

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

Civil Action No. _____

GENETIC TECHNOLOGIES LIMITED,
an Australian corporation,

Plaintiff,

v.

AMERICAN ESOTERIC LABORATORIES, a Delaware corporation;
CLINICAL PATHOLOGY LABORATORIES, INC., a Georgia corporation;
CLINICAL PATHOLOGY LABORATORIES SOUTHEAST, a Georgia corporation;
EAST SIDE CLINICAL LABORATORY, a Rhode Island corporation;
FAIRFAX MEDICAL LABORATORIES, INC., D/B/A CLINICAL PATHOLOGY
LABORATORIES MID-ATLANTIC, a Virginia corporation;
PATHOLOGY LABORATORIES, INC., an Ohio corporation; and
SONIC HEALTHCARE USA, INC., a Delaware corporation;

Defendants.

COMPLAINT WITH JURY DEMAND

Plaintiff Genetic Technologies Limited ("GTG") files this Complaint against Defendants American Esoteric Laboratories ("AEL"), Clinical Pathology Laboratories, Inc. ("CPL"), Clinical Pathology Laboratories Southeast ("CPLS"), East Side Clinical Laboratory ("ESCL"), Fairfax Medical Laboratories, Inc., d/b/a Clinical Pathology Laboratories Mid-Atlantic ("FML"), Pathology Laboratories, Inc. ("PL"), and Sonic Healthcare USA, Inc. ("SHUSA") (hereinafter referred to collectively as "Defendants" unless otherwise specified) alleging as follows:

I. THE PARTIES

1. Plaintiff GTG is an Australian corporation with a principal place of business in Victoria, Australia.

2. Upon information and belief, AEL is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business located at 9737 Great Hills Trail, Suite 100, Austin, Texas 78759, and forms all or part of the Midsouth Division of SHUSA.

3. Upon information and belief, CPL is a corporation organized and existing under the laws of the state of Texas, with its principal place of business located at 9737 Great Hills Trail, Suite 100, Austin, Texas 78759, and forms all or part of the Southwest Division of SHUSA.

4. Upon information and belief, CPLS is a corporation organized and existing under the laws of the state of Georgia, with its principal place of business located at 1520 North Leg Road, Augusta, Georgia 30909, and forms all or part of the Southeast Division of SHUSA.

5. Upon information and belief, ESCL is a corporation organized and existing under the laws of the state of Rhode Island, with its principal place of business located at 9737 Great Hills Trail, Suite 100, Austin, Texas 78759, and together with Sunrise Medical Laboratories, Inc. ("Sunrise"), forms a part of the Northeast Division of SHUSA.

6. Upon information and belief, FML is a corporation organized and existing under the laws of the state of Virginia, with its principal place of business located at 4200 Pleasant Valley Road, Chantilly, Virginia 20151, and forms all or part of the Mid-Atlantic Division of SHUSA.

7. Upon information and belief, PL is a corporation organized and existing under the laws of the state of Ohio, with its principal place of business located at 1946 North 13th Street, Suite 301, Toledo, Ohio 43604, and forms all or part of the Midwest Division of SHUSA.

8. Upon information and belief, SHUSA is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business located at 9737 Great Hill Trail, Suite 100, Austin, Texas 78759.

II. JURISDICTION AND VENUE

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

10. Upon information and belief, each of the Defendants is owned by Sonic Healthcare Limited ("SHL"), located in Sydney, Australia. SHL is an international medical diagnostics company which owns a number of diagnostic practices throughout the world that comprise a network of laboratory, medicine/pathology and radiology service providers.

11. Upon information and belief, Defendants AEL, CPL, CPLS, ESCL, FML and PL (collectively "Defendant Laboratories") each have minimum contacts with the Western District of Texas such that this forum is a fair and reasonable one. Collectively, Defendant Laboratories comprise a federation of member laboratories. (*See*, highlighted copy of SHUSA website, reproduced as Exhibit A attached hereto and incorporated by reference in its entirety.) Defendant SHUSA, located in Austin, Texas, is SHL's U.S. lead office. According to SHL, SHUSA is authorized and responsible for planning, directing and controlling SHL's U.S. operations, which includes each of the named Defendant Laboratories, as well as Sunrise Medical Laboratories, Inc. ("Sunrise"), and has been since at least 2007. (*See*, highlighted copy of SHL website, p. 4, reproduced as Exhibit B attached hereto and incorporated by reference in its entirety.) Defendant Laboratories have a collaborative and interactive relationship, coordinated by and through SHUSA in Austin, Texas. Upon information and belief, Defendant Laboratories have each committed such purposeful acts and/or transactions in Texas that they

reasonably knew and/or expected that they could be hailed into court as a future consequence of such activity. Upon information and belief, Defendant Laboratories have transacted and/or, at the time of the filing of this Complaint, are transacting business within the Western District of Texas. For these reasons, personal jurisdiction exists and venue 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

12. On March 18, 1997, United States Patent No. 5,612,179 ("the '179 Patent") was duly and legally issued for an "Intron Sequence Analysis Method for Detection of Adjacent Locus Alleles as Haplotypes." A true and correct copy of the '179 Patent is attached hereto as Exhibit C.

13. GTG is the owner of the '179 Patent with the exclusive right to enforce and collect damages for infringement of the '179 Patent during all relevant times to this action.

14. The '179 Patent generally relates to methods of analysis of non-coding DNA sequences.

15. The Abstract of the '179 Patent relevantly provides:

The present invention provides a method for detection of at least one allele of a genetic locus and can be used to provide direct determination of the haplotype. The method comprises amplifying genomic DNA with a primer pair that spans an intron sequence and defines a DNA sequence in genetic linkage with an allele to be detected. The primer-defined DNA sequence contains a sufficient number of intron sequence nucleotides to characterize the allele. Genomic DNA is amplified to produce an amplified DNA sequence characteristic of the allele. The amplified DNA sequence is analyzed to detect the presence of a genetic variation in the amplified DNA sequence such as a change in the length of the sequence, gain or loss of a restriction site or substitution of a nucleotide. The variation is characteristic of the allele to be detected and can be used to detect remote alleles.

16. Independent Claims 1 and 26 of the '179 Patent read:

1. A method for detection of at least one coding region allele of a multi-allelic genetic locus comprising: a) amplifying genomic DNA with a primer pair

that spans a non-coding region sequence, said primer pair defining a DNA sequence which is in genetic linkage with said genetic locus and contains a sufficient number of non-coding region sequence nucleotides to produce an amplified DNA sequence characteristic of said allele; and b) analyzing the amplified DNA sequence to detect the allele.

26. A DNA analysis method for determining coding region alleles of a multi-allelic genetic locus comprising identifying sequence polymorphisms characteristic of the alleles, wherein said sequence polymorphisms characteristic of the alleles are present in a non-coding region sequence, said non-coding region sequence being not more than about two kilobases in length.

17. Certain claims of the '179 Patent, including Claim 26, were recently subjected to an ex parte reexamination before the United States Patent and Trademark Office ("USPTO") that was initiated by an unknown entity. On February 4, 2010, the USPTO issued a Notice of Intent to Issue Ex Parte Reexamination Certificate indicating that the subject claims were confirmed as valid without amendment.

IV. ENFORCEMENT AND LICENSING OF THE '179 PATENT BY GTG

18. The '179 Patent is presumed valid and enforceable pursuant to 35 U.S.C. §282.

19. The '179 Patent was previously asserted by GTG in the matter of *Genetic Technologies Ltd. v. Applera Corp.*, Case No. C 03-1316-PJH, in the United States District for the Northern District of California (the "Applera Action"). A true and correct copy of an order from the Applera Action construing certain '179 Patent claim terms is attached hereto as Exhibit D. The Applera Action was ultimately settled with Applera Corporation taking a license to the '179 Patent, among others.

20. The '179 Patent was the subject of a declaratory judgment action initiated by Monsanto in the matter of *Monsanto Company v. Genetic Technologies Ltd.*, Case No. 06-cv-00989-HEA, in the United States District Court for the Eastern District of Missouri, Eastern Division (the "Monsanto Action"). The Monsanto Action was ultimately settled with Monsanto

taking two licenses to the '179 among other Patents, one for plant applications and the other for pig applications.

21. In addition to Monsanto and Applera Corporation, the '179 Patent and related patents have been licensed to at least the following entities: AgResearch Ltd.; ARUP Laboratories, Inc.; Australian Genome Research Facility Ltd.; Bio Reference Laboratories (subsidiary GeneDx); Bionomics Ltd.; BioSearch Technologies Inc.; Pfizer Animal Health; C Y O'Connor ERADE Village Foundation (incorporating the Immunogenetics Research Foundation and the Institute of Molecular Genetics and Immunology Incorporated); Crop and Food Research Ltd.; DNA Diagnostics Ltd.; General Electric Co. and its subsidiary GE Healthcare Bio-Sciences Corp.; Genosense Diagnostics GmbH; Genzyme Corp.; Innogenetics N.V.; Kimball Genetics, Inc.; Laboratory Corporation of America Holdings, Inc.; Livestock Improvement Corporation Ltd.; MetaMorphix, Inc.; Millennium Pharmaceuticals Inc.; Myriad Genetics, Inc.; Nanogen, Inc.; New Zealand Blood Service; Optigen, L.L.C.; Ovita Ltd.; Perlegen Sciences, Inc.; Prometheus Laboratories Inc.; Qiagen, Inc.; Quest Diagnostics Inc.; Sciona, Inc.; Sequenom, Inc.; Syngenta Crop Protection AG; Thermo Fisher Scientific Inc.; TIB MOLBIOL Syntheselabor GmbH; and Tm Bioscience Corporation.

22. At least as early as 2006, GTG contacted other members of the SHL network of diagnostic laboratories, including Bioscientia GmbH, The Doctors Laboratory Limited and Sunrise regarding licensing opportunities with respect to intellectual property owned by GTG, including the '179 Patent. Sunrise is a member laboratory of the federation of laboratories directed and controlled by SHUSA. Although discussions ensued, no license agreements resulted from the discussions. However, on information and belief, knowledge of the '179 Patent was provided to Defendant Laboratories as a result of these discussions.

23. The '179 Patent is currently the subject matter of a patent infringement action initiated by GTG in the matter of *Genetic Technologies Limited v. Beckman Coulter, Inc. et al.*, in the United States District Court for the Western District of Wisconsin, Civil Action No. 10-0069-BBC ("the Wisconsin Action"). One of the originally named Defendants in the Wisconsin Action is Sunrise. Sunrise is one of the member laboratories, along with Defendant Laboratories, who comprise the federation of laboratories directed and controlled by SHUSA. Sunrise conducts the same type of testing as conducted by Defendant Laboratories. Sunrise was dismissed from the Wisconsin Action for lack of jurisdiction. However, following dismissal GTG and Sunrise continued to discuss the underlying substantive dispute, which has now been settled. On information and belief, Defendant Laboratories and SHUSA are aware of the situation between GTG and Sunrise.

24. In addition to the entities identified in paragraph 21, *supra*, at least the following entities have been licensed under the '179 Patent since the initiation of the Wisconsin Action: Beckman Coulter, Inc.; Gen-Probe, Inc.; Interleukin Genetics Incorporated; Molecular Pathology Laboratory Network, Inc.; Monsanto Company; Pioneer Hi-Bred International, Inc.; Qiagen Sciences, LLC; Clinical Data, Inc.; TIB MOLBIOL Syntheselabor GmbH; Laboratoires Réunis; and Eragen Biosciences, Inc.

V. DEFENDANTS' INFRINGEMENT

25. Upon information and belief, and as further described below, Defendant Laboratories manufacture, make, have made, use, practice, import, provide, supply, distribute, sell, and/or offer for sale products and/or services that infringe one or more claims of the '179 Patent; and/or Defendant SHUSA, by virtue of its direction and control over the other Defendant

Laboratories, induces and/or contributes to the infringement of one or more of the claims of the '179 Patent by others.

26. Defendant AEL offers and provides one or more genetic testing services that utilize the methods set forth in one or more claims of the '179 Patent. By way of example only, AEL performs testing services using non-coding information for Cystic Fibrosis, Fragile-X, Prothrombin, PAI-1, lactose intolerance, HLA tissue typing (at least Class 1), drug test Warfarin VKORC1, and UGT1A1. AEL's activities are an infringement of at least Claim 1 of the '179 Patent.

27. Upon information and belief, Defendant CPL offers and provides one or more genetic testing services that utilize the methods set forth in one or more claims of the '179 Patent. By way of example only, CPL performs testing services using non-coding information for Cystic Fibrosis, Fragile-X, Myotonic Dystrophy, Prothrombin, PAI-1, lactose intolerance, HLA tissue typing (at least Class 1), and Drug Test Warfaring VKORC1. CPL's activities are an infringement of at least Claim 1 of the '179 Patent.

28. Upon information and belief, Defendant CPLS offers and provides one or more genetic testing services that utilize the methods set forth in one or more claims of the '179 Patent. By way of example only, CPLS performs testing services using non-coding information for Cystic Fibrosis, Fragile-X, Prothrombin and HLA tissue typing (at least Class 1). CPLS's activities are an infringement of at least Claim 1 of the '179 Patent.

29. Upon information and belief, Defendant ESCL offers and provides one or more genetic testing services that utilize the methods set forth in one or more claims of the '179 Patent. By way of example only, ESCL performs testing services using non-coding information for Prothrombin. ESCL's activities are an infringement of at least Claim 1 of the '179 Patent.

30. Upon information and belief, Defendant FML offers and provides one or more genetic testing services that utilize the methods set forth in one or more claims of the '179 Patent. By way of example only, FML performs testing services using non-coding information for Cystic Fibrosis, Fragile-X, Myotonic Dystrophy, Prothrombin, PAI-1; and HLA tissue typing (at least Class 1). FML's activities are an infringement of at least Claim 1 of the '179 Patent.

31. Upon information and belief, Defendant PL offers and provides one or more genetic testing services that utilize the methods set forth in one or more claims of the '179 Patent. By way of example only, PL performs testing services using non-coding information for Cystic Fibrosis, Fragile-X, Myotonic Dystrophy, Prothrombin, PAI-1, lactose intolerance, HLA tissue typing (at least Class 1), and drug test Warfarin VKORC1. PL's activities are an infringement of at least Claim 1 of the '179 Patent.

VI. FIRST CLAIM FOR RELIEF
(Patent Infringement)

**(Defendants American Esoteric Laboratories; Clinical Pathology Laboratories, Inc.;
Clinical Pathology Laboratories Southeast; East Side Clinical Laboratory;
Fairfax Medical Laboratories, Inc., d/b/a Clinical Pathology Laboratories Mid-Atlantic;
Pathology Laboratories, Inc.)**

32. GTG incorporates herein by reference each and every allegation in paragraphs 1 through 31 as though fully set forth herein.

33. Defendant Laboratories manufacture, make, have made, use, practice, import, provide, supply, distribute, sell, and/or offer for sale products and/or services that infringe one or more claims of the '179 Patent in violation of 35 U.S.C. § 271(a) and/or are inducing direct infringement of the '179 Patent by others by actively instructing, assisting and/or encouraging others to practice one or more of the inventions claimed in the '179 Patent in violation of 35 U.S.C. § 271(b) and/or are contributing to direct infringement of the '179 Patent by others by offering to sell, selling or providing one or more items which constitute a material part of an

invention defined by claims of the '179 Patent, knowing the same to especially made or adapted for use in an infringement of the '179 Patent, which components are not staple articles or commodities of commerce suitable for substantial non-infringing use in violation of 35 U.S.C. § 271(c).

34. One or more of these Defendant Laboratories' actions in infringing the '179 Patent have been, and are, willful, deliberate and/or in conscious disregard of GTG's rights, making this an exceptional case within the meaning of 35 U.S.C. § 285 and entitling GTG to the award of its attorneys' fees.

35. GTG has been damaged as a result of Defendant Laboratories' infringing conduct. Defendant Laboratories are 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. SECOND CLAIM FOR RELIEF
(Inducing Patent Infringement - Defendant Sonic Healthcare USA, Inc.)

36. GTG incorporates herein by reference each and every allegation in paragraphs 1 through 35 as though fully set forth herein.

37. SHUSA plans, directs and controls the other named Defendant Laboratories.

38. SHUSA has been aware of the '179 Patent and potential liability for infringement of the '179 Patent since at least 2006. Despite this knowledge, SHUSA took no steps to alter or modify the laboratory testing services provided by the Defendant Laboratories with respect to infringement of the '179 Patent. SHUSA knowingly allowed and directed the Defendant Laboratories to continue their laboratory testing services within the United States, including providing testing services which directly infringe the '179 Patent. SHUSA is inducing direct infringement of the '179 Patent by the Defendant Laboratories by instructing, assisting and/or

encouraging the Defendant Laboratories to practice or more of the inventions in the '179 Patent in violation of the 35 U.S.C. § 271(b) and/or contributing to direct infringement of the '179 Patent by the Defendant Laboratories by offering to sell, selling or providing one or more items which constitute a material part of the invention defined by the claims of the '179 Patent, knowing the same to be especially made or adapted for use in an infringement of the '179 Patent, which components are not staples, articles or commodities of commerce suitable for substantial non-infringing use in violation of 35 U.S.C. § 271(c).

39. SHUSA's actions in infringing the '179 Patent have been and are willful, deliberate and/or in conscious disregard of GTG's rights, making this an exceptional case within the meaning of 35 U.S.C. § 285 and entitling GTG to an award of attorney's fees.

40. GTG has been damaged as a result of SHUSA's infringing conduct. SHUSA is 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 cost as fixed by this Court under 35 U.S.C. § 284.

VIII. JURY DEMAND

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

IX. PRAYER FOR RELIEF

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

A. Judgment that one or more claims of the '179 Patent has been infringed, either literally, and/or under the doctrine of equivalents, by one or more Defendant Laboratories and/or

by others to whose infringement Defendant Laboratories have contributed and/or by others whose infringement has been induced by Defendant Laboratories;

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

C. That such damages be trebled where allowed by law for a Defendant Laboratory's willful infringement;

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

E. That this Court declare this an exceptional case and award GTG its reasonable attorney's fees and costs in accordance with 35 U.S.C. § 285; and

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

SHIELDS, BRITTON & FRASER
A Professional Corporation

Dated: January 18, 2011

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