UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT SEATTLE

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| GENETIC TECHNOLOGIES LIMITED, an Australian Corporation<br><br>Plaintiff,<br><br>v.<br><br>GENELEX CORPORATION, a Washington Corporation,<br><br>Defendant. | Civil Action No. 12-cv-2190<br><br>COMPLAINT<br><br>JURY DEMAND |

Plaintiff Genetic Technologies Limited ("GTG") for its Complaint against Defendant Genelex Corporation ("Genelex"), 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, Genelex is a corporation organized and existing under the laws of the State of Washington, with its principal place of business located at 3101 Western Ave., Suite 100, Seattle, WA 98121. Genelex can be served with process through its registered agent, Howard Coleman, 3101 Western Ave., Suite 100, Seattle, WA 98121.



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



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> 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



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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



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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.



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## IV. GENELEX'S INFRINGEMENT

22. Genelex is based in Seattle, Washington, and claims to provide comprehensive DNA testing services, including paternity, forensics, and phramacogenetic testing, to individuals and companies worldwide. Genelex claims to provide the broadest range of identity tests available through its dual medical laboratory and paternity accreditation. Additionally, Genelex is the creator of GeneMedRx, an algorithm-driven, gene-drug interaction software, that "helps physicians optimize medication regimens by correlating the genetic makeup of the patient with all the medicines they are taking."

23. Genelex's marketing materials indicate that Genelex offers a number of commercial tests for warfarin (testing the VKORC1 gene), irinotecan (testing the UGT1A1 gene for a genetic variation called UGT1A1*28 or UDP-glucuronosyltransferase), other prescription and non-prescription drugs (testing the CYP2D6, CYP2C19, CYP1A2 genes), and paternity profiling. All of these tests interrogate non-coding polymorphisms in multi-allelic genes.

24. Genelex's marketing materials suggest that cytochrome P450 2D6 ("CYP2D6") "acts on one-fourth of all prescription drugs, including selective serotonin reuptake inhibitors (SSRI), tricylic antidepressants (TCA), betablockers" and more, because "CYP2D6 is responsible for activating the pro-drug codeine into its active form." Genelex's marketing materials state that Genelex tests for nucleotide variants in the CYP2D6 gene, including CYP2D6*2 allele (-1584C>G variant, rs1080985) and CYP2D6*41 allele (-2988G>A variant, rs28371725). Both variants are located in non-coding regions of the multi-allelic CYP2D6 gene.

25. Genelex's marketing materials also indicate that cytochrome P450 2C19 ("CYP2C19") "is associated with the metabolism of carisoprodol, diazepam, Dilantin, and Prevacid." Genelex's marketing materials state that Genelex tests for nucleotide variants in the CYP2C19 gene, including a CYP2C19*17 allele ("-806C>T variant"). The -806C>T variant is located in a non-coding region of the multi-allelic CYP2C19 gene.



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26. Genelex's marketing materials describe how cytochrome P450 1A2 ("CYP1A2") is associated with the metabolism of acetaminophen, amitriptyline, olanzapine, haloperidol, caffeine, estrogens, and more. Genelex's marketing materials state that Genelex tests for the major nucleotide variants in the CYP1A2 gene: CYP1A2*1C allele (-3860G>A variant) and CYP1A2*1F allele (-163C>A variant). Both variants are located in non-coding regions of the multi-allelic CYP1A2 gene.

27. The gene amelogenin—AMELX on the X chromosome and AMELY on the Y chromosome—is commonly used for gender identification (sex-typing) in conjunction with Short Tandem Repeat ("STR") typing kits. Both AMELX and AMELY are multi-allelic genetic loci. The AMELX carries a small deletion in the first intron, facilitating the design of amelogenin specific Polymerase Chain Reaction ("PCR") primers enabling amplicons from the X-chromosome and Y-chromosome to be distinguished from one another when separation is performed and allowing gender identification in humans. The DNA sequence being amplified is in an intron of the amelogenin gene, thus it is an intrinsic part of the gene and is linked to the coding region allele.

28. Genelex's marketing materials indicate that Genelex uses STR methods to perform DNA analysis. Upon information and belief, Genelex is using STR kits that utilizes the primer set targeting the non-coding 6 bp variation in the intron 1 of the amelogenin gene. Additionally, upon information and belief, the STR kits used by Genelex target the non-coding region to perform amplification and analysis of non-coding mutations of the amelogenin gene for gender identification.

29. Upon information and belief, during the term of the '179 Patent, Genelex 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, including at least the testing services described above in Paragraphs 22 through 28.



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30. By way of example only, one of the defects for which Genelex provides screening services is mutations in vitamin K epoxide reductase complex subunit 1 (i.e., VKORC1). Genelex's marketing materials describe how mutations in VKORC1 have been identified to be associated with warfarin (brand name Coumadin) effect and dosage. The VKORC1 gene has many coding region alleles and, therefore, is multi-allelic. According to Genelex's marketing materials, "[s]ingle nucleotide polymorphisms in the VKORC1 gene [(-1639 G>A)] have been associated with lower dose requirements for warfarin." Additionally, Genelex's marketing materials indicate that Genelex uses PCR amplification technology for its DNA testing services.

31. Upon information and belief, Genelex performs VKORC1 genotyping by amplifying genomic DNA using a primer pair. Because the polymorphism of interest (-1639 G>A) is in the non-coding region of the gene, the amplification primers used by Genelex must span a non-coding region sequence. Upon information and belief, Genelex amplifies a DNA sequence in the non-coding promoter region of the gene, which is an intrinsic part of the gene and, therefore, linked to the coding region allele. The VKORC1 non-coding promoter polymorphism is characteristic of the coding region alleles that determine a patient's trait or phenotype, *e.g.*, the likely response to warfarin. According to Genelex's marketing materials, Genelex uses this information to determine the appropriate warfarin dosage level for the patient. Overall, Genelex's marketing materials indicate that the key objective of Genelex's test is to determine the promoter polymorphism in the VKORC1 gene and make inferences about the patient's phenotype associated with drug response to warfarin.

32. Upon information and belief, Genelex 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)**



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

34. As described herein, Genelex 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).

35. GTG has been damaged as a result of Genelex's infringing conduct. Genelex 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 Genelex, 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 Genelex;

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



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Respectfully submitted,

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