

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF WISCONSIN**

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**GENETIC TECHNOLOGIES LIMITED,**

Plaintiff,

Civil Action No. 10 CV 0069

vs.

**BECKMAN COULTER, INC., a Delaware corporation,  
GEN-PROBE, INC., a Delaware corporation,  
INTERLEUKIN GENETICS INCORPORATED,  
a Delaware corporation,  
MOLECULAR PATHOLOGY LABORATORY  
NETWORK, INC., a Tennessee corporation,  
MONSANTO, INC, a Delaware corporation,  
ORCHID CELLMARK, INC., a Delaware corporation,  
PIC USA, INC., a Wisconsin corporation,  
PIONEER HI-BRED INTERNATIONAL, INC.,  
an Iowa corporation, and  
SUNRISE MEDICAL LABORATORIES,  
a New York corporation,**

Defendants.

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**GENETIC TECHNOLOGIES LIMITED’S COMPLAINT WITH JURY DEMAND**

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Plaintiff Genetic Technologies Limited (“GTG”) files this Complaint against Defendants Beckman Coulter, Inc. (“Beckman”), Gen-Probe, Inc. (“Gen-Probe”), Interleukin Genetics Incorporated (“Interleukin”), Molecular Pathology Laboratory Network, Inc. (“MPLN”), Monsanto, Inc. (“Monsanto”), Orchid Cellmark, Inc. (“Orchid”), PIC USA, Inc. (“PIC”), Pioneer Hi-Bred International, Inc. (“Pioneer”), and Sunrise Medical Laboratories, Inc. (“Sunrise”) (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, Beckman is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business located at 4300 North Harbor Boulevard, Fullerton, California 92835. Beckman can be served with process through its registered agent Corporation Service Company, 2730 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

3. Upon information and belief, Gen-Probe is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business located at 10210 Genetic Center Drive, San Diego, California 92121. Gen-Probe can be served with process through its registered agent C T Corporation System, 818 West Seventh Street, Los Angeles, California 90017.

4. Upon information and belief, Interleukin is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business located at 135 Beaver Street, Waltham, Massachusetts 02452. Interleukin can be served with process through its registered agent National Registered Agents, Inc., 303 Congress Street, 2nd Floor, Boston, Massachusetts 02110.

5. Upon information and belief, MPLN is a corporation organized and existing under the laws of the state of Tennessee, with its principal place of business located at 250 East Broadway, Maryville, Tennessee 37804. MPLN can be served with process at its principal place of business.

6. Upon information and belief, Monsanto is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business located at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167. Monsanto can be served with process through its registered agent CSC-Lawyers Incorporating Service Company, 221 Bolivar Street, Jefferson City, Missouri 65101.

7. Upon information and belief, Orchid is a corporation organized and existing under the laws of the state of Delaware, with its principal place of business located at 4390 U.S. Route One, Princeton, New Jersey 08540. Orchid can be served with process through its registered agent CSC-Lawyers Incorporating Service, 50 West Broad Street, Suite 1800, Columbus, Ohio 43215.

8. Upon information and belief, PIC is a corporation organized and existing under the laws of the state of Wisconsin, with its principal place of business located at 100 Bluegrass Common Boulevard, Suite 2200, Hendersonville, Tennessee 37075. PIC can be served with process through its registered agent National Registered Agents, Inc., 901 South Whitney Way, Madison, Wisconsin 53711.

9. Upon information and belief, Pioneer is a corporation organized and existing under the laws of the state of Iowa, with its principal place of business located at 7100 NW 62nd Avenue, Johnston, Iowa 50131. Pioneer can be served with process through its registered agent The Corporation Trust Company Corporation, Trust Center 1209 Orange Street, Wilmington, Delaware 19801.

10. Upon information and belief, Sunrise is a corporation organized and existing under the laws of the state of New York, with its principal place of business located at 240

Motor Parkway, Hauppauge, New York 11788. Sunrise can be served with process at its principal place of business.

## **II. JURISDICTION AND VENUE**

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

12. Upon information and belief, Defendants each have minimum contacts with the Western District of Wisconsin such that this forum is a fair and reasonable one. Defendants have each committed such purposeful acts and/or transactions in Wisconsin that they reasonably knew and/or expected that they could be haled into court as a future consequence of such activity. Upon information and belief, Defendants have transacted and/or, at the time of the filing of this Complaint, are transacting business within the Western District of Wisconsin. 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**

13. 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 A.

14. 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.

15. The ‘179 Patent generally relates to methods of analysis of non-coding DNA sequences.

16. 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.

17. 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.

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 B. 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. 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. DEFENDANTS’ INFRINGEMENT**

23. Upon information and belief, and as further described below, Defendants 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 Defendants induce and/or contribute to the infringement of one or more of the claims of the ‘179 Patent by others.

24. Defendant Beckman offers and provides one or more genotyping and genomic services that utilize the methods set forth in one or more claims of the ‘179 Patent. By way of example only, Beckman performs genotyping and genomic testing on a range of commercially available platforms, including ABI sequencers, Roche 454 Genome Sequencer FLX, ABI SOLiD, Illumina Genome Analyzer and Affymetrix MegAllele platforms. These instruments require Beckman to perform the step of amplification and enable analysis of non-coding segments of DNA. Indeed, Beckman claims to have “performed in excess of 1,500 clinical genotyping studies for . . . pharmaceutical and biotechnology customers, and analyzed over 150,000 [DNA] samples. The results of these studies have been successfully reported and used in IND and NDA submissions.” Until August 2009, Beckman offered its infringing genotyping and genomic services through a wholly owned subsidiary known as Agencourt Biosciences. Beckman’s activities are an infringement of at least Claim 1 of the ‘179 Patent.

25. Defendant Orchid negotiated with GTG for, among other things, a license to the '179 Patent to cover its "Elucigene" range of kit products. However, before those negotiations were concluded, the Elucigene range of kits was sold to Tepnel PLC ("Tepnel"). GTG then contacted Tepnel, complaining that the Elucigene kits infringed the '179 Patent. Tepnel responded by arguing that the Elucigene kits were previously licensed by Orchid, even though Orchid had actually failed to execute the agreement with GTG. Defendant Gen-Probe subsequently acquired Tepnel and its Elucigene range of kits in April of 2009. Defendant Gen-Probe directly, and/or through its related company Tepnel, offers and sells, among other products, Elucigene kits in the United States. By way of example only, third parties who use Gen-Probe's Elucigene kits for the analysis of CFTR gene mutations associated with cystic fibrosis utilize the methods set forth in one or more claims of the '179 Patent.

26. Defendant Interleukin offers and provides one or more genetic risk assessment testing services that utilize the methods set forth in one or more claims of the '179 Patent. By way of example only, Interleukin offers and provides a PST Genetic Susceptibility Test, which has been marketed as "the first and only genetic test that analyzes two interleukin 1 (IL1) genes for variations that identify an individual's predisposition for over-expression of inflammation and risk for periodontal disease." The PST Genetic Susceptibility Test utilizes the methods claimed in the '179 Patent.

27. Defendant MPLN 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, MPLN provides genetic testing for cystic fibrosis tests. In providing cystic fibrosis testing, MPLN detects 33 mutations from the CFTR gene, including the 25 mutations

recommended by the American College of Medical Genetics and American College of Obstetricians and Gynecologists. Among the mutations detected, many are located in non-coding regions of DNA. At least some of these non-coding mutations are characteristic of least alleles in the coding region of DNA and determine the severity of the disease in a patient. Some mutations from the CFTR gene are associated with cystic fibrosis and some are associated with congenital bilateral absence of the vas deferens. Upon information and belief, MPLN utilizes Oligonucleotide Ligation Assay (OLA) kits to detect the 33 mutations. The use of OLA kits requires MPLN to perform methods claimed in the '179 Patent.

28. Upon information and belief, Defendant Monsanto is utilizing methods set forth in one or more claims of the '179 Patent. By way of example only, Monsanto recently was and/or remains active in cattle genetics for identifying commercially important traits in cattle such as milk-related traits and whether an animal is horned or polled. Upon information and belief, Monsanto's international patent applications WO 2005/030789 A1, WO 2008/039257, WO 2008/140467 A2, and WO 2009/045289 A2, as well as a number of scientific publications, describe how Monsanto has performed amplification and analysis of coding and non-coding of DNA to determine and characterize commercially important traits in cattle. These activities require performance of methods claimed in the '179 Patent.

29. Defendant Orchid offers and provides one or more analysis services that utilize methods set forth in one or more claims of the '179 Patent. By way of example only, according to Orchid marketing materials, "[t]he majority of [Orchid's] forensic DNA analysis is carried out using STR (Short Tandem Repeat) profiling." Upon information and belief, Orchid uses the following commercial kits for its forensic DNA analysis that include Amelogenin locus to allow gender identification: AmpFLSTR Profiler Plus; AmpFLSTR

COfiler; Powerplex 16; and AmpFLSTR identifier. Use of these kits requires Orchid to perform methods claimed in the '179 Patent.

30. Defendant PIC offers and provides a number of genetically engineered pig lines for commercial production that were developed utilizing the methods set forth in one or more claims of the '179 Patent. By way of example only, PIC reports that each of its pig lines has particular traits that were developed through a genetic selection program, including leanness, improved pH tenderness, growth rates, feed efficiency, and productivity. According to the 2008 annual report issued by PIC's parent company, Genus plc, 150 genetic markers have been adopted and are used by PIC in its genetic selection program. According to a PIC newsletter, "[a]s of January 2009, PIC is using 59 genetic markers related to ultimate pHu, 17 genetic markers related to loin color, and 15 genetic markers related to marbling" in connection with the design of its pig lines that carry these traits. PIC has also marketed its PIC280 boar product as being "produced under PIC's most intensive meat quality improvement program to date. This line begins in our genetic nucleus and is selected for long-term improvement in lean, growth rate and feed efficiency. The PIC280 is then genotyped for range of exclusive PICmarq DNA markers for improved pH." Upon information and belief, PIC's U.S. Patent Application Publication No. 2007/0003956, entitled "APPROACHES TO IDENTIFYING GENETIC TRAITS IN ANIMALS," describes how PIC performs amplification and analysis of coding and non-coding DNA in developing its pig lines and shows PIC has utilized technology claimed in the '179 Patent.

31. Defendant Pioneer offers and provides a number of plant products that were developed utilizing the methods set forth in one or more claims of the '179 Patent. By way of example only, Pioneer reports that it employs a number of genetic technologies to develop

new plant products. These technologies include the use of polymorphic DNA markers in non-coding regions of DNA which are linked to plant traits of interest expressed in coding regions of DNA. According to literature available on Pioneer's website, "polymorphism involves the existence of different forms (alleles) of the same gene in plants or population of plants. These differences are tracked as molecular markers to identify desired genes and the resulting trait. Differences between the DNA sequences of these genes can be responsible for making a plant sensitive or resistant to a particular disease. And differences in DNA sequences near the gene can be used as markers to locate the gene and track that desired results in breeding programs." Pioneer also offers soybean products that were, upon information and belief, developed using processes for amplification and analysis of coding and non-coding DNA described in Pioneer's U.S. Patent No. 7,595,432. At least one or more of these activities require performance of methods claimed in the '179 Patent.

32. Defendant Sunrise 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, Sunrise provides cystic fibrosis prenatal screening/carrier testing which detects 23 of 25 mutations recommended by the American College of Medical Genetics and American College of Obstetricians and Gynecologists, including several mutations located in the non-coding region of DNA. Upon information and belief, Sunrise has utilized the Elucigene CF kit and the Third Wave Technology CF kit, the use of which requires performance of methods claimed in the '179 Patent.

**V. FIRST CLAIM FOR RELIEF  
(Patent Infringement)**

33. GTG incorporates herein by reference each and every allegation in paragraphs 1 through 32.

34. Defendants 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 be 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).

35. One or more of these Defendants' 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.

36. GTG has been damaged as a result of Defendants' infringing conduct. Defendants 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.

## **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 Defendants, 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 Defendants and/or by others to whose infringement Defendants have contributed 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 such damages be trebled where allowed by law for a Defendant's willful infringement;

D. 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;

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.

