/or their research, development, marketing and/or patent application activities. Indeed, 23andMe's ACTN3 marketing materials, of which LabCorp is aware, point to two publications by the named inventor of the '342 Patent,

Kathryn Nance North. Upon information and belief, Defendants also had actual knowledge of the '342 Patent through their awareness of and interactions with GTG.

**V. FIRST CLAIM FOR RELIEF**  
**(LabCorp's Patent Infringement – U.S. Patent No. 7,615,342)**

21. GTG incorporates by reference each and every allegation in paragraphs 1 through 20 as though fully set forth herein.

22. As described herein, LabCorp has manufactured, made, had made, used, practiced, imported, provided, supplied, distributed, sold, and/or offered for sale genotyping services that infringe one or more claims of the '342 Patent in violation of 35 U.S.C. § 271(a), has performed all the steps of one or more methods claimed in the '342 Patent personally and through its direction or control over 23andMe in violation of 35 U.S.C. § 271(a), and/or has induced direct infringement of the '342 Patent by others, including 23andMe, by having actively instructed, assisted and/or encouraged others to practice one or more of the inventions claimed in the '342 Patent in violation of 35 U.S.C. § 271(b).

23. GTG has been damaged as a result of LabCorp's infringing conduct. LabCorp is thus liable to GTG in an amount that adequately compensates GTG for such infringement which cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

**VI. SECOND CLAIM FOR RELIEF**  
**(23andMe's Patent Infringement – U.S. Patent No. 7,615,342)**

24. GTG incorporates by reference each and every allegation in paragraphs 1 through 23 as though fully set forth herein.

25. As described herein, 23andMe has manufactured, made, had made, used, practiced, imported, provided, supplied, distributed, sold, and/or offered for sale genotyping

services that infringe one or more claims of the '342 Patent in violation of 35 U.S.C. § 271(a), has performed all the steps of one or more methods claimed in the '342 Patent personally and through its direction or control over LabCorp in violation of 35 U.S.C. § 271(a), and/or has induced direct infringement of the '342 Patent by others, including LabCorp, by having actively instructed, assisted and/or encouraged others to practice one or more of the inventions claimed in the '342 Patent in violation of 35 U.S.C. § 271(b).

26. GTG has been damaged as a result of 23andMe's infringing conduct. 23andMe is thus liable to GTG in an amount that adequately compensates GTG for such infringement which cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

#### **VII. JURY DEMAND**

GTG hereby requests a trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure.

#### **VIII. PRAYER FOR RELIEF**

GTG requests that the Court find in its favor and against Defendants, and that the Court grant GTG the following relief:

A. Judgment that one or more claims of the '342 Patent has been infringed, either literally, and/or under the doctrine of equivalents, by one or more Defendants and/or by others whose infringement has been induced by Defendants;

B. Judgment that Defendants account for and pay to GTG all damages to and costs incurred by GTG because of Defendants' infringing activities and other conduct complained of herein in an amount not less than a reasonable royalty;

C. That GTG be granted pre-judgment and post-judgment interest on the damages caused to it by reason of Defendants' infringing activities and other conduct complained of herein;

D. Temporarily, preliminarily and permanently enjoining Defendants, their officers, directors, employees, agents, servants, and all persons in active concert with any of them, from infringing and/or inducing others to infringe and/or contributing to the infringement of the '342 Patent; and

E. That GTG be granted such other and further relief as the court may deem just and proper under the circumstances.

Dated: December 20, 2012

**BENESCH, FRIEDLANDER, COPLAN  
& ARONOFF LLP**

By: /s/ Raymond H. Lemisch  
Raymond H. Lemisch, Esquire (No. 4204)  
222 Delaware Avenue, Suite 801  
Wilmington, DE 19801  
(302) 442-7008 Telephone  
(302) 442-7012 Facsimile  
[rlemisch@beneschlaw.com](mailto:rlemisch@beneschlaw.com)

- and -

Robert R. Brunelli, Esquire  
[rbrunelli@sheridanross.com](mailto:rbrunelli@sheridanross.com)  
Benjamin B. Lieb, Esquire  
[blieb@sheridanross.com](mailto:blieb@sheridanross.com)  
SHERIDAN ROSS P.C.  
1560 Broadway, Suite 1200  
Denver, Colorado 80202-5141  
(303) 863-9700  
(303) 863-0223 (facsimile)  
[litigation@sheridanross.com](mailto:litigation@sheridanross.com)

*Attorneys for Plaintiff Genetic Technologies  
Limited*