IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

Genetic Technologies Limited, an Australian corporation, Plaintiff, v. Reproductive Genetics Institute, Inc., an Illinois corporation, Defendants.	Civil No. 1:12-cv-06857 **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff Genetic Technologies Limited ("GTG") for its Complaint against Defendant Reproductive Genetics Institute, Inc. ("RGI") alleges as follows:

THE PARTIES

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

2. Upon information and belief, RGI is a corporation organized and existing under the laws of the state of Illinois, with its principal place of business located at 2825 North Halsted Street, Chicago, Illinois 60657. RGI can be served with process through its registered agent, Oleg Verlinsky, at 2825 North Halsted Street, Chicago, Illinois 60657.

JURISDICTION AND VENUE

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

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

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

6. Upon information and belief, RGI has minimum contacts with this judicial district such that this forum is a fair and reasonable one. RGI has also transacted and/or, at the time of the filing of this Complaint, is transacting business within the Northern District of Illinois. Further, upon information and belief, RGI has committed acts of patent infringement complained of herein within the Northern District of Illinois. For these reasons, personal jurisdiction exists over RGI 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).

THE PATENT-IN-SUIT

7. 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 as Exhibit A.

8. GTG is the owner of the '179 Patent by assignment from Genetype AG, who was originally assigned the technology by the inventor Dr. Malcolm Simons, with the exclusive right to enforce and collect damages for infringement of the '179 Patent during all relevant time periods.

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

10. 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.

11. 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.

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

13. 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"). The Applera Action was ultimately settled with Applera Corporation taking a license to the '179 Patent, among others.

14. 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"). That Monsanto Action was ultimately settled. Monsanto has now taken three licenses to the '179 Patent, among others.

15. The '179 Patent was asserted by GTG in the matter of *Genetic Technologies Ltd. v. Beckman Coulter, Inc., et al*, Case No. 10-cv-0069-BBC, in the United States District Court for the Western District of Wisconsin (the "Beckman Coulter Action"). The Beckman Coulter Action was resolved with at least Beckman Coulter, Inc., Gen-Probe, Inc., Interleukin Genetics Incorporated, Molecular Pathology Laboratory Network, Inc., Orchid Cellmark, Inc., Pioneer Hi-Bred International, Inc., and Sunrise Medical Laboratories, Inc. all taking a license to the '179 Patent, among others.

16. The '179 Patent was recently asserted by GTG in the matter of *Genetic Technologies Limited v. Agilent Technologies, Inc., et al*, Case No. 11-cv-01389-WJM-KLM in the United States District Court for the District of Colorado ("the Colorado Action"). In the Colorado Action at least Eurofins STA Laboratories, Inc. and GeneSeek, Inc. have taken a license to the '179 Patent, among others.

17. GTG has secured over $15 million in licensing revenue since the filing of the Beckman Coulter Action in 2010.

18. In addition to the licenses identified in the preceding paragraphs, 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.; GeneDX (a subsidiary of Bio Reference Laboratories); 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, LLC.; Quest Diagnostics Inc.; Sciona, Inc.; Sequenom, Inc.; Syngenta Crop Protection AG; Thermo Fisher Scientific Inc.; TIB MOLBIOL Syntheselabor GmbH; Tm Bioscience Corporation; Gen-Probe, Inc.; and others.

19. 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. A true and correct copy of that Reexamination Certificate is attached as Exhibit B.

20. The '179 Patent expired on March 9, 2010. However, GTG remains entitled to collect damages for past infringement occurring during the term of the '179 Patent pursuant to 35 U.S.C. §§ 284 and 286.

RGI'S INFRINGEMENT

21. RGI is based in Chicago, Illinois and maintains affiliated clinics in other countries around the world. RGI offers preimplantation genetic diagnosis services to others. More specifically, RGI claims that it "is recognized as a leading genetics institute for the prevention of genetic disease through preimplantation genetic diagnosis or PGD. [RGI] specialize[s] in PGD for genetic disease caused by a single gene defect, as well as testing for chromosome problems, such as chromosome translocations, inversions or aneuploidy, such as Down Syndrome."

22. According to RGI's marketing materials, "single gene disorders are genetic conditions caused by the alteration or the mutation of a specific gene and the affected person's DNA. Single gene disorders are inheritable and often run in families. Individuals with a family history of a single gene disorder may be at risk for passing the condition on to their children. Examples of single gene disorders include cystic fibrosis [("CF")], sickle cell anemia, Tay-Sachs disease, myotonic dystrophy, Duchenne and Becker muscular dystrophies, Fragile X syndrome and spinal muscular atrophy, to name a few." All of the foregoing single gene disorders have been linked to non-coding polymorphisms.

23. RGI's marketing materials describe the laboratory process it has utilized for analysis of genetic markers to include PCR amplification. Specifically, RGI describes that the "cells that are biopsied (polar bodies and/or blastomeres) are analyzed using a technique called polymerase chain reaction or PCR. PCR allows laboratories to use a small amount of DNA to obtain rapid and accurate results."

24. Upon information and belief, RGI has analyzed many non-coding DNA polymorphisms linked to coding region alleles using amplified DNA with a primer pair spanning a non-coding DNA region in the provision of its PGD services and during the term of the '179 Patent.

25. By way of example only, one of the single gene defects for which RGI provides screening services is CF. By 2011, over 1700 mutations in the Cystic Fibrosis Transmembrane Conductance Regulator gene ("CFTR") had been identified. The CFTR gene has over one thousand polymorphisms in both the coding and the non-coding regions of the gene and is therefore, multi-allelic. The American College of Medical Genetics ("ACMG"), American College of Obstetricians and Gynecologists ("ACOG"), and the National Human Genome Research Institute joint committee compiled a standard screening panel of 25 mutations, which represents the standard panel that is recommended for screening CF in the United States. This panel includes a number of non-coding markers. Upon information and belief, RGI utilizes the standard panel for its CF screening services. Both ACOG and ACMG recommend that all positive results for the coding R117H mutation require reflex testing for the non-coding polythymidine (T) variant 5T/7T/9T at intron 8 in the CFTR gene. As the 5T/7T/9T polymorphism is in the intron 8 in the CFTR gene, to amplify a sequence containing these mutations RGI must necessarily use at least a primer pair that spans the part of the non-coding region in which the mutations occur. The CFTR gene and surrounding sequences are in genetic linkage. The poly T variation occurs in the intron 8 of the CFTR gene, thus is in an intrinsic part of the gene and therefore linked to the coding region allele. The phenotypes associated with R117H mutations are modulated by the 5T/7T/9T polypyrimidine tract in intron 8, thus the non-coding variation is characteristic of the coding region allele and the trait. RGI's analysis of the amplified DNA sequence nucleotide to determine the presence of one of more genetic variations allows RGI to provide its CF screening services. Thus, RGI's analysis of the poly T variation at

intron 8 of the CFTR gene during the term of the '179 Patent directly infringed upon claims of the '179 Patent.

26. Upon information and belief, RGI had actual knowledge of the '179 Patent during times relevant to this action through at least its awareness of GTG, the knowledge of its employees, and/or its research, development and/or patent application activities.

CLAIM FOR RELIEF
(Patent Infringement – U.S. Patent No. 5,612,179)

27. GTG incorporates by reference each and every allegation in paragraphs 1 through 26 as though fully set forth herein.

28. Described herein, RGI has manufactured, made, had made, used, practiced, imported, provided, supplied, distributed, sold, and/or offered for sale services that infringed one or more claims of the '179 Patent in violation of 35 U.S.C. § 271(a).

29. GTG has been damaged as a result of RGI's infringing conduct. RGI 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.

JURY DEMAND

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

PRAYER FOR RELIEF

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

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

B. Judgment that RGI account for and pay to GTG all damages to and costs incurred by GTG because of RGI's 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 Defendant's infringing activities and other conduct complained of herein; and

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

Respectfully submitted,

/s/ Vasilios D. Dossas

Vasilios D. Dossas (dossas@nshn.com)
NIRO, HALLER & NIRO
181 West Madison Street, Suite 4600
Chicago, Illinois 60602
Telephone: (312) 236-0733
Fax: (312) 236-3137
Attorneys for Genetic Technologies Limited

Of Counsel:
Robert R. Brunelli
(rbrunelli@sheridanross.com)
Todd P. Blakely
(tblakely@sheridanross.com)
Benjamin B. Lieb (blieb@sheridanross.com)
SHERIDAN ROSS PC
1560 Broadway, Suite 1200
Denver, CO 80202
Telephone: (303) 863-9700
Fax: (303) 863-0223
Attorneys for Genetic Technologies Limited