IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENETIC TECHNOLOGIES LIMITED, a Australian corporation,	)	
Plaintiff,	)	Civil Action No. _____
v.	)	
HISTOGENETICS LLC, a Delaware limited liability company,	)	
Defendant.	)	

COMPLAINT WITH JURY DEMAND

Plaintiff Genetic Technologies Limited ("GTG") for its Complaint against Defendant HistoGenetics LLC ("HistoGenetics"), alleges 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, HistoGenetics is a limited liability company organized and existing under the laws of the State of Delaware, with a place of business located at 300 Executive Blvd., Ossining, NY 10562. HistoGenetics can be served with process through its registered agent, National Registered Agents, Inc., 160 Greentree Drive, Suite 101, Dover, Delaware 19904.

II. 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, HistoGenetics has minimum contacts with this judicial district such that this forum is a fair and reasonable one. HistoGenetics has also transacted and/or, at the time of the filing of this Complaint, is transacting business within the District of Delaware. Further, upon information and belief, HistoGenetics has committed acts of patent infringement complained of herein within the District of Delaware, including the offering for sale infringing DNA testing services. For these reasons, personal jurisdiction exists over HistoGenetics 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

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 and Remote 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 ("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 ("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 ("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 ("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 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. On May 10, 2012, a second ex parte reexamination of certain claims of the '179 Patent was requested by Merial Ltd. That ex parte reexamination request was granted on June 28, 2012. On September 26, 2012, the USPTO issued an Office Action indicating that Claims 2, 4-6, 10-12, 17, and 18 are confirmed as valid without amendment. A true and correct copy of the Office Action is attached as Exhibit C. Claims 1, 3, 7-9, 13-16, and 26-32 remain pending in the reexamination.

21. 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. Specifically, for infringement occurring in the period commencing six years from the filing date of this Complaint through March 9, 2010.

IV. HISTOGENETICS' INFRINGEMENT

22. HistoGenetics claims to provide tissue-typing services and specialize in human leukocyte antigen ("HLA") typing services by sequenced-based typing ("SBT") for blood stem cell transplants. HistoGenetics states that it has performed millions of HLA SBT. HistoGenetics provides HLA SBT for donor registries, pharmacogenomics, donor centers, cord blood typing, transplant centers, and HLA laboratories.

23. Functional HLA genes encode protein molecules that function in antigen within the immune system. Polymorphisms in the HLA gene are a major barrier against transplanting human organs and stem cells because HLA incompatibility between the donor and recipient can lead to graft rejection or graft versus host disease.

24. By way of example only, HLA typing is one of the tissue-typing services related to the '179 Patent that HistoGenetics provided during the relevant time period. HistoGenetics performs many types of HLA typing by SBT, including HLA-A, -B, -C, -DRB1, -DRB3, -DRB4, -DRB5, -DQA1, -DQB1, -DPA1, and -DPB1 high resolution/allele typing. The HLA genes located within the human major histocompatibility complex on chromosome 6 are some of the most polymorphic functional genetic loci known at this time. The number of alleles for the HLA loci now total more than 8,000 with over 6,000 alleles for Class I loci (HLA-A, -B, and -C loci) and over 1,000 alleles for Class II loci (HLA-DR, -DQ, and -DP loci).

25. HistoGenetics' marketing materials state that it uses two amplification-based methods to perform its HLA typing services: (1) polymerase chain reaction ("PCR") amplification followed by nucleic acid sequencing (i.e., SBT) for high resolution typing (HistoGenetics' Gold Standard) and registry level resolution typing (HistoGenetics' Silver Standard), and (2) PCR-sequence specific oligonucleotide ("SSO") probe hybridization for low resolution typing. Accordingly, HistoGenetics uses genomic DNA and PCR amplification using

a primer pair because both of these methods generate a product containing internally located polymorphisms that can be identified by either sequencing or SSO. The DNA sequence being amplified includes a non-coding region of the gene, thus it is an intrinsic part of the gene, and therefore is automatically linked to the coding region allele. The specific HLA primer pairs define the HLA gene as well as the group specific coding region alleles that will be amplified. Additionally, many primers are located in intron positions and each particular polymorphic nucleotide in the primer is linked to a specific group of coding alleles thereby yielding characteristic allele group specific amplification products. HistoGenetics' analysis of the amplified DNA sequence nucleotide to determine the presence of one of more genetic variations allows HistoGenetics to provide its HLA typing services. Thus, HistoGenetics' analysis and genotyping of the HLA gene during the term of the '179 Patent directly infringed one or more claims of the '179 Patent.

26. Upon information and belief, HistoGenetics 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 during the term of the '179 Patent in the provision of its HLA typing services. The provision of these testing services in this manner utilizes the invention as claimed in the '179 Patent and, thus, infringes upon one or more claims of the '179 Patent.

27. Upon information and belief, HistoGenetics 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.

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

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

29. As described herein, HistoGenetics 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).

30. GTG has been damaged as a result of HistoGenetics' infringing conduct. HistoGenetics 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. JURY DEMAND

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

VII. PRAYER FOR RELIEF

GTG requests that the Court find in its favor and against HistoGenetics, 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 HistoGenetics;

B. Judgment that HistoGenetics account for and pay to GTG all damages to and costs incurred by GTG because of HistoGenetics' 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 HistoGenetics' 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.

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

- and -

Robert R. Brunelli, Esquire
rbrunelli@sheridanross.com
Benjamin B. Lieb, Esquire
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

Attorneys for Plaintiff Genetic Technologies Limited