IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENEDX, INC.
Petitioner
v.
MYRIAD GENETICS, INC.
Patent Owner

U.S. Patent No. 6,051,379 to Lescallett *et al*.
Issue Date: April 18, 2000
Title: Cancer Susceptibility Mutations of BRCA2

Inter Partes Review No. Unassigned

Petition for *Inter Partes* Review of U.S. Patent No. 6,051,379 Under 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-.80, 42.100-.123

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I. INTRODUCTION

GENEDX, INC. petitions for *Inter Partes* Review, seeking cancellation of claims 7, 8, 13, 14, 16, 17, 19, 20, 32, and 33 of U.S. Patent No 6,051,379 to Lescallett ("the '379 patent") (GDX1001). According to the USPTO assignment database, the '379 patent is owned by MYRIAD GENETICS, INC.

II. OVERVIEW

The challenged claims of the '379 patent recite oligonucleotides and methods that are unpatentable over the art identified herein because they are the result of ordinary skill and common sense, and not innovation. Claims 7, 13, and 16 are directed to isolated oligonucleotides that are capable of detecting particular mutations at nucleotide numbers 5193, 6495, and 6909, respectively, of a *BRCA2* gene. Claims 19-20 are directed to oligonucleotides with a label bound thereto, including the oligonucleotides of claims 7, 13, and 16. Claims 8, 14, and 17 are directed to isolated oligonucleotides having the sequences of SEQ ID NOs:11, 19, and 23, respectively, or complementary oligonucleotides thereto. And claims 32-33 are directed to methods of detecting a predisposition or higher susceptibility to cancer in an individual, wherein the presence of a sequence variation at nucleotide number 2192, 3772, 5193, 5374, 6495, or 6909 indicates a predisposition or higher susceptibility to cancer.

BRCA2 sequences encompassing nucleotide numbers 5193, 6495, and 6909

were known in the prior art. GDX1026, 1:1[1]; GDX1027, 1, 4; GDX1023, 3:FIG. 2, 4:1; GDX1002, ¶¶54, 65, 69, 73, 119. *BRCA2* mutations had been identified from individuals in breast-cancer prone families (*i.e.*, individuals with inherited mutations) and individuals with pancreatic cancer. GDX1022, 2:3, 2090:1; GDX1024, 1:Abstract; GDX1023, 1; GDX1026, 2:1; GDX1002, ¶41. Before the earliest alleged priority date of September 23, 1997, persons of ordinary skill in the art ("POSAs") would have expected that additional *BRCA2* mutations remained to be identified in association with cancer. GDX1026, 1:1-4:1; GDX1023, 2-4; GDX1002, ¶41, 57-58, 121. Thus, a POSA would have had a strong motivation to continue screening *BRCA2* sequences from individuals of breast cancer-prone families and in individuals with suspected BRCA2-associated cancers in order to identify additional cancer-associated mutations, such as those recited in claims 7, 13, 16, and 32 of the '379 patent. GDX1026, 1:2-4:1; GDX1023, 4:1; GDX1029, 7:24-6:1, 11:23-12:2, 19:6-25; GDX1002, ¶¶58, 121. And, based on routine screening, a POSA would have had a reasonable expectation of success in identifying the mutations. GDX1026, 1:2-2:1, 336:1, 337:2; GDX1023, 2;

[1] Citations to GDX1001 use the format x:y:z, where x is the exhibit page number, y is the column number, and z is the line number(s). For GDX1029, x is the exhibit page number and y is the line number(s). For citations to all other non-patent publications, x is the exhibit page number and y is the column number.

GDX1029, 20:7-24:12; GDX1002, ¶¶42, 59-60, 122-123. After identifying the mutations, a POSA would have had a reason to combine teachings regarding known *BRCA2* sequences with teachings regarding the well-known and routine allele-specific hybridization assay to produce oligonucleotides, including labeled oligonucleotides, capable of detecting the mutations (claims 7, 13, 16, 19, and 20) and oligonucleotides capable of detecting wild-type (i.e., normal) sequences (such as the SEQ ID NOs or their complementary sequences of claims 8, 14, and 17). GDX1026, 1:1; GDX1023, 1-3; GDX1029, 20:25-28, 22:6-8; GDX1002, ¶¶39, 61, 68, 72, 85, 93, 99, 124, 130, 133. And based on well-known methods for designing oligonucleotides for allele-specific hybridization assays, a POSA would have had a reasonable expectation of success in producing the claimed oligonucleotides. GDX1018, 1-5; GDX1021[2], 1-8; GDX1002, ¶¶64, 68, 72, 88, 95-96, 101-102, 127, 130, 133, 148, 155, 163. A POSA also would have had a reason to combine teachings regarding known *BRCA2* sequences with teachings regarding methods for determining an individual's predisposition to cancer to develop methods for

[2] GDX1021 has an online publication date of May 1, 2001, but corresponds to the printed publication date of August 1995, as indicated at the bottom of page 1 of the document, which states "*Current Protocols in Human Genetics* (1995) 9.4.1-9.4.8." *See* GDX1021, 1. And, the '379 patent references the 1995 publication. *See* GDX1001, 9:15:52-54.

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