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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/572,121	10/01/2009	Julian R. Sampson	3004-00-2D	3274
26698	7590	11/18/2016	EXAMINER AEDER, SEAN E	
MYRIAD GENETICS INC. INTELLECTUAL PROPERTY DEPARTMENT 320 WAKARA WAY SALT LAKE CITY, UT 84108			ART UNIT	PAPER NUMBER
			1642	
			MAIL DATE	DELIVERY MODE
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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JULIAN R. SAMPSON and JEREMY PETER CHEADLE

Appeal 2014-003231
Application 12/572,121¹
Technology Center 1600

Before DONALD E. ADAMS, FRANCISCO C. PRATS, and
ERICA A. FRANKLIN, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to methods for detecting a mutation or nucleotide variant in an *MYH* nucleic acid resulting in the amino acid variant Y165C. The Patent Examiner rejected the claims as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 1–5, 7–9, and 18 are on appeal. Claim 1 is representative and reads as follows:

¹ Appellants identify the Real Party in Interest as Myriad Genetic, Inc. App. Br. 2.

1. A method for screening a sample for a mutation in an *MYH* nucleic acid comprising:
obtaining a sample of an individual;
analyzing an *MYH* nucleic acid in said sample; and
detecting a mutation in said *MYH* nucleic acid of said sample resulting in the amino acid variant Y165C.

The Examiner rejected claims 1–5, 7–9, and 18 under 35 U.S.C. §102(a) as being anticipated by Shinmura² and under 35 U.S.C. §102(b) as being anticipated by Wei³.

ANTICIPATION

For the first rejection, the Examiner found that Shinmura teaches a method comprising obtaining a sample from an individual, analyzing *MYH* nucleic acid in the sample, and determining whether the individual has any germ-line nucleotide variant in the *MYH* gene by sequencing the *MYH* nucleic acid of said sample. Ans. 3. Additionally, the Examiner found that Shimura teaches that the determining step comprises hybridizing oligonucleotides to the *MYH* gene, or a portion thereof, from a sample obtained from an individual, and sequencing the amplified *MYH* gene, or a portion thereof. *Id.* The Examiner found that Shinmura’s method identifies colorectal cancer patients, diagnoses individuals as having a predisposition to colorectal cancer, and “detects the presence or absence of all variants of [*MYH*] nucleic acid.” *Id.*

² Kazuya Shinmura et al., *Somatic mutations and single nucleotide polymorphisms of base excision repair genes involved in the repair of 8-hydroxyguanine in damaged DNA*, 166 *CANCER LETTERS*, 65–69 (2001).

³ Patent Application Publication No. WO 97/33903 by Ying-Fei Wei, published Sept. 18, 1997.

For the second rejection, the Examiner found that Wei teaches a method of diagnosing susceptibility to colon cancer comprising sequencing *MYH* cDNA and genomic DNA polynucleotides from samples obtained from patients comprising hybridizing primers to said polynucleotides. *Id.* at 4. According to the Examiner, such a method would “identify colorectal cancer patients and determine the presence or absence of all variants of [*MYH*] gene.” *Id.* Further, the Examiner found that patients in Wei are “identified” as having an increased risk for colorectal cancer. *Id.*

For each rejection, the Examiner found that the claims 1–5, 7–9, and 18 are drawn to methods of detecting an *MYH* nucleic acid mutation. Ans. 2, 3. Further, the Examiner states that “all mutations in nucleic acid genes are detected by sequencing the nucleic acid genes.” *Id.* at 2–4. According to the Examiner, the plain meaning of the term “detecting,” as recited by claim 1, includes “determining the existence or presence of”. *Id.* The Examiner reasoned that “[j]ust as methods of detecting alcohol in blood do not require the blood to comprise alcohol, the instant method of detecting the mutation recited in claim 1 do[es] not require the mutation to be present in a sample in order to detect the mutation in the sample.” *Id.* at 2, 4.

Appellants contend, among other things, that neither Shinmura nor Wei teach the “positive limitation of actually detecting the recited variant,” i.e., a mutation in an *MYH* nucleic acid of a sample that results in the amino acid variant Y165C. App. Br. 8, 11. Appellants assert that limitation is not taught by the prior art disclosure of a method involving sequencing *MYH* nucleic acid from a sample and determining whether or not a nucleotide variant in the *MYH* gene exists. *Id.* at 9. According to Appellants, a method that is “arguably capable of potentially discovering the recited variant . . .

does not teach the detection of the Y165C variant and thus cannot anticipate the present claims.” *Id.*

After considering the evidence and arguments, we conclude that the Examiner has not established that either Shinmura or Wei disclose each and every element set forth in the claim for the reasons set forth by the Appellants. *See Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). In particular, we note that the Examiner did not find that either cited reference discloses or otherwise indicates specific knowledge of the existence of a mutation in a *MYH* nucleic acid that results in the amino acid variant Y165C. Further, we disagree with the Examiner’s position that “the instant method of detecting the mutation recited in claim 1 do[es] not require the mutation to be present in a sample in order to detect the mutation in the sample.” Ans. 4. The plain meaning of the term “detect” includes “to discover or determine the existence, presence, or fact of.”⁴ We find that plain meaning requires positively *finding* the existence, presence, or fact of the object or target, and not merely *looking* for the presence *or absence* of it. Therefore, the claimed methods of detecting a “mutation” (claims 1–5, 7–9) or a “nucleotide variant” (claim 18) in an *MYH* nucleic acid resulting in the amino acid variant Y165C are methods that require actually *finding* that mutation or nucleotide variant. Because the Examiner has not established that either Shinmura or Wei disclose a method that *necessarily* finds the mutation or nucleotide variant recited in the claims, we reverse each of the anticipation rejections.

REVERSED

⁴ Merriam Webster Online Dictionary, M-W.COM, <http://www.merriam-webster.com/dictionary/detect> (last visited Nov. 17, 2016).

<i>Notice of References Cited</i>	Application/Control No. 12/572,121	Applicant(s)/Patent Under Reexamination Appeal No. 2014-003231	
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U.S. PATENT DOCUMENTS

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NON-PATENT DOCUMENTS

*	Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
U	Merriam Webster Online Dictionary, M-W.COM, http://www.merriam-webster.com/dictionary/detect (last visited Nov. 8, 2016).
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
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detect

play

verb de-tect \di-'tekt, dē-\

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Simple Definition of *detect*

- : to discover or notice the presence of (something that is hidden or hard to see, hear, taste, etc.)

Source: Merriam-Webster's Learner's Dictionary

Examples: *detect* in a sentence

- ..
- ..
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Full Definition of *detect*

1. **transitive verb**
2. *1* : to discover the true character of
3. *2* : to discover or determine the existence, presence, or fact of <*detect alcohol in the blood*>
4. *3* : demodulate
5. **intransitive verb**
6. : to work as a detective