

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT SEATTLE

GENETIC TECHNOLOGIES LIMITED, an
Australian Corporation

Plaintiff,

v.

GENELEX CORPORATION, a Washington
Corporation,

Defendant.

Civil Action No. 12-cv-2190

COMPLAINT

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.



1 **II. JURISDICTION AND VENUE**

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

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

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

7 6. Upon information and belief, Genelex has minimum contacts with this judicial
8 district such that this forum is a fair and reasonable one. Genelex has also transacted and/or, at
9 the time of the filing of this Complaint, is transacting business within the Western District of
10 Washington. Further, upon information and belief, Genelex has committed acts of patent
11 infringement complained of herein within the Western District of Washington. For these reasons,
12 personal jurisdiction exists over Genelex and venue over this action is proper in this Court under
13 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b).

14 **III. THE PATENT-IN-SUIT**

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

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

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

25 10. The Abstract of the '179 Patent relevantly provides:
26

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

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

15 1. A method for detection of at least one coding region allele of a multi-
16 allelic genetic locus comprising: a) amplifying genomic DNA with a
17 primer pair that spans a non-coding region sequence, said primer pair
18 defining a DNA sequence which is in genetic linkage with said genetic
19 locus and contains a sufficient number of non-coding region sequence
20 nucleotides to produce an amplified DNA sequence characteristic of said
21 allele; and b) analyzing the amplified DNA sequence to detect the allele.

22 26. A DNA analysis method for determining coding region alleles of a
23 multi-allelic genetic locus comprising identifying sequence
24 polymorphisms characteristic of the alleles, wherein said sequence
25 polymorphisms characteristic of the alleles are present in a non-coding
26 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

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

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

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

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

17 18. In addition to the licenses identified in the preceding paragraphs, the '179 Patent
18 and related patents have been licensed to at least the following entities: AgResearch Ltd.; ARUP
19 Laboratories, Inc.; Australian Genome Research Facility Ltd.; GeneDX (a subsidiary of Bio
20 Reference Laboratories); Bionomics Ltd.; BioSearch Technologies Inc.; Pfizer Animal Health; C
21 Y O'Connor ERADE Village Foundation (incorporating the Immunogenetics Research
22 Foundation and the Institute of Molecular Genetics and Immunology Incorporated); Crop and
23 Food Research Ltd.; DNA Diagnostics Ltd.; General Electric Co. and its subsidiary GE
24 Healthcare Bio-Sciences Corp.; Genosense Diagnostics GmbH; Genzyme Corp.; Innogenetics
25 N.V.; Kimball Genetics, Inc.; Laboratory Corporation of America Holdings, Inc.; Livestock
26 Improvement Corporation Ltd.; MetaMorphix, Inc.; Millennium Pharmaceuticals Inc.; Myriad



1 Genetics, Inc.; Nanogen, Inc.; New Zealand Blood Service; Optigen, L.L.C.; Ovita Ltd.;
2 Perlegen Sciences, Inc.; Prometheus Laboratories Inc.; Qiagen, LLC.; Quest Diagnostics Inc.;
3 Sciona, Inc.; Sequenom, Inc.; Syngenta Crop Protection AG; Thermo Fisher Scientific Inc.; TIB
4 MOLBIOL Syntheselabor GmbH; Tm Bioscience Corporation; Gen-Probe, Inc.; and others.

5 19. Certain claims of the '179 Patent, including Claim 26, were subjected to an ex
6 parte reexamination before the United States Patent and Trademark Office ("USPTO") that was
7 initiated by an unknown entity. On February 4, 2010, the USPTO issued a Notice of Intent to
8 Issue Ex Parte Reexamination Certificate indicating that the subject claims were confirmed as
9 valid without amendment. A true and correct copy of that Reexamination Certificate is attached
10 as Exhibit B.

11 20. On May 10, 2012, a second ex parte reexamination of certain claims of the '179
12 Patent was requested by Merial Ltd. That ex parte reexamination request was granted on June 28,
13 2012. On September 26, 2012, the USPTO issued an Office Action indicating that Claims 2, 4-6,
14 10-12, 17 and 18 are confirmed as valid without amendment. A true and correct copy of the
15 Office Action is attached as Exhibit C. Claims 1, 3, 7-9, 13-16 and 26-32 remain pending in the
16 reexamination.

17 21. The '179 Patent expired on March 9, 2010. However, GTG remains entitled to
18 collect damages for past infringement occurring during the term of the '179 Patent pursuant to 35
19 U.S.C. §§ 284 and 286. Specifically, for infringement occurring in the period commencing six
20 years from the filing date of this Complaint through March 9, 2010.

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), tricyclic 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.

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

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

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

22 29. Upon information and belief, during the term of the '179 Patent, Genelex has
23 analyzed many non-coding DNA polymorphisms linked to coding region alleles using amplified
24 DNA with a primer pair spanning a non-coding DNA region, including at least the testing
25 services described above in Paragraphs 22 through 28.
26

1 33. GTG incorporates by reference each and every allegation in paragraphs 1 through
2 32 as though fully set forth herein.

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

6 35. GTG has been damaged as a result of Genelex's infringing conduct. Genelex is
7 thus liable to GTG in an amount that adequately compensates GTG for such infringement which
8 cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court
9 under 35 U.S.C. § 284.

10 **VI. JURY DEMAND**

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

13 **VII. PRAYER FOR RELIEF**

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

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

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

21 C. That GTG be granted pre-judgment and post-judgment interest on the damages
22 caused to it by reason of Genelex 's infringing activities and other conduct complained of herein;
23 and

24 D. That GTG be granted such other and further relief as the court may deem just and
25 proper under the circumstances.
26

1 Dated: December 14, 2012

Respectfully submitted,

2
3 By: s/Richard R. Alaniz

Richard R. Alaniz, WSBA No. 26,194
alaniz@LoweGrahamJones.com

4
5 Mark L. Lorbiecki, WSBA No. 16796
Lorbiecki@LoweGrahamJones.com

6
7 LOWE GRAHAM JONES
701 Fifth Avenue, Suite 4800
8 Seattle, Washington 98104
T: 206.381.3300
9 F: 206.381.3301

10 Robert R. Brunelli (*Application Pro Hac Vice*)
rbrunelli@sheridanross.com

11 Benjamin B. Lieb (*Application Pro Hac Vice*)
blieb@sheridanross.com

12
13 SHERIDAN ROSS P.C.
14 1560 Broadway, Suite 1200
15 Denver, Colorado 80202-5141
16 Telephone: (303) 863-9700
17 Facsimile: (303) 863-0223
litigation@sheridanross.com

18 *Attorneys for Plaintiff Genetic Technologies*
19 *Limited*