

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEOGENOMICS LABORATORIES, INC.
Petitioner,

v.

NATERA, INC.
Patent Owner.

Patent No. 11,519,035

Inter Partes Review No. IPR2024-00812

PETITIONER'S UPDATED EXHIBIT LIST

Petitioner’s Updated Exhibit List for *Inter Partes* Review
of U.S. Patent No. 11,519,035

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Anthony P. Shuber et al., <i>A Simplified Procedure for Developing Multiplex PCRs</i> , 5 Genome Research 488 (1995)	1026
Sachiyo Inagaki et al., <i>A new 39-plex analysis method for SNPs including 15 blood group loci</i> , 144 Forensic Science Int'l 45 (2004)	1027
Peter M. Vallone, John M. Butler, <i>AutoDimer: a screening tool for primer-dimer and hairpin structures</i> , 37 BioTechniques 226 (2004)	1028
Fiona Kaper et al., <i>Parallel Preparation of Targeted Resequencing Libraries from 480 Genomic Regions Using Multiplex PCR on the Access Array™ System</i> , American Association for Cancer Research (2010)	1029
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Labrousse et al., <i>Evaluation of a tumor informed MRD assay with contrived breast cancer samples</i> , AACR General Meeting (2003)	1036
Natera Publication available at https://www.natera.com/wp-content/uploads/2020/11/Oncology-Clinical-Seeing-beyond-the-limit-Detect-residual-disease-and-assess-treatment-response-SGN_AV_WP.pdf	1037

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International Publication No. WO 2009/013492 (“Lo”)	1048
U.S. Patent Publication No. 2010/0227329 (“Cuppens”)	1049
RESERVED	1050
<i>Curriculum Vitae</i> of Niall J. Lennon, Ph.D.	1051
Image of Nucleotide available at genome.gov/genetics-glossary/Nucleotide	1052
Alberts, <i>DNA replication and recombination</i> , 421 Nature 23 (2003)	1053
Jackson, <i>Viruses and the Nucleus</i> , Ch. 1 (2006)	1054
Swaminathan & Butt, <i>Circulating Nucleic Acids in Plasma and Serum</i> , 1075 Ann. N.Y. Acad. Sci. 1-9 (2006)	1055
Schwarzenbach <i>et al.</i> , <i>Cell-free nucleic acids as biomarkers in cancer patients</i> , 11 Nature 426-37 (2011)	1056

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Elmore, <i>Apoptosis: A Review of Programmed Cell Death</i> , 35(4) Toxicol Pathol. 495 (2007)	1057
Bischoff <i>et al.</i> , <i>Cell-free fetal DNA in maternal blood: kinetics, source and structure</i> , 11 Human Reproduction Update 59 (2005)	1058
Kidess & Jeffrey, <i>Circulating tumor cells versus tumor-derived cell-free DNA: rivals or partners in cancer care in the era of single-cell analysis?</i> , 5 Genome Medicine 70 (2013)	1059
Dawson <i>et al.</i> , <i>Analysis of Circulating Tumor DNA to Monitor Metastatic Breast Cancer</i> , 368 N. Engl. J. Med. 13 (2013)	1060
U.S. Patent Publication No. 2010/0041048	1061
Schwarzenbach <i>et al.</i> , <i>Detection and Monitoring of Cell-Free DNA in Blood of Patients with Colorectal Cancer</i> , 1137 Ann. N.Y. Acad. Sci. 190 (2008)	1062
U.S. Patent No. 5,952,170	1063
U.S. Patent No. 6,156,504	1064
Bettegowda <i>et al.</i> , <i>Detection of Circulating Tumor DNA in Early- and Late-Stage Human Malignancies</i> , 6 Sci. Transl. Med. 224 (2014)	1065
Tong <i>et al.</i> , <i>Diagnostic developments involving cell-free (circulating) nucleic acids</i> , 363 Clinica Chimica Acta 187 (2006)	1066
Kumar <i>et al.</i> , <i>Plasma DNA level in predicting therapeutic efficacy in advanced nonsmall cell lung cancer</i> , 36 Eur. Respir. J. 885 (2010)	1067
Filice <i>et al.</i> , <i>Complex Mutations & Subpopulations of Deletions at Exon 19 of EGFR in NSCLC Revealed by Next Generation Sequencing: Potential Clinical Implications</i> (2012)	1068
Roberts <i>et al.</i> , <i>A comparative analysis of algorithms for somatic SNV detection in cancer</i> , 29 Bioinformatics 18 (2013)	1069
Mertes <i>et al.</i> , <i>Targeted enrichment of genomic DNA regions for next-generation sequencing</i> , 10 Briefings in Functional Genomics 6 (2011)	1070
Yang <i>et al.</i> , <i>Common SNPs explain a large proportion of heritability for human height</i> , 42 Nat. Genet. 7 (2010)	1071
RESERVED	1072
RESERVED	1073
U.S. Patent Application Publication No. 2004/0126760	1074

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Markoulatos <i>et al.</i> , <i>Multiplex Polymerase Chain Reaction: A Practical Approach</i> 16 J. Clin. Lab. Anal. 47 (2002)	1075
U.S. Patent Application Publication No. 2012/0270212	1076
Kaper <i>et al.</i> , <i>Abstract 1164: Parallel preparation of targeted resequencing libraries from 480 genomic regions using multiplex PCR on the Access Array System</i> , 70 Cancer Res 1164 (2010)	1077
Kaper <i>et al.</i> , <i>Parallel Preparation of Targeted Resequencing Libraries from 480 Genomic Regions Using Multiplex PCR on the Access Array™ System</i> , AACR 101 Annual Meeting (2010)	1078
May <i>et al.</i> , <i>Parallel Production of Barcoded Amplicon Libraries for 454 Sequencing using Individual and Multiplex PCR in Nanoliter Volumes</i> , AACR 101 Annual Meeting (2010)	1079
U.S. Patent Application Publication No. 2010/0285478	1080
U.S. Patent Application Publication No. 2010/0120038	1081
Varley & Mitra, <i>Nested Patch PCR enables highly multiplexed mutation discovery in candidate genes</i> , 18 Genome Research 1844 (2008)	1082
Wang <i>et al.</i> , <i>A genotyping system capable of simultaneously analyzing >1000 single nucleotide polymorphisms in a haploid genome</i> , 15 Genome Research 276 (2005)	1083
Kermekchiev <i>et al.</i> , <i>Cold-sensitive mutants of Taq DNA polymerase provide a hot start for PCR</i> , 31 Nucleic Acids Research 21 (2003)	1084
ThermoFischer SCIENTIFIC, <i>The History of PCR</i>	1085
ThermoFischer SCIENTIFIC, <i>How is Hot-Start Technology Beneficial For Your PCR?</i>	1086
Schochetman <i>et al.</i> , <i>Polymerase Chain Reaction</i> , 158 The Journal of Infectious Diseases 6 (1988)	1087
Definition of Polymerase Chain Reaction (PCR) available at genome.gov/genetics-glossary/Polymerase-Chain-Reaction	1088
U.S. Patent No. 4,683,195	1089
Hutchison, <i>DNA sequencing: bench to bedside and beyond</i> , 35 Nucleic Acids Research 18 (2007)	1090

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Mardis, <i>Next-Generation DNA Sequencing Methods</i> , 9 Ann. Rev. Genomics Hum. Genet. 387 (2008)	1091
Meyerson <i>et al.</i> , <i>Advances in understanding cancer genomes through second-generation sequencing</i> , 11 Nature Genetics 685 (2010)	1092
Shendure & Ji, <i>Next-generation NDA sequencing</i> , 26 Nature Biotechnology 10 (2008)	1093
Stratton <i>et al.</i> , <i>The cancer genome</i> , 458 Nature 719 (2009)	1094
<i>DNA Sequencing Costs: Data</i> , available at https://www.genome.gov/about-genomics/fact-sheets/DNA-Sequencing-Costs-Data	1095
Table of Sequencing Costs	1096
Narayan <i>et al.</i> , <i>Ultrasensitive Measurement of Hotspot Mutations in Tumor DNA in Blood Using Error-Suppressed Multiplexed Deep Sequencing</i> , 72 Cancer Res. 3492 (2012)	1097
Chiu <i>et al.</i> , <i>Noninvasive prenatal diagnosis of fetal chromosomal aneuploidy by massively parallel genomic sequencing of DNA in maternal plasma</i> , 105 PNAAS 20458 (2008)	1098
Korshunova <i>et al.</i> , <i>Massively parallel bisulphite pyrosequencing reveals the molecular complexity of breast cancer-associated cytosine-methylation patterns obtained from tissue and serum DNA</i> , 18 Genome Research 19 (2008)	1099
June 29, 2018 Declaration of Michael L. Metzker in IPR2018-01317	1100
U.S. Patent Application Publication No. 2020/0347454	1101
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October 18, 2023 Redacted Declaration of Brian Van Ness in 23-cv-00629-CCE-JLW (M.D.N.C.)	1103
Su <i>et al.</i> , <i>A Platform for Rapid Detection of Multiple Oncogenic Mutations With Relevance to Targeted Therapy in Non-Small-Cell Lung Cancer</i> , 13 J. Molecular Diagnostics 74 (2011)	1104
Excerpted File History of U.S. Provisional Application No. 62/066,514	1105
Excerpted File History of U.S. Provisional Application No. 62/148,173	1106
U.S. Patent No. 10,179,937	1107
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RESERVED	1109
U.S. Patent Application Publication No. 2011/0288780	1110
U.S. Patent Application Publication No. 2020/0347454	1111
RESERVED	1112
Craig <i>et al.</i> , <i>Identification of genetic variants using bar-coded multiplexed sequencing</i> , 5 Nature Methods 887 (2008)	1113
Guardant Health, Inc., Excerpted Form 10-K	1114
Igetei <i>et al.</i> , <i>Detection of p53 codon 249 mutation in Nigerian patients with hepatocellular carcinoma using a novel evaluation of cell-free DNA</i> , 7 Ann. Hepatology 339 (2008)	1115
Excerpt from Lela Buckingham & Maribeth L. Flaws, <i>Molecular Diagnostics Fundamentals Methods and Clinical Applications</i> (2007)	1116
U.S. Patent Application Publication No. 2017/0051355	1117
Copy of Tim Forshew <i>et al.</i> , <i>Non-invasive Identification and Monitoring of Cancer Mutations by Targeted Deep Sequencing of Plasma DNA</i> , 4(135) Translational Med. 1-12 (2012) (with Supplemental Materials, S1-S19) Cited in Ex.1038	1118
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