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KPPB LLP
2190 S. Towne Centre Place
Suite 300
Anaheim, CA 92806

EXAMINER
BRUSCA, JOHN S

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte FREDERICK DEWEY, EUAN ASHLEY, CARLOS DANIEL BUSTAMANTE, ATUL BUTTE, JAKE BYMES, and RONG CHEN

Appeal 2018-005489
Application 13/445,925
Technology Center 1600

Before JEFFREY N. FREDMAN, TAWEN CHANG, and DAVID COTTA, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal[1] under 35 U.S.C. § 134(a) involving claims to a method for resolving haplotype data. The Examiner rejected the claims 1, 4–11, 14–25, and 27–30 as directed to patent-ineligible subject matter. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

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[1] Appellants identify the Real Party in Interest as The Board of Trustees of the Leland Stanford Junior University (App. Br. 3). We have reviewed and considered the Specification of Apr. 13, 2012 ("Spec."); Final Office Act. of Mar. 28, 2017 ("Final Act."); Appeal Brief of Nov. 21, 2017 ("App. Br."); Examiner's Answer of Mar. 7, 2018 ("Ans."); and Reply Brief of May 7, 2018 ("Reply Br."). An oral hearing was held on July 8, 2019.

Statement of the Case

Background

The Specification teaches that "[w]hole genome sequencing of related individuals provides opportunities for investigation of human recombination and compound heterozygous loci contributing to Mendelian disease traits" (Spec. ¶ 3). However, "[o]ne of the challenges to the interpretation of massively parallel whole genome sequence data is the assembly and variant calling of sequence reads against the human reference genome" (Spec. ¶ 4). In particular, the Specification describes "a method for resolving long-range haplotype[2] phase based on family pedigree data, inheritance state determination, and population linkage disequilibrium data. A method according to an embodiment of the present invention provides for the evaluation of genome wide risk using phased haplotype data" (Spec. ¶ 13).

The Claims

Claims 1, 4–11, 14–25, and 27–30 are on appeal. Claim 1 is representative and reads as follows:

> 1. A method for resolving haplotype phase, comprising:
>
> receiving allele data describing allele information regarding genotypes for a family comprising at least a mother, a father, and at least two children of the mother and the father, where the genotypes for the family contain single nucleotide variants and storing the allele data on a computer system comprising a processor and a memory;
>
> receiving pedigree data for the family describing information regarding a pedigree for the family and storing the

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[2] A haplotype is composed of a set of genes in a single person that were inherited together as a unit from a single one of the parents. *See* https://www.merriam-webster.com/dictionary/haplotype

pedigree data on a computer system comprising a processor and a memory;

determining an inheritance state for the allele information described in the allele data based on identity between single nucleotide variants contained in the genotypes for the family using a Hidden Markov Model having hidden states implemented on a computer system comprising a processor and a memory,

wherein the hidden states comprise inheritance states, a compression fixed error state, and an MIE-rich fixed error state,

wherein the inheritance states are maternal identical, paternal identical, identical, and non-identical;

receiving transition probability data describing transition probabilities for inheritance states and storing the transition probability data on a computer system comprising a processor and a memory;

receiving population linkage disequilibrium data and storing the population disequilibrium data on a computer system comprising a processor and a memory;

determining a haplotype phase for at least one member of the family based on the pedigree data for the family, the inheritance state for the information described in the allele data, the transition probability data, and the population linkage disequilibrium data using a computer system comprising a processor and a memory;

storing the haplotype phase for at least one member of the family using a computer system comprising a processor and a memory; and

providing the stored haplotype phase for at least one member of the family in response to a request using a computer system comprising a processor and a memory.

The Rejection

The Examiner rejected claims 1, 4–11, 14–25, and 27–30 under 35 U.S.C. § 101 as directed to an abstract idea (Final Act. 2–5).

Principles of Law

An invention is patent-eligible if it claims a "new and useful process, machine, manufacture, or composition of matter." 35 U.S.C. § 101. However, the Supreme Court has long interpreted 35 U.S.C. § 101 to include implicit exceptions: "[l]aws of nature, natural phenomena, and abstract ideas are not patentable." *See, e.g.*, *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014).

In determining whether a claim falls within an excluded category, we are guided by the Supreme Court's two-step framework, described in *Mayo* and *Alice*. *Id.* at 217–18 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 75–77 (2012)). In accordance with that framework, we first determine what concept the claim is "directed to." *See Alice*, 573 U.S. at 219 ("On their face, the claims before us are drawn to the concept of intermediated settlement, *i.e.*, the use of a third party to mitigate settlement risk."); *see also Bilski v. Kappos*, 561 U.S. 593, 611 (2010) ("Claims 1 and 4 in petitioners' application explain the basic concept of hedging, or protecting against risk.").

Concepts determined to be abstract ideas, and therefore patent ineligible, include certain methods of organizing human activity, such as fundamental economic practices (*Alice*, 573 U.S. at 219–20; *Bilski*, 561 U.S. at 611); mathematical formulas (*Parker v. Flook*, 437 U.S. 584, 594–95 (1978)); and mental processes (*Gottschalk v. Benson*, 409 U.S. 63, 69 (1972)). Concepts determined to be patent eligible include physical and

chemical processes, such as "molding rubber products" (*Diamond v. Diehr*, 450 U.S. 175, 191 (1981)); "tanning, dyeing, making water-proof cloth, vulcanizing India rubber, smelting ores" (*id.* at 184 n.7 (quoting *Corning v. Burden*, 56 U.S. 252, 267–68 (1853))); and manufacturing flour (*Benson*, 409 U.S. at 69 (citing *Cochrane v. Deener*, 94 U.S. 780, 785 (1876))).

In *Diehr*, the claim at issue recited a mathematical formula, but the Supreme Court held that "[a] claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula." *Diehr*, 450 U.S. at 176; *see also id.* at 191 ("We view respondents' claims as nothing more than a process for molding rubber products and not as an attempt to patent a mathematical formula."). Having said that, the Supreme Court also indicated that a claim "seeking patent protection for that formula in the abstract . . . is not accorded the protection of our patent laws,[] and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment." *Id.* (citing *Benson* and *Flook*), 187 ("It is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.").

If the claim is "directed to" an abstract idea, we turn to the second step of the *Alice* and *Mayo* framework, where "we must examine the elements of the claim to determine whether it contains an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application." *Alice*, 573 U.S. at 221 (quotation marks omitted). "A claim that recites an abstract idea must include 'additional features' to ensure 'that the [claim] is more than a drafting effort designed to monopolize the [abstract idea].'" *Id.* (quoting *Mayo*, 566 U.S. at 77).

"[M]erely requir[ing] generic computer implementation[] fail[s] to transform that abstract idea into a patent-eligible invention." *Id.*

The United States Patent and Trademark Office published revised guidance on the application of 35 U.S.C. § 101. USPTO's *2019 Revised Patent Subject Matter Eligibility Guidance* ("Guidance").[3] Under the Guidance, in determining what concept the claim is "directed to," we first look to whether the claim recites:

> (1) any judicial exceptions, including certain groupings of abstract ideas (i.e., mathematical concepts, certain methods of organizing human activity such as a fundamental economic practice, or mental processes) (Guidance Step 2A, Prong 1); and
>
> (2) additional elements that integrate the judicial exception into a practical application (*see* MPEP § 2106.05(a)–(c), (e)–(h)) (Guidance Step 2A, Prong 2).

Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then look to whether the claim contains an "'inventive concept' sufficient to 'transform'" the claimed judicial exception into a patent-eligible application of the judicial exception. *Alice*, 573 U.S. at 221 (quoting *Mayo*, 566 U.S. at 82). In so doing, we thus consider whether the claim:

> (3) adds a specific limitation beyond the judicial exception that are not "well-understood, routine and conventional in the field" (*see* MPEP § 2106.05(d)); or

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[3] *2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50–57 (January 7, 2019).

> (4) simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception.

(Guidance Step 2B). *See* Guidance, 84 Fed. Reg. at 54–56.

Analysis

Applying the Revised Guidance to the facts on this record, we find that Appellants' claims 1, 4–11, 14–25, and 27–30 are directed to patent-ineligible subject matter. Because the same issues are present in each of the claims, we focus our consideration on representative claim 1. The same analysis applied below to claim 1 also applies to the other rejected claims.

A. Guidance Step 2A, Prong 1

The Revised Guidance instructs us first to determine whether any judicial exception to patent eligibility is recited in the claim. The Revised Guidance identifies three judicially-excepted groupings identified by the courts as abstract ideas: (1) mathematical concepts, (2) certain methods of organizing human behavior such as fundamental economic practices, and (3) mental processes.

The Examiner finds that the claims are

> directed to a judicial exception of an abstract idea of analyzing family quartet genotype data and pedigree data, determining inheritance states of alleles using a hidden Markov model, and determining haplotype phasing in at least one member of the family quartet, which is similar to the abstract idea of organizing information through mathematical correlations

(Final Act. 3).

We agree with the Examiner that claim 1 recites patent-ineligible subject matter. More specifically, claim 1, reproduced above, recites the following steps: (1) "receiving allele data," (2) "receiving pedigree data,"

(3) "determining an inheritance state . . . using a Hidden Markov Model," (4) "receiving transition probability data," (5) "receiving population linkage disequilibrium data," (6) "determining a haplotype phase," (7) "storing the haplotype phase," and (8) "providing the haplotype phase" (App. Br. 85–86). Under the broadest reasonable interpretation, limitations (1), (2), (4), (5), (7), and (8) recite mental steps of receiving, storing, or providing information, which are actions that can be performed in the mind. Likewise, under the broadest reasonable interpretation, limitations (3) and (6) drawn to determining steps recite mathematical concepts.

The claimed invention is described in the Specification as a solution to a problem in using haplotype pedigree and population data for personal genomic risk prediction because "[c]urrent risk prediction pipelines do not incorporate parent-of-origin into pipelines for genome annotation, despite evidence for specific effects of risk alleles for common disease, including diabetes type II, depending on parent of origin." (Spec. ¶ 17).

The Specification explains that "[h]aplotype phase is important to understanding genetic risk in patients with and without disease phenotypes" and teaches a formula to perform such phasing:

$$L(t;h)=\left\{\begin{matrix}1, r_i^2=1,\\ \frac{1}{n}\sum_n r_i^2, r_i^2\neq 1\end{matrix}\right\} \qquad (1)$$

(Spec. ¶ 91; *cf.* claim 25).

The Federal Circuit has "recognize[d] that defining the precise abstract idea of patent claims in many cases is far from a 'straightforward' exercise." *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1150 (Fed. Cir. 2016) (quoting *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d

1245, 1257 (Fed. Cir. 2014)). However, "we continue to 'treat[] analyzing information by steps people [could] go through in their minds, or by mathematical algorithms, without more, as essentially mental processes within the abstract-idea category.'" *Id.* at 1146–47 (quoting *Electric Power Grp., LLC v. Alstom S.A.,* 830 F.3d 1350, 1354 (Fed. Cir. 2016) (citations omitted)). The Federal Circuit has recognized that "a claim for a new abstract idea is still an abstract idea." *Id.* at 1151. It is well established that mental processes are abstract ideas.

CyberSource instructs that "a method that can be performed by human thought alone is merely an abstract idea and is not patent-eligible under § 101." *CyberSource Corp. v. Retail Decisions, Inc.*, 654 F.3d 1366, 1373, 1375 (Fed. Cir. 2011) ("That purely mental processes can be unpatentable, even when performed by a computer, was precisely the holding of the Supreme Court in *Gottschalk v. Benson*."). And, "if a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory." *Parker v. Flook*, 437 U.S. 584, 595 (1978).

Here, the claims recite steps for receiving and/or analyzing information, which people could go through in their minds, or by mathematical algorithms, which is a mental process within the abstract-idea category. The focus "is on selecting certain information, analyzing it using mathematical techniques, and reporting or displaying the results of the analysis. That is all abstract." *SAP America, Inc. v. Investpic, LLC*, 898 F.3d 1161, 1167 (Fed. Cir. 2018). Moreover, the claims recite making computational predictions using mathematical formulas. Accordingly, we

conclude that the steps of claim 1 recite the judicial exceptions of mathematical concepts and mental processes.

B. Guidance Step 2A, Prong 2

Having determined that the claims are directed to a judicial exception, the Revised Guidance directs us to next consider whether the claims integrate the judicial exception into a practical application. Guidance Step 2A, Prong 2. "[I]ntegration into a practical application" requires that the claim recite an additional element or a combination of elements, that when considered individually or in combination, "apply, rely on, or use the judicial exception in a manner that imposes a meaningful limit on the judicial exception, such that the claim is more than a drafting effort designed to monopolize the judicial exception." Guidance at 54.

Here, there is no practical integration of the abstract idea. Other than the limitations directed to the abstract idea, discussed above, the invention is claimed at a very high level of generality and is only limited in the type of data used in computationally resolving the haplotype phase or how the results are displayed. Furthermore, the end result of the claimed method is providing the data, including for uses such as prognosis in dependent claim 10. The end result here is like the "indicates a need" language found insufficient in *Mayo*, 566 U.S. at 74, 86. Moreover, claim 1 does not include a step equivalent to the treatment step in *Vanda Pharm. Inc. v. West-Ward Pharm. Int. Ltd.*, 887 F.3d 1117, 1134 (Fed. Cir. 2018).

Appellants argue that

> In *Ambry*, the claims at issue compared a patient's gene sequence to a wild-type sequence to identify differences and similarities between the two sequences. [*In re BRCA1- &*

> *BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014)]. In contrast to *Ambry*, Appellant's claim 1 determines inheritance states based on a Hidden Markov Model with particular hidden states, and generates a haplotype phase based on transition probabilities, inheritance states, and population disequilibrium data. Appellant's claim 1 possesses no reference sequence and does not produce a list of similarities and differences between a subject and target data. Thus, claim 1 describes a unique and technical method for generating haplotype phase; it does not simply perform a comparison. Thus, claim 1 is unlike *Ambry*.

(App. Br. 19).

We find this argument unpersuasive as it acknowledges that the claims use mental processes to receive types of data and then apply mathematical transformations like the Hidden Markov Model to natural phenomena such as inheritance states and haplotype data to determine a "haplotype phase," with this determination being stored in a computer. As in *BRCA1*, the "covered comparisons are not restricted by the purpose of the comparison or the alteration being detected. Because of its breadth, the comparison step covers detection of yet-undiscovered alterations." *BRCA1*, 774 F.3d at 764.

We are unpersuaded by Appellants' reliance on *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016) (*see* App. Br. 20). *Enfish* explains that "the first step in the Alice inquiry . . . asks whether the focus of the claims is on the specific asserted improvement in computer capabilities . . . or, instead, on a process that qualifies as an 'abstract idea' for which computers are invoked merely as a tool." *Enfish*, 822 F.3d at 1335–6. Applied to claim 1, the claimed method does not teach a technical

improvement in a computer processor, but rather use the computer as a tool to improve data analysis (*see* claim 1, Spec. ¶ 61, which states that "the present invention is not limited to computer system 100 as known at the time of the invention. Instead, the present invention is intended to be deployed in future computer systems with more advanced technology that can make use of all aspects of the present invention."). "[T]he focus of the claims is not any improved computer or [device], but the improved mathematical analysis; and indeed, the specification makes clear that off-the-shelf . . . technology is usable to carry out the analysis." *SAP*, 898 F.3d at 1168.

While Appellants compare the improvement in computer animation in *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299 (Fed. Cir. 2016) to the instant claims, we find the comparison unpersuasive. Appellants contend that like "*McRO*, the recited claim describes specific rules and features (through the use of a Hidden Markov Model having specific hidden states) to identify inheritance states in order to solve the problem of determining accurate, long-range phased haplotypes for a member of a family" (App. Br. 22). Appellants contend "the specific solution Appellant's claim 1, as described above, solves the technical problem of the inability to generate accurate, long-range phased haplotypes" (App. Br. 23).

In *McRO*, the method integrated specific process steps of phoneme analysis to obtain facial expression control of animated characters, thereby integrating the improvement into the animation process. *See McRO*, 837 F.3d at 1315. *McRO* was a computer based process that improves operations on the computer animation process itself, while claim 1 uses naturally occurring data composed of allele and pedigree information in a

mathematical operation with the Hidden Markov Model to process and determine haplotype phase data. Unlike *McRO*, the computer in claim 1 is simply used as a tool to perform the mathematical operation, and the claim does not improve the computer itself. Claim 1 does not integrate the process steps into a practical improvement because the final step simply provides data, generated by the mathematical algorithm based on naturally occurring information, for further consideration. Therefore, contrary to *McRO*, where the ultimate product produced was a synchronized computer animation that was itself the transformative use, the result of the presently claimed method is information itself, without being directed to any particular use of that information other than "providing the haplotype phase . . . in response to a request" (Claim 1). *See Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1355 (Fed. Cir. 2016) ("[M]erely selecting information, by content or source, for collection, analysis, and display does nothing significant to differentiate a process from ordinary mental processes.")

Appellants' arguments regarding the use of the Hidden Markov Model mathematical formula reinforces the finding that the claims are merely directed to the abstract ideas of mathematical concepts. In *McRO*, the Federal Circuit held that claims that "set out meaningful requirements for [a] first set of rules" by which a computer could synchronize animated lip movements to spoken sounds were not directed to an abstract idea but to "a process specifically designed to achieve an improved technological result," that result being a computer-generated animation having automatically synchronized mouth movements. *McRO*, 837 F.3d at 1313, 1316. The present claims do not recite the claimed specificity of technological

improvement that the Federal Circuit found present in the invention of *McRO*.

We find the instant claims similar to those in *SmartGene*, where the Federal Circuit held that claims directed to "comparing new and stored information and using rules to identify medical options" did not satisfy *Alice* step one. *See SmartGene, Inc. v. Advanced Biological Labs., SA*, 555 F. App'x 950, 951–52, 955–56 (Fed. Cir. 2014) (nonprecedential). As in *Smartgene*, the instantly claimed steps do not rely on an inventive device or technique for displaying information or new techniques for obtaining biological information, but rather constitute a recitation of steps for mathematically manipulating naturally occurring data. *See SmartGene*, 555 Fed. Appx. at 954 (holding claims were patent ineligible because they did "no more than call on a 'computing device,' with basic functionality for comparing stored and input data and rules, to do what doctors do routinely.").

Therefore, on this record, we conclude that the ineligible subject matter in Appellants' claim 1 is not integrated into a practical application.

C. Guidance Step 2B

Having determined that the judicial exception is not integrated into a practical application, the Revised Guidance requires us to evaluate the additional elements individually and in combination to determine whether they provide an inventive concept, such as a specific limitation beyond the judicial exception that is not well-understood, routine, conventional in the field, or simply appends well-understood, routine, conventional activities

previously known to the industry, specified at a high level of generality, to the judicial exception. *See* 84 Fed. Reg. 51.

Appellants contend that "claim 1 adds significantly more than [an] abstract idea because it recites a non-conventional and non-generic arrangement of elements, which also improve a technical field" (App. Br. 24). Appellants assert

> the particular arrangement of Appellant's claim 1 includes a specific Hidden Markov Model to determine inheritance states, and utilizes the determined inheritance state, along with linkage disequilibrium and transition probability inputs to determine accurate, long-range, haplotype phases. Other attempts at determining a haplotype for an individual have not necessarily relied on these features, much less all of these features in this arrangement.

(App. Br. 24). Appellants conclude that "claim 1 is not directed to merely performing mathematical operations on a computer, but rather imposes meaningful limits on any such operations in that the mathematical operations are applied to improve an existing technology" (App. Br. 25).

We are not persuaded by Appellants' arguments. We do not dispute that the use of mathematical operations may be "a positive and valuable contribution to science. But even such valuable contributions can fall short of statutory patentable subject matter, as it does here." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1380 (Fed. Cir. 2015). There is nothing in the Specification indicating that, other than the patent-ineligible abstract ideas, any steps or components recited in the claims are not generic or conventional. The methods recited in the claims may be implemented by "a digital computer system 100 such as generally shown in Figure 8. Such a digital computer or embedded device is well-known in the art" (Spec. ¶ 56).

The Specification explains that an ordinary artisan "is familiar with the use of computers and software languages and, with an understanding of the present disclosure, will be able to implement the present teachings for use on a wide variety of computers" (Spec. ¶ 62).

Appellants point to no additional steps that could not be performed mentally or without using a generic computer. The use of a generic computer to perform generic computer functions that are "well-understood, routine, conventional activit[ies]" previously known in the industry is not enough to transform the abstract idea into a patent-eligible invention. *See Alice*, 573 U.S. at 225–26.

We find that Appellants' claims do not require anything other than the use of conventional and well-understood techniques and equipment to gather and process data according to the recited judicial exception. Accordingly, the preponderance of evidence of record supports the Examiner's finding that Appellants' claimed invention is directed to patent-ineligible subject matter. The rejection of claim 1 under 35 U.S.C. § 101 is affirmed.

As to claims 7, 8, 10, 11, 17, 18, 20, and 21, while these claims are separately argued, the same analysis discussed above applies and these claims fall with claim 1 for the reasons given above.

Claims 9 and 19

These two claims differ from claim 1 because they recite a final step of "providing the drug for treatment" based on the mathematical calculations performed in claims 1 and 11 respectively. While this limitation is facially similar to *Vanda*, with a final drug administration step, in *Vanda*, the administration step was specifically directed to connecting a CYP2D6 poor metabolizer genotype with iloperidone treatment. *Vanda*, 887 F.3d at 1121.

Vanda distinguished *Mayo* by finding "the claims here are directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome." *Id.* at 1136.

The instant claims 9 and 19, unlike those in *Vanda*, are not directed to a specific method of treatment, do not identify specific patients, do not recite a specific compound, do not prescribe particular doses, and do not identify the resulting outcome. Therefore, the reasoning in Vanda supports a finding that the instant claims are not patent eligible, because the claims do not recite a new treatment for an ailment but rather recite application of a mathematical algorithm to identify treatments that might be used for particular conditions, just as a doctor uses ordinary medical judgement to identify treatments which might then be used to treat a patient. Accordingly, the preponderance of evidence of record supports the Examiner's finding that Appellants' claimed invention is directed to patent-ineligible subject matter. The rejection of claims 9 and 19 under 35 U.S.C. § 101 is affirmed.

CONCLUSION

We affirm the Examiner's rejection of claims 1, 4–11, 14–25, and 27–30 under 35 U.S.C. § 101.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED